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Table of contents

1 Index ... 13

2 Important information ... 17

2.1 How to use the Instructions for Use ... 17

2.2 Significance of warnings ... 18

2.3 Significance of notes ... 18

2.4 Significance of tips ... 18

2.5 Brief description ... 19

2.6 Intended purpose and related definitions ... 20
2.6.1 Intended purpose ... 20
2.6.2 Medical indication ... 20
2.6.3 Intended patient population ... 20
2.6.4 Intended user group and intended environment ... 21
2.6.5 Performance characteristics and clinical benefits ... 21
2.6.5.1 Performance characteristics ... 21
2.6.5.2 Clinical benefits ... 21

2.7 Side effects ... 23
2.7.1 Reporting of serious incidents ... 24
2.7.2 Medical Information and precautions for prevent side effects ... 24

2.8 Contraindications ... 27
2.8.1 Product-specific and therapy-related contraindications ... 27
2.8.2 Relative contraindications ... 28

2.9 Interaction with other systems ... 29

2.10 Therapy restrictions ... 30
2.10.1 Target group ... 30

2.11 Please note the following when working on the device ... 30

2.12 Expected service life ... 31

2.13 Duties of the responsible organisation ... 31

2.14 Operator responsibility ... 32

2.15 Disclaimer of liability ... 33

2.16 Warnings ... 34
2.16.1 Warnings about electrical safety ... 34
2.16.2 Warnings relating to consumables and accessories ... 35

2.17 SVHC (REACH) ... 36

2.18 Addresses ... 37

3 Design ... 39

3.1 Views of the device ... 39
3.1.1 Front view ... 39
3.1.2 Rear view ... 40
3.1.2.1 Connector strip ... 41
3.1.3 Left side view ... 42
3.1.4 Right side view ... 43

3.2 Controls and indicators ... 44
3.2.1 Monitor front ... 44
3.2.2 Monitor rear ... 45
3.2.3 Positioning the monitor ... 46
3.2.4 Using the card slot ... 47
3.2.5 Positioning the filter holder ... 47
3.2.6 Heparin pump ... 48
3.2.7 Heater ... 49
3.2.8 Extracorporeal Blood Circuit Module ... 50

3.3 User interface ... 51

3.4 General operating concept ... 52
3.4.1 Colour coding on the device and single-use articles ... 52
3.4.2 Screen colours ... 52
3.4.3 Context-specific information ... 53

3.5 Basic input procedures ... 54
3.5.1 Changing settings with the rocker switch buttons ... 54
3.5.2 Changing settings with the number buttons ... 54
3.5.3 Entering data with the keyboard ... 55
3.5.4 On/Off button ... 56
3.5.5 Viewing the ratio of the UF rate to the blood flow rate ... 57
3.5.6 Viewing the pressure values ... 57
3.5.7 Setting the pressure alarm limit values ... 59

4 Operation ... 61

4.1 Application principles ... 61

4.2 CRRT treatments ... 68
4.2.1 Switching on the device and starting the function test ... 68
4.2.2 Selecting the treatment option ... 69
4.2.3 Continuing the previous treatment ... 69
4.2.4 Start requirements ... 70
4.2.5 Mounting the cassette ... 70
4.2.5.1 Mounting the return system ... 71
4.2.5.2 Mounting the access system ... 72
4.2.5.3 Mounting the filtrate system ... 73
4.2.5.4 Loading the solution bags ... 73
4.2.5.5 Mounting the dialysate/substituate systems ... 74
4.2.5.6 Inserting the heparin syringe ... 75
4.2.5.7 Cassette mounting completed ... 76
4.2.6 Filling and rinsing the cassette ... 77
4.2.6.1 Filling the tubing system ... 77
4.2.6.2 Entering the Patient ID and Case ID ... 77
4.2.6.3 Entering treatment parameters ... 78

4.2.6.4 UF Rinse ... 79
4.2.7 Circulation ... 80
4.2.8 Connecting the patient ... 81
4.2.9 Treatment ... 82
4.2.9.1 Treatment screen ... 82
4.2.9.2 Menus ... 83
4.2.9.3 Histories ... 83
4.2.9.4 System Parameters ... 84
4.2.10 Changing the treatment mode ... 84
4.2.10.1 Changing the treatment mode from CVVHDF to CVVH ... 85
4.2.10.2 Changing the treatment mode from CVVHDF to CVVHD ... 86
4.2.11 End of treatment ... 87
4.2.11.1 Preparing the end of treatment ... 87
4.2.11.2 End of treatment with blood reinfusion ... 88
4.2.11.3 Starting blood reinfusion ... 88
4.2.11.4 NaCl solution detected ... 89
4.2.11.5 Disconnecting the patient ... 90
4.2.11.6 Dismantling the tubing system ... 90

4.3 CRRT Ci-Ca treatments ... 91
4.3.1 Switching on the device and starting the function test ... 91
4.3.2 Selecting the treatment option ... 92
4.3.3 Continuing the previous treatment ... 92
4.3.4 Start requirements ... 93
4.3.5 Mounting the cassette ... 93
4.3.5.1 Mounting the return system ... 94
4.3.5.2 Mounting the access system ... 95
4.3.5.3 Mounting the filtrate system ... 96
4.3.5.4 Loading the solution bags ... 96
4.3.5.5 Mounting the dialysate/substituate systems ... 98
4.3.5.6 Mounting the Ci-Ca system ... 99
4.3.5.7 Inserting the heparin syringe ... 100
4.3.5.8 Cassette mounting completed ... 102
4.3.6 Filling and rinsing the cassette ... 102
4.3.6.1 Filling the Ci-Ca system ... 102
4.3.6.2 Checking the Ci-Ca lines ... 103
4.3.6.3 Filling the tubing system ... 103
4.3.6.4 Entering the Patient ID and Case ID ... 103
4.3.6.5 Entering treatment parameters ... 105
4.3.6.6 UF Rinse ... 106
4.3.7 Circulation ... 107
4.3.8 Connecting the patient ... 108
4.3.9 Treatment ... 109
4.3.9.1 Treatment screen ... 110
4.3.9.2 Menus ... 111
4.3.9.3 Histories ... 111
4.3.9.4 System Parameters ... 112
4.3.10 End of treatment ... 112
4.3.10.1 Preparing the end of treatment ... 112
4.3.10.2 End of treatment with blood reinfusion ... 113
4.3.10.3 Starting blood reinfusion ... 113
4.3.10.4 NaCl solution detected ... 114
4.3.10.5 Disconnecting the patient ... 115
4.3.10.6 Dismantling the tubing system ... 115

4.4 TPE treatments ... 117
4.4.1 Switching on the device and starting the function test ... 117

4.4.2 Selecting the treatment option ... 118
4.4.3 Start requirements ... 118
4.4.4 Mounting the cassette ... 119
4.4.4.1 Mounting the return system ... 119
4.4.4.2 Mounting the access system ... 121
4.4.4.3 Mounting the filtrate system ... 121
4.4.4.4 Loading the solution bags ... 122
4.4.4.5 Mounting the plasma system ... 122
4.4.4.6 Inserting the heparin syringe ... 123
4.4.4.7 Cassette mounting completed ... 124
4.4.5 Filling and rinsing the cassette ... 125
4.4.5.1 Filling the tubing system ... 125
4.4.5.2 Entering the Patient ID and Case ID ... 125
4.4.5.3 Entering treatment parameters ... 126
4.4.5.4 UF Rinse ... 127
4.4.6 Circulation ... 128
4.4.7 Filling the plasma system ... 129
4.4.8 Patient connection ... 130
4.4.9 Preparing plasmafiltration ... 131
4.4.10 Treatment ... 132
4.4.10.1 Treatment screen ... 132
4.4.10.2 Menus ... 133
4.4.10.3 Histories ... 133
4.4.10.4 System Parameters ... 134
4.4.10.5 Performing a plasma bag change ... 134
4.4.10.6 Performing filtrate bag change (TPE) ... 136
4.4.11 End of treatment ... 136
4.4.11.1 Preparing the end of treatment ... 136
4.4.11.2 Exchanging residual plasma ... 137
4.4.11.3 Selecting blood reinfusion ... 138
4.4.11.4 End of treatment with blood reinfusion ... 139
4.4.11.5 Disconnecting the patient ... 141
4.4.11.6 Dismantling the tubing system ... 142

4.5 Paediatric CRRT treatments ... 143
4.5.1 Switching on the device and starting the function test ... 143
4.5.2 Selecting the treatment option ... 144
4.5.3 Continuing the previous treatment ... 144
4.5.4 Start requirements ... 145
4.5.5 Mounting the cassette ... 146
4.5.5.1 Mounting the return system ... 146
4.5.5.2 Mounting the access system ... 148
4.5.5.3 Mounting the filtrate system ... 148
4.5.5.4 Loading the solution bags ... 149
4.5.5.5 Mounting the dialysate system ... 149
4.5.5.6 Inserting the heparin syringe ... 150
4.5.5.7 Cassette mounting completed ... 151
4.5.6 Filling and rinsing the cassette ... 152
4.5.6.1 Filling the tubing system ... 152
4.5.6.2 Entering the Patient ID and Case ID ... 152
4.5.6.3 Entering treatment parameters ... 153
4.5.6.4 UF Rinse ... 154
4.5.7 Circulation ... 155
4.5.8 Connecting the patient when the extracorporeal blood circuit is primed with blood substitute ... 157

4.5.9 Connecting the patient without priming the extracorporeal blood circuit with blood substitute ... 159
4.5.10 Treatment ... 160
4.5.10.1 Treatment screen ... 160
4.5.10.2 Menus ... 161
4.5.10.3 Histories ... 161
4.5.10.4 System Parameters ... 162
4.5.11 End of treatment ... 162
4.5.11.1 Preparing the end of treatment ... 162
4.5.11.2 End of treatment with blood reinfusion ... 163
4.5.11.3 Starting blood reinfusion ... 164
4.5.11.4 NaCl solution detected ... 165
4.5.11.5 Disconnecting the patient ... 165
4.5.11.6 Dismantling the tubing system ... 166

4.6 Treatment displays ... 167
4.6.1 Pressure / alarm history ... 167
4.6.2 Next operator action ... 167

4.7 Menus ... 168
4.7.1 Setting the level in the bubble catcher ... 168
4.7.2 Cancelling preparation ... 168
4.7.3 Treatment pause ... 168
4.7.3.1 Treatment pause with blood reinfusion (CRRT only) ... 169
4.7.3.2 Treatment pause without blood reinfusion ... 173
4.7.4 Switching balancing off/on ... 178
4.7.5 Change syringe ... 179
4.7.6 Care mode is active ... 179
4.7.7 Switching between predilution and postdilution ... 181
4.7.8 Bag change (substituate/dialysate/filtrate) ... 181
4.7.9 Ci-Ca information ... 182
4.7.10 Ca bag change ... 183
4.7.11 Citrate bag change ... 184
4.7.12 Switching off Ci-Ca anticoagulation ... 184
4.7.13 Switching on Ci-Ca anticoagulation ... 185
4.7.14 Plasma volume calculation / Target volume input (TPE only) ... 187
4.7.15 Switching blood leak monitoring off (TPE only) ... 188

4.8 Histories ... 190
4.8.1 Balance data ... 190
4.8.1.1 CRRT ... 190
4.8.1.2 TPE ... 192
4.8.2 Balance history ... 193
4.8.3 Events ... 193

4.9 System Parameters ... 195
4.9.1 Access without UserCard ... 195
4.9.1.1 Pressure selection ... 196
4.9.1.2 Device information ... 196
4.9.1.3 Basic settings ... 197
4.9.2 Access with UserCard ... 198
4.9.2.1 Applications ... 198
4.9.3 User setup ... 200
4.9.3.1 Heparin ... 200
4.9.3.2 User interface ... 201
4.9.3.3 Paediatric CRRT treatments ... 202
4.9.3.4 CRRT ... 204
4.9.3.5 TPE ... 208

4.10 Network ... 211
4.10.1 Observe before use ... 211
4.10.2 PDMS connection ... 212

5 Alarm processing ... 213

5.1 Repeated confirmation of a message ... 213

5.2 Alarm schemes ... 214
5.2.1 Alarm scheme one ... 215
5.2.2 Alarm scheme two ... 215

5.3 High-priority alarm conditions ... 216

5.4 Alarm system ... 217

5.5 Response of the alarm system ... 218

5.6 Messages ... 220

5.7 Messages during the functional test ... 221

5.8 UF/BF message ... 221

5.9 Ratio of calcium flow to filtrate flow ... 222

5.10 Ratio of citrate flow to blood flow ... 223

5.11 Ratio of plasma rate to blood flow ... 223

5.12 Pressure deviation messages ... 224
5.12.1 Resetting the alarm limit windows ... 224
5.12.2 Reducing the access pressure ... 225

5.13 Message “Air detected downstream of the bubble catcher” ... 226
5.13.1 Before beginning deaeration procedures ... 226
5.13.2 Air detected ... 227
5.13.3 Deaeration procedures ... 227

5.14 Message “Microbubbles detected downstream of bubble catcher” ... 230
5.14.1 Before removing the microbubbles ... 230
5.14.2 Microbubbles detected ... 231

5.15 Blood leak ... 232

5.16 Dynamic pressure test, return/insertion line ... 233

5.17 Power failure (mains power failure) ... 234
5.17.1 During preparation ... 234
5.17.2 During treatment ... 235

5.18 Display failure ... 236

5.19 Manual blood reinfusion ... 236

5.20 Manually opening the pressure measurement units ... 237

6 Cleaning / disinfection ... 239

6.1 Surface cleaning / surface disinfection ... 239
6.1.1 Cleaning the display ... 240

6.1.2 Detachable device components ... 240
6.2 Disinfectants and cleaning agents ... 241

7 Functional description ... 243

7.1 Device functions ... 243
7.2 Description of therapies ... 243
7.2.1 Continuous renal replacement therapy ... 243
7.2.1.1 CVVH ... 245
7.2.1.2 CVVHD ... 248
7.2.1.3 CVVHDF ... 250
7.2.2 Therapeutic plasma exchange ... 253
7.2.3 Paediatric CRRT treatments ... 257
7.3 Anticoagulation ... 259
7.3.1 Systemic anticoagulation ... 259
7.3.2 CVVHD or postCVVHDF with the Ci-Ca protocol (regional citrate anticoagulation) ... 261
7.3.2.1 Treatment prescription and essentials ... 262
7.3.2.2 Solutions for the Ci-Ca protocol ... 264
7.3.2.3 Therapy settings and monitoring with the Ci-Ca protocol ... 267
7.3.2.4 Monitoring technique and frequencies during normal operation ... 275
7.3.2.5 Unusual situations during treatment ... 278

8 Consumables, accessories, additional equipment ... 281

8.1 Consumables ... 282
8.1.1 multiFiltratePRO Treatment kits ... 282
8.1.2 Haemofilters/plasma filters ... 283
8.1.3 Isotonic NaCl solutions ... 283
8.1.4 Dialysate and haemofiltration solutions ... 283
8.1.5 Citrate solution ... 284
8.1.6 Disposable syringes ... 284
8.1.7 Other single-use items ... 285
8.2 Additional equipment ... 286

9 Installation ... 287

9.1 Connection requirements ... 287
9.1.1 Environment ... 287
9.1.2 Power supply network ... 287
9.1.3 Electrical installation ... 288
9.2 Installation / initial start-up requirements ... 288
9.3 Important information on initial start-up ... 289

10 Transport / storage ... 291

10.1 Relocation ... 291

10.2 Transport ... 293

10.3 Storage ... 293
10.3.1 Storage conditions ... 294

10.4 Environmental compatibility / disposal ... 294

11 Technical Safety Checks / maintenance procedures ... 295

11.1 Important information on the Technical Safety Checks / maintenance procedures ... 295

12 Specifications ... 297

12.1 Dimensions and weight ... 297

12.2 Identification label (device marking) ... 297
12.2.1 Identification label of the device ... 297
12.2.2 Power label ... 298

12.3 Electrical safety ... 298

12.4 Electric power supply ... 299

12.5 Information on electromagnetic compatibility (IEC 60601-1-2:2014) ... 299
12.5.1 Minimum distances between radiation source and medical electrical equipment ... 300
12.5.2 Guidance and manufacturer's declaration on EMC ... 301

12.6 Operating conditions ... 303

12.7 Storage conditions ... 304

12.8 External connection options ... 304

12.9 Operating programs ... 306

12.10 Balancing/dialysate circuit and safety systems ... 306

12.11 Extracorporeal blood circuit and safety systems ... 309

12.12 Materials used ... 314

13 Definitions ... 321

13.1 Definitions and terms ... 321

13.2 Abbreviations ... 323

13.3 Symbols ... 325

13.4 Certificates ... 328

14 Options 329

14.1 Chapter without content 329

15 Appendix 331

15.1 Instructions on the use of “free software” 331

1 Index

A

Abbreviations 323
Access pressure 309, 321
Access pressure measurement unit (red) 50
Access system 321
Accessories 286
Accessories case 40
Additional equipment 286
Air bubble detector 50, 311
Air detected 227
Alarm function check 321
Alarm limit 321
Alarm output 326
Alarm priorities 218
Alarm processing 213
Alarm scheme one 215
Alarm scheme two 215
Alarm schemes 214
Alarm system 217
Ambient temperature sensor 309
Anticoagulation 259
Appendix 331
Application principles 61
Audible tone 312
Audio paused 44

B

Bag change 181
Bag change (substituate/dialysate/filtrate) 181
Balance data 190
Balance history 193
Balancing 191, 243
Balancing error 191, 308
Basic input procedures 54
Battery 293, 321
Blood circuit module 50
Blood leak 233
Blood leak detector 321
Blood leak detector (yellow) 50
Blood leak/haemolysis detector 306
Blood pump 50, 311, 321
Blood reinfusion 236
Bubble catcher 168

C

Ca bag change 183
Calcium drip counter (white) 50
Calcium fill level detector (white) 50
Calcium flow 321
Calcium pump (white) 50, 313, 321
Cancel preparation 72, 95, 121, 148
Card for use by service engineers 323
Card slot 43, 45, 321
Care mode is active 179
Cassette detector 50, 313
Certificates 328
Change syringe 179
Changing settings with the number buttons 54
Changing settings with the rocker switch buttons 54
Ci-Ca drip counter 313
Ci-Ca fill level detector 313
Circulation 306
Citrate bag change 184
Citrate dose 321
Citrate drip counter (green) 50
Citrate fill level detector (green) 50
Citrate flow 321
Citrate pump (green) 50, 313, 321
Citrate solution 284
Cleaning 239
Cleaning agents 241
Cleaning the display 240
Connection options 304
Connector strip 40, 41
Consumables 282
Context-specific information 53
Continuous renal replacement therapy 243
Contraindications 27
Controls and indicators 44
Convection 322
CRRT Ci-Ca treatments 91
CRRT types 244
CVVHD 248

D

Deaeration procedures 227
Definitions 321
Device functions 243
Dialysate 283, 322
Dialysate pump 50
Diffusion 322
Dimensions 297
Disclaimer of liability 33
Disinfectants 241
Disinfection 239
Display failure 236
Disposable syringes 284
Duties of the responsible organisation 31

E

Electrical installation 288
Electrical safety 298
Electromagnetic emissions 301
Electromagnetic immunity 301
Electrostatic discharge 29
End of treatment / Blood reinfusion 306
Environmental compatibility / disposal 294
Equipotential bonding 41
Events 193
Exchange volume 322
Expected service life 31
External connection options 304

Extracorporeal blood circuit 243, 322
Extracorporeal blood circuit and safety systems 309
Extracorporeal Blood Circuit Module (CRRT) 50

F

Fill level detector 50, 311
Filling the tubing system 306
Filter holder 43
Filter life 191, 322
Filtrate bag 322
Filtrate pressure measurement unit (yellow) 50
Filtrate pump 50
Filtration 322
Flow rates 307
Free software 331
Front view of device 39
Functional description 243
Functional test 243, 306

G

General operating concept 52

H

Haemodialysis 322
Haemofilters/plasma filters 283
Haemofiltration 322
Haemofiltration solutions 283
Heater (green) 42
Heater (white) 42
Heater microswitch 309
Heparin pump 43, 48, 312, 322
High-priority alarm conditions 216
Histories 190
Hook-up test 322
How to use the Instructions for Use 17

I

Identification 40
Identification label 40
Important information 17
Important information on initial start-up 289
Important information on the Technical Safety Checks / maintenance procedures 295
Initial start-up 289
Initial start-up requirements 288
Insertion switch 323
Installation 287
IV pole (left and right) 39

K

Keyboard 55
Kit service life 323

L

LAN (local area network) network connection 41
LAN (network) 326
Left side view of the device 42
Limit monitoring 57
Limit values 57
Line occlusion clamp (blue) 50
Line occlusion clamp (red) 50
Loudspeaker 45

M

Mains power failure (power failure) 234
Maintenance procedures 295
Manual blood reinfusion 236
Manually opening the pressure measurement units 237
Materials 314
Menu bar 51
Menu panel 52
Menus 168
Messages 220
Microbubbles 230
Microbubbles detected downstream of bubble catcher 230
Monitor 39, 44
Monitor arm 45
Monitor rear 45
Monitor/buttons 44

N

NaCl solutions 283
Net UF volume 323
Network (LAN) 326
Next operator action 167
Note symbol, significance 18
Nurse call port 41

O

On/Off button 56
Operating conditions 303
Operating programs 306
Operating status indicator (traffic light) 44
Operator responsibility 32
Optical detector 50, 311

P

Patient connection 306
Performing filtrate bag change (TPE) 136
Positioning the filter holder 47
Positioning the monitor 46
Post CVVH 245
Postdilution 75, 150, 323
Post-filter calcium concentration 323
Power failure (mains power failure) 234
Power label 40
Power supply connection 41
Power switch 41
Pre CVVH 245
Predilution 74, 150, 323
Predilution substituate pump 50
Pre-filter pressure 310
Pre-filter pressure measurement unit (red) 50
Preparation 306
Preparation time 323
Pressure / alarm history 167
Pressure alarm windows 59
Pressure displays 51
Pressure measurement units 41
Pressure values 57

Progress bar 51

R

Ratio of calcium flow to filtrate flow 222
Ratio of citrate flow to blood flow 223
Rear view of device 40
Recessed grip 45
Recommended separation distances 303
Regional citrate anticoagulation 261
Relocation 291
Resetting the alarm limit windows 224
Return pressure 309, 323
Return pressure sensor (blue) 50
Return system 323
Right side view of the device 43
Rinsing 306
Rocker switch buttons 52
RS 232 port 41

S

Scale 1 (green) 40
Scale 2 (white) 40
Scale system 308
Scales 39
Screen colours 52
Screen failure sensor 44
Service port 41
ServiceCard 321, 323
Setting the level in the bubble catcher 168
Setting the pressure alarm limit values 59
Side effects 23
Specifications 297
Status bar 51
Storage 293
Storage conditions 294
Substituate 323
Substituate pump 50
Surface cleaning / surface disinfection 239
Switching balancing off/on 178
Switching off Ci-Ca anticoagulation 184
Switching on Ci-Ca anticoagulation 185
Symbols 325
System Parameters 195, 306
Systemic anticoagulation 259
Systemic calcium concentration 323

T

Target group 30
Technical Safety Checks / maintenance procedures 295
Temperature 79, 106, 127, 154
Terms 321
Therapies, description 243
Therapy restrictions 30
Tip symbol, significance 18
TMP 310
Touchscreen panel 44
Transport 293
Treatment 306
Treatment data, CVVH 247
Treatment data, CVVHD 250
Treatment data, CVVHDF 253
Treatment data, Pre-post CVVH 248
Treatment data, TPE 256
Treatment displays 167
Treatment pause 306
Treatment pause (circulation with NaCl solution) 174
Treatment pause (circulation with recirculation connector) 175
Treatment pause without blood reinfusion 173
Treatment therapies and fields of application 23
Treatment time 191, 323
Trolley with brakes 39

U

UF rate 57
UF/BF 221
Ultrafiltration 307
User interface 51
UserCard 321, 323
Using the card slot 47

V

Vascular access 244

W

Warning about electrical safety 34
Warning symbol, significance 18
Warnings relating to consumables and accessories 35
Warnings, electrical 34
Weight 297
Wheels with brakes 42

2 Important information

2.1 How to use the Instructions for Use

Device type

In this document, unless otherwise stated, the word “device” on its own always refers to the multiFiltratePRO device.

Identification

The document can be identified by the following information on the title page and on the labels, if any:
– Software version of the device
– Edition of the document
– Date of issue of the document
– Part number of the document

Footer

The footer contains the following information:
– Company name
– Device type
– The English abbreviation for the document type and the international abbreviation for the document language, e.g., IFU-EN means Instructions for Use in English.
– The edition identification, for example, 13A-2020 refers to edition 13A released in 2020.
– The page identification

Organisation of the chapters

To facilitate the use of documents from Fresenius Medical Care, the organisation of the chapters has been standardised in all manuals. There may therefore be chapters within this document without any content. Chapters without content are marked accordingly.

Styles used in the document

The following text styles may be used in the document:

Style	Description
Keys and buttons	Keys and buttons on the device are shown in **bold type**. Example: **OK** button
Display messages	Device messages are shown in **bold type**. Example: Message: **Mains power failure**
➢ Instructions	Instructions are indicated by an arrow ➢ . Instructions must be followed. Example: ➢ Press the **OK** button to apply the displayed data.

Illustrations

The illustrations used in the documents may differ from the original if this does not have any influence on the function.

Importance of the instructions

The Instructions for Use are part of the accompanying documents and are an essential part of the device. They include all the necessary information for operating the device.

The Instructions for Use must be carefully studied before attempting to operate the device.

Changes

Changes to documents will be released as new editions or supplements. In general, this manual is subject to change without notice.

Reproduction

Reproduction, even in part, is only permitted with written approval.

2.2 Significance of warnings

Advises the operator of hazards that carry the risk of serious to potentially life-threatening bodily injury to persons, unless the measures for avoiding the risk described are followed.

Warning

Type of hazard and risk

Possible consequences of exposure to the risk.

➢ Measures for avoiding the risk.

Warnings can deviate from the above template in the following cases:
– If a warning describes several risks
– If no specific risks can be detailed in the warning

2.3 Significance of notes

Note

Advises the operator that the following effects can be expected in the event of failure to observe this information:
– Damage to the device.
– Required functions failing to run at all or running incorrectly.

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description

The device enables extracorporeal blood purification procedures to be performed. It controls and monitors the extracorporeal blood circuit.

There are four operating buttons on the monitor. Input of treatment parameters and operator control is effected mostly by way of a high-resolution touchscreen. While treatment is in progress, the treatment parameters are displayed.

Tube pumps are used to convey the blood, filtrate, dialysate, substituate or blood plasma, as well as the citrate and calcium solutions if citrate anticoagulation is used, depending on the procedure. For volume replacement therapies, balancing is gravity-controlled using scales, while integrated heaters can be used to heat the dialysate, substituate or replacement plasma as necessary, depending on the treatment mode.

In the extracorporeal blood circuit, the blood is passed through a filter or an adsorber. The blood can be continuously anticoagulated. An air bubble detector prevents the infusion of air to the patient. Any dangerous loss of blood is prevented by a blood leak detector and by monitoring the return pressure. The access pressure monitoring unit can detect an occlusion of the needle or catheter, e.g. due to suction to the vessel wall.

2.6 Intended purpose and related definitions

2.6.1 Intended purpose

Control, operation and monitoring of extracorporeal treatment.

2.6.2 Medical indication

- Acute renal insufficiencies requiring continuous renal replacement therapy (CRRT).
- Volume overloads requiring continuous renal replacement therapy (CRRT).
- Certain intoxications requiring continuous renal replacement therapy (CRRT).
- Diseases requiring the exchange of blood plasma by TPE.
- Diseases requiring CRRT combined with haemoperfusion in order to remove additional pathogens from the blood.
- Diseases requiring CRRT combined with ECCO2R for the purposes of additional CO2 removal.
- Diseases requiring CRRT in addition to extracorporeal gas exchange (oxygenation and decarboxylation) intended to provide extracorporeal cardiac and/or pulmonary assist.

2.6.3 Intended patient population

CVVHD, CVVHDF and CVVH treatments in adult mode are to be used in all patients requiring CRRT without or with systemic anticoagulation and with a body weight of 40 kg and more, irrespective of their age.

Ci-Ca CVVHD and Ci-Ca post-CVVHDF treatments are to be used in adult patients requiring CRRT-RCA, with a body weight of 40 kg and more.

CVVHD treatments in paediatric mode are to be used in all patients requiring CRRT without or with systemic anticoagulation with a body weight of 8 to 40 kg, irrespective of their age.

TPE treatment is to be used in patients with a body weight of 40 kg and more, irrespective of their age.

The combined CRRT + ECCO2R treatment is to be used in adult patients with a body weight of 40 kg and more. In addition, the patient restrictions defined in the relevant Instructions for Use must also be taken into consideration.

The combined CRRT + haemoperfusion (Cytosorb or Seraph) treatment is to be used in adult patients with a body weight of 40 kg and more. In addition, the patient restrictions defined in the relevant Instructions for Use must also be taken into consideration.

The combined CRRT + ECMO (with iLA membrane ventilator/iLA activve iLA kit (IPS) equipped with a CRRT connector) treatment is to be used in adult patients with a body weight of 40 kg and more. In addition, the patient restrictions defined in the relevant Instructions for Use must also be taken into consideration.

There is no data available on the use of the device in pregnant or breastfeeding women. The device must not be used during pregnancy and breastfeeding unless the clinical condition of the woman requires treatment with the device.

2.6.4 Intended user group and intended environment

The device must only be installed, operated and used by individuals with the appropriate training, knowledge and experience, and who are certified to have been trained.

The device enables treatment in intensive care units or under similar conditions, where it must be used with close medical supervision and continuous monitoring for the applied treatment.

2.6.5 Performance characteristics and clinical benefits

2.6.5.1 Performance characteristics

See the functional treatment description in Chapter 7 for details of the performance characteristics.

2.6.5.2 Clinical benefits

Specific to CRRT

Clinical benefits of the CRRT treatment in critically ill patients with acute renal insufficiency, fluid overload or intoxications may include improved morbidity and survival outcomes by gentle control of fluid. In addition, acid-base and electrolyte balance as therapy can be timewise stretched up to continuous application, limiting the rate of changes in the patient (haemodynamic stability with slow fluid status changes and lower risk of cerebral oedema with slow osmotic pressure changes).

The combined use of CRRT within the ECMO circuit provides the patients the benefit of both treatment modes using one extracorporeal access. The combined circuit does not change the clinical benefit of CRRT (fluid management, treatment of acute renal insufficiencies and/or intoxications in critically ill patients) or of ECMO. Clinical benefit of ECMO is dependent on the iLA device equipped with CRRT connector.

Specific to the combination therapy with haemoperfusion

The clinical benefits of haemoperfusion depend on the adsorber used.

Specific to the combination therapy with ECCO2R	Only limited data is available regarding the clinical benefits of combining ECCO2R with CRRT.
Specific to TPE	Clinical benefits of TPE may include improved morbidity and survival outcomes by a rapid removal of the pathological substances contained within the plasma. Example indications in the ICU setting include TTP, HUS and intoxications.

2.7 Side effects

Device- and treatment-related

Organ class (IMDRF)	Side effects
Nervous system	Seizures, cerebral oedema, demyelination
Blood and lymphatic system	Anaemia, coagulation disorders (incl. thrombocytopenia), hypovolaemia and hypovolaemic shock (through blood loss, excess ultrafiltration), (sustained) hypervolaemia and oedema, haemolysis (leading to e.g. fever and chills, flushes, abdominal/flank pain)
Immune system	Hypersensitivity/allergic reaction (leading to e.g. dyspnea, hypotension, urticaria, fever and chills, flushes, loss of consciousness, abdominal/flank pain), heparin-induced thrombocytopenia (HIT)
Vascular system	Bleeding/blood loss (also: catheter-related), air embolism, thrombosis and thrombo-embolism
Heart	Cardiac arrhythmia, cardiac arrest
Respiratory system	Bronchospasm, respiratory arrest, pleural effusion (TPE)
Gastro-Intestinal system	Nausea, Vomiting, abdominal pain
Metabolism and nutrition	Removal of nutrients, acidosis (e.g. from citrate accumulation), alkalosis (e.g. from citrate overload), electrolyte imbalance (including hypokalaemia when using low-potassium solutions, hypophosphataemia especially when using phosphate-free solutions; systemic hypocalcaemia or hypercalcaemia, hypernatraemia (especially when using RCA); glucose imbalance (e.g. in patients with diabetes mellitus)
Musculoskeletal system	Cramps/muscle spasms, bone fractures
Infections	Bacterial infection (also: catheter-related) leading to sepsis
Other/generalised disorders	Hypotension, hypothermia, headache

Additional side effects might be specific for other products or drugs used in the therapy (e.g. central venous catheters, adsorbers).

2.7.1 Reporting of serious incidents

If any serious incident occurs in relation to the device, including those not listed in this leaflet, the treating physician must be informed immediately. Within the EU the user must report any serious incident that has occurred in relation to the device to the manufacturer according to labelling ( ) and the competent authority of the EU Member State in which the user is established.

A serious incident can be any incident that directly or indirectly leads to the death of a patient, user or other person; to the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; or a serious public health threat.

2.7.2 Medical Information and precautions for prevent side effects

All treatments

- When using systemic anticoagulation and in the case of a regional citrate anticoagulation, the treatments must be performed according to a protocol (see Chapter 7). The use of no or an incorrectly dosed anticoagulant can lead to early clogging or clotting (with a loss of blood if the extracorporeal system needs to be replaced) or to bleeding, for example through thrombocytopenia or systemic anticoagulant excess.
- In order to ensure that there is a sufficient blood flow throughout the therapy, there must be an appropriate vascular access in the patient (e.g. central venous double-lumen catheter of appropriate size – refer to the Instructions for Use to select the correct size). The use of an already existing arterio-venous graft or fistula (which are required for chronic application) in CRRT treatments can lead to these being damaged. A peripheral vascular access or an AV fistula if available can be used for TPE.
- Adjust the fluid prescription according to the current serum electrolyte and acid-base values or to the indication of the patient being treated and their coagulation status (TPE). To avoid severe disturbances, the fluid balance, acid-base status, serum electrolytes (e.g. Ca2+, Na+, K+, Mg2+, inorganic phosphate), as well as blood glucose must be monitored at regular intervals prior to and during treatment. If necessary, the prescription should be adjusted.
  Any severe imbalance must be counteracted using established medical procedures. Severe disturbances are more likely to occur when using high-volume CRRT and when treating multiple plasma volumes under TPE.
- Some patients may be in a suspected hypercoagulative state (e.g. COVID-19, HIT). In these patients, intravascular and extracorporeal clotting tendencies may be increased. This may lead to early filter clotting, poor treatment quality and thrombo-embolic events. In this case a suitable systemic anticoagulant may be necessary. RCA may also be used in addition to further improve filter patency.
- The patient's temperature must be continuously monitored in order to avoid undesired hypothermia. Environmental factors such as room temperature, the temperature of the dialysate and the substituate must be taken into consideration.

Specific to CRRT

– Excessive net ultrafiltration rates may increase the occurrence of hypotensive events, resulting in fluid administration and volume overloads, and the occurrence of cardiac rhythm disruptions. Current evidence indicates that the weight of the patient must be taken into consideration in the net ultrafiltration rates and the value should be kept low.

Specific to systemic anticoagulation

– Systemic anticoagulation increases the risk of bleeding. There is also the risk of heparin-induced thrombocytopenia, particularly when using unfractionated heparin. The patient information leaflet for the anticoagulants used must be observed.
– Under systemic anticoagulation, loss of filter performance (i.e. clogging, clotting) may lead to a (sustained) metabolic acidosis and electrolyte imbalance, and limited removal of uraemic toxins (CRRT) or a reduced removal of pathological substances (TPE, HP). An increase in TMP may be recognised. A timely change of the filter and extracorporeal circuit should then be considered. In severe cases, blood reinfusion may not be possible, resulting in blood loss.

Specific to CRRT with regional citrate anticoagulation

– A pre-existing ionised hypocalcaemia may have to be treated before initiating the CRRT procedure to reduce the risk of any clinically relevant hypocalcaemia during the first hours of treatment.
– Severe dysnatraemia generally requires a slow patient serum sodium normalisation as otherwise severe complications can result, e.g. demyelination or cerebral oedema.
– In patients with reduced citrate metabolism, as for example in patients with reduced hepatic function, hypoxemia or a disturbed oxygen metabolism, regional citrate anticoagulation can lead to citrate accumulation. Signs are ionised hypocalcaemia, an increased need for calcium substitution, a ratio of total to ionised calcium above 2.25 or metabolic acidosis. The Ci-Ca dialysate flow may then have to be increased and the blood flow reduced, or the use of sodium citrate 4 % for anticoagulation stopped and an alternative blood anticoagulation agent used. Intensified monitoring is recommended.
– When using RCA, loss of filter performance (i.e. clogging) limits removal of uraemic toxins and may lead to citrate excess. Signs of citrate excess are metabolic alkalosis, hypernatraemia and hypercalcaemia. In these cases, the extracorporeal circuit should be replaced.
– Patients in a prolonged immobilised position may undergo bone remodelling/demineralisation, ultimately leading to bone fractures. Under RCA, the early sign of an ionized hypercalcaemia may be masked by a decrease in the calcium infusion rate. In patients under RCA for longer than 2 weeks or in whom the calcium infusion rate is progressively decreasing, bone turnover markers should be closely monitored.
– Fibrin thread formation in the venous return line downstream of the calcium inlet and into the catheter may occur. The treatment must then be terminated, and the circuit exchanged. Regular monitoring is required. Evidence suggests that the risk of fibrin thread formation is higher when the post-filter iCa value is above the recommended range.

Specific to CRRT in children

- A blood leak of the applied filter, which can lead to a loss of blood of up to 400 ml within 12 hours, may not be detected by the blood leak detector of the device, which can be significant in the paediatric patient. It is recommended to monitor the filtrate line and bag for red discolouration every 2 hours.
- Due to the relatively large ECC surface area and low dialysate flows, blood cooling is a potential risk in the treatment of small children. Countermeasures (increasing the room temperature, external blood warmers, electric blanket, etc.) must be considered.
- Priming of the circuit with diluted red blood cells and/or a ~5 % albumin solution can be necessary to avoid haemodilution and associated haemodynamic instability in case the extracorporeal volume of the circuit exceeds 10 % of the circulating blood volume of the patient, in case the patient is anaemic, and/or in case the patient is haemodynamically unstable. For the dilution of red blood cells, choosing a buffered crystalloid generally is preferable over saline. Furthermore, it must be observed that donor erythrocyte concentrates may contain elevated concentrations of extracellular potassium (up to 50 mmol/l), which may cause or aggravate hyperkalaemia.
- Small patients may experience post-procedure fluid overload if the extracorporeal blood volume is reinfused upon treatment termination. Options to consider, depending on patient haematocrit and clinical status are:
  - Trying to achieve a slightly volume-depleted patient status prior to termination.
  - Reinfusing only the initial (darker red, undiluted) extracorporeal blood volume.
  - If necessary, not reinfusing any of the extracorporeal blood volume.

Specific to CRRT combination therapies with haemoperfusion

- Ensure that the filter and the whole-blood adsorber are combined in the correct order as presented in the inserts in the associated kits.

Specific to CRRT combination therapies with ECCO2R

- For CRRT treatment modes, the blood flow for adults is limited to 500 ml/min. The Ci-Ca treatment mode is further limited to 200 ml/min in order to restrict the citrate load. Please observe the Instructions for Use of the ECCO2R filter to clarify whether at these blood flows the device can provide a clinically relevant CO2 removal. Evidence suggests that ECCO2R with blood flows of ≤ 300 ml/min may not provide lung-protective ventilation.
- Ensure that the filters are combined in the correct order as presented in the insert in the associated kit.

Specific to therapeutic plasma exchange

- The required continuous infusion of chosen systemic anticoagulant (e.g. heparin), after the initial bolus, may be higher than in CRRT due to losses into the separated plasma. These losses depend on the plasma filtration rate. The anticoagulant protocol must be adapted accordingly.
- TPE requires precision isovolaemic replacement with a colloid-containing solution, e.g. albumin diluted in a suitable crystalloid (to ~5 %) or fresh frozen plasma (FFP). If diluted albumin does not replace e.g. plasma coagulation factors, the latter may put the patient at risk for transfusion reactions. When the patient's plasma volume is exchanged without the replacement of plasma coagulation factors, both the PT (INR) and aPTT may increase considerably.
  - This is a transient coagulopathy in otherwise healthy individuals, in whom the deficiencies may return to normal by the next day even after a series of exchanges. In these patients, systemic anticoagulation can be reduced accordingly towards the end of treatment to avoid any unnecessary risk of bleeding.
  - Although generally, FFP is strictly required for rare cases only (e.g. in TTP), especially the ICU, post-surgery or post-biopsy patient may be at increased risk for bleeding. FFP or cryoprecipitates may be considered in these patients, especially among the final volumes of the exchange. Intensified monitoring is recommended in patients at increased risk of bleeding.

Additional medical information might be specific for other products or drugs used in the therapy.

2.8 Contraindications

2.8.1 Product-specific and therapy-related contraindications

All treatments

- Inability to establish the required vascular access.

Specific to CRRT

- Treatment with normal-potassium (K4) solutions in severe hyperkalaemia.
- Treatment with low-potassium (K0/K2) solutions in hypokalaemia.
- Treatment with phosphate-containing solutions in severe hyperphosphataemia.
- The use of high molecular weight cut-off haemofilters, such as the Ultraflux EMiC2, in CVVHDF or CVVH.

Specific to heparin as a systemic anticoagulant or for priming

- A known heparin-induced thrombocytopenia type II (HIT-II).

Specific to CRRT with regional citrate anticoagulation

- A known severely impaired citrate metabolism (see medical information and precautions to prevent side effects).

Specific to the combination therapies with haemoperfusion or ECCO2R	– ECCO2R: the need to provide extracorporeal membrane oxygenation in addition to CO2 removal.
Specific to therapeutic plasma exchange	– None known.

2.8.2 Relative contraindications

Predictors for poor treatment outcome – treatment decision on an individual basis.

All treatments	– Terminal disease with no reasonable expectations for recovery.
Specific to CRRT	– The need to have treatment effects reached more rapidly, e.g. in certain intoxications, than can be accomplished with CRRT treatment. Intermittent HD may be more appropriate in these cases. – Access via an existing arterio-venous graft or fistula that is required for chronic treatment.
Specific to systemic anticoagulation	– Patients with active bleeding or at a high risk of bleeding. – Heparin as systemic anticoagulant in a known heparin-induced thrombocytopenia type I (HIT-I).
Specific to regional citrate anticoagulation	– Mitochondrial dysfunction potentially leading to impaired citrate metabolism (e.g. paracetamol and metformin intoxications). – Severe dysnatraemias might be better managed with a different anticoagulation method in which it is more straightforward to modify the impact on serum sodium concentration. – The need to extend the treatment beyond 4 weeks continuously.
Specific to the combination therapies with hemoperfusion	– The need to have more rapid pathological substance removal than can be accomplished in combination with CRRT treatment.
Specific to the combination therapies with ECCO2R	– The need to establish higher blood flows to enable more rapid CO2 removal than can be accomplished in combination with CRRT treatment.
Specific to therapeutic plasma exchange	– Active bleeding or a severely increased bleeding tendency (e.g. due to thrombocytopenia) when the treatment is performed outside of an ICU or specialised unit, where close medical supervision and continuous monitoring are missing.

Additional contraindications might be specific for other products or drugs used in the therapy.

2.9 Interaction with other systems

Interactions with other medical devices / the medical environment

- The use of line roller pumps may lead to minimal electrostatic discharge into the tubing system due to friction on the pump segment. As the charge is very low, these discharges do not represent a direct hazard to patients or operators. If ECG units are used at the same time, these discharges may, in rare cases, cause periodic interferences of the ECG signal. In order to minimise this interference, it is advisable to observe the recommendations of the ECG device manufacturer, e.g.:
  - Correct positioning of the electrodes.
  - Use of specific electrodes with low contact impedance.

It must be ensured that the blood gas analyser is capable of measuring the ionised calcium within the necessary range downstream of the filter. A device from Radiometer was used in order to validate the Ci-Ca protocol.

Interactions with drugs/nutrients

- Crystalloids, (par)enteral nutrition and other infusions are commonly given in intensive care medicine. Interactions may be expected with medicinal products whose purpose or side effect is the alteration of the blood electrolyte, acid-base content, or fluid status of the patient.
- CRRT may reduce the blood concentration of certain medicinal products and nutrients (specifically, those with a low protein binding capacity, with a small distribution volume, and with a molecular weight below the cut-off of the haemofilter). An appropriate revision of the dose of such medicinal products may be required.
  The removal of important nutrients should be compensated by an adapted (par)enteral nutrition. These infusions are preferably not given via the access line of the ECC; lipid parenteral nutrition can clog the applied membrane and reduce its performance.
- TPE may alter the blood plasma concentration of almost all administered medicinal products and nutrients. An appropriate revision of the dose of such medicinal products may be required, and the medicines should preferably be given to the patient once the treatment has been completed. The removal of important nutrients should be compensated by an adapted (par)enteral nutrition.
  Lipid-rich parenteral nutrition administered before the treatment can clog the applied plasma membrane and reduce its performance.
- The cardiac toxicity of cardiac glycosides, in specific digoxin, may be exacerbated upon the correction of hyperkalaemia, hypermagnesaemia or hypocalcaemia, as well as the development of hyponatraemia or an alkalosis.
- Some drugs and treatments can lead to red discolouration of the effluent solution, which can lead to a false positive blood alarm being triggered (resulting from the measuring principle of the optical absorption method (red/green ratio)). This effect must be borne in mind before starting the haemodialysis. One medicinal product that is known to have this effect is hydroxocobalamin, which is used to treat cyanide poisoning.

2.10 Therapy restrictions

Regional citrate anticoagulation

Citrate anticoagulation is available for adult patients for CVVHD and CVVHDF.

2.10.1 Target group

The device must only be installed, operated and used by individuals with the appropriate training, knowledge and experience, and who are certified to have been trained.

2.11 Please note the following when working on the device

Warning

Risk of injury for the patient and operator as a result of improper servicing performed on the device

Improper servicing can impair the safe functioning of the device.

➢ Make sure that start-up, extensions, adjustments, calibrations, maintenance procedures, modifications or repairs are only carried out by the manufacturer or persons authorised by the manufacturer.

More information on installation (see Chapter 9 on page 287).

More information on Technical Safety Checks and maintenance procedures (see Chapter 11 on page 295).

Use only spare parts approved by the manufacturer.

For identifying and ordering spare parts, test equipment and tools, always use the electronic spare parts catalogue.

For additional information about transportation and storage, (see Chapter 10 on page 291).

2.12 Expected service life

If the Technical Safety Checks are performed to the full extent specified and at the prescribed intervals, the safe operation of the device in the time between them is guaranteed.
In addition, the manufacturer recommends that maintenance procedures be performed at the same time intervals to avoid device malfunctions caused by wear and tear.
With each Technical Safety Check, the “expected service life” according to IEC 60601-1 will therefore be prolonged until the next prescribed Technical Safety Check.

2.13 Duties of the responsible organisation

Specification

The responsible organisation is responsible for ensuring that the following specifications are met:
– Compliance with the national or local regulations concerning the installation, operation, use, and maintenance of the device.
– Compliance with the accident prevention regulations.
– Ensuring the proper and safe condition of the device.
– Ensuring the permanent availability of the Instructions for Use.
– The device may only be operated under the operating conditions specified by the manufacturer.

To enhance treatment quality and patient safety, the manufacturer recommends following IEC/TR 62653 “Guideline for safe operation of medical devices used for haemodialysis treatment”. The guideline describes the requirements for using haemodialysis systems safely and for their intended purpose.

Training and instruction

Before the responsible organisation may begin operating the device, the individual responsible for operation must have been instructed by the manufacturer on how to use the device, with certification of their instruction, and must be thoroughly familiar with the contents of the Instructions for Use.
The device must only be operated by individuals who have been trained and certified in the proper operation and handling of the device.

The manufacturer provides training for this device.

The local service support organisation is available to answer any further questions (see Chapter 2.18 on page 37).

Reporting of incidents

Within EU Member States, the user must report all serious incidents that occur in relation to the product to the manufacturer according to the labelling ( ) and the competent authority of the Member State in which the treatment is taking place.

Therapy information

The manner in which relevant therapy information is provided to the patient is left to the judgement of the treating physician.

2.14 Operator responsibility

The addresses given herein must be used to notify the manufacturer of any unexpected operation behavior or other incidents
(see Chapter 2.18 on page 37).

Warning

Risk of injury as a result of a device defect

Treatment cannot be performed properly and safely with a defective device.

➢ Do not perform a treatment with a defective device.

➢ Take the device out of service and disconnect it from the power supply.

➢ If a treatment is in progress, start a blood reinfusion and terminate the treatment. Perform a manual blood reinfusion, if necessary (see Chapter 5.19 on page 236).

➢ Notify the responsible organisation or service support.

➢ Replace any damaged accessories.

The device can be considered defective in any of the following cases:
– The device has mechanical defects
– The power cable is damaged
– The device does not react as expected
– The performance characteristics of the device deteriorate

The following must be observed when entering parameters:
– The parameters entered must be verified by the operator, i.e., the operator must check that the values entered are correct.
– If this check reveals a deviation between the desired parameters and the parameters displayed on the device, the setting must be corrected before activating the function.
– The actual values displayed must be compared with the prescribed target values.
– The attending physician must be consulted whenever the difficulties are device-, procedure- or health-related.

2.15 Disclaimer of liability

Warning

Chapter 8 (see Chapter 8 on page 281) contains a list of consumables and accessories that are suitable for use with this device and can be used safely with it.

The manufacturer cannot guarantee that other consumables and accessories than those listed in this chapter are suitable for use with this device. The manufacturer cannot guarantee that the safety and performance of the device will remain unimpaired if consumables and accessories other than those listed in this chapter are used.

If other consumables and accessories are used, their suitability must be verified beforehand. This can be done with the aid of the information in the instructions accompanying such consumables and accessories.

The manufacturer accepts no liability for damage to the device resulting from the use of unsuitable consumables or accessories.

2.16 Warnings

The following list of warnings is only an excerpt. Knowledge of all warnings mentioned in these Instructions for Use is required for the safe operation of the device.

2.16.1 Warnings about electrical safety

Warning

Risk of injury as a result of an electric shock

Without a protective earth connection, there is a risk of electric shock.

➢ Always connect the device to a power supply network with a protective earth.

Warning

Risk of injury as a result of an electric shock

There is a risk of electric shock if the patient comes into contact with the pins or contacts of the device's connectors, whether directly or indirectly through the operator.

➢ Avoid touching connector pins or contacts during treatment.

Warning

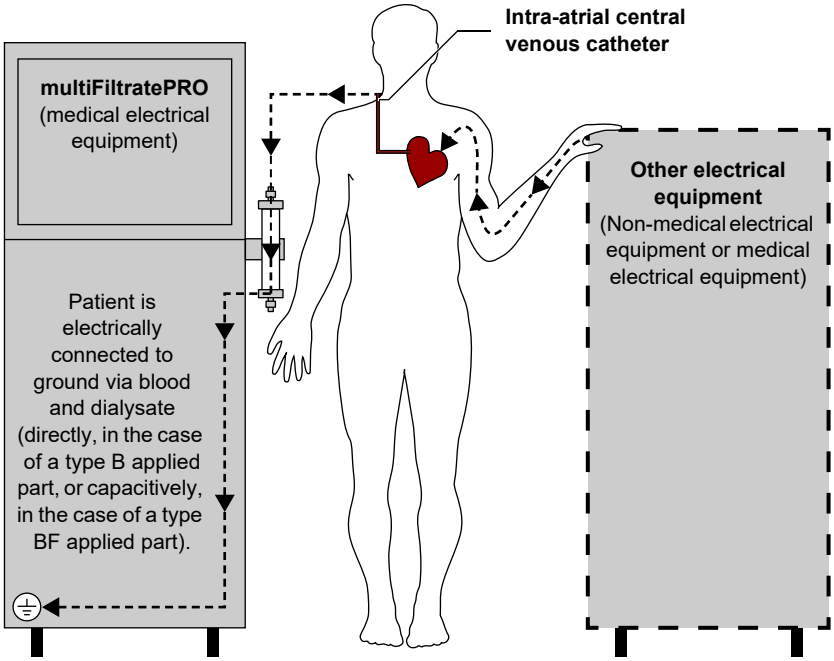
Risk of injury as a result of an electric shock

For treatments using a central venous catheter, if the tip is positioned in the patient's right atrium, the following precautions must be observed:

➢ Make sure the device (multiFiltratePRO) is connected to the grounded equipotential zone of the installation.

➢ Move all non-medical and medical electrical equipment with touch currents or patient leakage currents in excess of the limits for type CF applied parts out of reach of the patient (more than 1.5 metres away in every direction).

The touch current or patient leakage current of non-medical or medical electrical equipment can be conducted to ground over the patient's central venous catheter and over the type B or BF applied part of the device (multiFiltratePRO).



Patient leakage current limits for type CF applied parts:
– 10 µA AC / DC (normal condition, i.e., no fault condition)
– 50 µA AC / DC (single fault condition)

Please address any queries to the local service support organisation.

2.16.2 Warnings relating to consumables and accessories

Warning

Risk of contamination as a result of improper handling of connection sites

Pathogens can enter the extracorporeal blood circuit.

➢ Use aseptic technique for all blood system connections and all the connections of the sterile solutions to be used.

Warning

Risk of cross-contamination as a result of contaminated consumables

There is a risk of spreading germs.

➢ Consumables must be discarded after a treatment in compliance with the regulations for the disposal of potentially contaminated materials.

2.17 SVHC (REACH)

For information on the topic of SVHC in accordance with Article 33 of Regulation (EC) 1907/2006 (“REACH”), visit the following website:

www.freseniusmedicalcare.com/en/svhc

2.18 Addresses

Manufacturer

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY
Phone: +49 6172 609-0
www.freseniusmedicalcare.com

Service support, international

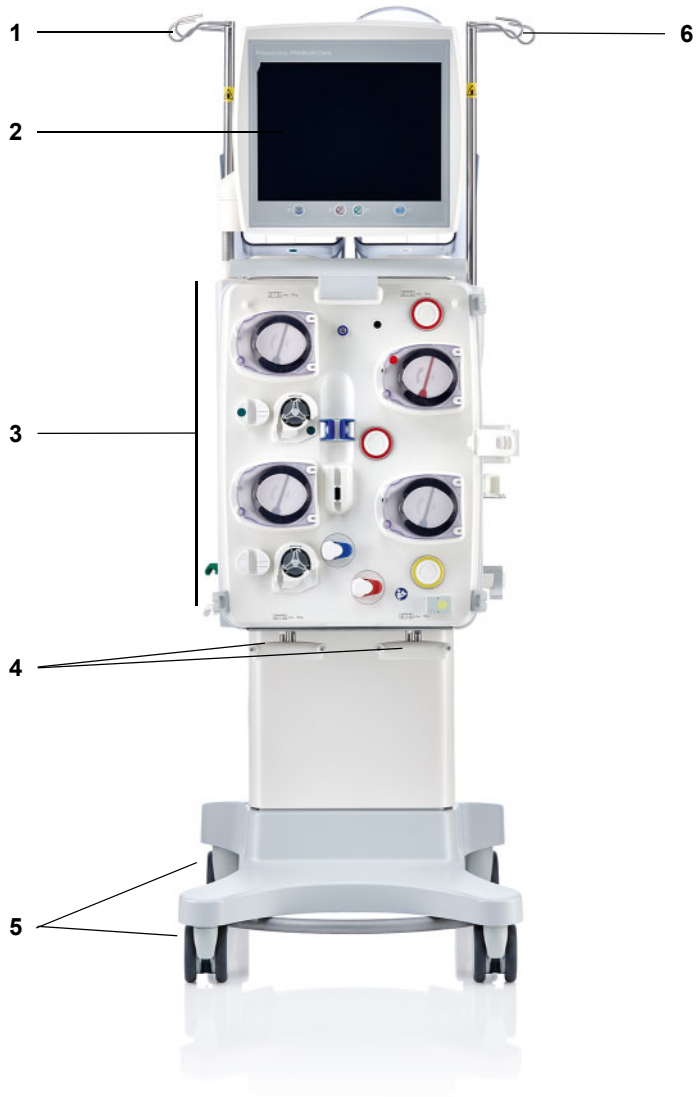
Fresenius Medical Care
Deutschland GmbH
Technical Operations
Technical Coordination Office (TCO)
Hafenstrasse 9
97424 Schweinfurt
GERMANY

Service support, local

3 Design

3.1 Views of the device

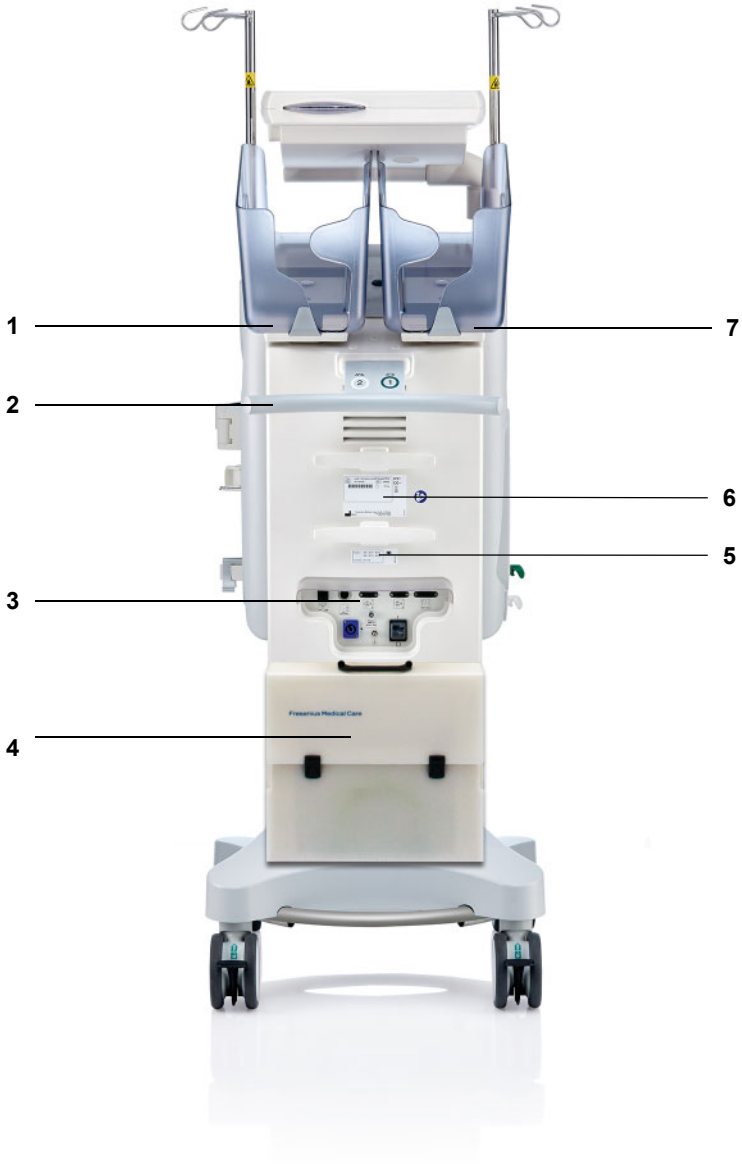
3.1.1 Front view



Legend

1	Left IV pole	**4**	Scales 3 and 4
2	Monitor	**5**	Trolley with brakes
3	Extracorporeal Blood Circuit Module	**6**	Right IV pole

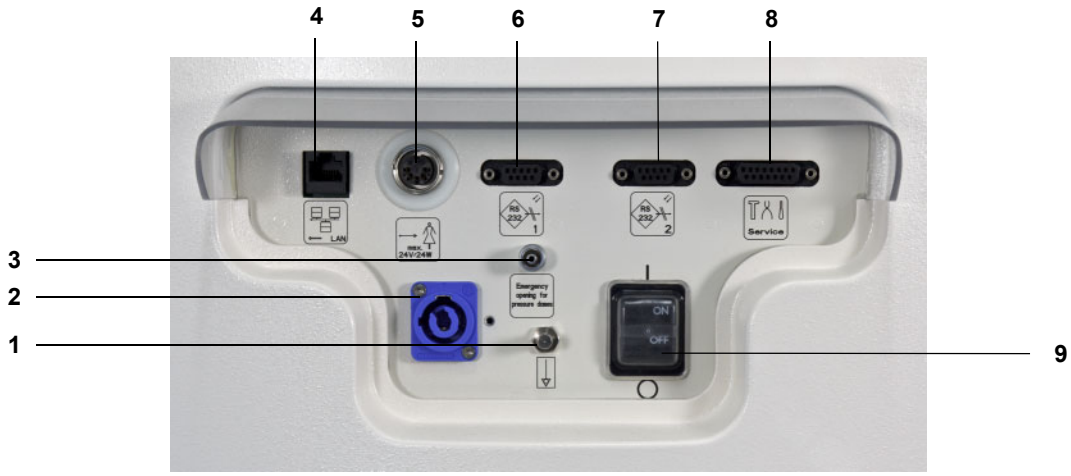
3.1.2 Rear view



Legend

1 Scale 2 (white)
2 Push handle
3 Connector strip
4 Accessories case
5 Power label
6 Identification label
7 Scale 1 (green)

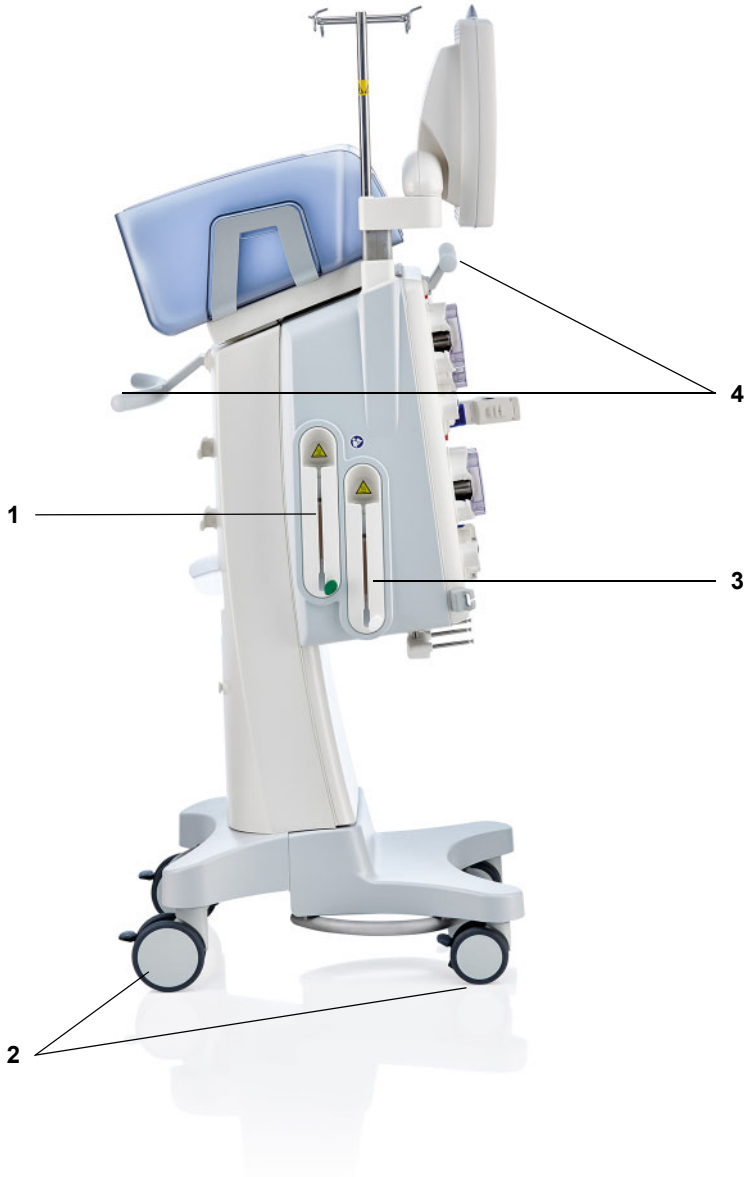
3.1.2.1 Connector strip



Legend

1 Equipotential bonding connection
2 Power supply connection
3 Luer lock connection for manually opening the pressure measurement units
4 LAN (local area network) network connection
5 Nurse call port
6 1st RS 232 serial port with 5 V power supply
7 2nd RS 232 serial port
8 Service port (only for service engineers)
9 Power switch

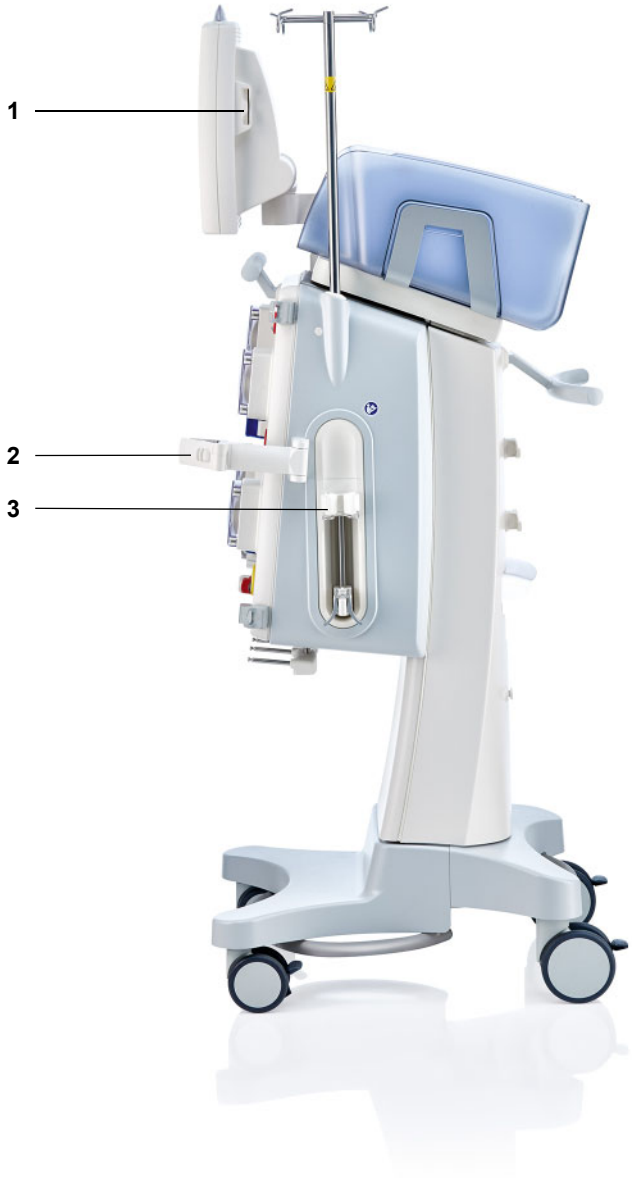
3.1.3 Left side view



Legend

1 Heater (green)
2 Wheels with brakes
3 Heater (white)
4 Push handles

3.1.4 Right side view

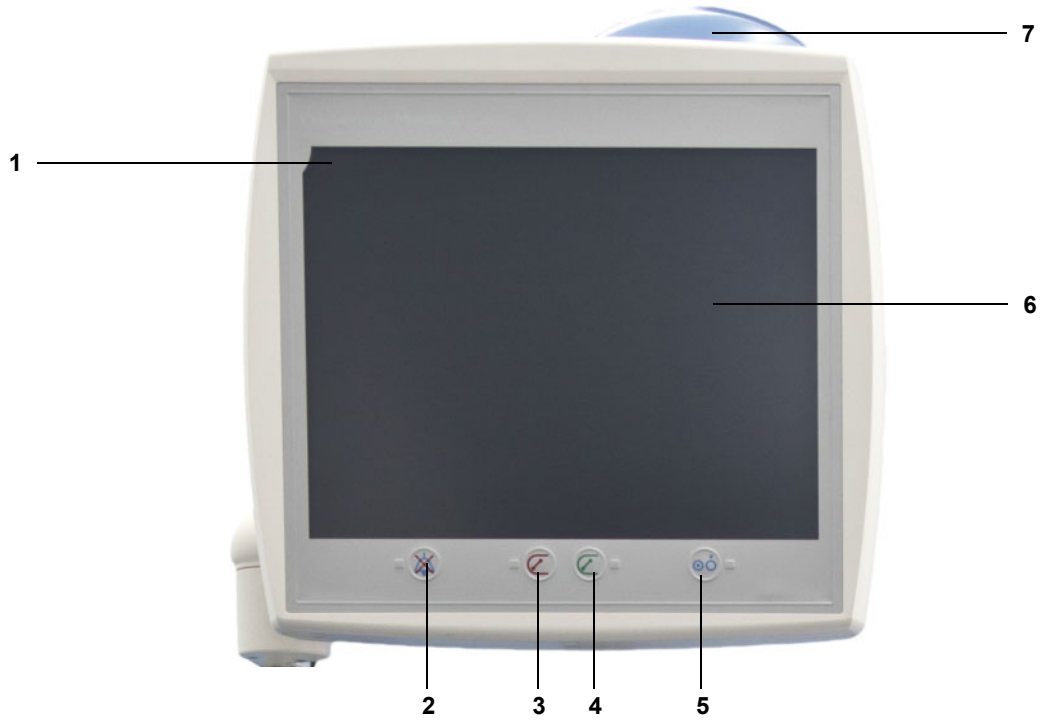


Legend

1 Card slot
2 Filter holder
3 Heparin pump

3.2 Controls and indicators

3.2.1 Monitor front



Legend

1 Screen failure sensor (hidden)

2 LED/button **Audio paused** (red)
- **LED flashes** – Message/alarm with audible tone is being signalled
- **LED is lit** – Audible tone of current message/alarm has been suppressed by pressing the **Audio paused** button
- **LED off** – No message/alarm

3 LED/button **Stop pumps** (red)
- **LED is lit** – Blood pump has been stopped
- **LED off** – Blood pump is running

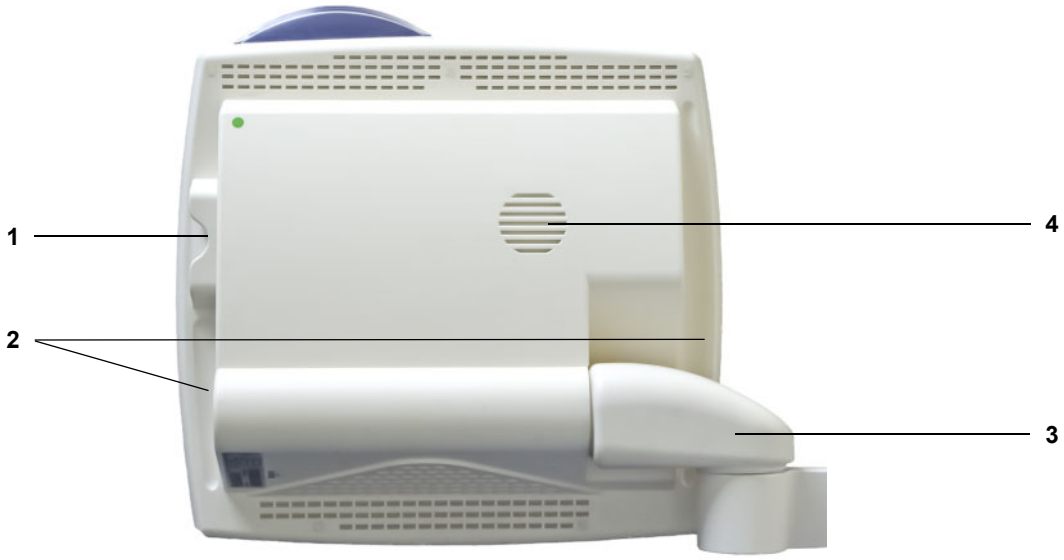
4 LED/button **Start pumps** (green)
- **LED flashes** – Blood pump has been stopped with the **Stop pumps** button
- **LED is lit** – Blood pump is running
- **LED off** – Blood pump has been stopped by device

5 LED/button **On/Off** (green)
- **LED flashes slowly** – Device off, battery is being charged
- **LED flashes rapidly** – Device on/off, battery is not being charged
- **LED is lit** – Device on, battery is being charged
- **LED off** – Device off, battery is not being charged

6 Touchscreen panel

7 Operating status indicator (traffic light)
Further information: (see Chapter 5.2 on page 214)

3.2.2 Monitor rear

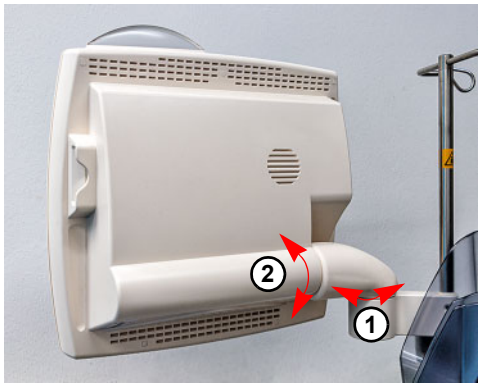


Legend

1 Card slot
2 Recessed grip
3 Monitor arm
4 Loudspeaker

3.2.3 Positioning the monitor

Position the monitor with the aid of the recessed grips on either side.

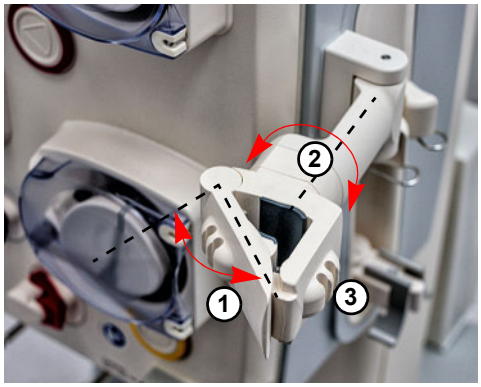


Positioning the monitor:
The monitor can be adjusted by two axes (1) and (2) to the desired position.

3.2.4 Using the card slot

Insert the card into the card slot.

3.2.5 Positioning the filter holder

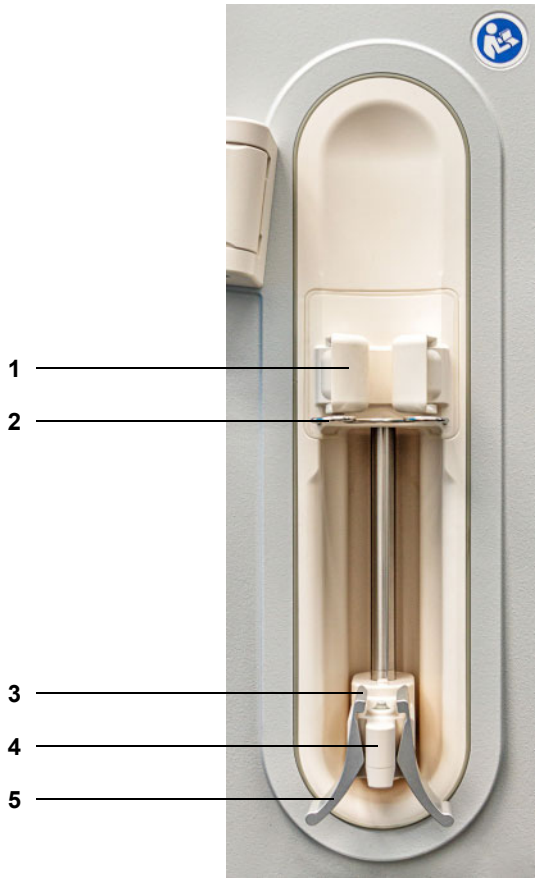


Open the lever (**1**) towards the left and insert the filter.

Turn the filter holder until the filter is in the required position (**2**).

Insert the tubing systems into the line holders intended for them (**3**).

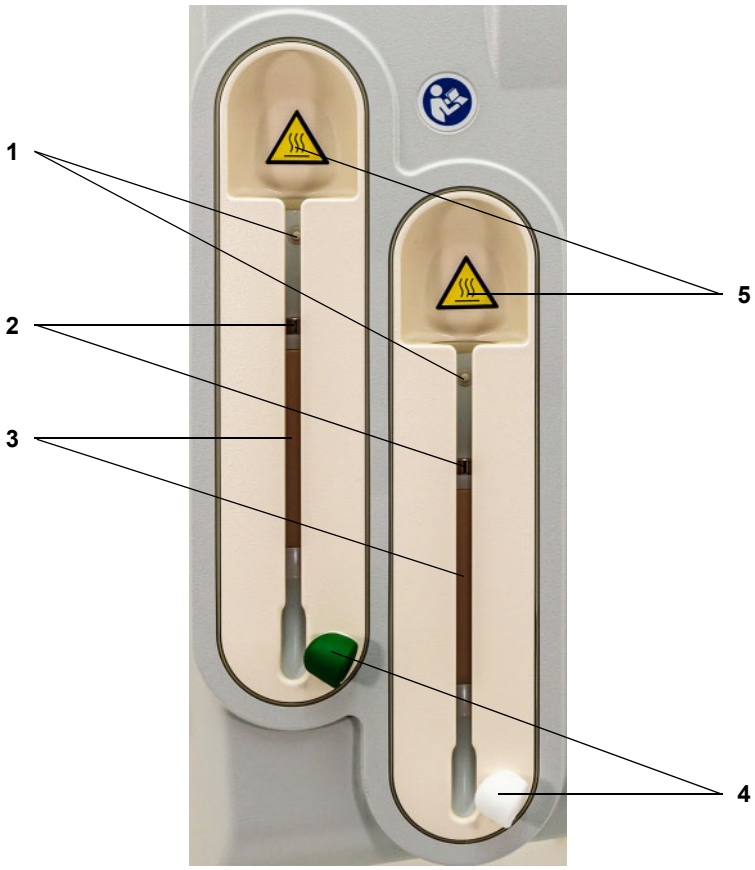
3.2.6 Heparin pump



Legend

1 Barrel holders with syringe detector
2 Bracket
3 Jaws of the spring clip
4 Stock
5 Spring clip

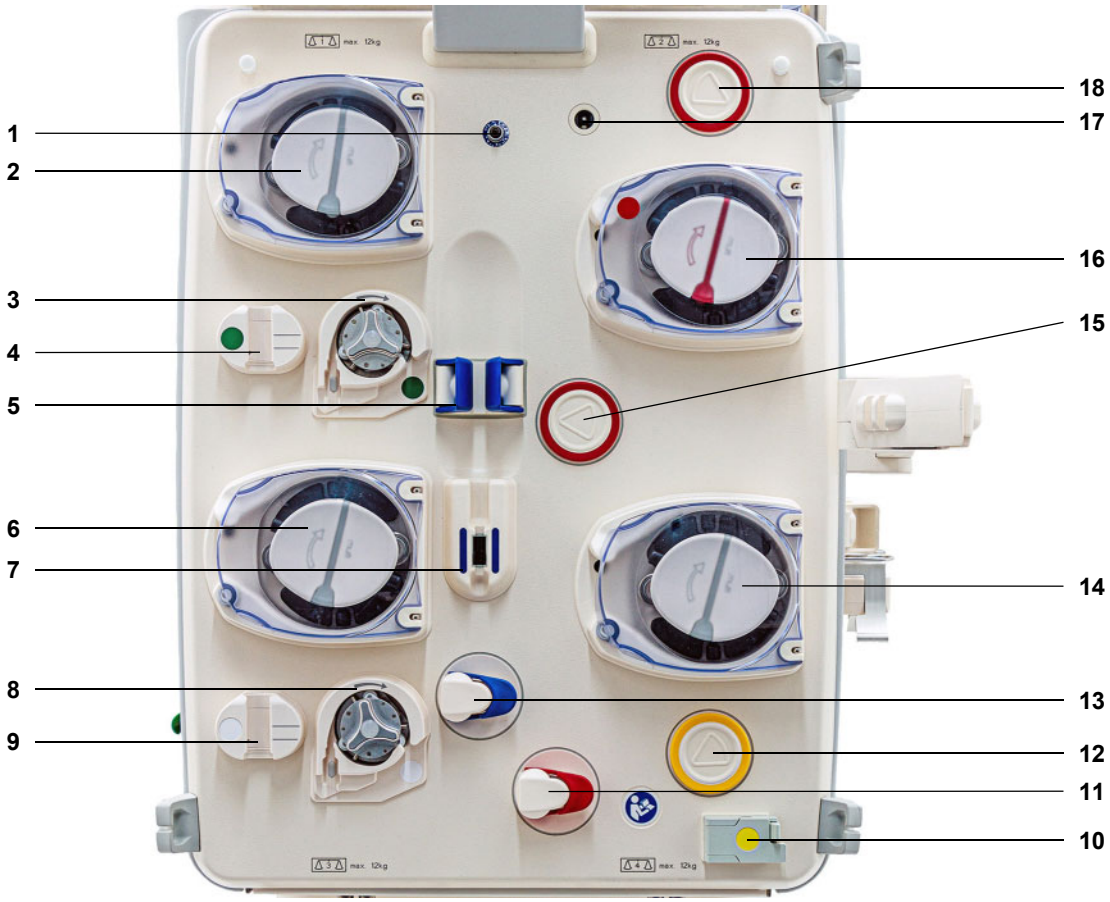
3.2.7 Heater



Legend

1	Microswitch
2	Temperature sensors
3	Heating element
4	Line holder (green or white)
5	Label Warning: Hot surface

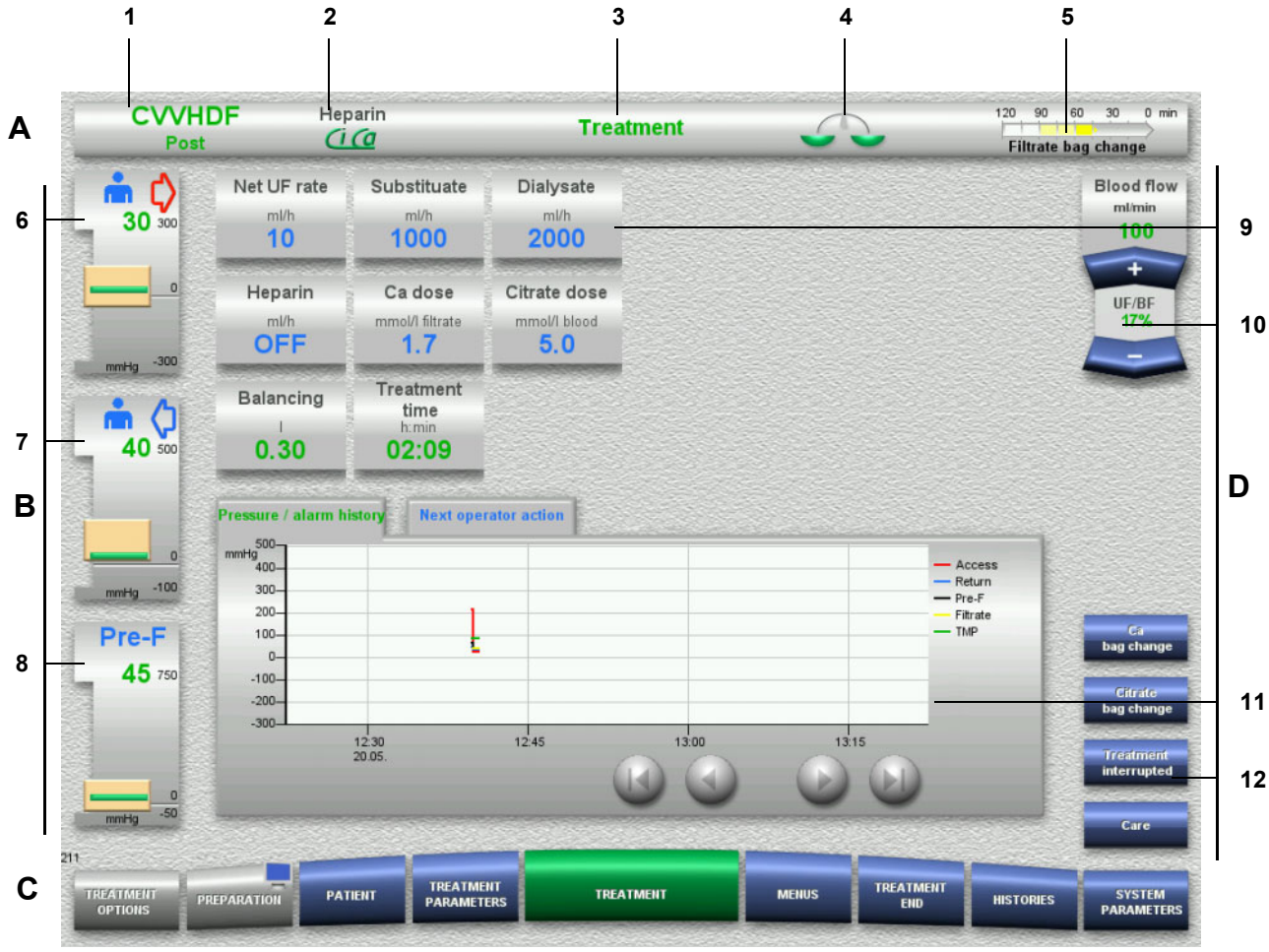
3.2.8 Extracorporeal Blood Circuit Module



Legend

1 Return pressure sensor (blue)
2 Dialysate pump/Predilution substituate pump (depends on treatment mode)
3 Citrate pump (green)
4 Citrate drip counter/Citrate fill level detector (green)
5 Fill level detector
6 Substituate pump
7 Air bubble detector/Optical detector
8 Calcium pump (white)
9 Calcium drip counter/Calcium fill level detector (white)
10 Blood leak detector (yellow)
11 Line occlusion clamp (red)
12 Filtrate pressure measurement unit (yellow)
13 Line occlusion clamp (blue)
14 Filtrate pump
15 Access pressure measurement unit (red)
16 Blood pump
17 Cassette detector
18 Pre-filter pressure measurement unit (red)

3.3 User interface



Legend

A **Status bar**
1 Treatment mode
2 Anticoagulation method
3 Current menu
4 Balancing status/plasma treatment status indicator
green: Balancing/plasma treatment on
yellow: Balancing/plasma treatment off
5 Progress bar:
Time remaining before next operator action/
time remaining for processes in progress

B **Pressure displays**
6 Access pressure
7 Return pressure
8 Pre-filter pressure

C **Menu bar**
During operation, each menu will open automatically as needed. Alternatively, you can press on any of the available menu buttons to open the menu concerned.
Monitor symbol in menu button PREPARATION (deactivates/reactivates the monitor for cleaning during operation).

D **Menu panel**
The main part of the screen shows the appropriate data fields of the active menu.
9 Display/input field
10 Rocker switch buttons
11 Information area
Shows messages and graphs
12 Quick access buttons
For menu options

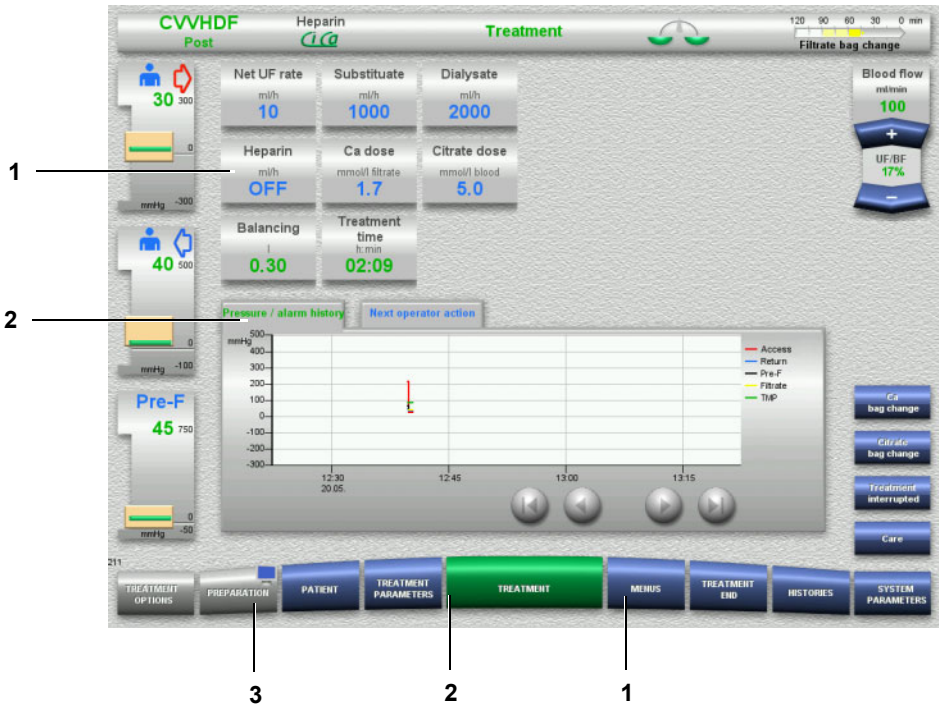
3.4 General operating concept

3.4.1 Colour coding on the device and single-use articles

Mistake proofing

The colour coding on the device and on the single-use articles helps you identify connections correctly and insert items in their proper place.

3.4.2 Screen colours



Legend

1 BLUE means: can be selected
Examples: **Heparin** field and **MENUS** button
2 GREEN means: active
Examples: Information tab Pressure / alarm history and **TREATMENT** button
3 GREY means: not active/cannot be selected
Example: **PREPARATION** button

3.4.3 Context-specific information

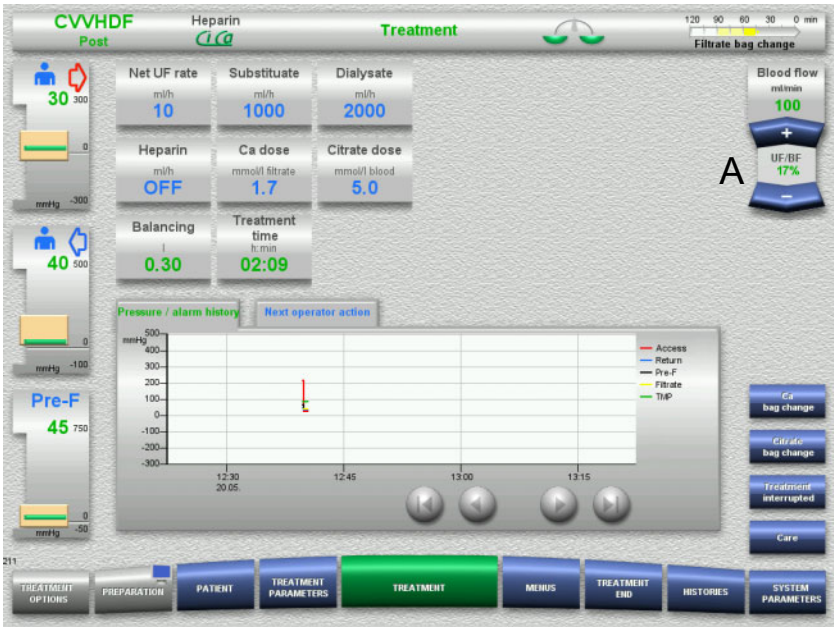
In the input windows of the display/input fields, additional, important information is shown on the left of the number buttons.

➢ Press the **Ca dose** field.
The input window opens.
On the left of the number buttons, additional, context-specific information is displayed.

➢ Press the **Ca** button in the context-specific information area.
The calcium dosage target range and adjustment steps are displayed.

3.5 Basic input procedures

3.5.1 Changing settings with the rocker switch buttons



➢ Use the **+ / –** rocker switch buttons (A) to set the required flow.

3.5.2 Changing settings with the number buttons

➢ Press the relevant display/input field.
The input window opens.

➢ Enter the new value with the aid of the number buttons.
Grey buttons prevent invalid entries.

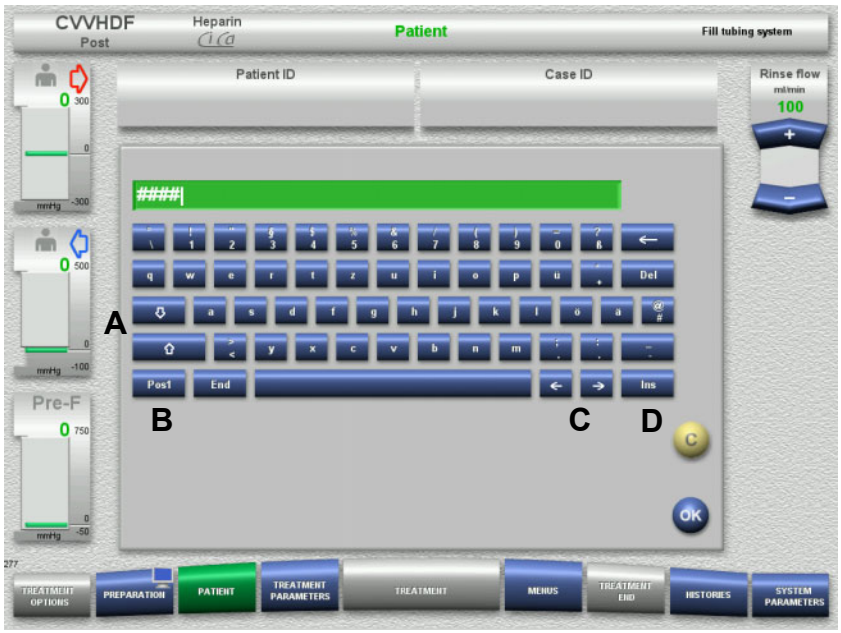
➢ Check the new value against the target value.

➢ To correct your entry, press the **C** button.
The last active value will be displayed.

➢ Press the **OK** button to apply the displayed value.
The input window is closed.

➢ The applied value is checked.

3.5.3 Entering data with the keyboard



➢ Press the relevant display/input field.
The input window opens.

➢ Use the keyboard to enter the required data.
(A) Shift between upper case and lower case letters using the **arrow (up/down)** buttons.
(B) Press the **Pos1** button to move the cursor to the beginning of the line.
(C) Move the cursor to a different position in the line using the **arrow (left/right)** buttons.
(D) Press the **Ins** button to switch between overtype mode and insert mode.

➢ Check the entered data.

➢ To correct your entry, press the **C** button.

➢ Press the **OK** button to apply the displayed data.
The input window is closed.

3.5.4 On/Off button

➢ Press the **Heparin** field.
The input window opens.

➢ Press the **I/O** button.
This activates the input window (number buttons).

➢ Enter the required heparin flow with the aid of the number buttons.
Grey buttons prevent invalid entries.

➢ Check the new value against the target value.

➢ To correct your entry, press the **C** button.
The last active value will be displayed.

➢ Press the **OK** button to apply the displayed value.
The input window is closed.

➢ The applied value is checked.

3.5.5 Viewing the ratio of the UF rate to the blood flow rate

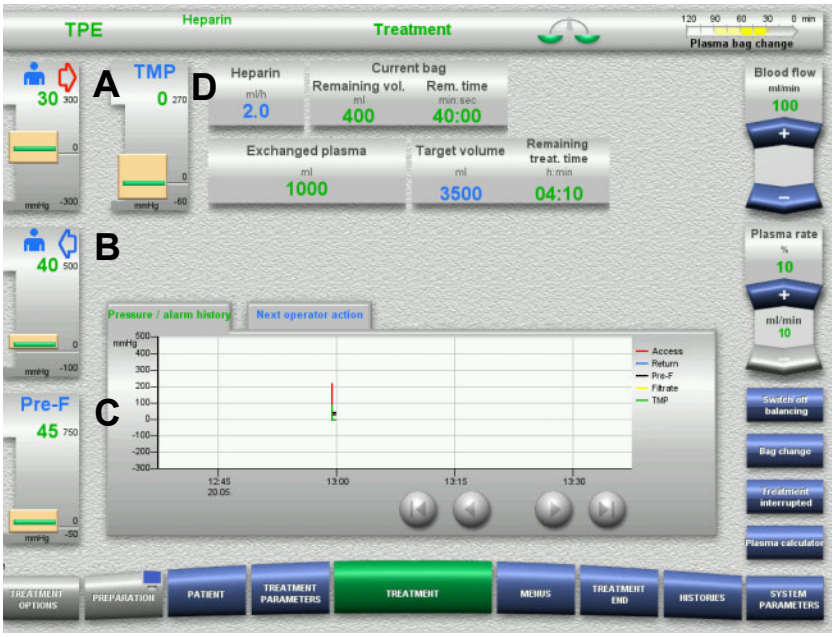
The **UF/BF** ratio is shown in the field between the rocker switch buttons of the blood pump, and also in the input windows of the following fields, as context-specific information:

Substituate (in postdilution mode)
Net UF rate
Blood flow

3.5.6 Viewing the pressure values

The device incorporates an automatic limit monitoring system. This helps avoid superfluous error messages that could otherwise occur, for example, when a patient shifts position.

The asymmetric return pressure limit values are set by default to ensure a rapid reaction to a loss of pressure.



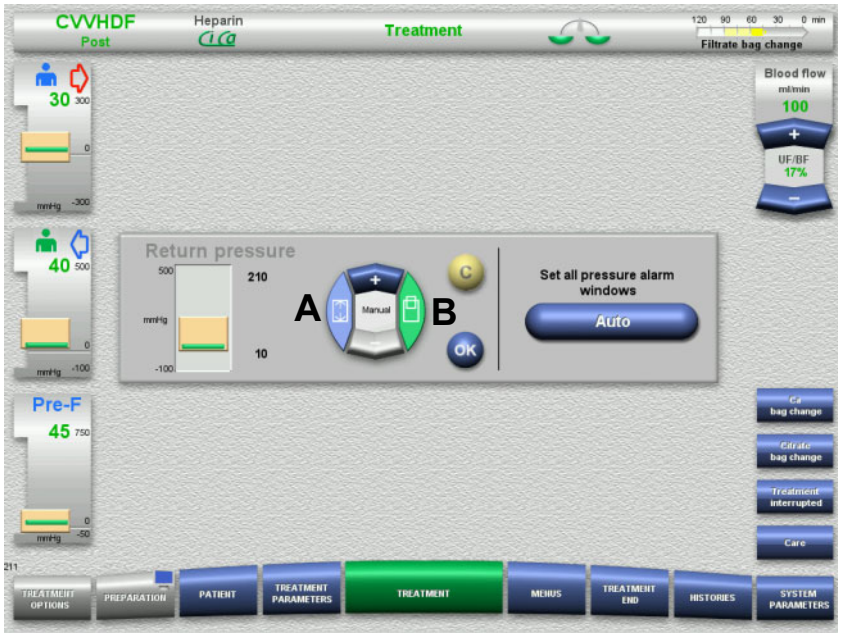
The pressure values are always shown on the left of the screen and depend on the treatment type.

(A) Access pressure (red arrow)
(B) Return pressure (blue arrow)
(C) Pre-filter pressure (Pre-F)
(D) Transmembrane pressure (TMP only displayed for TPE)

The actual values are shown as numerical values and indicated by the green line over the pressure alarm window in each case.

The pressure alarm window is shown in the form of a rectangular tile in each case.

3.5.7 Setting the pressure alarm limit values



➢ Press on the required pressure display field.
The input window opens.

➢ Select the type of change you wish to make.
(A) Change the pressure alarm window size
(B) Move the pressure alarm window position

➢ Use the **+ / –** rocker switch buttons to change the limit parameter values accordingly.

➢ Check the limit parameters you have set.

➢ Press the **OK** button to apply the new limit parameters.
The input window is closed.

➢ To correct your entry, press the **C** button.
The last active pressure alarm window will be applied.

By pressing the **Auto** button, you can reset the pressure alarm windows for all the pressure types automatically around the current values.
This does not change the size of the pressure alarm windows.

4 Operation

Note

The screens shown in the Instructions for Use may differ from those displayed on the device.

On the device, the current treatment mode is always displayed in the upper left-hand corner of the screen in the status bar. For technical reasons, the screens figuring in the Instructions for Use do not always represent the selected treatment mode.

The values shown in the screenshots are for illustrative purposes only. All treatment parameters must be entered as specified by the physician.

The device must be operated according to the instructions on the screen.

4.1 Application principles

Warning

Danger in case of excessive load on the IV pole (observe the maximum load)

An excessively heavy load on the IV poles can overturn the device.

➢ Do not exceed the maximum permitted load of 5.5 kg on the IV pole.

Warning

Risk of embolism as a result of particle reinfusion

➢ Use the dialysate and substituate in accordance with the manufacturer's instructions.

Warning

Risk of contamination as a result of infusion of unsuitable solutions that do not match the selected treatment mode

➢ After changing the treatment mode, change the solutions if necessary so that they match the selected treatment mode and the anticoagulation.

➢ For the treatment modes CVVHDF and CVVH, only solutions that are suitable for infusion must be used.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate and substituate

➢ Adjust the flow ratios of the solutions in relation to each other in relation to the blood flow.

Warning

Risk of cross-contamination as a result of tubing systems without hydrophobic filters

There is a risk of spreading germs.

➢ Only use tubing systems with hydrophobic filters in the pressure lines.

Warning

Risk of cross-contamination as a result of a wrong proceeding in case of a wet or defective hydrophobic filter

There is a risk of spreading germs.

➢ Never force back any fluid with a syringe (damages the hydrophobic filter).

➢ Make sure the pressure line is tightly sealed.

➢ Replace the affected tubing system. In the case of a pressure line with a wetted hydrophobic filter, use a replacement pressure line (accessory available from manufacturer).

If you cannot exclude the possibility that the device may have become contaminated:

➢ Take the device out of service after completing treatment.

➢ Have the device tested for contamination by service support.

If the device is contaminated, all affected parts must be disinfected or replaced by service support.

Warning

Risk of injury as a result of hot surfaces

Touching the inside of the heaters can result in burns.

➢ Do not touch the inside of the heaters during treatment.

Warning

Risk of crush injury from pressure measurement unit when closing

➢ Keep fingers clear of open pressure measurement units.

Warning

Risk of crush injury when closing line occlusion clamp

➢ Keep fingers clear of open line occlusion clamps.

Warning

Risk for the patient as a result of corrupted data

Objects placed on top of the tilted monitor can inadvertently change treatment data.

➢ Do not place any objects on top of the monitor.

Warning

Risk of contamination as a result of improper handling of single-use items and consumables

Single-use items and consumables can come into contact with germs when removed from their outer packaging.

➢ Do not unpack and insert single-use items and consumables until immediately before beginning treatment.

Warning

Risk of blood loss as a result of damaged tubing systems

Risk of circulatory disturbance as a result of fluid loss

There is a risk of blood and plasma loss.

➢ In long treatments, replace tubing systems before the end of their service life as specified by the manufacturer or when a warning message is displayed by the device.

Preparation times also count as part of the service life. The service life information is printed on the packaging of the tubing systems. Any specified limit values or warning messages of the device are ignored at the operator's own risk.

Warning

Risk of blood loss as a result of an undetectable dislocation

Risk of blood loss as a result of an undetectable leakage

A leak in the tubing system and/or a dislocation of the return line can result in the patient suffering a serious loss of blood.

➢ The lower return pressure limit value must be set as close as possible to the actual return pressure value.

Warning

Risk for the patient as a result of improper use of consumables

Treatment cannot be performed properly and safely if consumables are used incorrectly.

➢ Follow the instructions that come with the consumables used.

Warning

Risk of contamination as a result of damaged tubing systems

Risk of air embolism as a result of air in the tubing system

Risk of blood loss as a result of damaged tubing systems

Risk of blood loss as a result of connection sites not closed correctly

Risk of haemolysis as a result of a kinked and crushed tubing system

Risk of circulatory disturbance as a result of fluid loss

➢ When inserting the tubing system, observe the following:

– Only use the tubing system specified for the selected treatment mode.
– Consumables must only be used if the packaging and the consumable itself, including any protective caps or plugs, are undamaged. Protective caps and plugs must be in place and must not have fallen off.
– Before connecting the patient, make sure the tubing system is free of air.
– Insert tubing systems cleanly, without kinks, line tension, or twisting. Use the line holders provided.
– Make sure the tubing systems cannot become crushed or pinched.
– The device’s safety systems (access and return pressure monitoring) cannot always detect all kinks, constrictions, or crushing of the tubing.
– Make sure all screw-lock joints are properly tightened, particularly those of the patient connections, the dialyser connections, and the device connections. Take the appropriate corrective measures (e.g., tighten the Luer lock connections, or replace the tubing system if necessary).
– Always check the solution bags for visible leaks before connecting them to the tubing system.

Warning

Risk of air embolism as a result of air in the tubing system

Risk of haemolysis as a result of a kinked and crushed tubing system

Risk of blood loss as a result of connection sites not closed correctly

Risk of circulatory disturbance as a result of fluid loss

➢ Before starting a treatment, check the following:

– All the joints of the tubing system are securely connected
– There are no apparent leaks in the tubing system, either during or after filling
– Tighten connections as needed, or, if necessary, replace the entire tubing system
– The tubing system is free of air, is inserted cleanly without kinks, line tension or twisting, and all fluid levels are correct

Warning

Risk of air embolism as a result of air in the tubing system

Risk of haemolysis as a result of a kinked and crushed tubing system

Risk of blood loss as a result of connection sites not closed correctly

Risk of circulatory disturbance as a result of fluid loss

➢ During treatment, check the following at appropriate intervals:

– The condition of the patient.
– The volume balancing and fluid removal monitoring systems.
– The correct function of the device and the extracorporeal blood circuit. To protect the patient from dangerous blood loss, return pressure monitoring of the extracorporeal blood circuit is used as a safety system against external blood leaks. However, pressure monitoring cannot detect an external blood leak in all cases. Particularly critical occurrences are dislocations of the return line or small leaks in the high pressure components of the extracorporeal blood circuit. For this reason, the extracorporeal blood circuit must be checked regularly for leaks while treatment is in progress, paying particular attention to all the joints of the tubing system and the connections to the catheters.
– The tubing system, watching out for possible leaks, air ingress, or loosened joints. Particularly at the joints downstream of the air detector, negative pressure can permit air to enter into the extracorporeal blood circuit. This can be a problem when using central venous catheters.
– Check that the tubing system is not kinked, under tension, or twisted.
– The device’s safety systems (access and return pressure monitoring) cannot always detect all kinks, constrictions, or crushing of the tubing.
– The filtrate and dialysate circuits, watching out for leaks.

Warning

Risk for the patient due to haemolysis or blood loss due to bypassed blood leak detector

Risk for the patient due to haemolysis or blood loss due to the tubing not being correctly inserted into the blood leak detector

If the blood leak safety system is bypassed or the tubing is not correctly inserted into the blood leak detector, neither the haemolysis nor blood loss monitoring can function.

➢ During the treatment, check regularly for discolouration in the filtrate bag caused by blood loss.

Warning

Risk of contamination as a result of improper handling of connection sites

Pathogens can enter the extracorporeal blood circuit.

➢ Use aseptic technique for all blood system connections and all the connections of the sterile solutions to be used.

Warning

Risk of blood loss through excessive heparinisation

Excessive heparin dosages or the use of undiluted heparin can cause internal bleeding or severe secondary bleeding.

➢ Heparin dosage must be set as prescribed by the physician.

➢ Only use diluted heparin.

Warning

Risk of blood loss through insufficient heparinisation

If the heparin delivery rate is too low, this may lead to blood coagulation in the blood tubing system.

➢ When inserting the heparin syringe, observe the following: Insert the heparin syringe correctly into the heparin pump. Observe the description and the illustration.

Warning

Blood loss / risk of blood loss if dynamic pressure monitoring is deactivated
Plasma loss / risk of plasma loss if dynamic pressure monitoring is deactivated

If the dynamic pressure monitoring safety system is deactivated, the monitoring for dislocation of the patient lines is deactivated.

➢ In this case, the operator is responsible for the patient's safety

➢ Increasing the blood flow

➢ Changing the return pressure line

➢ Raising the level in the bubble catcher

Note

Scales:
The maximum load capacity of 12 kg per scale must not be exceeded. The weighing cell can even be permanently damaged by a short-term overload (e.g., pulling or lifting the device by the scales), in which case the device can no longer be used.

Note

Blood pump rotor:
The blood pump rotor has red markings, including the arrow showing the direction of rotation, and must only be installed in the blood pump, which is marked by a matching red dot.

Note

Blood leak/haemolysis monitoring:
The filtrate line must remain in the blood leak detector (yellow) for the entire duration of the treatment.

Note

When administering drugs or connecting infusions via the access line, make sure the substances used will survive the dialyser.
The effectiveness of the intended treatment may depend on this.

When working on the tubing system during a treatment, observe the following:

If you need to move any part of the tubing system out of position, make sure the correct layout of the entire tubing system is restored before continuing treatment, paying special attention to the correct placement of the positioners.

4.2 CRRT treatments

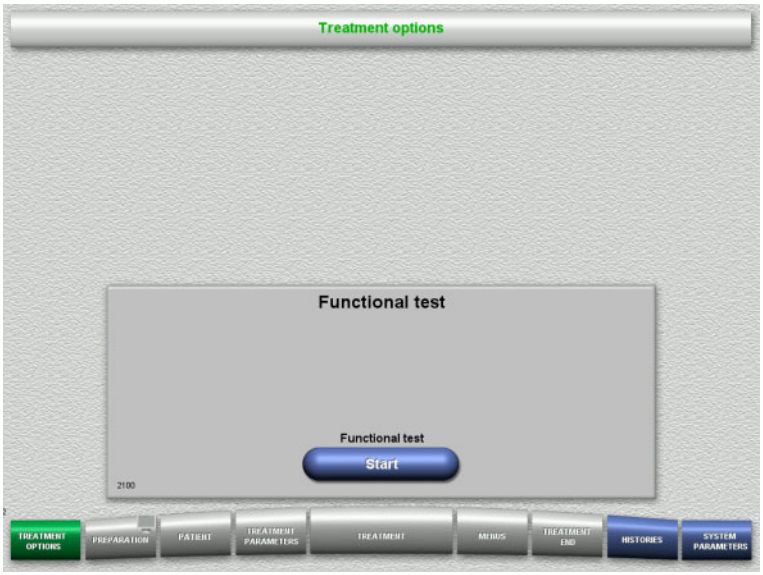
General description of the CVVH, CVVHD, CVVHDF and Pre-post CVVH procedures with information on the differences between the individual therapies.

4.2.1 Switching on the device and starting the function test

There must be no load on any of the scales.

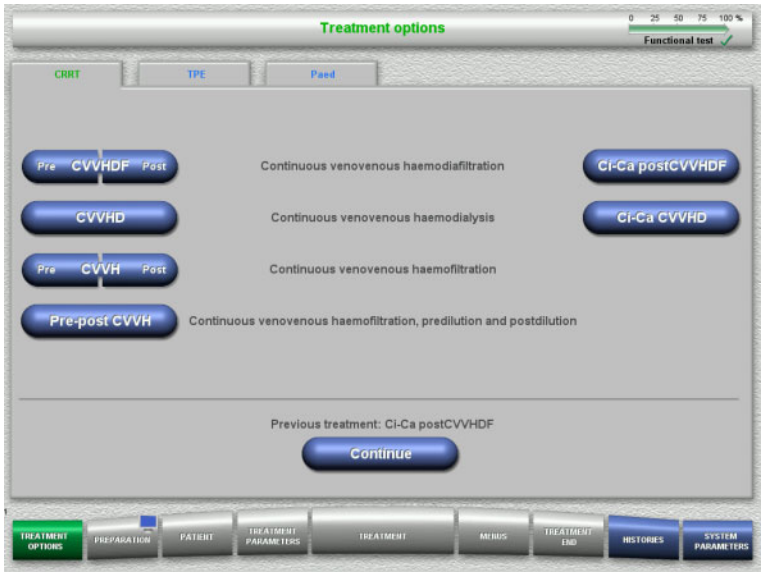
➢ Switch on the device with the **On/Off** button.

The software version, date and time will be displayed.



➢ Press the **Start** button to start the function test.

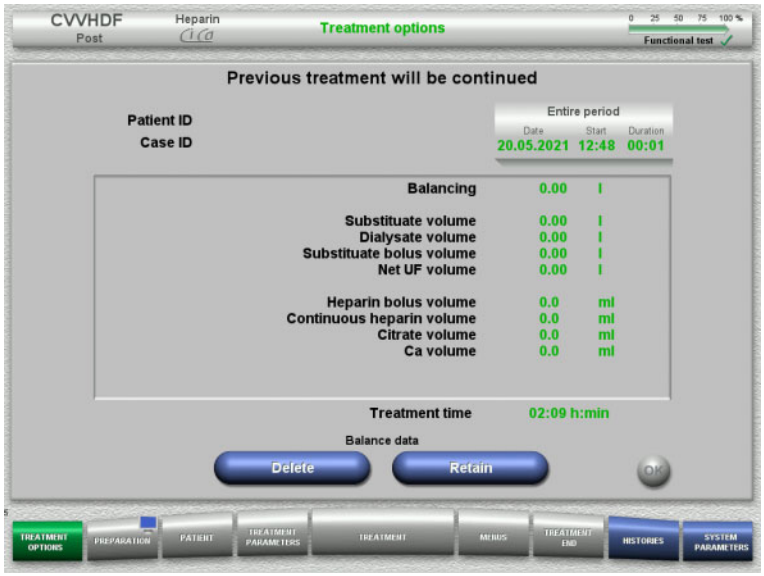
4.2.2 Selecting the treatment option



➢ Select the treatment option.

Press the **Continue** button to continue the previous treatment.

4.2.3 Continuing the previous treatment



➢ Press the **Retain** button to confirm the previous balance data.

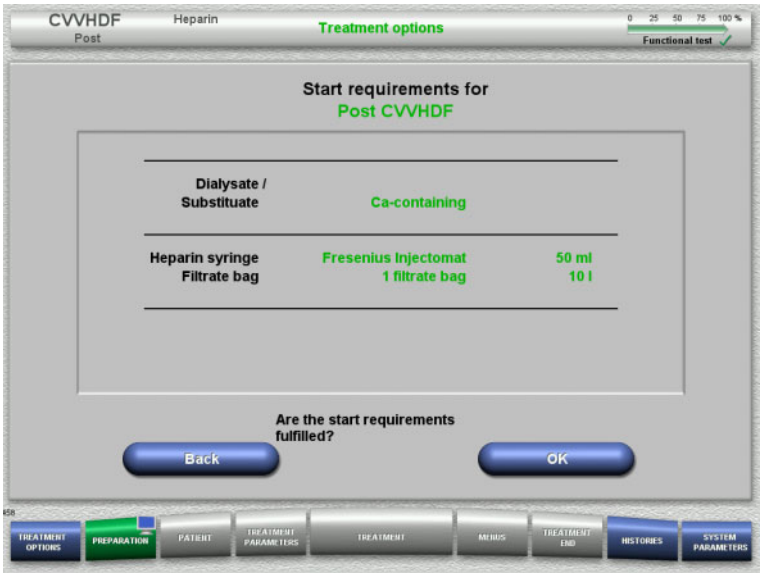
Or

➢ Press the **Delete** button to reset the previous balance data to 0.

The Patient ID and Case ID will not be deleted.

➢ Then press the **OK** button to confirm your previous selection (“Retain” or “Delete”).

4.2.4 Start requirements

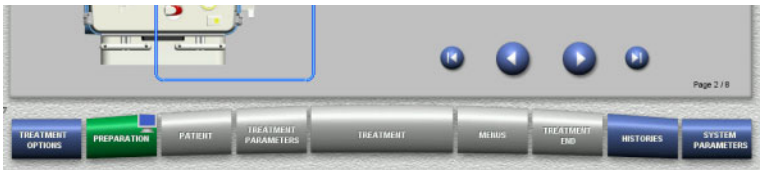


➢ Check the contents of the solution bags against the information shown on the screen.

➢ Press **OK** to confirm the start requirements.

Press the **Back** button to return to the treatment options screen.

4.2.5 Mounting the cassette



You can use the following buttons for mounting the cassette:

Press ▶ to go to the next step.

Press ▶| to jump to the end of the setup instructions.

Press ◀ to return to the previous step.

Press |◀ to jump back to the beginning of the setup instructions.

Note

For the CVVH, CVVHD, CVVHDF and Pre-post CVVH procedures, the multiFiltratePRO Kit HDF is used. For all these treatment modes, the substituate system and the dialysate system need to be mounted and filled. During the CVVHD procedure, the substituate pump is stopped. During the CVVH procedure, the dialysate pump is stopped.

➢ Hang up the cassette according to the instructions.

➢ Fix the filter in the filter holder.

➢ Press to go to the next step.

4.2.5.1 Mounting the return system

Warning

Risk of air embolism due to loss of function of the air detector

Blood clots (coagula) in the tubing system, contaminations and/or moisture on the air bubble detector can impair the correct function of the air bubble detector.

➢ Make sure that the air bubble detector is clean and dry.

➢ Do not use any ultrasound-conducting objects or media on the air bubble detector.

Warning

Risk of air embolism as a result of air in the tubing system

If the tubing system is not inserted properly, this can prevent the air detection system from working.

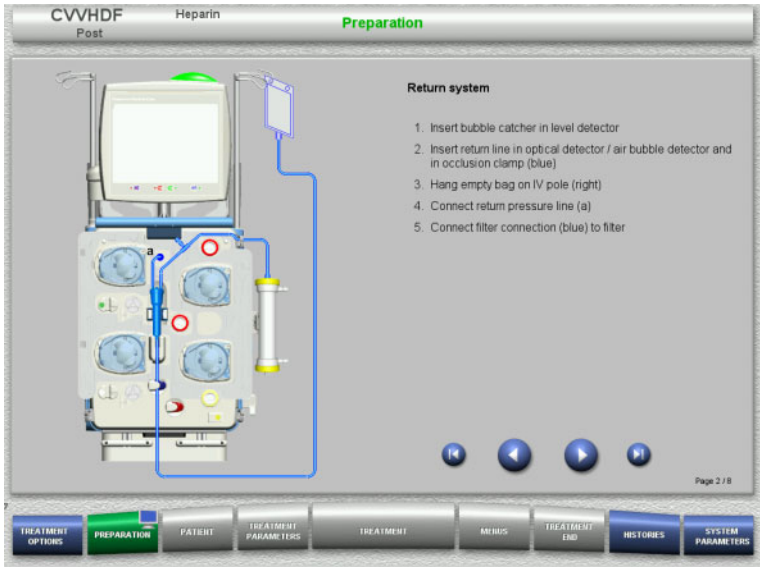
➢ When the tubing system is inserted into the air bubble detector/optical detector, the tube must lie along the full length of the tube holder.

Warning

Risk of air embolism as a result of air in the tubing system

➢ Insert the tubing system correctly into the line occlusion clamp.

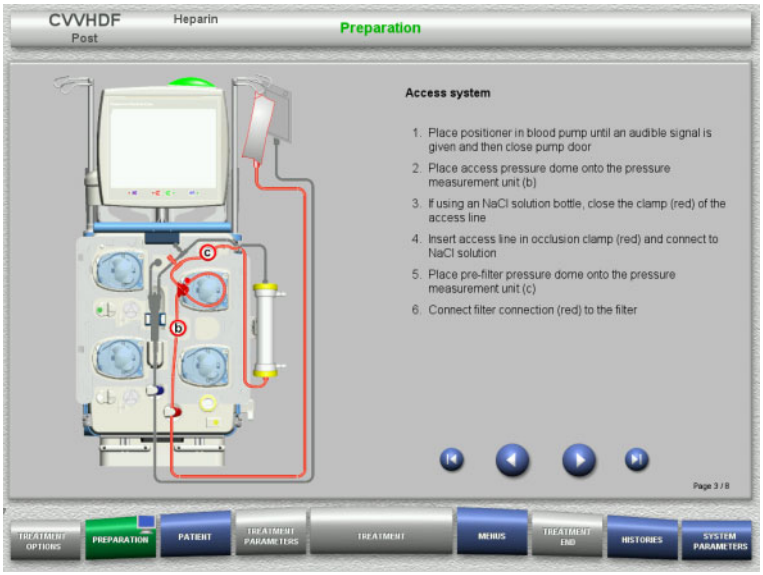
➢ Do not remove the tubing system from the line occlusion clamp during treatment.



➢ Mount the return system according to the instructions.

➢ Press ▶ to go to the next step.

4.2.5.2 Mounting the access system



➢ Mount the access system according to the instructions.

Check that the correct cassette has been mounted for the selected treatment option.

➢ Press ▶ to go to the next step.

Note

Once the first positioner has been inserted, the cassette system can only be dismantled and changed by cancelling the preparation (**Menus** / **Cancel preparation** (see Chapter 4.7.2 on page 168)).

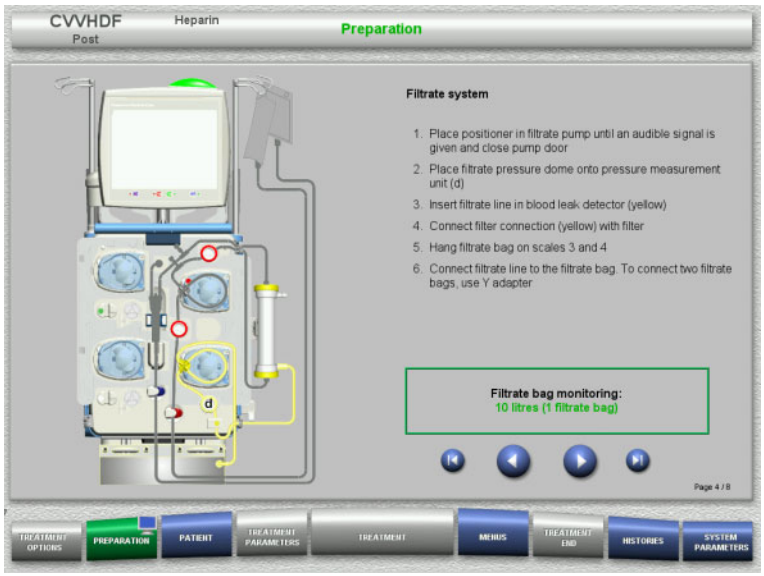
4.2.5.3 Mounting the filtrate system

Warning

Risk of contamination as a result of damaged bags

Bags can burst when dropped.

➢ Push filtrate bags as far back as possible onto the hooks of the lower scales.



➢ Mount the filtrate system according to the instructions.

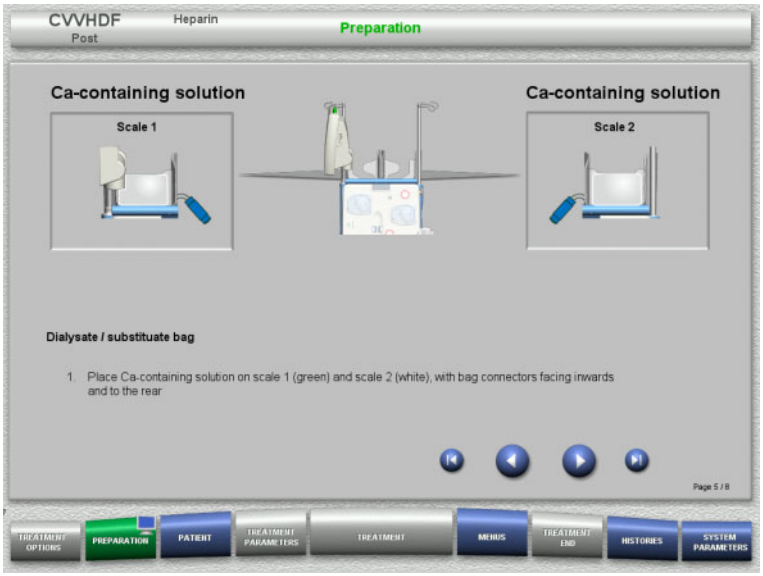
Filtrate bag monitoring can be set in the System Parameters, from 5 l to 20 l. If set to more than 10 l, two 10-litre bags must be connected with a Y adapter.

➢ Press to go to the next step.

4.2.5.4 Loading the solution bags

Note

When loading the solution bags onto the scales, make sure the connectors face inwards and to the rear.



➢ Load the solution bags onto the scales according to the instructions.

Maximum load per scale is 12 kg.
Observe the colour coding of the connectors.

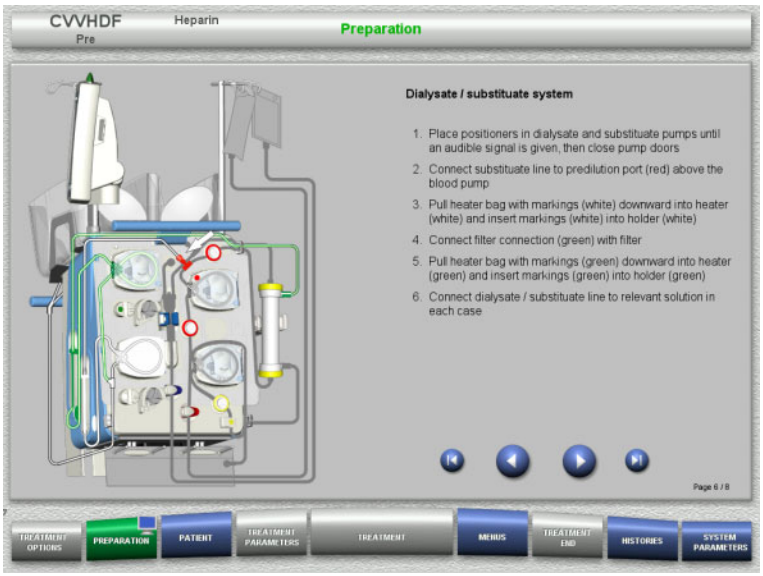
➢ Press ● to go to the next step.

4.2.5.5 Mounting the dialysate/substituate systems

Note

When inserting the heater bags, observe the correct colour coding.

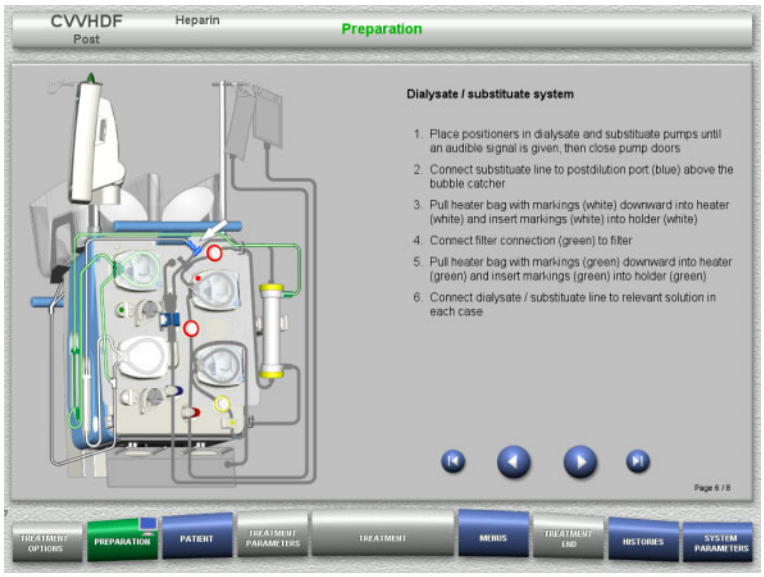
● **Predilution (CVVHDF / CVVH)**



➢ Mount the dialysate/substituate systems according to the instructions.

➢ Press ● to go to the next step.

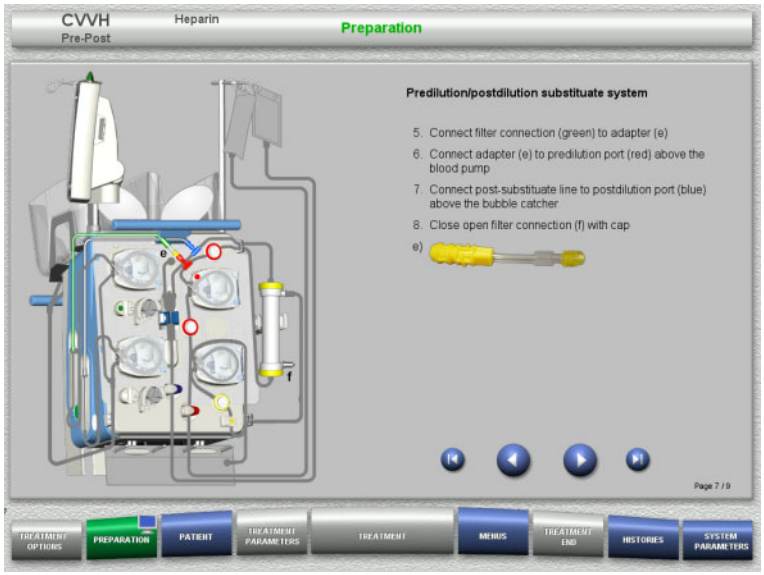
- **Postdilution (CVVHDF / CVVH / CVVHD)**



➢ Mount the dialysate/substitute systems according to the instructions.

➢ Press ▶ to go to the next step.

- **Predilution/postdilution substitute system (Pre-post CVVH)**



➢ Mount the predilution/postdilution substitute system according to the instructions.

➢ Connect the Pre-post CVVH adapter with the filter connection (green) of the dialysate system and the predilution port (red).

➢ Press ▶ to go to the next step.

4.2.5.6 Inserting the heparin syringe

Note

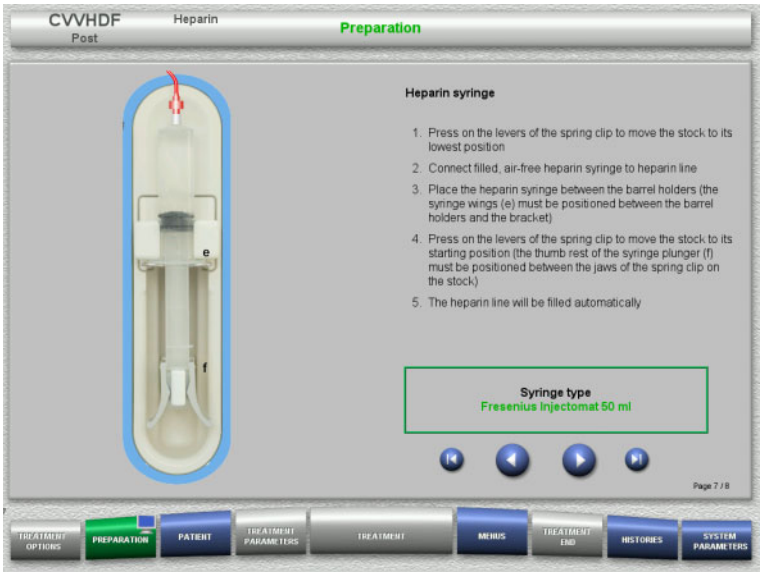
Only use the syringe type selected in the Setup and shown on the screen.

Note

When inserting the heparin syringe, observe the following:
– The syringe wings must be positioned between the barrel holders and the bracket.
– The thumb rest of the syringe plunger must be positioned between the jaws of the spring clip on the stock.

Tip

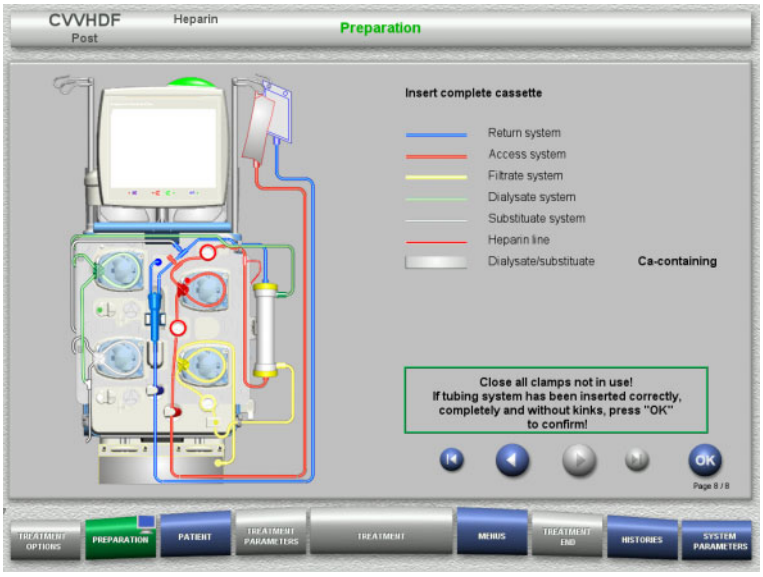
The heparin syringe can be inserted any time after starting treatment by choosing **MENUS / Change syringe** (only if heparin pump is activated).



➢ Insert the heparin syringe according to the instructions.

➢ Press ▶ to go to the next step.

4.2.5.7 Cassette mounting completed



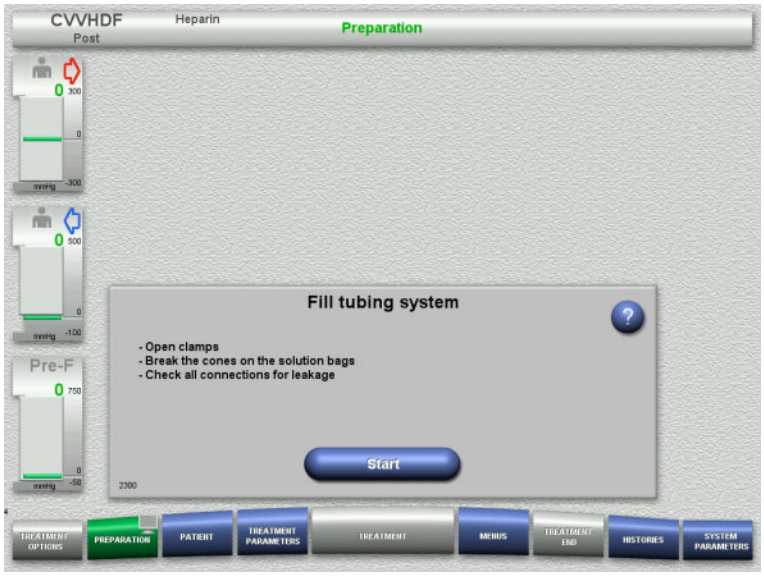
➢ Insert complete cassette.
If the **OK** button cannot be selected (greyed out), check the mounted tubing system according to the instructions on the screen.

➢ Press the **OK** button to confirm that the tubing system is fully mounted.

If heparin anticoagulation has been selected, the heparin line will be filled automatically after confirmation.

4.2.6 Filling and rinsing the cassette

4.2.6.1 Filling the tubing system



➢ Press the **Start** button to start filling the tubing system.

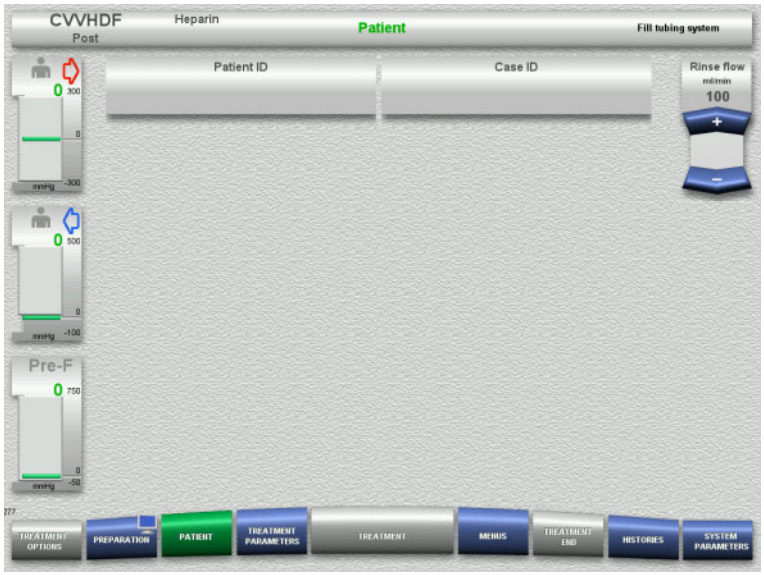
Rinsing starts automatically as soon as the correct fill level in the bubble catcher is detected.

The rinse flow can be changed with the **+/–** rocker switch buttons.

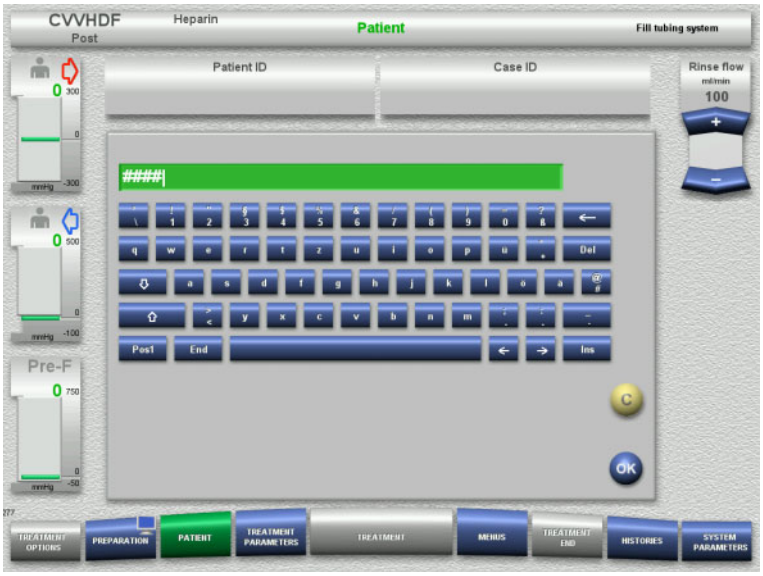
4.2.6.2 Entering the Patient ID and Case ID

Requirements

The **Patient** menu opens automatically when filling is started, if **Jump to Patient menu** is activated. Otherwise, the **Treatment parameters** menu will open automatically when filling is started (see Chapter 4.2.6.3 on page 78).



➢ Check the **Patient ID** and **Case ID** shown.
The fields will be empty if no data has yet been entered.



➢ To change or enter the **Patient ID** and **Case ID**, press the relevant field.

➢ Use the keyboard to enter the required **Patient ID** and **Case ID**.

➢ Press the **OK** button to apply the displayed value.

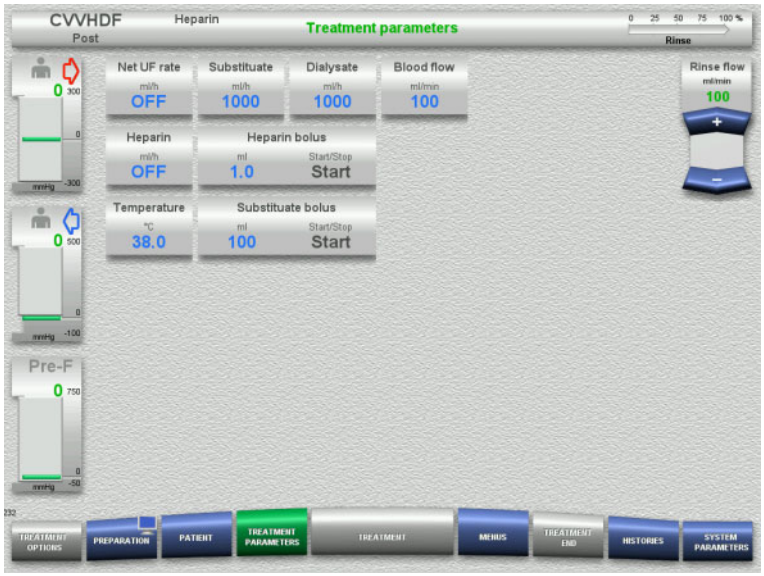
➢ Check the **Patient ID** and **Case ID** entered.

4.2.6.3 Entering treatment parameters

Note

The bolus function can be used if an initial heparin bolus needs to be administered.

The infusion of anticoagulation fluids is corrected automatically in the overall balance.



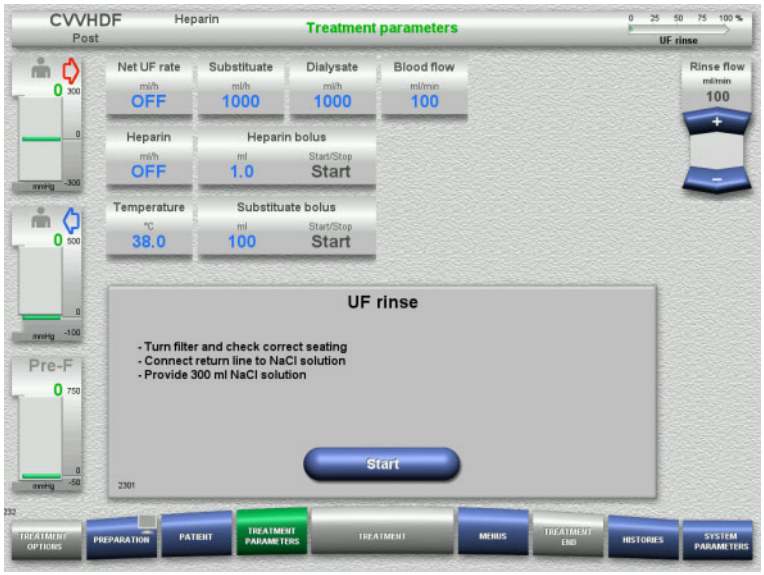
➢ Check the preset treatment parameters. If necessary, adjust the treatment parameters.

– Temperature:
Enter the temperature of the dialysate and the substituate (°C). The **Temperature** button can be used to switch the heater on and off.

4.2.6.4 UF Rinse

Note

When using NaCl bags with only one connector, make sure there is enough NaCl solution.



If using an NaCl bag with two connectors:

➢ Remove return line from empty bag and connect to NaCl solution.

➢ Press the **Start** button to start the UF rinse.

If using an NaCl bag with one connector:

➢ Leave the existing connections as they are.

➢ Press the **Start** button to start the UF rinse.

The level in the bubble catcher will be set automatically when the UF rinse is finished.

4.2.7 Circulation

Warning

Risk of contamination as a result of non-compliance with hygienic conditions

There is a risk of spreading germs.

➢ Keep preparation and circulation times before the treatment as short as possible.

Note

If the patient connection must be delayed, the extracorporeal circuit can be kept in circulation for a certain time after preparation.

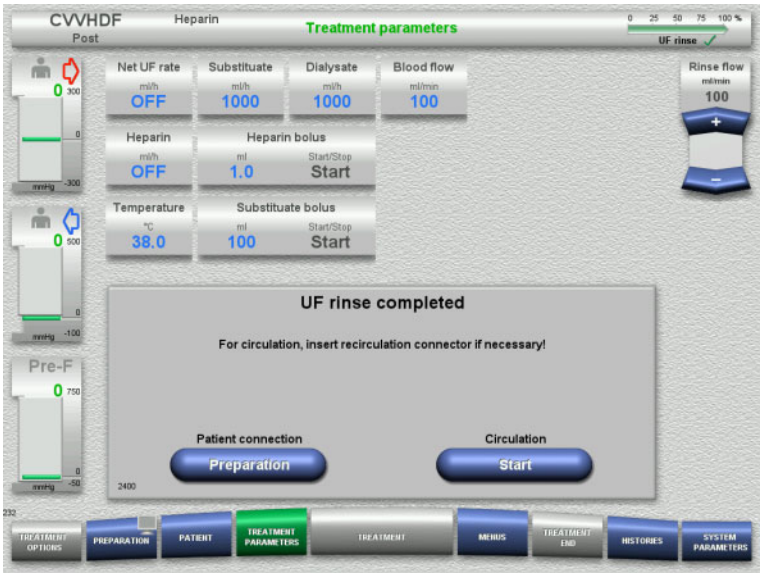
To avoid stressing the tubing system for too long, the circulation time is also taken into account when monitoring the kit service life.

Note

In the Setup, circulation can be set to start automatically or to be confirmed by the user.

The factory setting is **Confirm**, since an automatic changeover into circulation mode is only possible if an NaCl solution bag with two connections is used.

- **Stop before circulation**



After the rinse is completed, the blood pump will stop.

An audible tone is emitted.

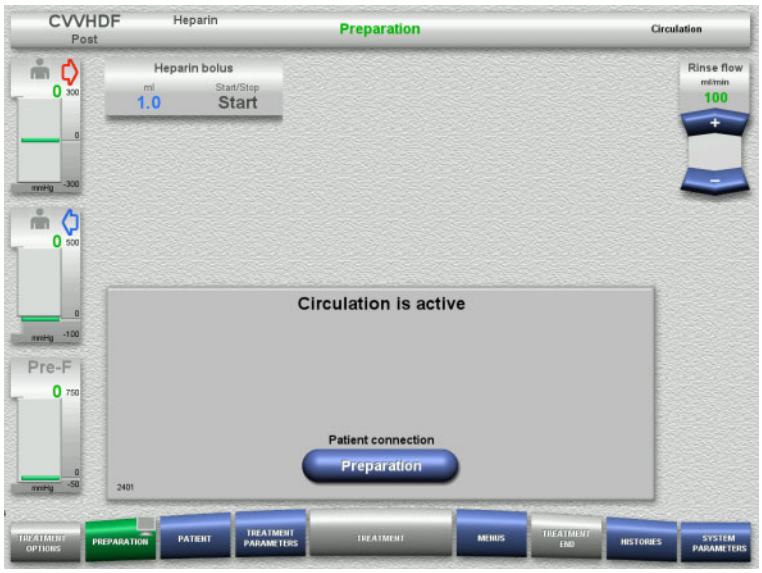
➢ Connect the access and return lines to the recirculation connector.

➢ Press the **Start** button to start the circulation.

Or

➢ Press the **Preparation** button to begin patient connection.

- **Automatic circulation**

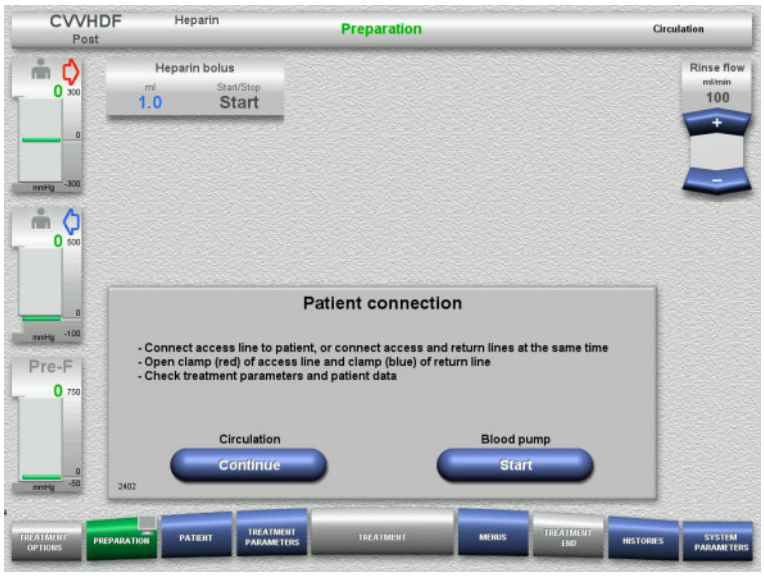


After the rinse is completed, the circulation will start automatically.

➢ Prepare to connect the patient.

➢ Press the **Preparation** button to stop the blood pump.

4.2.8 Connecting the patient

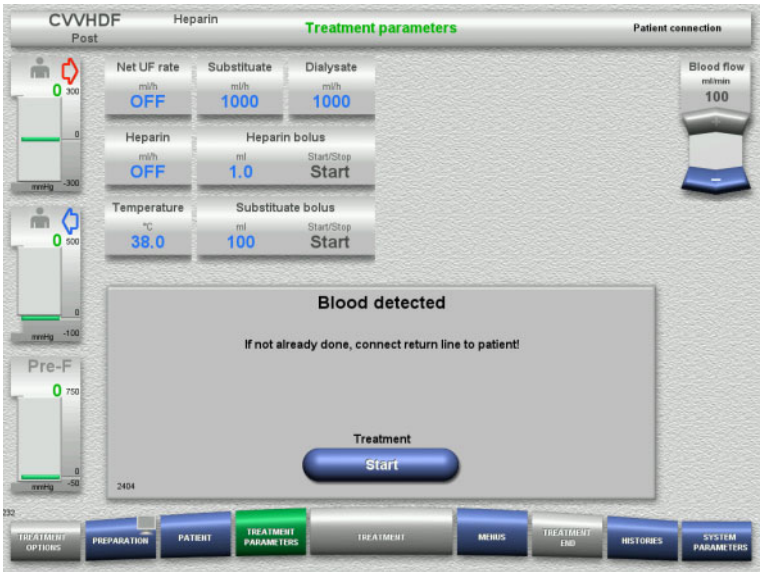


The blood pump is stopped.

➢ Press the **Start** button to start the blood pump.

The blood pump will continue operating until the optical detector has detected blood.
If necessary, administer a heparin bolus.

Press the **Continue** button to continue the circulation.



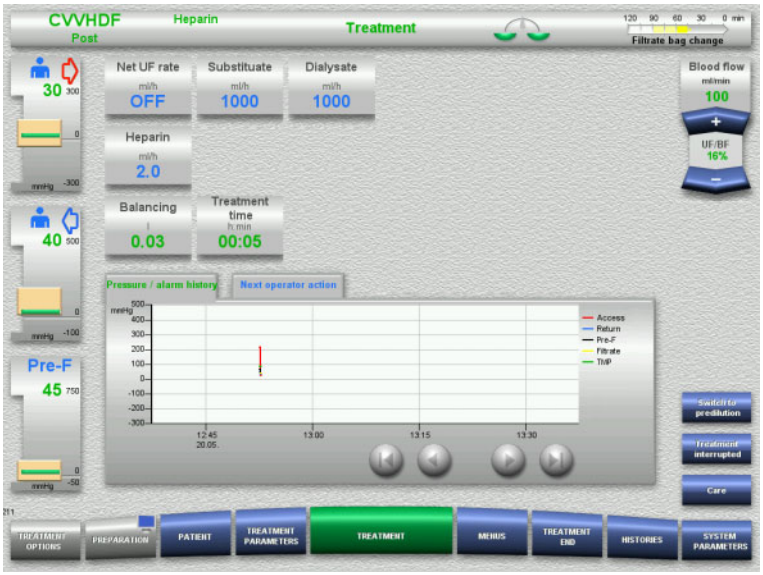
The optical detector has detected blood.

The blood pump is stopped.

➢ Press the **Start** button to start the treatment.

4.2.9 Treatment

4.2.9.1 Treatment screen

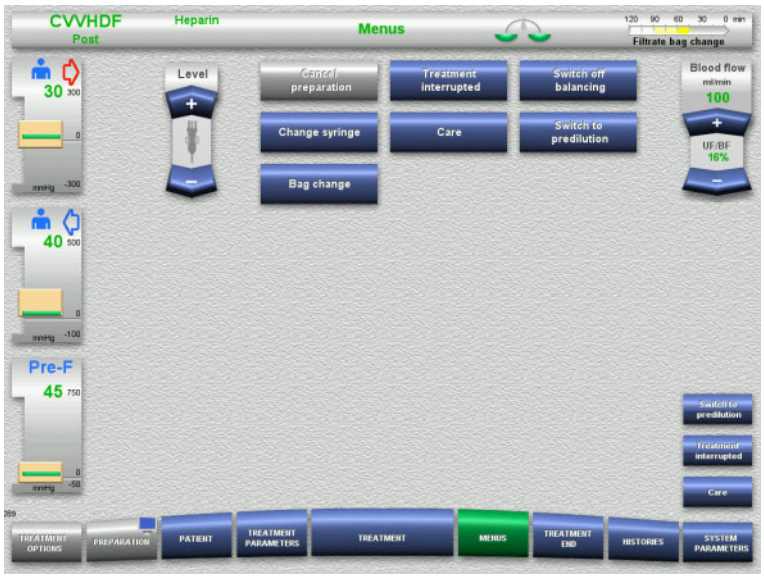


The treatment screen is displayed throughout the entire treatment.

The information area shows important treatment data:

Pressure / alarm history
Next operator action

4.2.9.2 Menus

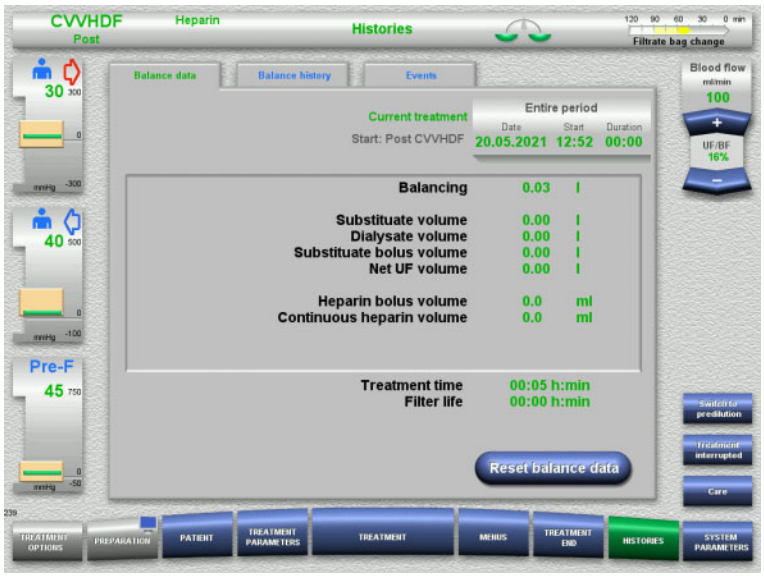


The following menu options can be selected:

– Rocker switch buttons for setting the level in the bubble catcher:
  For raising or lowering the level in the bubble catcher.
– Cancel preparation:
  For dismantling (user) / ejecting (device) the tubing system during preparation.
– Treatment interrupted:
  For pausing treatment.
– Switch balancing off/on:
  For switching balancing off and back on.
– Change syringe:
  For changing the heparin syringe.
– Care:
  For starting Care mode.
– Switch to predilution/postdilution:
  For changing between predilution and postdilution methods.
– Bag change:
  For changing the substituate and dialysate bags and emptying the filtrate bag.

Detailed description of menu options shown (see Chapter 4.7 on page 168).

4.2.9.3 Histories



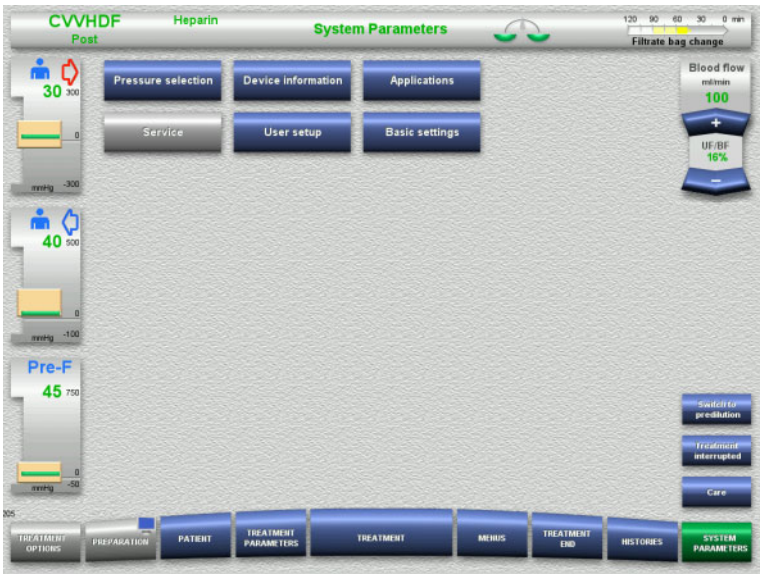
The following tabs can be selected:

– Balance data
– Balance history
– Events

(see Chapter 4.8 on page 190)

Pressing the **Reset balance data** button will reset all the cumulative volume information recorded so far to “zero”. The treatment time and the filter life will not be reset.

4.2.9.4 System Parameters



In the **System Parameters** screen, only the blue (activated) buttons can be used to open the appropriate options (see Chapter 4.9 on page 195).

To activate any grey buttons, you will need a ServiceCard or UserCard.

4.2.10 Changing the treatment mode

Warning

Risk of contamination as a result of infusion of unsuitable solutions that do not match the selected treatment mode

➢ After changing the treatment mode, change the solutions if necessary so that they match the selected treatment mode and the anticoagulation.

➢ For the treatment modes CVVHDF and CVVH, only solutions that are suitable for infusion must be used.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate and substituate

➢ Adjust the flow ratios of the solutions in relation to each other in relation to the blood flow.

Warning

Risk of contamination as a result of non-compliance with hygienic conditions

There is a risk of spreading germs.

➢ Observe service life of opened bags as specified by the manufacturer.

➢ If the service life is exceeded, leave substituate or dialysate deactivated or initiate end of treatment.

Note

Changing the treatment mode is always possible by switching the substituate flow or dialysate flow off/on.

A change of the treatment mode effected in this way can be undone. A change of the treatment mode is shown in the status bar by the greyed-out letters.

Depending on the treatment option you change over to, the various flows, ratios, and connections may need to be adapted. Observe and follow the instructions on the screen.

Note

From the Pre-post CVVH treatment mode, it is only possible to change to pre CVVH or post CVVH.

4.2.10.1 Changing the treatment mode from CVVHDF to CVVH

- ➢ Select **Dialysate** and switch off the flow with the **I/O** button.
- ➢ Press the **OK** button to apply the change.

A change of the treatment mode is shown in the status bar.

To undo this change, simply switch the dialysate flow back on with the **I/O** button.

4.2.10.2 Changing the treatment mode from CVVHDF to CVVHD

Note

A substituate bolus is not possible in the CVVHD treatment mode.

➢ Select **Substituate** and switch off the flow with the **I/O** button.

➢ Press the **OK** button to apply the change.

A change of the treatment mode is shown in the status bar.

To undo this change, simply switch the substituate flow back on with the **I/O** button.

4.2.11 End of treatment

4.2.11.1 Preparing the end of treatment

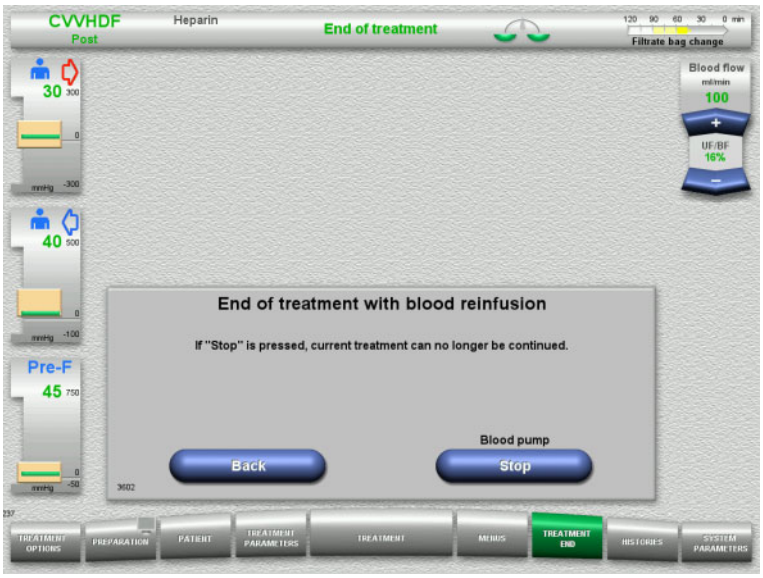
➢ Select **TREATMENT END** from the menu bar.

➢ Press the **Confirm** button to select blood reinfusion.

Press the **Continue** button to continue the treatment.

Press the **Confirm** button under **W/o blood reinfusion** and **Blood pump Stop** in the screen that follows to go straight to the **Disconnect the patient!** screen
(see Chapter 4.2.11.5 on page 90).

4.2.11.2 End of treatment with blood reinfusion

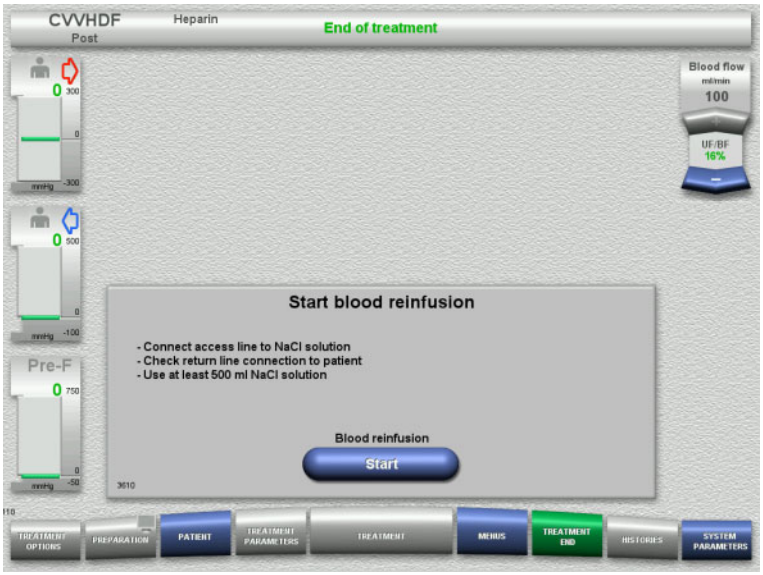


➢ Press the **Stop** button to stop the blood pump.

Balancing is switched off.

Press the **Back** button to return to the Prepare end of treatment screen.

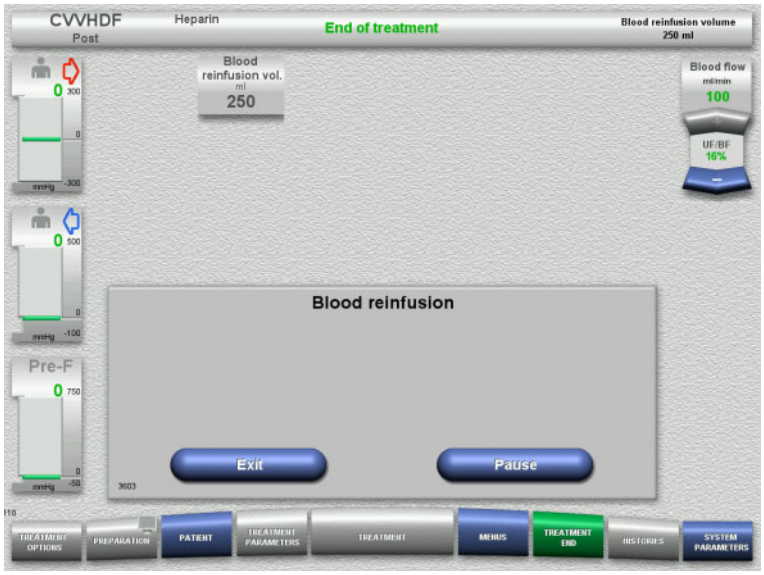
4.2.11.3 Starting blood reinfusion



➢ Disconnect the access line from the patient and connect it to an NaCl solution bag.

➢ Press the **Start** button to start blood reinfusion.

The blood flow is limited to 100 ml/min.

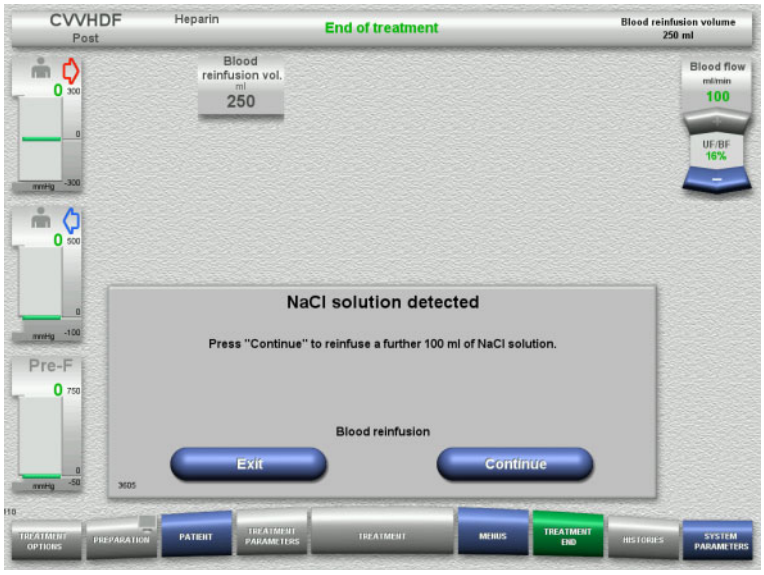


Blood reinfusion ends automatically as soon as the optical detector detects the NaCl solution.

Press the **Pause** button to stop the blood reinfusion.

Press the **Exit** button to terminate blood reinfusion.

4.2.11.4 NaCl solution detected

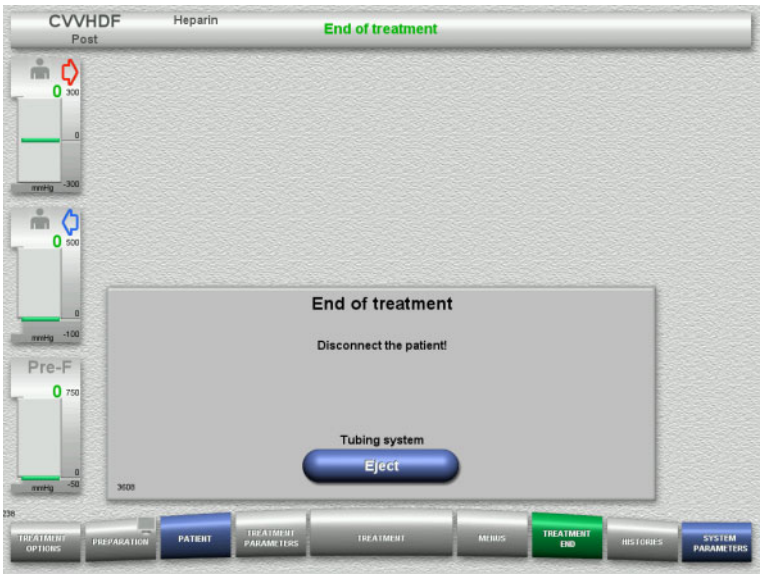


➢ Press the **Exit** button to terminate blood reinfusion.

Press the **Continue** button to reinfuse a further 100 ml of NaCl solution.

This can be repeated as needed.

4.2.11.5 Disconnecting the patient



➢ Disconnect the patient.

➢ Press the **Eject** button to start ejecting the tubing system.

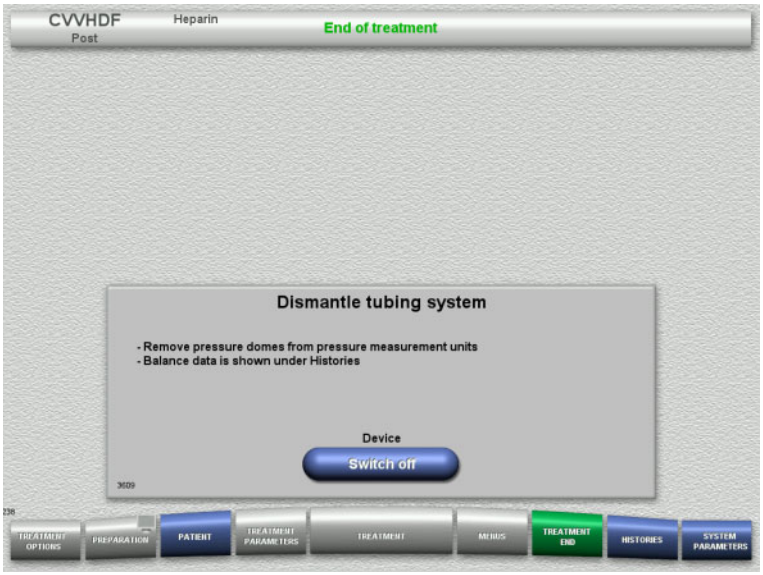
4.2.11.6 Dismantling the tubing system

Warning

Risk of cross-contamination as a result of contaminated consumables

There is a risk of spreading germs.

➢ Consumables must be discarded after a treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Dismantle the tubing system.

In the **Histories** menu, you can view the treatment data and events.

➢ Switch the device off with the **Switch off** button.

4.3 CRRT Ci-Ca treatments

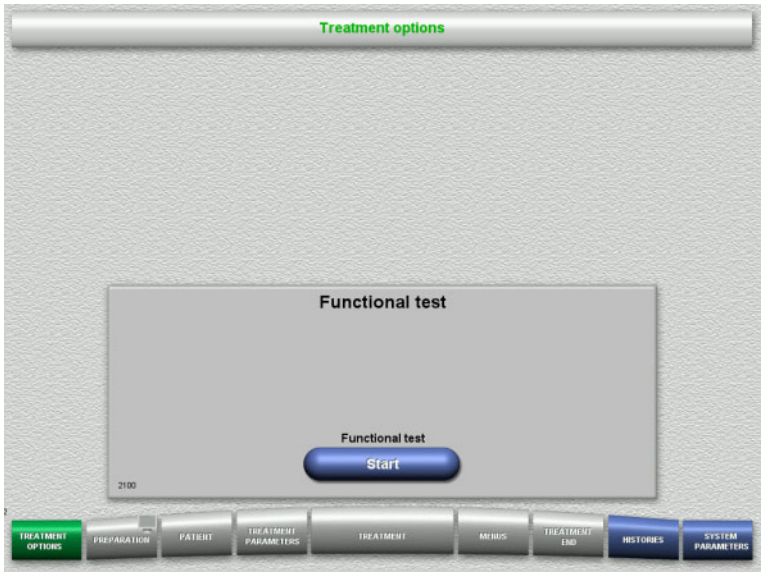
General description of the Ci-Ca CVVHD and Ci-Ca postCVVHDF procedures with information on the differences between the individual therapies.

4.3.1 Switching on the device and starting the function test

There must be no load on any of the scales. There must be no tubing systems inserted in the Ci-Ca pumps.

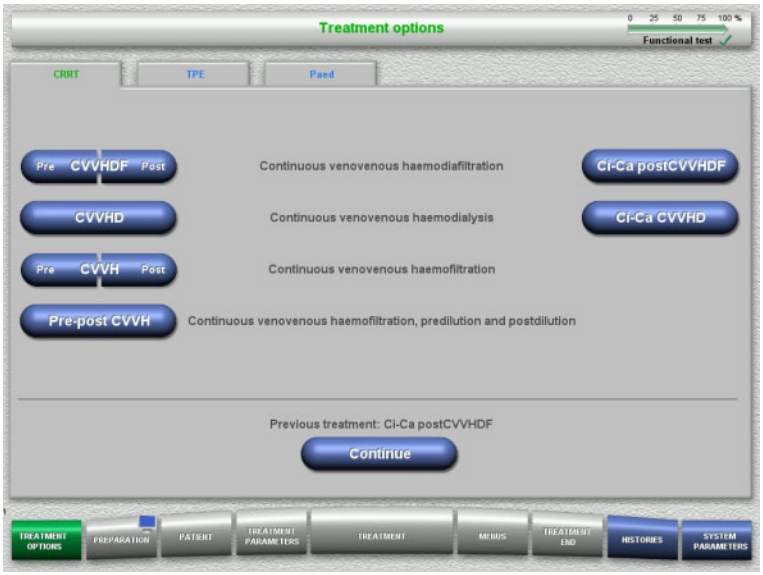
➢ Switch on the device with the **On/Off** button.

The software version, date and time will be displayed.



➢ Press the **Start** button to start the function test.

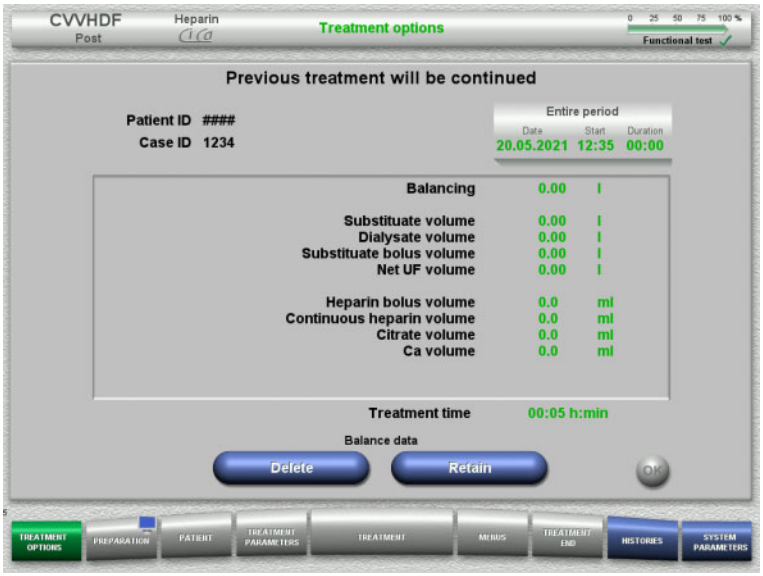
4.3.2 Selecting the treatment option



➢ Select the treatment option.

Press the **Continue** button to continue the previous treatment.

4.3.3 Continuing the previous treatment



➢ Press the **Retain** button to confirm the previous balance data.

Or

➢ Press the **Delete** button to reset the previous balance data to 0.

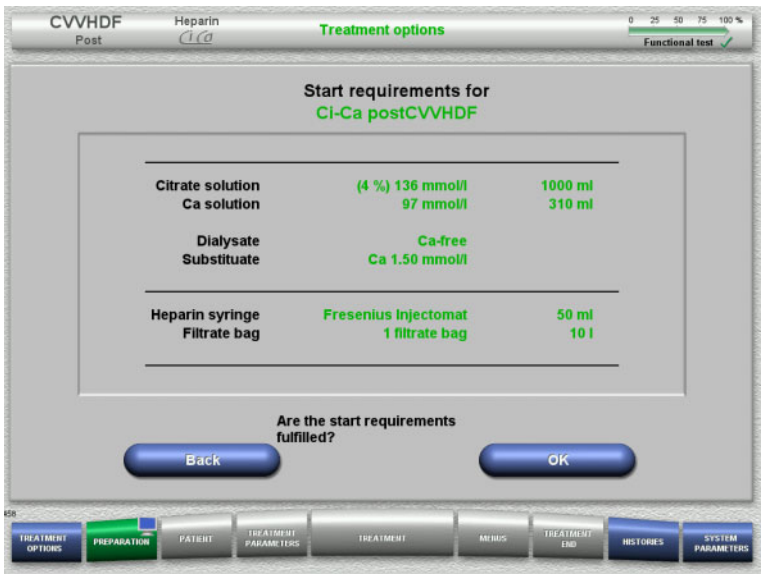
The Patient ID and Case ID will not be deleted.

➢ Then press the **OK** button to confirm your previous selection (“Retain” or “Delete”).

4.3.4 Start requirements

Note

It is strongly recommended that a fixed Ca solution be used for all Ci-Ca treatments in the hospital. Also, any later change would require coordinated changes of device settings and the applied calcium solution to avoid safety issues because of a mismatch of calcium concentrations.

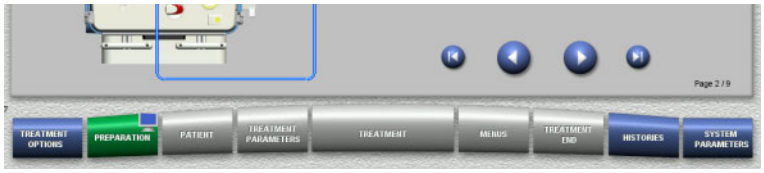


➢ Check the contents of the solution bags against the information shown on the screen.

➢ Press **OK** to confirm the start requirements.

Press the **Back** button to return to the treatment options screen.

4.3.5 Mounting the cassette



You can use the following buttons for mounting the cassette:

Press ▶ to go to the next step.

Press ▶| to jump to the end of the setup instructions.

Press ◀ to return to the previous step.

Press |◀ to jump back to the beginning of the setup instructions.

➢ Hang up the cassette according to the instructions.

➢ Fix the filter in the filter holder.

➢ Press to go to the next step.

4.3.5.1 Mounting the return system

Warning

Risk of air embolism due to loss of function of the air detector

Blood clots (coagula) in the tubing system, contaminations and/or moisture on the air bubble detector can impair the correct function of the air bubble detector.

➢ Make sure that the air bubble detector is clean and dry.

➢ Do not use any ultrasound-conducting objects or media on the air bubble detector.

Warning

Risk of air embolism as a result of air in the tubing system

If the tubing system is not inserted properly, this can prevent the air detection system from working.

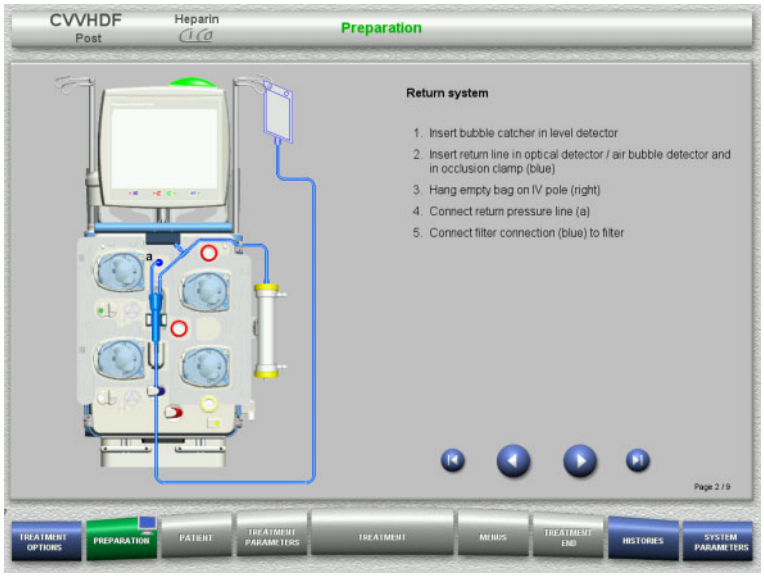
➢ When the tubing system is inserted into the air bubble detector/optical detector, the tube must lie along the full length of the tube holder.

Warning

Risk of air embolism as a result of air in the tubing system

➢ Insert the tubing system correctly into the line occlusion clamp.

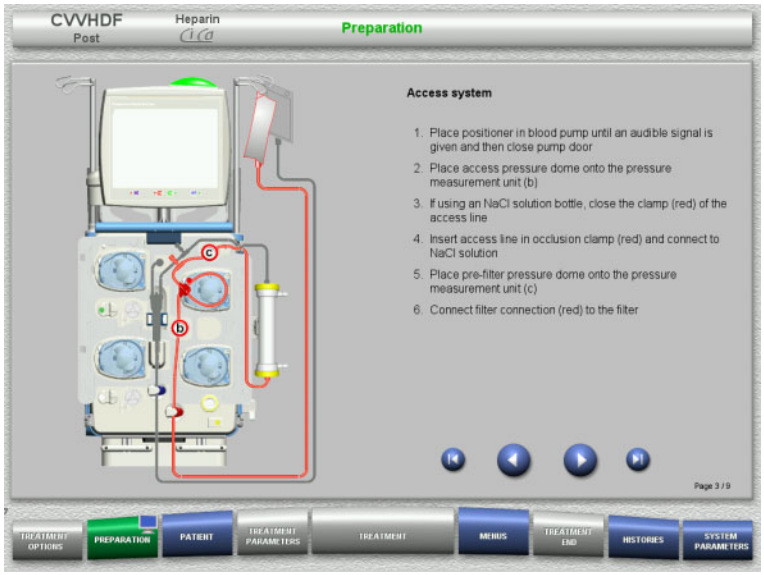
➢ Do not remove the tubing system from the line occlusion clamp during treatment.



➢ Mount the return system according to the instructions.

➢ Press to go to the next step.

4.3.5.2 Mounting the access system



➢ Mount the access system according to the instructions.

Check that the correct cassette has been mounted for the selected treatment option.

➢ Press to go to the next step.

Note

Once the first positioner has been inserted, the cassette system can only be dismantled and changed by cancelling the preparation (**Menus** / **Cancel preparation** (see Chapter 4.7.2 on page 168)).

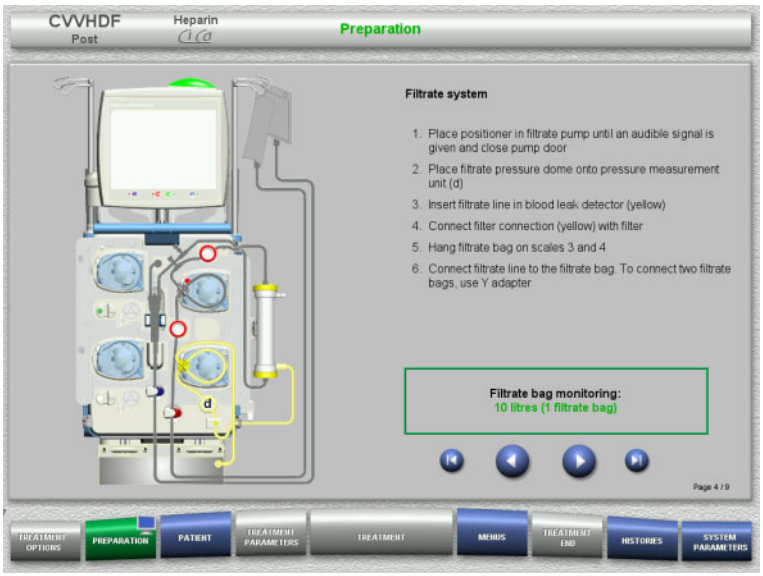
4.3.5.3 Mounting the filtrate system

Warning

Risk of contamination as a result of damaged bags

Bags can burst when dropped.

➢ Push filtrate bags as far back as possible onto the hooks of the lower scales.



➢ Mount the filtrate system according to the instructions.

Filtrate bag monitoring can be set in the System Parameters, from 5 l to 20 l.
If set to more than 10 l, two 10-litre bags must be connected with a Y adapter.

➢ Press to go to the next step.

4.3.5.4 Loading the solution bags

Note

When loading the solution bags onto the scales, make sure the connectors face inwards and to the rear.

- **CVVHDF**

Warning

Risk of blood loss as a result of clotting

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate

The use of calcium-containing dialysate for a Ci-Ca treatment can lead to blood clotting and/or hypercalcaemia.

➢ Only use calcium-free dialysate for treatments with citrate anticoagulation.

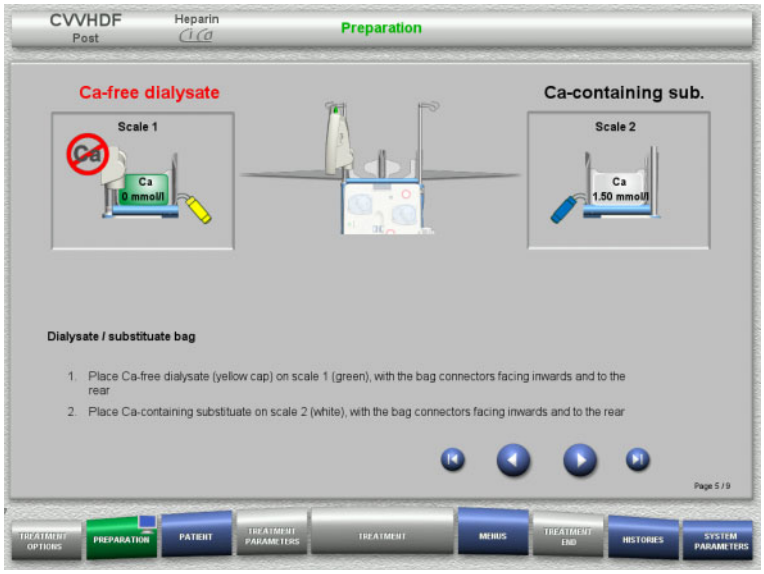
Warning

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of substituate

The use of substituate with the wrong calcium level for a Ci-Ca treatment can lead to an electrolyte imbalance in the patient.

➢ Only use calcium-containing substituate for treatments with citrate anticoagulation.

➢ Check that the calcium solution used corresponds to the type selected in the Setup and shown on the screen.



➢ Load the solution bags onto the scales according to the instructions.

Maximum load per scale is 12 kg.
Make sure you load the solutions onto the correct scales.
Observe the colour coding of the connectors.

➢ Press ▶ to go to the next step.

- **CVVHD**

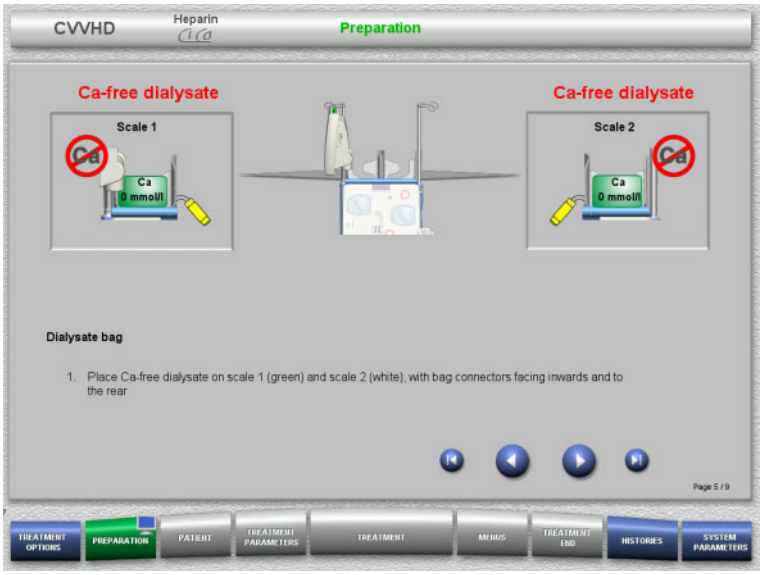
Warning

Risk of blood loss as a result of clotting

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate

The use of calcium-containing dialysate for a Ci-Ca treatment can lead to blood clotting and/or hypercalcaemia.

➢ Only use calcium-free dialysate for treatments with citrate anticoagulation.



➢ Load the solution bags onto the scales according to the instructions.

Maximum load per scale is 12 kg.
Observe the colour coding of the connectors.

➢ Press ● to go to the next step.

4.3.5.5 Mounting the dialysate/substituate systems

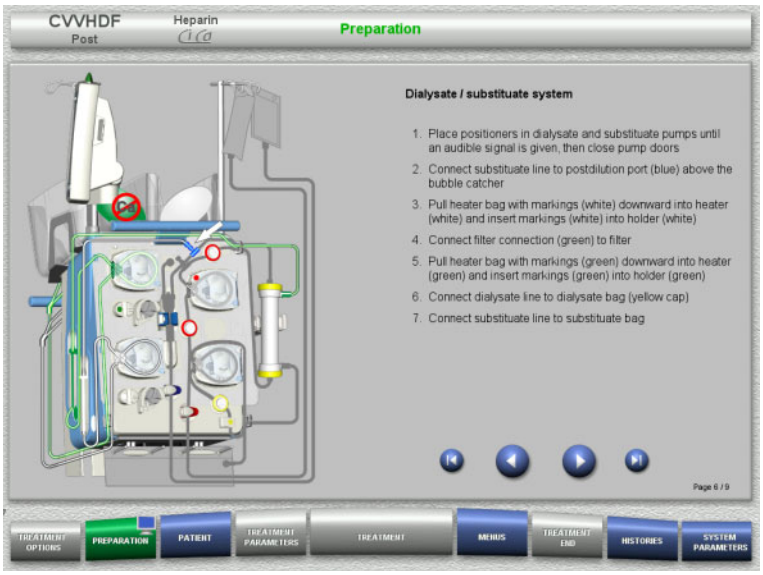
Note

When inserting the heater bags, observe the correct colour coding.

● **CVVHDF**

Note

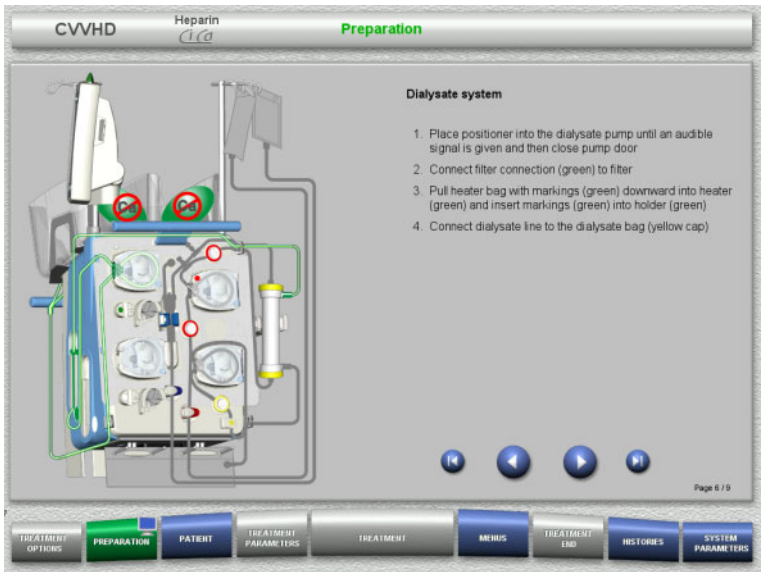
For a Ci-Ca postCVVHDF treatment, the substituate line must always be connected to the postdilution port.



➢ Mount the dialysate/substituate systems according to the instructions.

➢ Press ● to go to the next step.

- **CVVHD**



➢ Mount the dialysate system according to the instructions.

➢ Press ▶ to go to the next step.

4.3.5.6 Mounting the Ci-Ca system

Warning

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

➢ Check that the citrate and calcium solutions used correspond to the types selected in the Setup and shown on the screen.

Warning

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

➢ When mounting the Ci-Ca system, make sure the pump segments are correctly fixed and observe the correct colour coding of the Ci-Ca lines.

➢ Make sure you connect the lines of the citrate and calcium solutions correctly.

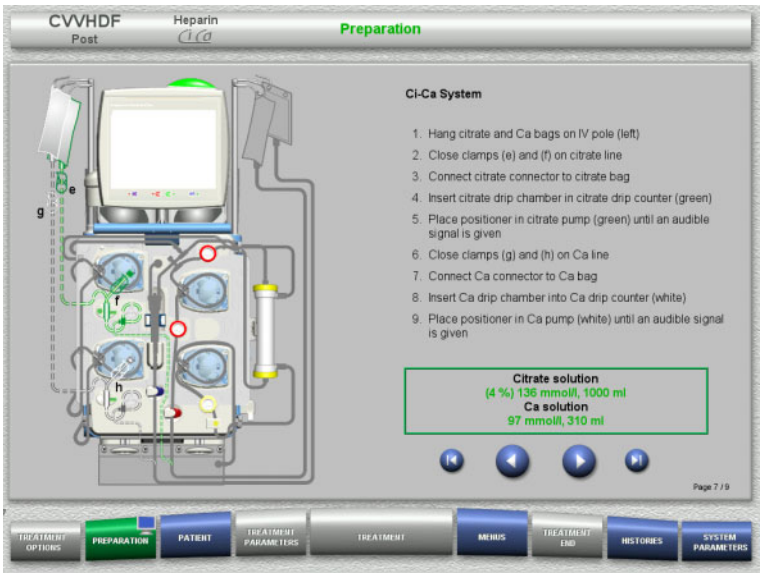
Warning

Risk for the patient as a result of a reduction in body temperature

If the temperature of the citrate and calcium solutions is too low, this can lead to hypothermia in the patient.

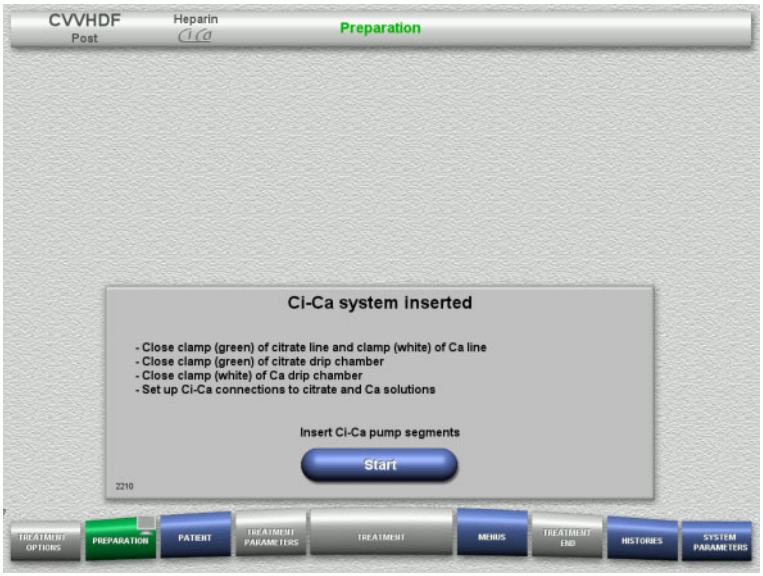
➢ The solutions must be at room temperature when used.

➢ Either select a suitable storage temperature or heat the bags to the required temperature before use.



➢ Mount the Ci-Ca system according to the instructions.

➢ Press ● to go to the next step.



➢ Check the Ci-Ca system.

➢ Press the **Start** button to start inserting the Ci-Ca pump segments.

4.3.5.7 Inserting the heparin syringe

If heparinisation is needed in addition to the Ci-Ca anticoagulation, a heparin syringe can be inserted.

Note

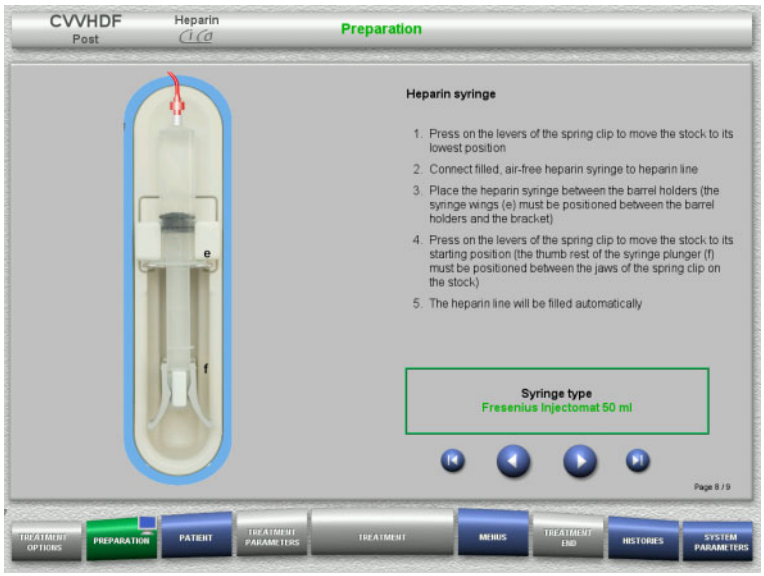
Only use the syringe type selected in the Setup and shown on the screen.

Note

When inserting the heparin syringe, observe the following:
– The syringe wings must be positioned between the barrel holders and the bracket.
– The thumb rest of the syringe plunger must be positioned between the jaws of the spring clip on the stock.

Tip

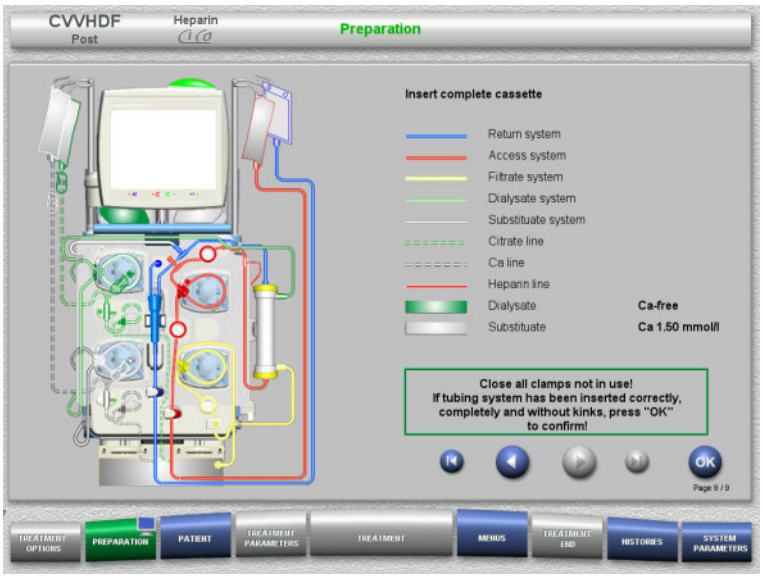
The heparin syringe can be inserted any time after starting treatment by choosing **MENUS / Change syringe** (only if heparin pump is activated).



➢ Insert the heparin syringe according to the instructions.

➢ Press ▶ to go to the next step.

4.3.5.8 Cassette mounting completed



➢ Insert complete cassette.

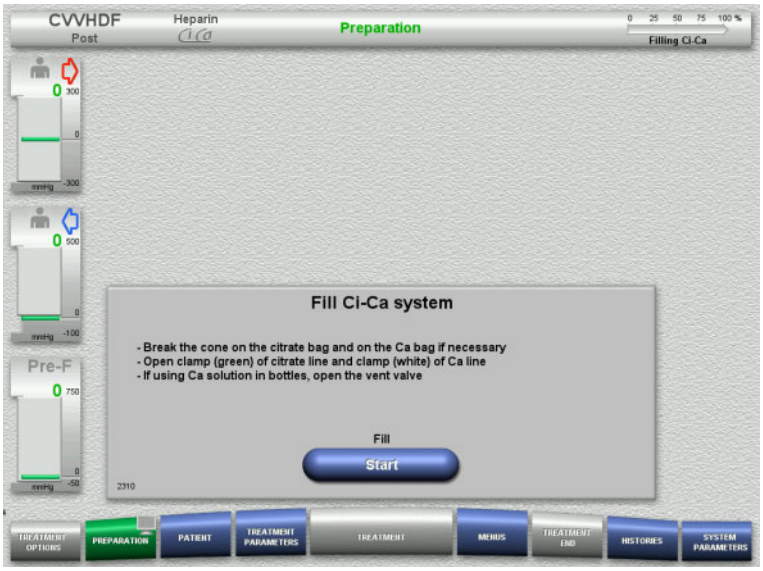
If the **OK** button cannot be selected (greyed out), check the mounted tubing system according to the instructions on the screen.

➢ Press the **OK** button to confirm that the tubing system is fully mounted.

If heparin anticoagulation has been selected, the heparin line will be filled automatically after confirmation.

4.3.6 Filling and rinsing the cassette

4.3.6.1 Filling the Ci-Ca system

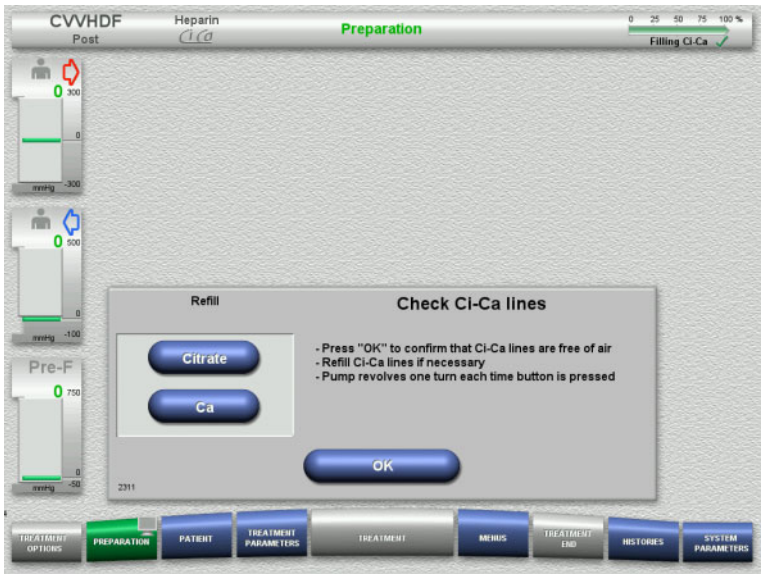


➢ Press the **Start** button to start filling the Ci-Ca system.

The level in the Ci-Ca fill level detectors is checked.

➢ If necessary, adjust the levels in the level detectors manually until they are between the markings.

4.3.6.2 Checking the Ci-Ca lines



➢ Visually check that the Ci-Ca lines are free of air.

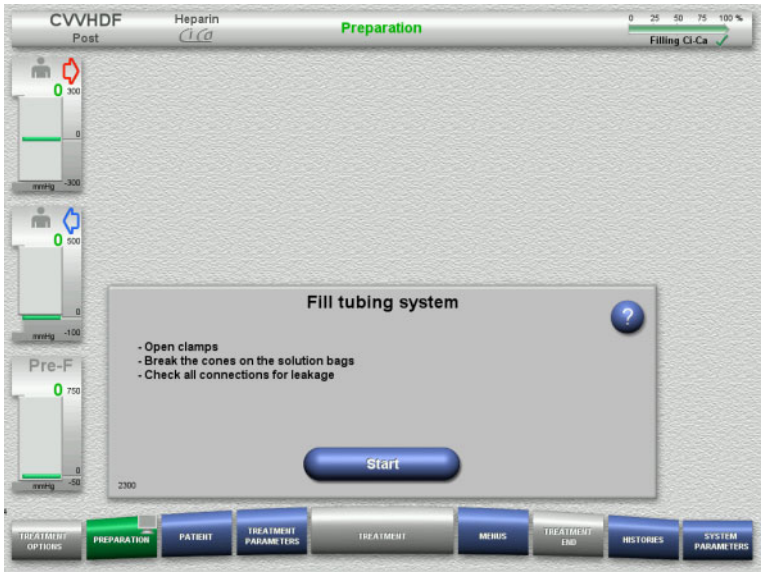
➢ Press the **OK** button to confirm that you have checked the Ci-Ca lines.

If there is still air in the Ci-Ca lines:

➢ Press the **Citrate** button to continue filling the citrate line.

➢ Press the **Ca** button to continue filling the calcium line.

4.3.6.3 Filling the tubing system



➢ Press the **Start** button to start filling the tubing system.

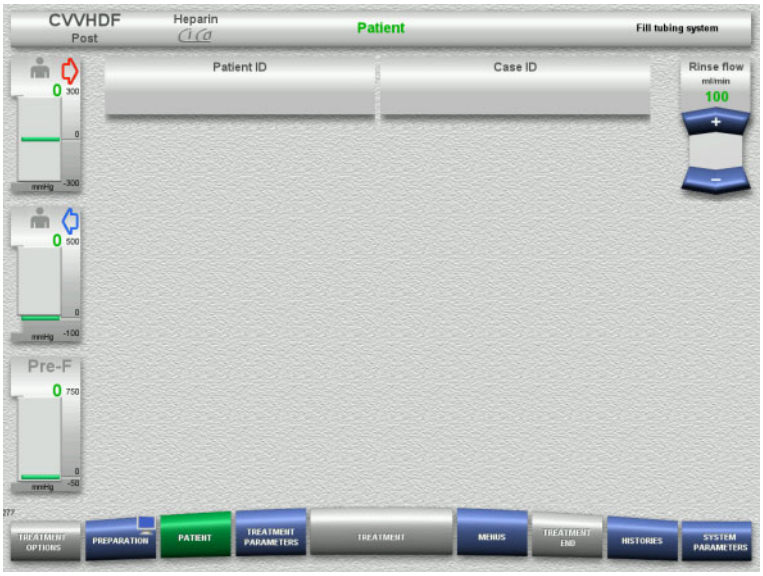
Rinsing starts automatically as soon as the correct fill level in the bubble catcher is detected.

The rinse flow can be changed with the **+/–** rocker switch buttons.

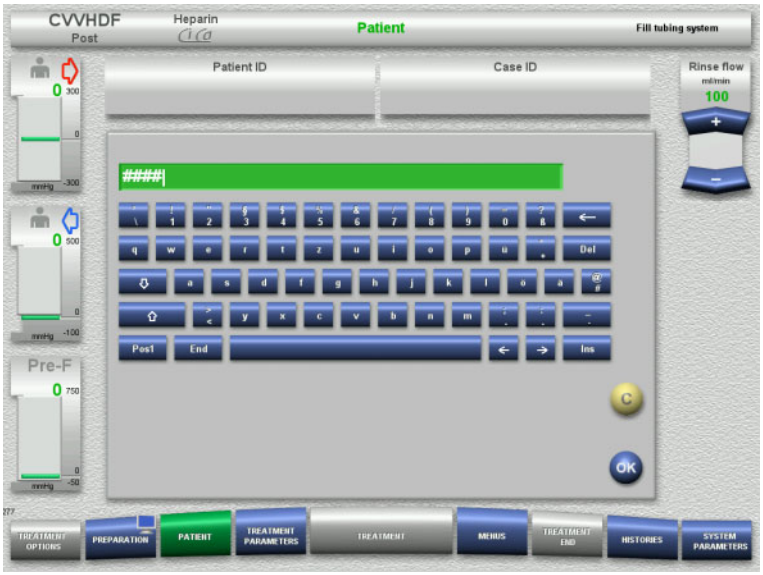
4.3.6.4 Entering the Patient ID and Case ID

Requirements

The **Patient** menu opens automatically when filling is started, if **Jump to Patient menu** is activated. Otherwise, the **Treatment parameters** menu will open automatically when filling is started (see Chapter 4.3.6.5 on page 105).



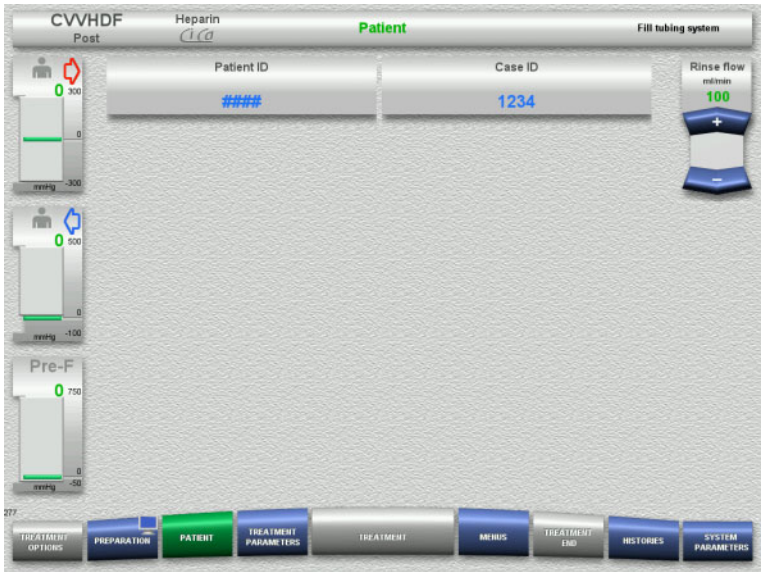
➢ Check the **Patient ID** and **Case ID** shown.
The fields will be empty if no data has yet been entered.



➢ To change or enter the **Patient ID** and **Case ID**, press the relevant field.

➢ Use the keyboard to enter the required **Patient ID** and **Case ID**.

➢ Press the **OK** button to apply the displayed value.



➢ Check the **Patient ID** and **Case ID** entered.

4.3.6.5 Entering treatment parameters

Note

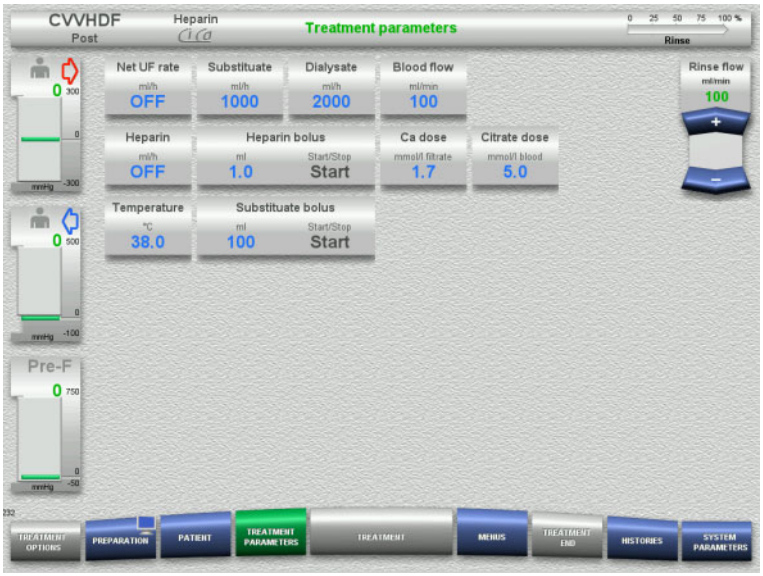
Setting the treatment parameters (citrate dose, calcium dose, blood flow, and dialysate flow) is described in a separate chapter (see Chapter 7.3.2 on page 261).

The correct ratio of the blood flow to the dialysate flow / substituate flow is important.

Note

Anticoagulation must be set as prescribed by the physician!
The bolus function can be used if an initial heparin bolus needs to be administered.

The infusion of anticoagulation fluids is corrected automatically in the overall balance.



➢ Check the preset treatment parameters. If necessary, adjust the treatment parameters.

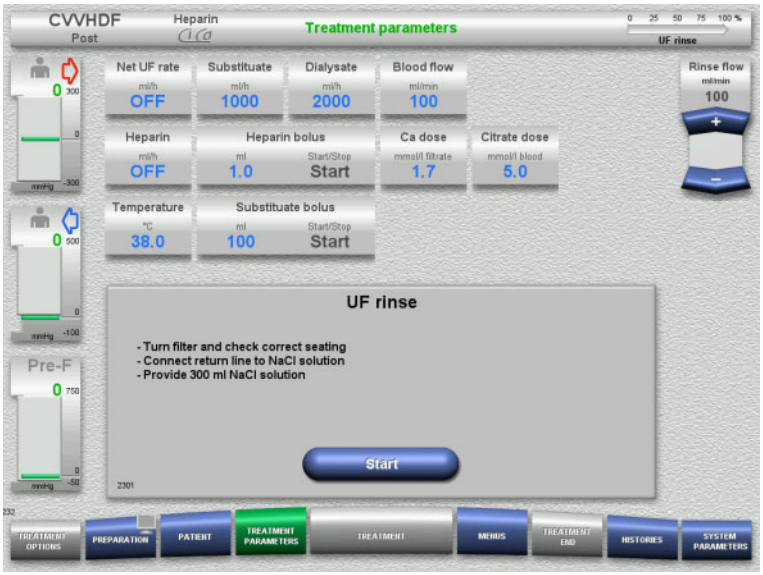
– Temperature:
Enter the temperature of the dialysate and the substituate (°C). The **Temperature** button can be used to switch the heater on and off.

– Calcium dose, Citrate dose:
Enter the calcium and citrate dosage.

4.3.6.6 UF Rinse

Note

When using NaCl bags with only one connector, make sure there is enough NaCl solution.



If using an NaCl bag with two connectors:

➢ Remove return line from empty bag and connect to NaCl solution.

➢ Press the **Start** button to start the UF rinse.

If using an NaCl bag with one connector:

➢ Leave the existing connections as they are.

➢ Press the **Start** button to start the UF rinse.

The level in the bubble catcher will be set automatically when the UF rinse is finished.

4.3.7 Circulation

Warning

Risk of contamination as a result of non-compliance with hygienic conditions

There is a risk of spreading germs.

➢ Keep preparation and circulation times before the treatment as short as possible.

Note

If the patient connection must be delayed, the extracorporeal circuit can be kept in circulation for a certain time after preparation.

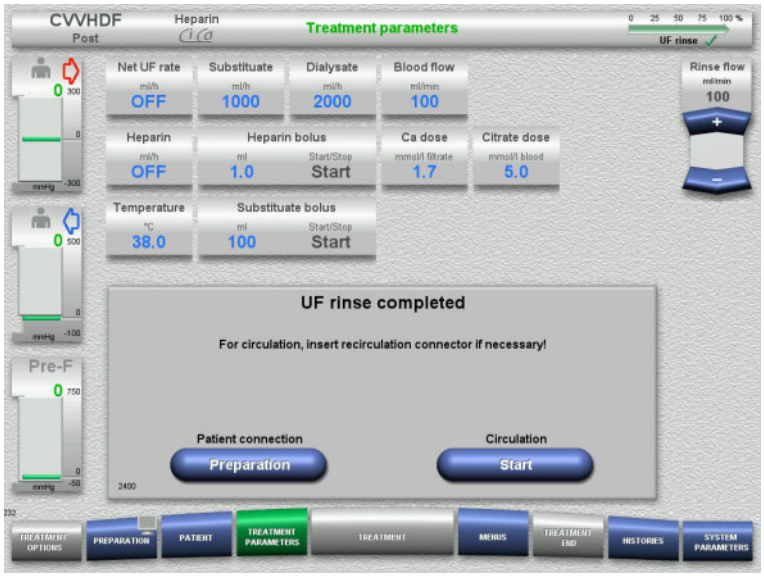
To avoid stressing the tubing system for too long, the circulation time is also taken into account when monitoring the kit service life.

Note

In the Setup, circulation can be set to start automatically or to be confirmed by the user.

The factory setting is **Confirm**, since an automatic changeover into circulation mode is only possible if an NaCl solution bag with two connections is used.

- **Stop before circulation**



After the rinse is completed, the blood pump will stop.

An audible tone is emitted.

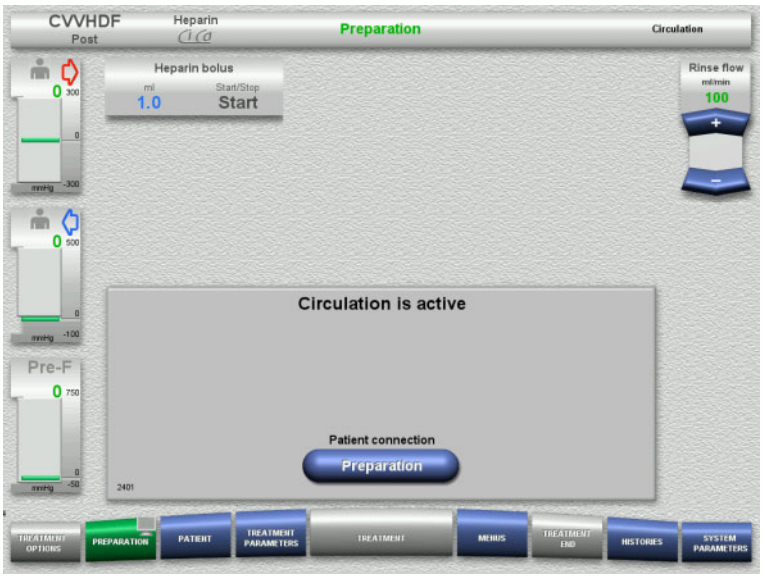
➢ Connect the access and return lines to the recirculation connector.

➢ Press the **Start** button to start the circulation.

Or

➢ Press the **Preparation** button to begin patient connection.

- **Automatic circulation**



After the rinse is completed, the circulation will start automatically.

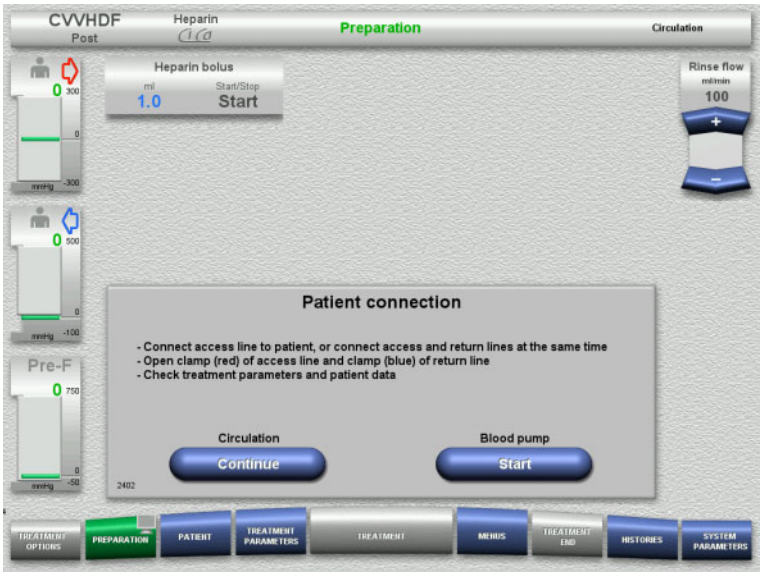
➢ Prepare to connect the patient.

➢ Press the **Preparation** button to stop the blood pump.

4.3.8 Connecting the patient

Note

Pressing the **Start** button under Blood pump also starts the citrate anticoagulation. If the blood pump delivers 300 ml without any blood being detected, a message is output and all pumps are stopped. If the patient detection runs for more than 10 minutes without any blood being detected, the Ci-Ca pumps will stop. The calcium pump starts after the start of treatment and balancing.

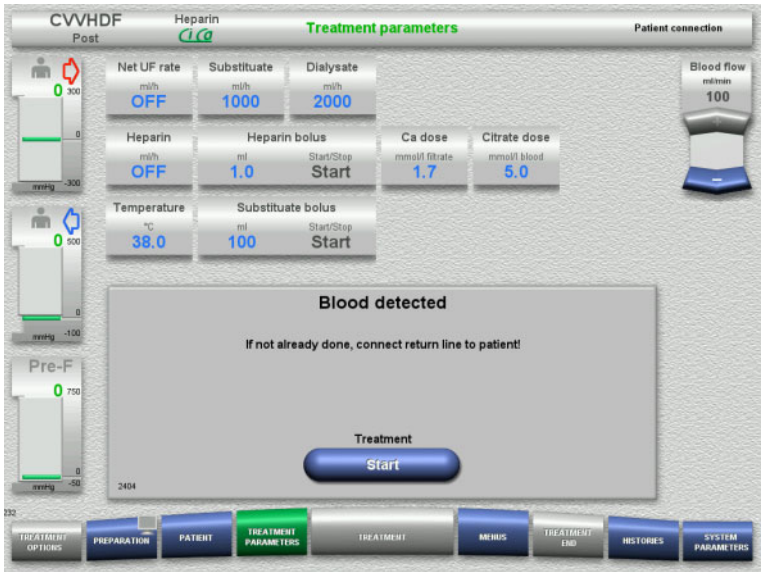


The blood pump is stopped.

➢ Press the **Start** button to start the blood pump.

The blood pump will continue operating until the optical detector has detected blood.
If necessary, administer a heparin bolus.

Press the **Continue** button to continue the circulation.



The optical detector has detected blood.
The blood pump is stopped.

➢ Press the **Start** button to start the treatment.

4.3.9 Treatment

Warning

Risk for the patient as a result of a disorder of the electrolyte balance

Mixing up the solution may lead to hypo-/hypercalcaemia.

➢ The post-filter calcium concentration must be checked 5 minutes after switching on the Ci-Ca anticoagulation and at regular intervals afterwards.

Warning

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

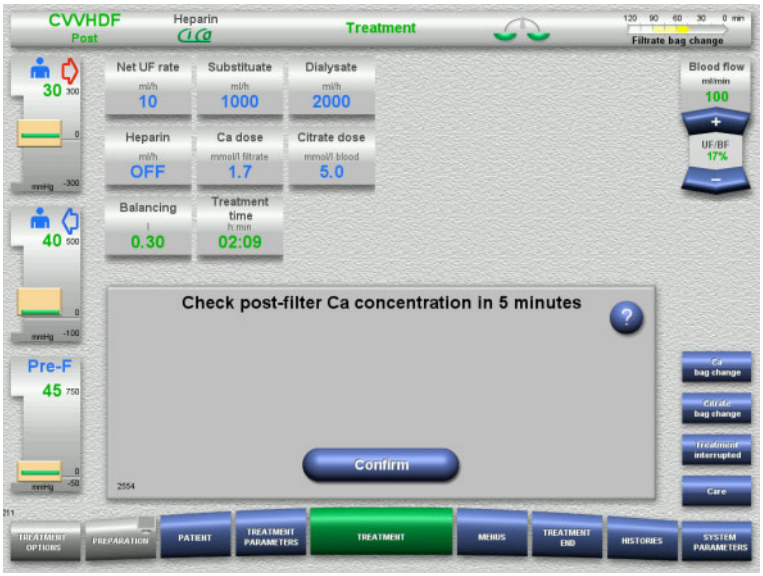
➢ Observe the instructions for taking a sample.

➢ In the event of widely varying measurement values of the electrolytes and the acid-base balance, consult a physician.

Observe the instructions for taking a sample (see Chapter 7.3.2 on page 261).

Note

The use of a calcium-containing substituate for the Ci-Ca postCVVHDF treatment means that a calcium substitution is performed. If the concentrations have been entered correctly in the **User setup** menu option, this is automatically taken into account in the calcium dose.



After the treatment has been started, a message is displayed prompting the operator to check the post-filter calcium concentration after 5 minutes.

4.3.9.1 Treatment screen

The treatment screen is displayed throughout the entire treatment.

The information area shows important treatment data:

Pressure / alarm history
Next operator action

4.3.9.2 Menus

The following menu options can be selected:

- Rocker switch buttons for setting the level in the bubble catcher:
  For raising or lowering the level in the bubble catcher.
- Cancel preparation:
  For dismantling (user) / ejecting (device) the tubing system during preparation.
- Treatment interrupted:
  For pausing treatment.
- Switch balancing off/on:
  For switching balancing off and back on.
- Change syringe:
  For changing the heparin syringe.
- Care:
  For starting Care mode.
- Bag change:
  For changing the dialysate bag and emptying the filtrate bag.
- Ci-Ca information:
  For viewing additional information on Ci-Ca anticoagulation.
- Ca bag change:
  For changing the calcium bag.
- Citrate bag change:
  For changing the citrate bag.
- Switch off/on Ci-Ca anticoagulation:
  For switching citrate anticoagulation off and back on.

Detailed description of menu options shown (see Chapter 4.7 on page 168).

4.3.9.3 Histories

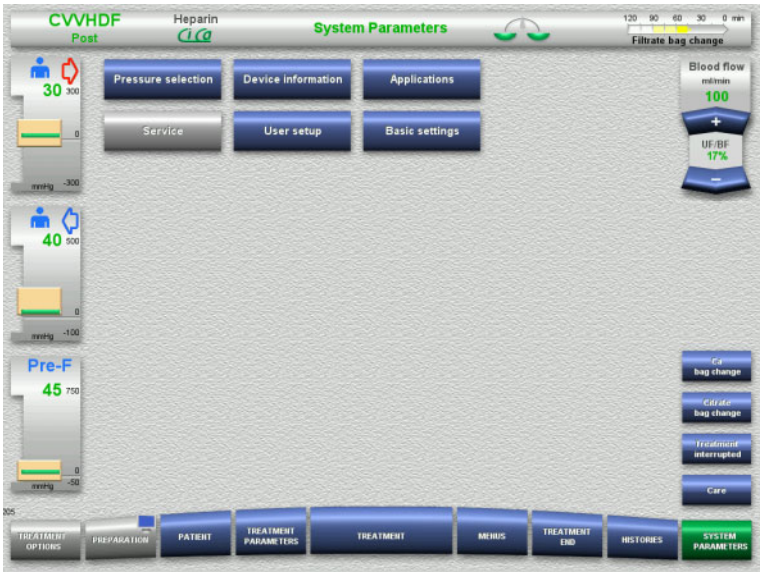
The following tabs can be selected:

- Balance data
- Balance history
- Events

(see Chapter 4.8 on page 190)

Pressing the **Reset balance data** button will reset all the cumulative volume information recorded so far to “zero”. The treatment time and the filter life will not be reset.

4.3.9.4 System Parameters

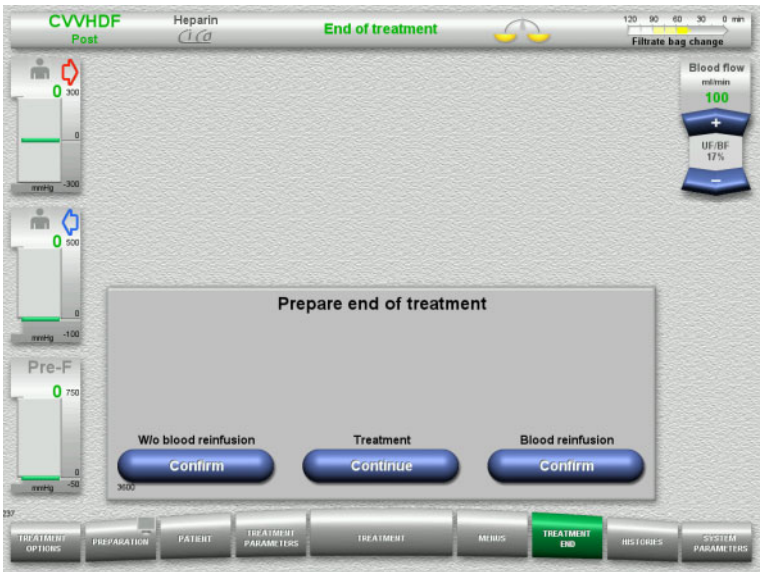


In the **System Parameters** screen, only the blue (activated) buttons can be used to open the appropriate options (see Chapter 4.9 on page 195).

To activate any grey buttons, you will need a ServiceCard or UserCard.

4.3.10 End of treatment

4.3.10.1 Preparing the end of treatment



➢ Select **TREATMENT END** from the menu bar.

➢ Press the **Confirm** button to select blood reinfusion.

Press the **Continue** button to continue the treatment.

Press the **Confirm** button under **W/o blood reinfusion** and **Blood pump Stop** in the screen that follows to go straight to the **Disconnect the patient!** screen (see Chapter 4.3.10.5 on page 115).

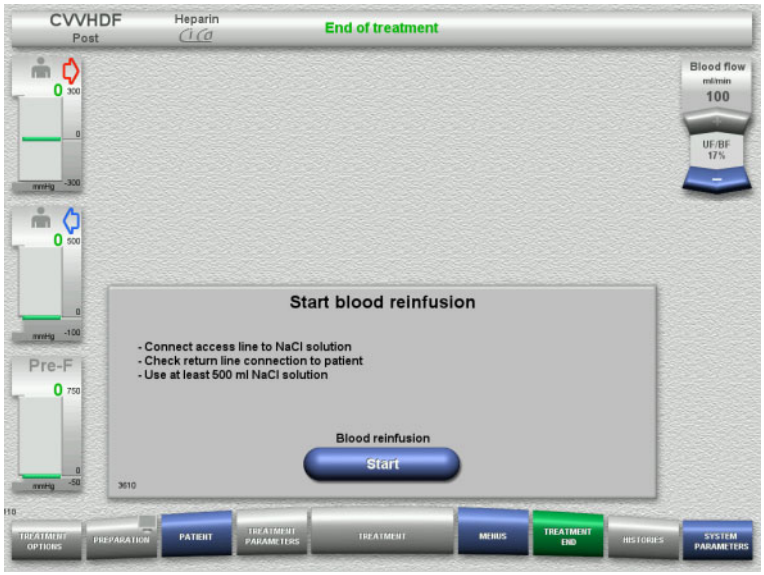
4.3.10.2 End of treatment with blood reinfusion

➢ Press the **Stop** button to stop the blood pump.

Balancing is switched off.

Press the **Back** button to return to the Prepare end of treatment screen.

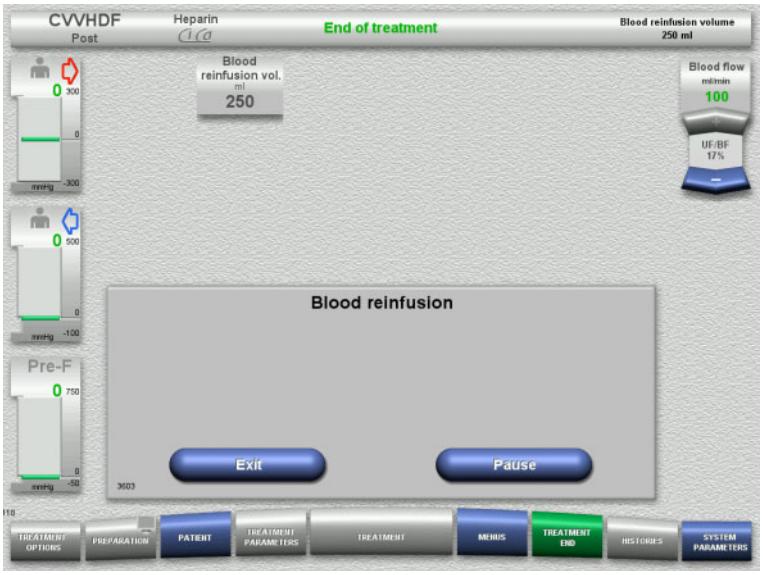
4.3.10.3 Starting blood reinfusion



➢ Disconnect the access line from the patient and connect it to an NaCl solution bag.

➢ Press the **Start** button to start blood reinfusion.

The blood flow is limited to 100 ml/min.
Ci-Ca anticoagulation is stopped.

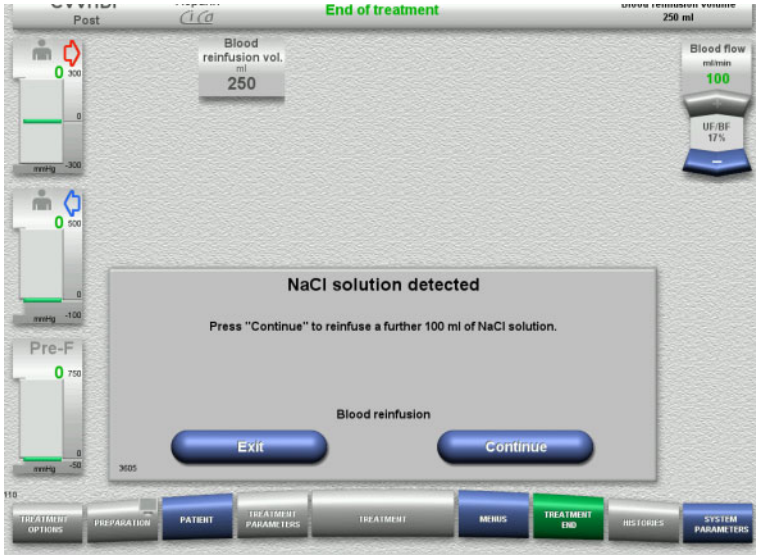


Blood reinfusion ends automatically as soon as the optical detector detects the NaCl solution.

Press the **Pause** button to stop the blood reinfusion.

Press the **Exit** button to terminate blood reinfusion.

4.3.10.4 NaCl solution detected



➢ Press the **Exit** button to terminate blood reinfusion.

Press the **Continue** button to reinfuse a further 100 ml of NaCl solution.

This can be repeated as needed.

4.3.10.5 Disconnecting the patient

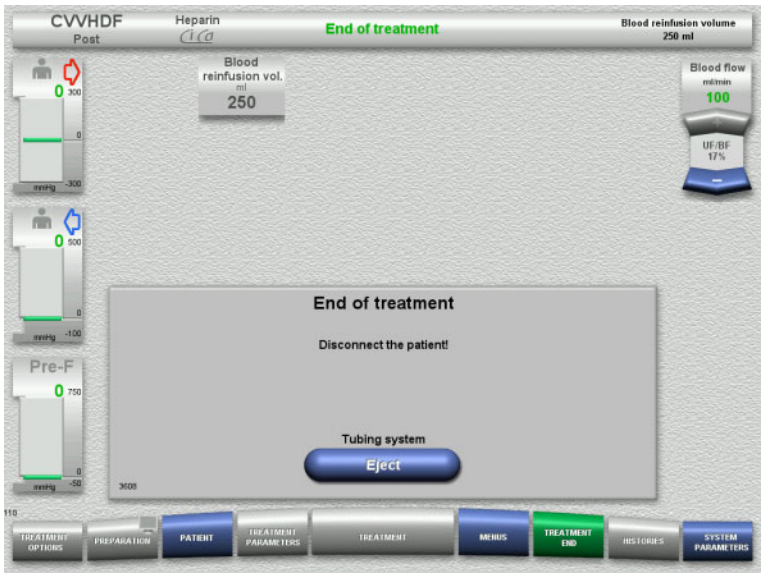
Warning

Risk of blood loss as a result of connection sites not closed correctly

Risk for the patient as a result of a disorder of the electrolyte balance

If pump segments of the Ci-Ca system are not inserted, there is a risk of blood loss or hypercalcaemia.

➢ It is forbidden to remove the Ci-Ca tubing system manually before the patient is disconnected.



➢ Disconnect the patient.

➢ Press the **Eject** button to start ejecting the tubing system.

4.3.10.6 Dismantling the tubing system

Warning

Risk of cross-contamination as a result of contaminated consumables

There is a risk of spreading germs.

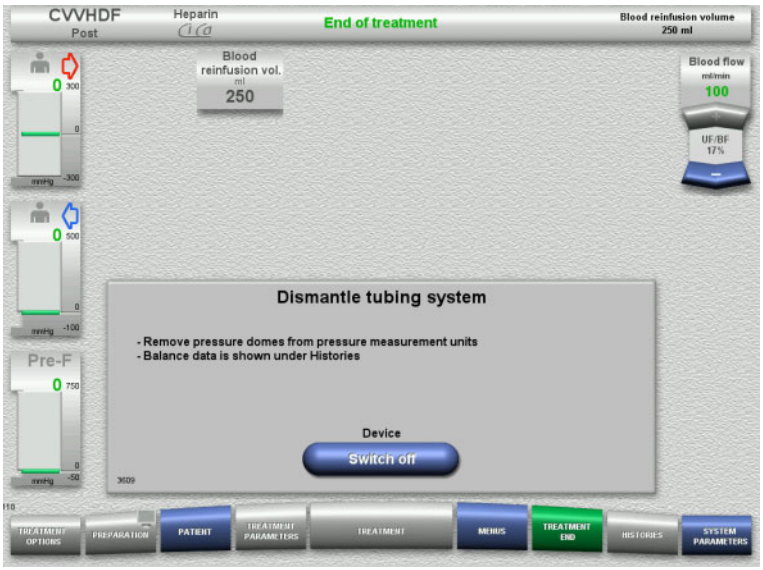
➢ Consumables must be discarded after a treatment in compliance with the regulations for the disposal of potentially contaminated materials.

Note

Use the positioner to remove the tubing from the stators of the Ci-Ca pumps in each case. The pump rotor will then begin to eject the pump segments. You can help the ejection of the pump segments by lightly pulling on the positioners.

Note

Contamination on the device caused by citrate or calcium solutions must be removed using a disposable paper towel dampened with alcohol-containing disinfectant.



➢ Dismantle the tubing system.

In the **Histories** menu, you can view the treatment data and events.

➢ Switch the device off with the **Switch off** button.

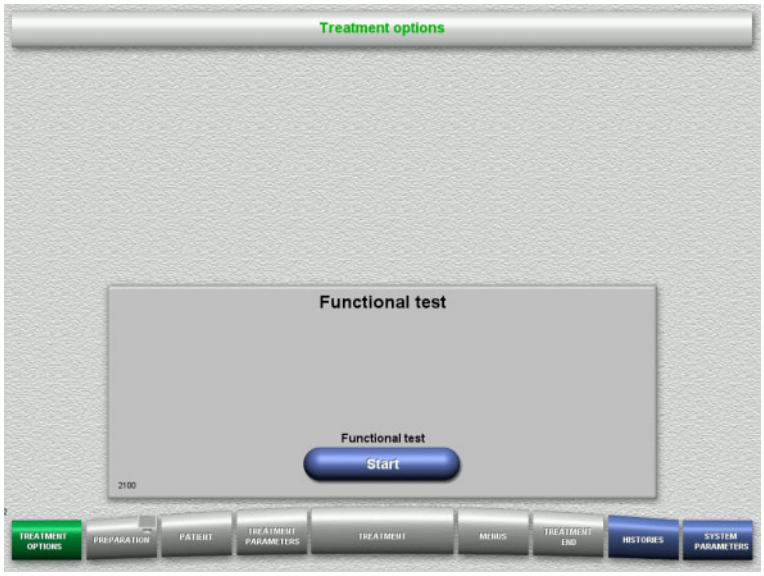
4.4 TPE treatments

4.4.1 Switching on the device and starting the function test

There must be no load on any of the scales.

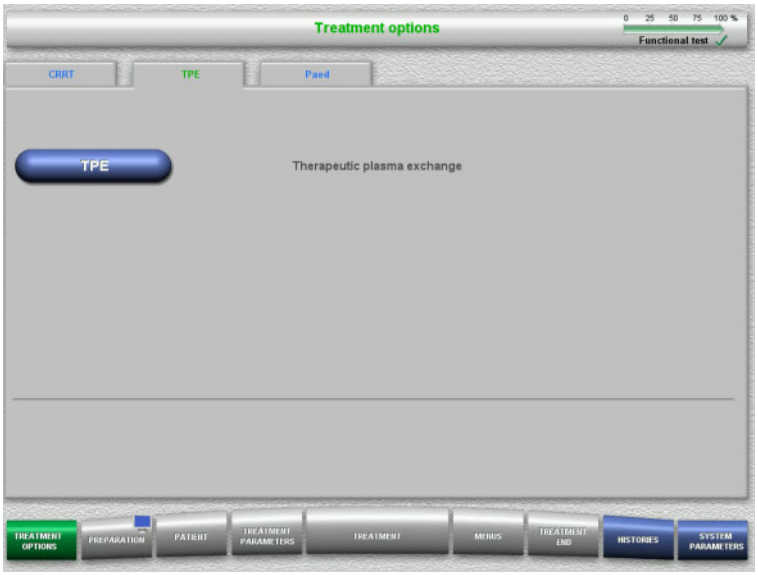
➢ Switch on the device with the **On/Off** button.

The software version, date and time will be displayed.



➢ Press the **Start** button to start the function test.

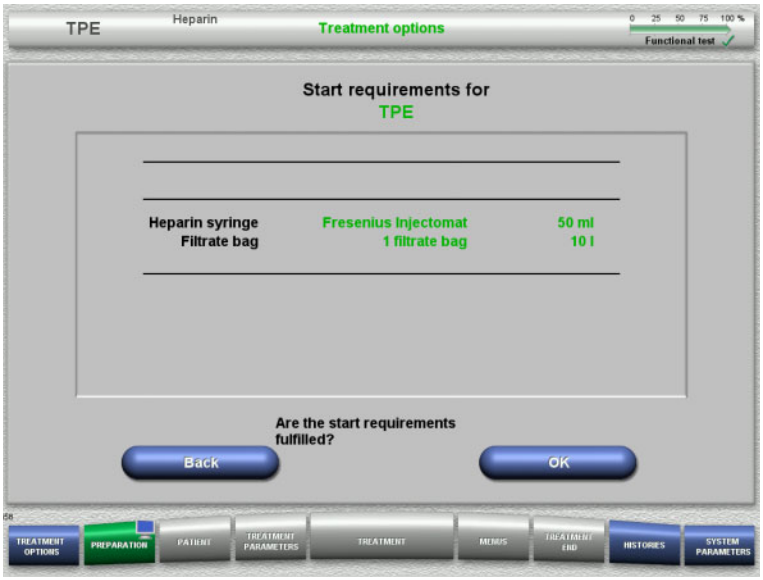
4.4.2 Selecting the treatment option



➢ Select the **TPE** tab.

➢ Select the treatment option **TPE**.

4.4.3 Start requirements

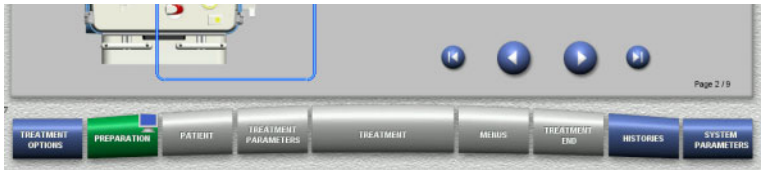


➢ Check heparin syringe type, number of filtrate bags and filtrate bag size against the information on the screen.

➢ Press **OK** to confirm the start requirements.

Press the **Back** button to return to the treatment options screen.

4.4.4 Mounting the cassette



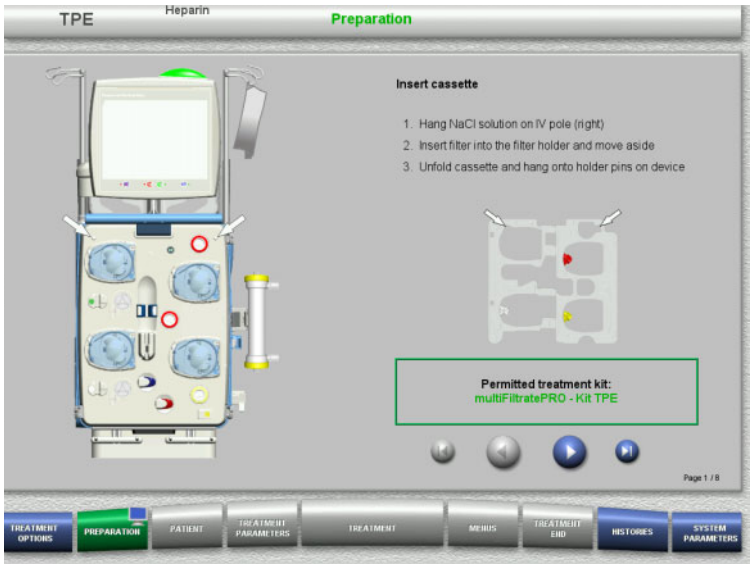
You can use the following buttons for mounting the cassette:

Press to go to the next step.

Press to jump to the end of the setup instructions.

Press to return to the previous step.

Press to jump back to the beginning of the setup instructions.



➢ Hang up the cassette according to the instructions.

➢ Fix the plasma filter in the filter holder.

➢ Press to go to the next step.

4.4.4.1 Mounting the return system

Warning

Risk of air embolism as a result of air in the tubing system

Blood clots (coagula) in the tubing system, contaminations and/or moisture on the air bubble detector can impair the correct function of the air bubble detector.

➢ The air bubble detector must be clean and dry.

➢ Do not use any ultrasound-conducting objects or media.

Warning

Risk of air embolism as a result of air in the tubing system

If the tubing system is not inserted properly, this can prevent the air detection system from working.

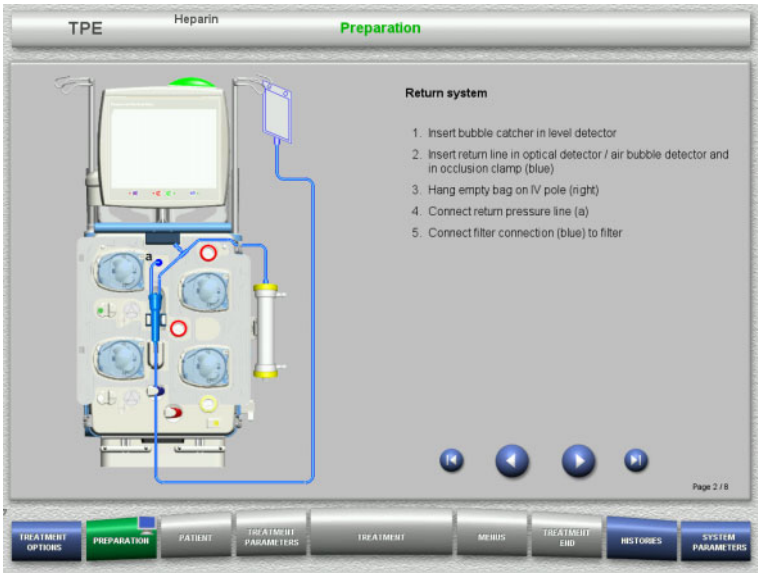
➢ When the tubing system is inserted into the air bubble detector/optical detector, the tube must lie along the full length of the tube holder.

Warning

Risk of air embolism as a result of air in the tubing system

➢ Insert the tubing system correctly into the line occlusion clamp.

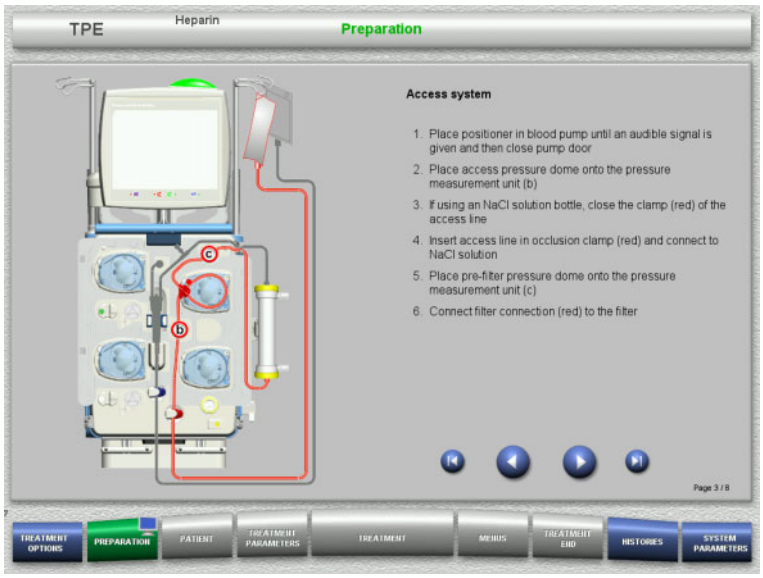
➢ Do not remove the tubing system from the line occlusion clamp during treatment.



➢ Mount the return system according to the instructions.

➢ Press to go to the next step.

4.4.4.2 Mounting the access system



➢ Mount the access system according to the instructions.

Check that the correct cassette has been mounted for the selected treatment option.

➢ Press to go to the next step.

Note

Once the first positioner has been inserted, the cassette system can only be dismantled and changed by cancelling the preparation (**Menus** / **Cancel preparation** (see Chapter 4.7.2 on page 168)).

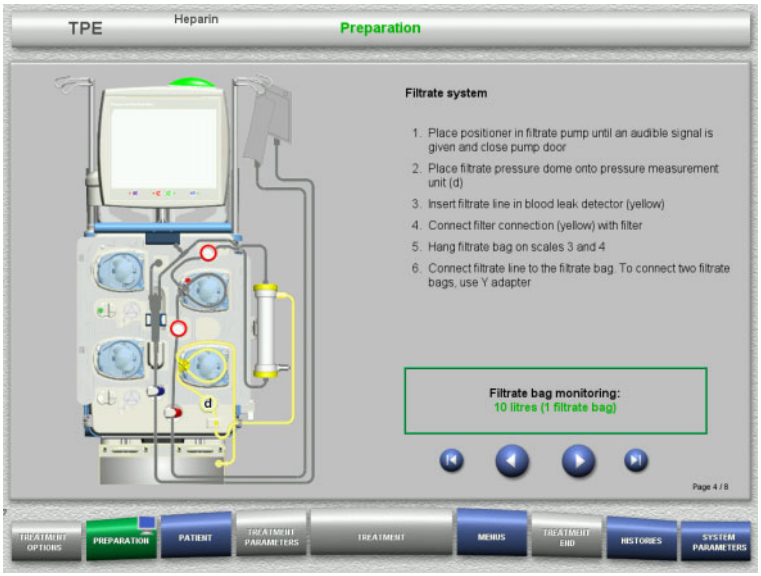
4.4.4.3 Mounting the filtrate system

Warning

Risk of contamination as a result of damaged bags

Bags can burst when dropped.

➢ Push filtrate bags as far back as possible onto the hooks of the lower scales.



➢ Mount the filtrate system according to the instructions.

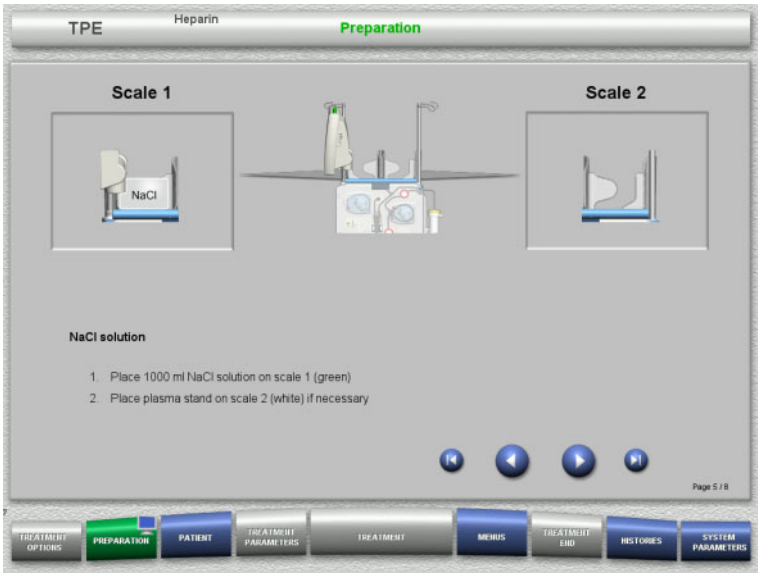
Filtrate bag monitoring can be set in the System Parameters, from 5 L to 20 L. If set to more than 10 L, two 10-litre bags must be connected with a Y adapter.

➢ Press ▶ to go to the next step.

4.4.4.4 Loading the solution bags

Note

When loading the solution bags onto the scales, make sure the connectors face inwards and to the rear.



➢ Load the NaCl solution onto scale 1 according to the instructions.

➢ If necessary, place the plasma bag holder on scale 2.

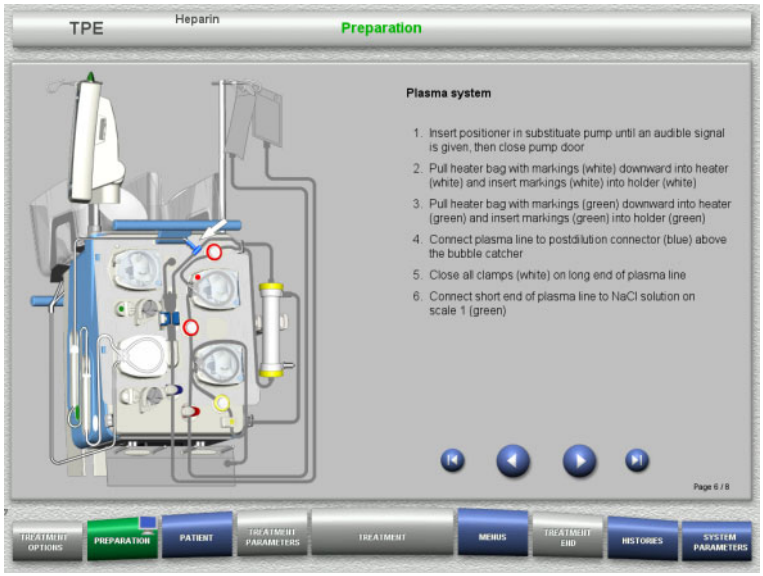
Maximum load per scale is 12 kg

➢ Press ▶ to go to the next step.

4.4.4.5 Mounting the plasma system

Note

When inserting the heater bags, observe the correct colour coding.



➢ Mount the plasma system according to the instructions.

➢ Press to go to the next step.

4.4.4.6 Inserting the heparin syringe

Note

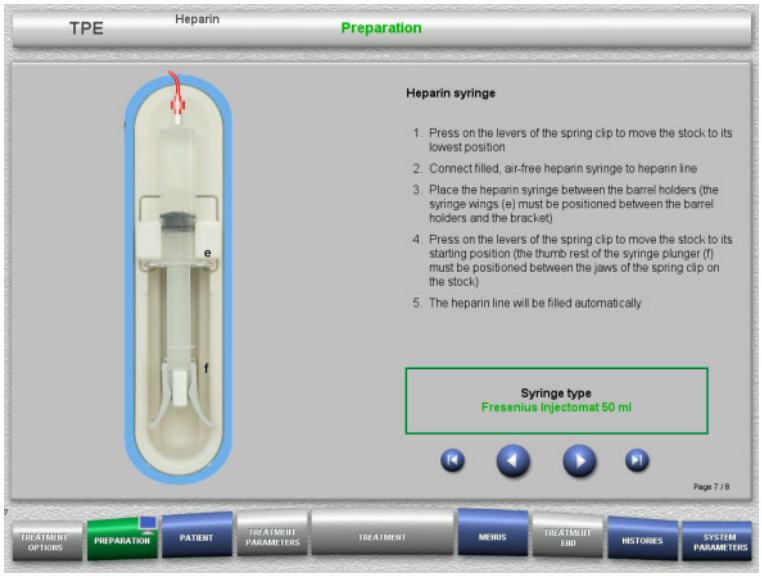
Only use the syringe type selected in the Setup and shown on the screen.

Note

When inserting the heparin syringe, observe the following:
– The syringe wings must be positioned between the barrel holders and the bracket.
– The thumb rest of the syringe plunger must be positioned between the jaws of the spring clip on the stock.

Tip

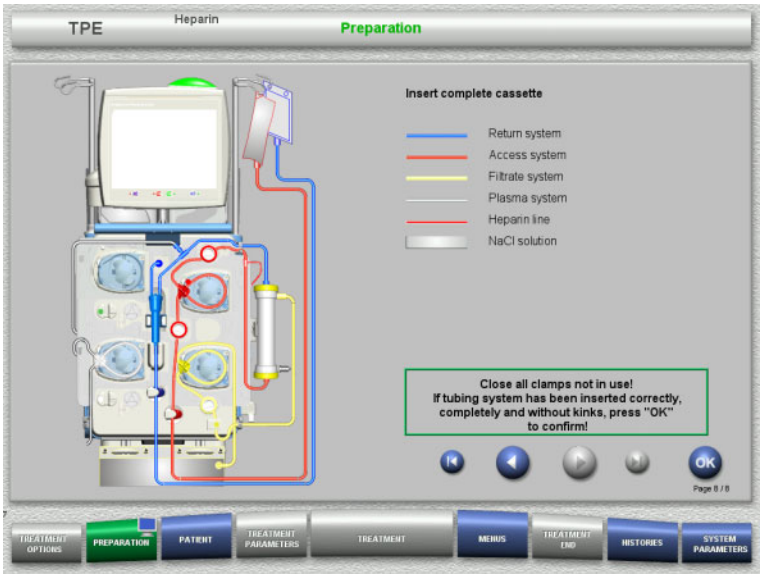
If a treatment has been started without heparin, a heparin syringe can be inserted any time by choosing **MENUS / Change syringe** (only if heparin pump is activated).



➢ Insert the heparin syringe according to the instructions.

➢ Press ▶ to go to the next step.

4.4.4.7 Cassette mounting completed



➢ Insert complete cassette.

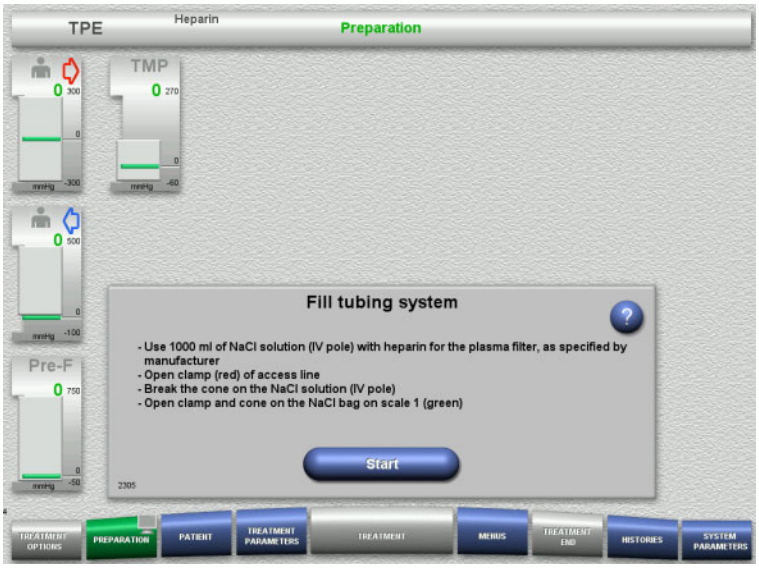
If the **OK** button cannot be selected (greyed out), check the mounted tubing system according to the instructions on the screen.

➢ Press the **OK** button to confirm that the tubing system is fully mounted.

If heparin anticoagulation has been selected, the heparin line will be filled automatically after confirmation.

4.4.5 Filling and rinsing the cassette

4.4.5.1 Filling the tubing system



➢ Press the **Start** button to start filling the tubing system.

Rinsing starts automatically as soon as the correct fill level in the bubble catcher is detected.

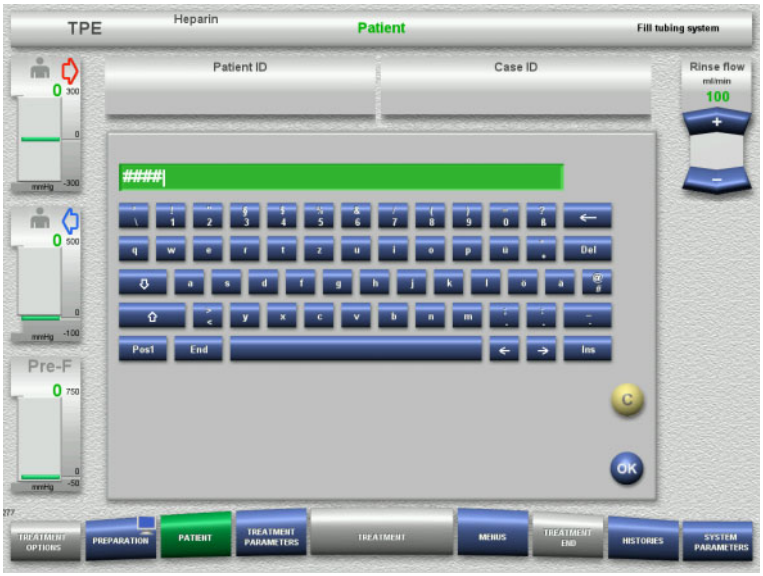
The rinse flow can be changed with the **+/–** rocker switch buttons.

4.4.5.2 Entering the Patient ID and Case ID

Requirements

The **Patient** menu opens automatically when filling is started, if **Jump to Patient menu** is activated. Otherwise, the **Treatment parameters** menu will open automatically when filling is started (see Chapter 4.3.6.5 on page 105).

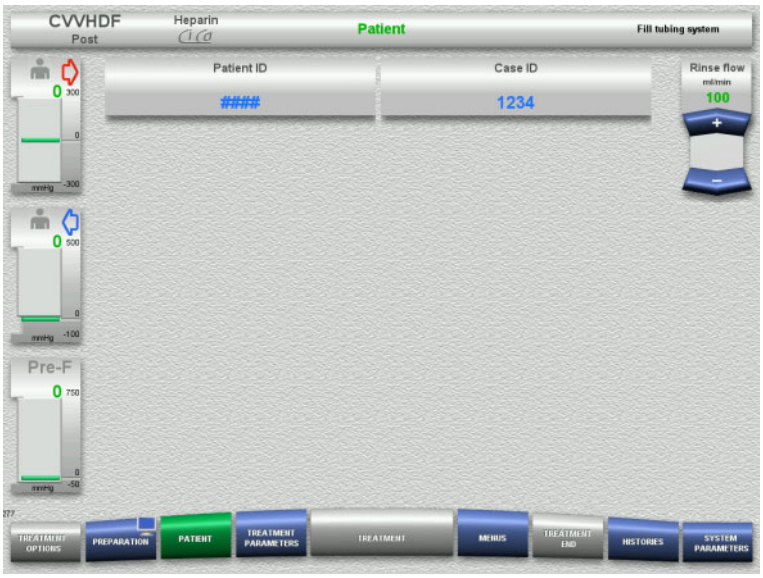
➢ Check the **Patient ID/Case ID** shown.
The fields will be empty if no data has yet been entered.



➢ To change or enter the **Patient ID/Case ID**, press the relevant field.

➢ Use the keyboard to enter the required Patient ID/Case ID.

➢ Press the **OK** button to apply the displayed value.



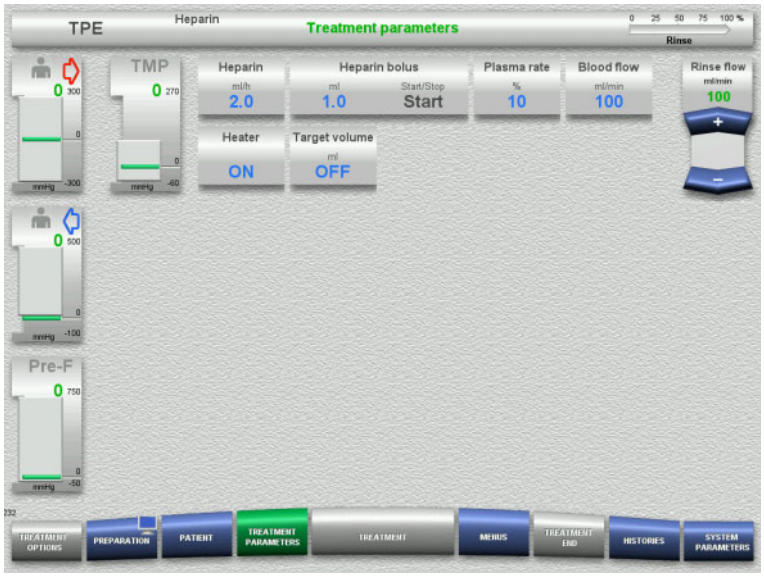
➢ Check the **Patient ID/Case ID** entered.

4.4.5.3 Entering treatment parameters

Note

The bolus function can be used if an initial heparin bolus needs to be administered.

The infusion of anticoagulation fluids is corrected automatically in the overall balance.



➢ Check the preset treatment parameters. If necessary, adjust the treatment parameters.

➢ Temperature:
Switch on the substituate or plasma heater.

Warning

Risk for the patient due to heat loss via the extracorporeal blood circuit if the temperature of the plasma replacement solution is too low

Haemodynamic instability due to the reduction in core body temperature.

➢ Preheat plasma replacement solution to at least 20 °C before treatment.

➢ Conduct treatment at a room temperature of at least 20 °C.

➢ Switch on heater.

➢ Avoid drafts during treatment.

➢ Regular monitoring of patient temperature.

➢ If necessary, take measures to maintain patient temperature, such as use of electric blankets.

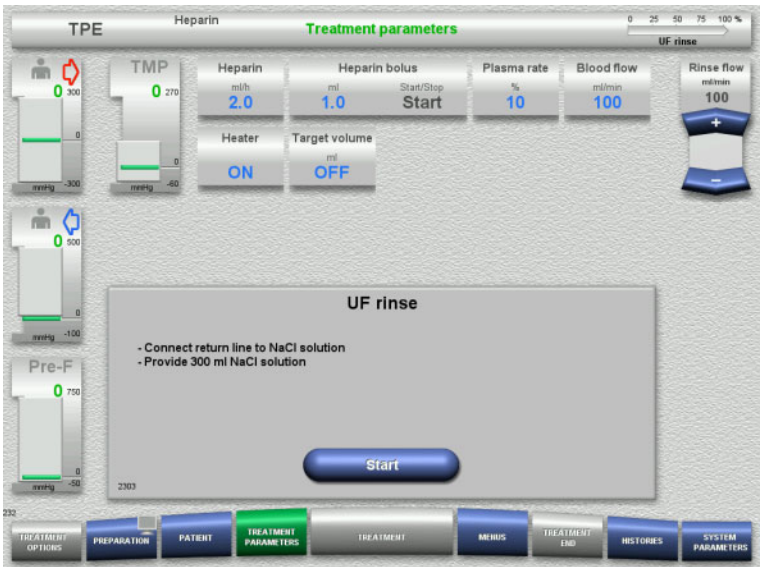
Note

In order to avoid damage to the proteins in donor plasma, the heating power in TPE treatments has been reduced. The temperature at the insertion site depends among other things on the ambient temperature (see Chapter 12 on page 297).

4.4.5.4 UF Rinse

Note

When using NaCl bags with only one connector, make sure there is enough NaCl solution.



If using an NaCl bag with two connectors:

➢ Remove return line from empty bag and connect to NaCl solution.

➢ Press the **Start** button to start the UF rinse.

If using an NaCl bag with one connector:

➢ Leave the existing connections as they are.

➢ Press the **Start** button to start the UF rinse.

The level in the bubble catcher will be set automatically when the UF rinse is finished.

4.4.6 Circulation

Warning

Risk of contamination as a result of non-compliance with hygienic conditions

There is a risk of spreading germs.

➢ Keep preparation and circulation times before the treatment as short as possible.

Note

If the patient connection must be delayed, the extracorporeal circuit can be kept in circulation for a certain time after preparation.

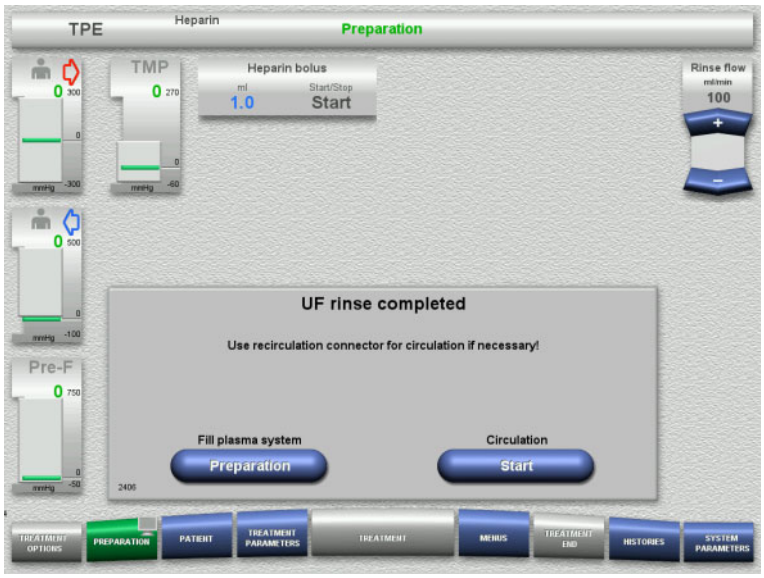
To avoid stressing the tubing system for too long, the circulation time is also taken into account when monitoring the kit service life.

Note

In the Setup, circulation can be set to start automatically (without recirculation connector) or to be confirmed by the user (with recirculation connector).

The factory setting is **Confirm**, since an automatic changeover into circulation mode is only possible if an NaCl solution bag with two connections is used.

- **Stop before circulation**



After the rinse is completed, the blood pump will stop.

An audible tone is emitted.

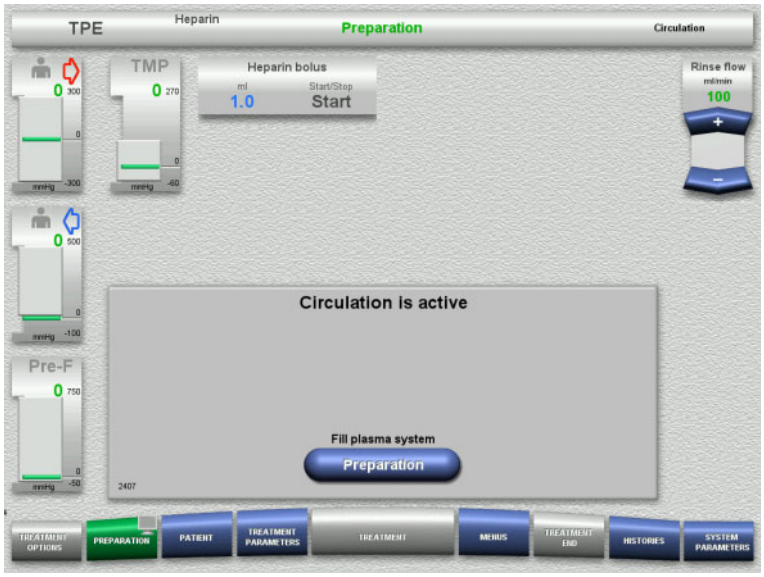
➢ Connect the access and return lines to the recirculation connector.

➢ Press the **Start** button to start the circulation.

Or

➢ Press the **Preparation** button to prepare the filling of the plasma system.

- **Automatic circulation**



After the rinse is completed, the circulation will start automatically.

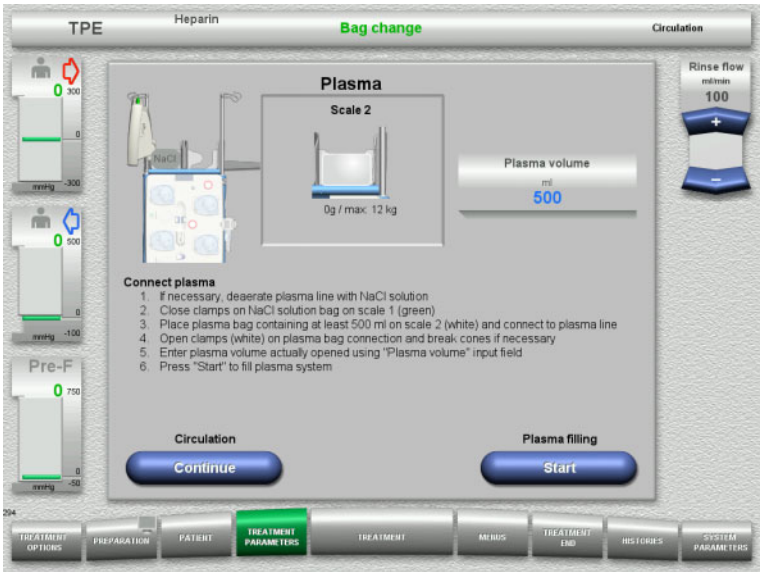
➢ Press the **Preparation** button to prepare the filling of the plasma system.

The blood pump is stopped.

4.4.7 Filling the plasma system

Note

After pressing the **Plasma filling Start** button, it is not possible to return to circulation. Plasma filling is completed after the blood pump stops, and this is followed by the **Patient connection**.



The blood pump is stopped.

➢ Close the clamp (white) on the line to the NaCl bag on scale 1.

➢ Load the plasma bag onto scale 2, or hang it on the plasma bag holder, and connect the plasma line.

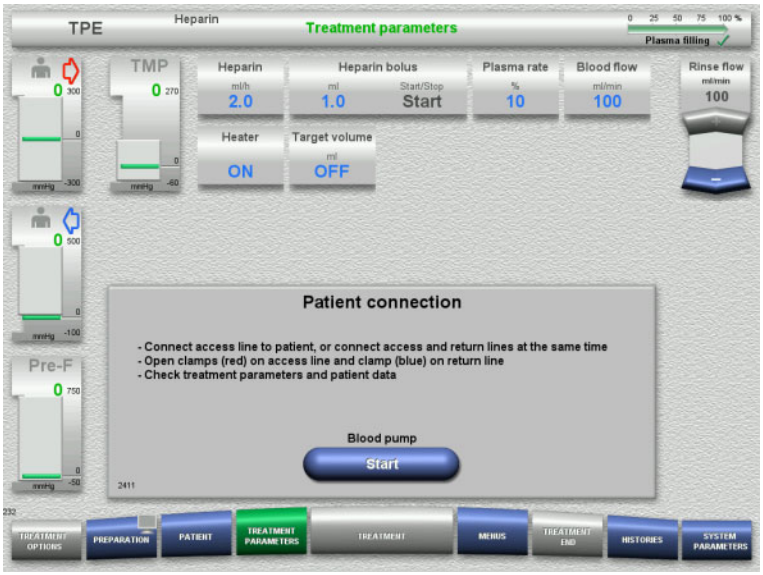
➢ Enter the volume of the opened plasma bags (see second screen).

➢ Press the **Start** button to start filling the plasma system.

The substituate pump delivers 270 ml.

Press the **Continue** button to continue the circulation.

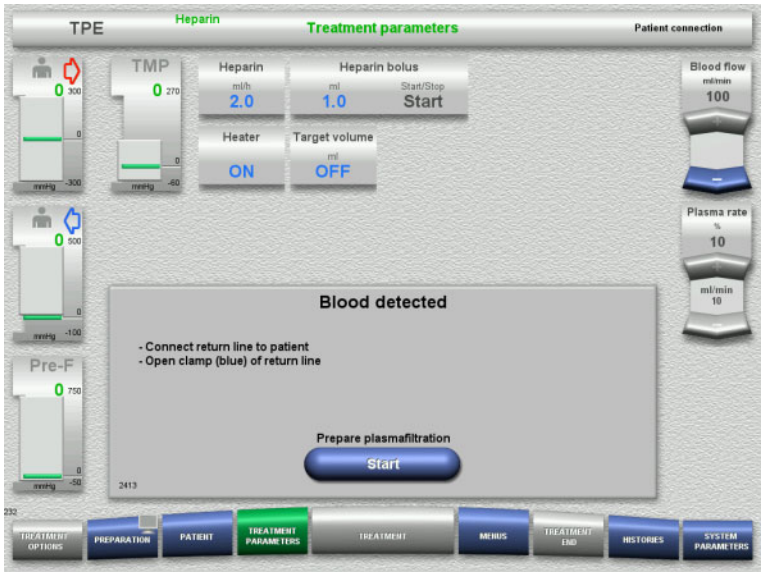
4.4.8 Patient connection



The blood pump is stopped.

➢ Press the **Start** button to start the blood pump.

The blood pump will continue operating until the optical detector has detected blood.
If necessary, administer a heparin bolus.

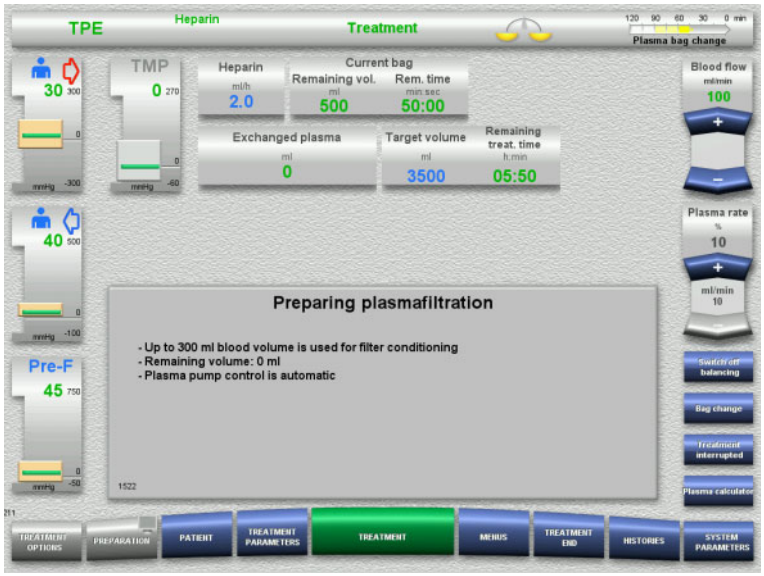


The optical detector has detected blood.

The blood pump is stopped.

➢ Press the **Start** button to start preparing plasmafiltration.

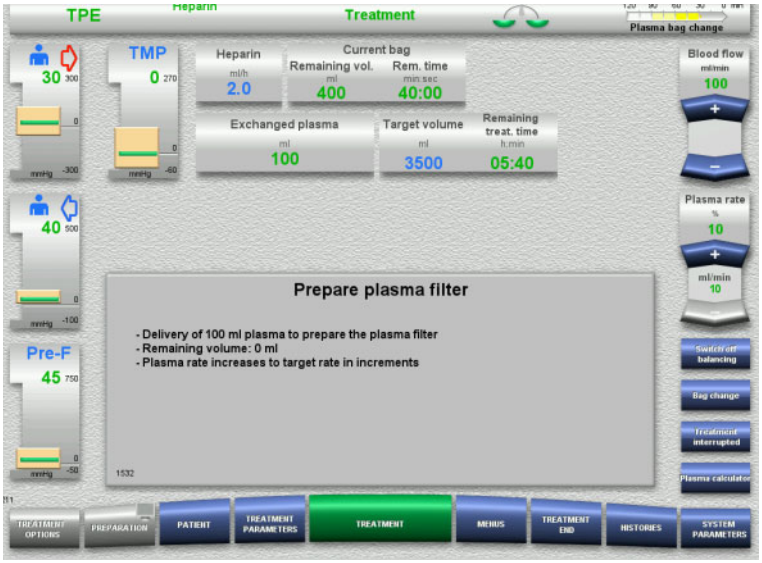
4.4.9 Preparing plasmafiltration



Filter conditioning with blood

The substituate pump and filtrate pump are stopped.

The transition to filter conditioning with plasma takes place automatically.

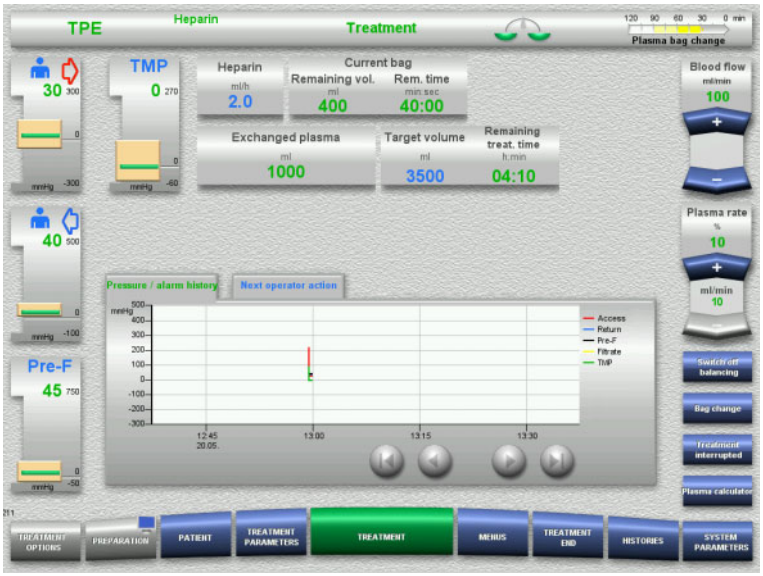


Filter conditioning with plasma.

The substituate pump is controlled automatically until the target rate is reached.

4.4.10 Treatment

4.4.10.1 Treatment screen

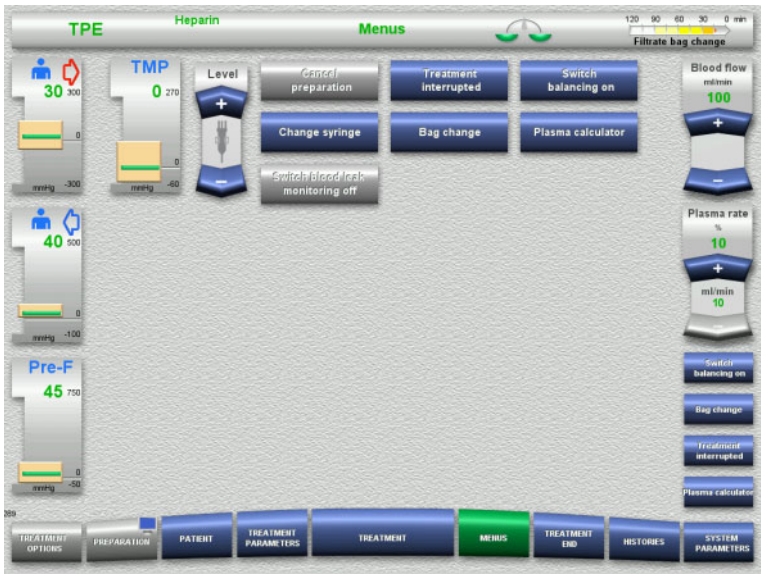


The treatment screen is displayed throughout the entire treatment.

The information area shows important treatment data:

Pressure / alarm history
Next operator action

4.4.10.2 Menus



The following menu options can be selected:

– Rocker switch buttons for setting the level in the bubble catcher:
  For raising or lowering the level in the bubble catcher.
– Cancel preparation:
  For dismantling (user) / ejecting (device) the tubing system during preparation.
– Treatment interrupted:
  For pausing treatment.
– Switch balancing off/on:
  For switching balancing off and back on.
– Change syringe:
  For changing the heparin syringe.
– Bag change:
  For changing the plasma bag.
– Plasma calculator:
  For calculating the plasma to be exchanged.
– Switch blood leak monitoring off/on:
  For switching blood leak monitoring off and back on.

Detailed description of menu options shown (see Chapter 4.7 on page 168).

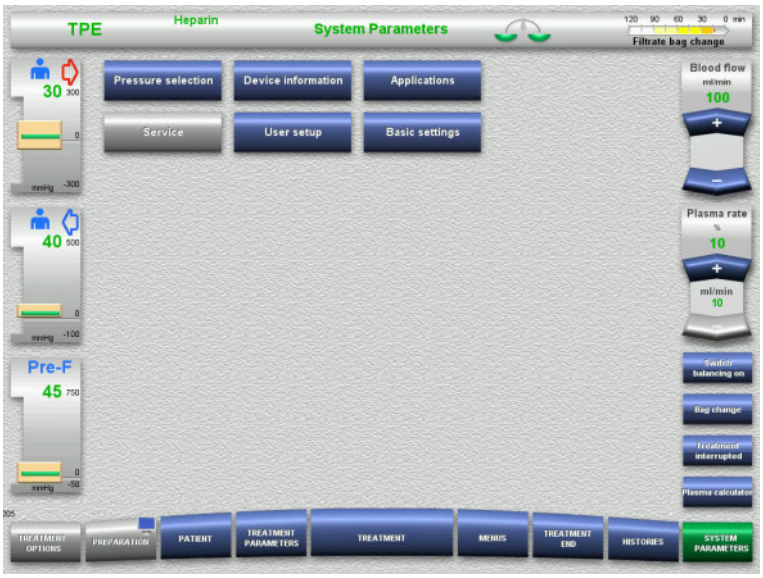
4.4.10.3 Histories

The following tabs can be selected:

– Balance data
– Balance history
– Events

(see Chapter 4.8 on page 190)

4.4.10.4 System Parameters



In the **System Parameters** screen, only the blue (activated) buttons can be used to open the appropriate options (see Chapter 4.9 on page 195).

To activate any grey buttons, you will need a ServiceCard or UserCard.

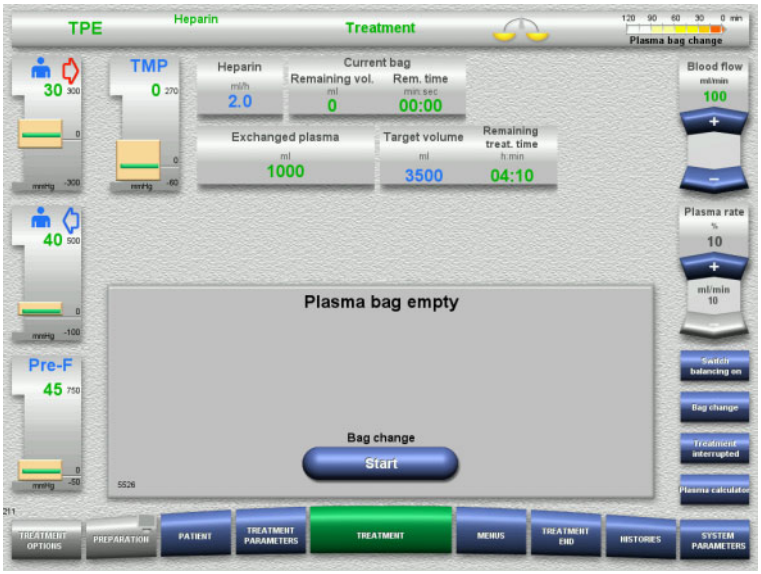
4.4.10.5 Performing a plasma bag change

The **Next operator action** tab indicates if the plasma bag needs to be changed in under 3 minutes.

➢ Select the **Bag change** menu option (see Chapter 4.7.8 on page 181).

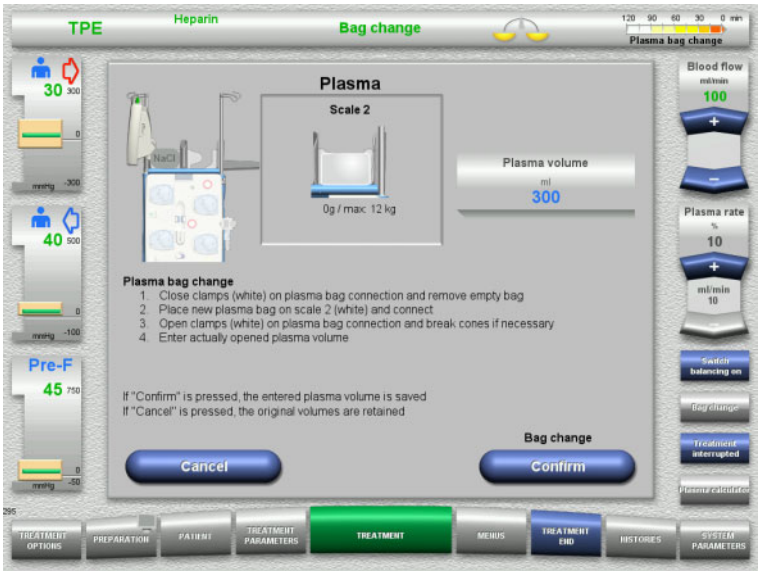
Or

➢ Wait until the **Plasma bag empty** message appears.



A message appears on the screen when the plasma bag is empty.

➢ Press the **Start** button to open the bag change menu.



➢ Change bags according to the instructions.

Balancing is switched off.
Make sure you load the solutions onto the correct scales.

➢ Enter the new volume of the opened plasma bags.

➢ Press the **Confirm** button to return to the treatment screen.

Balancing is started automatically.

Press the **Cancel** button to cancel the plasma bag change.

The entered plasma volume is not applied.

4.4.10.6 Performing filtrate bag change (TPE)

A filtrate bag change is displayed.

➢ Change bags according to the instructions.

Balancing is switched off.

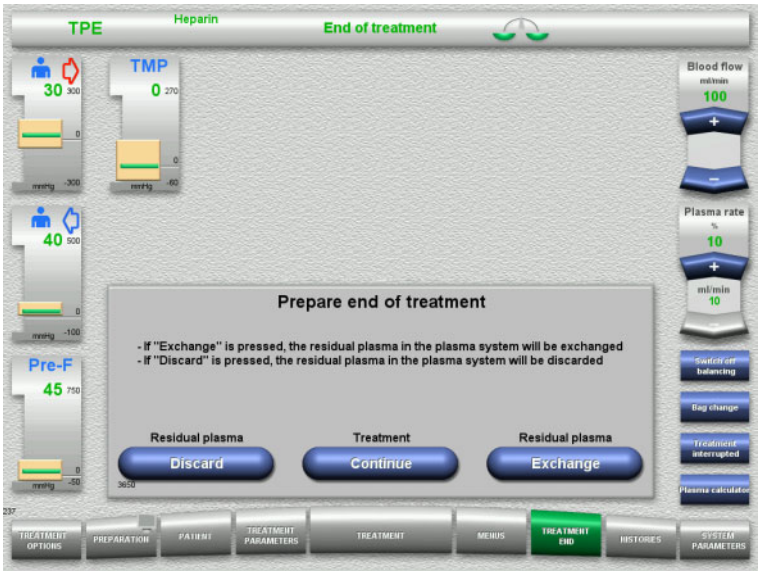
➢ Wait until the **Filtrate bag is full** message appears.

➢ Press the **Confirm** button to return to the treatment screen.

Treatment is continued with the current weight of each changed bag. Balancing is started automatically.

4.4.11 End of treatment

4.4.11.1 Preparing the end of treatment



➢ Select **TREATMENT END** from the menu bar.

➢ Select **Exchange** to end the treatment with a residual plasma exchange.

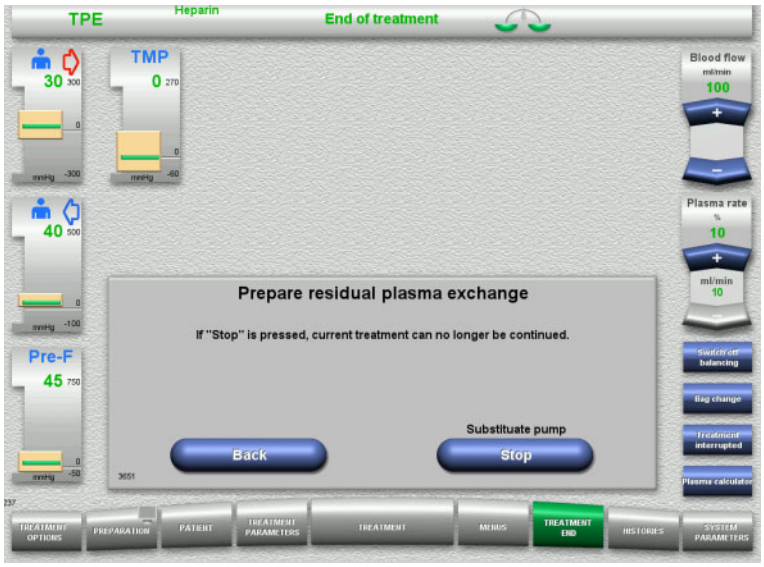
Press the **Continue** button to continue the treatment.

Press the **Discard** button to switch directly to the **Treatment ended without exchanging residual plasma** menu
(see Chapter 4.4.11.3 on page 138).

Note

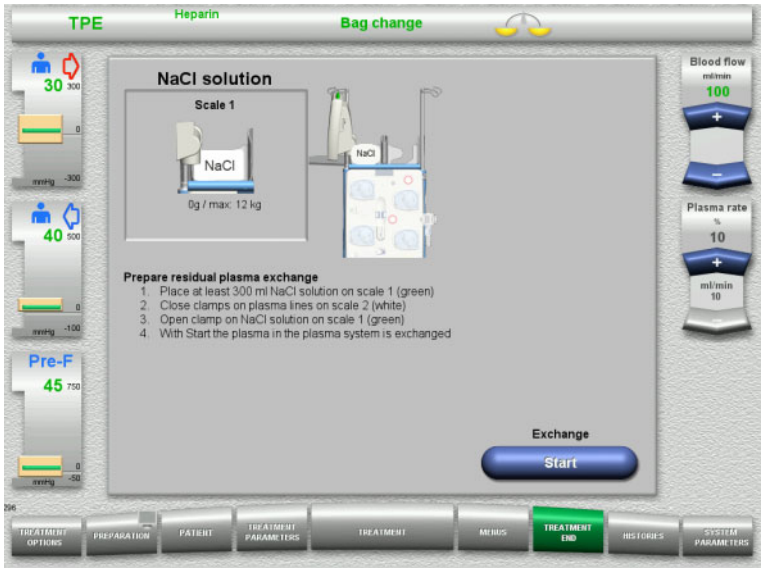
Residual plasma exchange is disabled under certain conditions.

4.4.11.2 Exchanging residual plasma



➢ Press the **Stop** button to stop the substituate pump.
Balancing is switched off.

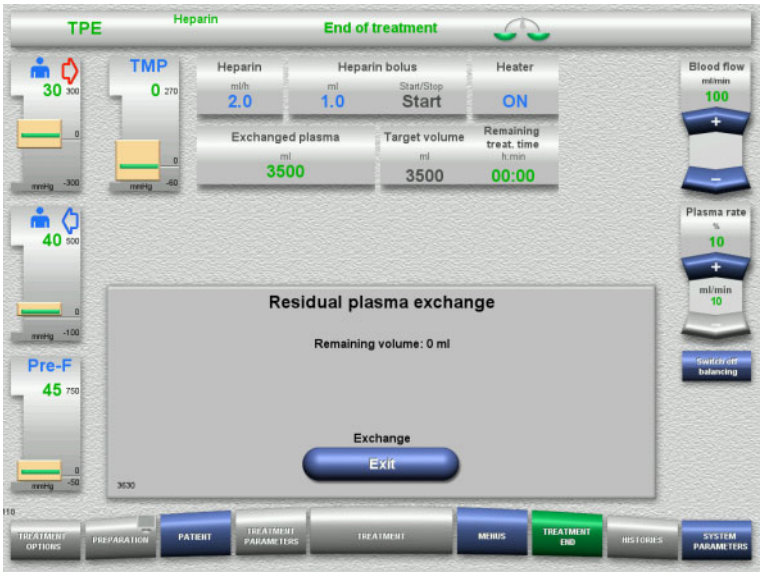
Press the **Back** button to return to the **Prepare end of treatment** screen.



➢ Load and connect the NaCl bag on scale 1.

➢ Close the clamp (white) on the plasma line to the plasma bag on scale 2.

➢ Press the **Start** button to start the residual plasma exchange.

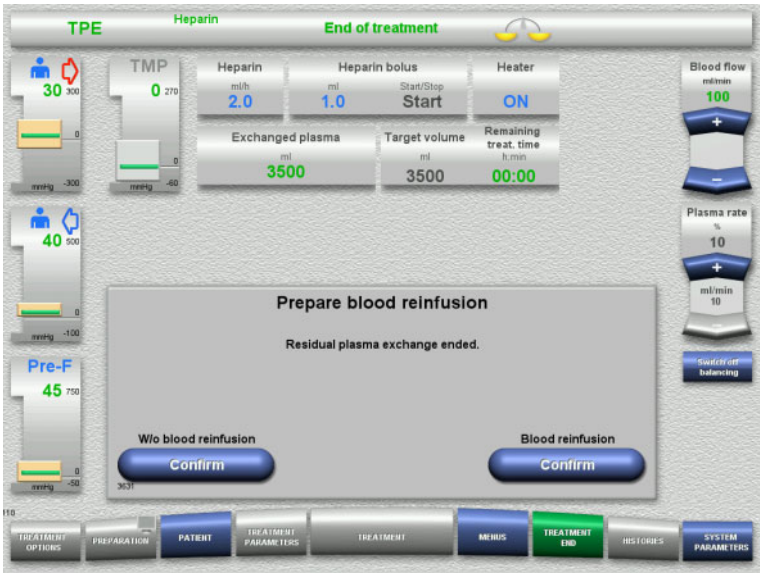


The remaining volume is displayed.

The substituate pump delivers 270 ml.

Press the **Exit** button to terminate the residual plasma exchange.

4.4.11.3 Selecting blood reinfusion



➢ Press the **Confirm** button to select blood reinfusion.

Press the **Confirm** button under **W/o blood reinfusion** and **Blood pump Stop** in the screen that follows to go straight to the **Disconnect the patient!** screen (see Chapter 4.4.11.5 on page 141).

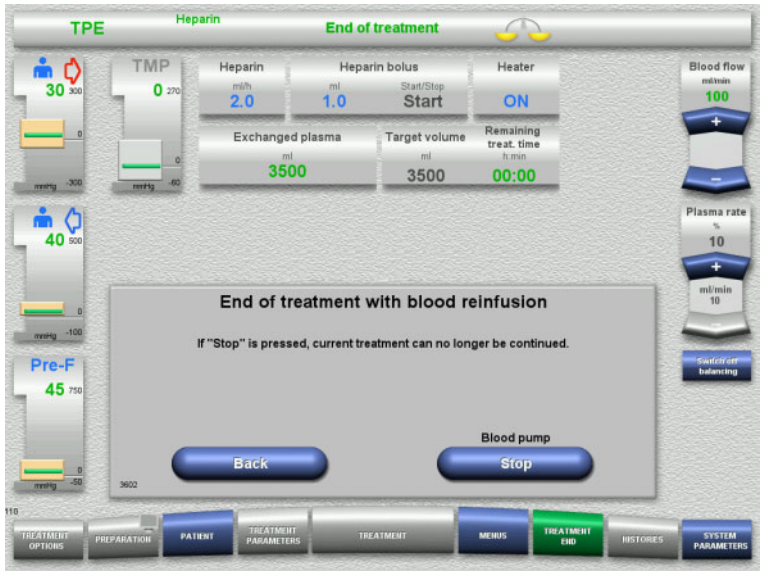
- **End of treatment without exchanging residual plasma**

➢ Press the **Confirm** button to select blood reinfusion.

Press the **Back** button to return to the Prepare end of treatment screen.

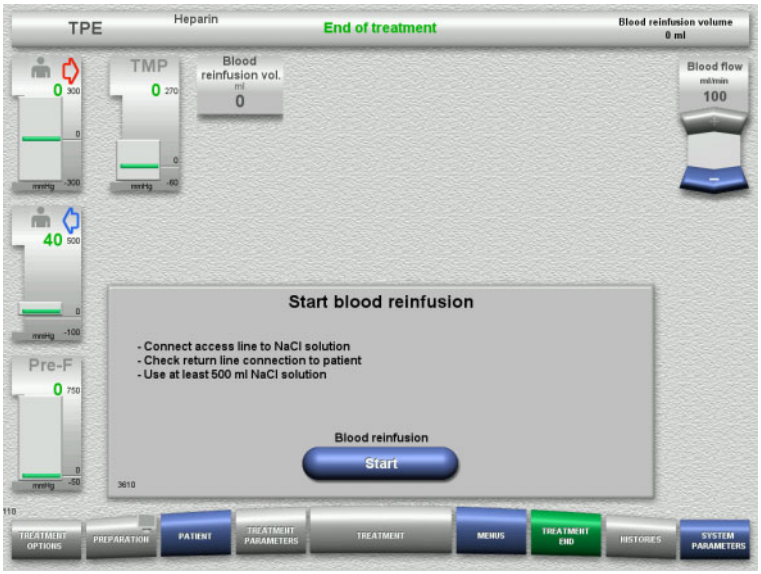
Press the **Confirm** button under **W/o blood reinfusion** and **Blood pump Stop** in the screen that follows to go straight to the **Disconnect the patient!** screen (see Chapter 4.4.11.5 on page 141).

4.4.11.4 End of treatment with blood reinfusion



➢ Press the **Stop** button to stop the blood pump.

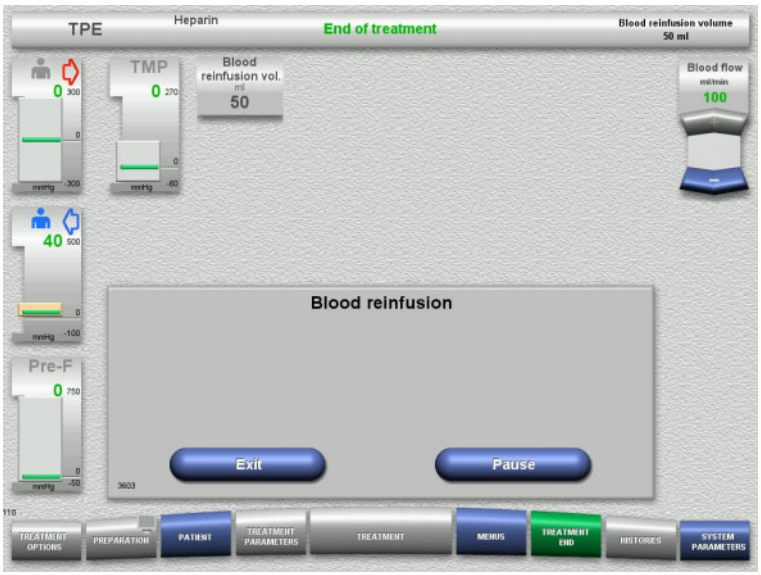
Press the **Back** button to return to the blood reinfusion selection screen.



➢ Disconnect the access line from the patient and connect it to an NaCl solution bag.

➢ Press the **Start** button to start the reinfusion.

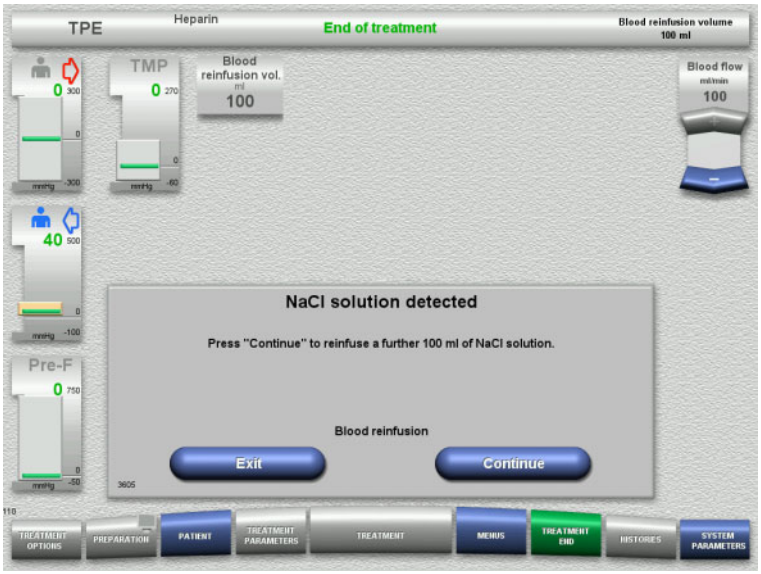
The blood flow is limited to 100 ml/min.



Blood reinfusion ends automatically as soon as the optical detector detects the NaCl solution.

Press the **Pause** button to stop the blood reinfusion.

Press the **Exit** button to terminate blood reinfusion.



➢ Press the **Exit** button to terminate blood reinfusion.

Press the **Continue** button to reinfuse a further 100 ml of NaCl solution.

This can be repeated as needed.

4.4.11.5 Disconnecting the patient

➢ Disconnect the patient.

➢ Press the **Eject** button to start ejecting the tubing system.

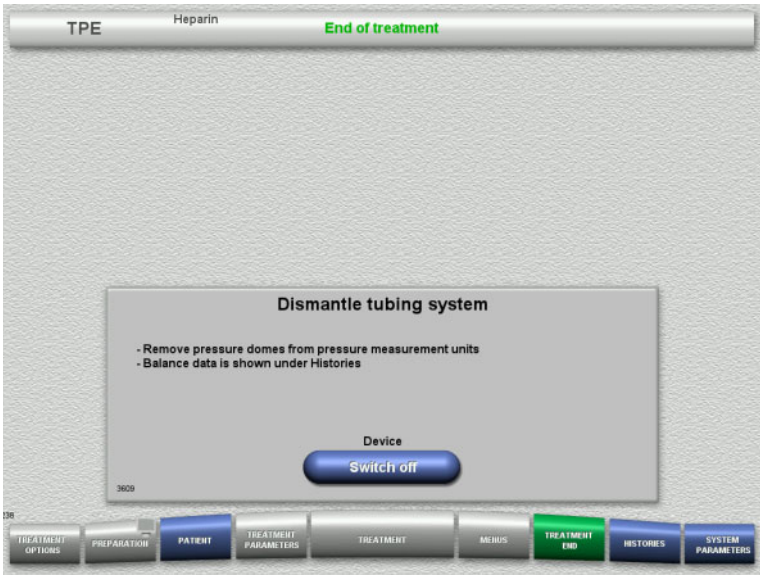
4.4.11.6 Dismantling the tubing system

Warning

Risk of cross-contamination as a result of contaminated consumables

There is a risk of spreading germs.

➢ Consumables must be discarded after a treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Dismantle the tubing system.

In the **Histories** menu, you can view the treatment data and events.

➢ Switch the device off with the **Switch off** button.

4.5 Paediatric CRRT treatments

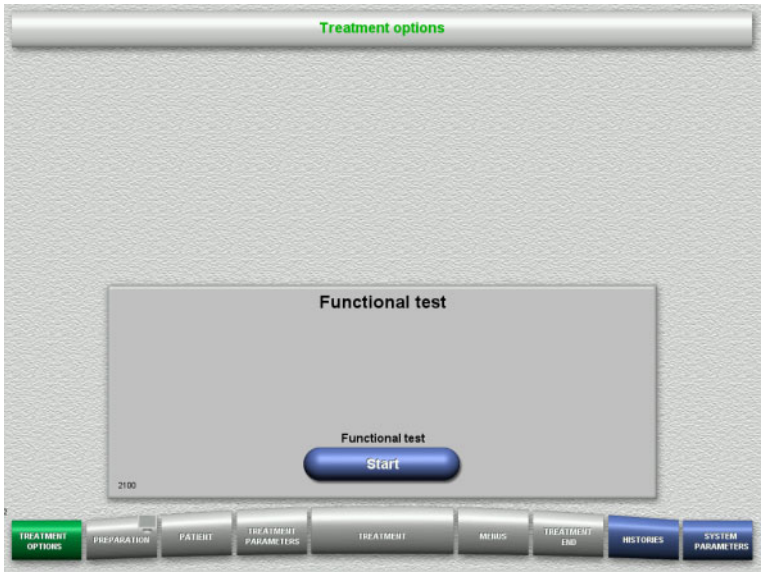
General description of the Paed CVVHD 8 kg to 16 kg and Paed CVVHD 16 kg to 40 kg procedures, with notes on the differences between the individual treatment options.

4.5.1 Switching on the device and starting the function test

There must be no load on any of the scales.

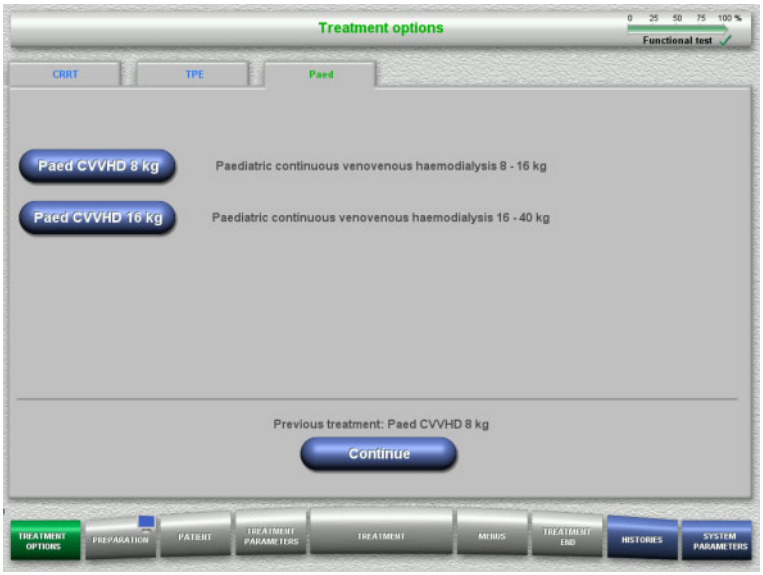
➢ Switch on the device with the **On/Off** button.

The software version, date and time will be displayed.



➢ Press the **Start** button to start the function test.

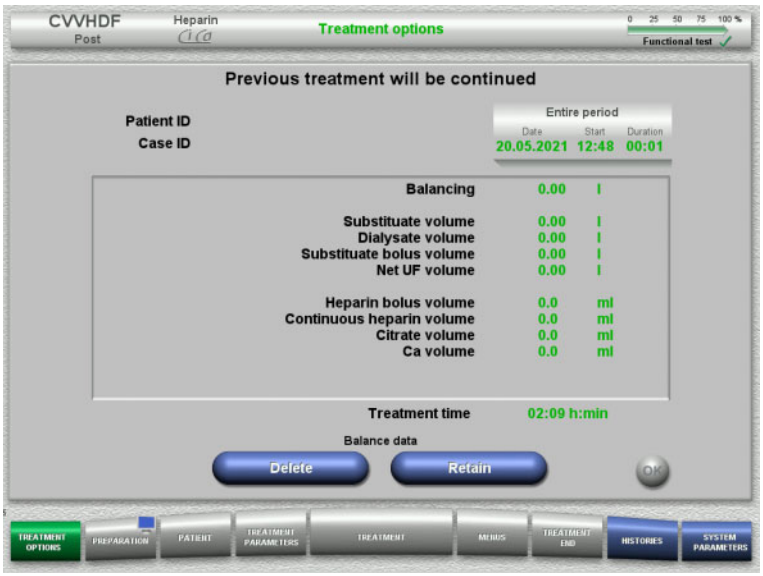
4.5.2 Selecting the treatment option



➢ Select the treatment option.

Press the **Continue** button to continue the previous treatment.

4.5.3 Continuing the previous treatment



➢ Press the **Retain** button to confirm the previous balance data.

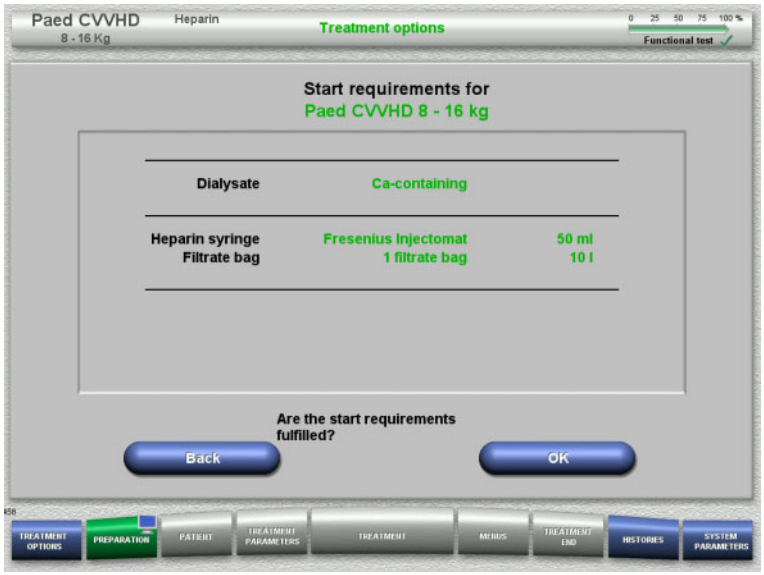
Or

➢ Press the **Delete** button to reset the previous balance data to 0.

The Patient ID and Case ID will not be deleted.

➢ Then press the **OK** button to confirm your previous selection (“Retain” or “Delete”).

4.5.4 Start requirements



➢ Check the contents of the solution bags against the information shown on the screen.

➢ Press **OK** to confirm the start requirements.

Press the **Back** button to return to the treatment options screen.

Warning

Risk for the patient due to heat loss via the extracorporeal blood circuit because of low ambient temperature and low dialysate/substituate flows

If the ambient temperature is too low or dialysate/substituate flows are too low, this can lead to patient hypothermia.

➢ Conduct treatment at a room temperature of at least 20 °C.

➢ Perform treatments with dialysate/substituate flows < 600 ml/h at a room temperature ≥ 25 °C.

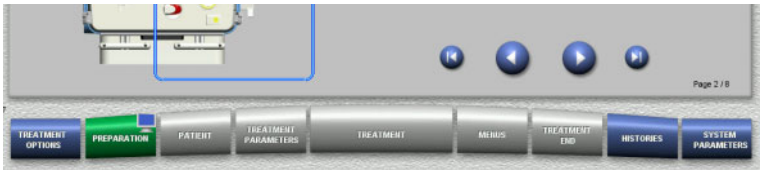
➢ Switch on heater.

➢ Avoid drafts during treatment.

➢ Regular monitoring of patient temperature.

➢ If necessary, take measures to maintain patient temperature, such as use of electric blankets.

4.5.5 Mounting the cassette



You can use the following buttons for mounting the cassette:

Press to go to the next step.

Press to jump to the end of the setup instructions.

Press to return to the previous step.

Press to jump back to the beginning of the setup instructions.

Note

The multiFiltratePRO-Kit Paed CVVHD is used for Paed CVVHD 8 kg to 16 kg and Paed CVVHD 16 kg to 40 kg treatment modes.

➢ Hang up the cassette according to the instructions.

➢ Fix the filter in the filter holder.

➢ Press to go to the next step.

4.5.5.1 Mounting the return system

Warning

Risk of air embolism due to loss of function of the air detector

Blood clots (coagula) in the tubing system, contaminations and/or moisture on the air bubble detector can impair the correct function of the air bubble detector.

➢ Make sure that the air bubble detector is clean and dry.

➢ Do not use any ultrasound-conducting objects or media on the air bubble detector.

Warning

Risk of air embolism as a result of air in the tubing system

If the tubing system is not inserted properly, this can prevent the air detection system from working.

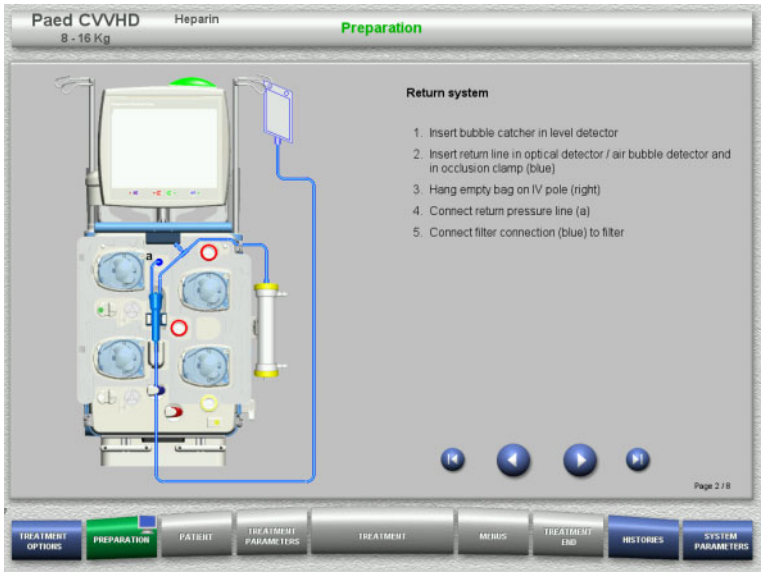
➢ When the tubing system is inserted into the air bubble detector/optical detector, the tube must lie along the full length of the tube holder.

Warning

Risk of air embolism as a result of air in the tubing system

➢ Insert the tubing system correctly into the line occlusion clamp.

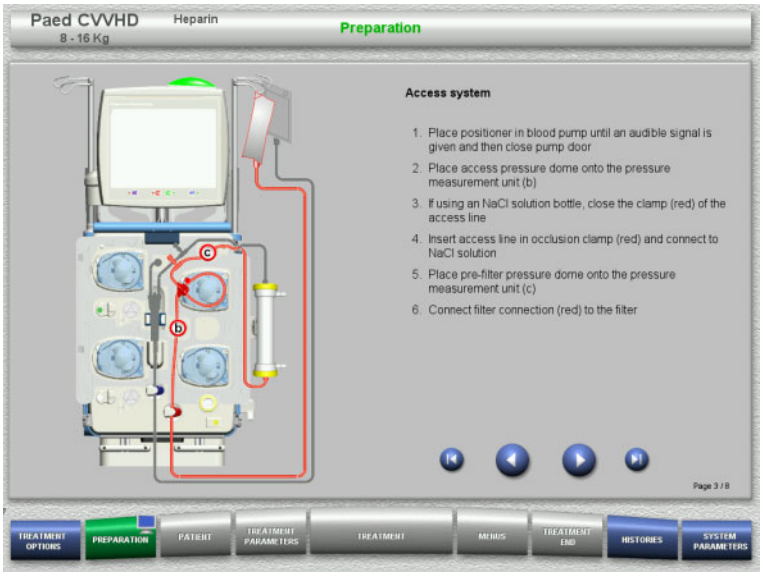
➢ Do not remove the tubing system from the line occlusion clamp during treatment.



➢ Mount the return system according to the instructions.

➢ Press to go to the next step.

4.5.5.2 Mounting the access system



➢ Mount the access system according to the instructions.

Check that the correct cassette has been mounted for the selected treatment option.

➢ Press to go to the next step.

Note

Once the first positioner has been inserted, the cassette system can only be dismantled and changed by cancelling the preparation (**Menus** / **Cancel preparation** (see Chapter 4.7.2 on page 168)).

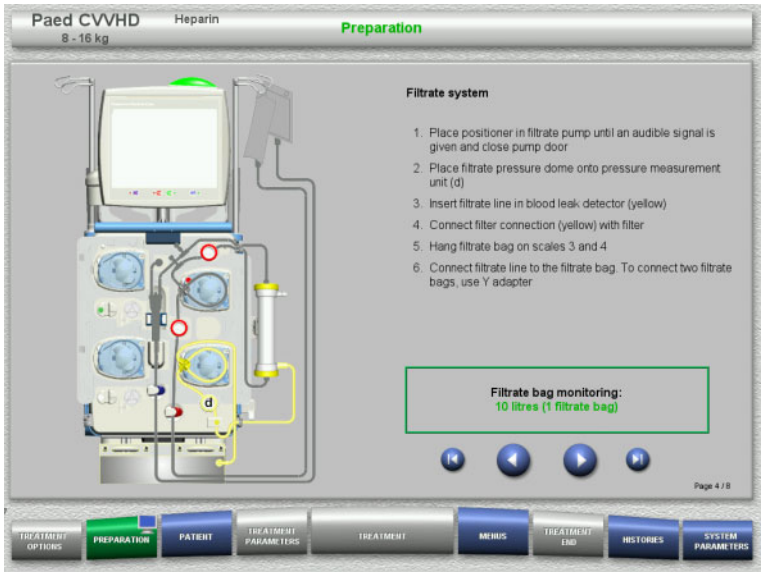
4.5.5.3 Mounting the filtrate system

Warning

Risk of contamination as a result of damaged bags

Bags can burst when dropped.

➢ Push filtrate bags as far back as possible onto the hooks of the lower scales.



➢ Mount the filtrate system according to the instructions.

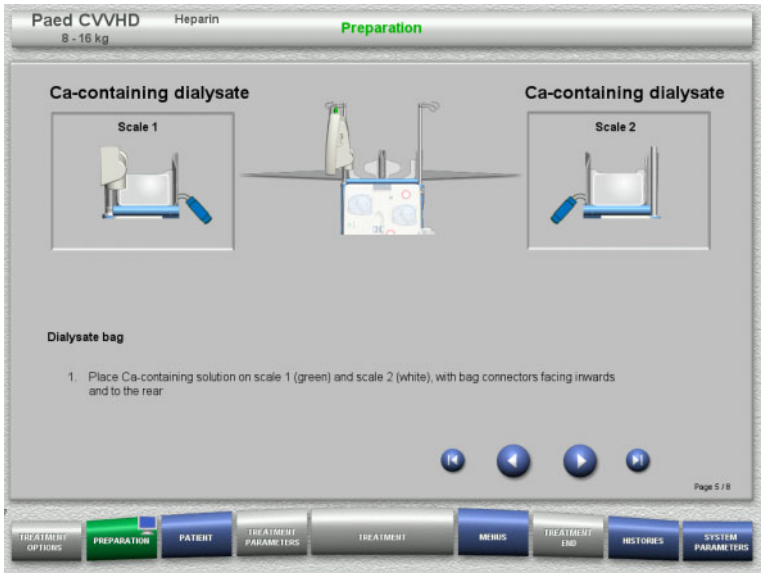
Filtrate bag monitoring can be set in the System Parameters, from 5 l to 10 l.

➢ Press ● to go to the next step.

4.5.5.4 Loading the solution bags

Note

When loading the solution bags onto the scales, make sure the connectors face inwards and to the rear.



➢ Load the solution bags onto the scales according to the instructions.

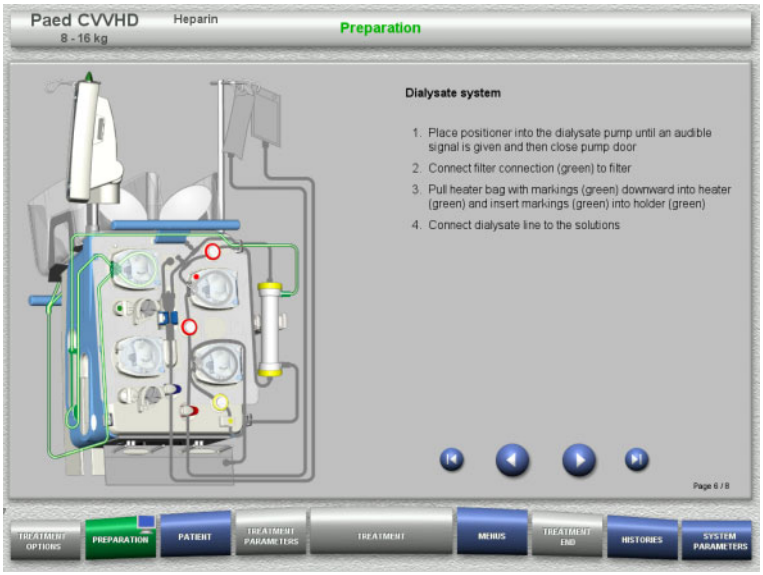
Maximum load per scale is 12 kg.

➢ Press ● to go to the next step.

4.5.5.5 Mounting the dialysate system

Note

When inserting the heater bags, observe the correct colour coding.



➢ Mount the dialysate system according to the instructions.

➢ Press ▶ to go to the next step.

4.5.5.6 Inserting the heparin syringe

Warning

Risk of over- or underheparinisation

Low delivery rates can lead to over- or underheparinisation because of imprecisions in the heparin syringe pump.

In order to ensure the delivery rate of the heparin syringe pump is precise,

➢ the delivery rate must be set to higher than 1 ml/h.

➢ the heparin concentration in the syringe must be adjusted to the delivery rate.

Note

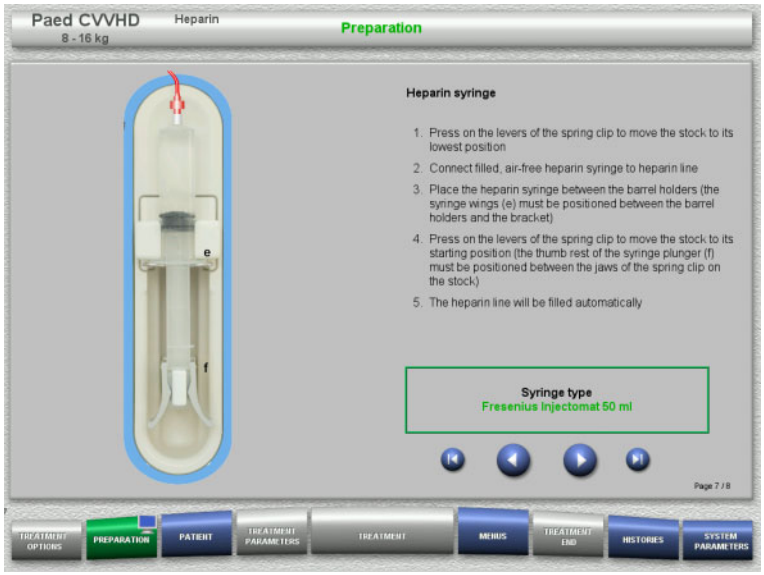
Only use the syringe type selected in the Setup and shown on the screen.

Note

When inserting the heparin syringe, observe the following:
– The syringe wings must be positioned between the barrel holders and the bracket.
– The thumb rest of the syringe plunger must be positioned between the jaws of the spring clip on the stock.

Tip

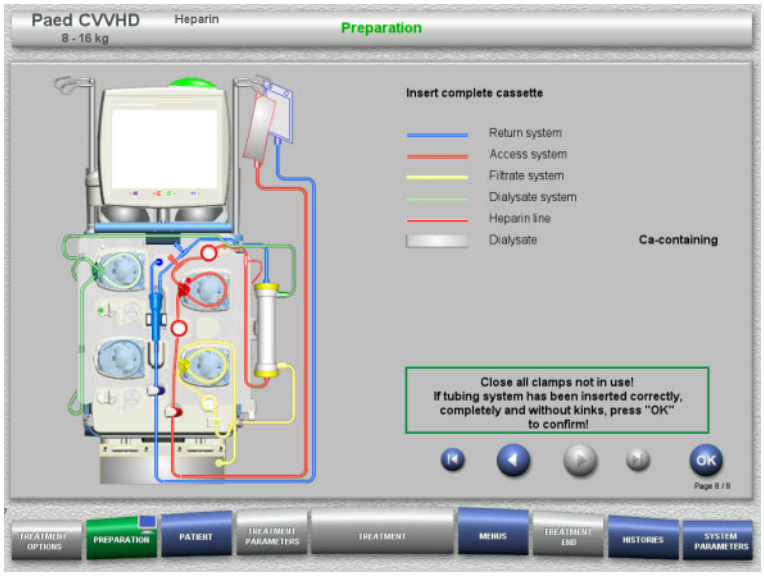
The heparin syringe can be inserted any time after starting treatment by choosing **MENUS / Change syringe** (only if heparin pump is activated).



➢ Insert the heparin syringe according to the instructions.

➢ Press to go to the next step.

4.5.5.7 Cassette mounting completed



➢ Insert complete cassette.

If the **OK** button cannot be selected (greyed out), check the mounted tubing system according to the instructions on the screen.

➢ Press the **OK** button to confirm that the tubing system is fully mounted.

If heparin anticoagulation has been selected, the heparin line will be filled automatically after confirmation.

4.5.6 Filling and rinsing the cassette

4.5.6.1 Filling the tubing system

➢ Press the **Start** button to start filling the tubing system.

Rinsing starts automatically as soon as the correct fill level in the bubble catcher is detected.

The rinse flow can be changed with the **+/–** rocker switch buttons.

4.5.6.2 Entering the Patient ID and Case ID

Requirements

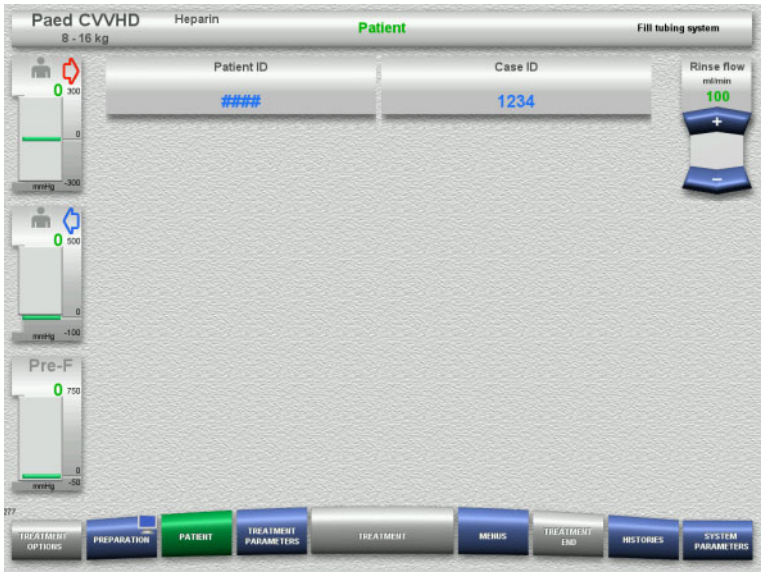
The **Patient** menu opens automatically when filling is started, if **Jump to Patient menu** is activated. Otherwise, the **Treatment parameters** menu will open automatically when filling is started (see Chapter 4.5.6.3 on page 153).

➢ Check the **Patient ID** and **Case ID** shown.
The fields will be empty if no data has yet been entered.

➢ To change or enter the **Patient ID** and **Case ID**, press the relevant field.

➢ Use the keyboard to enter the required **Patient ID** and **Case ID**.

➢ Press the **OK** button to apply the displayed value.



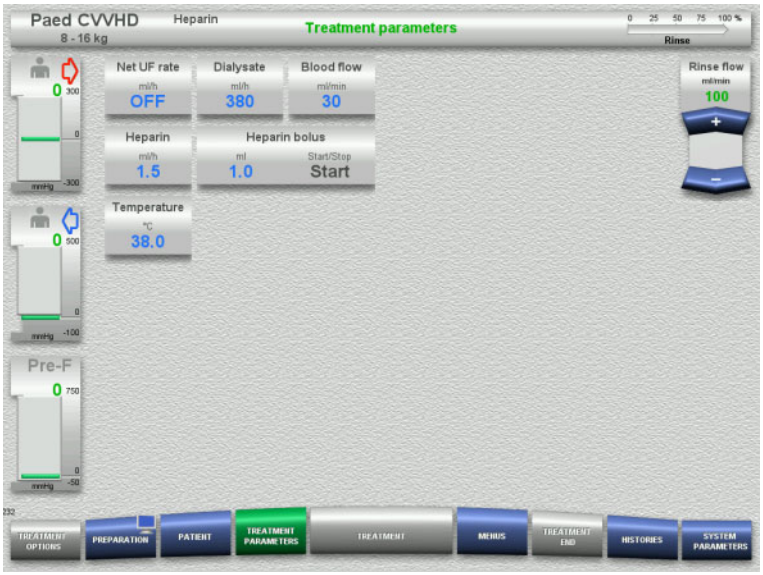
➢ Check the **Patient ID** and **Case ID** entered.

4.5.6.3 Entering treatment parameters

Note

The bolus function can be used if an initial heparin bolus needs to be administered.

The infusion of anticoagulation fluids is corrected automatically in the overall balance.



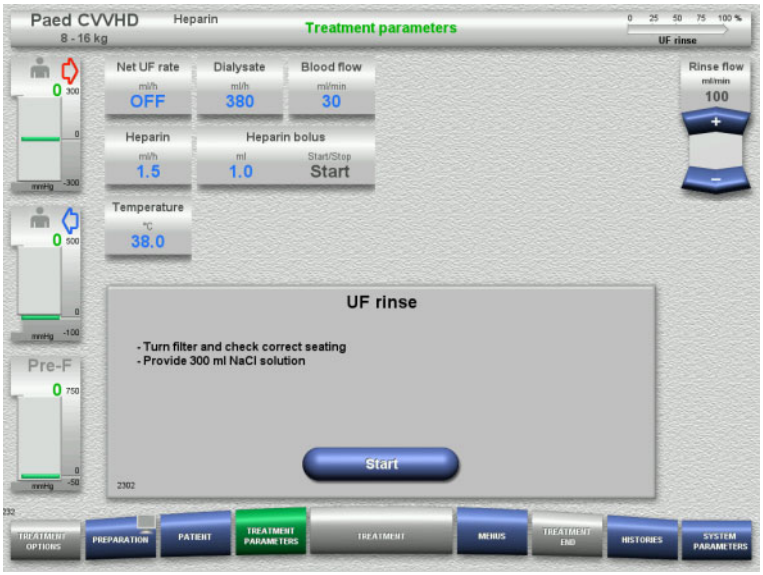
➢ Check the preset treatment parameters. If necessary, adjust the treatment parameters.

– Temperature:
Enter the dialysate temperature (°C).
The **Temperature** button can be used to switch the heater on and off.

4.5.6.4 UF Rinse

Note

When using NaCl bags with only one connector, make sure there is enough NaCl solution.



If using an NaCl bag with two connectors:

➢ Remove return line from empty bag and connect to NaCl solution.

➢ Press the **Start** button to start the UF rinse.

If using an NaCl bag with one connector:

➢ Leave the existing connections as they are.

➢ Press the **Start** button to start the UF rinse.

The level in the bubble catcher will be set automatically when the UF rinse is finished.

4.5.7 Circulation

Warning

Risk of contamination as a result of non-compliance with hygienic conditions

There is a risk of spreading germs.

➢ Keep preparation and circulation times before the treatment as short as possible.

Note

If the patient connection must be delayed, the extracorporeal circuit can be kept in circulation for a certain time after preparation.

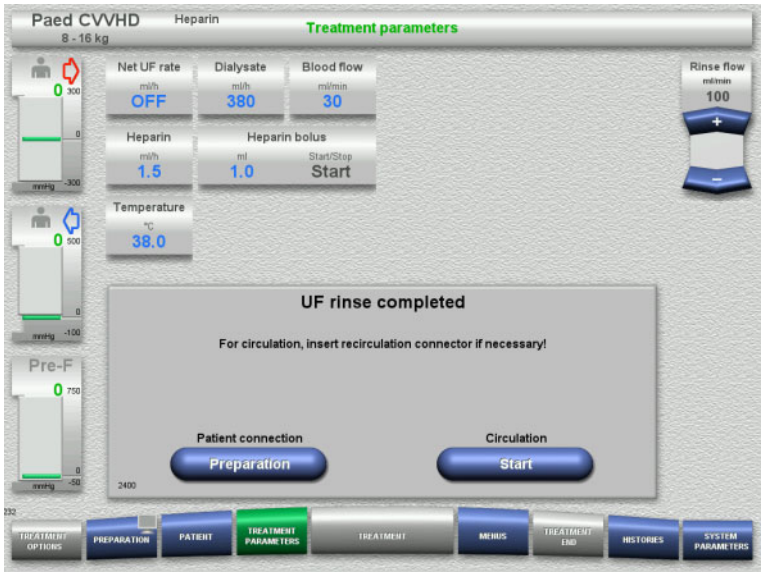
To avoid stressing the tubing system for too long, the circulation time is also taken into account when monitoring the kit service life.

Note

In the Setup, circulation can be set to start automatically or to be confirmed by the user.

The factory setting is **Confirm**, since an automatic changeover into circulation mode is only possible if an NaCl solution bag with two connections is used.

- **Stop before circulation**



After the rinse is completed, the blood pump will stop.

An audible tone is emitted.

➢ Connect the access and return lines to the recirculation connector.

➢ Press the **Start** button to start the circulation.

Or

➢ Press the **Preparation** button to begin patient connection.

● Automatic circulation

After the rinse is completed, the circulation will start automatically.

➢ Prepare to connect the patient.

➢ Press the **Preparation** button to stop the blood pump.

4.5.8 Connecting the patient when the extracorporeal blood circuit is primed with blood substitute

If prescribed by the physician, the extracorporeal blood circuit can be primed with blood substitute. In order to ensure the device is operated safely, the steps must be followed in the stated order.

Warning

Risk of overdosage of heparin

After priming with blood substitute, no initial recirculation is possible.

➢ The patient should be fully cannulated.

➢ The patient should be ready for the CRRT treatment.

➢ Connect the patient immediately after priming with blood substitute is complete.

Warning

Lack of volume due to extracorporeal blood volume

In order to counteract a lack of volume, the extracorporeal blood circuit can be primed to capacity with blood substitute. When doing so, the following points must be noted:

➢ The extracorporeal blood volume consists of the blood volume of the tubing system being used and of the filter. The relevant volumes must be taken from the corresponding Instructions for Use.

➢ Fill the extracorporeal blood circuit to capacity with blood substitute.

Example extracorporeal blood volume calculation for the Paed CVVHD kit:
Tubing system blood volume 61 ml + AV400S tubing system blood volume 52 ml = 113 ml of extracorporeal blood volume

Warning

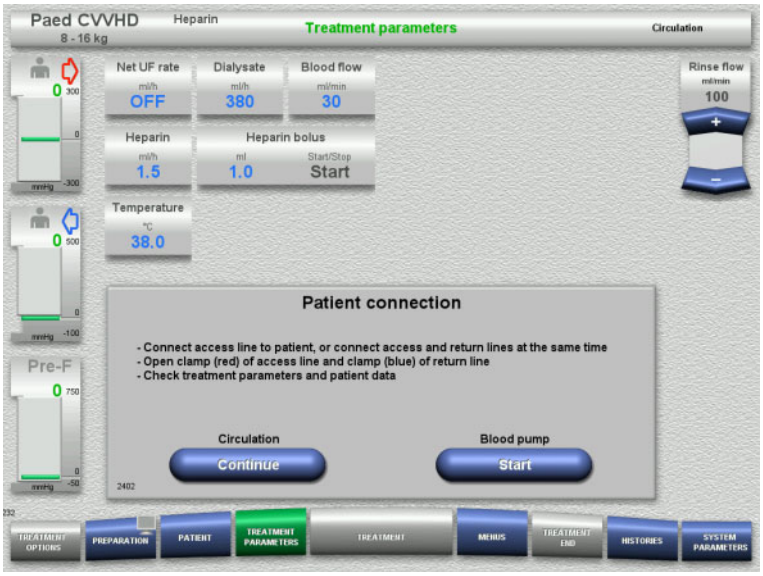
Fluid bolus through blood reinfusion

For treatments where the extracorporeal blood circuit is primed with a blood substitute solution, the blood reinfusion leads to a positive fluid balance.

➢ Pause the treatment without blood reinfusion.

➢ End the treatment without blood reinfusion.

The treating physician may deviate from this depending on the clinical situation.



The blood pump is stopped.

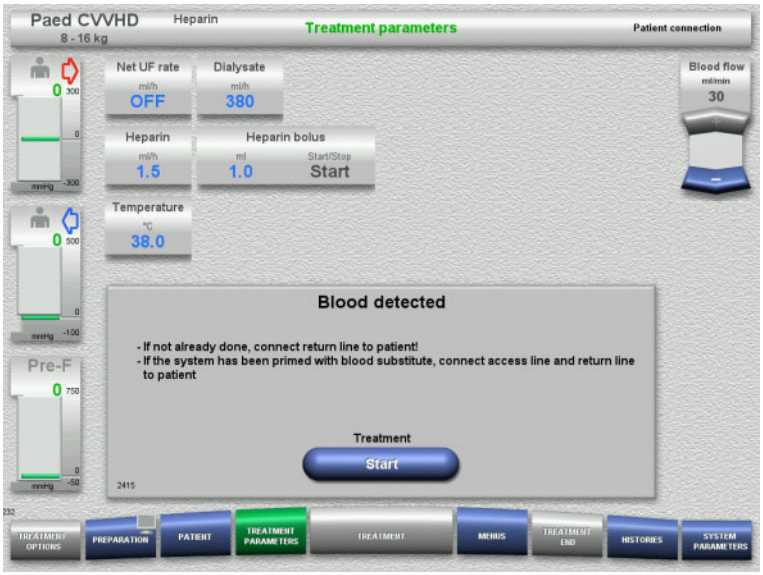
➢ Prepare the blood substitute solution.

➢ Hang the prepared blood substitute solution on the right IV pole.

➢ Connect the access line (red) to the blood substitute solution, open the clamp.

➢ Press the **Start** button to start the blood pump.

The blood pump will continue operating until the optical detector has detected blood.

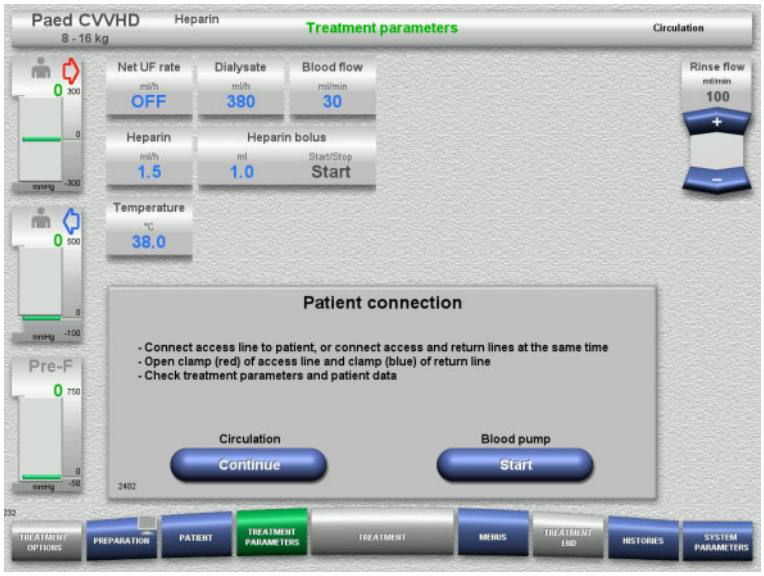


➢ If blood is detected (message 2404 or 7401 appears), connect the access line and the return line to the patient.

➢ If using blood substitute solutions that do not trigger blood detection, stop the blood pump again when the extracorporeal circuit is full to capacity of blood substitute solution. Connect the access and return lines to the patient.

➢ Press the **Start** button to start the treatment.

4.5.9 Connecting the patient without priming the extracorporeal blood circuit with blood substitute

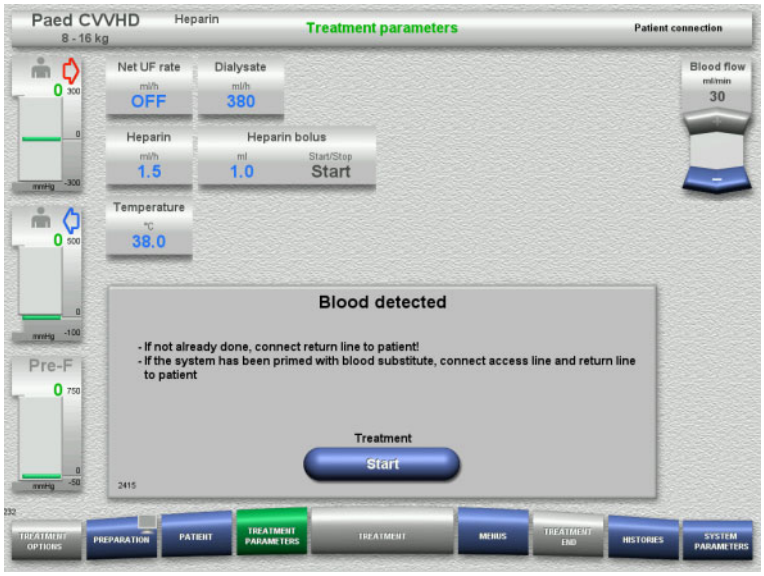


The blood pump is stopped.

➢ Press the **Start** button to start the blood pump.

The blood pump will continue operating until the optical detector has detected blood.
If necessary, administer a heparin bolus.

Press the **Continue** button to continue the circulation.



The optical detector has detected blood.

The blood pump is stopped.

➢ Press the **Start** button to start the treatment.

4.5.10 Treatment

4.5.10.1 Treatment screen

The treatment screen is displayed throughout the entire treatment.

The information area shows important treatment data:

Pressure / alarm history
Next operator action

Once treatment has started, the blood flow can be adjusted using the rocker:

– Delivery rates of 10 ml/min to 50 ml/min can be set with a resolution of 1 ml/min.
– Delivery rates of 50 ml/min to 100 ml/min can be set with a resolution of 5 ml/min.
– Delivery rates of 100 ml/min to 200 ml/min can be set with a resolution of 10 ml/min (only with the **Paed CVVHD 16 kg to 40 kg** treatment option)

4.5.10.2 Menus

The following menu options can be selected:

– Rocker switch buttons for setting the level in the bubble catcher:
  For raising the level in the bubble catcher.
  For lowering the level in the bubble catcher.
– Cancel preparation:
  For dismantling (user) / ejecting (device) the tubing system during preparation.
– Treatment interrupted:
  For pausing treatment.
– Switch balancing off/on:
  For switching balancing off and back on.
– Change syringe:
  For changing the heparin syringe.
– Care:
  For starting Care mode.
– Bag change:
  For changing the dialysate bag and emptying the filtrate bag.

Detailed description of menu options shown (see Chapter 4.7 on page 168).

4.5.10.3 Histories

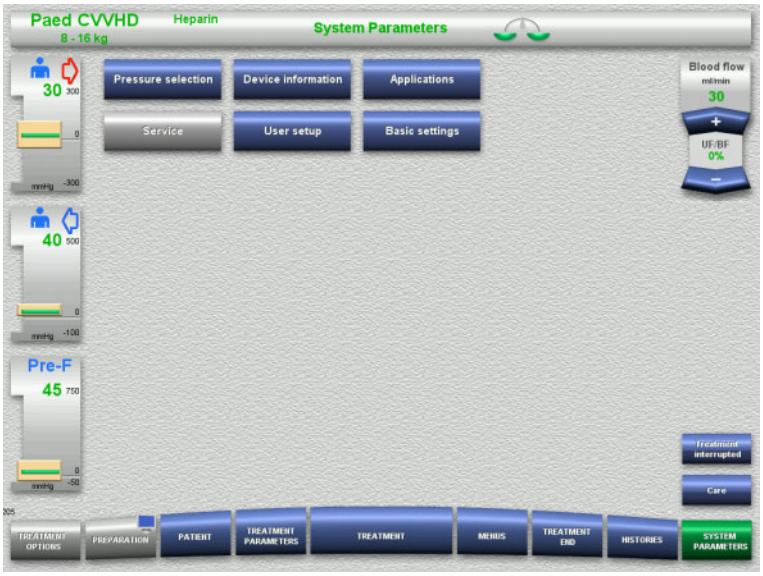
The following tabs can be selected:

– Balance data
– Balance history
– Events

(see Chapter 4.8 on page 190)

Pressing the **Reset balance data** button will reset all the cumulative volume information recorded so far to “zero”. The treatment time and the filter life will not be reset.

4.5.10.4 System Parameters

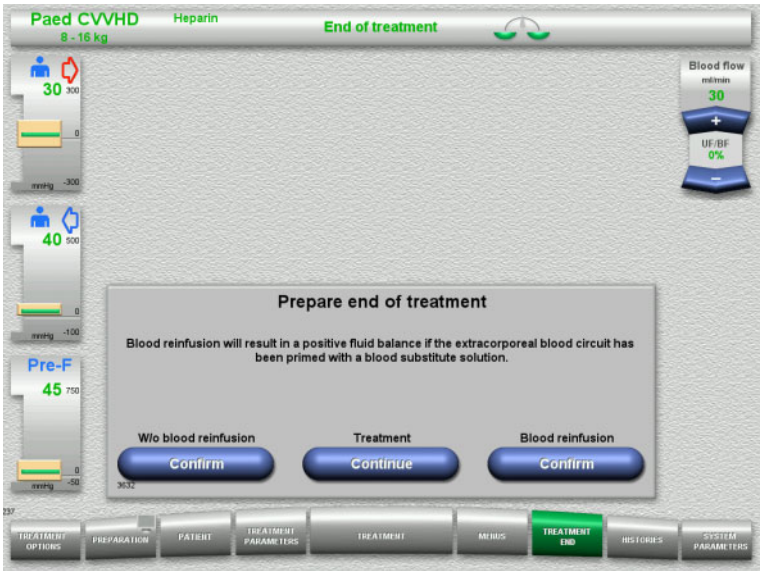


In the **System Parameters** screen, only the blue (activated) buttons can be used to open the appropriate options (see Chapter 4.9 on page 195).

To activate any grey buttons, you will need a ServiceCard or UserCard.

4.5.11 End of treatment

4.5.11.1 Preparing the end of treatment



➢ Select **TREATMENT END** from the menu bar.

➢ Press the **Confirm** button to select blood reinfusion.

Press the **Continue** button to continue the treatment.

Press the **Confirm** button under **W/o blood reinfusion** and **Blood pump Stop** in the screen that follows to go straight to the **Disconnect the patient!** screen (see Chapter 4.5.11.5 on page 165).

4.5.11.2 End of treatment with blood reinfusion

Warning

Positive fluid balance by increasing the blood reinfusion volume at the end of the treatment

If the blood reinfusion volume is increased at the end of the treatment (as a result of blood reinfusion continuing after the NaCl solution is detected), this can lead to a positive fluid balance.

➢ The blood reinfusion volume must be taken into account when setting the ultrafiltration amount.

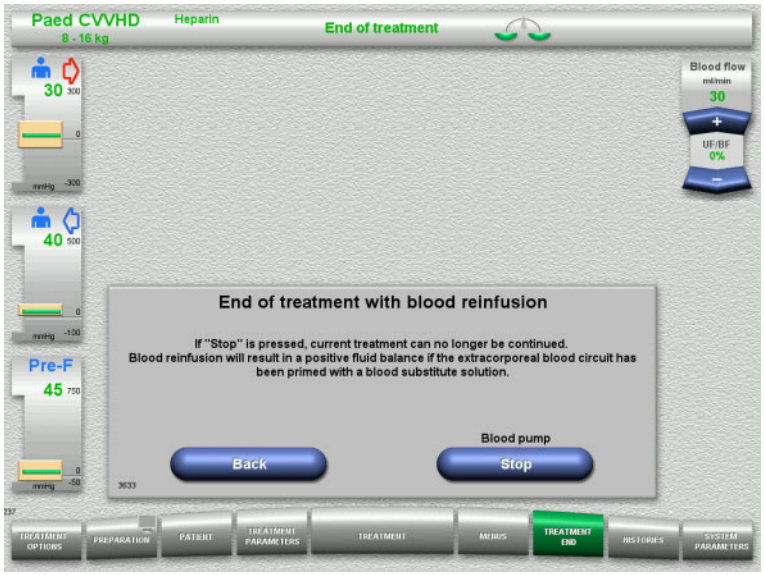
Warning

Fluid bolus through blood reinfusion

For treatments where the extracorporeal blood circuit is primed with a blood substitute solution, the blood reinfusion leads to a positive fluid balance.

➢ Pause the treatment without blood reinfusion.

➢ End the treatment without blood reinfusion.

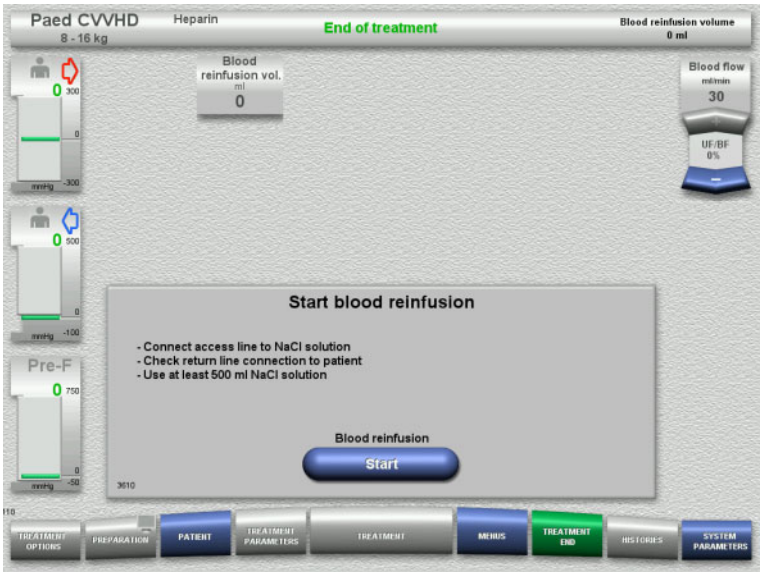


➢ Press the **Stop** button to stop the blood pump.

Balancing is switched off.

Press the **Back** button to return to the Prepare end of treatment screen.

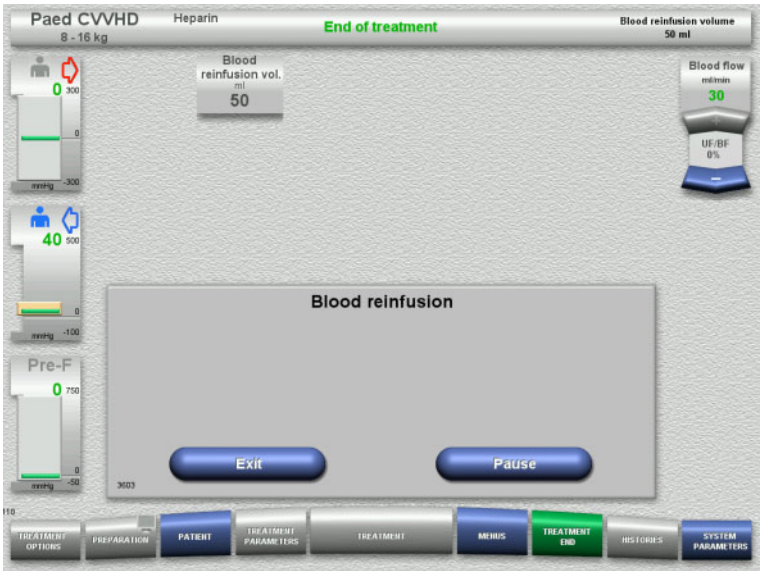
4.5.11.3 Starting blood reinfusion



➢ Disconnect the access line from the patient and connect it to an NaCl solution bag.

➢ Press the **Start** button to start blood reinfusion.

The blood flow is limited to 100 ml/min.

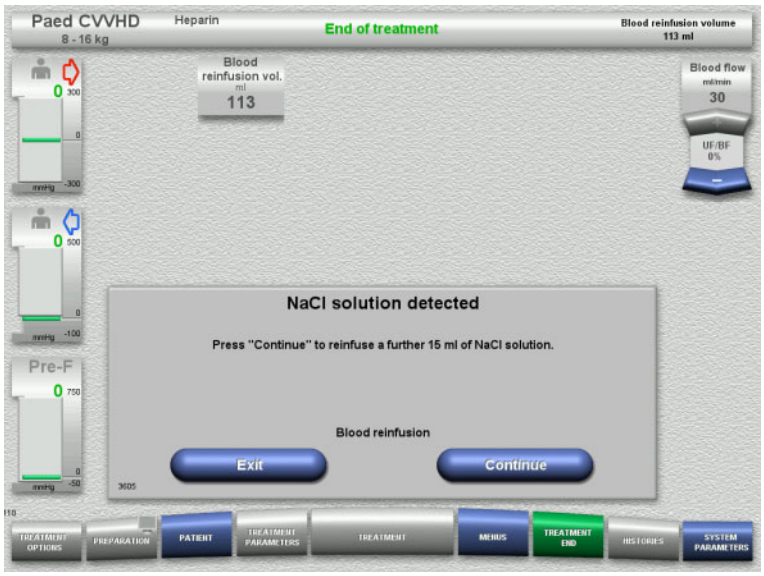


Blood reinfusion ends automatically as soon as the optical detector detects the NaCl solution.

Press the **Pause** button to stop the blood reinfusion.

Press the **Exit** button to terminate blood reinfusion.

4.5.11.4 NaCl solution detected



➢ Press the **Exit** button to terminate blood reinfusion.

Press the **Continue** button to reinfuse a further 15 ml of NaCl solution.

This can be repeated five times.

4.5.11.5 Disconnecting the patient

➢ Disconnect the patient.

➢ Press the **Eject** button to start ejecting the tubing system.

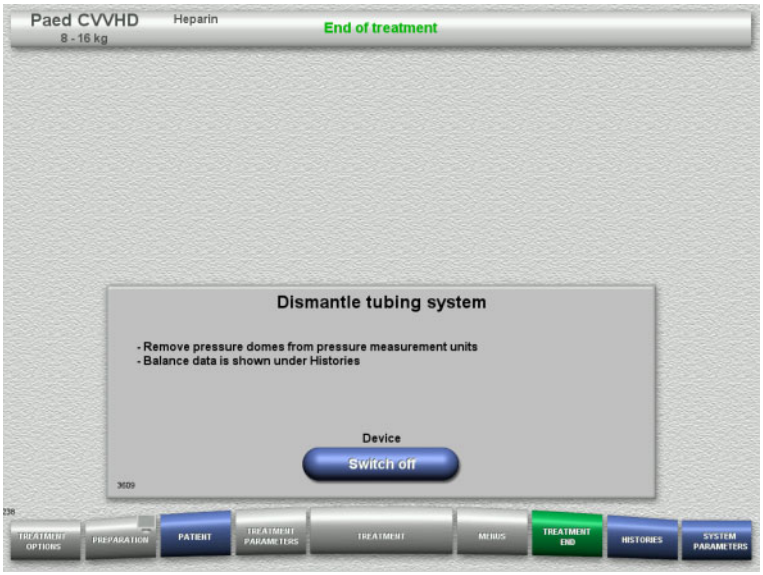
4.5.11.6 Dismantling the tubing system

Warning

Risk of cross-contamination as a result of contaminated consumables

There is a risk of spreading germs.

➢ Consumables must be discarded after a treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Dismantle the tubing system.

In the **Histories** menu, you can view the treatment data and events.

➢ Switch the device off with the **Switch off** button.

4.6 Treatment displays

4.6.1 Pressure / alarm history

The **Pressure / alarm history** tab shows the different pressures recorded over time.
The Pressure / alarm history display can be configured in the System Parameters menu option.

Use the buttons to shift the time frame shown.

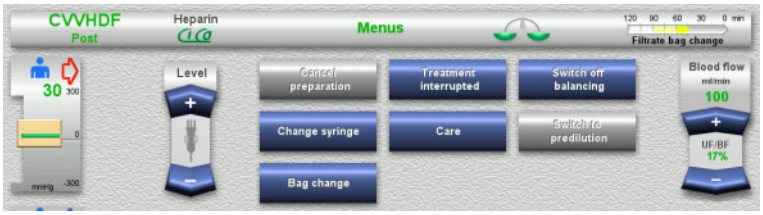
4.6.2 Next operator action

The **Next operator action** tab lists the tasks that remain to be performed during the treatment in chronological order.

If the time for performing the next task is less than 15 minutes away, the **Next operator action** tab will jump to the foreground (of the treatment display).

4.7 Menus

4.7.1 Setting the level in the bubble catcher



➢ Use the **Level** rocker switch buttons to set the level in the bubble catcher manually.

4.7.2 Cancelling preparation

➢ Select the **Cancel preparation** menu option.

➢ Press the **Start** button to start ejecting the tubing system.

Press the **Back** button to carry on mounting the tubing system.

4.7.3 Treatment pause

The **Treatment pause** function allows the patient to be disconnected from the device for a short time during treatment.

Warning

Risk for the patient as a result of cross-contamination / immune response

Reconnecting a patient to the wrong device after a treatment pause can lead to cross-contamination and elicit an immune response.

➢ After a treatment pause, make absolutely certain that you only reconnect the same patient to the device.

Warning

Risk of contamination as a result of improper handling of connection sites

Pathogens can enter the extracorporeal blood circuit.

➢ Use aseptic technique for all blood system connections and all the connections of the sterile solutions to be used.

➢ Select the **Treatment interrupted** menu option.

➢ Press the **With blood reinf.** button to pause the treatment with a blood reinfusion (cannot be selected with TPE).

Or

➢ Press the **W/o blood reinfusion** button to pause the treatment without a blood reinfusion.

Press the **Continue** button to continue the treatment.

4.7.3.1 Treatment pause with blood reinfusion (CRRT only)

Warning

Fluid bolus through blood reinfusion

For treatments where the extracorporeal blood circuit is primed with a blood substitute solution, the blood reinfusion leads to a positive fluid balance.

➢ Pause the treatment without blood reinfusion.

➢ End the treatment without blood reinfusion.

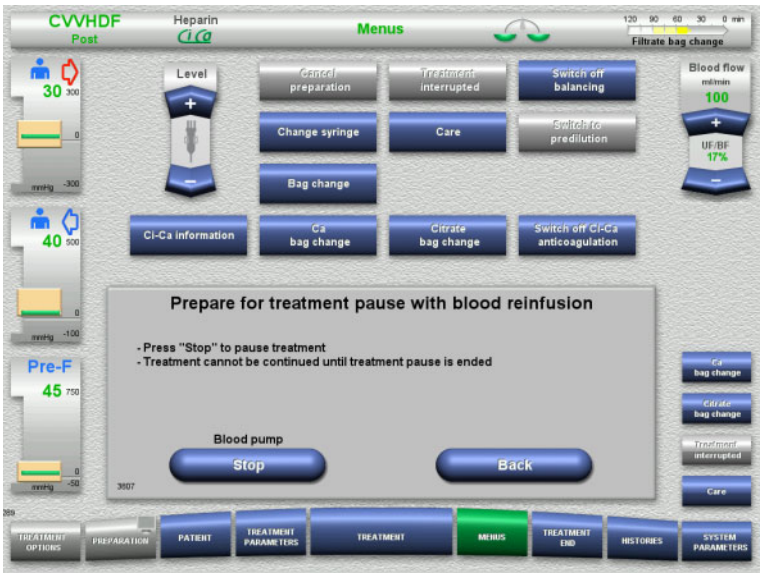
Warning

Risk of contamination as a result of long dwell time of fluids in the tubing system

➢ For reasons of hygiene, and taking local rules and regulations into account, a treatment pause should be kept as short as possible.

Note

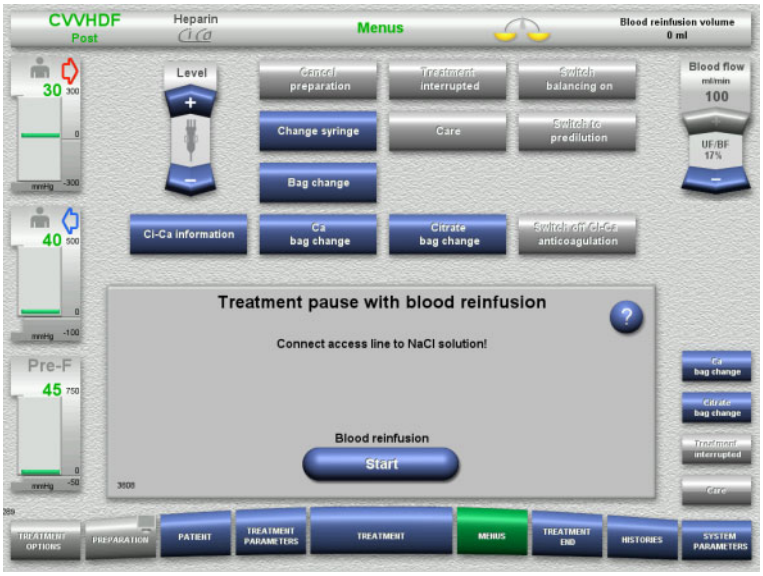
Treatment pause with blood reinfusion can also be accessed directly, if the optical detector no longer detects blood during treatment and the Treatment pause with blood reinfusion is started.



➢ Press the **Stop** button to stop the blood pump.
The treatment pause **must now be completed**!

The blood pump is stopped.
Balancing is switched off.
Anticoagulation is switched off.
The upper limits of the pressures are monitored.

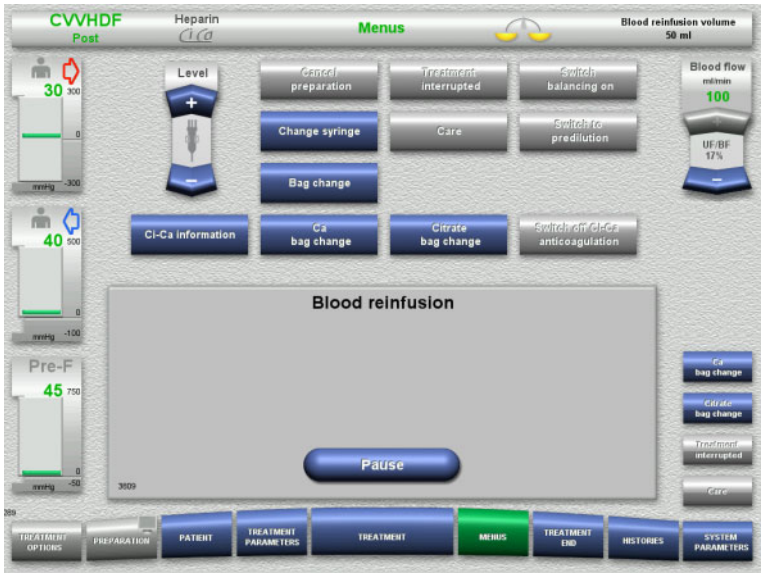
Press the **Back** button to return to the Prepare for treatment pause screen.



➢ Connect the access line to an NaCl solution bag.

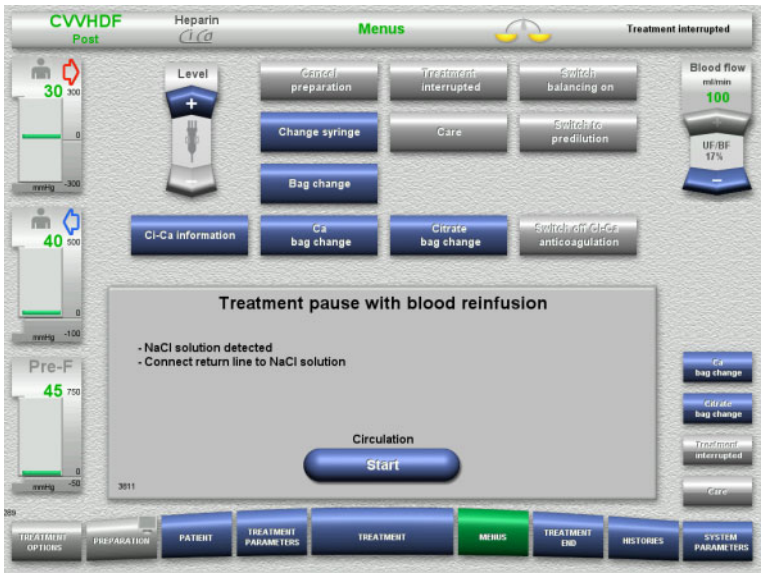
➢ Press the **Start** button to start blood reinfusion.

The blood flow is automatically limited to 100 ml/min if it was set to more than 100 ml/min for treatment.
Balancing remains switched off.
Anticoagulation remains switched off.



Blood reinfusion ends automatically as soon as the optical detector detects the NaCl solution.

Press the **Pause** button to interrupt the blood reinfusion.



➢ Connect the return line to an NaCl solution bag.

➢ Press the **Start** button to start the treatment pause.

The blood flow is automatically limited to 100 ml/min if it was set to more than 100 ml/min for treatment.
Balancing remains switched off.
Anticoagulation remains switched off.

The treatment pause is running.

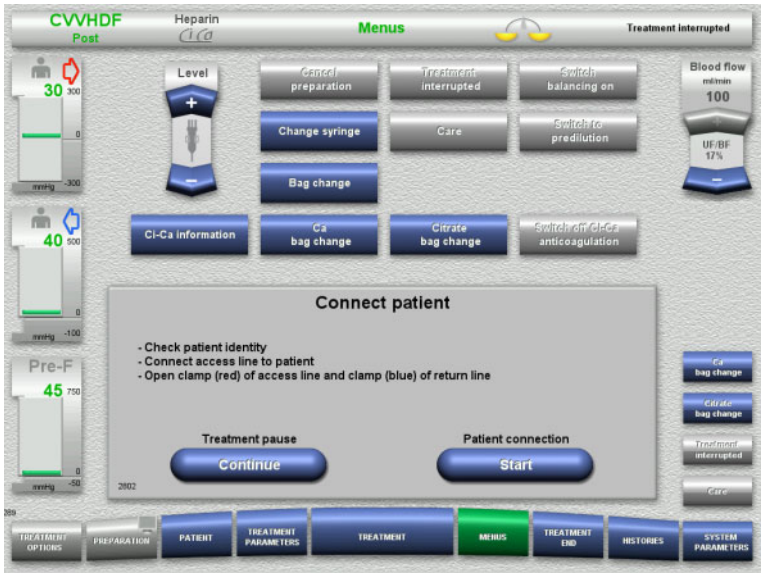
The elapsed time is displayed.

➢ Press the **Preparation** button to begin patient connection.

- **Prepare to connect the patient**

➢ Press the **Confirm** button to confirm the correct identity of the patient.

Press the **Continue** button to continue the treatment pause.

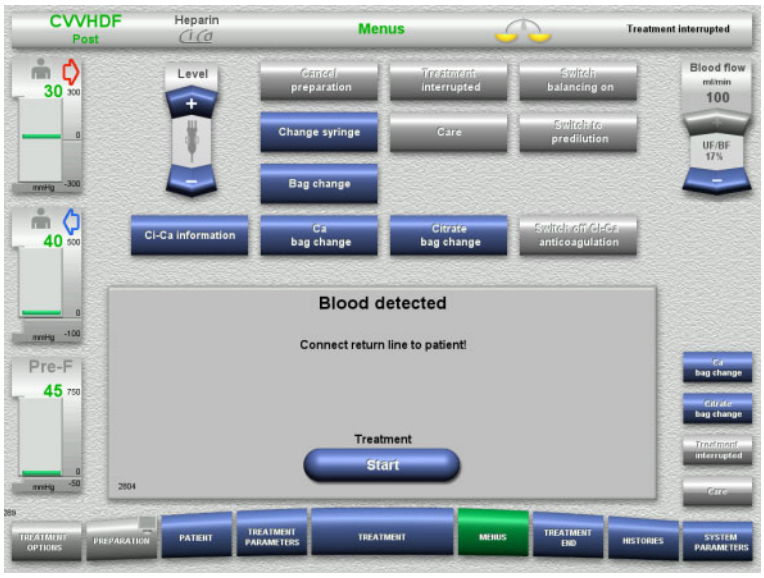


➢ Connect the access line to the patient.

➢ Press the **Start** button to start the patient connection.

The blood pump will continue operating until the optical detector has detected blood.

Press the **Continue** button to continue the treatment pause.



The optical detector has detected blood.

The blood pump is stopped.

➢ Connect the return line to the patient.

➢ Press the **Start** button to start the treatment.

Balancing is switched on.
Anticoagulation is switched on.

4.7.3.2 Treatment pause without blood reinfusion

Warning

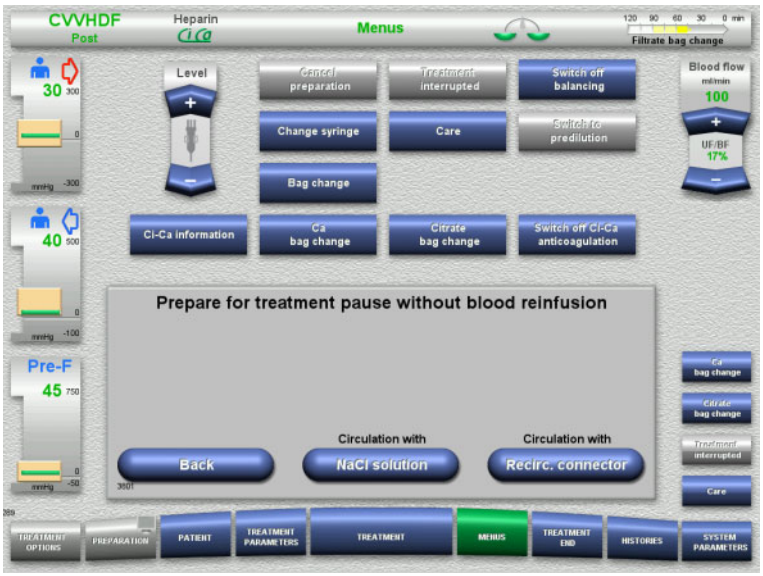
Risk of contamination as a result of long dwell time of blood in the tubing system

Risk of haemolysis as a result of a crushed tubing system

Risk of blood loss as a result of clotting

➢ Taking local rules and regulations into account, a treatment pause without blood reinfusion should be kept as short as possible.

A short treatment pause is defined as lasting no more than 10 minutes. The treatment pause can be extended for a further 10 minutes, but only after confirmation by the operator.
If the treatment pause is expected to last longer, a treatment pause with blood reinfusion must be selected instead.



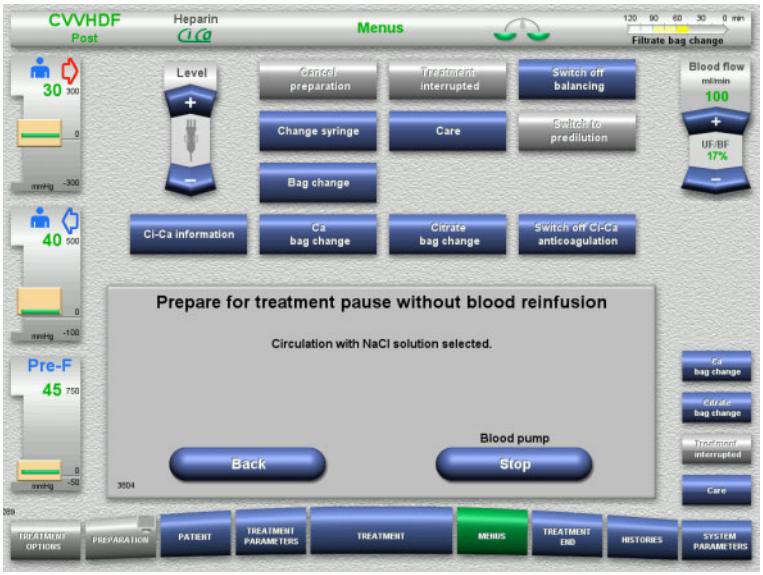
➢ Press the **NaCl solution** button to start a treatment pause using NaCl solution.

Or

➢ Press the **Recirc. connector** button to start a treatment pause using the recirculation connector.

Press the **Back** button to return to the Prepare for treatment pause screen.

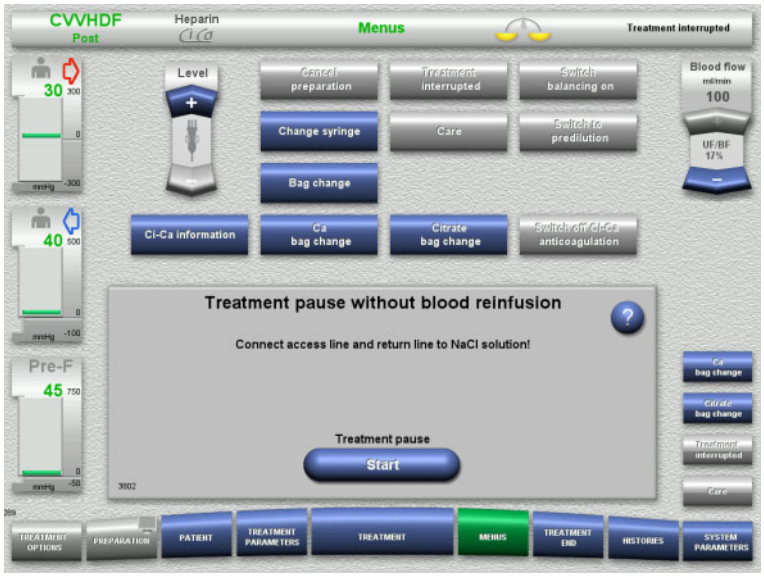
● Circulation with NaCl solution



➢ Press the **Stop** button to stop the blood pump.

The blood pump is stopped.
Balancing is switched off.
Anticoagulation is switched off.

Press the **Back** button to return to the Prepare for treatment pause without blood reinfusion screen.

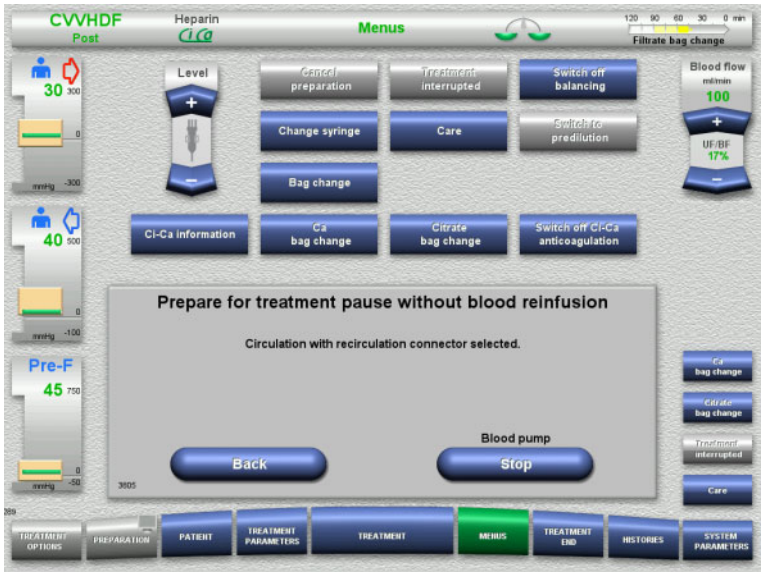


➢ Connect the access and return lines to an NaCl solution bag.

➢ Press the **Start** button to start the treatment pause.

The blood flow is automatically limited to 100 ml/min if it was set to more than 100 ml/min for treatment.
Balancing remains switched off.
Anticoagulation remains switched off.

- **Circulation with recirculation connector**



➢ Press the **Stop** button to stop the blood pump.

The blood pump is stopped.
Balancing is switched off.
Anticoagulation is switched off.

Press the **Back** button to return to the Prepare for treatment pause without blood reinfusion screen.

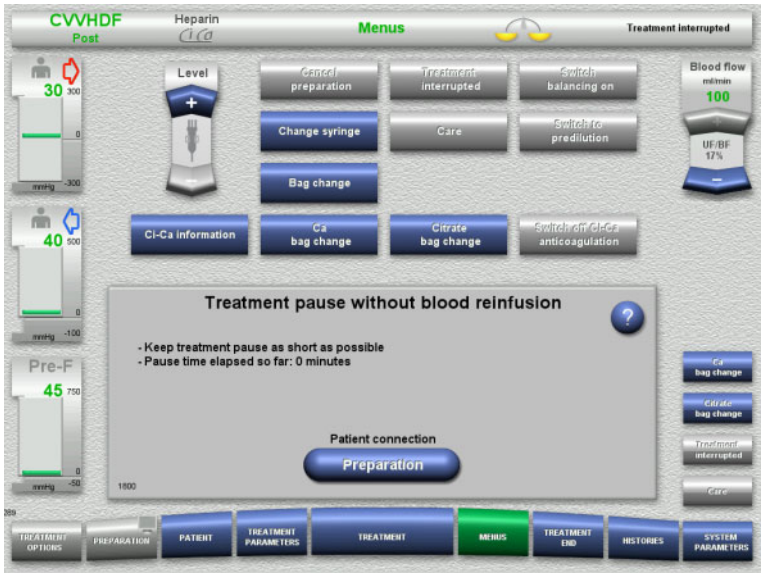
➢ Connect the access and return lines to the recirculation connector.

➢ Press the **Start** button to start the treatment pause.

The blood flow is automatically limited to 100 ml/min if it was set to more than 100 ml/min for treatment.
Balancing remains switched off.
Anticoagulation remains switched off.

The pressure test for testing the connections of the recirculation connector will start automatically.

If the pressure test is completed successfully, the treatment pause will start automatically.



The treatment pause is running.

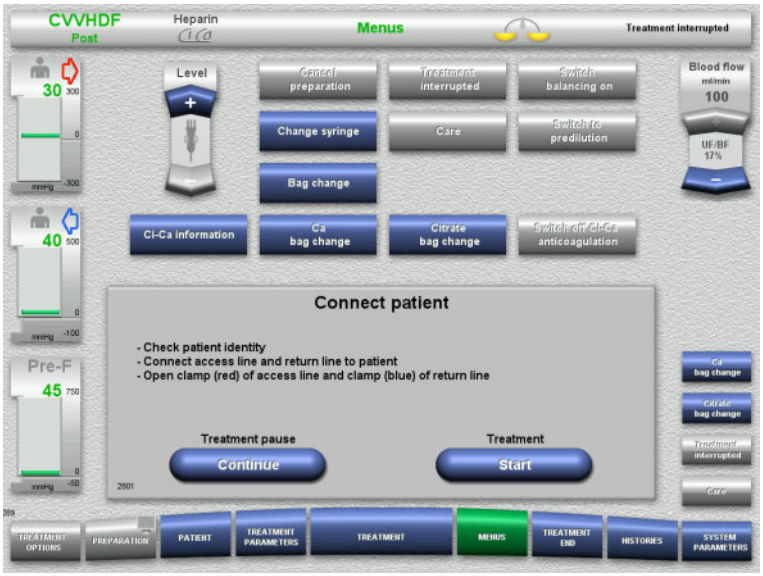
The elapsed time is displayed.

➢ Press the **Preparation** button to begin patient connection.

● **Prepare to connect the patient**

➢ Press the **Confirm** button to confirm the correct identity of the patient.

Press the **Continue** button to continue the treatment pause.



➢ Connect the access and return lines to the patient.

➢ Press the **Start** button to start the treatment.

Balancing is switched on.
Anticoagulation is switched on.

Press the **Continue** button to continue the treatment pause.

4.7.4 Switching balancing off/on

Note

A substituate bolus is not possible if balancing is switched off.

If balancing remains switched off for more than 10 minutes, a warning is issued.

Note

If balancing is switched off during a treatment with Ci-Ca anticoagulation, the calcium substitution is stopped. The citrate supply continues running until the message “Balancing switched off” is displayed.

If balancing remains switched off, the citrate supply will be stopped after a further 6 minutes.

When balancing is switched on, Ci-Ca anticoagulation starts automatically.

➢ To switch balancing off, select the **Switch off balancing** menu option.

The balancing scales in the status bar will turn yellow.

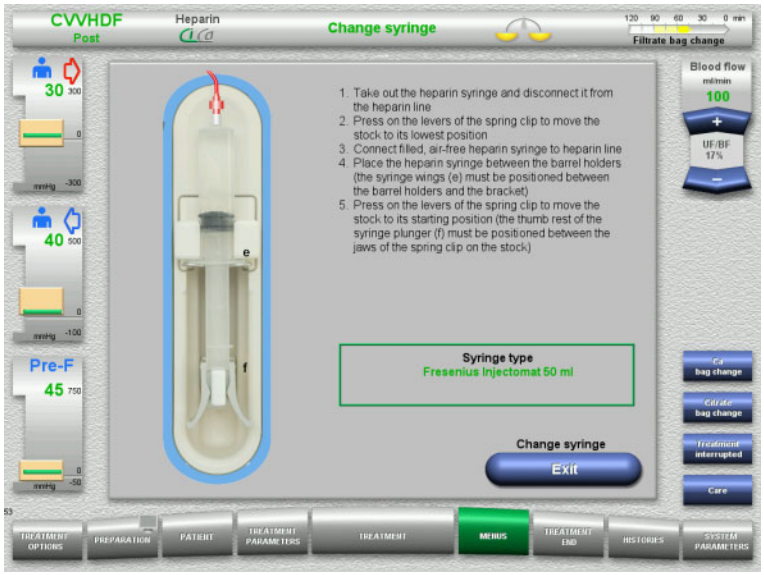
➢ To switch balancing on, select the **Switch balancing on** menu option.

The balancing scales in the status bar will turn green.

4.7.5 Change syringe

Note

If the syringe change takes longer than 5 minutes, a message will be displayed.



➢ Select the **Change syringe** menu option.

➢ Change the syringe according to the instructions.

Balancing is switched off.

➢ Press the **Exit** button to return to the treatment screen.

Treatment will be continued with the heparin rate set. Balancing is started automatically.

4.7.6 Care mode is active

The Care mode temporarily reduces the blood flow and extends the alarm limit windows to allow patient care procedures to be performed.

➢ Select the **Care** menu option.

The blood flow is reduced to 40 ml/min.
Balancing is switched off.
Anticoagulation is switched on.
The upper limits of the pressures are monitored.

➢ To continue with the treatment, press **Continue**.

Treatment is continued, with the blood flow rate previously set for treatment.

After a blood volume of 200 ml has been delivered, a screen prompt appears.

➢ To repeat the Care mode, press **Repeat**.

➢ To continue with the treatment, press **Continue**.

Treatment is continued, with the blood flow rate previously set for treatment.

Note

For the Paed CVVHD 8 kg to 16 kg treatment mode the volume of blood delivered at which the screen prompt appears is 30 ml.

For the Paed CVVHD 16 kg to 40 kg treatment mode the volume of blood delivered at which the screen prompt appears is 60 ml.

4.7.7 Switching between predilution and postdilution

Note

The Ci-Ca postCVVHDF treatment option is a pure postdilution treatment. Switching to predilution is not permitted during a Ci-Ca postCVVHDF treatment. For this treatment option, switching to predilution is only possible if the citrate anticoagulation is switched off first. However, citrate anticoagulation cannot be reactivated in this case, except if the treatment mode is switched from predilution back to postdilution first.

➢ Select the **Switch to predilution/postdilution** menu option.

➢ Reconnect the substituate line according to the instructions.

Balancing is stopped.

➢ Press the **Confirm** button to confirm the switchover.

Press **Cancel** to cancel the process.

4.7.8 Bag change (substituate/dialysate/filtrate)

Warning

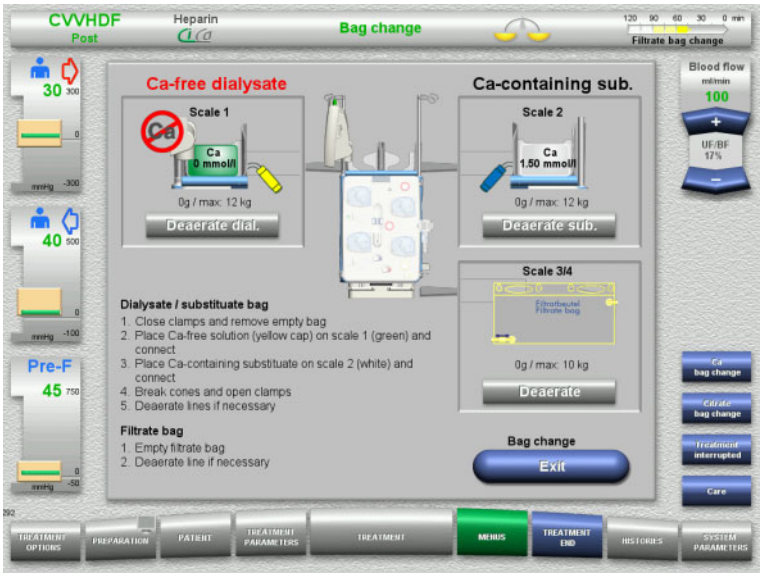
Risk of circulatory disturbance as a result of excessive fluid removal

➢ After emptying the filtrate bag, make sure the drain valve is closed tight and not dripping.

Note

Bags must only be changed after selecting the **Bag change** menu option.

If the bag change takes longer than 10 minutes, a message will be displayed.



➢ Select the **Bag change** menu option.

➢ Change bags according to the instructions.

Balancing is switched off.
Make sure you load the solutions onto the correct scales.
Observe the colour coding of the connectors.

➢ Visually check that the tubing systems are free of air.

If there is still air in any of the tubing systems:

➢ Press the appropriate **Deaerate** button for the tubing systems concerned.

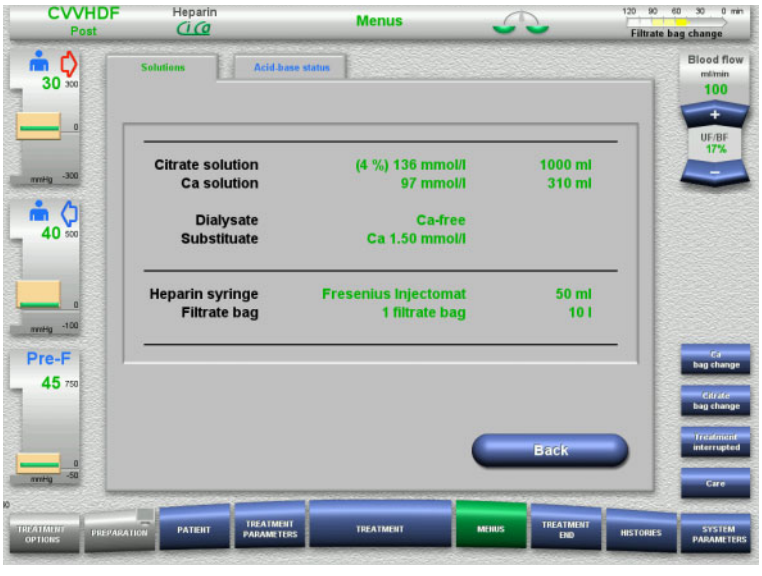
➢ Press the **Exit** button to return to the treatment screen.

Treatment is continued with the current weight of each changed bag. Balancing is started automatically.

Note

The deaerate function is not available when using the Paed CVVHD 8 to 16 kg and Paed CVVHD 16 to 40 kg treatment options.

4.7.9 Ci-Ca information

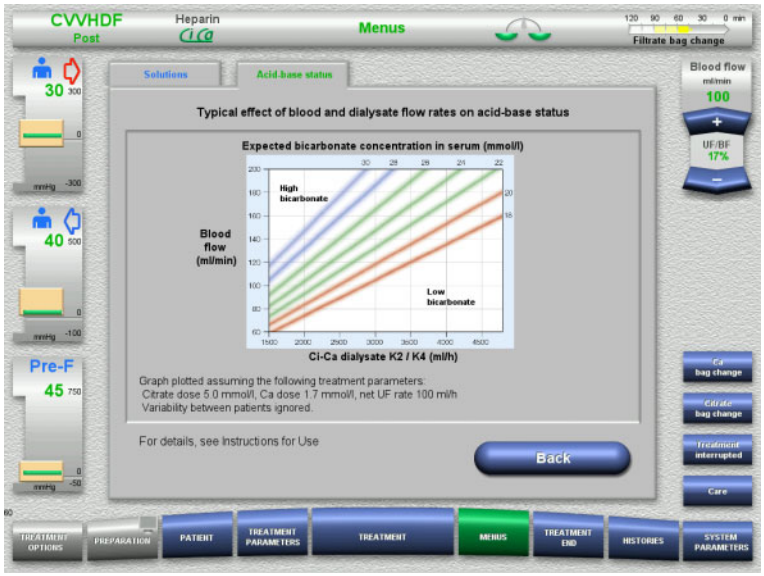


➢ Select the **Ci-Ca information** menu option.

The following tabs can be selected:
– Solutions
– Acid-base status

The **Solutions** tab contains information on the required solutions.

➢ Press the **Back** button to return to the **Menus** screen.



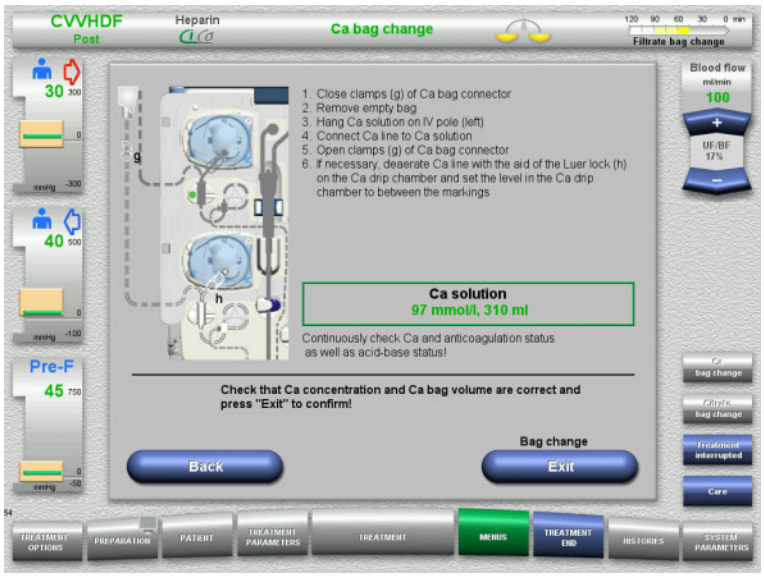
The **Acid-base status** tab contains information on the effects on the acid-base balance.

➢ Press the **Back** button to return to the **Menus** screen.

4.7.10 Ca bag change

Note

If the bag change takes longer than 2 minutes, a message will be displayed.



➢ Select the **Ca bag change** menu option.

➢ Change bags according to the instructions.

Balancing is stopped automatically.
The calcium pump is stopped.
The citrate pump continues running.

➢ Press the **Exit** button to return to the treatment screen.

Treatment is continued with the new volume of the changed bag.

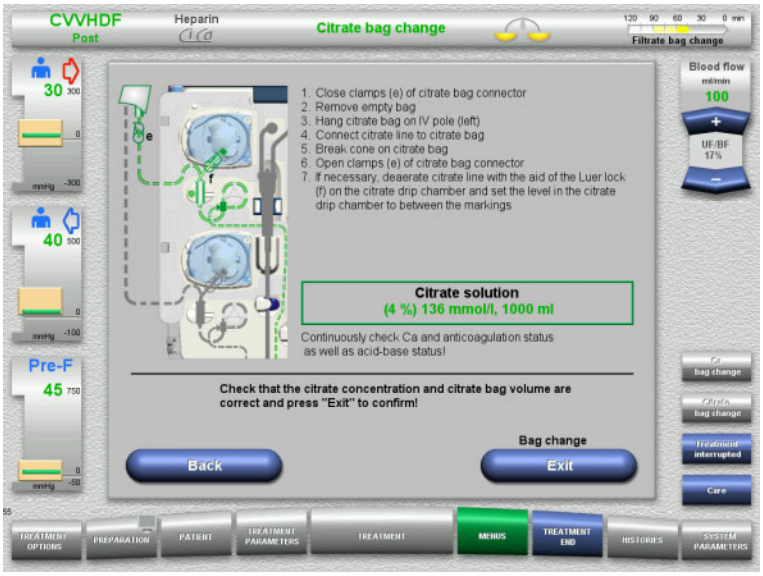
Press the **Back** button to cancel the bag change.

As soon as the screen is closed, balancing is automatically switched on and the calcium pump starts.

4.7.11 Citrate bag change

Note

If the bag change takes longer than 2 minutes, a message will be displayed.



➢ Select the **Citrate bag change** menu option.

➢ Change bags according to the instructions.

Balancing is stopped automatically. The Ci-Ca pumps are stopped.

➢ Press the **Exit** button to return to the treatment screen.

Treatment is continued with the new volume of the changed bag.

Press the **Back** button to cancel the bag change.

As soon as the screen is closed, balancing is automatically switched on and the Ci-Ca pumps start.

4.7.12 Switching off Ci-Ca anticoagulation

Warning

Risk for the patient as a result of wrong composition of the solutions

There is a risk of hypocalcaemia.

➢ If Ci-Ca anticoagulation is switched off, CVVHD or CVVHDF treatment must only be continued or performed with a calcium-containing solution.

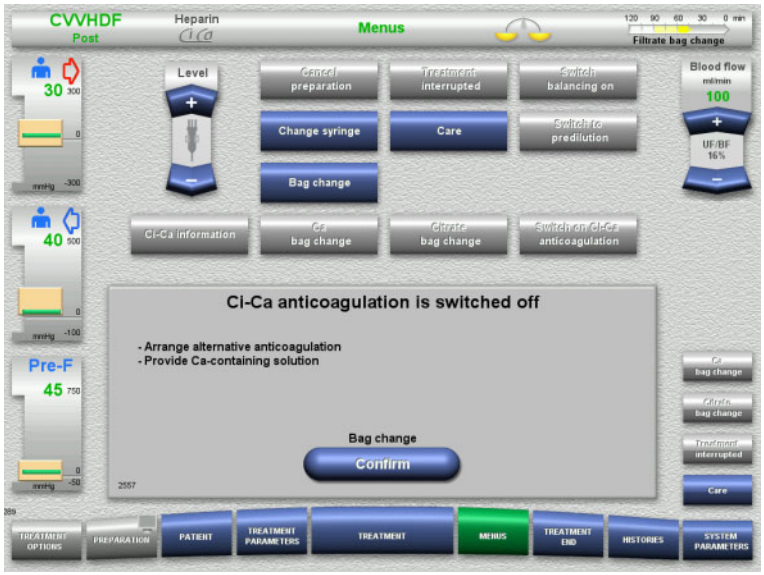
The following must be observed when Ci-Ca anticoagulation is switched off:

– It is mandatory that the solution bags be changed
– An alternative anticoagulation method must be selected by the operator
– The Ci-Ca lines must not be removed from the pumps until the treatment has ended and the patient has been completely disconnected

➢ Select the **Switch off Ci-Ca anticoagulation** menu option.

➢ Press **Yes** to switch off the citrate anticoagulation.

Press **No** to continue the treatment.



➢ Press the **Confirm** button to go to the **Bag change** menu screen.

➢ Change bags according to the instructions and exit.

4.7.13 Switching on Ci-Ca anticoagulation

Warning

Risk for the patient as a result of wrong composition of the solutions

There is a risk of hypercalcaemia.

➢ If Ci-Ca anticoagulation is switched on, CVVHD treatment must only be continued or performed with a calcium-free solution.

➢ If Ci-Ca anticoagulation is switched on, CVVHDF treatment must only be continued or performed with a calcium-free dialysate and a calcium-containing substituate.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance

Mixing up the solution may lead to hypo-/hypercalcaemia.

➢ The post-filter calcium concentration must be checked 5 minutes after switching on the Ci-Ca anticoagulation and at regular intervals afterwards.

Note

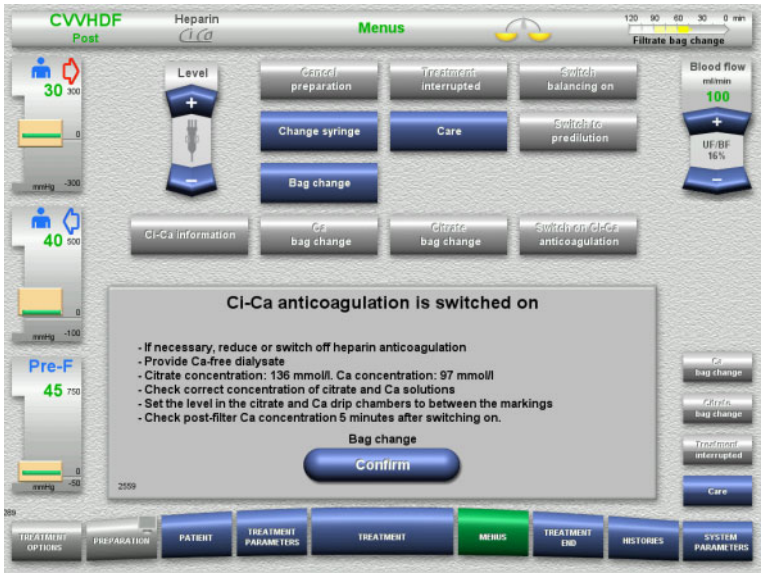
Check that the citrate and calcium solutions have the correct concentration in each case.

Make sure the levels in the citrate and calcium drip chambers are between the markings.

➢ Select the **Switch on Ci-Ca anticoagulation** menu option.

➢ Press **Yes** to switch on the citrate anticoagulation.

Press **No** to continue the treatment.



➢ Press the **Confirm** button to go to the **Bag change** menu screen.

➢ Change bags according to the instructions and exit.

4.7.14 Plasma volume calculation / Target volume input (TPE only)

➢ Select the **Plasma volume** menu option.

➢ Enter the patient data for calculating the plasma volume (PV).

The plasma volume for treatment (PV factor) is calculated and displayed.

The calculated plasma volume is displayed in the context-specific information when entering the target volume.

➢ Press the **Back** button to return to the **Menus** screen.

4.7.15 Switching blood leak monitoring off (TPE only)

Warning

Risk for the patient due to haemolysis or blood loss / risk of blood loss due to bypassed blood leak detector

When the blood leak safety system is bypassed, monitoring for haemolysis or blood loss is deactivated temporarily or for the entire treatment.

➢ In this case, the operator is responsible for the patient's safety.

➢ Especially when treating permanently haemolytic plasma, look for additional dark colouration in the plasma circuit in the event of a blood leak.

Note

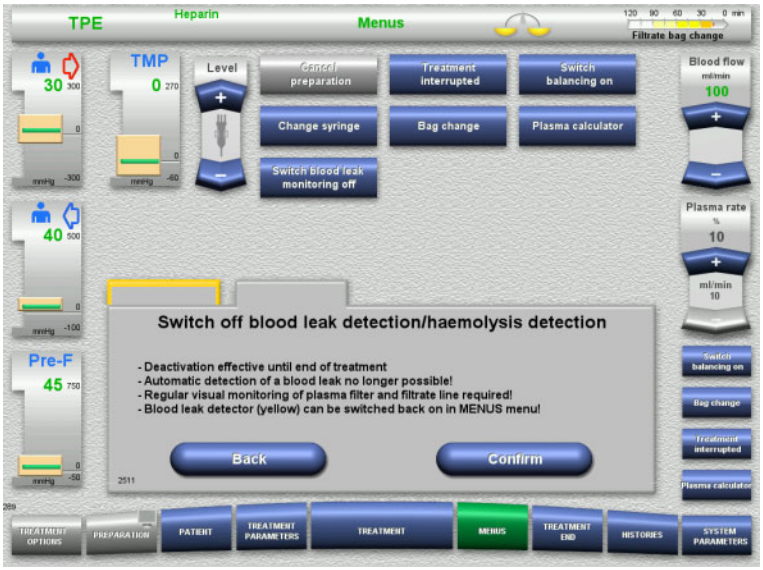
If the message **Blood leak detected** is pending, the treatment option TPE allows you to deactivate the safety system. This means that monitoring for haemolysis and blood leaks is cancelled for the duration of the current treatment. The safety system is reactivated when the device is switched on again.

Note

If during the observation phase with the blood leak detector deactivated it is noted there is no more haemolysis, it is strongly recommended to switch on the blood leak monitoring again.

Note

If a blood leak is detected during treatment with the safety system deactivated, the message **Blood leak detected** still has to be acknowledged.



A blood leak message is pending:

➢ In the menu, select **Switch blood leak monitoring off**.

➢ Press **Confirm** to switch the blood leak monitoring off.

The treatment screen indicates that blood leak monitoring is deactivated.

Look for additional dark colouration in the plasma line in the event of a blood leak!

Monitoring can be reactivated at any time in the Treatment menu.

4.8 Histories

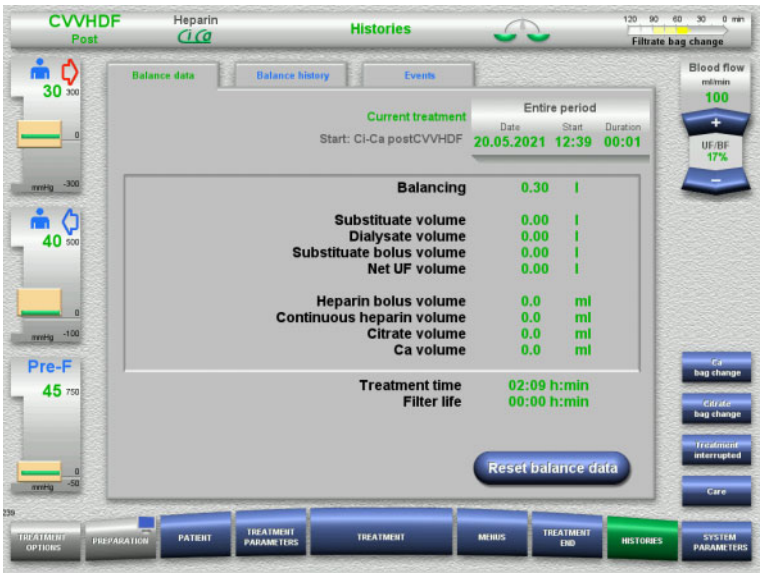
The following tabs can be selected:
– Balance data
– Balance history
– Events

The **Balance data** tab shows the current treatment duration and the treatment option selected at the start of treatment.

4.8.1 Balance data

The balance data shown by the device is based on the values measured by the scales, and is subject to the tolerance and error margins specified in the technical data.

4.8.1.1 CRRT



The **Balance data** tab shows detailed treatment parameters. It also shows:
Start date of treatment
Start time of treatment option
Elapsed time since the start of treatment or last balance data reset

Pressing the **Reset balance data** button will reset all the cumulative volume information recorded so far to “zero”. The treatment time and the filter life will not be reset.

Balancing

Balancing = (substituate bolus volume) + (net UF volume)
Example: -2.20 l = (0.20 l) + (-2.40 l)

- If no substituate bolus was administered, the balancing value corresponds to the net UF volume.
- If a substituate bolus is administered, the corresponding amount remains in the patient, i.e. the substituate bolus volume is not extracted by the filter. This is why the balancing value needs to be adjusted accordingly.
- The administered heparin volume is extracted by the filter (both bolus and continuous volumes). This means that the total administered heparin volume does not affect the balance.
- The total administered citrate and calcium solution volume is extracted by the filter. The citrate and calcium volumes therefore do not affect the balance.
- If treatment is performed without a net UF rate, and no substituate bolus was administered, the balancing value will read “0.00 l”.
- If fluid is removed from the patient without being returned, the balancing value will be negative (preceded by a minus sign).
- The balancing value can turn positive if the fluid removal is compensated by administering one or more substituate boluses. As a rule, the balancing value will either be negative or neutral.
- The calculation period of the balance data is shown under **Entire period**.
- Pressing the **Reset balance data** button will reset all the balance data to zero, and the calculation period will restart.

Treatment time

This is the effective treatment duration so far, not including messages and periods during which balancing is switched off. Pressing the **Reset balance data** button will not reset the treatment time.

Filter life

The filter life is the parameter that is used to monitor how long blood has been flowing through the tubing system. This is basically the same as the treatment time, but will normally be higher, because, while the treatment time count is suspended when balancing is interrupted, the filter life count continues.

Balancing error

If the total balancing error detected by the device exceeds 500 g, the treatment must be terminated. Balancing stops and cannot be continued.

Note

The balancing error for the Paed CVVHD 8 kg to 16 kg and Paed CVVHD 16 kg to 40 kg treatment options is 50 g. If the total balancing error detected by the device exceeds 50 g, the treatment must be terminated. Balancing stops and cannot be continued.

4.8.1.2 TPE

In **Balance data**, the detailed treatment parameters are displayed. It also shows:
– Start date of treatment
– Start time of treatment option
– Time since start of treatment

Pressing the **Reset balance data** button will reset all the cumulative volume information recorded so far to “zero”. The treatment time and the filter life will not be reset.

Exchanged plasma

The exchanged plasma is the plasma volume filtered off from the patient's blood and substituted by the plasma replacement solution.

The administered heparin volume is extracted by the filtrate pump (both bolus and continuous volumes). This means that the total administered heparin volume does not affect the balance.

The calculation period of the balance data is shown under “Period”.

Treatment time

This is the effective treatment duration so far, not including messages during which balancing is switched off.

Filter life

The filter life is the parameter that is used to monitor how long blood has been flowing through the tubing system. This is basically the same as the treatment time, but will normally be higher, because, while the treatment time count is suspended when balancing is interrupted, the filter life count continues.

Balancing error

If the total balancing error detected by the device exceeds 500 g, the treatment must be terminated. Balancing stops and cannot be continued.

4.8.2 Balance history

The **Balance history** tab shows the balance data during a particular period of the current treatment, depending on the treatment mode.

You can enter the Date, End, and Duration to view a calculation period of your choice.

The balance data in the Balance history tab is updated every 15 minutes.

4.8.3 Events

Warning

Risk for the patient as a result of misinterpreting data

Errors in the patient-specific treatment parameters can result from misinterpreting the data shown in the Events tab if the treatment parameters are determined on this basis.

➢ The data listed under Events must not be used as a basis for diagnosis and/or therapy-related decisions.

➢ Any irregularities indicated by this data must always be verified by an independent diagnosis.

The event log lists messages and parameter settings in chronological order. The messages are colour-coded according to priority.

The list of messages shows every single occurrence of an alarm condition, with the time of occurrence, message number, and message title (the alarm system cannot be switched off).

The maximum event log capacity cannot be exhausted even by the maximum possible treatment duration. The event log contents are automatically deleted if the device starts a new patient connection.

A power failure will have no effect on the event log, provided the battery is working. In the event of a complete power failure (mains power failure and device voltage supply failure), all the entries in the event log will be lost.

Use the buttons to scroll back and forth between the individual pages of the list.

Use the buttons to jump to the beginning or end of the list.

The **Events** field allows you to filter the event list.

The **Events** field offers the following filters for the events list:
– All
– Messages
– Parameters

Press **OK** to apply your selected filter and return to the events list.

4.9 System Parameters

Note

The responsible organisation should define the most important configurable parameter settings itself (or confirm the default values) and have these set by service support as required.

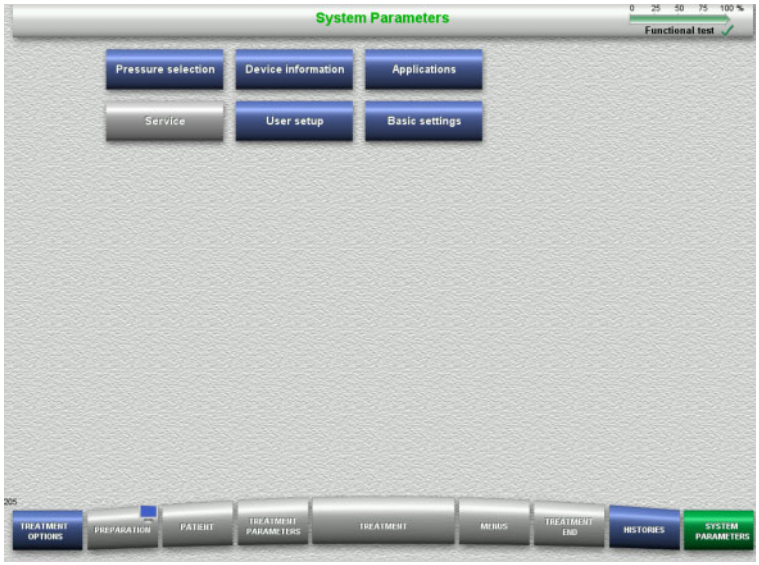
The **System Parameters** menu allows you to choose device and treatment settings.

Grey menu fields can only be selected with the appropriate access authorisation (e.g. UserCard).

The access authorisation level shown in the screens in this document can differ from the level you actually have (whether unrestricted access or defined by your UserCard).

System parameters that can be edited with unrestricted access or a UserCard are listed in tables, showing the default value, the possible value range, and the required access authorisation level.

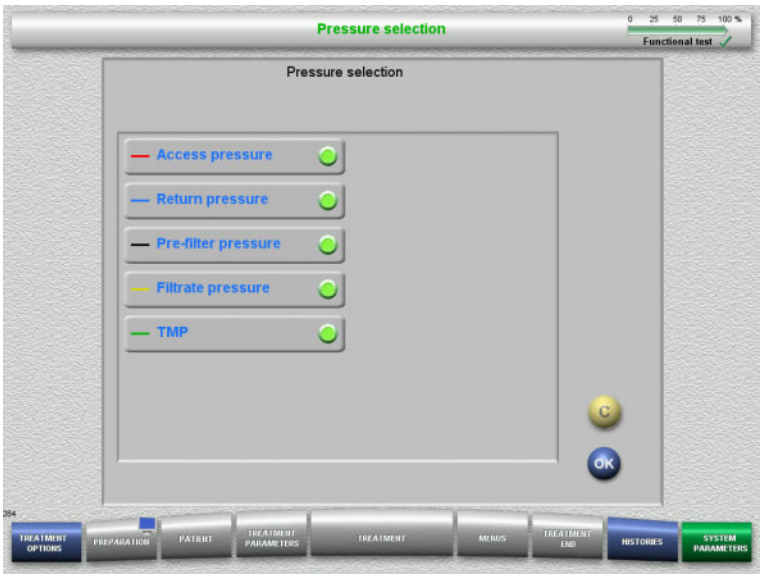
4.9.1 Access without UserCard



Menu fields that can be selected without a UserCard are:
- Pressure selection
- Device information
- Basic settings

➢ Select the menu option required.

4.9.1.1 Pressure selection



The **Pressure selection** menu option allows you to select the pressures you wish to have displayed in the Pressure / alarm history tab of the **Treatment** screen.

➢ Select the required pressures.

➢ Press the **OK** button to apply your selection.

4.9.1.2 Device information

The **Device information** menu option displays general information on the device.

For example: serial number, software version, operating hours, etc.

4.9.1.3 Basic settings

Note

After changing the date or time, the memory contents will no longer be in the correct chronological sequence, which may lead to problems in displaying the error logs, histories and event logs.

Switching the device off and back on again is recommended after changing the date or time.

After changing the language, the device must be restarted before the new language is applied.

The minimum possible value of the Sound volume range ensures that sounds emitted by the device remain audible. The sound volume adjustment only applies until the device is next switched off. When the device is switched back on, the sound volume will automatically return to the default value. The responsible organisation can only set the minimum sound volume and standard sound volume with a ServiceCard.

Tip

Local summer/winter time can be set in **Basic settings**.

The setup parameters shown in the table below can be set in the **Basic settings** menu.

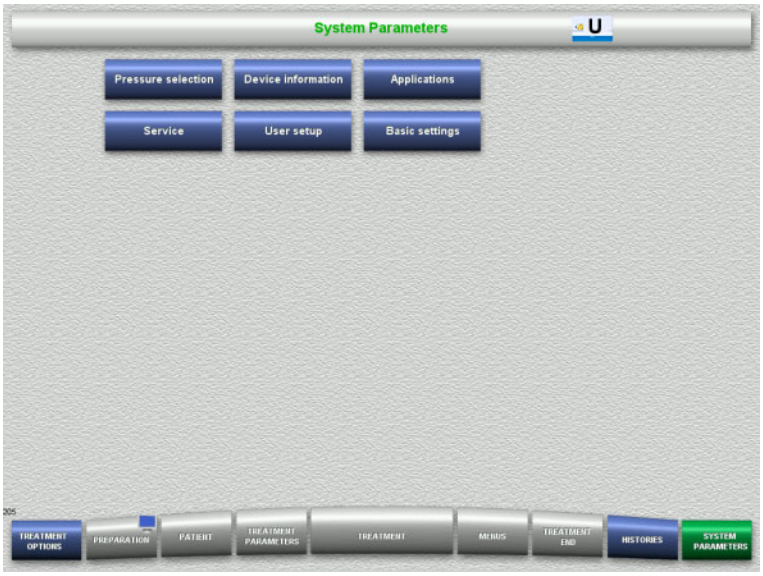
Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **System Parameters** screen.

Basic settings	Default value	Value range	Access level
Date	–	01.01.1999 to 31.12.2037	Unrestricted
Time	–	00:00:00 to 23:59:59	Unrestricted
Sound volume	6	Minimum sound volume up to 9	Unrestricted
Pressure history period	60 min	10 to 180 min	Unrestricted

Basic settings	Default value	Value range	Access level
Brightness	5	1 to 5	Unrestricted
Ca concentration of substituate	1.5 mmol/l	1 to 2 mmol/l	UserCard
Language	English	Depends on language package	UserCard

4.9.2 Access with UserCard

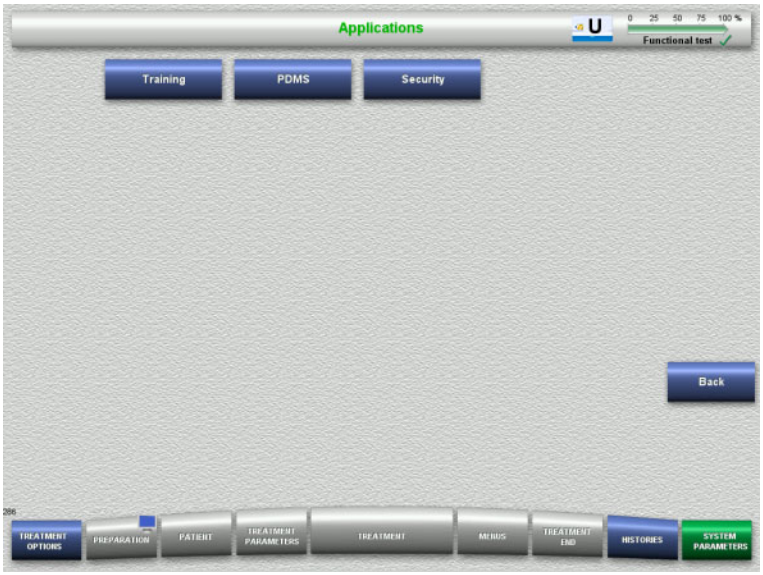


Menu fields that can be selected with a UserCard are:
– Applications
– User setup

➢ Insert the UserCard into the card slot.

➢ Select the menu option required.

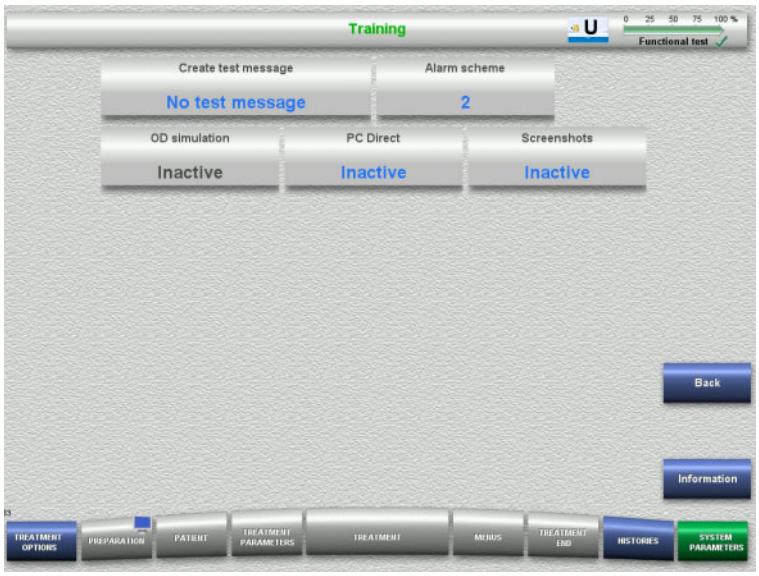
4.9.2.1 Applications



The **Applications** menu can be used for entering and viewing parameters for operator training and for the patient data management system (PDMS).

➢ Press the **Back** button to return to the **System Parameters** screen.

Training



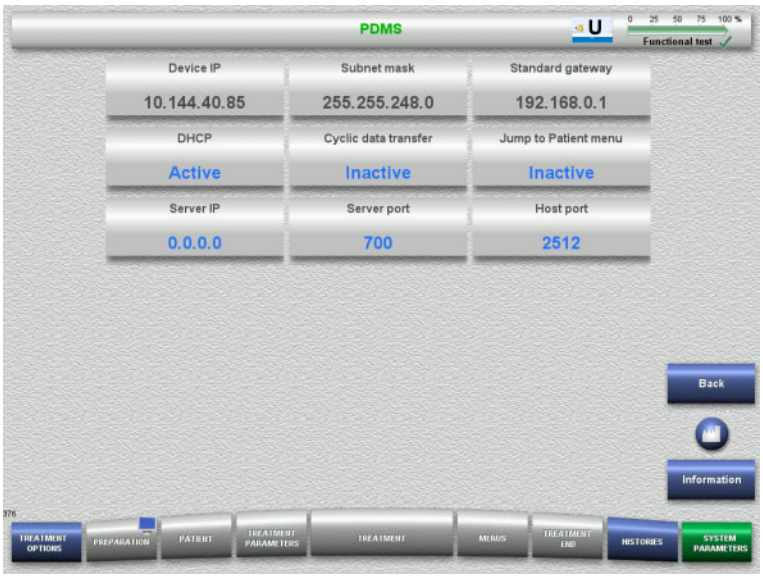
The **Training** menu can be used to activate the OD simulation, change the alarm scheme, and create test messages.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **Applications** screen.

Training	Default value	Value range
OD simulation	Inactive	Active, Inactive
Alarm scheme	2	1 to 2
Create test message	No test message	**For alarm scheme 1:** No test message Alarm / system error Warning Advisory **For alarm scheme 2:** No test message System error High priority alarm Medium priority alarm Low priority alarm High priority advisory

- **PDMS / PDMS Security**

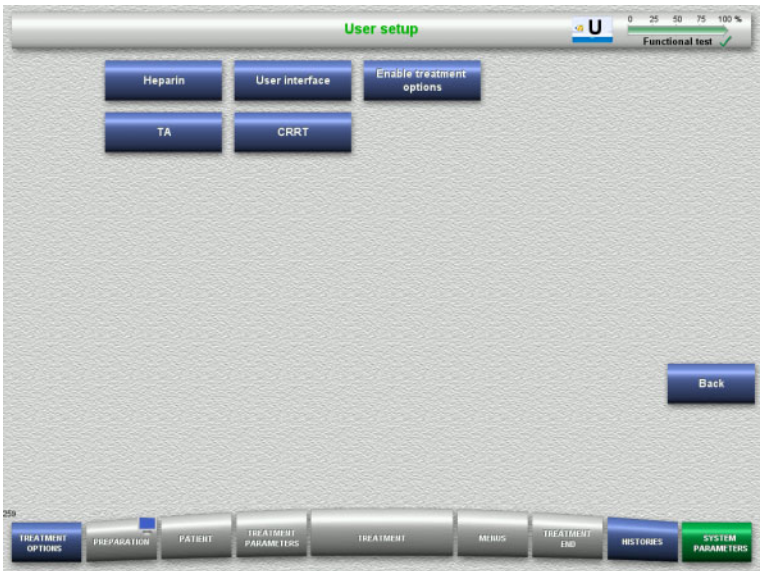


The **PDMS and PDMS Security** menus can be used to view the parameters for the patient data management system (PDMS).

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **Applications** screen.

4.9.3 User setup



The main configurable parameter values can be set in the **User setup** menu.
- Heparin
- User interface
- CRRT
- TA

➢ Press the **Back** button to return to the **System Parameters** screen.

4.9.3.1 Heparin

Note

Changes to the syringe type or the heparin bolus need to be made before the functional test is completed, so that the changes apply to the treatment that is to follow.

The **Heparin** menu can be used to set the parameters for heparin anticoagulation shown in the table below.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **User setup** screen.

Heparin	Default value	Value range
Syringe type	0 (invalid)	Fresenius Medical Care 30 ml B. Braun Omnifix 30 ml BD Perfusion 50 ml Fresenius Injectomat 50 ml B. Braun Perfusor 50 ml B. Braun Omnifix 50 ml BD Plastipak 50 ml
Heparin OFF alarm time	1 min	0 to 10 min
Heparin bolus	1 ml	0.1 to 5.0 ml

4.9.3.2 User interface

The system parameters of the user interface shown in the table below can be set in the **User interface** menu.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **User setup** screen.

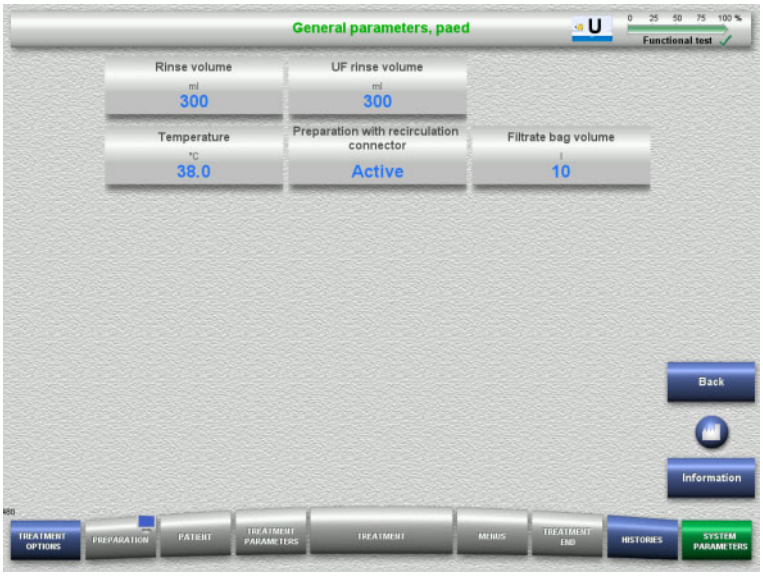
User interface	Default value	Value range
Return delay	11 min	11 to 30 min
Button sounds	Active	Inactive, Active
Alarm scheme	2	1, 2

4.9.3.3 Paediatric CRRT treatments

- **General parameters, paed**

Note

Changes to the “General parameters, paed” need to be made before the start of filling, so that the changes apply to the treatment that is to follow.



The **General parameters, paed** menu can be used for setting the general parameters shown in the table below that are to apply for all paediatric CRRT procedures.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

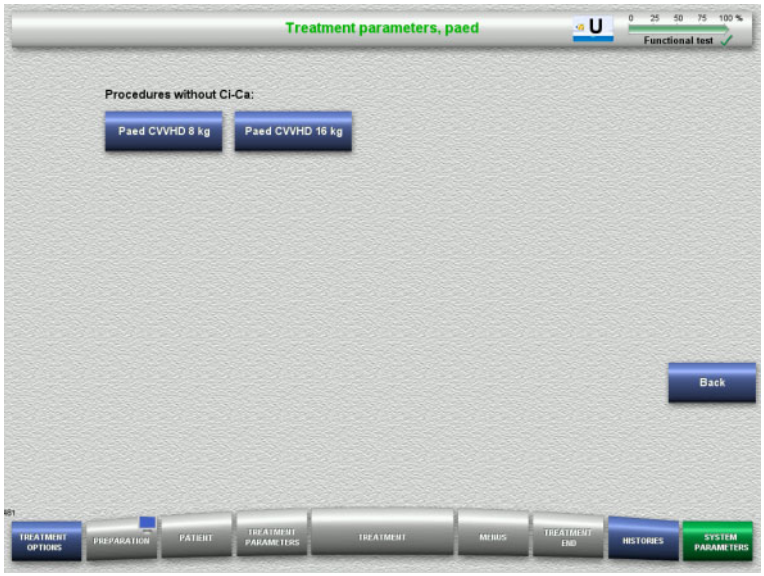
➢ Press the **Back** button to return to the **CRRT** screen.

General parameters, paed	Default value	Value range
Rinse volume	300 ml	300 to 5000 ml
UF rinse volume	300 ml	300 to 2000 ml

- **Treatment parameters, paed**

Note

Changes to the “Treatment parameters, paed” need to be made before the start of filling, so that the changes apply to the treatment that is to follow.



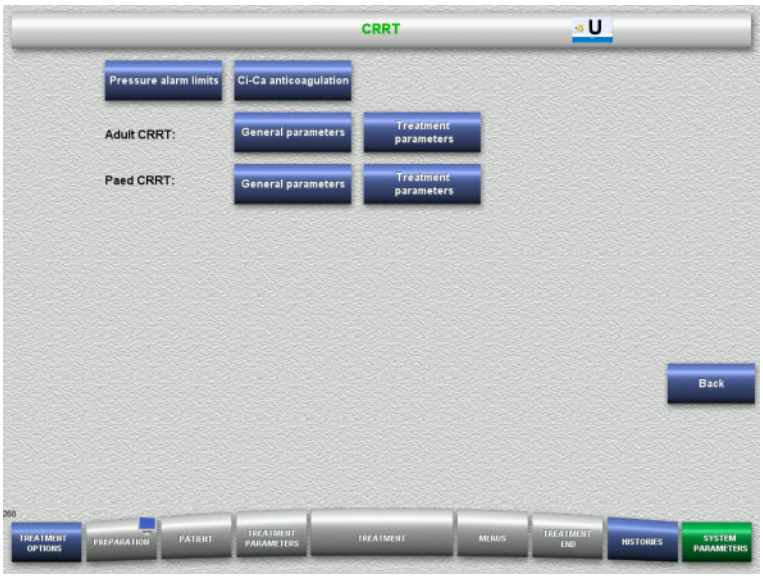
The **Treatment parameters, paed** menu can be used for setting the specific treatment parameters shown in the table below for the different paediatric CRRT procedures.

Treatment options without Ci-Ca anticoagulation.
– Paed CVVHD 8 kg to 16 kg
– Paed CVVHD 16 kg to 40 kg

Paed CVVHD 8 kg	Default value	Value range
Max. patient connection blood flow	30 ml/min	10 to 100 ml/min
Blood flow	30 ml/min	10 to 100 ml/min
Max. blood reinfusion flow	30 ml/min	10 to 100 ml/min
Dialysate	380 ml/h	380 to 1500 ml/h

Paed CVVHD 16 kg	Default value	Value range
Max. patient connection blood flow	50 ml/min	10 to 100 ml/min
Blood flow	50 ml/min	10 to 100 ml/min
Max. blood reinfusion flow	50 ml/min	10 to 100 ml/min
Dialysate	600 ml/h	380 to 2000 ml/h

4.9.3.4 CRRT



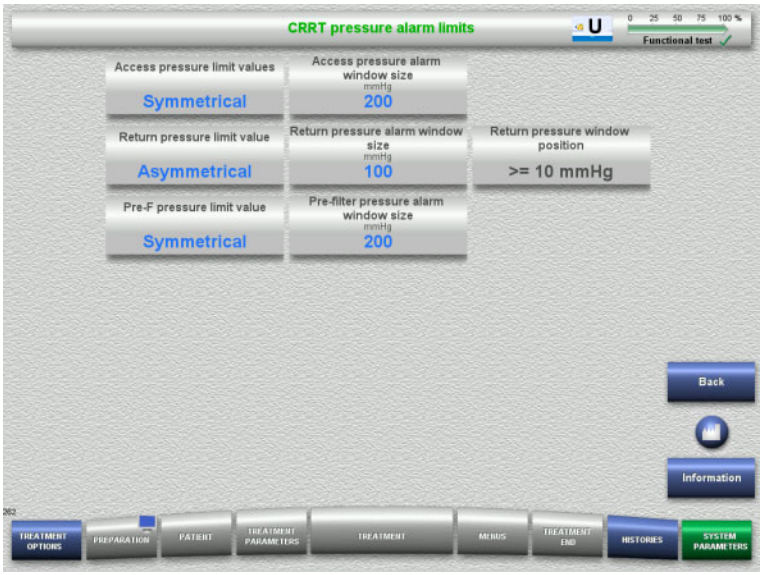
The **CRRT** screen allows you to set treatment-specific parameters.
– Pressure alarm limits
– Ci-Ca anticoagulation
– General parameters
– Treatment parameters

➢ Press the **Back** button to return to the **User setup** screen.

- **CRRT pressure alarm limits**

Note

Changes to the pressure alarm limits need to be made before the first pump segment is inserted, so that the changes apply to the treatment that is to follow.



The **CRRT pressure alarm limits** menu can be used to set the pressure parameters shown in the table below.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **CRRT** screen.

CRRT pressure alarm limits	Default value	Value range
Access pressure limit values	Symmetrical	Asymmetrical, Symmetrical
Access pressure alarm window size	200 mmHg	40 to 200 mmHg
Return pressure limit value	Asymmetrical	Asymmetrical, Symmetrical
Return pressure alarm window size	100 mmHg	40 to 200 mmHg
Pre-F pressure limit value	Symmetrical	Asymmetrical, Symmetrical
Pre-filter pressure alarm window size	200 mmHg	40 to 200 mmHg

- **Ci-Ca anticoagulation**

Pressing **Ci-Ca anticoagulation** allows you to view the parameters for Ci-Ca anticoagulation.

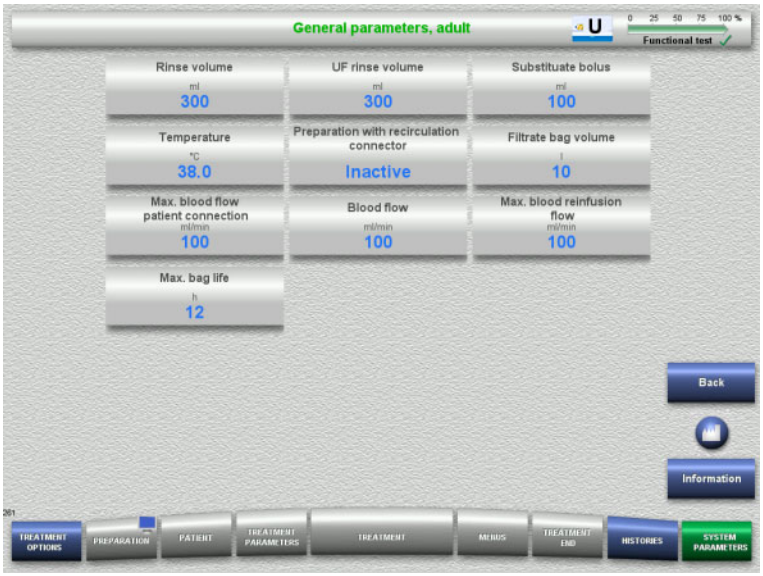
Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **CRRT** screen.

- **General parameters, adult**

Note

Changes to the “General parameters, adult” need to be made before the start of filling, so that the changes apply to the treatment that is to follow.



The **General parameters, adult** menu can be used for setting the general parameters shown in the table below that are to apply for all CRRT procedures.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

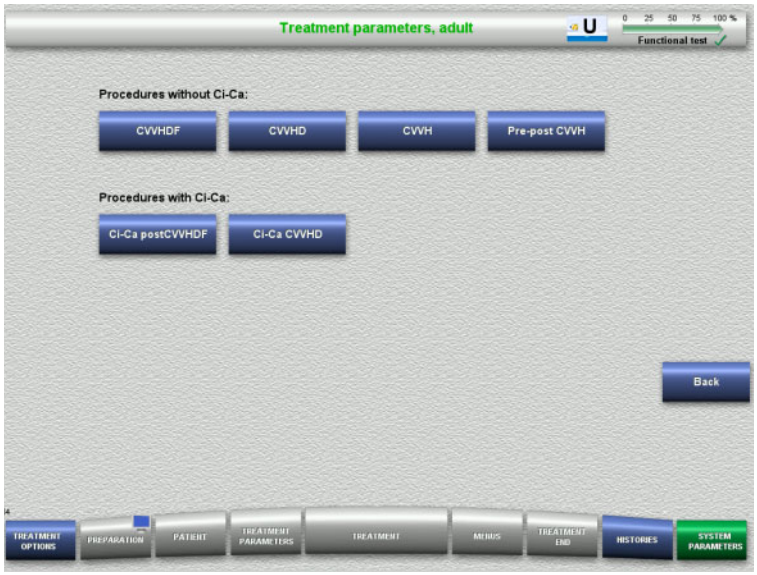
➢ Press the **Back** button to return to the **CRRT** screen.

General parameters, adult	Default value	Value range
Rinse volume	300 ml	300 to 5000 ml
UF rinse volume	300 ml	300 to 2000 ml
Max. blood flow patient connection	100 ml/min	10 to 100 ml/min
Blood flow	100 ml/min	10 to 200 ml/min
Max. blood reinfusion flow	100 ml/min	10 to 100 ml/min
Temperature	38 °C	35 to 39 °C
Substituate bolus	100 ml	100 to 200 ml

- **Treatment parameters, adult**

Note

Changes to the “Treatment parameters, adult” need to be made before the start of filling, so that the changes apply to the treatment that is to follow.



The **Treatment parameters, adult** menu can be used for setting the specific treatment parameters shown in the table below for the different CRRT procedures.

Treatment options without Ci-Ca anticoagulation.
- CVVHDF
- CVVHD
- CVVH
- Pre-post CVVH

Treatment options with Ci-Ca anticoagulation
- Ci-Ca postCVVHDF
- Ci-Ca CVVHD

➢ Press the **Back** button to return to the **CRRT** screen.

CVVHDF	Default value	Value range
Predilution substituate	1000 ml/h	600 to 4800 ml/h
Postdilution substituate	1000 ml/h	600 to 4800 ml/h
Dialysate	1000 ml/h	600 to 4800 ml/h

CVVHD	Default value	Value range
Dialysate	2000 ml/h	600 to 4800 ml/h

CVVH	Default value	Value range
Predilution substituate	1000 ml/h	600 to 4800 ml/h
Postdilution substituate	1000 ml/h	600 to 4800 ml/h

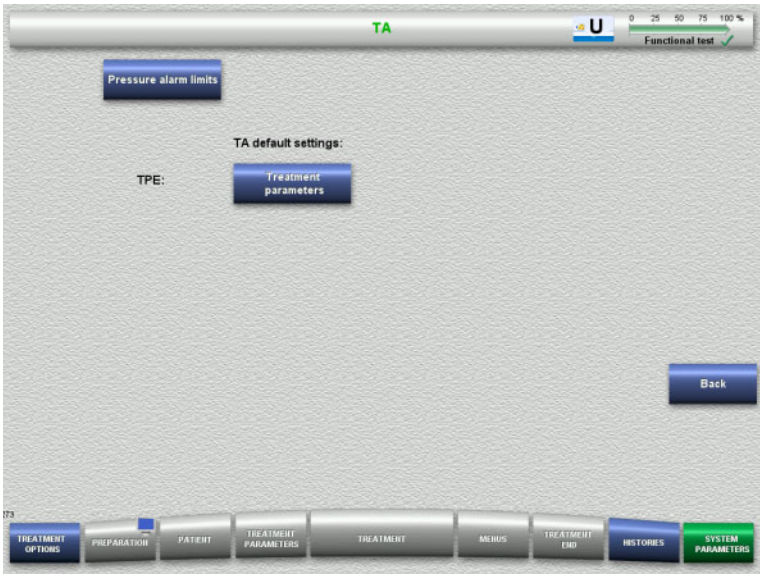
Pre-post CVVH	Default value	Value range
Predilution substituate	1000 ml/h	600 to 4800 ml/h
Postdilution substituate	1000 ml/h	600 to 4800 ml/h

Ci-Ca postCVVHDF	Default value	Value range
Postdilution substituate	1000 ml/h	600 to 2400 ml/h
Dialysate	2000 ml/h	600 to 4800 ml/h

Ci-Ca postCVVHDF	Default value	Value range
Citrate dose	5 mmol/l	2 to 6 mmol/l
Calcium dose	1.7 mmol/l	0.1 to 3.0 mmol/l
Ca concentration of substituate	1.5 mmol/l	1 to 2 mmol/l

Ci-Ca CVVHD	Default value	Value range
Dialysate	2000 ml/h	600 to 4800 ml/h
Citrate dose	4 mmol/l	2 to 6 mmol/l
Ca dose	1.7 mmol/l	0.0 to 3.0 mmol/l

4.9.3.5 TPE



The **TPE** menu allows you to set treatment-specific parameters:
– Pressure alarm limits
– Treatment parameters TPE

➢ Press the **Back** button to return to the **User setup** screen.

- **TPE pressure alarm limits**

Note

Changes to the pressure alarm limits need to be made before the first pump segment is inserted, so that the changes apply to the treatment that is to follow.

The **TPE pressure alarm limits** menu can be used to set the pressure parameters.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

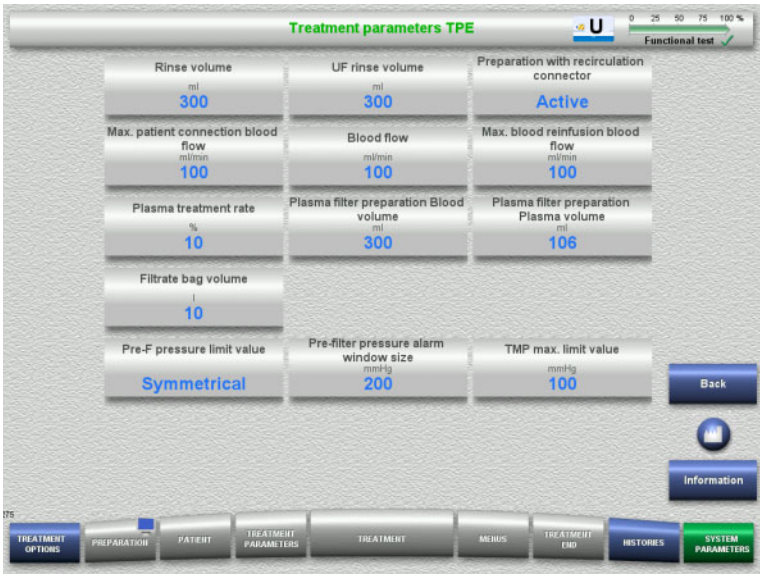
➢ Press the **Back** button to return to the **TPE** menu.

TPE pressure alarm limits	Default value	Value range
Access pressure limit values	Symmetrical	Asymmetrical, Symmetrical
Access pressure alarm window size	200 mmHg	40 to 200 mmHg
Return pressure limit value	Asymmetrical	Asymmetrical, Symmetrical
Return pressure alarm window size	100 mmHg	40 to 200 mmHg

- **Treatment parameters TPE**

Note

Changes to the treatment parameters TPE need to be made before the first pump segment is inserted, so that the changes apply to the treatment that is to follow.



The **Treatment parameters TPE** menu can be used for setting TPE-specific parameters.

Pressing the **Information** button will show you the changed parameters and when the changes will be applied.

➢ Press the **Back** button to return to the **TPE** menu.

Treatment parameters TPE	Default value	Value range
Rinse volume	300 ml	300 to 5000 ml
UF rinse volume	300 ml	300 to 2000 ml
Max. patient connection blood flow	100 ml/min	10 to 100 ml/min
Blood flow	100 ml/min	40 to 300 ml/min
Max. blood reinfusion blood flow	100 ml/min	10 to 100 ml/min
Pre-F pressure limit value	Symmetrical	Asymmetrical, Symmetrical
Pre-filter pressure alarm window size	200 mmHg	40 to 200 mmHg

4.10 Network

4.10.1 Observe before use

Warning

Risk for the patient as a result of corrupted data

Data corruption or data loss caused by the network and the server software cannot be detected by the device. This can lead to malfunctions.

➢ The system installer must ensure that device data is processed securely, e.g., in PC software applications.

➢ The network operator must ensure that any data transferred without encryption is protected.

Note

There are special requirements for further processing of the data.

The network operator is responsible for ensuring that the network is available for the required data transfer.

Data corruption affecting the correctness, plausibility and completeness of the data that is caused by the network and the server software is not detected by the device.

Note

Only devices complying with the regulations of (DIN) EN 60950-1:2006 or IEC 60950-1:2006 must be connected to the LAN ports.

When connecting the device to Ethernet, connect the cable first to the device, then to the external network. Only the shielded Cat 5 Ethernet cable listed under Additional equipment must be used for this purpose (see Chapter 8.2 on page 286).

Note

The network operator is responsible for the protection of data transferred without encryption.

The data transfer of alarm states via the network must not be used for the purpose of external alerts (nurse call).

Note

In normal condition, the enclosure leakage current from or between components of the system must not exceed 0.1 mA within the patient environment (according to EN 60601-1-1). This must be ensured when installing the system.

4.10.2 PDMS connection

Warning

Risk for the patient as a result of corrupted data

➢ Data transferred to a patient data management system (PDMS) must not be used as a basis for diagnosis and/or therapy-related decisions.

Warning

Risk for the patient as a result of ignored alarm signals

The reliability of alarm signal transmissions to external alarm systems cannot be guaranteed, meaning that alarms can fail to be indicated externally.

➢ Stay close enough to the device to be able to notice any alarms it emits at all times.

A shielded Cat 5 patch cable (3 metres long) is included with the multiFiltratePRO for the connection to the data network of a patient data management system. Further cables can be ordered in different lengths if required.

5 Alarm processing

5.1 Repeated confirmation of a message

For the safety systems, the relevant alarm limits and alarm conditions described in Chapter 12 “Specifications”, under “Balancing/dialysate circuit and safety systems” and “Extracorporeal blood circuit and safety systems”, also apply.

Alarm processing changes can be made in the Setup.

Operators must stay close enough to the device to be able to notice any emitted visual or audible alarms at all times.

Warning

Risk for the patient as a result of repeated message confirmation

➢ Always correct the problem that caused the message before confirming it.

Note

When alarms and warnings occur, follow the information given in the messages, as well as any explanations given in the Help function (**?**).

If the following alarms and warnings are repeatedly confirmed without being corrected, this can endanger the patient as follows:

Alarms / warnings	Possible patient hazard
Pressure drop in the return line Access pressure and return pressure alarms	External blood leak Bleeding into tissue Haemolysis, through kinks in the tubing system
Anticoagulation alarms (e.g., heparin pump alarms)	Loss of blood through blood-clotting in the extracorporeal blood circuit Wrong dosage of anticoagulation medium
Blood leak alarms	Loss of blood into filtrate/plasma
Isolated citrate dosage with balancing switched off	Citrate accumulation/disruption of acid-base balance
Low temperature warnings	Hypothermia

5.2 Alarm schemes

Note

The alarm scheme used must be specified by the responsible organisation, and its suitability for the place of operation and the prevailing environmental conditions must be assessed.

Warning

Risk for the patient as a result of ignored alarm signals

If different alarm schemes are set for different devices, the same alarm condition can generate a different alarm response, depending on the device in use. This can lead to misinterpretation.

➢ Use the same alarm scheme for all devices.

The device features two alarm schemes. The chosen scheme is configured in the **System Parameters** menu.

Any switching between schemes must be authorised and performed by – or on behalf of – the organisation responsible for the use of the device.

The alarm scheme defines the information, warnings and alarms provided to the operator in the event of malfunctions, according to the alarm conditions.

An alarm always comprises a visual indication and an audible tone. The required information or cause of the alarm is also displayed as text on the screen.

All visual signalling of an alarm condition and priority is displayed using the operating status indicator (traffic light). This displays the appropriate colour (red, yellow, green) in a specific flashing pattern.

The audible signals generated by alarm conditions are correlated with the visual status indications. They also use a range of tone sequences and patterns of repetition to inform the operator about the priority and the relevance of the alarm condition.

Alarm scheme “one” displays a state-oriented system of alarms and corresponds to the former alarm schemes provided by the Fresenius Medical Care range of devices.

Alarm scheme “two” displays the potential danger presented by an alarm condition. It assigns a priority to every alarm and is based on the alarm standard EN 60601-1-8 for medical devices used in intensive medical care.

5.2.1 Alarm scheme one

This alarm scheme defines an absolutely unambiguous relationship between the alarm condition, device response and alarm signalling.

Basic assignment

Alarm condition stops the blood and balancing circuits:
The operating status indicator (traffic light) is red and the device emits an audible tone.

Alarm condition stops the balancing circuit:
The operating status indicator (traffic light) is yellow and the system emits an audible tone.

In addition, this scheme also provides an operator information function: Isolated audible tone without signalling the alarm condition via the operating status indicator (traffic light).

The alarm conditions are prioritised internally. A more urgent alarm will be displayed over a less urgent alarm on the screen.

5.2.2 Alarm scheme two

This scheme is based on assigning priority levels to alarm conditions. Priorities correspond to the danger level at hand and the time before a potential hazard occurs, according to the following table:

Possible result of failing to respond to the cause of the alarm condition	Start of potential injury		
	Instant	Soon	Delayed
Death or irreversible injury	High priority	High priority	Medium priority
Reversible injury	High priority	Medium priority	Low priority
Minor injury or discomfort	Medium priority	Low priority	Low priority or no signal

The signals and tone sequences corresponding to the various priorities are assigned uniformly within medical device groups: as a result, all devices for extracorporeal blood treatment will, as a rule, have a uniform set of alarm signals.

Basic assignment

The assignment of alarm priority to device response is as follows:

High priority:
Red flashing operating status indicator (traffic light) and repeated tone sequence of 10 beeps.

Medium priority:
Yellow flashing operating status indicator (traffic light) and repeated tone sequence of 3 beeps.

Low priority:
Yellow steady operating status indicator (traffic light) and repeated tone sequence of 2 beeps.

In addition, this scheme also provides an operator information function: Green flashing operating status indicator (traffic light) and repeated single tone.

In this way, each alarm condition is assigned a priority that defines the alarm response of the device.

5.3 High-priority alarm conditions

Since critical alarm conditions always place the device into safe mode (treatment or blood flow is stopped), high-priority alarms of this kind occur only in exceptional cases where a subsequent patient hazard remains possible despite the automatic device response.

In alarm scheme two, the following error conditions meet the requirements of a high-priority alarm:

– **Low return pressure alarm** message:
  Here, there is a possibility that the patient may have become disconnected from the device accidentally, but could still be losing blood through his or her vascular access site.
– **High access pressure alarm** message:
  Here, there is a possibility that the patient may have become disconnected from the device accidentally, but could still be losing blood through his or her vascular access site.
– Failure of the Ci-Ca pumps to detect the tubing system positioner:
  Here, there is a possibility that the patient may suffer air infusion or blood loss via the Ci-Ca tubing system (line occlusion cannot be detected).

In addition, the following conditions have an elevated risk and require intensive observation and monitoring:

– Device condition following an air alarm
– Bypass condition following a blood leak alarm

Warning

Risk of blood loss as a result of clotting

If the operator fails to react properly in the event of a blood pump standstill, this can lead to clotting and the loss of the patient's blood contained in the extracorporeal circuit at the time.

➢ Correct problems that cause an alarm condition with a blood pump standstill and start the blood pump again as fast as possible.

5.4 Alarm system

Pressure monitoring

To avoid unnecessary false alarms, the alarm limit window of a pressure can be temporarily extended, disabled, or repositioned around the current pressure, following changes to relevant parameters, after pressure alarms, or stopping/starting the pumps. Such conditions are only permitted for short times, and the current pressure monitoring status is always shown by the appropriate alarm limit window colour (yellow=active, grey=inactive). The monitoring of the maximum and minimum possible pressure limits remains unaffected.

Note

The pressure alarm limits used must be evaluated to ensure they are suitable for the patient and the selected treatment option.

In doing so, special attention must be paid to any alarm settings that could limit the effectiveness of the alarm system.

Lower return pressure limit

In the event of a low return pressure alarm, the lower limit of the return pressure can be extended from +10 mmHg (default value) to -100 mmHg as necessary, depending on the setting in the Service setup. This allows treatment to be performed with very low or even negative return pressures, if necessary.
(Factory setting: extending lower return pressure limit is deactivated)

Warning

Risk of blood loss as a result of an undetectable dislocation

Setting the lower limit of the return pressure to -100 mmHg restricts the possibilities for detecting a possible dislocation of the return line.

➢ This option should be configured only in exceptional cases that are medically necessary and performed with care and under close supervision.

Warning

Risk of blood loss as a result of connection sites not closed correctly

To protect the patient from dangerous blood loss, return pressure monitoring of the extracorporeal blood circuit is used as a safety system against external blood leaks. However, pressure monitoring cannot detect an external blood leak in all cases. Particularly critical occurrences are dislocations of the connections to the catheters or small leaks in the high pressure components of the extracorporeal blood circuit.

➢ The extracorporeal blood circuit must be checked regularly for leaks while treatment is in progress, paying particular attention to all the joints of the tubing system and the return line.

Air infusion

To ensure that the stringent limit values for detecting air infusion are always maintained, you may need to restrict the maximum blood flow for low-weight patients (see Chapter 12.11 on page 309).

Note

Air infusion limit values are dependent on blood flow and patient weight:

For Paed CVVHD 8 kg to 16 kg, full sensitivity at maximum blood flow is achieved with patients weighing upwards of 9 kg.

For Paed CVVHD 16 kg to 40 kg, full sensitivity at maximum blood flow is achieved with patients weighing upwards of 18 kg.

For CRRT (from 40 kg), full sensitivity at maximum blood flow is achieved with patients weighing upwards of 45 kg.

Alarm priorities

In an alarm state, subsequent alarms of the same priority or of a lower priority are not separately signalled by the device. Subsequent alarms of a higher priority are signalled.

5.5 Response of the alarm system

- **When starting treatment or resuming treatment after an alarm**

After confirming certain error messages, the activation of new error messages from the following components is delayed, or the alarm limits are reset, while the treatment is being resumed:

Air bubble detector

Warning

Risk of air embolism as a result of air in the tubing system

➢ While bypassing the monitoring system of the air bubble detector, the operator is responsible for the patient's safety.

– After starting active removal of air: 5 ml
– After the "Microbubbles detected" message: 2 minutes

The message **Microbubbles detected downstream of bubble catcher** can be overridden no more than 3 times in the course of a treatment. The next time the alarm occurs, **air removal** procedures must be performed.

Pressure displays

– The alarm limit windows of the pressures shown in the display are reactivated with a delay of up to 10 seconds.
– For the purpose of resuming treatment after pressure alarms, the alarm limit windows can be repositioned if this is cleared first.
– After a parameter change (e.g. stopping and starting the blood pump), the alarm limit windows are automatically deactivated for up to 10 seconds. In order to avoid repeat alarms, the alarm limit value is then either repositioned around the current pressure value, or kept as it is and reactivated, depending on the cause of the alarm.

- **Bypassing an alarm (temporarily deactivating an alarm)**

Warning

Risk for the patient due to haemolysis or blood loss / risk of blood loss due to bypassed blood leak detector

When the blood leak safety system is bypassed, monitoring for haemolysis or blood loss is deactivated temporarily or for the entire treatment.

➢ In this case, the operator is responsible for the patient's safety.

➢ Especially when treating permanently haemolytic plasma, look for additional dark colouration in the plasma circuit in the event of a blood leak.

Note

If the message **Blood leak detected** is pending, the treatment option TPE allows you to deactivate the safety system. This means that monitoring for haemolysis and blood leaks is cancelled for the duration of the current treatment. The safety system is reactivated when the device is switched on again (see Chapter 4.7.15 on page 188).

The **Bypass** button allows the following active alarms to be bypassed (deactivated) for a defined period:

Alarm	Bypass time
Massive blood leak	Maximum 1 minute
Haemolysis / blood leak	Maximum 2 minutes

- **Suppressing the alarm tone (Audio paused)**

The **Audio paused** button allows the operator to pause (deactivate) the audible tone of a signalled alarm for a certain time. This is only possible for active alarms and is indicated by the LED of the **Audio paused** button.

The **Audio paused** function cannot be cancelled before time. If a new alarm occurs during this time, the audible alarm tone of the new alarm is signalled regardless.

Name	Suppress time
Audio paused (SOUND OFF)	2 minutes

5.6 Messages

Note

Each message window has a colour-coded frame. The visual and audible signalling of the messages can differ, depending on the alarm scheme used.

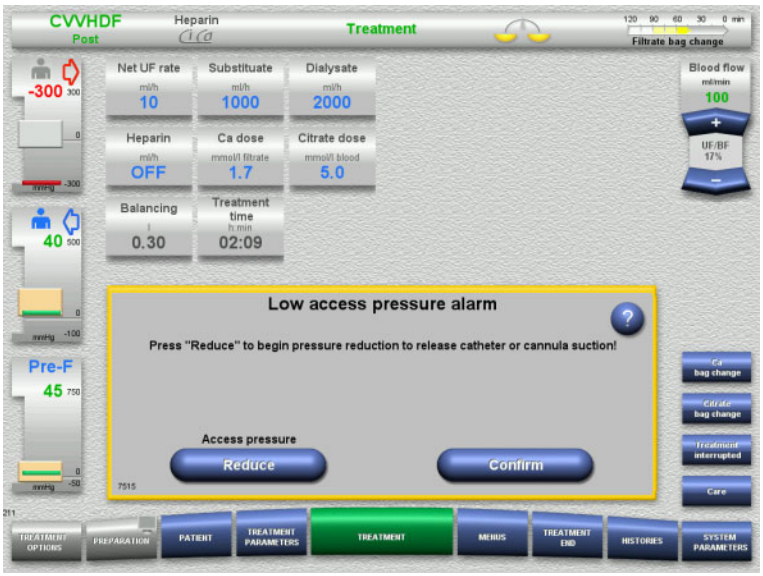
The **?** button can be used to access the Help function. This provides operators with further information on the possible cause as well as possible remedies.

Warning

Risk for the patient as a result of ignored alarm signals

If the sound volume of an alarm signal is set too low, background noises can prevent the operator from hearing the alarm tones.

➢ Set the sound volume so that alarm tones can be heard above any background noises.



Depending on the alarm scheme used, the messages have different window frame colours and different tones according to their priority. The sound volume of the audible alarm tone can be set in the **System Parameters** menu.

Each message window contains a short description of the problem and information on how to correct it. In some cases, problems are described with the aid of illustrations.

Each display message is identified by a number in the lower left-hand corner. If a problem cannot be corrected, this number will enable service support to provide faster assistance.

5.7 Messages during the functional test

Note

If the functional test repeatedly fails to complete successfully, the available treatment options may be restricted until the error can be corrected. Always contact service support in this case.

If the battery test is failed, no treatment will be permitted by the device.

If the battery test detects an incompletely charged battery, the device will allow a treatment to be performed. However, in the event of a mains power failure, emergency operation may be even more restricted than usual.

If the test of the **Ambient temperature sensor** is failed and treatment is started regardless, the heater performance can be significantly diminished, as only default values can be used. Additional, external heating and heat monitoring measures must be taken in this case.

If the heparin pump test fails, the heparin pump can be deactivated for the entire treatment if this can be managed without heparin anticoagulation.

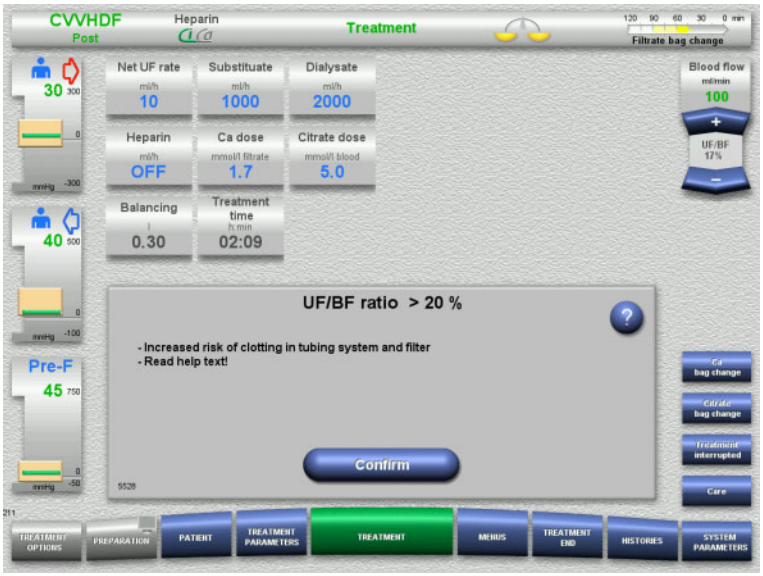
5.8 UF/BF message

Note

High filtrate rates in combination with low blood flow rates may lead to an inadequate concentration of blood in the haemofilter (massive increase of the TMP). To a great extent, the blood concentration required depends on the individual filter. For this reason, there is a general risk of clotting in the capillaries.

To avoid this reaction, it is advisable to keep the UF rate for postdilution to no more than 20 % of the blood flow rate.

If an inadvisable UF/BF ratio of over 20 % is set, the UF/BF ratio display changes from green to red.



If this message is simply confirmed with the **Confirm** button, this indicates that the operator accepts this imbalance, along with the possible resultant clotting in the filter and tubing system.

It is advisable to correct this imbalance by changing the parameters.

5.9 Ratio of calcium flow to filtrate flow

The calcium flow rate is calculated by the system depending on the filtrate flow (sum of the dialysate flow, substituate flow, net UF rate, citrate flow and calcium flow), or “filtrate” for short, the set calcium dose, and the concentration of the calcium solution used, which is defined in the Setup. The calcium flow is limited by the control range of the calcium pump.

Control range of the Ca pump: 1–100 ml/h.

If the settings of the various different flow rates in combination with the required calcium dose result in a calcium flow rate that is outside the pump control range, a message will be displayed.

In this case, the operator must adjust the filtrate flow accordingly, by modifying the dialysate and/or substituate flow and, if necessary, altering the calcium dose.

Note

If the modifications performed are inadequate for bringing the calcium flow rate back within the control range of the calcium pump, the message will be repeated after some seconds.

If a calcium flow rate message is ignored and simply confirmed, the calcium pump will be operated at the maximum or minimum possible rate, depending on whether the calcium flow is too high or too low.

The message will then be repeated after no more than 2 minutes.

5.10 Ratio of citrate flow to blood flow

The citrate flow rate is calculated by the system depending on the set citrate dose, the set blood flow, and the concentration of the citrate solution used (defined in the Setup), and is limited by the control range of the citrate pump.

Control range of the citrate pump: 10–600 ml/h

If the initial settings result in a citrate flow outside the pump control range, a message will be displayed.

In this case, the operator must adjust the blood flow or, if necessary, alter the citrate dose to continue treatment.

Note

If the modifications performed are inadequate for bringing the citrate flow rate back within the control range of the citrate pump, the message will be repeated after some seconds.

If a citrate flow rate message is ignored and simply confirmed, the citrate pump will be operated at the maximum or minimum possible rate, depending on whether the citrate flow is too high or too low.

The message will then be repeated after no more than 2 minutes.

5.11 Ratio of plasma rate to blood flow

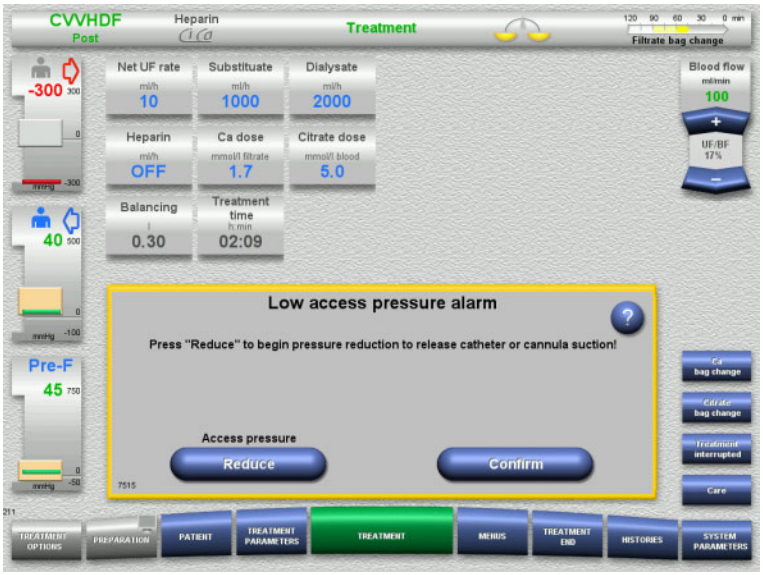
Note

High plasma rates in combination with low blood flow rates may lead to an inadequate concentration of blood in the haemofilter (massive increase of the TMP). This concentration of the blood depends on the respective filter used. For this reason, there is a general risk of haemolysis and clotting in the capillaries.

To avoid this reaction, the plasma rate can only be set to a maximum of 30 % of the blood flow.

5.12 Pressure deviation messages

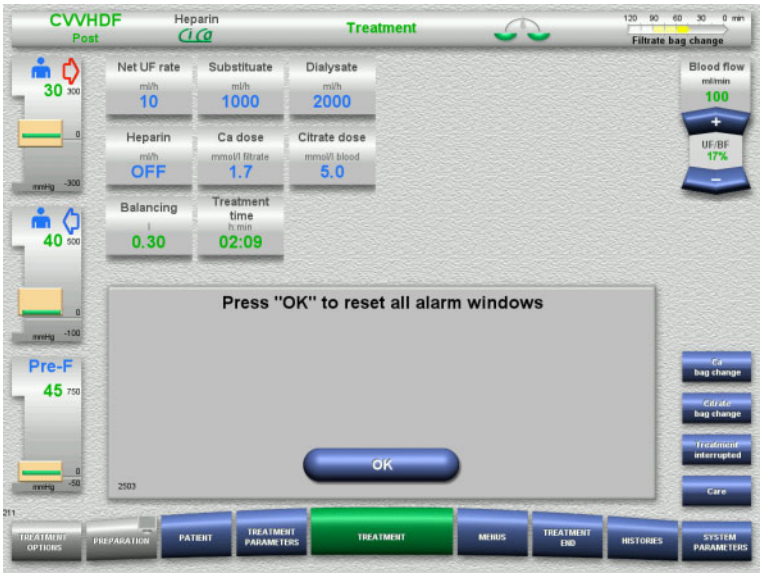
5.12.1 Resetting the alarm limit windows



The actual pressure value lies outside the alarm limit window.

An audible tone is emitted.
The system is stopped.

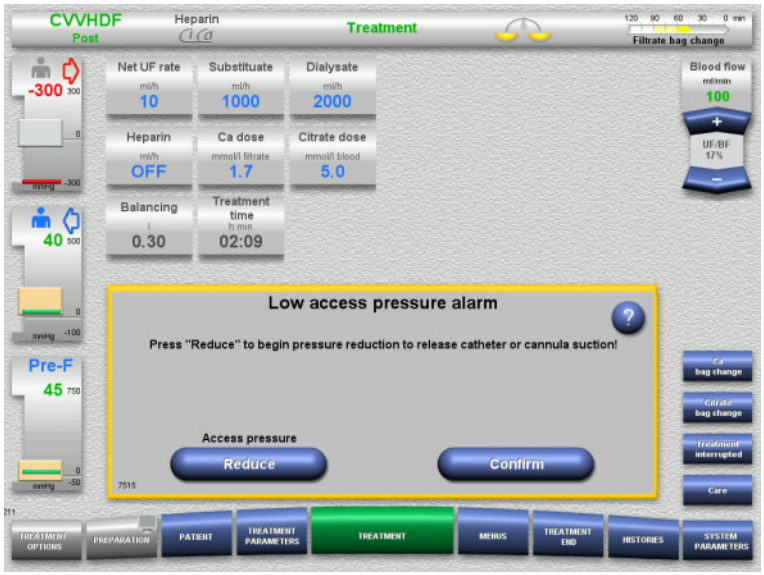
➢ Press **Confirm** to continue with the treatment.



➢ Press **OK** to reset all the alarm limit windows.

The size and position of the limit value windows will be applied.
If the alarm limit windows are not reset, this message will erase itself, and the previous alarm limit windows will be kept as they were.

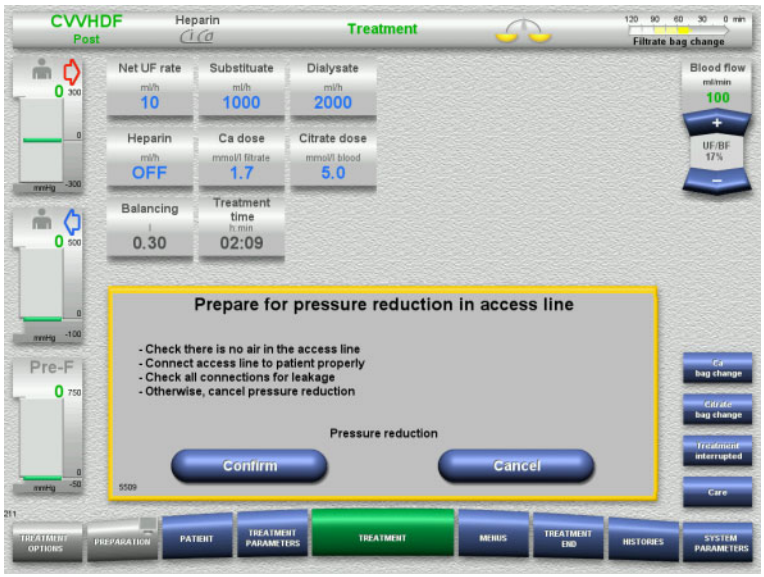
5.12.2 Reducing the access pressure



If a low access pressure alarm occurs due to an occlusion of the catheter or needle (suction to the vessel wall), the access pressure can be relieved automatically.

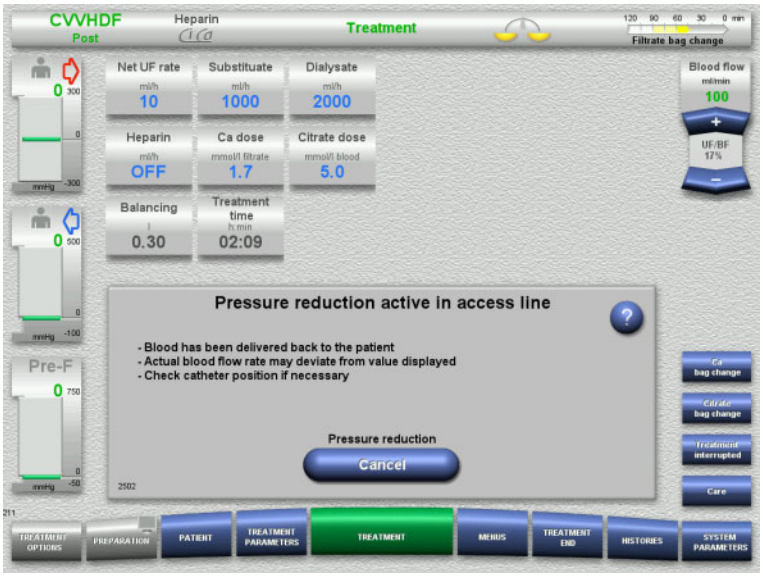
➢ Press the **Reduce** key to start the pressure reduction.

If the pressure has already been equalised due to the blood pump stopping, the **Confirm** button can be pressed to continue treatment.



➢ After making sure the access line is free of air, start the pressure reduction by pressing the **Confirm** button.

Press **Cancel** to cancel the process.



Treatment is resumed when the pressure reduction has been completed.

The process can be cancelled at any time by pressing **Cancel**.

5.13 Message “Air detected downstream of the bubble catcher”

5.13.1 Before beginning deaeration procedures

Warning

Risk of air embolism as a result of air in the tubing system

If deaeration procedures are not performed properly, this can lead to air infusion.

➢ Deaeration procedures must always be carried out in accordance with the instructions displayed by the device. The operator is responsible for following the instructions correctly.

➢ In addition, observe the following when performing deaeration procedures:
- Read the detailed descriptions of the messages by pressing the **?** button in each case.
- If the return pressure exceeds 40 mmHg, the pressure must first be reduced at the bubble catcher with the aid of a syringe until the device displays the next message with further instructions.
- While deaeration procedures are in progress, the blood flow rate is automatically lowered to 50 ml/min. To speed up the process of purging air pockets and microbubbles from the tubes, the blood flow rate can be raised as necessary.

5.13.2 Air detected

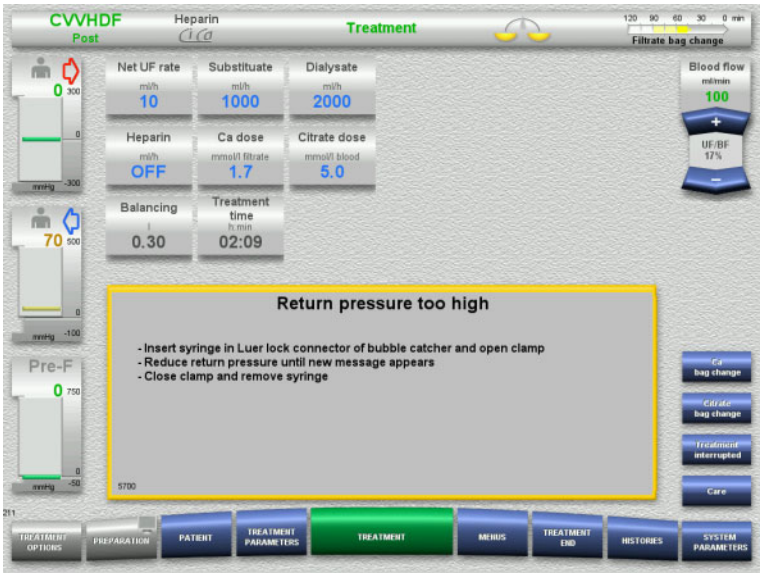
If air is detected in the return line downstream of the bubble catcher, this is indicated by an audible tone and a screen message.

Balancing is switched off.
The blood pump is stopped.

➢ Press **Confirm** to confirm that you have followed the instructions in the message.

5.13.3 Deaeration procedures

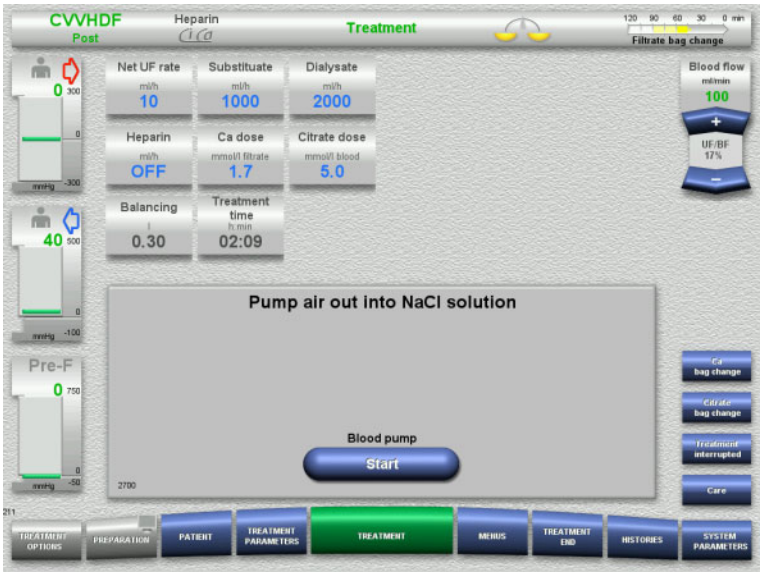
➢ Press **Confirm** in the confirmation prompt.



This message appears if the return pressure exceeds 40 mmHg.

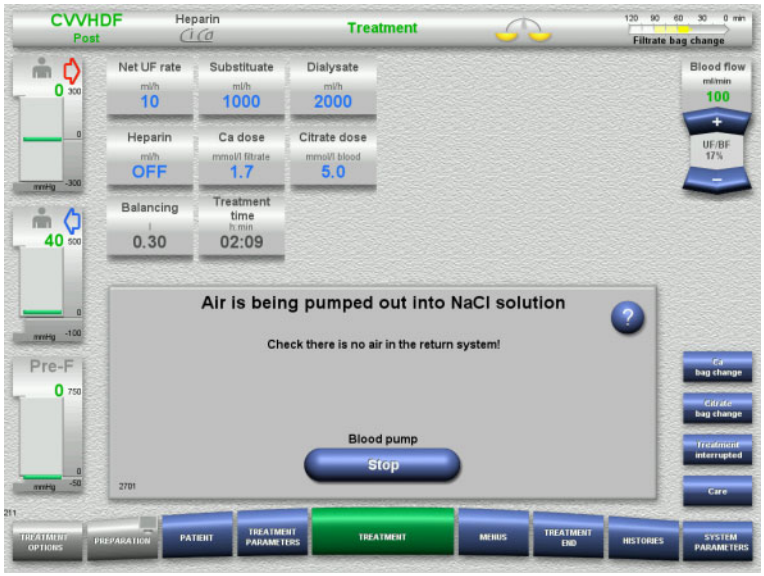
➢ Follow the instructions.

The next message appears automatically as soon as the return pressure has fallen below 40 mmHg.



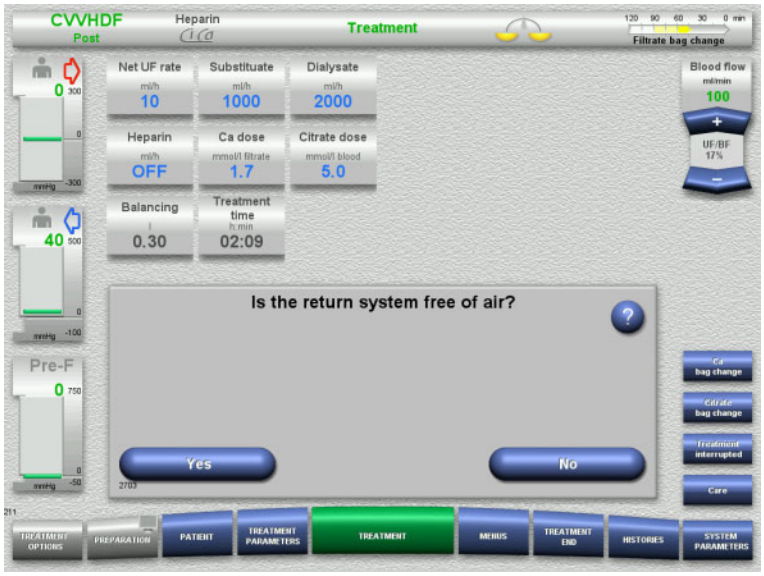
➢ Press **Start** to push the air out into the NaCl solution.

The blood pump is running at 50 ml/min.



Blood pump stops automatically after 100 ml.

The blood pump can also be stopped before reaching the 100 ml by pressing the **Stop** button, if the operator can no longer see any air in the system.

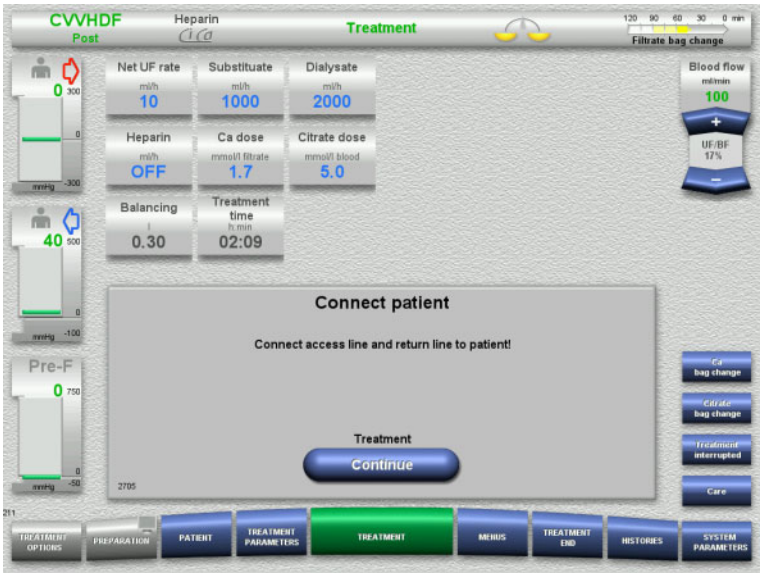


➢ Press **Yes** to confirm that the system is free of air.

Or

➢ Press **No** to continue removing any remaining air bubbles.

The previous message is automatically displayed.



➢ Connect the patient.

➢ Press the **Continue** button to resume the treatment.

The blood pump will run at the rate set previously.

➢ Check the blood pump rate and adjust it as necessary.

5.14 Message “Microbubbles detected downstream of bubble catcher”

5.14.1 Before removing the microbubbles

Warning

Risk of air embolism as a result of air in the tubing system

➢ While bypassing the monitoring system of the air bubble detector, the operator is responsible for the patient’s safety.

Warning

Risk of air embolism as a result of air in the tubing system

If deaeration procedures are not performed properly, this can lead to air infusion.

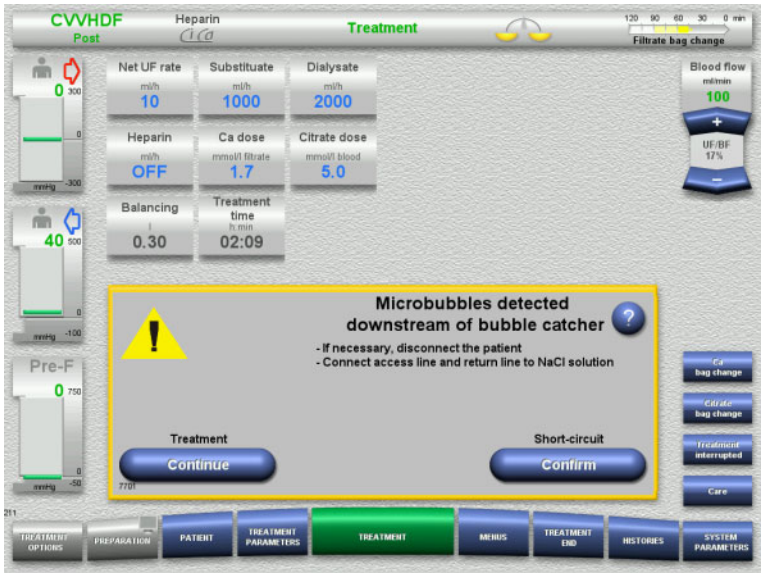
➢ Deaeration procedures must always be carried out in accordance with the instructions displayed by the device. The operator is responsible for following the instructions correctly.

➢ In addition, observe the following when performing deaeration procedures:
- Read the detailed descriptions of the messages by pressing the **?** button in each case.
- If the return pressure exceeds 40 mmHg, the pressure must first be reduced at the bubble catcher with the aid of a syringe until the device displays the next message with further instructions.
- While deaeration procedures are in progress, the blood flow rate is automatically lowered to 50 ml/min. To speed up the process of purging air pockets and microbubbles from the tubes, the blood flow rate can be raised as necessary.

5.14.2 Microbubbles detected

Note

The message can be bypassed up to 3 times in the course of a treatment, by pressing **Continue**. If microbubbles continue to be detected, deaeration procedures must be performed.



If microbubbles are detected in the return line downstream of the bubble catcher, this is indicated by an audible tone and a screen message.

➢ If there are **no microbubbles** to be seen, press the **Continue** button.

Or

➢ If there are microbubbles, follow the instructions and press **Confirm** when you have finished.

➢ Perform deaeration procedures (see Chapter 5.13.3 on page 227).

5.15 Blood leak

Warning

Risk for the patient due to haemolysis or blood loss / risk of blood loss due to bypassed blood leak detector

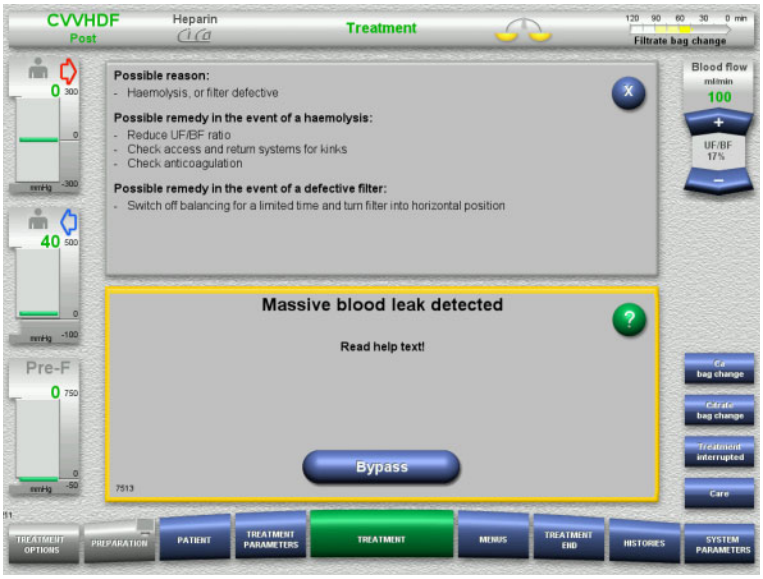
When the blood leak safety system is bypassed, monitoring for haemolysis or blood loss is deactivated temporarily or for the entire treatment.

➢ In this case, the operator is responsible for the patient's safety.

➢ Especially when treating permanently haemolytic plasma, look for additional dark colouration in the plasma circuit in the event of a blood leak.

Note

If the message **Blood leak detected** is pending, the treatment option TPE allows you to deactivate the safety system. This means that monitoring for haemolysis and blood leaks is cancelled for the duration of the current treatment. The safety system is reactivated when the device is switched on again (see Chapter 4.7.15 on page 188).



If the blood leak detector (yellow) detects blood in the filtrate line, this is indicated by an audible tone and a screen message.

Balancing is switched off.
All pumps are stopped.

➢ Press the **Bypass** button to continue treatment.

The bypass time for the blood leak detector message is 2 minutes.
1 minute, in the case of a massive blood leak.

➢ Read the help text and follow the instructions. Terminate the treatment if necessary.

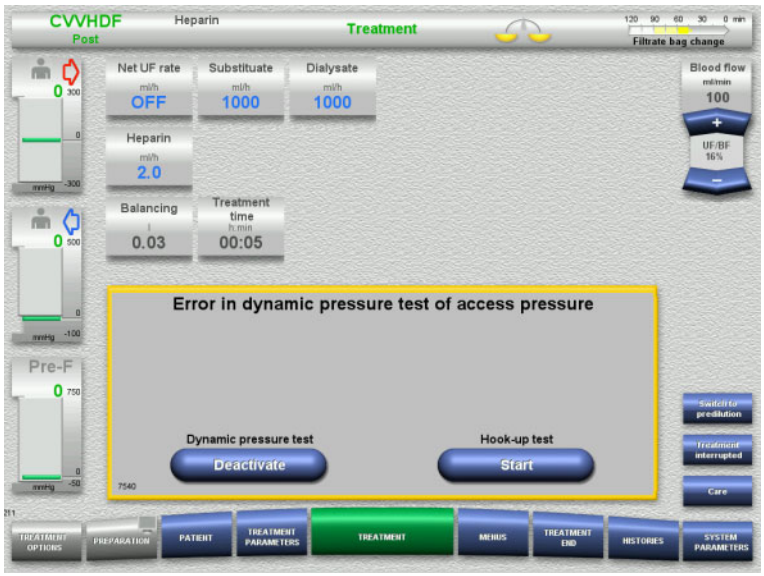
5.16 Dynamic pressure test, return/insertion line

Warning

Blood loss / risk of blood loss if dynamic pressure monitoring is deactivated
Plasma loss / risk of plasma loss if dynamic pressure monitoring is deactivated

If the dynamic pressure monitoring safety system is deactivated, the monitoring for dislocation of the patient lines is deactivated.

- ➢ In this case, the operator is responsible for the patient's safety
- ➢ Increasing the blood flow
- ➢ Changing the return pressure line
- ➢ Raising the level in the bubble catcher



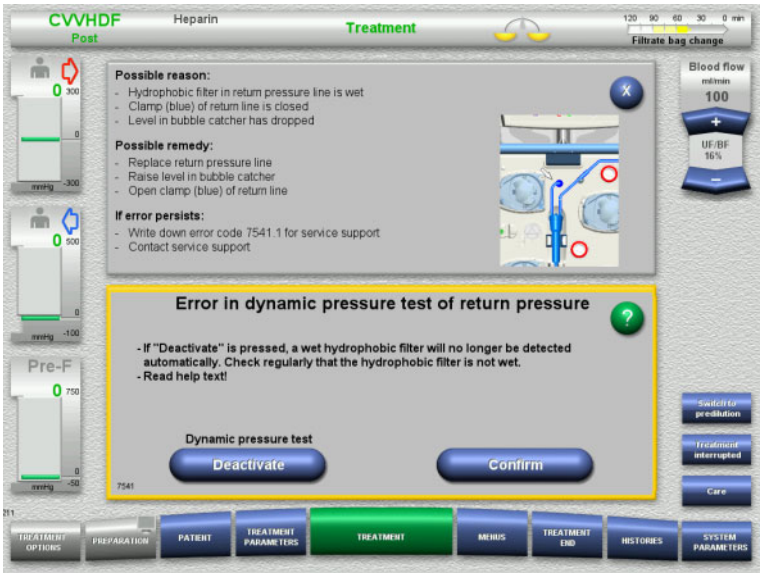
If the dynamic pressure test of the insertion line becomes impossible because the delivery rates are too low, this is indicated by an audible tone and a message.

Balancing is switched off.

- ➢ Press the **Start** button to start the hook-up test.

Or

- ➢ Press the **Deactivate** button to deactivate the insertion line dynamic pressure test.



If the dynamic pressure test of the return line becomes impossible because the delivery rates are too low, this is indicated by an audible tone and a message.

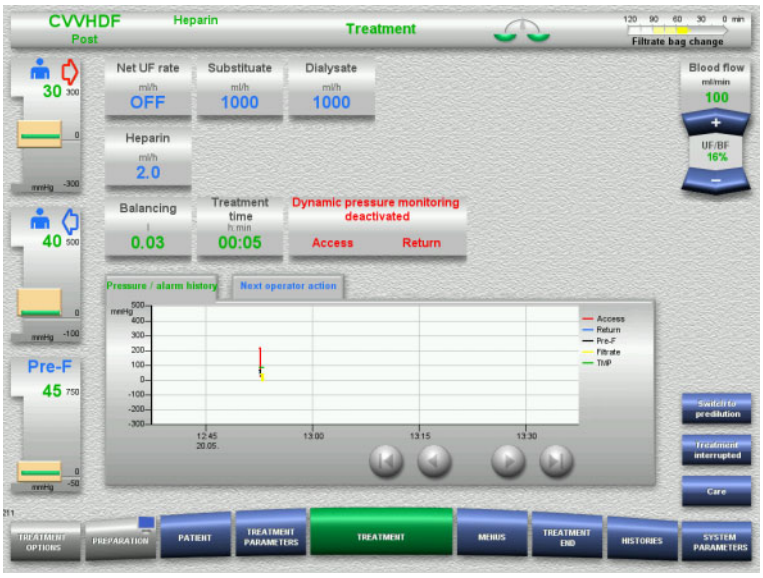
Balancing is switched off.

➢ Read the help text and adjust the delivery rate if necessary.

➢ Press the **Confirm** button to continue.

Or

➢ Press the **Deactivate** button to deactivate the return line dynamic pressure test.



The dynamic pressure test is displayed as deactivated on the treatment screen.

The dynamic pressure test of the insertion/return line is automatically reactivated when it becomes possible again.

5.17 Power failure (mains power failure)

5.17.1 During preparation

- **Tubing system not yet mounted**

  If a power failure occurs before the tubing system has been mounted, the device will shut down without delay.

- **Tubing system is mounted**

The **Mains power failure** message will be displayed.
The system is stopped completely.

When power is restored, the message **Voltage supply restored** must be confirmed by pressing the **Confirm** button.

5.17.2 During treatment

Note

If the battery test detected an incompletely charged battery, emergency operation following a power failure may be even more restricted than usual.

The **Mains power failure** message will be displayed.
An audible tone is emitted (without delay).
Balancing is switched off.
The blood pump is running.
Anticoagulation is switched on.
The heater is switched off.

If the blood pump is running, emergency operation is possible for a maximum of 15 minutes.

The message is repeated every 2 minutes and must be confirmed by pressing the **Confirm** button.

When power is restored, the system will start automatically.

When the 15 minutes have expired, or if the battery has less than minimum power remaining, the blood pump is stopped and cannot be started again until power is restored.

After a further 5 minutes, or if the minimum battery power is depleted even further, the device will shut down.

In this case, terminate the treatment with manual blood reinfusion, if necessary (see Chapter 5.19 on page 236).

5.18 Display failure

Screen goes dark or menu buttons no longer respond.

Warning

Risk for the patient as a result of a device malfunction

Treatment cannot be performed safely in the event of a display failure, as the device cannot be operated any longer.

➢ Press the **Stop Pumps** button (red).
The pumps will be stopped.

➢ Perform a manual blood reinfusion (see Chapter 5.19 on page 236).

5.19 Manual blood reinfusion

Warning

Risk of air embolism as a result of air in the tubing system

If the manual blood reinfusion is not performed properly, this can lead to air infusion.

➢ The following must be observed when performing a manual blood reinfusion:

– Turn the emergency operation hand crank of the blood pump only in the direction indicated by the arrow, to avoid the risk of air infusion via the access line.

– Visually check that return line is free of air, to avoid the risk of air infusion.

Warning

Risk of blood loss and risk of air embolism as a result of manual blood reinfusion

➢ The instructions for performing a manual blood reinfusion must be strictly followed.

➢ Disconnect the access line from the patient and connect it to the NaCl solution. Break the cone, if necessary.

➢ Remove the access and return lines from their respective line occlusion clamps.

➢ To return the blood to the patient, use the hand crank integrated in the pump rotor.

Turn only clockwise, as shown on the rotor.

➢ Keep visually checking that the tube is free of air.

5.20 Manually opening the pressure measurement units

Warning

Risk of blood loss as a result of damaged tubing systems

➢ Before manually opening the pressure measurement units, the pressure in the tubing system will need to be reduced at the bubble catcher, with the aid of an empty syringe.

The pressure measurement units will need to be manually opened to remove the tubing system in the following situations:

– Power failure and empty battery
– Defective pneumatics

In this case, terminate the treatment with manual blood reinfusion, if necessary (see Chapter 5.19 on page 236).

Requirements

– Syringe
– Emergency venting set
  Adapter
  Check valve

➢ Use the adapter to connect an empty syringe to the Luer lock connector on the rear of the device.

➢ Repeatedly build up pressure with the aid of the syringe, until the pressure measurement units open.

6 Cleaning / disinfection

Warning

Risk of cross-contamination as a result of insufficient disinfection

Risk of contamination as a result of insufficient disinfection

There is a risk of spreading germs.

➢ A surface disinfection must always be performed after each treatment.

➢ Disinfections of the device must be performed according to the instructions in the Instructions for Use. If unsuitable procedures are followed, effective disinfection or cleaning is not possible.

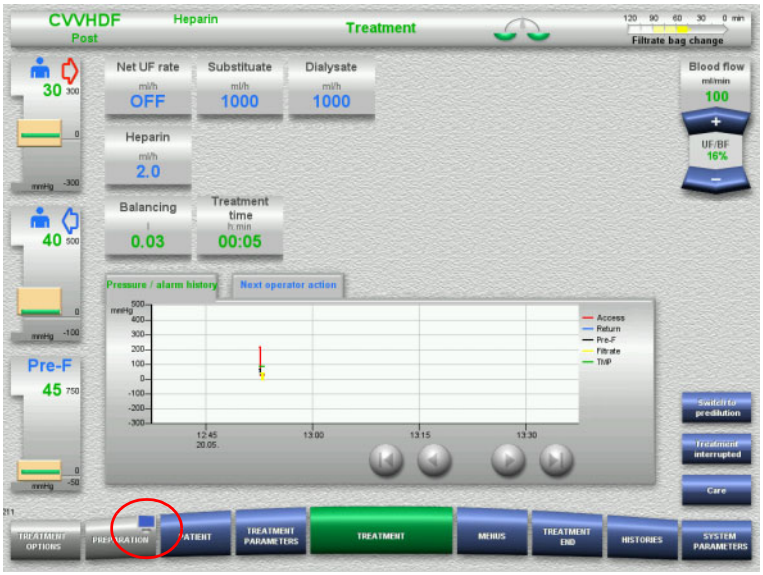
➢ Only the disinfectants and cleaning agents listed in Chapter 6 must be used.

6.1 Surface cleaning / surface disinfection

Switch the device off and disconnect it from any external power sources before cleaning and disinfection. A surface disinfection must always be performed after each treatment. Make sure that the area around sensors and actuators is clean to avoid an impairment of the functions.

Dirt, for example, blood and filtrate, must be removed immediately with a disposable paper towel dampened with disinfectant. The surface must then be disinfected a second time by wiping or spray disinfection. Do not use any sharp objects for cleaning.

6.1.1 Cleaning the display



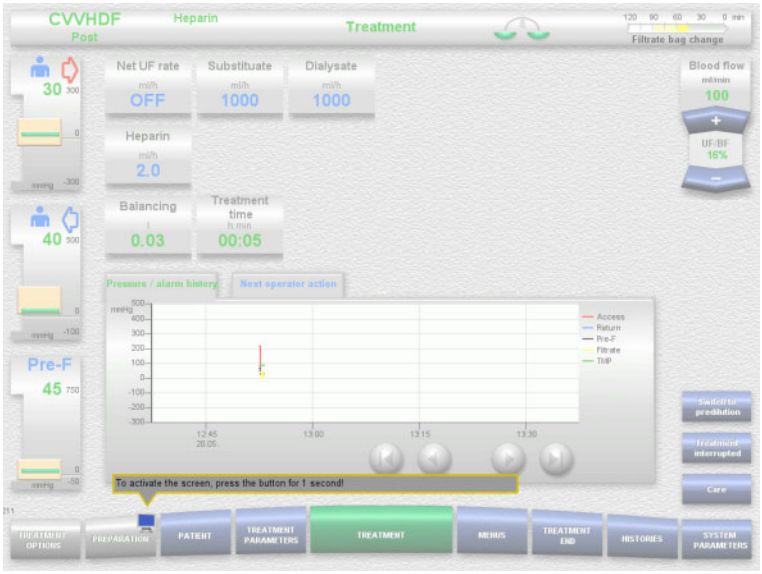
➢ Press the **monitor symbol** on the **PREPARATION** button for approximately 3 seconds.

This “deactivates” the display.

➢ Clean the display.

Note

The “deactivated” display will automatically become active once more as soon as a message is displayed.



➢ Press the **monitor symbol** on the **PREPARATION** button for approximately 1 second.

This “reactivates” the display.

6.1.2 Detachable device components

The following device components can be detached for easier cleaning:
– Pump rotors (blood pump, dialysate pump, substituate pump, filtrate pump)
– Scale trays

6.2 Disinfectants and cleaning agents

The following disinfectants have been tested for use on the device. The recommended applied concentrations correspond to the specifications of the manufacturers of the disinfectants at the time of publishing these Instructions for Use. Always check the application concentration against the current product information of the disinfectants.

Incidin Extra N

Active substance base: aldehyde-free preparation
Disinfection type: wipe disinfection
Applied concentration: 1 % in water
Acting time: 15 min

ClearSurf

Active substance base: cationic surfactants
Disinfection type: wipe disinfection
Applied concentration: 0.5 % in water
Acting time: 60 min
Applied concentration: 1 % in water
Acting time: 15 min

ClearSurf Wipes

Ready-to-use wipes
Active substance base: cationic surfactants
Disinfection type: wipe disinfection
Applied concentration: 1 % in water
Acting time: 15 min

Freka-NOL

Active substance base: ethanol
Disinfection type: wipe disinfection
Applied concentration: undiluted
Acting time: 1 min
Recommended use: Freka-WIPES disposable cloths soaked with Freka-NOL in their dispenser.

7 Functional description

Make sure to read the medical information
(see Chapter 2.6 on page 20) before reading this chapter.

7.1 Device functions

Extracorporeal blood circuit

The device features a pump-controlled extracorporeal blood circuit. The extracorporeal blood circuit is monitored during treatment.

Balancing

Roller pumps are used to convey the filtrate, substituate, dialysate, plasma, and rinsing solutions, depending on the procedure.
The balancing is gravity-controlled using integrated scales with which each of the fluids necessary for a treatment are weighed.
The two integrated heaters control the set treatment temperature across the entire flow range. This can be selected in the relevant menus.

Handling

Treatment parameters and menu buttons are displayed on a large screen. The device is operated with a touchscreen, e.g., for selecting fields displayed on the screen.

Functional test

As soon as it is switched on, the device performs an automatic functional test of all operating, display, monitoring, and alarm functions to ensure their proper operation. Some of these tests are repeated at intervals during treatment.

Anticoagulation

The device contains a syringe pump intended for heparin infusion as well as citrate and calcium pumps to realise regional citrate anticoagulation.

During a Ci-Ca treatment a corresponding amount of calcium is removed from the patient's blood. For this reason, a calcium substituate is infused into the return line by the integrated calcium pump.

7.2 Description of therapies

7.2.1 Continuous renal replacement therapy

The different continuous renal replacement therapies (CRRT) can be indicated whenever the removal of urinary excreted substances and/or volume removal is required. This also applies if electrolyte imbalances or disorders of the acid-base balance are to be corrected and can encompass application in certain intoxications where the toxin is permeable through the haemofilter membrane.

Vascular access

The CRRT therapies use a veno-venous vascular access, i.e., blood is both removed from and, after treatment, reinfused into a vein of the patient. Usually a large-bore central venous double-lumen catheter is used for the vascular access.

Net ultrafiltration

Net ultrafiltration is prescribed according to clinical needs. It provides a small contribution to total CRRT dose.

CRRT modes

The device offers continuous veno-venous haemodialysis (CVVHD) and continuous haemofiltration (CVVH). CVVH can be performed as predilution CVVH (Pre CVVH for short) or as postdilution CVVH (Post CVVH for short). In addition, the device also supports CVVH with both pre-filter and post-filter dilution (Pre-post CVVH for short). Finally, the device offers the possibility of a combined haemofiltration and haemodialysis procedure (CVVHDF). Depending on where the substituate is infused into the extracorporeal circuit, there are two types of CVVHDF procedure (Pre CVVHDF and Post CVVHDF for short). The type of CRRT procedure and the patient-specific parameters are individually prescribed by the attending physician in each case.

Effectiveness of CRRT therapies / filtrate flow

The effectiveness of a CRRT depends on the molecular mass of the substances to be removed. The prescription parameters must be selected specifically for each procedure and directly affect the effectiveness of the treatment. Solute clearance must result from the diffusion or convection mechanisms applied, or a combination of both. Delivered CRRT dose may be lower than prescribed CRRT dose due to e.g. treatment interruptions. This should be considered when prescribing CRRT dose.

The main prescription parameters for a CRRT treatment are as follows:
- Blood flow
- Dialysate flow
- Ultrafiltration goal or continuous net UF rate
- Substituate flows, for haemofiltration or haemodiafiltration
- Dialyser/haemofilter choice (e.g. the effective surface area and the membrane permeability, among other attributes)

The overall prescribed filtrate flow results from the sum of all flow rates and the desired net ultrafiltration rate. This value is indicated by the multifiltratePRO as filtrate flow.

Haemofilters

For all CRRT modes using the multiFiltratePRO, the use of a sufficiently large high-flux haemofilter is recommended that provides clearance at the required level for the chosen CRRT mode and over the required filter life, also when CVVHD is chosen as the CRRT mode (e.g. AV 600 S, AV 1000 S).

Clotting risk in CRRT therapies

The risk of clotting in the extracorporeal blood circuit differs according to the individual CRRT procedures. With a diafiltration procedure using postdilution, there is a haemoconcentration of the blood at the filter outlet, depending on the ratio of the filtrate flow to the blood flow and on the patient's haematocrit. This is assumed to be the reason for the shorter service lives of the filters in Post CVVH compared to Pre CVVH.

7.2.1.1 CVVH

Post CVVH

Postdilution refers to when the substituate is infused downstream of the filter after the ultrafiltrate has been removed. As a consequence, the blood at the filter outlet has a higher concentration of cells and proteins (haemoconcentration). This can increase the risk of clotting in the extracorporeal blood circuit. To avoid a critical haemoconcentration, the haemoconcentration at the filter outlet (UF/BF ratio) should not be set at more than 30 %, taking the treatment parameters determined by the physician into account.

Pre CVVH

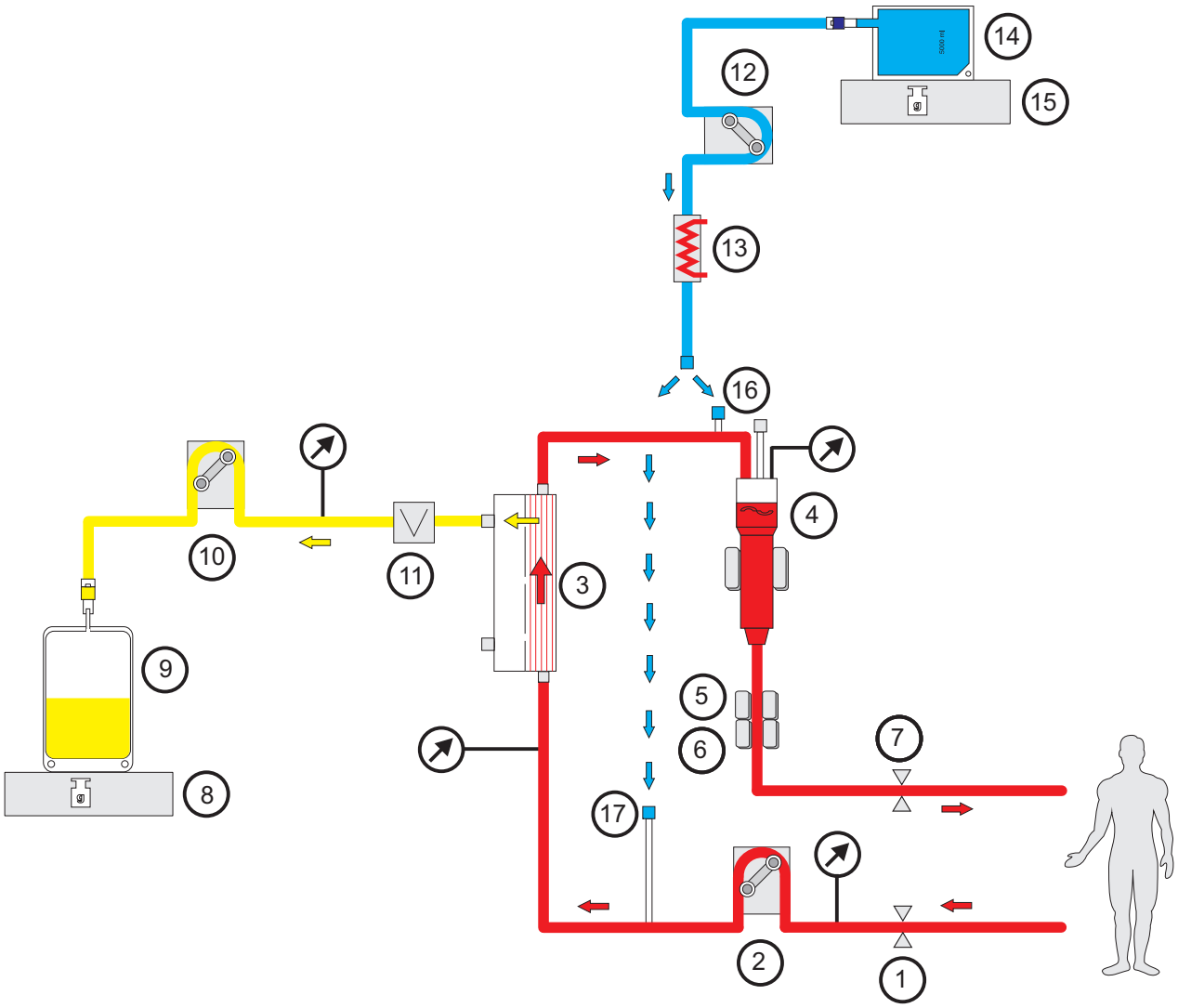
Predilution involves the substituate being infused into the extracorporeal circuit upstream of the filter, thereby reducing the risk of a critical haemoconcentration. There is, however, a disadvantage to this process, which is that diluted blood enters the filter. This means that the concentration of toxins is lower, so fewer toxins are removed per litre of ultrafiltrate than would be removed through Post CVVH. The same volume of substituate used in predilution is less effective than postdilution. The disadvantage caused by this dilution can be reduced by increasing the blood flow rate. Alternatively, It is always possible to select a different CRRT therapy.

Pre-post CVVH

Pre CVVH + Post CVVH => Pre-post CVVH

This reduces the disadvantages and combines the advantages of the separate procedures. Depending on the application conditions, the treatment can thus be optimised.

Fig.: Flow diagram of the different CVVH procedures



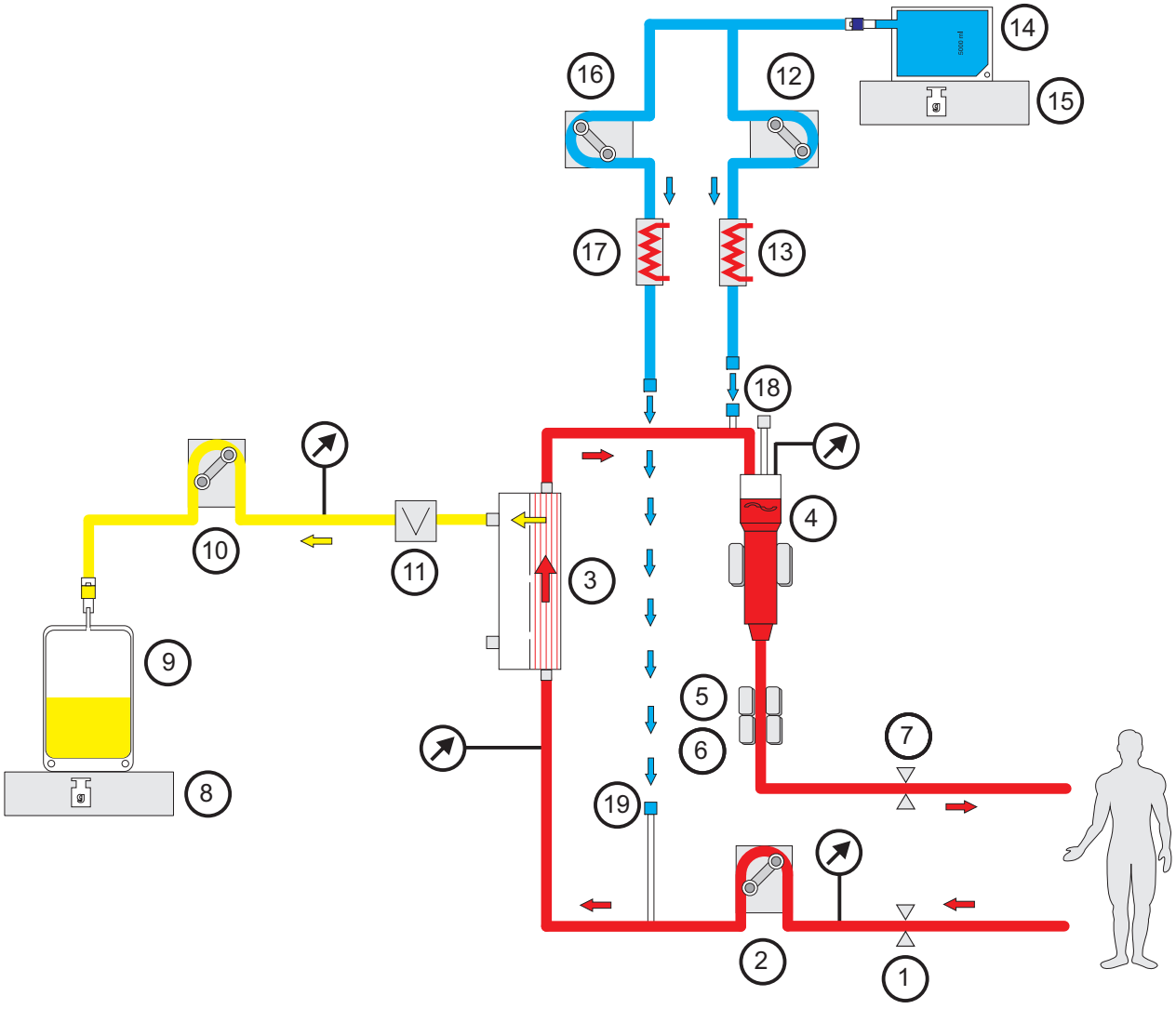
Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Substituate pump
13 Heater (white)
14 Substituate
15 Scale
16 Postdilution port
17 Predilution port

Treatment data

CVVH	Min.	Max.	Resolution	Unit
Blood flow	0	500	10	ml/min
Net UF rate	Off / 10	990	10	ml/h
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Anticoagulation bolus	Off / 0.1	5	0.1	ml
Substituate	600	4800	10	ml/h
Temperature	Off / 35	39	0.5	°C

Fig.: Pre-post CVVH flow diagram



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter

4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Postdilution substituate pump
13 Heater (white)
14 Substituate
15 Scale
16 Predilution substituate pump
17 Heater (green)
18 Postdilution port
19 Predilution port

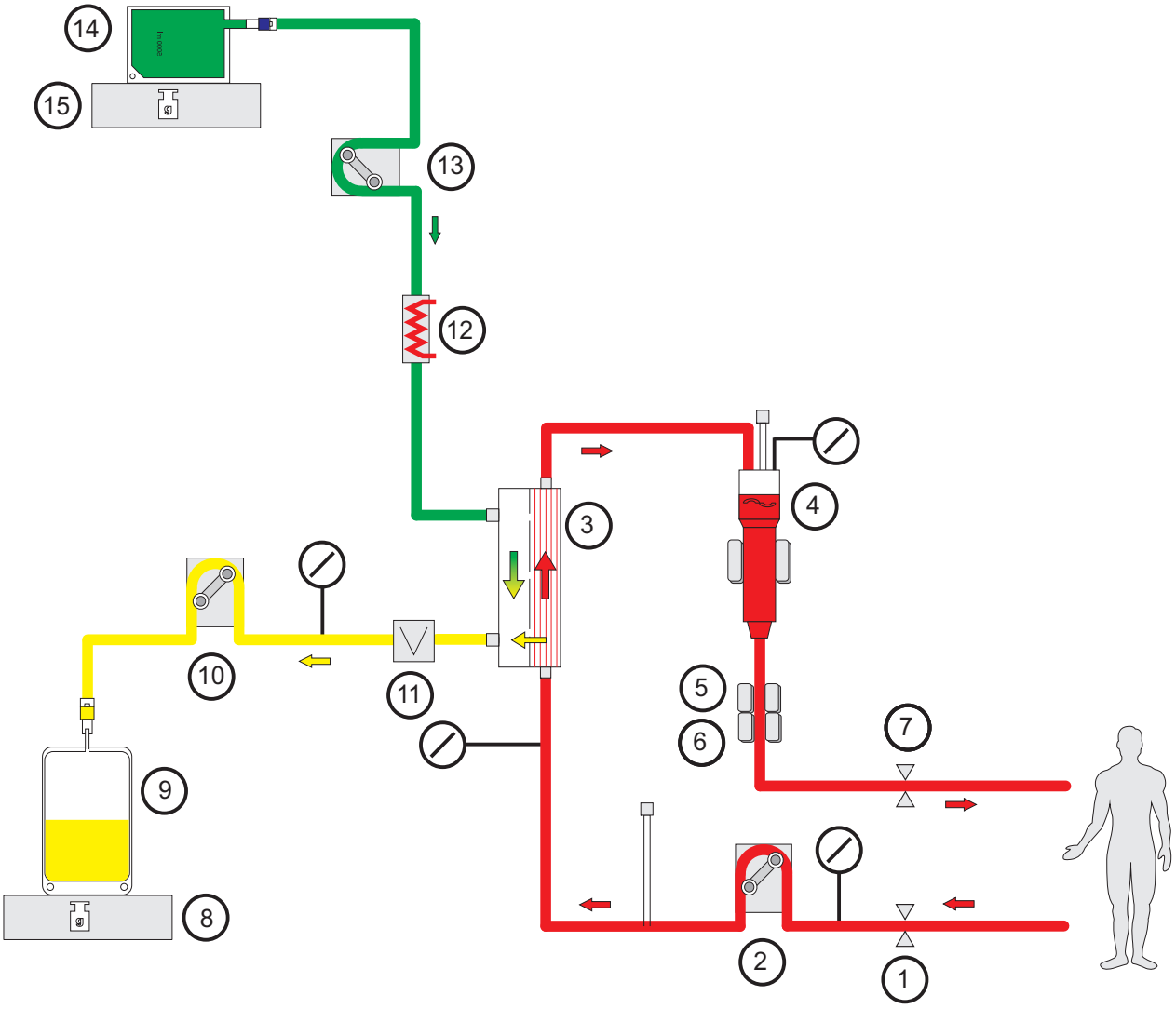
Treatment data

Pre-post CVVH	Min.	Max.	Resolution	Unit
Blood flow	0	500	10	ml/min
Net UF rate	Off / 10	990	10	ml/h
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Anticoagulation bolus	Off / 0.1	5	0.1	ml
Predilution substituate	600	4800	10	ml/h
Postdilution substituate	600	4800	10	ml/h
Temperature	Off / 35	39	0.5	°C

7.2.1.2 CVVHD

With CVVHD, the blood is purified mainly through dialysis. In addition to the diffusion, which mainly removes toxins during this procedure, convection also takes place. Under typical CRRT conditions, where the blood flow is considerably higher than the dialysate flow, an almost complete saturation of the dialysate with toxins of a low molecular weight, such as urea and creatinine, can normally be expected.
The efficiency of a CVVHD procedure is therefore comparable with that of a Post CVVH procedure. As the speed of diffusion depends on the molecular mass, the full saturation of the dialysate with larger, so-called middle-molecular weight solutes may not be achieved, depending on the blood and dialysate flows set and the filter used. The clearance rate achieved for these substances is thus lower than with Post CVVH (if the same dialysate and substituate quantities are used). This disadvantage of CVVHD can be compensated at least partially through the use of filters with a large active surface and High-Flux membranes. On the other hand, CVVHD can enable setting a lower blood flow than in Pre CVVH and Post CVVH.

Fig.: CVVHD flow diagram



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Heater (green)
13 Dialysate pump
14 Dialysate
15 Scale

Treatment data

CVVHD	Min.	Max.	Resolution	Unit
Blood flow with heparinisation	0	500	10	ml/min
Net UF rate	Off / 10	990	10	ml/h
Blood flow with Ci-Ca anticoagulation	0	200	10	ml/min
Citrate dose	2	6	0.1	mmol/l
Calcium dose	0	3	0.1	mmol/l
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Anticoagulation bolus	Off / 0.1	5	0.1	ml
Dialysate	600	4800	10	ml/h
Temperature	Off / 35	39	0.5	°C

7.2.1.3 CVVHDF

Combination of the basic therapies

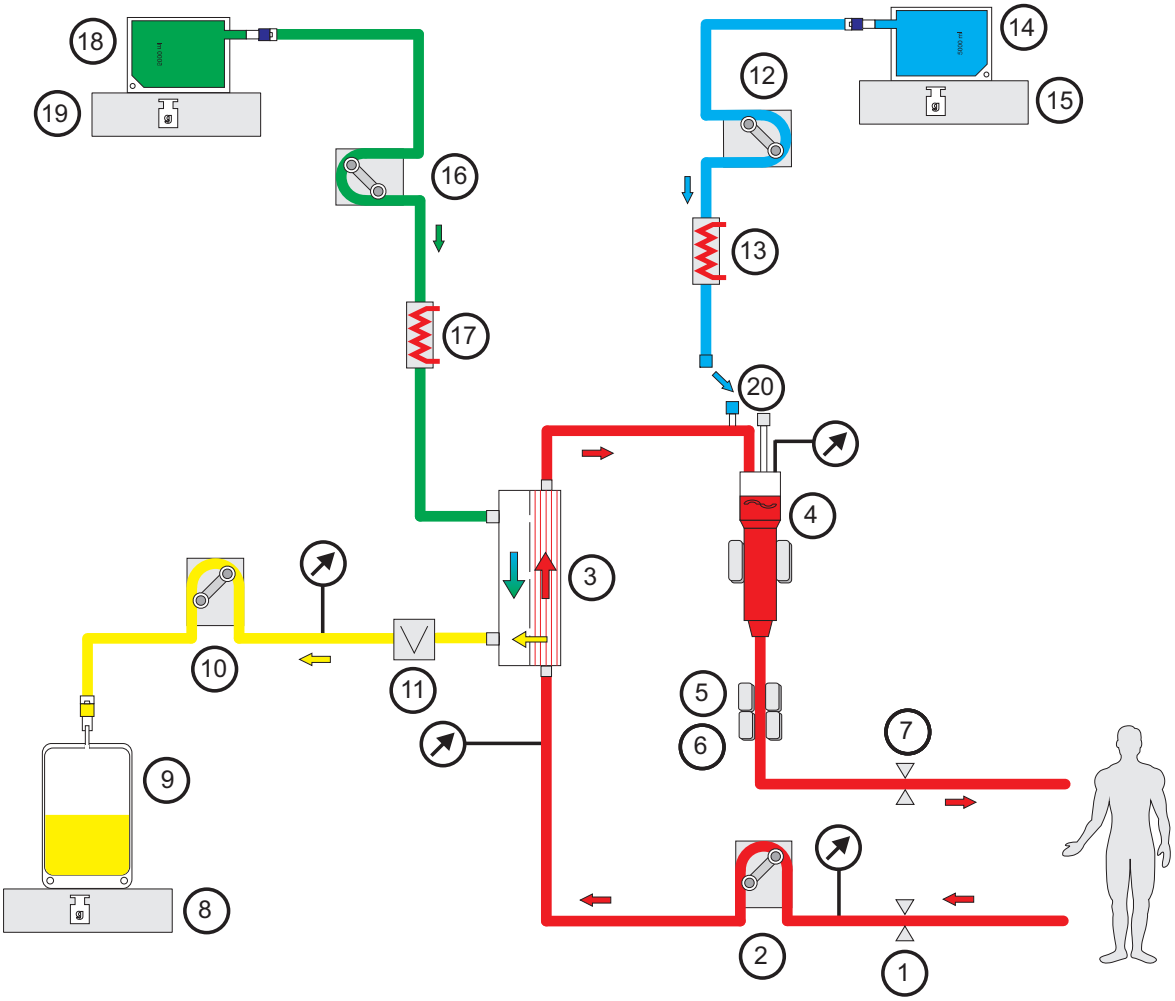
These basic therapies can be combined in pairs:

Pre CVVH + CVVHD => Pre CVVHDF

Post CVVH + CVVHD => Post CVVHDF

A part of the CRRT solution required for the targeted CRRT dose is applied as dialysate, which reduces the blood flow requirements compared to pure Pre or Post CVVH. Depending on the application conditions, the treatment can thus be optimised. For example, Post CVVHDF makes it possible to select the highest possible filtrate flow relative to the achievable blood flow in order to keep haemoconcentration in the filter within acceptable limits. The dialysis component of a Post CVVHDF procedure further increases treatment efficiency, typically without additional blood flow requirements, as the UF/BF ratio is not affected by this.

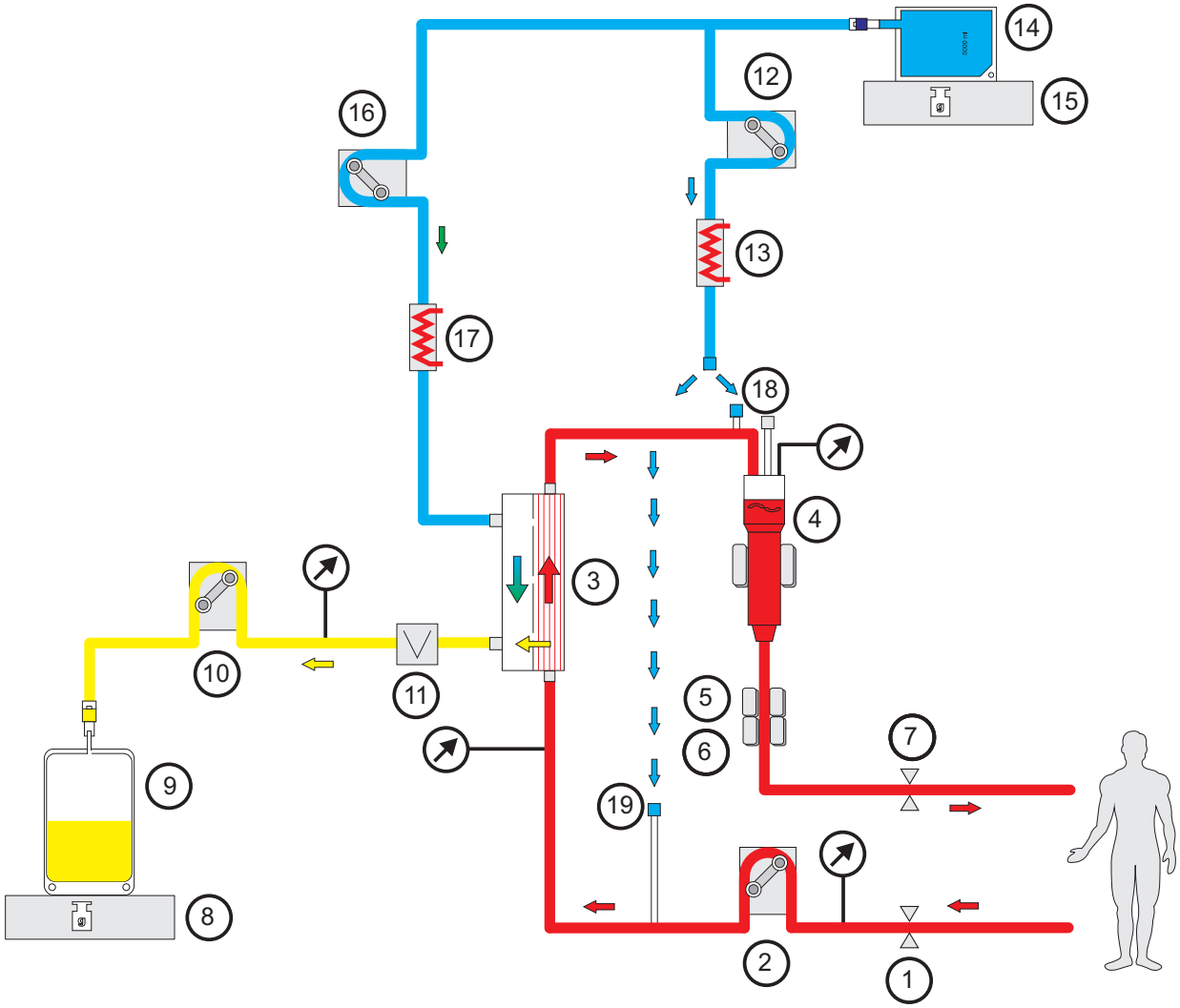
Fig.: Post CVVHDF (Ci-Ca) flow diagram



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Substituate pump
13 Heater (white)
14 Substituate
15 Scale
16 Dialysate pump
17 Heater (green)
18 Dialysate
19 Scale
20 Postdilution port

Fig.: Flow diagram of the different CVVHDF procedures



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Substituate pump
13 Heater (white)
14 Substituate / dialysate
15 Scale
16 Dialysate pump
17 Heater (green)
18 Postdilution port
19 Predilution port

Treatment data

CVVHDF	Min.	Max.	Resolution	Unit
Blood flow with heparinisation	0	500	10	ml/min
Net UF rate	Off / 10	990	10	ml/h
Blood flow with Ci-Ca anticoagulation	0	200	10	ml/min
Citrate dose	2	6	0.1	mmol/l
Calcium dose	0.1	3	0.1	mmol/l
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Anticoagulation bolus	Off / 0.1	5	0.1	ml
Substituate	600	4800	10	ml/h
Substituate with Ci-Ca anticoagulation	600	2400	10	ml/h
Dialysate	600	4800	10	ml/h
Temperature	Off / 35	39	0.5	°C

7.2.2 Therapeutic plasma exchange

General aspects

Therapeutic plasma exchange is a well-established extracorporeal blood purification technique either performed by centrifugation or membrane plasma separation. The device supports TPE application in the form of membrane plasma separation. The therapeutic effects of TPE may include the removal of pathological substances from the blood, such as monoclonal autoantibodies and paraproteins by exchanging plasma with a replacement fluid.

Extracorporeal blood circuit and balancing

The extracorporeal blood circuit in TPE differs only slightly from that in CRRT. The balancing circuit is basically structured the same as for Post CVVH. However, to ensure gentle warming of the replacement solution, which may be donor plasma, there are two heater bags connected in series to minimise risks due to local overheating of the plasma. Further, there is an adapted TMP and blood leak monitoring.

Plasma filters

In TPE, filters with a particularly permeable membrane are used that are permeable for all plasma components, but not the cellular components of the blood and are therefore known as plasma filters.
In TPE, the plasma including the components to be removed is filtered off and a suitable replacement solution is infused using gravimetric balancing.

Replacement solution

Removed plasma must be replaced with either fresh frozen plasma (FFP) or iso-oncotic colloidal replacement solutions (e.g. albumin solutions) to compensate the loss of colloido-osmotically active proteins in the blood.

As one option, an iso-oncotic human albumin solution can be used. A lack of coagulation factors (e.g. hypofibrinogenaemia) or other essential plasma components occurring independently or as a result of plasma exchange can be counteracted by using fresh frozen plasma (FFP) in whole or in part (then preferably towards the end of treatment) as a replacement solution. The device enables precise isovolaemic replacement.

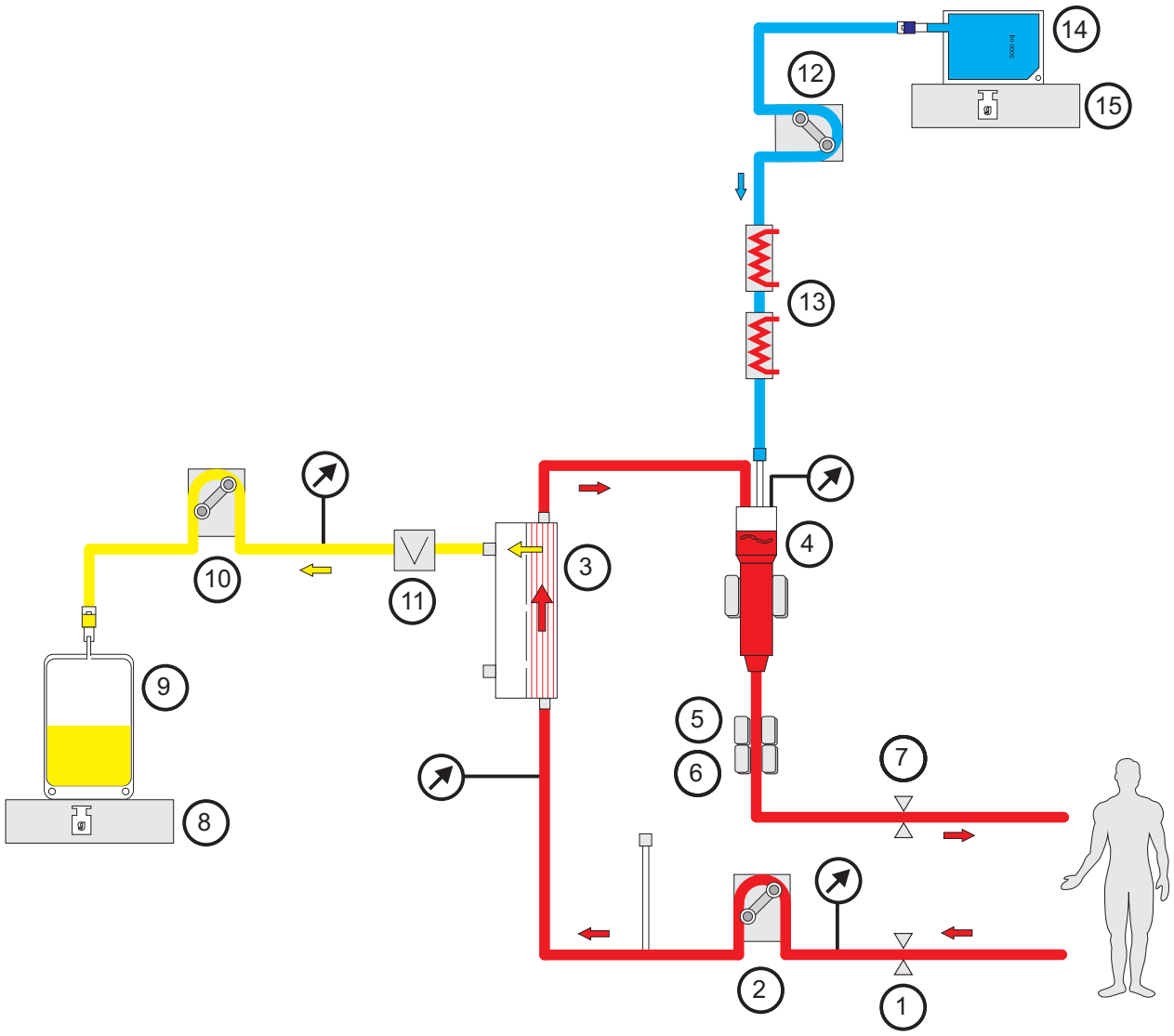
In some cases, such as thrombotic thrombocytopenic purpura (TTP), in addition to the removal of pathological plasma components, the infusion of all plasma components with the replacement solution is an essential part of the treatment. In such cases, plasma-based products generally are suitable replacement solutions, e.g., FFP.

Dosage

In TPE, typically 1 to 2 times the plasma volume of the patient is exchanged.

Because of the decrease in the plasma concentration of the substances to be removed in the course of the TPE treatment, TPE is terminated after the prescribed plasma exchange. If and as long as clinically necessary, further TPE treatments will be administered on one of the following days.

Fig.: TPE flow diagram



Legend

1	Line occlusion clamp (red)
2	Blood pump
3	Filter
4	Fill level detector
5	Optical detector
6	Air bubble detector
7	Line occlusion clamp (blue)
8	Scale
9	Filtrate
10	Filtrate pump
11	Blood leak detector (yellow)
12	Substituate pump
13	Heater (white) and heater (green)
14	Plasma
15	Scale

Treatment data

TPE	Min.	Max.	Resolution	Unit
Blood flow	10	300	10	ml/min
Ratio of plasma rate to blood flow	0	30	1	%
Plasma	Off / 10	50	1	ml/min
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Anticoagulation bolus	Off / 0.1	5	0.1	ml
Target volume	Off / 10	39990	10	ml
Temperature	Off	On	-	-

Technical specifics

The blood flow should be applied based on the plasma filter and the vascular access used. With hollow-fibre filters, the blood flow should be at minimum 50 ml/min to avoid clotting.

TMP should be as low as possible during the procedure. Clogging of the membrane leads to TMP increase, with erythrocytes expectedly sucked onto the filter membrane and eventually rupturing their cell membrane, releasing free haemoglobin (Hb) into the filtrate.

Warning

Disruption of the filter function through membrane clogging

Risk for patient through haemolysis or loss of blood

In the event of a TMP increase caused by membrane clogging, erythrocytes can be sucked onto the filter membrane and destroyed. This causes free haemoglobin (Hb) to reach the plasma side, leading to a blood leak alarm and the treatment being stopped as a result.

- ➢ The TMP must be checked regularly for any increase during the treatment.
- ➢ In the event of a noticeable increase, the treatment should be adjusted, e.g. reduction of the filtration rate or optimisation of the anticoagulation.
- ➢ If a blood leak alarm is triggered, the extracorporeal circuit must be replaced. In this case, the option to deactivate the blood leak alarm should not be used.

Haemolysis is a common side effect in TPE that can lead to a reddish discolouration of the patient's plasma and can trigger a blood leak alarm. Haemolysis can be distinguished from a blood leak, if necessary, by collecting a blood sample for cell identification.

Note

TMP should be monitored according to the recommendation of the used plasma filter. Upon signs of TMP increase, the blood flow, filtration fraction and anticoagulation must be reassessed in order to avoid haemolysis.

Warning

Risk for the patient due to heat loss via the extracorporeal blood circuit if the temperature of the plasma replacement solution is too low

Haemodynamic instability due to the reduction in core body temperature.

- ➢ Preheat plasma replacement solution to at least 20 °C before treatment.
- ➢ Conduct treatment at a room temperature of at least 20 °C.
- ➢ Switch on heater.
- ➢ Avoid drafts during treatment.
- ➢ Regular monitoring of patient temperature.
- ➢ If necessary, take measures to maintain patient temperature, such as use of electric blankets.

Note

In order to avoid damage to the proteins in donor plasma, the heating power in TPE treatments has been reduced. The temperature at the insertion site depends among other things on the ambient temperature (see Chapter 12 on page 297).

Anticoagulation

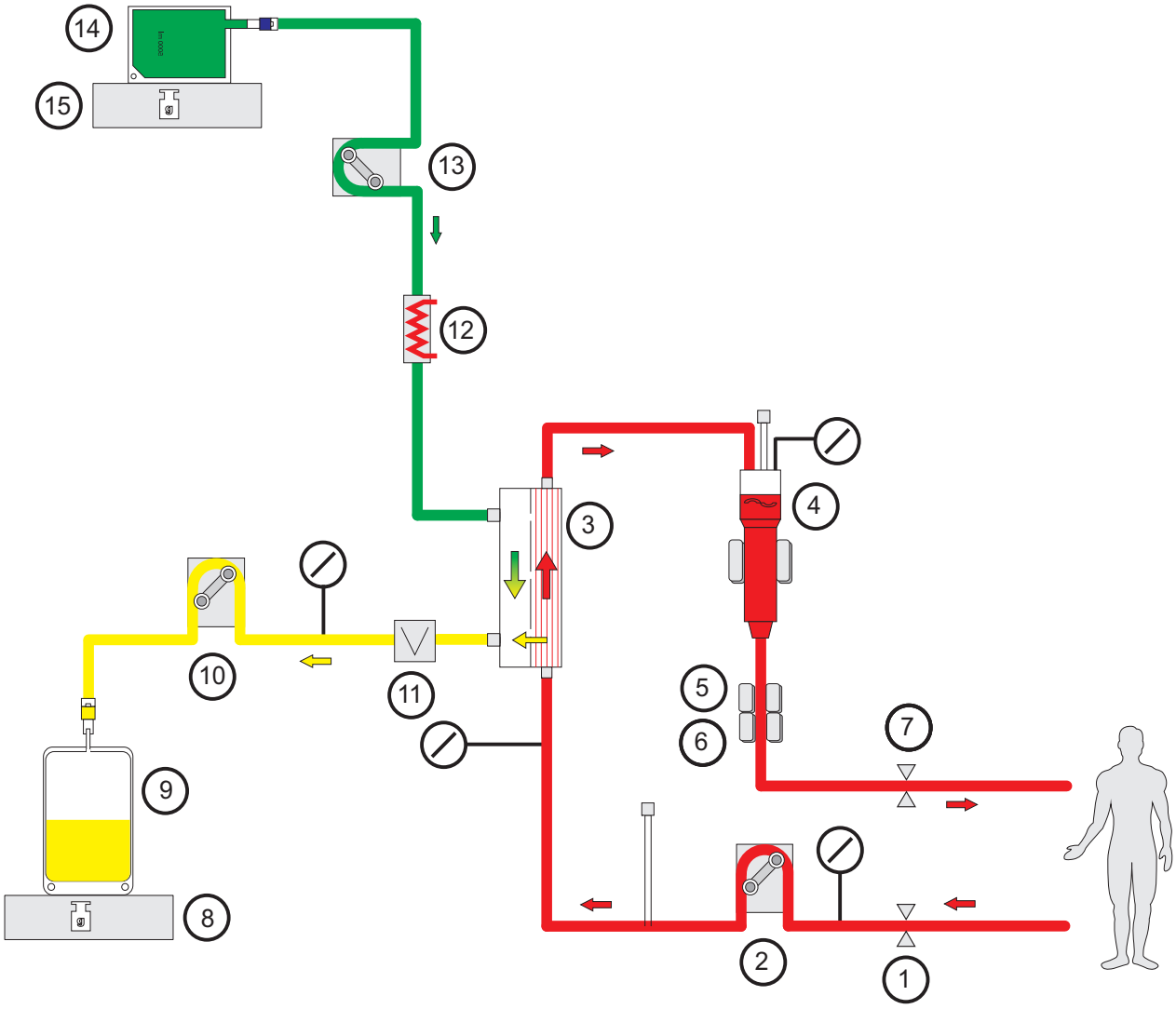
For anticoagulation, heparin is normally used in TPE with the device. More detailed information (see Chapter 7.3.1 on page 259), including on the possibility of a loss of heparin during the TPE treatment (see Chapter 2.6 on page 20).

7.2.3 Paediatric CRRT treatments

Special treatment mode for small children

For small children the desired CRRT effectiveness (see Adjusting the CRRT prescription in children in the table below) can be achieved using the tubing system developed specifically for this purpose. The blood filling volume of the tubing system has also been reduced compared to the standard consumable. The paediatric tubing system can be used to perform the Paed CVVHD 8 kg to 16 kg and Paed CVVHD 16 kg to 40 kg treatments.

Fig.: Paed CVVHD flow diagram



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector
6 Air bubble detector
7 Line occlusion clamp (blue)
8 Scale
9 Filtrate
10 Filtrate pump
11 Blood leak detector (yellow)
12 Heater (green)
13 Dialysate pump
14 Dialysate
15 Scale

Treatment data

Paed CVVHD 8 kg to 16 kg	Min.	Max.	Resolution	Unit
Blood flow	0	100	10–50 in 1 50–100 in 5	ml/min
Net UF rate	Off / 10	200	10	ml/h
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Dialysate	380	1000	10	ml/h
Temperature	Off / 35	39	0.5	°C

Paed CVVHD 16 kg to 40 kg	Min.	Max.	Resolution	Unit
Blood flow	0	200	10–50 in 1 50–100 in 5 100–200 in 10	ml/min
Net UF rate	Off / 10	400	10	ml/h
Continuous heparin administration	Off / 0.5	25	0.1	ml/h
Dialysate	380	1500	10	ml/h
Temperature	Off / 35	39	0.5	°C

7.3 Anticoagulation

Requirement for anticoagulation

When performing extracorporeal blood treatments, anticoagulation of the blood is generally required. It prevents blood-clotting in the extracorporeal blood circuit and ensures an adequate operating life of the filters used.

All treatments

Anticoagulation should be monitored at regular intervals. More frequent monitoring of anticoagulation efficiency is usually required after the anticoagulant dose has been adapted and immediately following treatment initiation.

7.3.1 Systemic anticoagulation

Systemic anticoagulants

Different substances can be used for systemic anticoagulation. Substance (e.g. unfractionated heparin (UFH) or low-molecular-weight heparin (LMWH), heparinoids, pentasaccharides or direct thrombin inhibitors), dose and method of systemic anticoagulation must be decided by the attending physician on an individual basis. A patient that already receives systemic therapeutic anticoagulation may not require additional anticoagulation.

The information below focuses primarily on heparin.

Heparin priming

Heparin priming may be required or recommended for the filter applied. For priming the circuit, heparinised isotonic saline solution (e.g. 5000 IU/L) can be used unless otherwise clinically indicated (please refer to the IFU of the applied filter).

Heparin dose/dosing

The dose of heparin must be prescribed by the responsible physician in consideration of the patient's condition and of the clinical situation (e.g. post-surgery period, bleeding risk, thromboembolism risk, patient's body weight). The prescribed dose of heparin can consist of a bolus followed by a continuously applied dose. The SmPC or the IFU of the applied heparin and filter/adsorber, respectively, must always be observed.

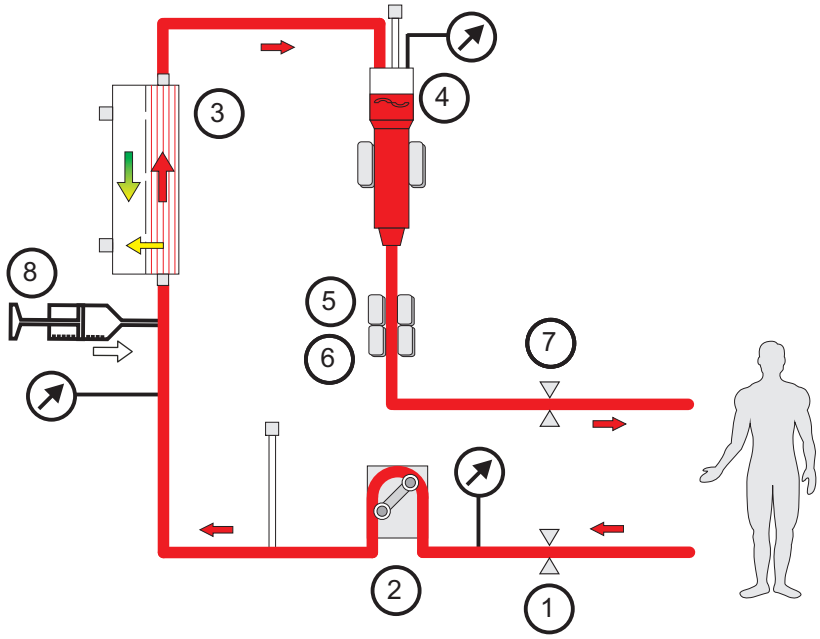
Monitoring

Coagulation should be monitored at regular intervals considering also bleeding risk and heparin dose changes (e.g. measurement of the activated clotting time (ACT) or activated partial thromboplastin time (aPTT)).

Integrated heparin pump for anticoagulation

A heparin pump for the continuous infusion of anticoagulants is integrated in the device. An infusion line for anticoagulants is included in the tubing system. The pH value of the solution must be ≤ 10. Continuous infusion can be started with the initiation of treatment. A prescribed initial bolus can be administered using the heparin pump. Subsequently, during treatment a bolus can be applied via the heparin pump. The integrated heparin pump automatically pauses infusion during treatment interruptions.

Fig.: Schematic of systemic anticoagulation



Legend

1 Line occlusion clamp (red)
2 Blood pump
3 Filter
4 Fill level detector
5 Optical detector

6 Air bubble detector
7 Line occlusion clamp (blue)
8 Heparin pump

Anticoagulation-free CRRT

When the CRRT procedure is performed without anticoagulant, the haemofilter may show early reduced performance and clot more frequently in the extracorporeal circuit.

Note

The degree of clogging and clotting depends on the patient's degree of coagulopathy.

Tip

In anticoagulation-free CRRT choosing CVVHD or a treatment mode with a predilution component may improve filter patency.

7.3.2 CVVHD or postCVVHDF with the Ci-Ca protocol (regional citrate anticoagulation)

Warning

Risk of contamination as a result of infusion of unsuitable solutions that do not match the selected treatment mode

➢ After changing the treatment mode, change the solutions if necessary so that they match the selected treatment mode and the anticoagulation.

➢ For the treatment modes CVVHDF and CVVH, only solutions that are suitable for infusion must be used.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance

If the balancing is interrupted too often (e.g. through frequent balancing alarms), this can lead to an unintended citrate load in the patient, which can in turn lead to metabolic alkalosis and hypernatraemia.

Note: Every time the filtrate flow is interrupted, the calcium substitution is also interrupted.

➢ Interruptions of the balancing, particularly in the case of citrate anticoagulation, must be kept to a minimum.

7.3.2.1 Treatment prescription and essentials

On the multiFiltratePRO integrated regional citrate anticoagulation is available with the CRRT modes CVVHD and post-dilution CVVHDF.

Ci-Ca protocol

The integrated protocol for RCA is identified as the Ci-Ca protocol (Ci-Ca CVVHD and Ci-Ca postCVVHDF, respectively). The multiFiltratePRO must be mounted with the respective tubing system that features an integrated citrate line in the pre-pump segment of the access system (“access line”) and an integrated calcium line in the return system (“return line”).

In RCA, citrate binds ionised calcium in the extracorporeal blood and forms calcium-citrate complexes. The resulting reduction of the ionised calcium concentration results in inhibition of several steps in the coagulation cascade. With the Ci-Ca protocol, a relevant portion of the calcium-citrate complexes is cleared via the filter. The residual quantity of citrate, the “citrate load”, is infused into the patient, resulting in the generation of bicarbonate buffer once metabolised. A sufficiently large high-flux haemofilter is required, which does not limit the transport of buffer bases and calcium-citrate complexes. The maximum blood flow is limited to 200 ml/min to limit citrate load. As the blood flow is commonly set in the lower range of blood flows applicable for these filters, please observe the IFU of the respective filter for the minimum blood flow limit.

The Ci-Ca protocol requires a combination of complementing solutions, which are recommended to be used in specific ratios (see the example system settings below):

– A concentrated trisodium citrate solution (4 % w/v or 136 mmol/l in short: “citrate solution”)
– A dialysate that is calcium-free, and has tailored sodium and bicarbonate concentrations to reflect use of the citrate solution (in short: “Ci-Ca dialysates”)
– A concentrated calcium solution (in short: “calcium solution”)
– A substituate that has a calcium concentration of typically 1.5 mmol/l (e.g. haemofiltration solution for infusion; Ci-Ca postCVVHDF only)

Ci-Ca CVVHD

Supports typical prescribed doses up to ~2500 ml/h. If required, higher doses up to ~4 000 mL/h can also be applied. Middle molecule clearance can be improved with the selection of a cut-off haemofilter, e.g. EMiC2. As calcium-citrate complexes and buffer bases are relatively small molecules, similar clearances result with EMiC2 and a standard high-flux haemofilter used for CRRT and, thus, the same Ci-Ca CVVHD protocol can be applied.

	Combination 1	Combination 2	Combination 3
Blood flow	80 ml/min	100 ml/min	120 ml/min
Citrate dose (4 % citrate)	4.0 mmol/l	4.0 mmol/l	4.0 mmol/l
Dialysate flow	1600 ml/h	2000 ml/h	2400 ml/h
Substituate flow	-	-	-
Calcium dose	1.7 mmol/l	1.7 mmol/l	1.7 mmol/l

Applies for the AV-filters AV 600 S and AV 1000 S and EMiC2.

Example system settings for Ci-Ca CVVHD: As a standard setting, the dialysate flow is set at 33 % of the blood flow. This ratio is presented in the user interface of the multiFiltratePRO. This ratio corresponds to a numerical ratio of “20:1” between dialysate and blood flows as these are indicated in “mL/h” and “mL/min”, respectively. The citrate dose is prescribed in ratio to the blood flow; the calcium dose is prescribed in ratio to the filtrate flow.

Ci-Ca postCVVHDF

Increases the prescribed dose by 50 % compared to CVVHD while maintaining the same blood flow. Supports typical prescribed doses up to ~3 750 mL/h. If required, higher doses up to ~6 000 mL/h can also be achieved. The increase in the delivered dose can be slightly lower, as the complete saturation of the effluent reaches its limits. The AV 1000 S or an equivalent haemofilter must be used. The EMiC2 must not be used in this mode, as this might result in excessive albumin losses.

	Combination 1	Combination 2	Combination 3
Blood flow	80 ml/min	100 ml/min	120 ml/min
Citrate dose (4 % citrate)	5.0 mmol/l	5.0 mmol/l	5.0 mmol/l
Dialysate flow	1600 ml/h	2000 ml/h	2400 ml/h
Substituate flow	800 mL/h	1000 mL/h	1200 mL/h
Calcium dose	1.7 mmol/l	1.7 mmol/l	1.7 mmol/l

Example system settings for Ci-Ca postCVVHDF: As a standard setting, the dialysate flow is set at 33 % of the blood flow. This ratio is presented in the user interface of the multiFiltratePRO. This ratio corresponds to a numerical ratio of “20:1” between dialysate and blood flows as these are indicated in “mL/h” and “mL/min”, respectively. The substituate flow should be chosen at 17 % of the blood flow. This correlates with a numerical ratio between substituate and blood flows of “10:1”, as the substituate flow is indicated in “mL / h” and the blood flow in “mL / min”. The haemoconcentration at the filter outlet (UF/BF ratio) should, if possible, not exceed 20 %. If the haemoconcentration at the filter outlet exceeds 20 % due to the required Ca flow and a clinically required ultrafiltration, the substituate flow can be reduced accordingly. The citrate dose is prescribed in ratio to the blood flow; the calcium dose is prescribed in ratio to the effluent flow. The calcium infusion with the substituate is automatically considered when calculating the required calcium solution flow.

Changing from RCA to heparin anticoagulation

There are specific clinical conditions (like severe dysnatraemia, citrate accumulation and others) where a change from RCA to heparin anticoagulation is necessary.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate and substituate

➢ Adjust the flow ratios of the solutions in relation to each other in relation to the blood flow.

Note

Despite citrate anticoagulation, localised clotting can occur in the tubing system during the treatment. Perform regular visual checks of the blood lines, especially in the area from the venous chamber to the connection of the return line to the vascular access. If clot formations become apparent (“white bands”), replace the cassette.

7.3.2.2 Solutions for the Ci-Ca protocol

The following solutions are suitable for use with the Ci-Ca protocol:

CRRT treatments	Citrate solution	HF solution / dialysate	Ca solution
Ci-Ca CVVHD	4 % Na_3 citrate (corresponding to 136 mmol/l citrate) 1.5 litre bag	Ci-Ca Dialysate K2, Ci-Ca Dialysate K4, Ci-Ca Dialysate K2 Plus, Ci-Ca Dialysate K4 Plus per 5 litre bag	$CaCl_2$ solution in the appropriate concentration (50 to 500 mmol/l calcium ions); preferably approx. 100 mmol/l
Ci-Ca postCVVHDF	4 % Na_3 citrate (corresponding to 136 mmol/l citrate) 1.5 litre bag	Ci-Ca Dialysate K2, Ci-Ca Dialysate K4, Ci-Ca Dialysate K2 Plus, Ci-Ca Dialysate K4 Plus per 5 litre bag Additionally, a calcium-containing, bicarbonate-buffered substituate	$CaCl_2$ solution in the appropriate concentration (50 to 500 mmol/l calcium ions); preferably approx. 100 mmol/l

CRRT solutions

It is recommended to separately store the Ci-Ca dialysates from other solution for dialysis and haemofiltration to avoid accidental mix-up.

Note

Please always read the label before connecting any solution to the patient or the extracorporeal circuit, to confirm that the correct prescription will be delivered. Prior to application, the used solutions must have a temperature of at least +20 °C to support the integrated warming procedure of the multiFiltratePRO.

Note

Depending on clinical requirements, the dialysate and haemofiltration solution should be warmed immediately before use to approximately 36.5 °C to 38.0 °C. The temperature must be set accordingly.

Citrate and calcium solutions

The citrate and calcium solutions must be suitable for infusion. Depending on the citrate and calcium solutions used locally, the concentration of the citrate and calcium ions, respectively, and the volumes of these solutions are internally stored by the device and can be viewed in the Ci-Ca bag change menu. The initial storage is done by Technical Service personnel. If available use ready-to-use citrate and calcium solutions, i.e. no dilution to the final concentration required. Products with suitable connectors to connect with the integrated citrate and calcium lines of the multiFiltratePRO SecuKit tubing system are favoured (see Chapter 8 on page 281).

For Ci-Ca CVVHD and Ci-Ca postCVVHDF, the sole approved citrate solution is 4 % Na_3Citrate solution, containing 136 mmol/l of citrate ions.

The concentration of the calcium solution used may be basically within a range from 50 to 500 mmol/l. Use of a calcium solution with approximately 100 mmol/l calcium is recommended. Higher calcium concentrations lead to lower calcium flows and can increase the risk of local clot formation due to less mixing at the calcium infusion site. Although calcium chloride or calcium gluconate are generically available as concentrates that can be diluted to the desired concentration, a calcium chloride solution is preferred.

It is strongly recommended to use a fixed calcium solution for all Ci-Ca treatments in the hospital. Later changes would require coordinated changes of device settings and the applied calcium solution to avoid safety issues because of a mismatch of calcium concentrations.

Note

Please check that the calcium concentration in the solution conforms with the concentration selected in the setup and shown on the screen.

Warning

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

➢ Check that the citrate and calcium solutions used correspond to the types selected in the Setup and shown on the screen.

Warning

Risk for the patient as a result of a reduction in body temperature

If the temperature of the citrate and calcium solutions is too low, this can lead to hypothermia in the patient.

➢ The solutions must be at room temperature when used.

➢ Either select a suitable storage temperature or heat the bags to the required temperature before use.

Ci-Ca dialysates

In order to effectively use the citrate mechanism of action in the haemofilter, the Ci-Ca dialysates do not contain calcium (0 mmol/l Ca^{2+}). As a sodium citrate solution is applied for citrate anticoagulation, there is at first glance the possibility of hypernatremia. Consequently, the sodium concentration in all Ci-Ca dialysates must be low. To compensate for the indirect buffer provision of the 4 % tri-sodium citrate solution, the bicarbonate concentration must also be reduced. The Ci-Ca dialysates must be connected with the dialysis line of the multiFiltratePRO tubing system. Some Ci-Ca dialysates provide a colour coding (e.g. yellow connector) for correct connection.

Warning

Risk of blood loss as a result of clotting

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of dialysate

The use of calcium-containing dialysate for a Ci-Ca treatment can lead to blood clotting and/or hypercalcaemia.

➢ Only use calcium-free dialysate for treatments with citrate anticoagulation.

Substitution solution

The Ci-Ca postCVVHDF protocol was designed for use with the bicarbonate-buffered haemofiltration solutions. As these solutions usually contain calcium (e.g. 1.5 mmol/l Ca^{2+}), there is at first glance the possibility of clotting in the return line and venous chamber of the circuit. A comparatively stronger suppression of post-filter ionised calcium (0.20-0.29 mmol/l) limits the risk of clotting related to HF solution infusion. The slightly higher citrate dose (5 mmol/l blood) in combination with the bicarbonate content of the HF solution (e.g. 35 mmol/l) also compensates for the comparatively higher filter removal of citrate (indirect buffer base) and bicarbonate (direct buffer base) due to the added diffusive and convective effluent dose. The use of a substituate of this type with 1.5 mmol/l calcium and 35 mmol/l bicarbonate is recommended.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance due to incorrect selection of substituate

The use of substituate with the wrong calcium level for a Ci-Ca treatment can lead to an electrolyte imbalance in the patient.

➢ Only use calcium-containing substituate for treatments with citrate anticoagulation.

➢ Check that the calcium solution used corresponds to the type selected in the Setup and shown on the screen.

7.3.2.3 Therapy settings and monitoring with the Ci-Ca protocol

Citrate solution

The primary intended effect with the 4 % citrate solution is to achieve anticoagulation in the extracorporeal circuit corresponding to a prescription of a citrate dose. A part of the citrate is directly removed with the effluent, another part will be infused systemically. Under normal conditions, the infused citrate is metabolised, resulting in the generation of bicarbonate as a secondary effect.

Dosage

The citrate dose is defined as the volume of citrate ions (in mmol) that is infused per litre of processed blood, for which reason its unit is that of a concentration. The citrate dose can be set within a range from 2 to 6 mmol/l. Usually, an initial value of 4.0 mmol/l blood is appropriate with Ci-Ca CVVHD and a slightly higher initial value of 5.0 mmol/l blood with Ci-Ca postCVVHDF. This slightly higher initial value, in comparison to Ci-Ca CVVHD, compensates for the effects of the haemofiltration component of Ci-Ca postCVVHDF on the acid-base balance and counter-acts a premature increase in the concentration of ionised calcium following infusion of the calcium-containing substituate at the postdilution stage.

Under normal circumstances, this citrate dose should result in a post-filter ionised calcium-level of 0.25 to 0.35 mmol/l blood in Ci-Ca CVVHD and 0.21 to 0.29 mmol/l blood in Ci-Ca postCVVHDF. Lowering values to below 0.35 mmol/l of ionised calcium in the extracorporeal blood circuit (downstream of the filter) is associated with only a minor risk of clotting in the extracorporeal blood circuit.

The citrate dosing should remain within 3 to 5 mmol/l for CVVHD and 3 to 5.5 mmol/l for postCVVHDF to reduce the risk of hypo- or hypernatremia. If the initial value does not result in the desired post-filter ionised calcium level, the dosing should be adapted according to the table below.

In order to limit interruptions of citrate anticoagulation, citrate infusion continues for a limited time span during balancing alarms and most bag changes.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance

If the balancing is interrupted too often (e.g. through frequent balancing alarms), this can lead to an unintended citrate load in the patient, which can in turn lead to metabolic alkalosis and hypernatraemia.

Note: Every time the filtrate flow is interrupted, the calcium substitution is also interrupted.

➢ Interruptions of the balancing, particularly in the case of citrate anticoagulation, must be kept to a minimum.

Post-filter calcium adjustments

For requirements on the measurement of post-filter ionised calcium see: (see Chapter 7.3.2.4 on page 275). Adjustments in citrate dose alter the ionised calcium in the circuit (measured usually postfilter) within a few minutes (when the extracorporeal blood volume was replaced at the applied blood flow). The citrate dose can be set in increments of 0.1 mmol/l. After the citrate dose has been readjusted, the new setting can be checked only a few minutes later and readjusted if necessary.

Ci-Ca CVVHD: Schemes for adaptation of the citrate dose (depending on local experience it might be appropriate to define other values that trigger alerting the physician). In case of post-filter ionised calcium measurements lower than 0.20 mmol/l or above 0.35 / 0.40 mmol/l (for requirements on the measurement see Chapter 2.6.10), solutions and settings should be carefully checked.

Ci-Ca postCVVHDF: Schemes for adaptation of the citrate dose (depending on local experience it might be appropriate to define other values that trigger alerting the physician). In case of post-filter ionised calcium measurements lower than 0.20 mmol/l or above 0.35 / 0.40 mmol/l (for requirements on the measurement see Chapter 2.6.10), solutions and settings should be carefully checked.

Ca solution

The primary intended effect with the calcium solution is to replenish the calcium losses that result from the clearance of calcium-citrate complexes via the filter. Without or with only insufficient calcium substitution, the patient would have a negative calcium balance which could lead to a clinically relevant hypocalcaemia. The calcium solution is infused systemically via the venous bloodline closely prior to the connection with the venous catheter lumen. The substitution of calcium must be adapted to the patient's needs to avoid hypocalcemia or hypercalcemia. The infused amount of calcium must be adjusted accordingly to control the systemic ionized calcium concentration (please refer to the table below).

Note

Downstream of the calcium inlet, fibrin stripe formation in the venous return line and into the catheter may occur. The treatment must then be terminated, and the circuit exchanged. Regular monitoring is required. Reports suggest that the risk of fibrin stripe formation is higher when the post-filter iCa is above the recommended range.

Dosage

The calcium dose is defined as the amount of calcium ions (in mmol) infused per litre of effluent produced. The Ca dose (in the display: calcium/filtrate ratio) can be adjusted for Ci-Ca CVVHD within a range of 0.0 to 3.0 mmol/l. With Ci-Ca postCVVHDF, the calcium dose equals the overall calcium infusion, i.e., the sum of calcium infused with the calcium solution and the calcium in the substituate, in relation to the filtrate flow. Unlike with Ci-Ca CVVHD, very small values for the calcium dose cannot be set for Ci-Ca postCVVHDF, since it is essential that calcium is infused with the substituate. In particular, a calcium dose of 0.0 mmol/l can never be set for Ci-Ca postCVVHDF. The upper configuration threshold is identical, at 3.0 mmol/l.

To facilitate dosing of the calcium solution, the user defines the calcium substitution proportional to the effluent rate and adjusts this to achieve the targeted systemic ionised calcium concentration. With systemic ionised calcium concentrations in the normal range at the start of therapy and using the exemplary system settings, a suitable starting dose is 1.7 mmol of calcium per litre effluent. For all Ci-Ca therapies, this is the suggested initial value, matching theoretically expected calcium losses into the effluent under typical treatment conditions. Experience has shown that there are individual differences between patients. This means that the calcium dose must be adjusted, particularly during the first treatment phase. Moreover, changing target ranges, at the discretion of the attending physician, might be useful in some patients.

The direct coupling of the calcium dose to the filtrate flow has the effect that the calcium substitution is interrupted whenever the filtrate flow stops, and the balancing is interrupted. Also, the calcium dose is automatically adjusted to the efficiency of the treatment, which means, for example, that in case of an elevated calcium removal, caused by an increase of the dialysate flow, the calcium substitution is automatically increased.

Verification of the calcium substitution

Adequate calcium substitution is determined by regular checks of the systemic ionised calcium.

For the collection of the blood sample to check the systemic ionised calcium, observe the instructions for taking a sample/systemic blood sample (see Chapter 7.3.2.3 on page 267).

Unless clinically contraindicated, the systemic ionised calcium values should be within the normal range.

Serum calcium balance

It can take up to 12 hours or longer until a change of the calcium dose shows its full effect on the systemic ionised calcium concentration and a new balance has been established. After adjustments for moderate out-of-range measurements, the next adjustment should normally not be made within the next 6 to 8 hours.

Ci-Ca CVVHD: Generally suggested schemes for adaptation of the calcium dose, which the prescribing physician might modify to match patient needs (depending on local experience it might be appropriate to define other values that trigger alerting the physician). In case of systemic ionised calcium measurements below 1.00 mmol/l or above 1.35 mmol/l solutions and settings should be carefully checked. However, certain patient clinical conditions might also sufficiently explain such measurements.

Ci-Ca postCVVHDF: Generally suggested schemes for adaptation of the calcium dose, which the prescribing physician might modify to match patient needs (depending on local experience it might be appropriate to define other values that trigger alerting the physician). In case of systemic ionised calcium measurements below 1.00 mmol/l or above 1.35 mmol/l solutions and settings should be carefully checked. However, certain patient clinical conditions might also sufficiently explain such measurements.

Delayed effect in case of changed calcium dose

Note

Unlike changes to the citrate dose, the effect of a change to the calcium dose can be assessed only after some time has passed.

This is caused by the fact that the systemic distribution volume must first develop a new balance. Depending on the efficiency of the CRRT treatment and the size of the patient (or his/her distribution volume for calcium), first effects can be seen after a few hours; however, the full effect can only be assessed after approximately one day.

This must be particularly taken into account if several equivalent changes are made within short intervals as then there may be an overshooting response (e.g., hypercalcaemia if the calcium dose is increased repeatedly at short intervals).

High calcium dose: Possible citrate accumulation

If the calcium dose necessary for stabilising the systemic ionised calcium is higher than 2.1 mmol/l, this might be indicative of a citrate accumulation. The device alerts the operator to this fact when setting such high calcium doses and recommends a measurement of the total calcium. For more information on citrate accumulation: (see Chapter I on page 279)

Low calcium dose: Possible evidence of a clogged membrane

If a calcium dose of less than 1.3 mmol/l is sufficient for the stabilisation of the systemic ionised calcium, this may be indicative of a clogged membrane (clotting) with reduced permeability for calcium-citrate complexes. More information about clotting: (see Chapter I on page 278)

Ci-Ca dialysates

The intended effect of Ci-Ca dialysate is to provide clearance as intended with the targeted CRRT efficacy.

Metabolic control

Once the Ci-Ca dialysate dosage has been determined, the blood flow should normally be set to three times that flow (QD/QB ratio 33 %). It is possible to deviate from this, for example if a different value of serum bicarbonate is being targeted. The proposed combinations (see Chapter 7.3.2.1 on page 262) should be respected as a starting point in normal operation, as with a mismatched dialysate-to-blood flow ratio a metabolic alkalosis or acidosis could develop. It must be noted that an increase of the dialysis flow causes a shift towards acidosis. This differs from the application of other solutions (with e.g. 35 mmol/l bicarbonate), which are used with CRRT without anticoagulation or in combination with systemic anticoagulation.

The impact on the metabolic acid-base status of the patient can be changed by the ratio between blood flow (i.e. the infusion of buffer bases) and Ci-Ca dialysate flow (i.e. the removal of buffer bases). If during operation the dialysate-to-blood flow ratio needs to be adapted, the following steps theoretically will have an effect of approximately 4 mmol/l on the serum bicarbonate concentration (please refer to the illustration below):

– A 20 % change of one of the flows in Ci-Ca CVVHD/Ci-Ca EMiC2
– A 30 % change of one of the flows in Ci-Ca postCVVHDF

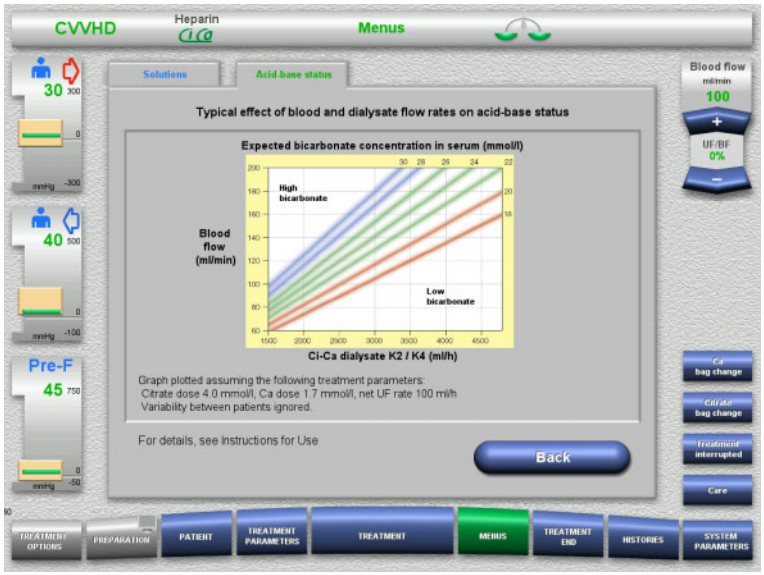
Depending on the dimension of the effect intended, smaller or larger stepwise adjustments may be necessary.

Note

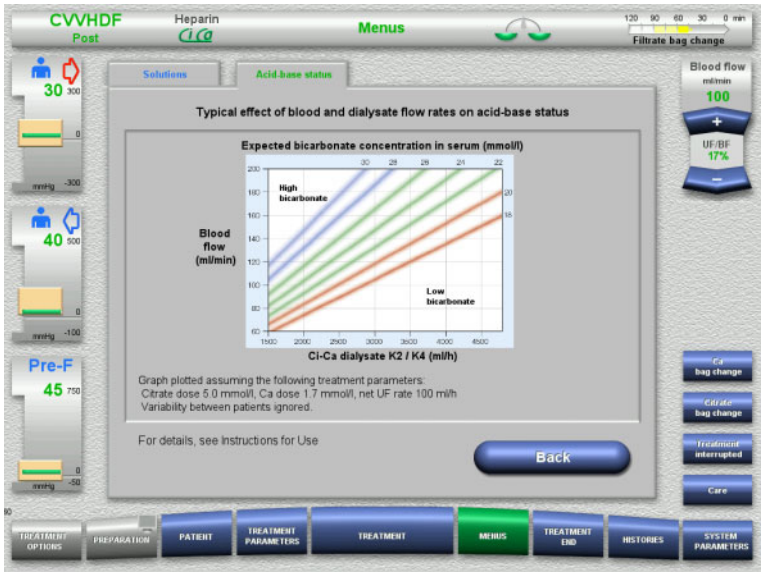
With Ci-Ca postCVVHDF, adjusting the blood flow – even to alter the acid-base balance – also requires adjustment of the substituate flow.

Serum acid-base status

It can take several hours until the change in the dialysate-to-blood flow ratio shows its full effect, as the hourly CRRT dose is small in relation to the effective distribution volume of bicarbonate in the patient. After adjustments for moderate out-of-range measurements, the next adjustment should normally not be made within the next 6 to 8 hours. This must be particularly taken into account if several equivalent changes are made at short intervals, as these may cause an excessive response. In any unwanted dysregulation of the acid-base state, other influencing factors should also be considered.



Expected serum bicarbonate concentration for Ci-Ca CVVHD in relation to the blood and dialysate flow. The illustrations represent a numerical model with a citrate dose of 4.0 mmol/l and 5.0 mmol/l respectively, a calcium dose of 1.7 mmol/l, a substituate flow at 17 % of the blood flow for Ci-Ca postCVVHDF, and a net ultrafiltration of 100 ml/h – for orientation only.



Expected serum bicarbonate concentration for Ci-Ca postCVVHDF in relation to the blood and dialysate flow. The illustrations represent a numerical model with a citrate dose of 4.0 mmol/l and 5.0 mmol/l respectively, a calcium dose of 1.7 mmol/l, a substituate flow at 17 % of the blood flow for Ci-Ca postCVVHDF, and a net ultrafiltration of 100 ml/h – for orientation only.

Electrolyte control

Ci-Ca dialysates with different concentrations of potassium, phosphate and magnesium are available. Many patients may initially present with hyperkalaemia, hypermagnesemia and/or hyperphosphatemia because of the acute kidney injury or disease. These values can change during therapy. It is recommended to choose the Ci-Ca dialysate prescription matching with the patient's course of disease and plasma serum levels of especially potassium and phosphate. Alternatively, the patient may receive separate (continuous) infusion of required electrolytes.

Magnesium, like calcium, forms dialysable complexes with citrate. Furthermore, it is to be expected that citrate converts a part of the protein-bound magnesium to membrane permeable magnesium-citrate complexes. This must be considered with the magnesium concentration of the Ci-Ca dialysate variants. CRRT removes phosphate very efficiently from the blood. Therefore, some Ci-Ca dialysate variants contain a phosphate concentration within the normal range for serum phosphate.

The Ci-Ca dialysates do not provide the flexibility in sodium provision that patients with a severe dysnatraemia may need. In such cases, a switch to systemic anticoagulation and individually adjusted sodium concentrations of substitution solution/CRRT fluid is suggested.

Ca-containing substituate

In addition to the solutions needed for Ci-Ca CVVHD, Ci-Ca postCVVHDF will also require a calcium-containing, bicarbonate-buffered substituate.

Metabolic control

Please note that varying the substituate flow (35 mmol/l bicarbonate) theoretically has a limited impact on the resulting serum bicarbonate concentration in Ci-Ca postCVVHDF and should therefore not be used for intentionally modifying the serum bicarbonate concentration.

Electrolyte control

With respect to potassium control, different potassium concentrations are available for Ci-Ca dialysates and substitution solutions used with Ci-Ca postCVVHDF. As the dialysate flow is higher than the substituate flow, the potassium concentration of the used Ci-Ca dialysate has a higher impact than that of the substituate.

7.3.2.4 Monitoring technique and frequencies during normal operation

Note

The systemic acid-base balance, systemic ionised calcium and post-filter ionised calcium must be regularly checked during the Ci-Ca treatment. The intervals necessary for these regular determinations depend on the patient's clinical situation.

Note

It is absolutely necessary to ensure that the measurements of systemic ionised calcium and post-filter ionised calcium are not mistaken for each other.

Note

Whenever a situation is not clear and is possibly associated with an abnormal concentration of systemic ionised calcium or with a disturbed acid-base balance, these parameters should be checked immediately.

Warning

Risk for the patient through unavailability of blood value monitoring, e.g. prompt measuring of the systemic ionised calcium

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

➢ During the treatment, the analyser for determining the acid-base balance and the concentrations of ionised calcium must be located in the immediate vicinity of the device, so that results are directly available.

Post-filter ionised calcium/anticoagulation

The post-filter ionised calcium level has proven useful for the monitoring of anticoagulation in the circuit. Please refer to the schemes for adaptation of the citrate dose given above.

Sampling

To monitor the anticoagulation/ionised calcium in the extracorporeal circuit, the post-filter sampling point ("blue" sampling point) in the return line of the multiFiltratePRO tubing system should be used. It is located downstream of the haemofilter and prior to any infusion of calcium or substitution solution. The volume to be drawn depends on the required sample volume of the blood gas analyser.

Initial measurement

The set-up of the Ci-Ca treatment must be carefully checked prior to the start of the treatment and confirmed with an initial measurement of the post-filter ionised calcium. Measuring the citrate-induced drop of the ionized calcium concentration in the extracorporeal circuit confirms the correct setup of the system (citrate solution correctly connected with the "citrate" line).

If this drop is missing, the set-up must be re-checked as a mixing-up of, e.g., the citrate and calcium solutions can lead to severe electrolyte imbalances and acid-base disturbances. Moreover, the citrate solution cannot exert its anticoagulant function within the filter.

The use of a calcium-containing dialysate can be responsible for a drop of post-filter ionised calcium concentration smaller than expected.

Warning

Risk for the patient as a result of a disorder of the electrolyte balance

Mixing up the solution may lead to hypo-/hypercalcaemia.

➢ The post-filter calcium concentration must be checked 5 minutes after switching on the Ci-Ca anticoagulation and at regular intervals afterwards.

Note

If no significant reduction of the post-filter ionised calcium is detected during the first measurement performed 5 minutes after the start of the treatment, the treatment must be stopped immediately. This may be indicative of an incorrect connection, it must especially be checked that the citrate and calcium solution have not been reversed.

Frequency of follow-up measurements

Further checks of the post-filter ionised calcium should be made routinely every 6 to 8 hours and as clinically required. Under stable conditions, the postfilter ionised calcium should be monitored every 8 to 12 hours. The effect of citrate dosage adjustments can be reviewed after a few minutes. Normally, 5 minutes is sufficient for a complete exchange of the blood in the extracorporeal blood circuit.

Alternative monitoring techniques

Alternatively, the activated clotting time (ACT) might be used for the monitoring of anticoagulation in the circuit. However, no scheme for the adaptation of the citrate dose based on the ACT is currently available. Other measures of anticoagulation, such as the activated partial thromboplastin time (aPTT) and prothrombin time (PR/INR) typically involve citrate-anticoagulated blood samples and, thus, are not suitable to monitor citrate anticoagulation.

Electrolyte and acid-base status in the patient serum

With regional citrate anticoagulation, acid-base and electrolyte status (sodium, potassium, calcium, magnesium, phosphate) of the patient must be closely controlled. This should facilitate the recognition of possible trends towards metabolic disturbances or shifts in the electrolyte status well in time in order to enable timely corrections.

Before treatment

The systemic acid-base balance and systemic ionised calcium should be checked prior to the treatment. If there is no other clinical indication, a hypocalcaemia should be corrected before the start of the Ci-Ca treatment.

Measuring frequency

The patient ionised calcium, pH and bicarbonate, sodium, and lactate must be measured at least 1 hour before the start of the therapy according to clinical need. Further exemplary measurement frequencies are up to 6-8-hourly for CVVHD and postCVVHDF. More intensified monitoring can be required. The exact frequency depends on the status of the patient and how rapidly the treatment can invoke changes to the blood volume and composition of the patient (e.g., CRRT dose in relation to patient size). Furthermore, a regular monitoring of the patient's clinical signs (including blood pressure and cardiac rhythm monitoring), fluid status as well as fluid responsiveness, and body core temperature is required when performing CRRT.

Sampling

For monitoring, a systemic blood sample, preferably from an available arterial access, should be used. If such an arterial access is not available, a central or peripheral venous blood sample can be used instead. Using the access sampling point ("red" sampling point) in the access line of the multiFiltratePRO tubing system is a suboptimal alternative, i.e. should only be used if other options are not available or practical. If used nevertheless, the blood sample must be taken slowly from the sampling site (red) of the access line while the blood pump is running.

Note

If the sampling site on the access line is used, it must be ensured that the blood pump is running while the sample is collected and that the blood sample is aspirated slowly to prevent citrate from being admixed from the citrate infusion. Even when observing this, unrecognised recirculation at the catheter tip is possible and would result in falsely low systemic ionised calcium and possibly widely varying measurements. This might erroneously lead to a decision to increase the calcium dose for the patient.

➢ Unexpectedly low ionised calcium measurements should be double-checked, e.g. using peripheral venepuncture.

Note

In situations presenting an increased risk for recirculation, e.g. reverse catheter connection or femoral catheter position, the sampling site on the access line must not be used. Unexpectedly low measurement values of the systemic ionised calcium of samples collected at this site must always be checked by measuring a separately collected systemic sample.

Warning

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

➢ Observe the instructions for taking a sample.

➢ In the event of widely varying measurement values of the electrolytes and the acid-base balance, consult a physician.

7.3.2.5 Unusual situations during treatment

- **Clotting despite RCA**

Clotting as well as clogging are two different forms of impaired hollow-fibre membrane function. In case of membrane clogging, constituents from the patient's blood are deposited on the membrane and block solute transport across the membrane. The diffusive and convective permeability of the haemofilter membrane is impaired after some time of treatment. Blood flow along the hollow fibre can stay largely unimpaired, resulting in little or no effect on the pressures in the extracorporeal blood circuit.

In case of membrane clogging, this impaired solute transport across the membrane is indicated by:
– Hypercalcaemia and / or decreasing calcium substitution need, due to less removal of calcium-citrate complexes
– Alkalosis, due to less removal of calcium-citrate complexes and more citrate being metabolised resulting in additional bicarbonate generation
– Less removal of uraemic toxins (urea, creatinine)
– Hypernatraemia, due to less diffusive sodium removal

Tip

The multiFiltratePRO indicates a possible membrane clogging by displaying a specific note in case of setting a calcium dose below the expected range (1.3 to 2.1 mmol/l). A need for a calcium dose ≤ 1.2 mmol/l can be a sign of filter clogging.

Early membrane clogging can be patient dependent.

Subsequent precautionary circuit changes could be considered at defined intervals, e.g. every 24 hours. This could avoid further episodes of reduced clearance, alkalosis and hypercalcaemia.

Procedure in the event of membrane clogging

Warning

Loss of filter performance through membrane clogging because of reduced removal of calcium, citrate, sodium, uraemic toxins, etc.

Risk for the patient as a result of incorrect Ci-Ca anticoagulation and changes in the patient's acid-base balance

Risk for the patient as a result of a disorder of the electrolyte balance

Reduced filter performance can lead to hypercalcaemia, metabolic alkalosis, hypernatraemia and insufficient treatment effectiveness. A restricted citrate metabolism increases the risk of citrate accumulation.

➢ The concentration of the acid-base balance and the ionised calcium must be monitored regularly during the treatment.

➢ In the event of hypercalcaemia or unusually low calcium substitution combined with alkalosis, the possibility of clogging must be considered and, if necessary, the extracorporeal circuit replaced.

● Citrate accumulation

Insufficient citrate metabolism and citrate accumulation

The systemically infused citrate is usually metabolised quickly. In patients who have, or develop, a metabolic disorder for citrate, the metabolism is slower. This results in an elevated systemic citrate concentration. As the systemic citrate concentration is only measured in exceptional cases in the hospital, it is assessed indirectly by its effects.

The systemically accumulated citrate also binds calcium ions. As a consequence, the ratio of total to ionised calcium increases. Generally, the increased total-to-ionised-calcium ratio initially is due to a drop of the systemic ionised calcium concentration. The protocol suggests then increasing the calcium dose. A high calcium dose setting on the device can be indicative of a possible citrate accumulation.

After a stabilisation of the systemic ionised calcium by an appropriate calcium substitution, the increase in the ratio of total calcium to systemic ionised calcium is shown by an increased total calcium.
This corresponds to more calcium-citrate complexes circulating in the blood in case of citrate accumulation.

Citrate accumulation may also cause a mild metabolic acidosis. This can, however, also be a symptom of a variety of other causes and is therefore not specific for a metabolic citrate disorder.

Note

The multiFiltratePRO indicates a possible citrate accumulation by displaying a specific note in case of setting a calcium dose above the expected range (1.3 to 2.1 mmol/l). A need for a calcium dose of ≥ 2.2 mmol/l can be a sign of citrate accumulation.

Note

A calcium dose > 3.0 mmol/l cannot be selected. Change of treatment should be considered. As a short-term solution, administer further calcium manually.

Alkalosis / hypercalcemia after citrate anticoagulation

After completion of the treatment, the accumulated calcium-citrate complexes are metabolised by the patient. This may result in alkalosis and hypercalcemia. If clinically indicated, these risks can be reduced by continuing the CRRT treatment without citrate anticoagulation till normalisation of the total-to-ionised-calcium ratio.

8 Consumables, accessories, additional equipment

Warning

Chapter 8 contains a list of consumables and accessories that are suitable for use with this device and can be used safely with it.

The manufacturer cannot guarantee that other consumables and accessories than those listed in this chapter are suitable for use with this device. The manufacturer cannot guarantee that the safety and performance of the device will remain unimpaired if consumables and accessories other than those listed in this chapter are used.

If other consumables and accessories are used, their suitability must be verified beforehand. This can be done with the aid of the information in the instructions accompanying such consumables and accessories.

The manufacturer accepts no liability for damage to the device resulting from the use of unsuitable consumables or accessories.

Warning

Risk for the patient as a result of improper use of consumables

Treatment cannot be performed properly and safely if consumables are used incorrectly.

➢ Follow the instructions that come with the consumables used.

Warning

Risk of loss of blood through blood clotting in the extracorporeal blood circuit

Blood flow rates below the filter's recommended blood flow range can lead to blood clotting in the extracorporeal circuit.

➢ The patient's coagulation status must be monitored regularly.

The local service support organisation will provide information on further accessories, consumables and other additional equipment on request.

Symbols on consumables:

When using consumables, it is important to take note of the following symbols:

Single-use article
Identified by the symbol:

Do not re-use.

Use-by date
Identified by the symbol:

Use by

Long-term operation
Identified by the symbol:

Indication of max. operating time and max. delivery volume

8.1 Consumables

8.1.1 multiFiltratePRO Treatment kits

Product	Information
multiFiltratePRO Kit Ci-Ca® HD EMiC®2	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® EMiC®2
multiFiltratePRO Kit Ci-Ca® HD 1000	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® AV 1000 S
multiFiltratePRO Kit Ci-Ca® HDF 1000	multiFiltratePRO Ci-Ca® HDF treatment cassette with Ultraflux® AV 1000 S
multiFiltratePRO Kit HDF 1000	multiFiltratePRO treatment cassette for HDF, HD, HF with Ultraflux® AV 1000 S
multiFiltratePRO Kit HDF 600	multiFiltratePRO treatment cassette for HDF, HD, HF with Ultraflux® AV 600 S
multiFiltratePRO-Kit TPE P1 dry	multiFiltratePRO treatment cassette for TPE with Plasmaflux® P1 dry
multiFiltratePRO-Kit TPE P2 dry	multiFiltratePRO treatment cassette for TPE with Plasmaflux® P2 dry
multiFiltratePRO-Kit Paed CVVHD	multiFiltratePRO treatment cassette for paediatric CRRT treatment
multiFiltratePRO SecuKit Ci-Ca® HD 1000	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® AV 1000 S
multiFiltratePRO SecuKit Ci-Ca® HD EMiC®2	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® EMiC®2
multiFiltratePRO SecuKit Ci-Ca® HDF 1000	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® AV 1000 S
multiFiltratePRO SecuKit Ci-Ca® HD 400	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® AV 400 S
multiFiltratePRO SecuKit Ci-Ca® HDF 400	multiFiltratePRO Ci-Ca® HD treatment cassette with Ultraflux® AV 400 S

8.1.2 Haemofilters/plasma filters

- **Haemofilters**

Product	Information
Ultraflux® AV 400 S	Ultraflux® haemofilter, steam-sterilised, 0.7 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 52 ml
Ultraflux® AV 600 S	Ultraflux® haemofilter, steam-sterilised, 1.4 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 100 ml
Ultraflux® AV 1000 S	Ultraflux® haemofilter, steam-sterilised, 1.8 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 130 ml

- **Plasma filters**

Product	Description
plasmaFlux® P1 *dry*	Plasma filter (dry on delivery), steam sterilised, 0.3 m^2 surface, blood fill volume 35 ml, Fresenius Polysulfone® membrane
plasmaFlux® P2 *dry*	Plasma filter (dry on delivery), steam sterilised, 0.6 m^2 surface, blood fill volume 67 ml, Fresenius Polysulfone® membrane

8.1.3 Isotonic NaCl solutions

Suitable NaCl solutions must be used. For rinsing the tubing system, amongst other uses.

8.1.4 Dialysate and haemofiltration solutions

Product	Information
Ci-Ca® Dialysate K2	Calcium-free dialysate for regional citrate anticoagulation. 5 l double-chamber bag containing 2 mmol/l potassium
Ci-Ca® Dialysate K4	Calcium-free dialysate for regional citrate anticoagulation. 5 l double-chamber bag containing 4 mmol/l potassium

Product	Information
Ci-Ca® Dialysate K2 ***Plus***	Calcium-free dialysate for regional citrate anticoagulation, 5 l double-chamber bag containing 2 mmol/l potassium and 1.25 mmol/l inorganic phosphate
Ci-Ca® Dialysate K4 ***Plus***	Calcium-free dialysate for regional citrate anticoagulation, 5 l double-chamber bag containing 4 mmol/l potassium and 1.25 mmol/l inorganic phosphate
multi***Plus*** K^+ 2 mmol/l	Phosphate-containing bicarbonate-buffered dialysate, 5-l double-chamber bag containing 2 mmol/l potassium and 1 mmol/l inorganic phosphate

8.1.5 Citrate solution

Product	Information
4 % citrate solution	Original Fresenius solution Trisodium citrate solution for regional citrate anticoagulation, 1.5 l bag

8.1.6 Disposable syringes

Product	Information
Fresenius Medical Care 30 ml	Internal diameter: 22.00 mm
Fresenius Injectomat 50 ml	Internal diameter: 28.84 mm
B. Braun Perfusor 50 ml	Internal diameter: 27.79 mm

Note

The measurements below were taken from a number of sample items.

Fresenius Medical Care cannot be held responsible for possible changes to the syringe measurements.

Product	Information
B. Braun Omnifix 30 ml	Internal diameter: 22.04 mm
B. Braun Omnifix 50 ml	Internal diameter: 27.79 mm
BD Perfusion 50 ml	Internal diameter: 27.79 mm
BD Plastipak 50 ml	Internal diameter: 26.47 mm

8.1.7 Other single-use items

Product	Information
CAVH/D - CVVH/D dialysate connector	Original Fresenius single-use item Adapter for connecting substituate system (with male connector) to haemofilter, e.g. for change of treatment mode
2 x HF female / 4 x HF male adapter	Original Fresenius single-use item For connecting 4 solution bags to one substituate or dialysate system
HF female / Luer lock female PF adapter	Original Fresenius single-use item Adapter for connecting infusion equipment to HF tubing systems
HF female / Luer lock male adapter	Original Fresenius single-use item For connecting solution bags to the substituate system
HF female / spike adapter	Original Fresenius single-use item For connecting solution bags with septum to substituate systems
Hansen male / Luer lock male adapter	Original Fresenius single-use item For setting up a Pre-post CVVH treatment
Spike connector	Original Fresenius single-use item Spike connector / Luer lock female
Spike connector vented	Original Fresenius single-use item Spike connector vented / Luer lock female
Luer lock SN adapter	Original Fresenius single-use item When using two filtrate bags
Y-adapter for filtrate bags, 2x female Luer lock / 1x male Luer lock	Original Fresenius single-use item When using two filtrate bags
Luer Lock female adapter	Original Fresenius single-use item For connecting 2 male Luer lock connectors
Luer lock male adapter	Original Fresenius single-use item For connecting 2 female Luer lock connectors
Collection bag, 2000 ml	Original Fresenius single-use item 2000 ml collection bag with female Luer lock connector
10 litre filtrate bag	Original Fresenius single-use item Filtrate collection bag with drain valve, male Luer lock connector
10 litre single-use filtrate bag	Original Fresenius single-use item Single-use filtrate collection bag with male Luer lock
Pressure line	Original Fresenius single-use item Complete pressure line with filter, male Luer lock connector, 30 cm, blue
Forceps	Original Fresenius single-use item For closing off lines

Product	Information
Freka-Flex transfer system	Original Fresenius single-use item Infusion system with roller clamps and drip chamber
75-cm extension	Original Fresenius single-use item Tube extension male / female Luer lock
Recirculation connector	Original Fresenius single-use item Tube adapter with 2 female Luer lock connectors and grommet

8.2 Additional equipment

Product	Information
Equipotential bonding cable	Original Fresenius accessories Length: 4 m
Equipotential bonding cable	Original Fresenius accessories Length: 8 m
Staff call cord	Original Fresenius accessories
Accessory bag without contents	Original Fresenius accessories
Ethernet cable	Shielding: CAT5 or better Length: 3 m
Power cable	Original Fresenius accessories Length: 3 m
Power cable	Original Fresenius accessories Length: 7 m
Plasma bag holder	Original Fresenius accessories

9 Installation

9.1 Connection requirements

9.1.1 Environment

The following considerations need to be taken into account for the operating environment:
– No splash water area
– Ceilings, walls, floors: smooth, liquid-tight, scrub-resistant, suitable for wet disinfection
– Ensure adequate load-carrying capacity of the floors
– Space requirements of each device approx. 1 m^2
– Emergency lighting (for at least 1 hour in case of power failure)
– Distances to areas such as MRI scanner rooms

9.1.2 Power supply network

Power supply network requirements:
– The requirements specified by IEC 60364-7-710 for Group 1 rooms must be met.
– Power failures < 20 ms
– A grounding system must be installed as prescribed.
– A power socket with a protective earth connection is required.
– The line cross-section and the line lengths to the wall outlet must ensure that the voltage tolerance and the function of the protective devices is always guaranteed. Recommended line cross-section to the power socket: at least 3 x 1.5 mm^2 copper core for 220 V to 240 V and at least 3 x 2.5 mm^2 copper core for voltages of less than 220 V.
– Each electric circuit is protected from damage through fault conditions with an automatic, fast-acting circuit-breaker (recommended: 16 A at 220 V - 240 V and 20 A for voltages < 220 V).
– No more than 1 device per wall outlet and electric circuit.
– The use of power strips and extension cables is prohibited.
– Residual-current devices (RCDs) which protect against dangerous shock currents in the event of fault conditions. One residual-current device (RCD less than 30 mA) for each device or electric circuit.
– Overvoltage / lightning protection in the main and emergency power supply networks.
– An equipment bonding connection must be available for an additional equipotential bonding conductor.

9.1.3 Electrical installation

Warning

Risk of injury as a result of an electric shock

Without a protective earth connection, there is a risk of electric shock.

➢ Always connect the device to a power supply network with a protective earth.

Power supply connection	The national standards and regulations must be observed when connecting the device to the power supply network.
Electromagnetic compatibility (EMC)	Observe during installation and start-up: (see Chapter 12.5 on page 299)
Protective earth	For safety class I devices, the quality of the protective earth conductor of the installation is of particular importance.
Power supply cord	If the power supply cord needs to be replaced, use only the power supply cord approved by the manufacturer and listed in the spare parts catalogue. The use of additional power strips and extension cables is prohibited.
Equipotential bonding	Connect the equipotential bonding conductor to the rear of the device using accessories approved by the manufacturer if this is required by law at the place of installation.
Leakage currents	If additional equipment not listed in the Accessories chapter is connected to the device, there is a danger that the permitted leakage currents will be exceeded.

9.2 Installation / initial start-up requirements

Note

In order to minimise the risk of using incorrect citrate or calcium containers, it is advisable to have only one container of each type (one size and one concentration in each case) available throughout the entire hospital or dialysis centre. The same citrate and calcium container settings must be made in the Setup of all the devices of this organisation institution.

After bringing the device from a cooler room into a warmer room, allow approximately 2 hours for the system to adjust to the ambient temperature before turning it on.

Charging the built-in battery

On receipt of the device, charge the battery as follows:
– Use the power supply cord to connect the device to the power supply.
– Switch the power switch of the device to “on”.
– Leave the power switch of the device on for 10 hours.

9.3 Important information on initial start-up

For initial start-up only

The following information is only intended for the initial start-up. This information does not apply to recommissioning devices that have been taken out of service even temporarily.

Environmental conditions

Variations in temperature during transport may cause water condensation on electrical parts. In the event of major variations in temperature, allow sufficient time for the device to adjust to the ambient temperature before start-up.

Qualification requirements of testers

The initial start-up must only be performed by the manufacturer's service support organisation or a person authorised by it.

The initial start-up must only be performed by personnel qualified to perform the required procedures correctly based on their education, training, knowledge and experience. Furthermore, the persons performing the checks must be permitted to do so independently and without outside interference.

Specifications

The information contained in the Specifications chapter must be observed.

Documentation

The initial start-up report and detailed explanations of how to perform the procedures are described in the Service Manual.

Reports are available upon request.

The completion of the initial start-up must be entered in the Medical Device Register.

10 Transport / storage

Warning

Risk of injury from a tilting device

Tilt hazard when pushing the device or leaning against it or if maximum inclination of 5° is exceeded

If lateral force is exerted or the inclination is > 5°, this may result in tilting or slipping of the device.

➢ Make sure you follow the instructions for relocation and transport.

➢ Ensure that the device is standing in a stable position.

Note

Never pull or push the device while holding onto the scales.

For moving the device, always use the push handles at the front and back.

The device must not be carried. Use a lift, ramp or similar to overcome level differences.

10.1 Relocation

After the initial start-up, a device must only be relocated inside the same building or ward.

Moving the device

The device rests on a trolley and can therefore be moved to different locations without any problems. The trolley features 4 wheels, each of which has a locking brake. The rear wheels can also be locked for pushing.

Using the handles at the front and back, the device can be turned, pushed and pulled in any direction.

Directional stability

After locking the rear wheels into position, use the front handle to push the device before you. Look out for obstacles in your path.

Uneven surfaces

Level differences up to 1 cm.

To avoid damaging or overturning the device, observe the following:

➢ Using the front handle, push the device slowly before you until the obstacle is reached.

➢ Gently push the device over the obstacle, placing one foot on the trolley bar of the device for extra support.

Locking the brakes

Once the device has been moved to its final position for treatment, the brakes on all 4 wheels must be locked.

● **If preparation has already been started, observe the following**

Requirements for relocation

– The functional test has been completed.
– The tubing systems (cassette) have been mounted, filled and rinsed.
– The treatment data has been entered.
– The device is in “Circulation” mode.
– Fold the filter holder forward.
– Swivel and tilt the monitor back against the device.
– The weights carried by the IV poles and the scales must not exceed the following values. The rear hooks on the IV poles should be used.

Left IV pole	5.5 kg
Substituate / dialysate scale, each	12 kg
Right IV pole	5.5 kg

Interrupting the power supply

The device can be disconnected from the power supply by pulling out the power plug. The device indicates a power failure. Press the **Audio paused** button to suppress the audible alarm signal for 2 minutes. The device must be relocated as fast as possible, as battery operation is only possible for a limited time.

Checks after relocation

Particular attention should be paid to the information in chapter 4.1 “Application principles”.

Warning

Risk of air embolism as a result of air in the tubing system

Risk of blood loss as a result of connection sites not closed correctly

➢ Check the following after relocation:

– Make sure all screw-lock joints are properly tightened.
– Ensure that the filtrate bag hangs freely and does not touch any other objects.
– Visually check that the tubing systems (cassette) and the solution bags are not damaged or leaking and that they are properly mounted.

10.2 Transport

The device must never be transported with mounted tubing systems or with any load on the scales.

If the device needs to be transported to a location that is not within the immediate vicinity of its current location, then the relocation goes beyond the scope of the previous section. In this case, the full initial start-up procedure must be performed again at the destination.

Always transport the device in the original packaging. A device transport must only be performed by the manufacturer, or by a person authorised by the manufacturer for this purpose.

10.3 Storage

Note

To ensure that the internal battery is always charged and ready for use, the device must be connected to the power supply and the power switch must be set to “on”.

The device must be stored upright in a well-ventilated room with low variations in temperature.

Maintenance of the built-in battery

On receipt of the device, charge the battery as follows:
– Use the power supply cord to connect the device to the power supply.
– Switch the power switch of the device to “on”.
– Leave the power switch of the device on for 10 hours.

If the device is not used, repeat this procedure every six months.

10.3.1 Storage conditions

Temperature	-20 °C to +60 °C
Relative humidity	30 % to 75 %, temporarily 95 %
Atmospheric pressure	500 hPa to 1060 hPa

10.4 Environmental compatibility / disposal

Warning

Risk of contamination as a result of non-compliance with hygienic measures

The device could still be contaminated when it is returned.

➢ Before the disposal measures begin, the responsible organisation must inform the disposal company responsible for disassembling and disposing of the device that complying with suitable precautionary measures, such as wearing personal protective equipment, is mandatory during disassembly.

Within the EU member-states, the device must be disposed of in accordance with the “Directive on waste electrical and electronic equipment” (WEEE Directive). Also observe the applicable local regulations.

Before the device is sent off for disposal, the responsible organisation must ensure that all consumables attached to the device are removed and the device is disinfected as specified by the manufacturer (see Chapter 6 on page 239).

Moreover, the responsible organisation must ensure that the waste disposal company is informed of the following facts before the dismantling process is begun:

– For information on the batteries and other materials used, consult these Instructions for Use (see Chapter 12.12 on page 314).
– Batteries must be properly disposed of in accordance with the applicable national regulations.
– The device includes electronic circuit boards and an LCD screen.
– More information will be made available by the manufacturer to waste disposal services on request.

11 Technical Safety Checks / maintenance procedures

11.1 Important information on the Technical Safety Checks / maintenance procedures

Technical Safety Checks (TSC)

The first TSC are required before the end of the 24th month following initial start-up after delivery from the factory. All further TSC are required before the end of the 24th month following the last TSC performed.

Maintenance procedures (MA)

The maintenance procedures (MA) are a recommendation of the manufacturer. The maintenance procedures help ensure trouble-free operation, and must be carried out for the first time before the end of the 24th month following initial start-up after delivery from the factory.
All further MA should be performed before the end of the 24th month following the last MA performed.

Qualification requirements of testers

The checks must be performed by the manufacturer’s service support organisation or a person authorised by it.

The specified checks may only be performed by personnel qualified to perform them correctly based on their education, training, knowledge and experience. Furthermore, the persons performing the checks must be permitted to do so independently and without outside interference.

Specifications

The information contained in the Specifications chapter must be observed.

Documentation

The TSC, MA and detailed explanations of how to perform them are described in the Service Manual.

Reports are available upon request.

The completion of the TSC must be entered in the Medical Device Register.

12 Specifications

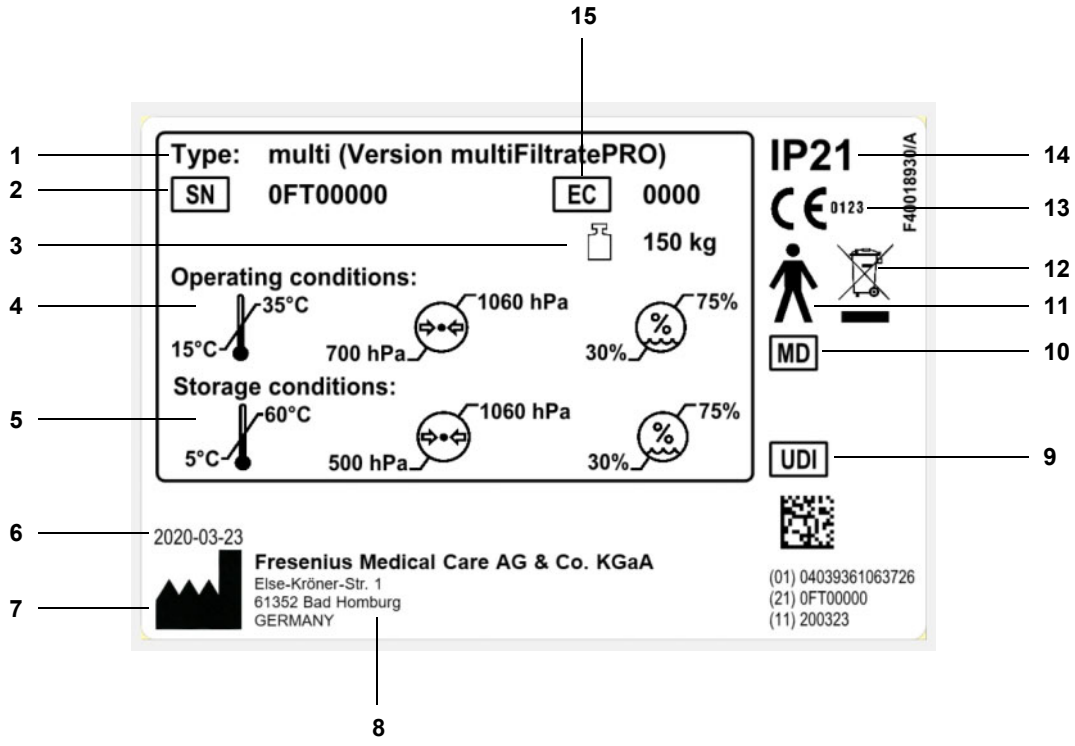
12.1 Dimensions and weight

Dimensions	Height: approx. 167 cm Width: approx. 65 cm Depth: approx. 69 cm (not counting filter holder)
Weight	Weight: approx. 95 kg Safe working load: 45 kg Maximum total weight: approx. 140 kg

12.2 Identification label (device marking)

12.2.1 Identification label of the device

The identification label shown is only an example. Always go by the information shown on the identification label affixed to the device itself.

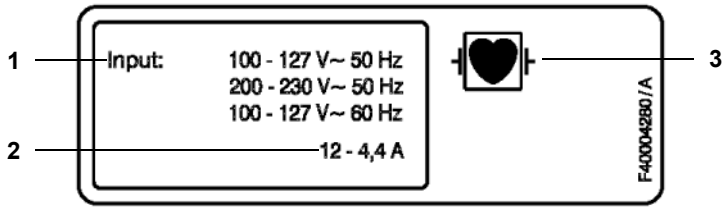


Legend

1 Type identification
2 Serial number
3 Maximum total weight (empty weight plus safe working load)
4 Operating conditions
(temperature range, air pressure, relative humidity)
5 Storage conditions
(temperature range, air pressure, relative humidity)
6 Date of manufacture
7 Manufacturer symbol
8 Manufacturer address
9 Unique Device Identification
10 Medical device
11 Applied part type (degree of protection for the patient): Type B
12 Symbol for the marking of electrical and electronic equipment
13 CE mark
14 Degree of protection against ingress of foreign bodies and liquids
2: Protection against touch and foreign bodies with a diameter greater than 12.5 mm
1: Protection against vertically falling water drops
15 Equipment code (EC)

12.2.2 Power label

The power label shown is only an example. Always go by the information shown on the power label affixed to the device itself.



Legend

1 Power supply rating
2 Operating current
3 Applied part type (degree of protection for the patient)

12.3 Electrical safety

Classification according to EN 60601-1, IEC 60601-1

Degree of protection against electric shock

Protection class I

Applied part

Depending on the treatment procedure, the applied part comprises the extracorporeal blood circuit, the dialysate, substituate, and plasma circuits, and all components with a permanent, conductive connection to these circuits.

Applied part type (degree of protection for the patient)	200 to 230 V AC, 50 Hz: type CF applies 100 to 127 V AC, 50 Hz: type CF applies 100 to 127 V AC, 60 Hz: type CF applies 240 V AC, 50 Hz: type BF applies 200 to 240 V AC, 60 Hz: type BF applies
Defibrillator-proof applied part	The applied part is defibrillator-proof, irrespective of the single-use items used.
Degree of protection against ingress of foreign bodies and liquids	IP21, symbol: **IP21** 2: Protection against touch and foreign bodies with a diameter greater than 12.5 mm 1: Protection against vertically falling water drops
Leakage currents	according to EN 60601-1

12.4 Electric power supply

Line voltage	100 to 240 V AC, 50 to 60 Hz (Always go by the line voltage, frequency and current consumption information specified on the identification label attached to the device itself.)
Power supply connection	16 A at 230 V, determined according to VDE 0100 Part 710
Operating current	Max. 4.4 A, (at 240 V AC) Max. 12 A, (at 100 V AC)
Power supply (internal)	+24 V DC ± 5 %, 35 A short-circuit-proof 800 W total output power
Power switch	All-pole, simultaneous disconnection
Battery	Lead-acid battery (maintenance-free) 2 x 12 V, ≥ 7.2 Ah

12.5 Information on electromagnetic compatibility (IEC 60601-1-2:2014)

Specifications refer to the requirements of IEC 60601-1-2:2014.

This information is valid for devices with a date of manufacture of 2019 and later.

12.5.1 Minimum distances between radiation source and medical electrical equipment

Medical electrical devices are subject to special protective measures with regard to electromagnetic compatibility (EMC).

Warning

Risk for the patient as a result of a device malfunction

Portable RF communications equipment (radio equipment including its accessories such as antenna cables and external antennas) should not be used at a distance less than 30 cm (12 inches) from the device parts and cables designated by the manufacturer. Non-compliance may result in impairment in the performance of the device.

➢ Always maintain a distance of at least 30 cm between portable and mobile RF communication devices and the device.

Portable and mobile RF communication devices can include the following sources of radiation (example devices):
mobile phone, smartphone, tablet PC, cordless phone, notebook/laptop, wireless keyboard, wireless mouse, wireless speaker, wireless remote control (The device-specific wireless remote control provided by the manufacturer is not affected.)

Warning

Risk for the patient as a result of a device malfunction

The use of electrical accessories and cables other than those specified in the Instructions for Use can lead to an increase in electromagnetic emissions or a reduction in electromagnetic immunity of the device.

➢ Only use the accessories and cables approved by the manufacturer.

Warning

Risk for the patient as a result of electromagnetic incompatibility between devices

Electromagnetic interference from other devices can cause device malfunctions.

➢ Do not operate the device in the immediate vicinity of other devices.

If operation in the immediate vicinity of other devices cannot be avoided:

➢ Monitor the device to verify that it is working properly.

12.5.2 Guidance and manufacturer's declaration on EMC

- **Electromagnetic emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The multiFiltratePRO device is intended for use in the electromagnetic environment specified below. The customer or the user of the multiFiltratePRO device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1, Class A	The multiFiltratePRO device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The multiFiltratePRO device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

- **Electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The multiFiltratePRO device is intended for use in the electromagnetic environment specified below. The customer or the user of the multiFiltratePRO device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The multiFiltratePRO device is intended for use in the electromagnetic environment specified below. The customer or the user of the multiFiltratePRO device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles (5 s)	0 % U_T for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles (5 s)	In the event of power supply interruptions, the rechargeable battery of the multiFiltratePRO device temporarily takes over the supply for parts of the system without delay. Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level			
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM bands between 150 kHz and 80 MHz	3 V_{rms} 6 V_{rms} in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

- **Test specifications for IMMUNITY of COVERINGS against high-frequency wireless communication devices**

Test frequency MHz	Frequency band MHz	Radio-frequency communication service	Modulation	Maximum power W	Distance m	Immunity test level V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	Pulse modulation 18 Hz	2	0.3	28

Test frequency MHz	Frequency band MHz	Radio-frequency communication service	Modulation	Maximum power W	Distance m	Immunity test level V/m
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

12.6 Operating conditions

Operating temperature range +15 to +35 °C

Atmospheric pressure 700 to 1060 hPa

Relative humidity 30 % to 75 %, temporarily 95 %

Operating altitude Maximum operating altitude up to 3000 m
The operating altitude depends on the atmospheric pressure and can vary accordingly. A lower atmospheric pressure than the minimum value specified can restrict the functions of the device and cause delays in opening the pressure measurement units.

Inclination during operation Maximum angle of inclination during operation: 5°

Load-bearing capacity per IV pole Maximum: 5.5 kg

Scale load capacity	Maximum: 12 kg each for scales 1 and 2 Maximum: 24 kg total for scales 3 and 4
Plasma bag holder load-bearing capacity	Maximum: 8 plasma bags with a volume of 320 ml each Maximum load per hook: 2 plasma bags with a volume of 320 ml each

12.7 Storage conditions

Temperature	-20 °C to +60 °C
Relative humidity	30 % to 75 %, temporarily 95 %
Atmospheric pressure	500 hPa to 1060 hPa

12.8 External connection options

Warning

Risk of injury as a result of an electric shock

There is a risk of electric shock if the patient comes into contact with the pins or contacts of the device's connectors, whether directly or indirectly through the operator.

➢ Avoid touching connector pins or contacts during treatment.

Other, additional equipment connected to this device must verifiably comply with the applicable IEC or ISO standards (e.g. IEC 60950-1 for information technology equipment).

Furthermore, all device configurations must comply with the requirements for medical electrical systems (see EN 60601-1:2006 section 16 and annex I).

Connecting the device to an IT network that contains components not installed and validated by the manufacturer can introduce unknown risks for patients, operators or third parties. These risks must be identified, analysed, evaluated and controlled by the responsible organisation. For assistance, refer to IEC 80001-1:2010 and annexes H6 and H7 of EN 60601-1:2006.

Any modifications to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore require a repeat analysis. Especially problematic activities include:

– Changes to the IT network configuration
– Connection of additional components and devices to the IT network
– Removal of components and devices from the IT network
– Updates or upgrades of components and devices in the IT network

Note that local laws take priority over the above-mentioned normative requirements. Please address any queries to the local service support organisation.

Relevant documentation for the network connection is available on request.

LAN port

Interface for data exchange.
Electrically isolated by transformer.
Port: RJ 45
Shielding: CAT5 or better
Length: 3 m

RS232 port

The serial port is deactivated during treatment in normal operation.
Electrically isolated by optocoupler.
Port: DSUB 9-pin
Length of a serial line: max. 3 m, shielded

Service / diagnostics port

Serial port for diagnostics equipment.
Only for use by service support.
Port: DSUB 15-pin

Alarm output

For connecting an external alerting system, e.g. nurse call (potential-free alarm output, alternating contact maximum 24 V / 24 W).
Port: 5-pin diode plug via shielded line, shielding must be grounded at both ends.

Only accessories and cables approved by the manufacturer must be used.

Signal transmissions to external alerting systems are not monitored by the device. Connecting an external alerting system has no influence on the visual and audible alarms on the device itself.

Warning

Risk for the patient as a result of ignored alarm signals

The reliability of alarm signal transmissions to external alarm systems cannot be guaranteed, meaning that alarms can fail to be indicated externally.

➢ Stay close enough to the device to be able to notice any alarms it emits at all times.

12.9 Operating programs

Functional test	Automatic test of the operating and safety systems. The functional test is mandatory after power on (not following a power failure).
Preparation	Defined by the optical detector in the return line, below the bubble catcher. Preparation is terminated as soon as the optical detector senses blood in the tubing system.
Filling the tubing system	The tubing systems are automatically filled and deaerated. Filling is terminated automatically.
Rinsing	Rinse volume: 300 to 5000 ml, can be set in the System Parameters menu. UF rinse: 300 to 2000 ml, can be set in the System Parameters menu.
Circulation	After rinsing, the extracorporeal circuit can be kept in circulation until the patient is connected. This is also sometimes referred to as “short-circuiting”.
Patient connection	Connecting the patient
Treatment	Treatment starts as soon as the optical detector senses blood in the tubing system.
Treatment pause	The Treatment pause function allows the patient to be disconnected from the device for a short time during treatment. – Treatment pause without blood reinfusion for short periods – Treatment pause with blood reinfusion
End of treatment / Blood reinfusion	Blood reinfusion continues until the optical detector no longer detects blood, and can be extended for short periods afterwards.
System Parameters	After the functional test has been completed and a treatment has been selected, the volume (loudness) of the audible alarm, screen brightness, key sounds, and the standard values for the selected treatment can be entered as required in the Setup.

12.10 Balancing/dialysate circuit and safety systems

Blood leak/haemolysis detector (yellow)	Optical absorption method (red/green ratio). Response threshold of ≤ 0.5 ml blood loss per minute, dependent on the filtrate flow rate (including measurement tolerance). The response threshold is set to allow a maximum filtrate flow and haematocrit value of 32 %. This corresponds to a maximum possible blood loss of 0.5 ml per minute. Basic measuring accuracy ±0.1 ml/min.

For paediatric treatments and the maximum filtrate flow possible for them, the response threshold is set so that at a haematocrit of 32 % a blood loss of ≥ 0.1 ml/min will be detected.

Flow rates

Depending on the treatment option:

Blood flow*	0 / 10 to 500 ml/min ±10 %
Substituate flow*	0 / 10 to 80 ml/min
Dialysate flow*	0 / 6.3 to 80 ml/min
Citrate flow*	0 / 10 to 600 ml/h
Calcium flow*	0 / 1 to 100 ml/h
Ultrafiltration rate (UF rate)	0 / 10 to 180 ml/min
Filtrate flow	0 / 10 to 180 ml/min
Net UF rate	0 / 10 to 990 ml/h

Pump type: tube pumps with spring-loaded rollers, fully-occluding.

The delivery accuracy of the pumps is ± 10 %, unless regulated by the scales. If regulated (for treatment procedures with scale balancing), the individual delivery accuracy of each pump depends on the accuracy of the associated scale. In this case, the total delivery accuracy corresponds to the specified balancing accuracy.

Ultrafiltration* / net fluid removal

The overall ultrafiltration or UF rate is automatically determined by the set substituate flow, the net UF rate, and the anticoagulation flow.
The net fluid removal of the patient can be selected through the net UF rate.
The ratio of the UF rate to the effective blood flow (UF/BF ratio) is monitored during treatment to ensure that the maximum limit value is not exceeded. If a discrepancy occurs (risk of excessive haemoconcentration), a warning will be displayed after approximately 5 seconds.

Balancing/dialysate circuit

Volume deviation < 1 %, relative to the total delivery volume (depending on the treatment option), if device is standing level or with an angle of inclination of no more than 5°.
If standard treatment parameters are used, and under normal operating conditions, a maximum balancing deviation of 30 ml/h can be expected for HDF treatment types.

For Ci-Ca treatment types, further deviation is possible, depending on the relevant volumes administered (see Page 12-12 for information on the delivery accuracy of the citrate and calcium pumps).

Maximum balancing error during treatment

500 g during the treatment of an adult
50 g during paediatric treatments

Once this maximum balancing error value is reached, either through the addition of individual, smaller deviations or through a single serious balance monitoring error, balancing is automatically deactivated.

In normal operation (scale balancing active and error-free), even a deviation of only a few grams (depending on the flow rate) from the target value will result in a balancing warning. In the event of an error condition (scale defective or minor leaks), greater deviations are possible.

– Maximum balancing deviation < 100 ml/h
– Greater deviations are detected within a total maximum volume deficit of 500 g in adults or 50 g in paediatric treatments (functional test of scales)
– Once the maximum balancing error value is reached, balancing is automatically deactivated.

Balancing error

$E = E_{UF} + E_{SUB} + E_{Anticoagulation}$ (see also under “Balancing/dialysate circuit”)

E = balancing error
E_{UF} = Ultrafiltration error
E_{SUB} = Substitution error
$E_{Anticoagulation}$ = Heparin or Ci-Ca anticoagulation error

Scale system

Maximum load: 12 kg per scale
Weighing range: 0 to 12 kg
Resolution: 1 g
Maximum linear deviation: ≤ ±1 % or 1 g (the higher value always applies)

Substituate/ dialysate temperature*

Treatment options: all treatment modes with exception of TPE and Paed CVVHD

– Adjustable range: off, 35 to 39 °C
– Resolution: 0.5 °C
– At ambient temperatures of ≥20 °C and when using solutions at ambient temperatures, the set temperature is reached in normal operation (active balancing / alarm-free state) with an accuracy of +1.5 °C / -3 °C.
– For ambient room temperatures < 20 °C, greater downward deviations are possible due to heat losses. Additional, external measures must be undertaken as needed in these cases.

There are two alarm threshold values. As soon as an inflow temperature of 42 °C is exceeded, this starts an override condition during which the alarm is not yet sounded. After 120 ml at this temperature, or if an inflow temperature of 46 °C is reached, the alarm is sounded and the fluid inflow is stopped, This must be confirmed by the operator. An automatic restart is not performed until the temperature has dropped below the temperature alarm threshold.

Treatment option: Paed CVVHD

– Adjustable range: off, 35 to 39 °C
– Resolution: 0.5 °C

– At ambient temperatures of ≥ 20 °C and when using solutions at ambient temperatures, with the dialysate flow rates at ≥ 600 ml/h, the set temperature is reached in normal operation (active balancing/alarm-free state) with an accuracy of +1.5 °C / -3 °C.
With dialysate flow rates < 600 ml/h, a temperature of at least 33 °C is reached at the insertion site (connection point between dialysate line and the dialyser).

– For ambient room temperatures < 20 °C and/or where there is a draft, greater downward deviations are possible due to heat losses. Additional, external measures must be undertaken as needed in these cases.

Donor plasma - temperature* (FFP)

Treatment option: TPE

At ambient temperatures of 20 °C to 35 °C, a temperature between 25 °C and 38 °C at the insertion site is achieved when substituate or plasma heaters (active balancing/alarm-free state) are switched on.

Ambient temperature sensor

This temperature sensor measures the ambient room temperature. The measured temperature is used for regulating the integrated heaters. External additional heaters are not regulated.
Accuracy: ±1 °C

Heater microswitch

The microswitch is used for detecting a distended or incorrectly inserted heater bag.

(* = essential features for IEC 60601-1)

12.11 Extracorporeal blood circuit and safety systems

Return line pressure measurement

The hydrophobic filter in the return pressure line is determined to be fully wetted when the return pressure sensor (blue) fails to detect any pressure fluctuations.

Access pressure

Display range: -300 to +300 mmHg
Resolution: 5 mmHg
Accuracy: 10 mmHg

No blood detected:
Access pressure alarm window size: -300 to +300 mmHg

Blood detected:
Access pressure alarm window size: +40 to +200 mmHg

Default value adjustable in User setup,
Factory setting: +200 mmHg

If the access pressure drops below the lower limit, the access line clamp will remain open to allow the pressure in the system to disperse. In the event of any further pressure alarm, the clamp will close.

Return pressure (safety system against external blood leaks)

Display range: -100 to +500 mmHg
Resolution: 5 mmHg
Accuracy: 10 mmHg

No blood detected:
Return pressure alarm window size: -100 to +500 mmHg

Blood detected:
Return pressure alarm window size: +40 to +200 mmHg

Default value adjustable in User setup,
Factory setting: +100 mmHg
Alarm window position can be set over a range from +10 to +500 mmHg (switchover to between -100 and +500 mmHg possible in the event of an alarm, if extending low return pressure alarm is activated in Service setup)

Factory setting: extending lower return pressure limit is deactivated.

Pre-filter pressure

Display range: -50 to +750 mmHg
Resolution: 5 mmHg
Accuracy: 10 mmHg

No blood detected:
Pre-filter pressure alarm window size: -50 to +750 mmHg

Blood detected:
Pre-filter pressure alarm window size: +40 to +200 mmHg

Default value adjustable in User setup,
Factory setting: +200 mmHg

TMP (CRRT)

Display range: -300 to +500 mmHg
Lower alarm limit: -60 mmHg
Upper alarm limit: +520 mmHg
Accuracy: 20 mmHg
Displayed only in Pressure / alarm history tab of treatment screen.
The TMP is calculated and displayed according to the following formula:

$TMP = ((P_{ven} + P_{pre}F) / 2) – P_{fil} + Offset$

TMP = transmembrane pressure
P_{ven} = return pressure
$P_{pre}F$ = pre-filter pressure
P_{fil} = filtrate pressure
Offset = 20 mmHg (correction value to compensate for hydrostatic pressure differences)

TMP (TPE)

Display range: -60 to +270 mmHg
Pressure alarm windows
- Lower alarm limit: -60 mmHg
- Upper alarm limit: +50 mmHg to maximum upper alarm limit
  Maximum upper alarm limit can be defined in User setup between +50 and +100 mmHg

Accuracy: 20 mmHg
The TMP is calculated and displayed according to the following formula:
$TMP = ((P_{ven} + P_{pre}F) / 2) – P_{fil} + Offset$
TMP = transmembrane pressure
P_{ven} = return pressure
$P_{pre}F$ = pre-filter pressure
P_{fil} = filtrate pressure
Offset = 20 mmHg (correction value to compensate for hydrostatic pressure differences)

Blood pump

Spring-loaded rollers, fully occluding, pressure-limited to 2 bar for standard line with pump segment 6.4 x 1.8 (when using the prescribed tubing systems).

Warning

Risk for the patient as a result of insufficient detoxification

If the access pressure before the blood pump reaches extreme negative values, the blood flow can be reduced, which will impair the effectiveness of the treatment.

➢ Take suitable steps to avoid an extreme negative access pressure.

Delivery rate:
CRRT: 10 to 500 ml/min
CRRT with citrate anticoagulation: 10 to 200 ml/min
TPE: 10 to 300 ml/min

Resolution: 10 ml/min

Delivery rate:
Paed CVVHD 8 kg – 16 kg: 10 to 100 ml/min
Paed CVVHD 16 kg – 40 kg: 10 to 200 ml/min

Resolution:
Delivery rates of 10 ml/min to 50 ml/min can be set with a resolution of 1 ml/min.
Delivery rates of 50 ml/min to 100 ml/min can be set with a resolution of 5 ml/min.
Delivery rates of 100 ml/min to 200 ml/min can be set with a resolution of 10 ml/min.

Flow accuracy over
Pressure range ≥ -300 mmHg ≤ 10 %
Standard line with pump segment 6.4 x 1.8 mm
System accuracy of the delivered blood volume: ±10 % considered over the entire treatment duration and valid in typical treatment situations.

Blood pump stop alarm:
time-based standstill monitoring as a safety system against blood loss through clotting.
Alarm delay when blood pump stops:
1 minute (during treatment)
3 minutes (while patient is being connected or disconnected)
Alarm repeat if blood pump standstill continues: every 60 s

Fill level detector

Method:
Capacitive measurement

Switching point 13 mm, ±4 mm from upper edge

Optical detector

Method: infrared transmission

Distinguishes between:
– No blood detected (NaCl solution or air in tubing)
– Blood detected (blood in tubing)

Air bubble detector

Method:
Ultrasound transmission measurement through tubing

Detects:
– Air bubbles
– Microbubbles

Air alarm in the following cases:
– Microbubbles
– Blood flow rate < 100 ml/min:
  Air bubble: volume ≥ 20 µl
– Blood flow rate ≥ 100 ml/min:
  10 air bubbles with a bubble volume of ≥ 20 µl to < 50 µl each
  or 1 air bubble with a bubble volume of ≥ 50 µl

The above data is based on a worst-case assumption, at a blood flow rate of 0 to 500 ml/min using the prescribed tubing systems.

Full sensitivity at the maximum blood flow is achieved with patients weighing upwards of 45 kg.

In order to ensure a similar sensitivity with patients weighing less than 45 kg in a worst-case scenario (level in bubble catcher has dropped), select a lower maximum blood pump rate according to the following table.

General limit value: 0.03 (ml/min) per kg		
Patient weight	Max. infused air for lowest possible hazard	Limited max. blood flow (condition: wetted)
8 kg	0.24 ml/min	91.6 ml/min
9 kg	0.27 ml/min	100 ml/min
16 kg	0.48 ml/min	183.2 ml/min
18 kg	0.54 ml/min	200 ml/min
40 kg	1.2 ml/min	458 ml/min
From 45 kg	≥ 1.35 ml/min	≥ 500 ml/min

Heparin pump

Pump type: syringe pump
Delivery rate: 0.5 to 25 ml/h
Resolution: 0.1 ml/min
Accuracy: ±5 % for delivery rate 1 to 25 ml/h measured over 2 hours with up to 1.2 bar counterpressure. At delivery rates < 1.0 ml/h, the tolerance could exceed the specified ±5 %.
Bolus administration: 0.1 to 5 ml in increments of 0.1 ml (preset maximum bolus volume is 5 ml. This parameter can be set to a lower volume in the System Parameters).
Bolus rate: 30 ml/min

Audible tone

Sound pressure level settings of the audible alarm:
Volume range: 50 to 80 dB ±5 dB
Factory setting: ≥ 65 dB
High-priority alarm: 60 to 80 dB ±5 dB
Medium priority alarm: 60 to 80 dB ±5 dB

Ci-Ca drip counter	Measuring range: 0 to 4 drips per second (independently for citrate and calcium) Measuring method: optical To permit drips to be detected accurately, the fluid level must be within or below the markings.
Citrate pump	Pump type: roller pump Delivery accuracy: ±10 % Delivery rate: 10 to 600 ml/h, depending on citrate/blood ratio. Dose can be set. Concentration of citrate per litre of delivered blood: 2 to 6 mmol/l in 0.1 mmol/l increments Default value: 4.0 mmol/l
Calcium pump	Pump type: roller pump Delivery accuracy: ±10 %, at delivery rates < 6 ml/h the deviation can be ±20 % Delivery rate: off, 1 to 100 ml/h, depending on calcium/filtrate ratio. Dose can be set. Concentration of calcium per litre filtrate: 0 to 3 mmol/l in 0.1 mmol/l increments Default value: 1.7 mmol/l The Ci-Ca pumps run at a higher delivery rate (400 ml/h) while the Ci-Ca tube segments are being inserted/removed and the tubing system is being filled.
Ci-Ca fill level detector	Function: for detecting and differentiating between a full or empty Ci-Ca drip chamber (independently for citrate and calcium). Measuring method: optical To permit a filled drip chamber to be detected accurately, the fluid level must be within or above the markings.
Cassette detector	Differentiates between cassettes with and without a Ci-Ca system using a colour sensor and colour codes on the cassettes. Cassette without Ci-Ca (patient weighing 40 kg and upwards): blue marking Ci-Ca cassette: yellow marking Paed cassette without Ci-Ca (patient weighing 8 kg to 40 kg): magenta marking

12.12 Materials used

- **Plastics and cast resins**

Abbreviation	Material
ABS	(PBT+ABS)-GF20 ALTECH PBT+ABS A 2020/620 GF20 UV Albis RAL 9001-GL, cream WT1028-08, Albis (PC+ABS)-GF8 FR ROMILOY 9035 GF8 UV Romira RAL 9001-GL, cream 16882, Romira ABS-SE Osstyrol Hagedorn Plastirol RAL 9001-GL, cream MB Hacoplast HP 45427-1, Habich's Söhne
Vinyl	ERT-SOAF-VSGN-10046 ERT-SOAF-VW-10635
Duplobond	Duplobond 360.2 plus, polyethylene paper, pure acrylate, polyester film
Eastar	Eastar DN011
EPDM	EPDM Shore 70 A EPDM-XPP Shore 64 A
GV	Grivory GV-4H natural Grivory GV-5H natural
HY/EPDM medium resistance	Cellular rubber
Iglidur	Iglidur J Iglidur W300
Kapton film	MT50SK polyimide film
LD-PE	LD-PE (SK-03) polyethylene
Lupolen	Lupolen 1800 H, colourless
NBR	N7LM (70 Shore A)
PA6.6	PA6.6, natural PA6.6, black
PA6	PA6 GF15 PA6 GF10/GK20 (Frianyl) PA6 G, black PA6-(GF10+GB20) NILAMID B3 GFB1020 WT 9001/F Celanese RAL 9001-GL, cream
PA66	GF30 Ultramid A3EG6, black Ultramid A3K
PBT	Glass fiber-reinforced PBT composite

Abbreviation	Material
PEEK	Polyether ether ketone
PET	PET (P) natural, cream
PETG	Polyethylene terephthalate copolymer, cream
POM	Hostaform C 13021 Polyoxymethylene, natural Polyoxymethylene, cream RAL 9001 POM -C GF 25
PP	Hostacom G2UO2
Polyester	Polyester 100 %, Cu+Ni
PU	8052 white (similar to RAL 9001) MG 804 GR, black MG 804 GF, black GM959 white (similar to RAL 9001) PX 515, cream RAL 9001 SG95, transparent
PT	PT WN1452 VZ
PVC, hard	PVC, hard
PVC, soft	PVC, soft 65 +/- Shore A
PVC U	PVC U
Pocan	Pocan KU2-7125
Santoprene	Santoprene 271-80 R RAL 7038 agate grey Santoprene 271-73, 73 +-5 Shore A RAL 7038 agate grey
Elastosil silicone	LR 3003-50 45° Shore A, agate grey RAL 7038 LR 3003-70 Shore, natural, transparent LR 3003-70, agate grey RAL 7038 LR 3003-60 Shore A, cream RAL 9001 GL P60 (MVQ) WEHA-SI 5250 agate grey RAL 7038
Silicone	SIL (F163.900) fiberless insulating rubber bushing Silicone rubber bushing Silicone-coated paper
TPE	Alruna W50 RAL 9001 Alruna W60 RAL 9001
Nonwoven fabric	Nonwoven fabric, acrylic copolymer
Zytel	Zytel (nylon)

- **Metals, glass, graphite, ceramics**

Abbreviation	Material
Al	Aluminum Al Cu Mg Pb anodised E6 EV1, colourless Al Mg3 F25 DIN 1784 Al Mg Si 0,5 F22 Al Mg 1 F21 Al Mg 1 F21 coil-anodised E6 EV1 Al Mg 3 DIN EN ISO 9445 Al Mg 4.5 Mn Al Mg Si1 F28, RD EN 755-3 Al Mg Si1 W28
Bimetallic strip	Bimetallic strip
Cu	Copper
EP GC	Epoxy resin glass cloth EPGC 202 DIN 7735, type 2372.1, thickness 0.5 mm
Spring steel	Spring steel blank, DIN471 Form A
Float glass	Float glass
Brass 58	CuZn39Pb3
Brass	CuZn39Pb3 F44 Brass DIN 9021
Steel	Steel 8 zp. blue passivated, DIN 985 1.3541 (X47Cr14 DIN EN ISO 683-17) 1.0330 (ST12), sheet-steel DIN EN ISO 10131 1.0330 (ST12ZE), zinc electroplated zinc plated, chromated Steel blue annealed 5 µ, stamped Tempering class 5.8, gunmetal finish, case-hardened to 0.2 - 0.4 mm depth Steel 45H A2-2, DIN 914 Steel 9 S MnPb 28 K Steel 8.8, ISO 7380m zinc-plated Steel 8.8, zinc plated, DIN 7985
Stainless steel	1.4021 1.4037 (X65Cr13) 1.4122 1.4301 (V2A, X5CrNi18-10) 1.4305 1.4310 (X10CrNi18-8) 1.4401 (V4A) 1.4404 1.4568 (spring wire) A1, A2, A4 DIN 965-TX
Tin plate	1.0375

- **Electrical equipment**

Component	Material
Thermistor	Silicon
	Copper
	Silver
	PTFE
	Epoxy resin
Weighing cell platform	Aluminum, silicone rubber, PVC
Power switch	Thermoplastic case
	Copper
	Tin
	Bronze contacts
	Glass fiber-reinforced thermoplastic
Power supply unit	Aluminum
	FR-4 (PCB base material)
	Copper
	Tin
	Silicon
	Polyester
	Polyurethane
	Iron cores
	Ferrite cores
	PVC
Noise filter	Iron cores
	Ferrite cores
	Copper
	Tin
	PVC
	Polyester
Plug connectors	Copper + tin
	Glass fiber-reinforced thermoplastic
Cables	Copper

Component	Material
	PVC
	Teflon
Electronics	Electronic circuit boards
	LCD screen
	Glass fiber-reinforced thermoplastic
	Ferrite cores
	Copper
	Tin
	Silicon
	Lithium batteries
	Lead-acid rechargeable batteries
Drives	Ferrite rubber magnet
	Polyester / PTZTR (Avery Dennison)
	Micares X 1087 GY (Micafil)
	Delrin 500 (DuPont)
	RNF-100 (Raychem)
	Magnesol U-180 (Lacroix + Kress)
	PA Ultramid A3HG7nc (BASF)
	Glass-reinforced epoxy resin FR-4
	Polyester / PTWTR (Avery Dennison)
	Loctite 603
	Hardloc red 903686 (Denka)
	Hardloc green 906245 (Denka)
	PA66
Motor-gearbox combination	Polyamide, reinforced
	Steel
	Esters + polyolefin oil, lithium soap

Component	Material
	Brass
	Perfluorinated polyether, polytetrafluoroethylene (PTFE)
	Urethane methacrylate, butylcyclohexyl methacrylate, acrylic acid, butylene glycol dimethacrylate, hydroxypropyl methacrylate, acetylphenylhydrazine, octylphenoxy polyethoxy ethanol, cumene hydroperoxide

- **Auxiliary materials**

Auxiliary material group	Material
Felt	Wool, carbonised viscose
Gear lubricant	Molykote L-1122
Silicone sealant	DOW Corning 794F Aloxy Sealant
Silicone rubber	Material 70105070, Wacker Silicones E 41 transparent, 10-g tube, neutral
Double-sided adhesive tape	Adhesive: acrylate A 20, backing material: polyurethane foam (open-cell)
Adhesive	Araldite 2021-1, two-component toughened methacrylate adhesive system
Adhesive	Araldite 2029, two-component toughened methacrylate adhesive system
Adhesive	Araldite 2048-1, two-component toughened methacrylate adhesive system
Adhesive	Loctite 243 (acrylate, dimethacrylate ester)
Adhesive	Loctite 401
Adhesive	Loctite 406 (cyanoacrylate, ethyl cyanoacrylate)
Adhesive	Loctite 454 (cyanoacrylate, ethyl cyanoacrylate)
Adhesive	Cyanolit
Adhesive	Hysol 3421

Auxiliary material group	Material
Adhesive	Polysiloxane
Primer	Loctite 770 (polyolefin)
Lubricating oil	Paraliq P460: paraffin. Mineral oil, synthetic hydrocarbon oil, colourless - light yellow

- **Lacquers**

Auxiliary material group	Material
Top coat (powder coat)	Top coat DURAMix 331 RAL 9006, white aluminium Top coat Freopox PB3012A RAL 9001 - GL, cream Top coat FREOPOX PB1031A RAL 7035, light grey
Wet coating, filler primer	Filler primer Alexit 484, signal grey Filler primer Alexit 484, white Alexit 342-67
Wet coating, top coat	Top coat Alexit 5300 RAL 7035, light grey Top coat Alexit 5300 RAL 9001 - GL, cream Alexit 346-18 Freopox PB 10 13 A
Print colours	Printing TD RAL 9005, deep black Printing TD RAL 9003, signal white Printing TD RAL 9029, mint green
Print colours, top coat	TP-218 / 65-HD NT TP-218 / 60 TP-218 / C-MIX 2000

13 Definitions

13.1 Definitions and terms

The terms used in this document correspond to the terminology defined in DIN 58352. Below is a selection of terms that may require further explanation.

Access pressure The access pressure is the pressure in the access system, between the patient's vascular access and the blood pump.

Access system The part of the extracorporeal blood circuit from the patient to the inlet of the filter.

Alarm function check The alarm function check is the verification of the proper function of the alarm equipment.

Alarm limit The alarm limit is a measured value which, if reached, will trigger an alarm.

Blood leak detector The blood leak detector is a device that detects the presence of blood in the filtrate and plasma lines.

Blood pump The blood pump is the device that transports the blood in the extracorporeal circuit.

Blood substitute Solutions such as albumin solutions with physiological, colloidal concentrations or appropriately diluted erythrocyte concentrates.

Battery Internal emergency power supply capable of supporting emergency operation for a limited time in the event of power failures.

Calcium flow The calcium flow is the volume of calcium solution added to the patient’s blood per time unit.

Calcium pump The calcium pump is used for adding calcium solution to the patient’s blood in the extracorporeal circuit.

Card slot The card slot is for inserting the UserCard / ServiceCard.

Citrate dose The citrate dose is the volume of citrate solution added to the patient’s blood in relation to the blood flow. The dose is specified in mmol per litre of blood.

Citrate flow The citrate flow is the volume of citrate solution added to the patient’s blood per time unit.

Citrate pump The citrate pump is used for adding citrate solution to the patient’s blood in the extracorporeal circuit.

Convection	Convection describes the transport of solutes together with the solvent (drag effect, e.g., haemofiltration).
Dialysate	Dialysate is the term for the solution that removes water and waste from the blood in haemodialysis. In the dialyser, it flows around the blood in the opposite direction to it, separated only by the semipermeable membrane.
Diffusion	In haemodialysis, diffusion is the term used to describe the change in concentration of the solutes as they are transported in the solutions.
Exchange volume	The exchange volume is the amount of fluid filtered out of the blood and replaced with substituate on a 1:1 basis (flow rate specified as ml/h or ml/min). The effectiveness of the treatment is significantly proportional to the quantity of the exchange volume. The flow rate is the indicator of the speed at which the exchange is performed.
Extracorporeal blood circuit	The extracorporeal blood circuit is the blood circuit outside the body, e.g., in the haemodialysis device.
Filter life	The filter life is the parameter that is used to monitor how long blood has been flowing through the tubing syste1m. This is basically the same as the treatment time, but will normally be higher, because, while the treatment time count is suspended when balancing is interrupted, the filter life count continues.
Filtrate bag	The filtrate bag is the collection bag for the filtrate (ultrafiltrate), otherwise known as waste.
Filtrate / filtrate flow	Filtrate or filtrate flow is the sum total of the dialysate, substituate, net UF, heparin, citrate and calcium flow. The filtrate or filtrate flow forms the basis for the internal calculation of the calcium dose by the system.
Filtration	Filtration describes the convective flow of solvents, e.g., water, through a membrane, in following a hydrostatic and/or osmotic pressure gradient. Dissolved particles are also carried along (convective transport) if they are not retained by the membrane.
Haemodialysis	Haemodialysis describes the diffusion and exchange process that takes place between the dialysate and the patient's blood in the extracorporeal blood circuit.
Haemofiltration	Haemofiltration is the ultrafiltration of plasma water and its solutes to eliminate endogenous and exogenous toxins and water while simultaneously replacing the ultrafiltrate with appropriate amounts of electrolyte solution.
Heparin pump (anticoagulant pump)	The heparin pump is used for adding the heparin anticoagulant to the patient’s blood in the extracorporeal circuit.
Hook-up test	The hook-up test is used for verifying that the pressure measurements via the pressure domes are working properly. It is also a test of the tubing system.

Insertion switch	Insertion switches are provided in the pump beds of the citrate and calcium pumps. The system uses the insertion switches to detect whether or not the respective Ci-Ca line pump segments have been correctly inserted.
Kit service life	This is a parameter that shows how long the tubing system has been in use. The kit service life is measured from the start of filling and generates a repeated alarm if the maximum time in operation and/or the maximum transported blood volume is exceeded. The kit should be replaced without delay in this case.
Net UF volume	This is the volume of fluid filtered out of the patient's blood that is not returned, i.e., is used to control the patient's body weight (the net UF rate is specified in ml/h).
Predilution	Adding substituate upstream of the haemofilter.
Post-filter calcium concentration	The post-filter calcium concentration indicates the efficiency of the regional citrate anticoagulation and can be used as a control parameter.
Postdilution	Adding substituate downstream of the haemofilter.
Preparation time	The preparation time begins when filling is started and ends when blood is detected while the patient is being connected. A single warning is displayed if the maximum preparation time is exceeded. Preparation can be continued after confirming the message. The preparation time also counts as part of the kit service life.
Return pressure	The return pressure is the pressure in the return line (e.g., in the bubble catcher).
Return system	The return system is the part of the extracorporeal blood circuit from the filter outlet back to the patient.
ServiceCard	Card for use by service engineers
Substituate	The substituate is the substitution fluid used in haemofiltration.
Systemic calcium concentration	This means the systemic, ionised calcium concentration in the patient. This measured value is used to verify and control calcium substitution.
Treatment time	This is the effective treatment duration so far, not including messages and periods during which balancing is switched off.
UserCard	Card for use by operators

13.2 Abbreviations

AC	Alternating current
AV	Arterio-venous

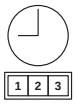
BF	Blood flow
Ca	Calcium
Ci	Citrate
CO2	Carbon dioxide
CRRT	Continuous renal replacement therapy
CVVH	Continuous venovenous haemofiltration
CVVHD	Continuous venovenous haemodialysis
CVVHDF	Continuous venovenous haemodiafiltration
DC	Direct current
ECCO2R	Extracorporeal carbon dioxide reduction
ECG	Electrocardiography
FFP	Fresh frozen plasma
Fig.	Figure
HD	Haemodialysis
HF	Haemofiltration
HIT	Heparin-induced thrombocytopenia
HP	Haemoperfusion
HUS	Haemolytic-uraemic syndrome
iCa	Ionised calcium
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulation Forum
LED	Light-emitting diode
P	Pressure
Pre-post CVVH	High-volume continuous venovenous haemofiltration
RCA	Regional citrate anticoagulants
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
TSC	Technical Safety Checks

SVHC	Substance of Very High Concern
TMP	Transmembrane pressure
TPE	Therapeutic plasma exchange
TTP	Thrombotic thrombocytopenic purpura
UF	Ultrafiltration
MA	Maintenance procedures

13.3 Symbols

Symbol	Description
	Applied part type (degree of protection for the patient): Type B
	Applied part type (degree of protection for the patient): Type BF
	Applied part type (degree of protection for the patient): Type BF, defibrillator-proof
	Applied part type (degree of protection for the patient): Type CF
	Applied part type (degree of protection for the patient): Type CF, defibrillator-proof
IP21	Degree of protection against ingress of foreign bodies and liquids 2: Protection against touch and foreign bodies with a diameter greater than 12.5 mm 1: Protection against vertically falling water drops
	Alternating current
	Protective earth
	Functional earth
	Equipotential bonding

Symbol	Description
	Dangerous electrical voltage
	Dangerous electrical voltage
I	ON
O	OFF
I/O	ON / OFF
	On / Off
CE 0123	The CE mark documents compliance with the current European medical device regulations. Notified body: TÜV SÜD Product Service GmbH (0123)
	Symbol for the marking of electrical and electronic equipment (Do not dispose of the device with household waste.)
	Corrosive substance warning
	Blood pump
	LAN (local area network) network connection
	Service port
	Alarm output
	Alarm output
	Non-ionising electromagnetic radiation
	Maximum total weight

Symbol	Description
	Warning, hot surface
	Manufacturer with date of manufacture
	Serial number
	Medical device
	Unique Device Identification
	Follow instructions for use
	Warning, tilt hazard when pushing the device or leaning against it
	General warning
	Warning, do not overload (respect the maximum load)
	Operating hours counter
	Printer port
	Scales
	RS 232 port
	Max. operating time and max. delivery quantity
	Direction of rotation, e.g., of a rotor
	Audio paused

Symbol	Description
	Scale 1 marker (green)
	Scale 2 marker (white)
	Wheel direction can be locked Wheel can be swivelled Wheel can be locked (brake function)

13.4 Certificates

The acute dialysis system is approved within the European Union (EU) under the Medical Device Regulation (MDR) as a Class IIb medical device.

The current versions of the EC certificates will be provided by your local service support organisation on request.

14 Options

14.1 Chapter without content

To facilitate the use of documents from Fresenius Medical Care, the organisation of the chapters has been standardised in all manuals. There may therefore be chapters within this document without any content.

15 Appendix

15.1 Instructions on the use of “free software”

Content

A. Device – “Free software”
B. Notice required according to German Medical Devices Act
C. Information and remarks on the free software contained in the device
D. License texts

A. Device – “Free software”

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LGPLv2
https://www.gnu.org/licenses/old-licenses/lgpl-2.0.en.html

LGPLv2.1
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C. Information and remarks on the free software contained in the device

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We should be pleased to provide you by mail with a DVD containing a full machine-readable copy of the source text of any or all free software packages used and licensed under GPL or LGPL, for a period of three years starting at the time when this device was put into circulation (i.e., when the device was acquired). Only the usual copying and transfer costs will be charged. If you want us to send this CD to you, please inform us accordingly, by e-mail, telefax or mail, under the address given in the Operating Instructions. Please do not forget to specify the system type and the system number.

List of free software packages:

The following list includes all open source software packages used in the operating system, along with the applicable license(s) under which the software is circulated plus any associated copyright notices. The names of the software packages correspond to the labels in the package list of the Linux distribution used, “ElinOS 5.1”. The exact license texts are listed in the next chapter.

Explanation of abbreviations:

BSD	Berkeley Software Distribution (licensed by the University of California, Berkeley (UCB))
BZIP2	Special license for the bzip2 library
GPL	GNU General Public License
LGPL	GNU Lesser General Public License (special license for libraries)
MIT	Massachusetts Institute of Technology
PD	Public Domain (software not subject to any license)
PNG	Portable Network Graphics (special license for this library)

ash:
Licenses: BSD

busybox:
Licenses: GPL 2

bzip2:
Licenses: BSD

e2fsprogs:
Licenses: GPL 2

fbset:
Licenses: GPL 2

gawk:
Licenses: GPL 2

gdbserver:
Licenses: GPL 2

glibc:
Licenses: LGPL

grub:
Licenses: GPL 2

hdparm:
Licenses: BSD, Mark Lord

Kernel:
Licenses: GLP 2

libnano-X:
Licenses: MPL, GPL 2

libpng12:
Licenses: libpng license

libstdc++:
Licenses: GPL 3 with exceptions

libxml2:
Licenses: MIT

libz:
Licenses: Other uncritical OpenSource License

ltt-control:
Licenses: GPL 2

microwindows-0.92:
Licenses: MPL, GLP 2

module-init-tools:
Licenses: GPL 2

nano:
Licenses: GPL 2

openssh:
Licenses: BSD

Openssl:
Licenses: dual OpenSSL, SSLeay license and Apache-style

stunnel:
Licenses: GLP 2

tinylogin:
Licenses: GPL 2

util-linux:
Licenses: GPL 2, LGPL 2, BSD, PD (check source)

vim:
Licenses: Charityware

D. License texts

1.GPL 2

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Version 2, June 1991

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If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

Otherwise, if the work is a derivative of the Library, you may distribute the object code for the work under the terms of Section 6. Any executables containing that work also fall under Section 6, whether or not they are linked directly with the Library itself.

6. As an exception to the Sections above, you may also compile or link a “work that uses the Library” with the Library to produce a work containing portions of the Library, and distribute that work under terms of your choice, provided that the terms permit modification of the work for the customer's own use and reverse engineering for debugging such modifications.

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For an executable, the required form of the “work that uses the Library” must include any data and utility programs needed for reproducing the executable from it. However, as a special exception, the source code distributed need not include anything that is normally distributed (in either source or binary form) with the major components (compiler, kernel, and so on) of the operating system on which the executable runs, unless that component itself accompanies the executable.

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If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

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