NEWTON IQ®
putting science to work for you

NEWTON IQ® CYCLER *operator manual*

FRESENIUS

START

STOP

SELECT

NEWTON IQ
putting science to work for you

<u>NEWTON IQ® CYCLER OPERATOR MANUAL</u>

*US Federal law restricts this device to sale only by or on the order of a
physician. Frequency, duration, and parameters of treatment are to be
determined by the prescribing physician.*

*Indications for use: the Fresenius NEWTON IQ Cycler is indicated for
acute and chronic peritoneal dialysis.*

FRESENIUS
MEDICAL CARE

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1. GETTING YOUR CYCLER READY

a. Receiving the Cycler

The Cycler is delivered to you at your home. Everything needed for the Cycler is included in one box. It is best if you set up the Cycler Stand first. Once the Cycler Stand is set up, the Cycler Control Unit, Manifold Holder and Pump-to-Drain simply hook onto the Cycler Stand.

b. Setting-Up the Cycler

A complete list of Cycler parts needed for setup is as follows:

1. Operator Instructions
2. Newton IQ Procedure Card P/N 470210
3. Newton IQ Assembly Procedure Card P/N 470211
4. Stand Poles (upper pole and lower pole)
5. Cycler Stand Base
6. 2 Hitch Pins (locking pins)
7. Hanger Rod (for hanging Cycler Control Unit onto Cycler Stand)
8. 20-Liter Bag Organizer (used on top of the Cycler Heater/Scale)
9. Cycler Control Unit
10. Drain Hook (for Drain Bag)
11. Pump-to-Drain
12. Pump-to-Drain Hanger Bracket
13. Manifold holder (used on top of the cycler stand)

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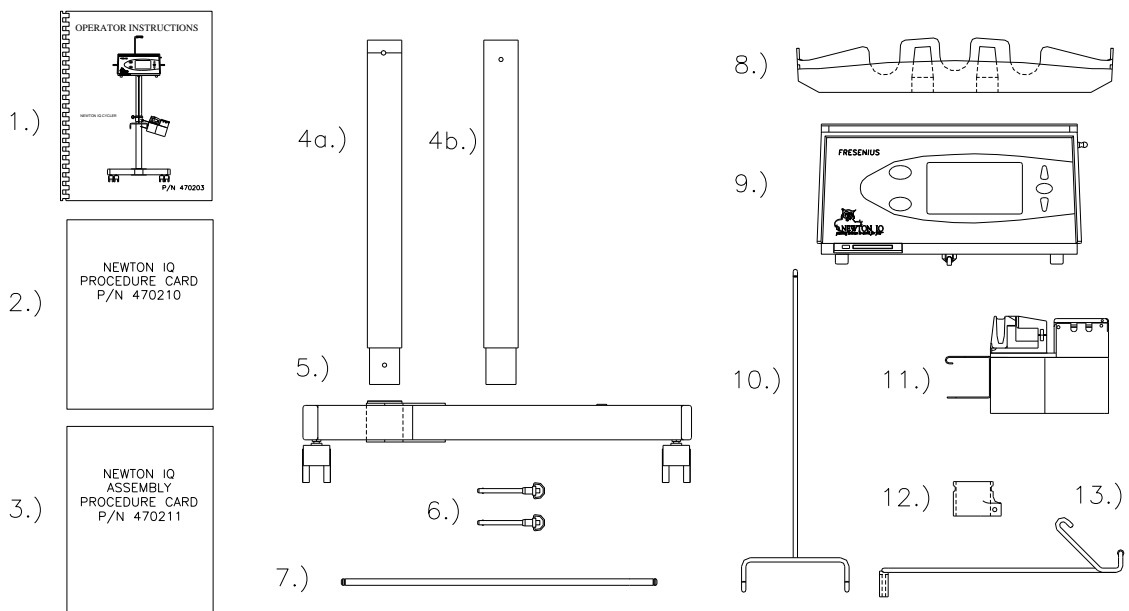
GETTING YOUR CYCLER READY (cont'd)

c. Cycler Stand Assembly Instructions

Hole for
Hanger Rod

Upper
Pole

Pump-to-Drain
Hanger Bracket

Upper
Hitch Pin

Lower
Pole

Lower
Hitch Pin

1.   Place the Lower Pole into the Cycler Stand Base. Make sure the holes in both the Lower Pole and the Cycler Stand Base are lined up so that the Lower Hitch Pin will go through both pieces to hold them together.

2.   Press and hold the button on the end of the Lower Hitch Pin to flatten the locking bearings. Push the Lower Hitch Pin through the lined-up holes in the Lower Pole and the Cycler Stand Base. Let go of the button. This locks the Lower Hitch Pin in place.

3.   Place the Upper Pole into the Lower Pole. Line up the holes in both poles. Slide the Pump-to-Drain Hanger Bracket over and down the Upper Pole. Line up the slot in the Pump-to-Drain Hanger Bracket with the Upper and Lower Pole holes and insert the Upper Hitch Pin through all three items.

4.   Remove the Hanger Rod from the Cycler shipping box. Push the Hanger Rod through the upper holes at the top of the Upper Pole. The Hanger Rod should form a "T" with the Upper Pole.

Cycler Stand Base

WARNING!   The Cycler Stand could potentially tip over and cause injury if a Cycler and Stand is used in a tilted position or if moved without appropriate care. Never place objects under the Cycler Stand wheels to level the stand!

Hanger Rod

GETTING YOUR CYCLER READY (cont'd)

d. Cycler Control Unit Setup

1. Pick up the Cycler by its bottom, front and back. Lift the Cycler out of its shipping box**.**

   CAUTION! Do not lift the Cycler by the Heater Tray/Scale. Doing this may damage the Cycler Scale.

2. Remove the Cycler from its protective foam. There are two hooks on the back of the Cycler. These hooks are used to hang the Cycler onto the Cycler Stand.

3. Face the front of the Cycler Stand. Lift the Cycler and hook it on to the Cycler Hanger Rod. The front of the Cycler should be facing towards the front of the Cycler Stand when properly positioned.

Bag Organizer

Manifold Holder
(hangs outside
of Cycler hooks).

Cycler Hooks
(Cycler hooks
onto the Cycler
Hanger Rod first,
then Manifold Holder
hangs on second.)

Make sure the Cycler Control Unit is positioned over the long legs of the base.

Pump to Drain

Drain Hook

SIDE VIEW

FRONT VIEW

3

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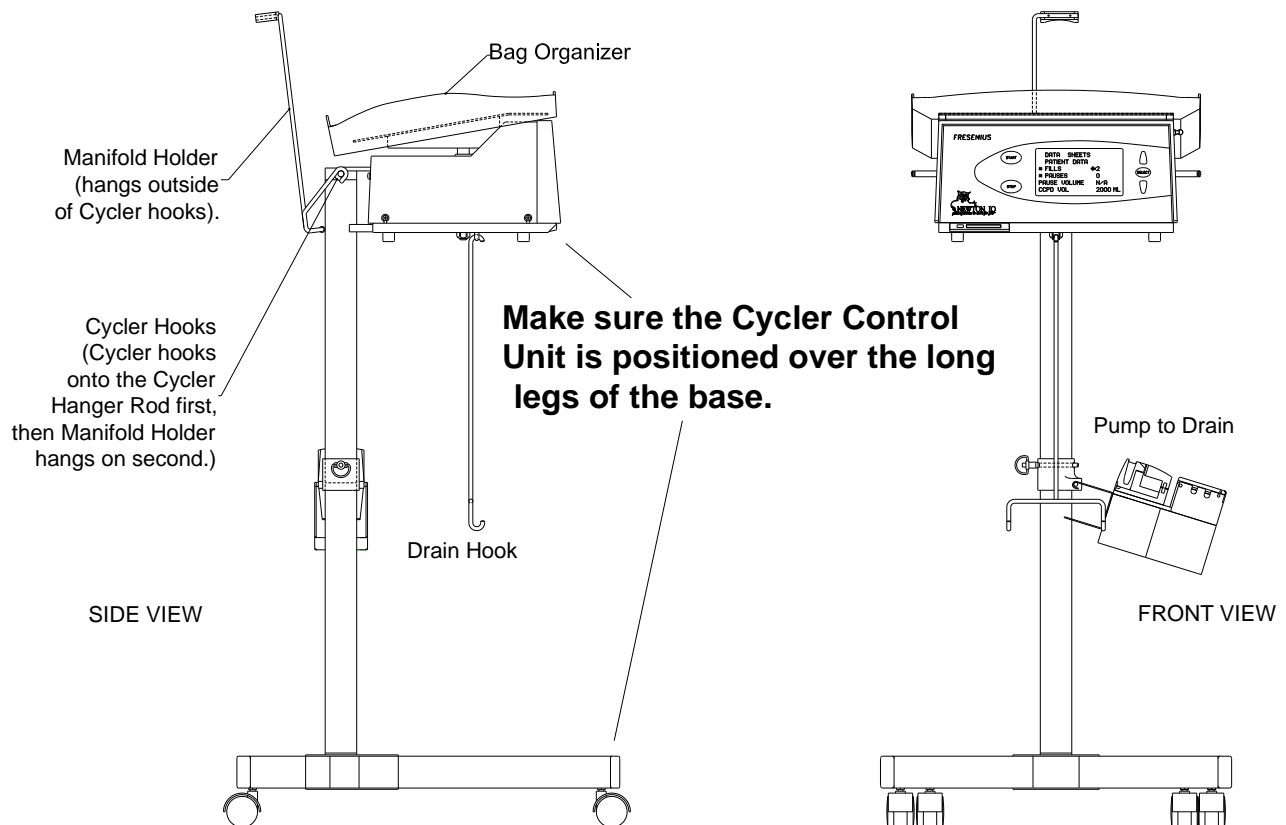
4. Remove the Pump-to-Drain from its protective packaging. Straighten out the Pump-to-Drain cord. The Pump-to-Drain has hooks on one end that hang onto the Pump-to-Drain mounting bracket located at the middle of the Cycler Stand.

5. Hook the Pump-to-Drain onto the Pump-to-Drain mounting bracket. You can position the Pump-to-Drain on either side of the Cycler Stand by changing the position of the Pump-to-Drain mounting bracket.

P/N 470203 Rev. H

Manifold Holder

Heater Tray / Scale

Heater Switch

Power Switch

POWER
I–ON
O–OFF/
RECHARGE

LINE

CIRCUIT BREAKERS

HEATER

HEATER
I–ON
O–OFF

DANGER: EXPLOSION HAZARD
DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
DANGER: RISQUE D'EXPLOSION
NE PAS EMPLOYER EN PRÉSENCE D'ANESTHÉSIQUES
INFLAMMABLES.
470123/REV.

20L CAPABILITY

Grounding reliability can only
be achieved when the equipment
is connected to an equivalent
receptacle marked "Hospital Only"
of "Hospital Grade".

DRAIN VALVE

CAUTION – Risk of electric
shock, do not remove cover.
refer servicing to qualified
service personnel.

PUMP TO DRAIN
ASSEMBLY
470198 REV.

Hanger Rod

Pump-to-Drain
plugs in here

Cycler Pole

Electrical Plug

6. Plug the Pump-to-Drain cable connector into the port labeled "Pump to Drain" located on the back of the Cycler Control Unit.

7. Connect the Drain Hook to the Cycler Control Unit. The Drain Hook has a rounded single hook at one end that hooks into an eyehook on the bottom center of the Cycler Control Unit.

8. Connect the Manifold Holder to the Cycler stand. The Manifold Holder has two rounded hooks that hook onto the hanger rod. The Manifold Holder should extend above the cycler Heater Tray approximately 9 inches.

9. Place the clear plastic Bag Organizer on the cycler Control Unit Heater/Scale. The Bag Organizer fits firmly onto the heater with its edges up and the three cutouts for the Dialysis Solution outlet ports at the back of the cycler.

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GETTING YOUR CYCLER READY (cont'd)

WARNING! Check the Heater Tray and Bag Organizer to be sure they are free of obstructions and do not touch the top of the Cycler Cabinet ❶ or the Stand Pole ❷ (see figures below). Interference with the Heater Tray may result in inaccurate weighing of Dialysis Solution. Check again when all Solution bags are on the Scale.

Check and make sure the Manifold Holder does not come in contact with the Bag Organizer, this may result in inaccurate weighing of Dialysis Solution.

NOTE: Save the Cycler shipping box and the foam inserts in case the Cycler needs to be repacked.
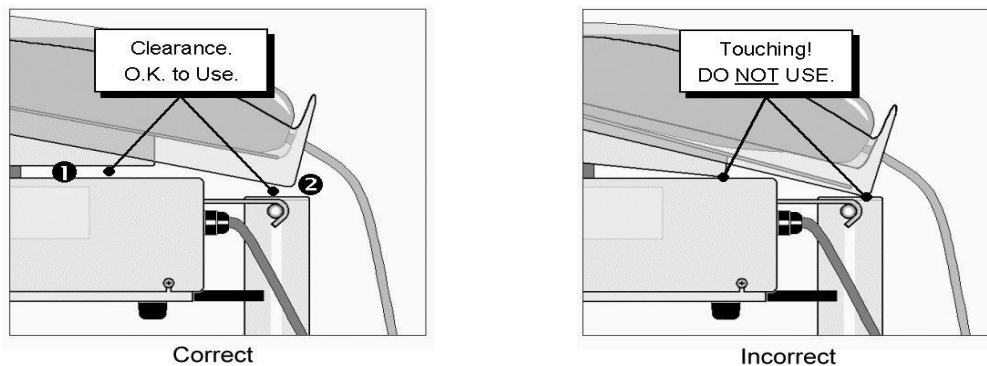
Correct — Clearance. O.K. to Use. ❶ ❷

Incorrect — Touching! DO NOT USE.

CAUTION! The Newton IQ Cycler is a computer controlled electromechanical medical device. The Newton IQ Cycler should be installed in an appropriate environment (indoors) free from extremes of temperature and humidity. The cycler should not be placed near sources of contamination such as dirt, dust, or liquids. Failure to install the Newton IQ Cycler according to these guidelines may result in improper operation or early failure of the device or its components.

CAUTION! Peritoneal dialysis solution should not be allowed to come into contact with the Pump-to-Drain assembly. Peritoneal dialysate leaves a dried salty residue that may be electrically conductive, leading to electrical shorts or corrosion of electrical or mechanical components. Mechanical components such as the valve heads or the cover may bind or corrode.

2.   THE CYCLER FRONT PANEL

There is a display screen and five buttons on the front of the Cycler.
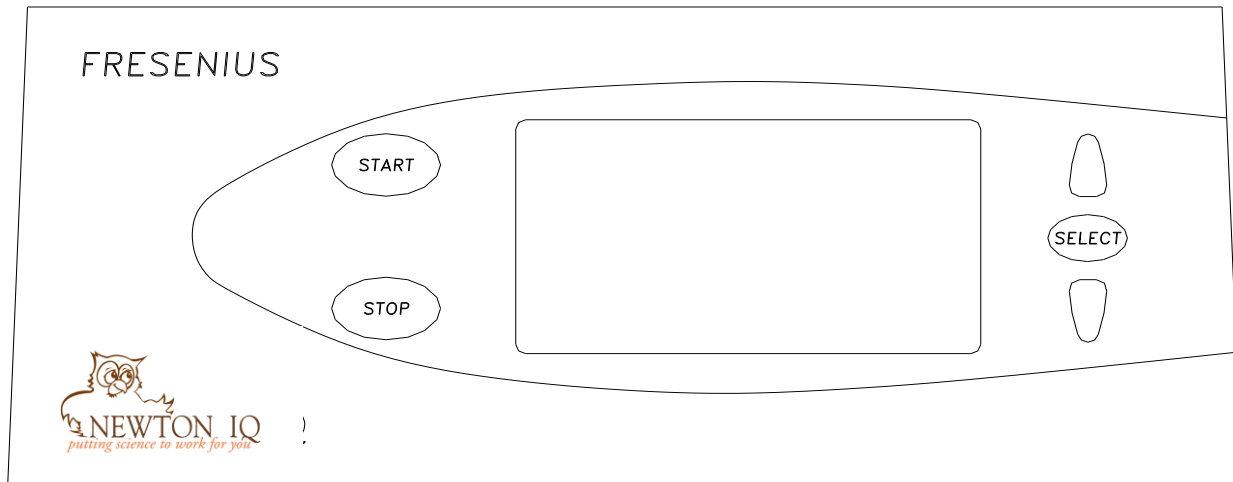
Messages for operating the Cycler are displayed on the screen. The five control buttons work as follows:

The [START] button is used to move forward through the phases of a treatment. After an alarm, pressing [START] continues the treatment. During programming, pressing [START] takes you back to the TREATMENT screens.

The [STOP] button mutes alarms. During the treatment set-up phase, pressing [STOP] allows you to repeat a tubing flush or patient line prime. During the treatment, pressing [STOP] interrupts the treatment.

The [SELECT] button takes you to the SETTINGS screen. A programming cursor (in the shape of an arrow) is located on the SETTINGS screen, between the treatment Setting and the Setting's value. The cursor normally points to the left towards the Settings. There are two ways to change a Setting as follows:

1.   For a Setting having only two values (for example, "YES" or "NO", or "ON" or "OFF"), use the [UP] or [DOWN] arrows to move the cursor on the screen to the Setting that needs to be changed. When the cursor is next to the desired Setting, press [SELECT] to change the Setting between "YES" and "NO" or "ON" and "OFF".

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THE CYCLER FRONT PANEL (cont'd)

2.   For a Setting having more than two values, use the [UP] or [DOWN]
        arrow to move the cursor on the screen to the Setting that needs to be
        changed. When the cursor is next to the desired Setting, press
        [SELECT] to point the cursor to the right towards the Setting Value.
        Next, use the [UP] or [DOWN] arrows to change the Setting Value as
        desired. After the Setting is programmed to the value you desire,
        press [SELECT] to "lock in" the new value. The cursor will now
        point to the left again.

The [UP] arrow and [DOWN] arrow buttons move the cursor on the screen to
the Setting that needs to be changed. You use the [UP] arrow and the
[DOWN] arrow to change Settings.

3. TYPES OF THERAPY

Four types of prescribed therapy are available for use with the Newton IQ Cycler. The therapies can also be divided into two subtypes: <u>Continuous Therapy</u> and <u>Intermittent Therapy</u>. In Continuous Therapy, you always have at least 50% or more of your usual Fill Volume present in your peritoneum. In Intermittent Therapy you may either be empty or have only a very small amount of Dialysis Solution present in your peritoneum for certain time periods.

Each therapy is prescribed for very specific reasons. The common factor in cycling therapy is that exchanges are done during the nighttime hours when you are usually in bed sleeping.

The main differences in the therapy types are what happens during the day while you are awake, and with how the solution is delivered to you during the night.

The four types of therapy are described below.

a. PD Plus Therapy

PD Plus Therapy is a continuous therapy in which one or more exchanges are received during the day from the Cycler, in addition to the nighttime exchanges. These daytime exchanges are called PAUSE exchanges. With PD Plus Therapy, you carry Dialysis Solution in your peritoneum during the day. This allows for continuous waste product and fluid removal. This type of therapy provides you with fresh Dialysis Solution from exchanges that take place nearly around-the-clock.

b. Continuous Cycling Peritoneal Dialysis (CCPD)

Continuous Cycling Peritoneal Dialysis (CCPD) is a Continuous Therapy. CCPD is the most common cycling therapy prescribed. With CCPD, you have Dialysis Solution in your peritoneum at all times but the exchanges are done only at night by the Cycler. You receive several exchanges while you sleep. The last thing that the Cycler will do is Fill you for the day. You do no other exchanges during the day. When you reconnect to the Cycler, you must first drain the dialysate that has been dwelling in you during the day. This type of therapy resembles a Continuous Ambulatory Peritoneal Dialysis (CAPD) schedule which is performed without a cycler, but with CCPD the exchanges are reversed. Three or more exchanges are done through the night, and one long exchange is done during the day.

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c. Intermittent Peritoneal Dialysis (IPD)

Intermittent Peritoneal Dialysis (IPD), as its name suggests, is an Interrupted or Intermittent Therapy. With IPD, you will receive your exchanges every night from the Cycler while you are sleeping, but you will not have any Dialysis Solution in your peritoneum during the day while you are awake. IPD is also sometimes referred to as Nightly Intermittent Peritoneal Dialysis (NIPD).

d. Tidal Peritoneal Dialysis (TPD)

Tidal Peritoneal Dialysis differs from other Dialysis therapies in the way that Dialysis Solution is delivered to you during the nighttime. With TPD you are filled with a prescribed amount of solution, then only a portion is drained and refilled with each exchange. Depending on your prescription, you may end the treatment with a Fill or a Drain.

Setting the different therapy types is done by programming the Newton IQ Cycler Settings and Options. Detailed instructions for programming the cycler for each of the four types of Peritoneal Dialysis therapies are on the following pages.

Your physician should prescribe the therapy that is best for you.

4. SETTING THE CYCLER DATE AND TIME

It is important to set the Cycler to the correct date and time if you want your PREWARMING and RX START TIME features to work on time. The Cycler is shipped with date and time set for the Pacific Time zone. You may need to reset the cycler for your specific time zone. To set the cycler date and time, you must enter the DIAGNOSTICS screen. To get to DIAGNOSTICS you must do the following:

1. From the STANDBY screen (the first screen upon power-up), press and hold the [UP] and [DOWN] arrows at the same time for about 3 seconds and the DIAGNOSTICS screen will appear as follows:

```
          ┌─────────────────────┐
          │  A TO D             │      △
  START   │  ALARMS             │
          │ ←CLOCK              │    SELECT
          │  INPUTS             │
  STOP    │  OPTIONS            │
          └─────────────────────┘      ▽
```
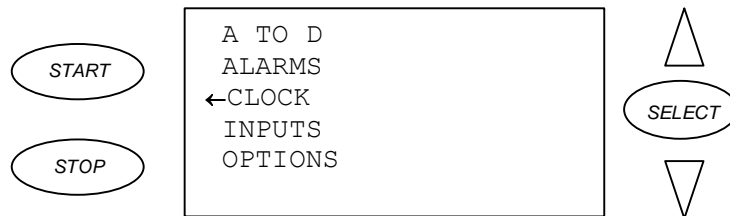
2. With the arrow on the screen lined up with CLOCK, press [SELECT] and the CLOCK screen will appear as follows:

```
          ┌─────────────────────┐
          │ YEAR       ←2002    │      △
  START   │ MONTH       1       │
          │ DATE        1       │    SELECT
          │ HOUR        9       │
  STOP    │ MINUTE      0       │
          │ SECOND      24      │      ▽
          └─────────────────────┘
```
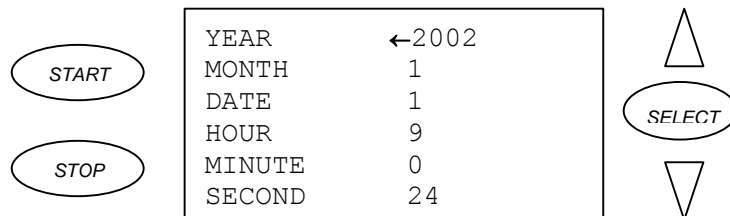
Set the current date and time using this screen. To navigate the screen, use the up and down arrows. Press [SELECT] when you reach your choice. You will program the HOUR Setting using a 24-Hour system; for example, enter 00:00 for 12 AM (midnight), 12:00 for 12 PM (noon), and 18:00 for 6 PM, etc. The time will be shown by the cycler at the STANDBY screen using a 12-Hour system with AM and PM after the time (for example, 6:00 AM, 12:00 PM, etc.). You must press [SELECT] after you make a change to the date or time to save it.

After you have updated the date and time at this screen, press [START] two times to return to the STANDBY screen. The date and time will be displayed in the lower right hand corner of this screen.

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5. TREATMENT SETTINGS AND OPTIONS

General treatment Settings and Options are programmed into the Newton IQ Cycler at the manufacturer. You must reprogram the Cycler Settings and Options for your personal prescription before you start your first treatment. Do the following to access the Settings and Options:

NOTE: You may skip this section and refer to the "USING THE PRESCRIPTION UPLOAD FEATURE" of these Operator Instructions if you are told by your physician or dialysis nurse to use the Upload feature.

1. Turn on the Cycler using the POWER switch located on the back panel of the Cycler. After the Cycler performs its power-up self-test, it will display the STANDBY screen as follows:
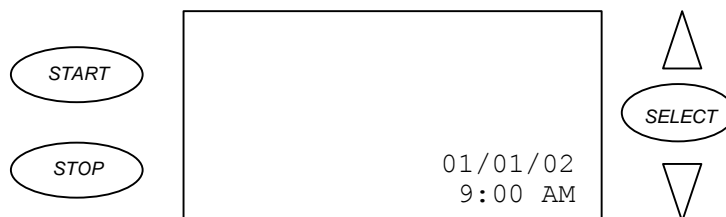
```
START                           △
                       SELECT
STOP         01/01/02
             9:00 AM     ▽
```

2. Press [START]. Instructions for programming or starting the treatment will appear.

```
          PRESS SELECT TO        △
START     PROGRAM SETTINGS.
          PRESS START TO      SELECT
STOP      BEGIN TREATMENT.
                               ▽
```
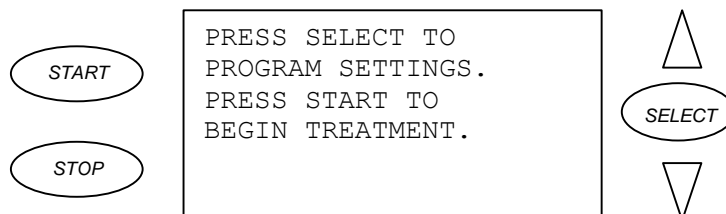
3. Press [SELECT] to enter the SETTINGS/OPTIONS screen as follows:

```
          ←DATA SHEETS           △
START       PATIENT DATA
          PT WEIGHT   ←125 LBS  SELECT
          # FILLS        5
STOP      # PAUSES       1
          PAUSE VOLUME  3000     ▽
```
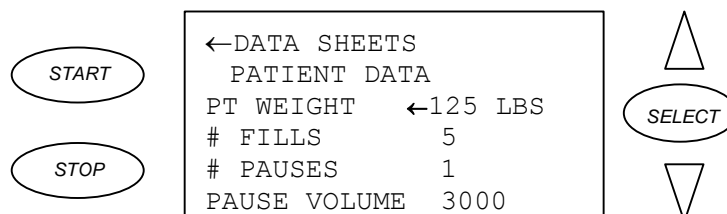
TREATMENT SETTINGS AND OPTIONS (cont'd)

Additional Settings and Options that are not displayed on the initial screen are available by pressing the [DOWN] arrow.

Descriptions of the various Settings and Options follow.

a. Patient Weight (PT WEIGHT)

(Range is 0, and 20 – 500 lbs. or 0 and 9 – 227 kgs.)

You may enter your initial weight here, in either pounds (lbs.) or kilograms (kgs.). Refer to the "ADDITIONAL OPTIONS" section of this manual to learn how to set the Cycler for recording your weight in either pounds or kilograms

The Patient Weight value will automatically be updated after each treatment if your physician or dialysis nurse has you use the Patient Data Entry feature of the Cycler. Refer to the "PATIENT DATA ENTRY" section of these instructions to learn how to use the Patient Data Entry feature of the Cycler.

b. Number of Fills (# FILLS)

(Range is 1 – 20 Fills)

The # FILLS is the number of times the peritoneum is filled will dialysate fluid. The # FILLS includes any programmed Pause volumes, CCPD volumes, and Last Fill volume. A Last Fill volume of zero is <u>not</u> counted in the number of Fills because no fill volume is delivered to the peritoneum.

NOTE: This number is prescribed by your physician.

c. Number of Pauses (# PAUSES)

(Range is 0 – 5 Pauses)

The # PAUSES indicates the number of PAUSES you are supposed to do during the treatment. A PAUSE is a special type of Dwell that allows you to Dwell while either connected <u>or</u> disconnected from the Cycler. It also differs from other Dwells because it is not a timed function; that is, you can PAUSE for as short or long as you would like.

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TREATMENT SETTINGS AND OPTIONS (cont'd)

Before each PAUSE, the Cycler will Drain and then Fill you. After the Fill, the Newton IQ Cycler automatically goes into a PAUSE. The Cycler will remain in the PAUSE phase indefinitely until you continue the treatment by pressing [START].

With PD Plus Therapy, you can program up to five PAUSES. The "USING MULTIPLE PAUSES" section of these Operator Instructions describes how to operate the Cycler when there is more than one PAUSE programmed.

You can only program one PAUSE when using Tidal Therapy.

NOTE: The number of pauses is prescribed by your physician.

d. Pause Volume (PAUSE VOL)

(Range is: 500 – 4,000 ML)

WARNING! It is possible to program the Cycler to fill with more than 3,000 ml. Do not fill with more unless you are told to do so by your physician or dialysis nurse.

The PAUSE VOL is the amount of solution that will be delivered during the Pause exchange(s). This amount cannot be more than 150% (1 ½) of the CCPD Volume.

You can not program a PAUSE VOL when # PAUSES is set to zero (0).

If you are doing PD Plus Therapy, you will probably program PAUSE VOL, CCPD VOL, and LAST FILL Volume.

If you are doing exchanges only while you are sleeping and then are receiving a Fill before you disconnect, you will not program a Pause exchange. In this case, you will program a CCPD VOL and a LAST FILL Volume.

NOTE: CCPD volumes and last fills are prescribed by your physician.

e. CCPD Volume (CCPDVOL)

(Range is: 500 – 4,000 ML)

WARNING! It is possible to program the Cycler to fill with more than 3,000 ml. Do not fill with more unless you are told to do so by your physician or dialysis nurse.

The CCPD VOL is the amount of solution that is delivered during the exchanges occurring while you are typically sleeping.

NOTE: The amount of solution is prescribed by your physician.

f. Last Fill Volume (LAST FILL)

(Range is: 0 or 50 – 4,000 ML)

WARNING! It is possible to program the Cycler to fill with more than 3,000 ml. Do not fill with more unless you are told to do so by your physician or dialysis nurse.

The LAST FILL is the amount of solution left in your peritoneum before disconnecting from the machine, at the completion of the treatment. The LAST FILL amount can not be programmed for more than 150% (1 ½) of the CCPD Volume.

If you plan to be empty during the day, you will program the LAST FILL to 0 ML.

NOTE: The last fill volume is prescribed by your physician.

NOTE: If the delivered volume of the last fill is greater than 90% of the prescribed volume and within 200 ml of the prescribed volume, an alarm will <u>not</u> sound during the last fill.

The cycler will display the delivered amount on the COMPLETE screen. However, if you consistently get a message that your fill is less than prescribed, notify your clinic.

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g. Total Volume (TOTAL VOL)

The TOTAL VOL tells you the amount of Solution needed for your treatment. The Cycler automatically calculates the TOTAL VOL for you based on the number of Fills and the Volumes you programmed (PAUSE VOL, CCPD VOL, and LAST FILL).

To get the correct TOTAL VOL displayed on the screen; you must program your Dialysis Fill Volumes starting with the CCPD VOL, then the PAUSE VOL, and finally the LAST FILL.

NOTE: This amount is prescribed by your physician.

h. Fill Time (FILL TIME)

(Range is 1 – 59 Minutes)

The FILL TIME is the amount of time needed to fill your peritoneum with Dialysis Solution. You may fill more quickly lying down than sitting or standing up because there is less pressure in your abdomen when you are lying down.

i. Dwell Time (DWELL TIME)

(Range is 5 Minutes – 9 Hours 55 Minutes)

The DWELL TIME is the time allowed for the actual dialysis to take place during each exchange. The time needed is usually decided by your physician.

j. Drain Time (DRAIN TIME)

(Range is 1 – 59 Minutes)

The DRAIN TIME is the time needed to completely drain your peritoneum. You may drain faster sitting or standing up than lying down because there is more pressure in your abdomen when you are sitting or standing up. Your position relative to the drain bags will also affect how well you drain.

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k. Sleep Time (SLEEP TIME)

The SLEEP TIME tells you the estimated amount of time, usually spent sleeping, that you'll need to complete the cycling exchanges.

The Cycler automatically calculates the SLEEP TIME for you based on the FILL, DWELL, and DRAIN times you program. Any treatment time prior to the last programmed PAUSE is not included in the SLEEP TIME calculation.

The SLEEP TIME is a "count-down" clock. As your treatment progresses, the SLEEP TIME value will decrease. At the completion of the treatment, the SLEEP TIME displays "0" minutes when viewed from the COMPLETE screen.

l. Data Sheet (DATA SHEET)

A DATA SHEET is a record of your treatment. The Cycler stores in its memory a Data Sheet for the treatment you are actively performing and Data Sheets for the seven most recent treatments you have performed.

To look at your Data Sheet, [SELECT] DATA SHEET from the SETTINGS screen. The Cycler will display another screen that appears as follows:

```
                DATA SHEETS
  START       ←ACTIVE TREATMENT
                 12/31/01
                 12/30/01          SELECT
  STOP           12/29/01
                 12/28/01
```
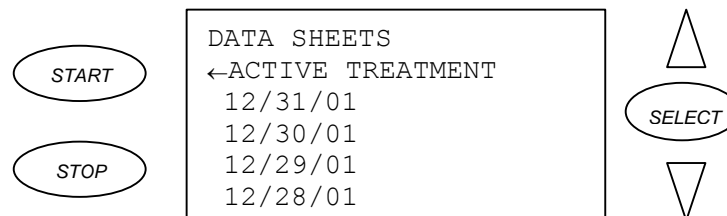
NOTE: Actual dates will vary. Additional Data Sheets are found by pressing the [DOWN] arrow.
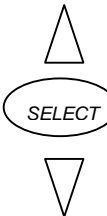
NOTE: The ACTIVE TREATMENT line will only be shown while a treatment is taking place.

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Press the [DOWN] arrow to line up the Cycler cursor with the Data Sheet you want to view and press [SELECT]. The Cycler will advance to the Data Sheet. The Data Sheet from your treatment will show your actual fill and drain volumes for each cycle of your treatment. A sample Data Sheet appears as follows.

```
        ┌─────────────────────────┐
 ╭─────╮│ CYC  FILL   DRAIN   UF  │    △
│START ││  0           1730    230 │
 ╰─────╯│  1   2000   2180    410 │  ╭──────╮
        │  2   2000   2300    710 │  │SELECT│
 ╭─────╮│  3   2000   2200    910 │  ╰──────╯
│ STOP ││  4   2000   2100   1010 │    ▽
 ╰─────╯└─────────────────────────┘
```

> **NOTE:** The displayed volumes will vary to reflect the actual
> volumes that occur during your treatments.

How to read a Data Sheet is found in the "LOOKING AT YOUR TREATMENT RECORD" section of these Operator Instructions.

m. Patient Data (PATIENT DATA)

PATIENT DATA may be a part of the record of your treatment. You will see this screen unless your clinic has "turned off" this option when your IQcard was programmed. At this screen, you are prompted to enter your blood pressure, weight, and solution used during your treatment. Refer to the "PATIENT DATA ENTRY FEATURE" section of these Operator Instructions for instructions on how to enter information into this screen.

n. Fast Fill/Drain (FAST FILL/DRAIN)

(Values are "YES" or "NO", Default is "YES")

When FAST FILL/DRAIN is set to "YES", the Cycler automatically goes into the next phase of the treatment when the Fill or Drain takes less time than programmed. The unused FILL TIME and DRAIN TIME will be added to your next Dwell.

An example of how this works is as follows:

<div style="text-align:center">

DRAIN TIME = 20 Minutes

FILL TIME = 10 Minutes

DWELL TIME = 1 Hour

</div>

If Drain #1 completes with 10 minutes left over, and Fill #2 completes with 3 minutes left over, 13 minutes will be added to Dwell #2. Dwell #2 will begin with "1 Hour 13 Minutes" displayed at the top of the screen.

Your Dwell Time (Dialysis time) will be longer, but your total Treatment Time will not be longer because your Fill and Drain Times are shorter than you programmed.

When FAST FILL/DRAIN is set to "NO", the Cycler performs your fills and drains based on the fill and drain times you programmed. The Cycler will not add any time saved during a shorter than expected Fill or Drain to the next Dwell.

o. Last Bag Alarm (LAST BAG ALARM)

(Values are "YES" or "NO")

When LAST BAG ALARM is set to "YES", a LAST BAG ALARM sounds just before the Last Fill of the treatment. It will alert you that it is time to prepare for your Last Fill. This alarm is useful if you have a separate bag of Solution that you will use only for your Last Fill.

When LAST BAG ALARM is set to "NO", a LAST BAG ALARM will not sound before the Last Fill of the treatment.

NOTE: This option is prescribed by your physician.

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p. Prewarm Bags (PREWARM BAGS)

(Values are "YES" or "NO")

When PREWARM BAGS is set to "YES", the Heater turns on to warm your Dialysis Solution before your first exchange. The Heater will remain on until the Solution Bags have reached a comfortable temperature. It takes about 3 hours for the Solution Bags to reach a comfortable temperature.

Once the bags are warm, the Heater will turn off and on to maintain a comfortable temperature. The Heater will turn off (and remain off) at the end of the treatment after you have returned the Cycler to the STANDBY screen.

In order for the Heater to automatically come on for the next treatment, the Cycler must:

- have the POWER switch "ON"

- have the HEATER switch "ON" and

- be at the STANDBY screen

When PREWARM BAGS is set to "NO", the Heater is on at all times, even between treatments. The Cycler Power switch or the Heater switch must be turned "OFF" to turn off the Heater.

q. RX Start Time (RX START TIME)

The RX START TIME is the time of day you usually start your first exchange using the Cycler. For example, if you are doing a PAUSE, you might set the RX START TIME for 6 PM. If you are doing your first exchange at bedtime, you might set the RX START TIME for 10 PM.

NOTE: The RX START TIME is only used to begin the pre-warming of the solution bags.

If PRE WARM BAGS is set to "NO", RX START TIME will display "N/A" and can not be changed.

TREATMENT SETTINGS AND OPTIONS (cont'd)

r. Tidal Settings (TIDAL SETTINGS)

(Values are "YES" or "NO")

WARNING! It is possible to program the Cycler to fill with more than 3,000 ml. Do not fill with more than instructed by your physician.

Most of the programming for Tidal Therapy is done through TIDAL SETTINGS.

By selecting TIDAL SETTINGS from the SETTINGS screen, you will enter another screen that appears as follows:
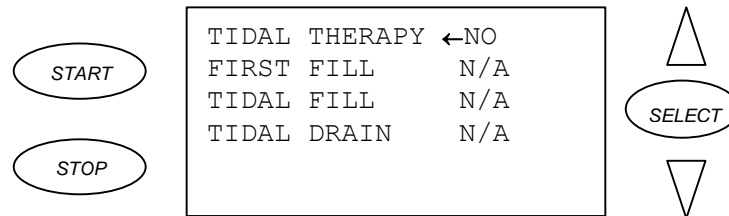
To program TIDAL THERAPY, press [SELECT], then press the [UP] or [DOWN] arrow keys to change the setting to "YES". Press [SELECT] again to lock-in TIDAL THERAPY.

After you set TIDAL THERAPY to "YES", you will then need to program the FIRST FILL. Next, set the TIDAL FILL and TIDAL DRAIN. To set all other Tidal Therapy Settings press [START] to go back to the SETTINGS screen.

When you set TIDAL THERAPY to "NO", FIRST FILL, TIDAL FILL and TIDAL DRAIN will all display "N/A" since they are only needed for TIDAL THERAPY.

Press [START] once to exit the TIDAL SETTINGS screen and return to the SETTINGS screen. Press [START] once more to exit the SETTINGS screen and to return to the STANDBY screen.

NOTE: Therapy type is prescribed by your physician.

6. <u>ADDITIONAL OPTIONS</u>

Several additional Cycler Options that you can program are as follows:

- Screen Blanking
- Speaker Volume
- Speaker Pitch
- Language
- Allow > 3L?
- Weight Units
- IQcard Used?
- Add Diurnal UF?

These Options are found in the DIAGNOSTICS screen, <u>not</u> from the SETTINGS screen. To get to DIAGNOSTICS and OPTIONS you must do the following:

1. From the STANDBY screen, press and hold the [UP] and [DOWN] arrows at the same time for about 3 seconds and the DIAGNOSTICS screen will appear as follows:

```
              ┌─────────────────┐          △
  ( START )   │←A TO D          │
              │ ALARMS          │       ( SELECT )
              │ CLOCK           │
              │ INPUTS          │
  ( STOP )    │ OPTIONS         │          ▽
              └─────────────────┘
```
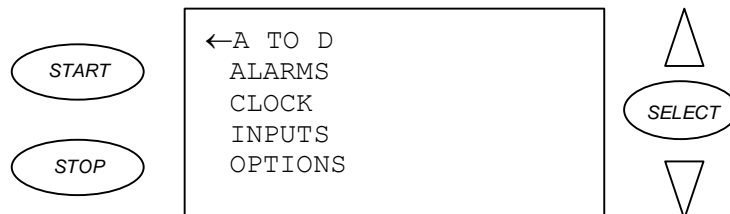
2. Press the [DOWN] arrow to move the cursor to OPTIONS.

3. Press [SELECT] and the OPTIONS screen will appear as follows:

```
              ┌──────────────────────┐          △
              │SCREEN BLANKING  ←OFF │
  ( START )   │SPEAKER VOLUME      6 │
              │SPEAKER PITCH       0 │
              │LANGUAGE      ENGLISH │       ( SELECT )
              │ALLOW>3 LITERS?    NO │
  ( STOP )    │WEIGHT UNITS      LBS │          ▽
              └──────────────────────┘
```
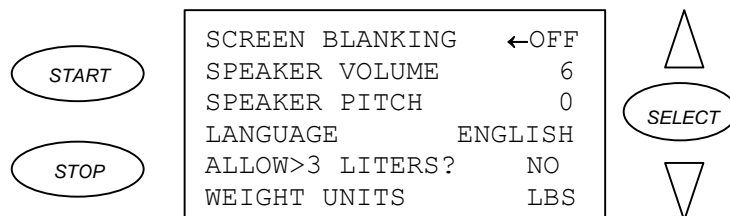
a. Screen Blanking (SCREEN BLANKING)

(Values are "YES" or "NO") (The Values Default is "NO")

When SCREEN BLANKING is set to "YES", the Cycler screen will go blank after 5 minutes if no button is pressed, or if no alarm sounds. If <u>any</u> button is pressed, or if there has been a Cycler alarm, the screen will reappear. If, after another 5 minutes, no buttons are pressed or no alarms sound, the screen will go blank again.

The cycler will continue the treatment even when the screen is blank. Use SCREEN BLANKING if you like to sleep without any lighting in your room.

When SCREEN BLANKING is set to "NO", the cycler screen stays on whenever the cycler is on.

b. Alarm Volume (ALARM VOLUME)

(Values are from "1" through "10") (The Values Default is "6")

The cycler is shipped with the Alarm Volume set to "6". You can adjust the volume between "1" (quiet) and "10" (loud), depending on the alarm volume you prefer.

c. Alarm Pitch (ALARM PITCH)

(Values are from "0" through "52") (The Values Default is "0")

The Cycler is shipped with the Alarm Pitch set to "0". You can adjust the pitch between "0" and "52" depending on the alarm pitch you prefer.

d. Language (LANGUAGE)

(LANGUAGE "ENGLISH" or "FRENCH" or "SPANISH")

The Cycler is shipped with all screens set to English. Use LANGUAGE to see the screens in French or Spanish.

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ADDITIONAL OPTIONS (cont'd)

e. Allow > 3 Liters? (ALLOW>3 LITERS?)

(Values are "YES" or "NO")

The largest fill volume is 4 liters. If your physician wants you to use more than 3 liters, you must set this option.

NOTE: If your IQcard has been programmed for more than 3 liters you must change the ALLOW > 3 LITERS to "YES" before inserting the IQcard. If you do not do this, you will get a TX SETTING CORRUPTED alarm when you place the IQcard into the Cycler.

f. Weight Units (WEIGHT UNITS)

(Values are "LBS" or "KGS") (The Values Default is "LBS")

Use the weights you have been taught by your dialysis facility, either LBS for pounds or KGS for kilograms.

g. IQcard Used? (IQCARD USED?)

(Values are "YES" or "NO") (The Values Default is "YES")

When IQCARD USED? is set to "YES", the cycler is aware that you plan to use an IQcard to record your treatment data. An IQcard must be inserted into the slot on the front of the cycler. All HELP screens and alarms for the IQcard are active when you set IQCARD USED? to "YES".

When IQCARD USED is set to "NO", the cycler is aware that you do not plan to use an IQcard to record your treatment data. All HELP screens and alarms for the IQcard are not active when you set IQCARD USED? to "NO".

h. Add Diurnal UF? (ADD DIURNAL UF?)

(The Diurnal UF Default is "YES")
When Add Diurnal UF? is set to "YES" the Drain 0 UF Volume will be added to the total UF volume calculated for that treatment.

When Add Diurnal UF? is set to "NO" the Drain 0 UF Volume will **not** be added to the total UF volume calculated for that treatment.

7. <u>USING THE PRESCRIPTION UPLOAD FEATURE</u>

When your clinic changes your prescription using the IQcard Software Program, the next time you put your IQcard into the cycler, your new prescription will automatically upload into your cycler.

The upload screen will come up with the new settings. You must view and either accept or reject the settings. You must scroll down through three screens to the last line, which reads USE NEW SETTINGS?. To accept the prescription change, press [SELECT] and "YES" will appear next to USE NEW SETTINGS?

```
←JONES,ROBERT
TIDAL THERAPY    NO
# FILLS           6
# PAUSES          1
PAUSE VOL     2500ML
CCPD VOL      3000ML
```

```
LAST FILL     ←2500ML
FILL TIME      20 MIN
DWELL TIME  1HR 30MIN
DRAIN TIME     30 MIN
FAST FILL/DRAIN    YES
LAST BAG ALARM     NO
```

```
DRAIN TIME       30 MIN
FAST FILL/DRAIN   YES
LAST BAG ALARM    NO
PRE WARM BAGS     YES
RX START TIME  10:00PM
USE NEW SETTINGS?←YES
```
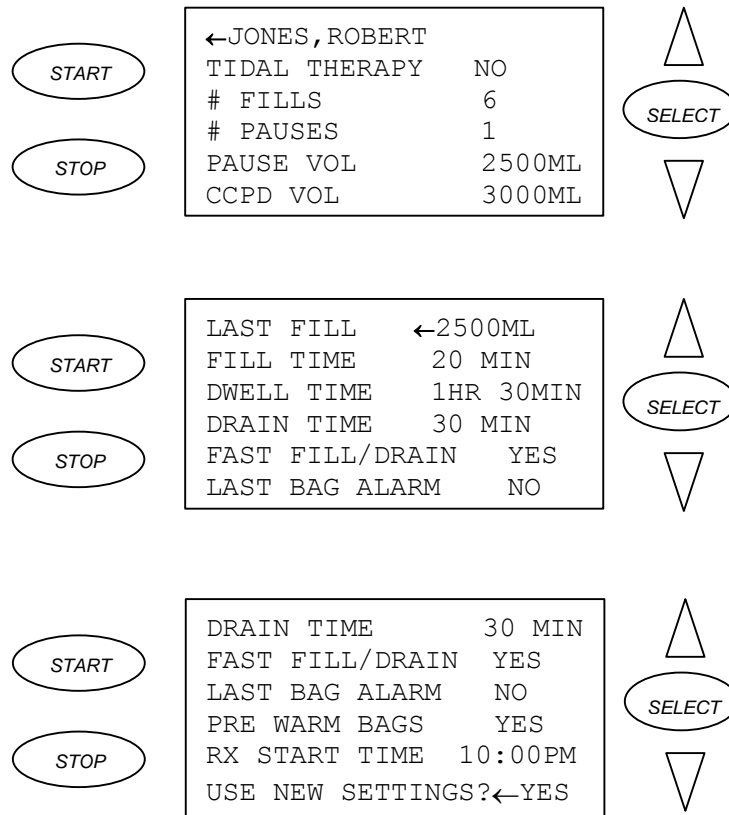
Press [START] to accept the upload and to return to the STANDBY screen. Your Cycler settings have been changed to the new prescription.

WARNING! Check the new prescription carefully. If <u>your</u> name is not shown or the new prescription is not right, change USE NEW SETTINGS? to "NO" and press [START]. If you do not accept the new settings, the upload screen will be shown every time you remove and reinsert your IQcard from the cycler.

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8. **<u>YOUR PERSONAL PRESCRIPTION</u>**

Have your clinic fill this sheet out for you and use it to check the prescription or to program your Cycler.

NAME: _____

TREATMENT SETTINGS AND OPTIONS:

# FILLS	_____
# PAUSES	_____
PAUSE VOL	_____
CCPD VOL	_____
LAST FILL	_____
FILL TIME	_____
DWELL TIME	_____
DRAIN TIME	_____
FAST FILL/DRAIN	YES or NO
LAST BAG ALARM	YES or NO
PREWARM BAGS	YES or NO
RX START TIME	_____ AM or PM

TIDAL SETTINGS

TIDAL THERAPY	YES or NO
FIRST FILL	_____
TIDAL FILL	_____
TIDAL DRAIN	_____

OTHER OPTIONS:

SCREEN BLANKING	YES or NO
LANGUAGE :	ENGLISH FRENCH SPANISH
ALLOW >3 LITERS	YES or NO
WEIGHT UNITS	LBS or KGS
ADD DIURNAL UF?	YES or NO

Checked by: _____   Date: _____

9. GETTING READY FOR YOUR TREATMENT

a. Prepare cycler for use

IF YOU ARE USING AN IQCARD BE SURE IT IS INSERTED BEFORE YOU TURN ON THE CYCLER.

Turn "ON" the cycler with the POWER switch on the back of the cycler. Do not have anything on the cycler scale (except for the Bag Organizer and Drain Hook) when turning on the Cycler.
The Cycler POWER and HEATER switches should be left "ON" after the first treatment for the Heater to automatically come on to warm your Solution Bags. Once the Cycler is left "ON", you can leave bags on the Cycler Scale.

WARNING! Do not use external heating sources not authorized by Fresenius Medical Care to warm your solution bags. Contact your clinic for more information.

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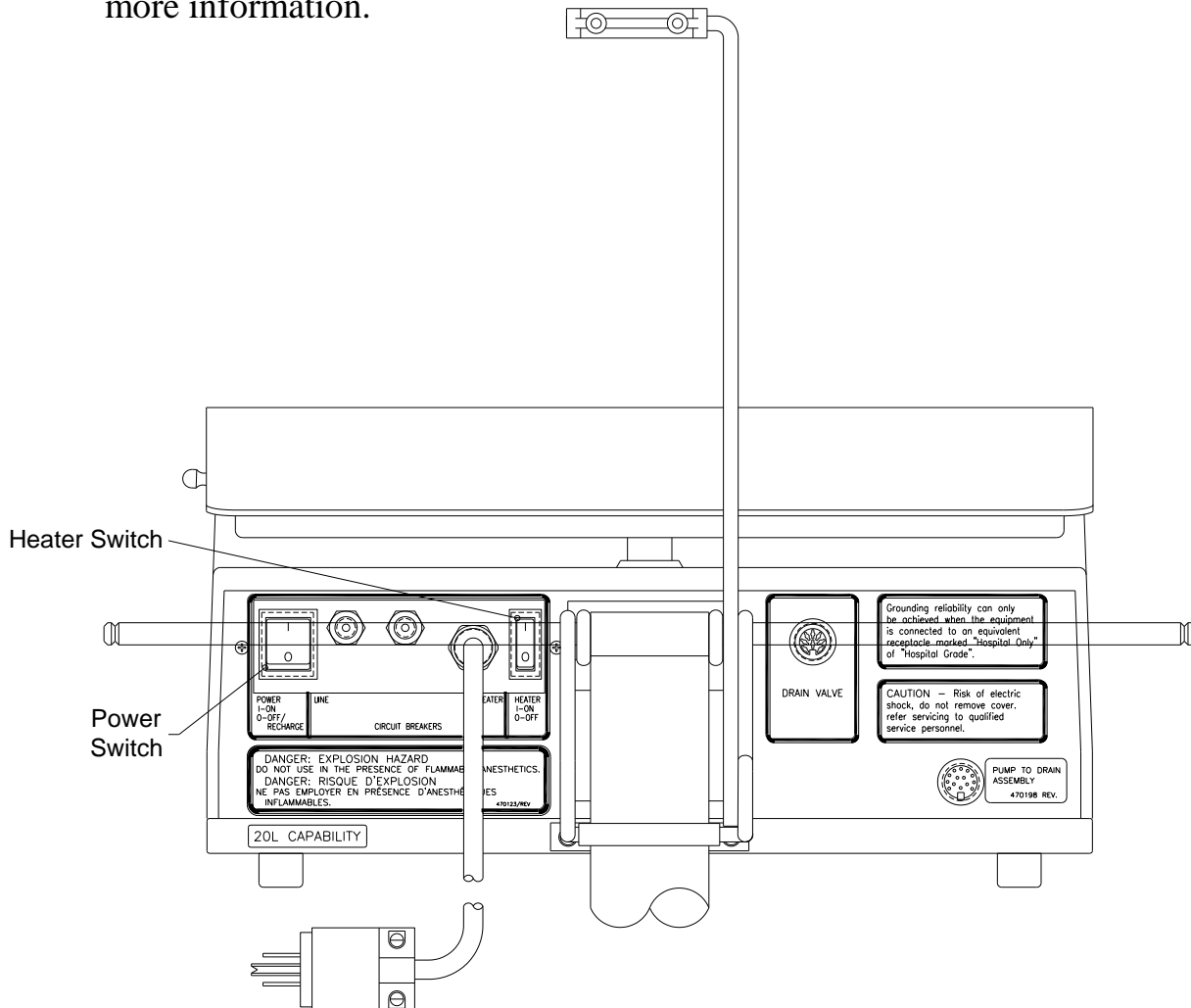
GETTING READY FOR YOUR TREATMENT (cont'd)

When you turn on the cycler, it will do a complete self-test of its electronics, heater, and scale. The Front Panel screen will display the cycler software version as well as a testing message as follows:

```
                  S/W VER. 1.XXN
   START
                   NEWTON IQ          SELECT
   STOP
                    TESTING…
```
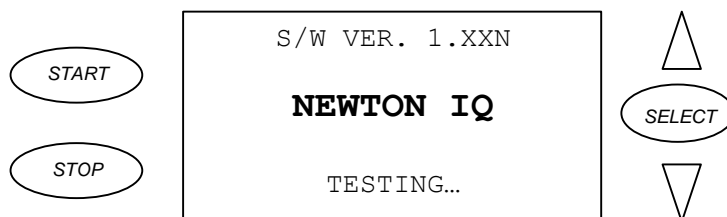
At the end of a successful power-up self-test, the cycler will display the STANDBY screen as follows:

```
   START
                                      SELECT
   STOP
                          01/01/02
                          10:00PM
```
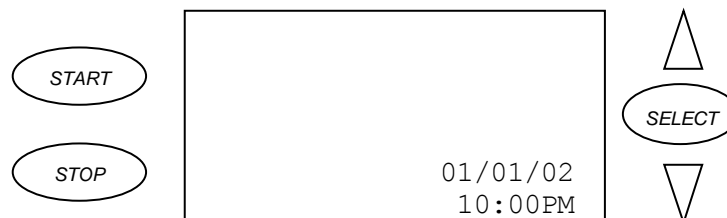
b. Tubing Set-Up

At this point, you can begin the cycler treatment setup.

Start the cycler treatment setup with clean hands. Gather your supplies.

1. Press [START]. Instructions for programming or starting the treatment will appear.

```
                  PRESS SELECT TO
                  PROGRAM SETTINGS.
   START
                  PRESS START TO      SELECT
                  BEGIN TREATMENT.
   STOP
```
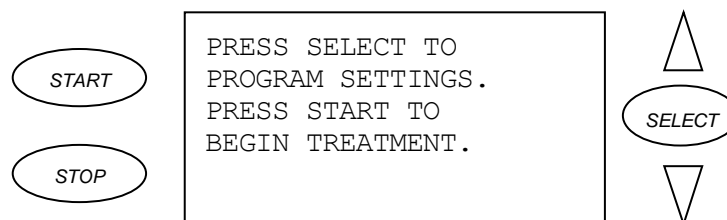
2. Press [START] again and follow the instructions on the screen.

```
 START            PUT BAGS ON SCALE.
                  LOAD TUBING.
                  CLOSE RED CLAMPS.          SELECT
                  OPEN YELLOW CLAMPS.
  STOP            PRESS START TO
                    CONTINUE.
```
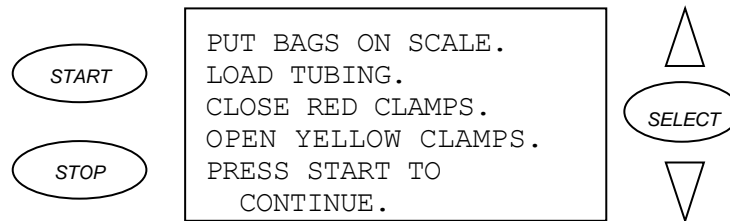
3. If your bags are not already on the heater, choose the bag(s) of Dialysis Solution for your treatment. Take off the outer cover of the bags, and put the bags in the Bag Organizer that sits on top of the cycler. The solution bags should be positioned with their outlet ports in the U-shaped cutouts in the Bag Organizer.

Five Important Dialysate bag checks

- Dialysate Strength

- Dialysate Volume

- Expiration Date

- Clear Fluid

- No Leaks

WARNING! When the bags are in the Bag Organizer, check the Heater Tray and Bag Organizer to be sure they are free of obstructions and do not touch the top of the cycler cabinet or the Stand Pole. Also check that the Manifold holder is not touching the Bag Organizer. Interference with the Heater Tray may result in inaccurate weighing of Dialysis Solution, and possibly result in patient injury.

4. Open the Newton IQ Set tubing and lay it on top of the solution bags. Close both red clamps. Only Newton IQ tubing sets can be used on the Newton IQ Cycler.

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GETTING READY FOR YOUR TREATMENT (cont'd)

5. Put the Patient Line in the tubing holder provided on the side of the cycler. The end of the Patient Line should be placed above the cycler's heater tray.

6. Place Tubing Manifold into the Manifold Holder. The single tubing line will face up with the 4 lines facing down.

   NOTE: Make sure there are no kinks in the tubing between the Manifold and the valve assembly.

7. Open the Pump-to-Drain valve cover. Align the white tubing cassette directly over the markers on the valves and press the cassette into place.

8. Close the Valve Cover.

   NOTE: If the Valve Cover will not close completely, check to see if the white tubing cassette is placed into the valve assembly correctly. The cassette will only fit properly into the valve assembly in one direction.

9. Open the Pump Cover.

10. Form a "V" shape with the pump segment tubing.

11. Press the bottom of the "V" into the middle of the pump opening

12. Pull the sides of the pump segment tubing down, so that they rest in the pump notches, and are centered in the pump.

13. Make sure the side of the tubing with the yellow clamp matches the side of the pump with the yellow strip.

14. Make sure that the direction of flow from drain bag to drain outlet matches the diagram on the pump.

15. Close the pump cover.

16. Make sure both red clamps are closed.

17. Open the yellow clamps.

18. Hang drain bag on hanger below the cycler.

19. Connect the tubing set's Drain Bag Line to a drain or drain bag.

20. Place the end of the drain line into a drain receptacle such as a toilet.

> **Warning!** If the drain is to a receptacle (rather than a floor bag), be sure there is clearance around the end of the drain line—do not allow the drain line to become submerged in the drain. An air gap is necessary to eliminate the possibility of back siphonage into the drain line.

c. Connecting to the solution bags

21. Press [START]. After approximately 5 seconds, while the cycler checks its scale, the following screen will appear:


```
                    MASK. WASH HANDS.
        START       CONNECT BAGS, BREAK
                       CONES.                   SELECT
                    PRESS START TO BEGIN
        STOP           FLUSH PROCEDURE.
```
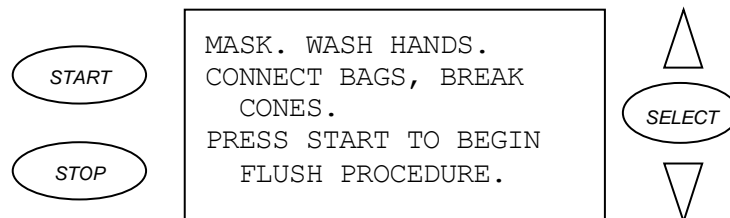
22. Mask and wash your hands. Using aseptic technique, connect the Solution Lines to the solution bags, one at a time. Slide the white clamp on each unused Solution Line down away from the end of the line to the tubing Manifold. Now close the white clamps on these unused Solution Lines. Leave your mask on through step 23. Be sure the single manifold line is not in the way of making the connections to the bags.

23. Break the cones in the outlet port of the solution bags by bending the ports back and forth. You may be able to see the clear cones floating up into the bags…this is OK!

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Checklist Before Continuing:

☑   Tubing Manifold inserted into the Manifold Holder.

☑   Both red clamps are closed.

☑   Patient Line is in tube holder on the side of the Cycler.

☑   Patient Line is above the heater tray.

☑   Solution Lines are connected to the solution bags

☑   White clamps on unused Solution Lines are closed.

☑   White clamps on used Solution Lines are open.

☑   Cones in solution bags are fully broken.

☑   White tubing cassette is placed over the valves and the valve cover is completely closed.

☑   Pump segment is loaded into the pump in the correct direction.

☑   Both yellow clamps are open.

☑   End of pump segment is connected to the Drain Line.

d. Tubing Flush and Prime

24. Press [START]. The cycler will flush the tubing set and perform tests to make sure that the Newton IQ Set is installed and working correctly. While this happens, the cycler will display the following screen:

```
             PERFORMING

         FLUSH PROCEDURE

      PLEASE WAIT
```

(START)   (STOP)   (SELECT)
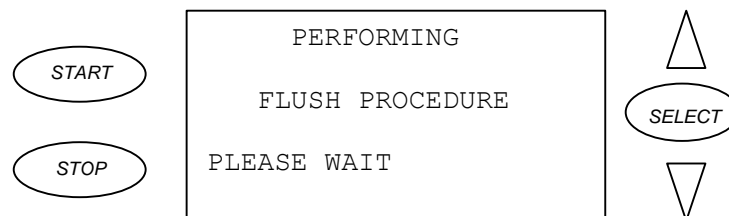
GETTING READY FOR YOUR TREATMENT (cont'd)

25. After the flush procedure is successfully completed., the following screen will appear:

```
                    FLUSH COMPLETE
  ( START )         PRESS STOP TO REFLUSH
                       -OR-                    ( SELECT )
                    LOWER MANIFOLD, OPEN
  ( STOP )            RED CLAMPS.
                    PRESS START TO PRIME.
```
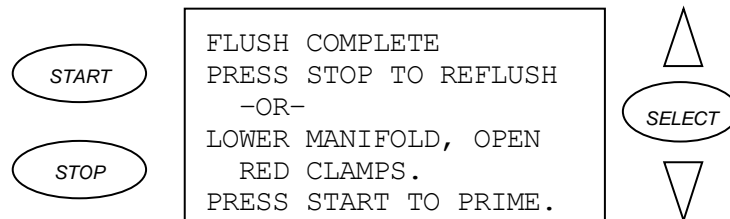
26. If you would like to repeat the flush procedure, press [STOP]. If you do not need to repeat the tubing flush, open both red clamps and press [START]. The Cycler will now prime the Patient Line. When you press [START] to prime the Patient Line, the following screen will appear:

```
                    WHEN PATIENT LINE
  ( START )         PRIMED, CLOSE BLUE
                    CLAMP.                     ( SELECT )
  ( STOP )          PRESS START.TO
                       CONTINUE.
```
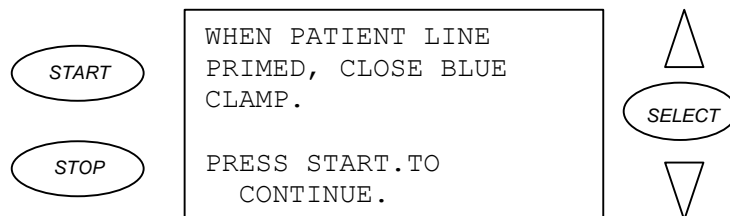
27. Hold the end of the Patient Line up above the Solution Bags on the top of the Cycler. The Solution will travel up the Patient Line to the end of the tubing as the Patient Line is gently lowered. This will remove air from the Patient Line and is referred to as "priming the line".

28. Close the blue clamp on the Patient Line when the Patient Line is completely primed and then press [START].

   NOTE: If you have programmed LAST BAG ALARM to "YES" and are using a separate bag of Solution for your LAST FILL, you must close the white clamp on this separate bag now.

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The next setup screen will appear as follows:

```
PRESS STOP TO REPRIME
   -OR-
CONNECT PATIENT.
OPEN BLUE CLAMP.
OPEN CATHETER CLAMP.
THEN PRESS START.
```

START

STOP

SELECT
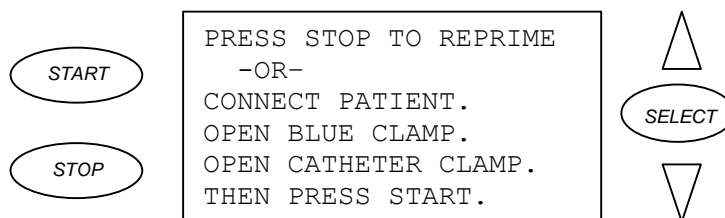
29. If you would like to repeat the Patient Line prime, press [STOP]. If you do not need to repeat the Patient Line prime, you may connect to the cycler at this point.

e. Connecting to the Cycler – Leave your mask on.

30. Clamp the catheter or transfer set.

31. Remove the protective cap from the end of the cycler tubing.

32. Depending on the catheter connection system you are using follow either the stay•safe or Safe-Lock connection procedure for connecting to the cycler set.

33. Open the blue clamp on the cycler's Patient Line. Open the clamp on your Catheter or Extension Line.

34. Press [START] to begin treatment

35. Check out flow for clarity and/or fibrin.

GETTING READY FOR YOUR TREATMENT (cont'd)

NOTE: Your treatment will always begin in Drain 0, which appears as follows:

```
                  ┌────────────────────────────────┐
     ╭───────╮    │ TIME LEFT:  20 MINUTES         │      △
     │ START │    │                                │  ╭────────╮
     ╰───────╯    │           DRAIN 0              │  │ SELECT │
     ╭───────╮    │                                │  ╰────────╯
     │ STOP  │    │ DRAIN VOLUME       0 ML        │      ▽
     ╰───────╯    └────────────────────────────────┘
```

FRESENIUS MEDICAL CARE
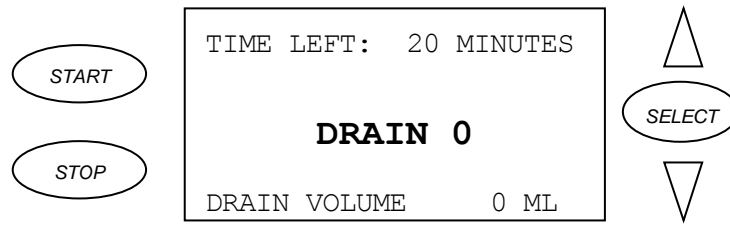
10. THE TREATMENT

a. Treatment Phases (All Therapy Types)

Your treatment will always start in DRAIN 0 and then go to FILL 1. After FILL 1, the treatment will go into PAUSE or DWELL (depending on your program). How many times your treatment Pauses depends upon how many Pauses you have programmed. If you have not programmed any Pauses the exchange order is always the same, starting with a Drain, then a Fill, and lastly, a Dwell.

As needed during the treatment, the cycler will test its drain system. While this brief process happens, the cycler will display a message at the bottom of the current screen stating that the Drain Bag is being tested.

In addition, as needed during the treatment, the cycler will pump the fluid from the Drain Bag to your waste site. While this process happens the cycler will display a message at the bottom of the current screen stating that the Drain Bag is being emptied. The cycler may leave a small amount of fluid in the Drain Bag after completing the emptying process – this is normal. At the end of the treatment, the cycler will leave approximately 500 ml of fluid in the drain bag – this also is normal.

The treatment will end with a Fill if a LAST FILL volume has been programmed. If you have set the Last Fill volume to 0 (zero), your treatment will end in a Drain.

THE TREATMENT (cont'd)

There is information about your treatment during each phase of the treatment. On the DRAIN and FILL screens you'll see which cycle you are in, how much time is left to Drain or Fill, how much fluid you have Drained or Filled, and other special messages.

```
TIME LEFT:  4 MINUTES


      DRAIN 0

DRAIN VOLUME   2300 ML
```

START

STOP

SELECT

```
TIME LEFT:  2 MINUTES


       FILL 1

FILL VOLUME   1850 ML
```

START

STOP

SELECT
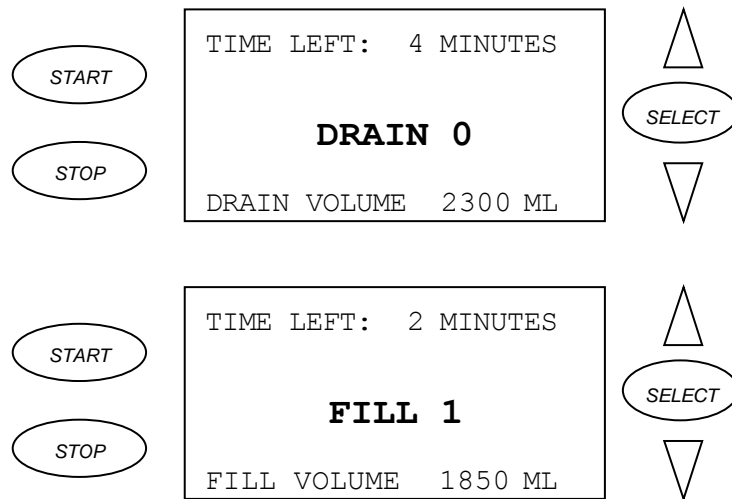
The PAUSE screen gives you instructions on how to continue your treatment when you return to the Cycler. Other special messages may also be displayed as needed on this screen.

```
        PAUSE 1
PRESS START TO
CONTINUE.
```

START

STOP

SELECT

37

FRESENIUS MEDICAL CARE
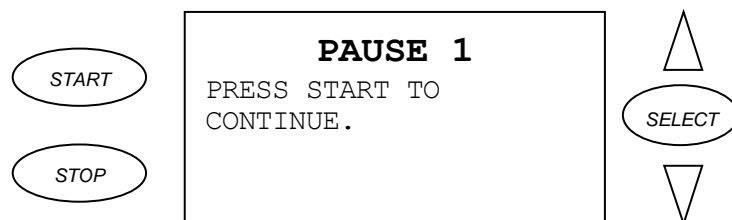
The DWELL screen tells you how much time is left to Dwell. This includes the extra time that is added to the Dwell if you have set FAST FILL/DRAIN to "YES". Other special messages may also be displayed as needed on this screen.

```
                    ┌──────────────────────────┐      △
       ╭───────╮    │ TIME LEFT: 1HR 30MIN     │
       │ START │    │                          │    ╭────────╮
       ╰───────╯    │       DWELL 2            │    │ SELECT │
                    │                          │    ╰────────╯
       ╭───────╮    │                          │
       │ STOP  │    │                          │      ▽
       ╰───────╯    └──────────────────────────┘
```
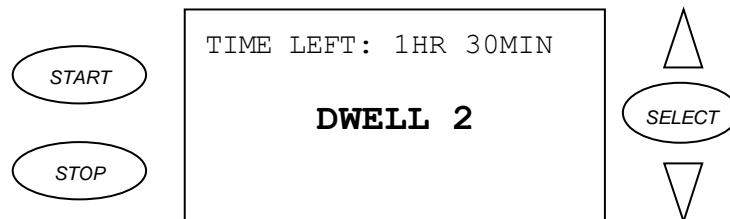
b. Using One PAUSE

Your physician will decide if you will be doing a Pause. If you are doing one Pause exchange, the cycler will automatically enter the PAUSE screen after FILL 1. The PAUSE screen will appear as follows:

```
                    ┌──────────────────────────┐      △
       ╭───────╮    │       PAUSE 1            │
       │ START │    │ PRESS START TO           │    ╭────────╮
       ╰───────╯    │ CONTINUE.                │    │ SELECT │
                    │                          │    ╰────────╯
       ╭───────╮    │                          │
       │ STOP  │    │                          │      ▽
       ╰───────╯    └──────────────────────────┘
```
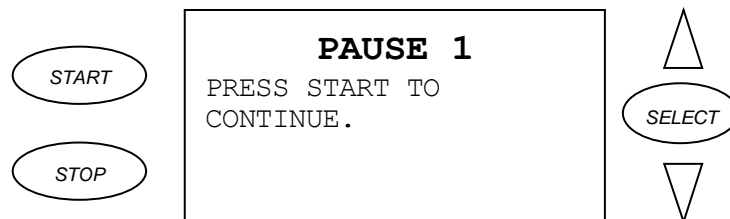
While the cycler is at the PAUSE screen, you can disconnect from the cycler.

To disconnect from the cycler after a pause exchange follow the disconnect procedure for your type of catheter connection either stay•safe or Safe-Lock

THE TREATMENT (cont'd)

The cycler will remain at the PAUSE screen until you press [START]. You don't need to press [START] until you are ready to reconnect to the cycler and continue your treatment.

When you are ready to continue the treatment, you follow the same steps that you did for connection earlier in the treatment.

Press [START], and a HELP screen will appear as follows:

```
           ┌──────────────────────┐      △
  START     │ MASK. WASH HANDS.    │
           │ CONNECT PATIENT.     │   SELECT
           │ OPEN ALL CLAMPS.     │
           │ THEN PRESS START.    │
  STOP      └──────────────────────┘      ▽
```

CONNECTING TO THE CYCLER AFTER A PAUSE EXCHANGE:

1. Clamp your catheter unless you have a transfer set that is already clamped.

2. Check to make sure the blue clamp on the patient end of the tubing set is closed.

3. Mask and wash your hands.

4. Remove the plastic shrink-wrap from the next patient connection on the cycler tubing.

5. Depending on the catheter connection system you are using follow either the stay•safe or Safe-Lock connection procedure for connecting to the cycler set.

6. Open the blue clamp on the Patient Line. Open the clamp on your Catheter or Extension Line. Press [START].

The treatment will begin again in DRAIN 1.

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c. Using Multiple PAUSES

Your physician will decide if you will be doing multiple Pauses. To perform multiple Pauses you will need to add a Multiple Tubing Segment (MTS) to the Patient Line of your Newton IQ Set tubing. Use a Two-Segment MTS for up to three programmed Pauses, and use a Four-Segment MTS for up to five programmed Pauses. Follow the instructions that come with the MTS set for its proper use.

WARNING! Do not reconnect to a Patient Line connector that has already been used.

If you are doing multiple Pauses, the cycler will automatically enter the first PAUSE screen after FILL 1. The PAUSE screen will appear as follows:

While the cycler is at the PAUSE screen, you can disconnect from the cycler.


```
              PAUSE 1
  START   PRESS START TO
          CONTINUE.            SELECT
  STOP
```
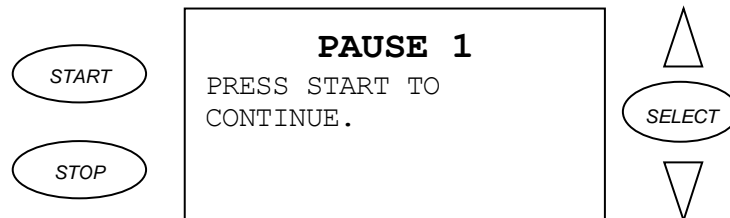
To disconnect from the cycler after a pause exchange (when using more than one pause)

1. Close the roller clamp on your transfer set (if you have a transfer set).

2. Close the blue clamp on the Patient Line.

3. To disconnect from the cycler follow the disconnect procedure for your type of catheter connection either stay•safe or Safe-Lock.

4. Place the end of the cycler tubing set in the tubing holder on either side of the cycler.

The cycler will remain at the PAUSE screen until you press [START]. You don't need to press [START] until you are ready to reconnect to the cycler and continue your treatment.
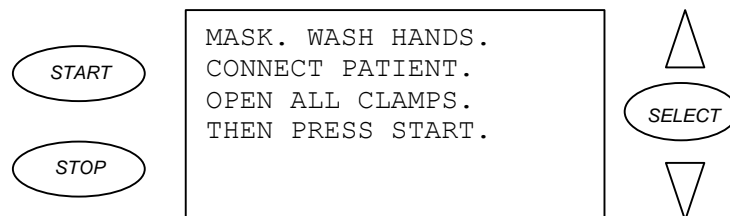
When you are ready to continue the treatment, you follow the same steps that you followed for connection earlier in the treatment.

Press [START], and a HELP screen will appear as follows:

```
                    ┌─────────────────────────┐       △
  ( START )         │  MASK. WASH HANDS.       │
                    │  CONNECT PATIENT.        │   ( SELECT )
                    │  OPEN ALL CLAMPS.        │
  ( STOP )          │  THEN PRESS START.       │       ▽
                    └─────────────────────────┘
```
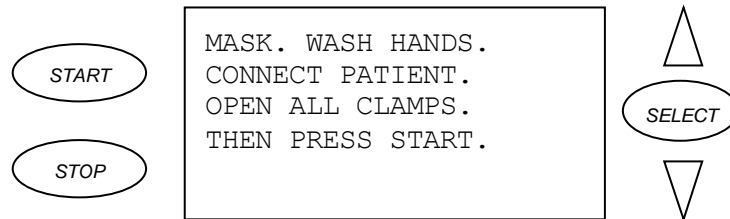
d. Connecting to the Cycler after more than one Pause Exchange:

1. Clamp your catheter unless you have a transfer set that is already clamped.

2. Check to make sure the blue clamp on the patient end of the tubing set is closed.

3. Mask and wash your hands.

4. Remove the plastic shrink-wrap from the next patient connection on the cycler tubing.

5. Depending on the catheter connection system you are using, follow either the stay•safe or Safe-Lock connection procedure for connecting to the cycler set.

6. Open the blue clamp on the Patient Line. Open the clamp on your Catheter or Extension Line. Press [START].

The treatment will begin again in DRAIN 1. When DRAIN 1 completes, the cycler will enter FILL 2. When FILL 2 completes, the cycler will enter the second PAUSE screen. The steps for performing the second and subsequent PAUSES are the same as described above for the first PAUSE.

At the completion of all your programmed PAUSES, the cycler will advance to the CCPD, or Last Fill phase of your treatment depending on your prescription.

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THE TREATMENT (cont'd)

e. Interrupting the Treatment

The treatment can be interrupted for 10 minutes at any time by pressing [STOP]. You should use INTERRUPT during a treatment before moving the cycler or anything on the cycler scale. The screen will display the following:

```
                    ┌──────────────────────────┐      △
  ( START )         │ TIME LEFT:  58 MINUTES    │
                    │                           │   ( SELECT )
                    │        INTERRUPT          │
  ( STOP )          │    S/W VER. 1.11N         │      ▽
                    └──────────────────────────┘
```
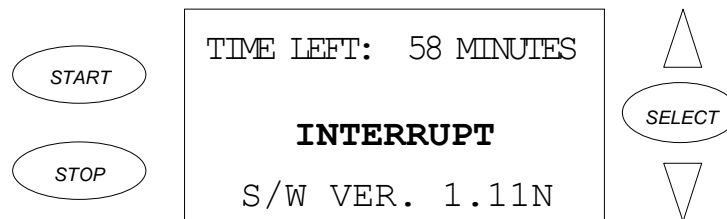
The TIME LEFT shown on the INTERRUPT screen is the time remaining in the current phase that the treatment was in before you interrupted the treatment. To resume the treatment, press [START].

If you don't resume the treatment within 10 minutes, the cycler will sound an alarm alerting you the treatment has been INTERRUPTED TOO LONG. An INTERRUPTED TOO LONG screen appears as follows:

```
                    ┌──────────────────────────┐      △
  ( START )         │        INTERRUPT          │
                    │        TOO  LONG          │   ( SELECT )
  ( STOP )          │                           │
                    │   PRESS STOP TO MUTE.     │      ▽
                    └──────────────────────────┘
```
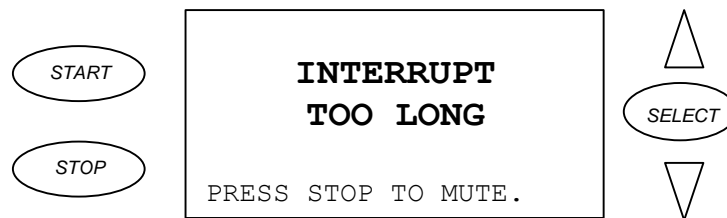
To clear this alarm, press [STOP] to mute the alarm, then [START] to continue the treatment.

f. Bypassing

Bypassing (or skipping) any phase of your treatment should be avoided unless you've discussed situations that may require bypassing with your doctor or dialysis nurse. If you need to BYPASS, press [START] twice quickly, and you will see a question asking you if you really want to bypass.

START

STOP

BYPASS?
PRESS START TWICE
TO BYPASS.

SELECT
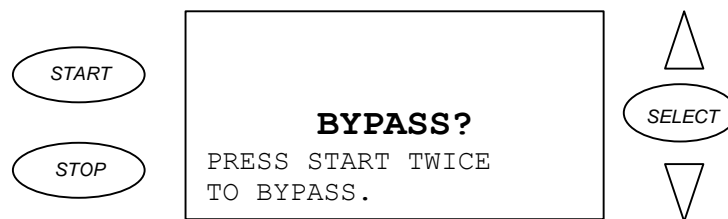
Press [START] twice again quickly to complete the BYPASS process. If you accidentally started the BYPASS process by pressing [START] twice, don't do anything, and in a few seconds the cycler will automatically return to where it was before you accidentally started the BYPASS.

g. Moving the cycler During Your Treatment

The Newton IQ cycler can be moved at any time during the treatment by doing the following:

1. Press [STOP] to INTERRUPT the treatment. This "freezes" the scale to allow moving the cycler without an alarm sounding.

2. Unplug the cycler if you are going any further than the length of the cycler electrical cord.

    NOTE: If you unplug the cycler, it will power off – this is normal. When you plug the cycler back in, special screens will guide you with resuming or ending the treatment.

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3. Stand behind the cycler. Grab the Hanger Rod located at the top of the Cycler Stand and pull (don't push) the cycler to its new location. The Hanger Rod provides a convenient "handle" for moving the cycler.

4. If you did not unplug the cycler, press [START] to continue the treatment.

5. If you unplugged the cycler, plug in the cycler into a properly grounded three-prong outlet. The cycler will power back on automatically and display screens to guide you with resuming or ending the treatment.

h. Completing the Treatment

At the end of your treatment, the cycler will automatically advance to the COMPLETE screen. If there is fluid in the drain bag, the cycler will empty all but 500 ml of the fluid in the drain bag, after the emptying is complete the screen will appear as follows:

```
                NET UF   1500 ML
  START
                  COMPLETE            SELECT
               PRESS STOP FOR
  STOP            STANDBY.
```
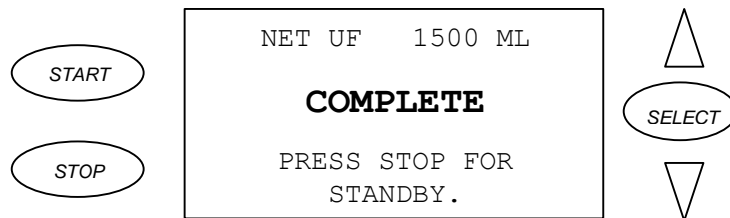
You may disconnect from the cycler at this point. Refer to "DISCONNECTING FROM THE CYCLER" section of these Operator Instructions for the procedure for disconnecting.

11. <u>DISCONNECTING FROM THE CYCLER</u>

1. Close the blue clamp on the Cycler Patient Line.

2. Close the clamp on your Catheter or Transfer Set (if you have a Transfer Set).

3. To disconnect from the cycler follow the disconnect procedure for your type of catheter connection either stay•safe or Safe-Lock.

4. Place the end of the Cycler tubing set in the tubing holder on either side of the Cycler.

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12. PATIENT DATA ENTRY FEATURE

Unless your clinic has turned off this feature, you can put your weight, blood pressure (B/P) and solutions right into the Cycler at the PATIENT DATA ENTRY screen. You will see this screen after pressing [STOP] to exit the COMPLETE screen. There are two screens for entering your patient data. The screens will appear as follows:

```
       ┌─────────────────────────────┐        △
       │ BP-SYSTOLIC      ← 0         │
( START )│ BP-DIASTOLIC       0         │
       │ PT WEIGHT          0LBS      │  ( SELECT )
       │ SOLUTION VOLUMES            │
( STOP ) │ DEXT. 1.5          0 ML      │
       │ DEXT. 2.5          0 ML      │        ▽
       └─────────────────────────────┘
```
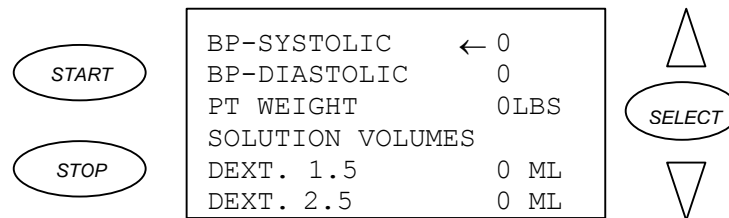
Scroll [DOWN] to see the rest of the values

```
       ┌─────────────────────────────┐        △
       │ SOLUTION VOLUMES            │
( START )│ DEXT. 1.5          0 ML      │
       │ DEXT. 2.5          0 ML      │  ( SELECT )
       │ DEXT. 4.25         0 ML      │
( STOP ) │ LAST BAG SOL'N TYPE:←       │        ▽
       └─────────────────────────────┘
```
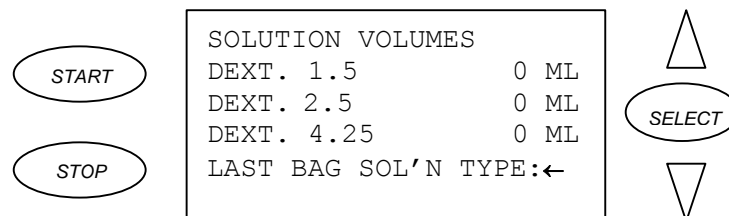
The very first time you use the Cycler, all the PATIENT DATA numbers will be 0 (zero) or blank. Once you record your B/P and weight, the settings will remain in the Cycler until you complete your next treatment.

To enter your B/P, weight, and dextrose volumes:

> With the arrow lined up to BP SYSTOLIC, press [SELECT] to enter your systolic (top) blood pressure number.

> Press [SELECT] to point the cursor back to BP SYSTOLIC and press the [DOWN] arrow to move arrow to BP DIASTOLIC.

> Continue until all numbers for blood pressure and weight have been put onto the screen.

> Volumes are entered in 500 ml amounts until you finally reach the volume you use.

> Arrow down to the "LAST BAG SOL'N TYPE" option. Press [SELECT]

which will turn the arrow around. Then by pressing the up and down arrows, choose from 1.5%, 2.5%, 4.25% or other.

NOTE: The Cycler will display the settings as 0 (zero) after each use. Once you press the [SELECT] key, the values will jump to the previously entered values.

NOTE: If you receive a new Cycler, the values will be set to 0 (zero).

NOTE: This data is collected and saved to the IQcard to help you with your record keeping and may be useful to your physician.

Press start to get out of the data screen.

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13. SETTING UP FOR THE NEXT TREATMENT

1. Close all the clamps on the cycler tubing set so you won't drip any fluid and remove the set from the cycler.

2. Dispose of the used cycler tubing set according to your dialysis unit's policy.

3. Wash your hands.

4. Choose the bags of dialysis solution for your next treatment. Leave the outer cover on each bag and place the bags on the Cycler Bag Organizer.

   WARNING! When the bags are in the Bag Organizer, check the Heater Tray to make sure there are no obstructions and it does not touch the top of the Cycler Cabinet or the Stand Pole. Interference with the Heater Tray may result in inaccurate weighing of dialysis solution, and possibly result in patient injury

5. To get ready for your next treatment refer to (GETTING READY FOR YOUR TREATMENT).

14. LOOKING AT YOUR TREATMENT RECORD

Recall from earlier, a DATA SHEET is a record of your treatment. The cycler stores in its memory, a Data Sheet for the treatment you are actively performing, plus, Data Sheets for the seven most recent treatments you have performed.

You can access your Data Sheets at any time, before, during or after your treatment. To review the steps needed to access an individual Data Sheet refer to the TREATMENT SETTINGS AND OPTIONS section of these instructions.

A sample Data Sheet follows to assist with defining the elements of the Sheet.

```
         CYC FILL   DRAIN   UF
 START    0         1730    230
          1  2000   2180    410
          2  2000   2300    710      SELECT
 STOP     3  2000   2200    910
          4  2000   2100    1010
```

a. Cycle (CYC)
This column lists the numbers of the cycles performed during the treatment. The Data Sheet displays up to four cycles on the initial display. If your treatment consisted of more than four cycles, use the [DOWN] arrow to scroll to the additional cycles. Our sample treatment above actually consisted of five cycles; so if we scroll down to display the fifth cycle the cycler would display the following:

```
         CYC FILL   DRAIN   UF
 START    1  2000   2180    410
          2  2000   2300    710
          3  2000   2200    910      SELECT
 STOP     4  2000   2100    1010
          5  1500
```

Notice that Cycle 5 is now displayed, and Cycle 0 has scrolled off the screen.

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b. Fill (FILL)

Values in this column represent the amount of fluid delivered during each Fill. The values will correspond with the Fill volumes you programmed for your treatment. It is normal for the Fill value recorded to vary by ±10 ml. For example, if your programmed Fill volume was 2000 ml, the amount actually delivered and recorded on your Data Sheet may be 1990 to 2010.

c. Drain (DRAIN)

Values in this column represent the amount of fluid drained from your peritoneum during each Drain. The fluid drained is normally composed of the amount of fluid you filled with in the preceding Fill, plus additional fluid referred to as Ultrafiltration (UF). For example, if you Drain 2300 ml of fluid and your previous Fill amount were 2000 ml, 300 ml of this Drain is considered Ultrafiltration.

d. Ultrafiltration (UF)

Values in this column represent the running total of Ultrafiltration. The Ultrafiltration is calculated by the cycler by subtracting the Fill volume of a particular cycle from the Drain volume of that same cycle.

Using our sample Data Sheet, let's see how the cycler calculated the UF for the treatment it represents.

If ADD DIURNAL UF? Is set to "YES" the following is true:

> Since a Fill does not occur during Cycle 0, the Cycler uses the LAST FILL volume programmed for use in calculating the UF for Cycle 0. In this particular treatment, the LAST FILL was programmed for 1500 ml. The Cycle 0 UF of 230 ml was calculated by subtracting 1500 ml (LAST FILL volume) from 1730 (Drain 0 volume). This value (230 ml) is recorded in the UF column.

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To calculate the UF for Cycle 1, the Fill 1 volume of 2000 ml is subtracted from the Drain 1 volume of 2180 ml, resulting in a Cycle 1 Ultrafiltration of 180 ml. This value (180 ml) is added to the Cycle 0 Ultrafiltration value (230 ml), and the result, 410 ml, is recorded in the UF column. Recall that the UF column displays a <u>running total</u> of the treatment Ultrafiltration.

If ADD DIURNAL UF? Is set to "NO" the following is true:

The cycler will not use the LAST FILL volume programmed for use in calculating the UF for Cycle 0. In this particular treatment, the LAST FILL was programmed for 1500ml.

To calculate the UF for Cycle 1, the Fill 1 volume of 2000 ml is subtracted from the Drain 1 volume of 2180 ml, resulting in a Cycle 1 Ultrafiltration of 180 ml. This value (180 ml) is added to the Cycle 0 Ultrafiltration value (0 ml), and the result, 180 ml, is recorded in the UF column. Recall that the UF column displays a <u>running total</u> of the treatment Ultrafiltration.

This process is repeated for each cycle of the treatment. In our example, there is no Ultrafiltration value recorded for Cycle 5 since the treatment ended in a Fill. If the treatment had been programmed to end in a Drain, a UF value would have been recorded for Cycle 5.

After fully reviewing your Data Sheet, pressing [START] will exit the Data Sheet and take you to the treatment's TOTAL CYCLER DWELL TIME screen as follows:

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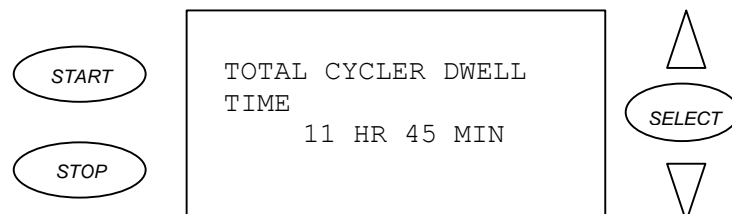
e. Total Cycler Dwell Time

The TOTAL CYCLER DWELL TIME of 11 hours and 45 minutes displayed in our example represents the total amount of time spent dwelling during the treatment. This time includes the time spent during each of the treatment's Pause and Dwell phases.

Press [START] to exit the TOTAL CYCLER DWELL TIME screen and return to the DATA SHEET menu. Press [START] again to exit the DATA SHEET menu and return to the SETTINGS screen. Press [START] one final time to exit the SETTINGS screen.

15. ALARMS

There are two common causes of cycler alarms. Alarms may occur because:

- the cycler cannot deliver the treatment that has been programmed or,
- there is an error in the cycler setup.

When an alarm occurs, an alarm message appears describing what type of alarm condition has occurred. In addition, an audible alarm will sound when the alarm screen appears. You should respond to the alarm by pressing [STOP]. Pressing [STOP] will:

- mute (quiet) the audible alarm,
- clear the alarm message from the screen and,
- bring up an alarm HELP screen.

You can correct an alarm condition by making the adjustments suggested on the alarm HELP screen. After making the necessary adjustments, press [START] to continue your treatment. You should experience fewer alarms as you get more familiar with operating the cycler.

Occasionally you may encounter an alarm that requires you to get help from your Dialysis clinic or Fresenius USA Technical Service. Before calling for any assistance, it is helpful if you write down the alarm that occurred so that your clinic or Fresenius USA Technical Service can more effectively assist you.

If you need assistance from Fresenius USA Technical Service, there is a toll-free 800 number available to you. **The number to reach Technical Service is (800) 227-2572**. Technical support is available 24 hours a day, 7days a week.

Descriptions of alarms that may occur are listed in alphabetical order on the following pages.

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ALARMS (cont'd)

a. Both Cover Open

A BOTH COVER OPEN alarm occurs if the cycler senses that both the Pump-to-Drain pump head and the valve cover are open when they should not be.

A BOTH COVER OPEN alarm will appear as follows:

```
  ╭───────╮    ┌─────────────────────┐        △
 ( START  )    │    BOTH  COVER      │
  ╰───────╯    │                     │     ╭────────╮
               │       OPEN          │    ( SELECT  )
  ╭───────╮    │  PRESS STOP TO MUTE │     ╰────────╯
 ( STOP   )    │                     │
  ╰───────╯    └─────────────────────┘        ▽
```
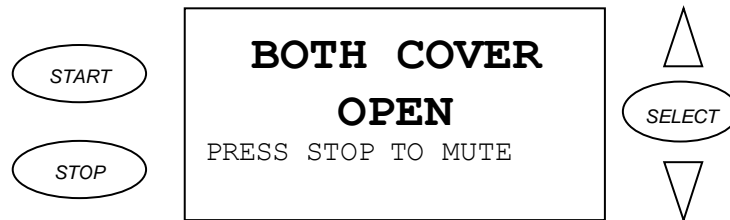
Press [STOP] to mute the audible alarm, to clear the BOTH COVER OPEN alarm screen, and to display the HELP screen as follows:

```
  ╭───────╮    ┌─────────────────────┐        △
 ( START  )    │    BOTH  COVER      │
  ╰───────╯    │                     │     ╭────────╮
               │       OPEN          │    ( SELECT  )
  ╭───────╮    │  PRESS START TO     │     ╰────────╯
 ( STOP   )    │  CONTINUE.          │
  ╰───────╯    └─────────────────────┘        ▽
```
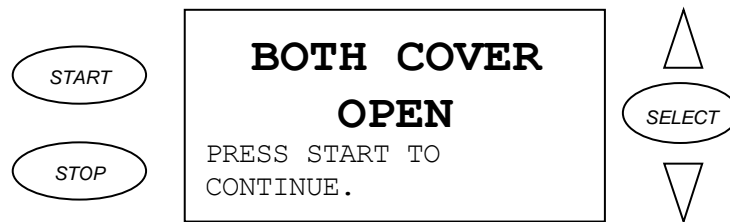
Close both the Pump-to-Drain pump head and valve cover and press [START] to continue the treatment.

If you continue to have BOTH COVER OPEN alarms when the Pump-to-Drain pump head and valve cover are closed, call Technical Service.

b. Cooling Alarm

A COOLING ALARM occurs if the Dialysis Solution remains too warm for over 5 minutes.

Before a COOLING ALARM occurs, a message will appear on the bottom of the cycler screen saying "HEATER PLATE COOLING". This message tells you that the cycler has sensed that the Solution is warmer than expected. You do not have to do anything when you see this message. The cycler will automatically turn off the heater to allow the solution to cool to the right temperature.

If the "HEATER PLATE COOLING" message occurs when entering or during a Fill phase, **the cycler will close the Fill valve and not allow you to Fill until the Solution has cooled to the right temperature**. If the Solution temperature does not drop to the right temperature within 5 minutes, a COOLING ALARM will occur.

A COOLING ALARM will appear as follows:

```
 ( START )          COOLING
                     ALARM              ( SELECT )
 ( STOP )      PRESS STOP TO MUTE
```

Press [STOP] to mute the audible alarm, to clear the COOLING ALARM screen, and to display the HELP screen as follows:

```
 ( START )          COOLING
                     ALARM              ( SELECT )
 ( STOP )      PRESS START T0
               CONTINUE.
```
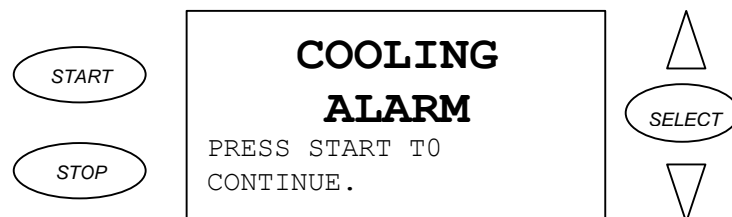
Make any adjustments needed and press [START] to continue the treatment.

You cannot BYPASS a COOLING ALARM.

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Call your clinic or Technical Service if this alarm does not clear.

c. Drain Alarm

A DRAIN ALARM occurs if the programmed DRAIN TIME has run out and you have not drained at least 85% of your Fill Volume. For example, if you filled with 1000ml of Solution, you must drain at least 850ml of Solution by the end of you programmed DRAIN TIME or a DRAIN ALARM will occur.

A DRAIN ALARM will appear as follows:

```
             ╱╲
START      DRAIN
           ALARM        SELECT
STOP   PRESS STOP TO MUTE
             ╲╱
```

Press [STOP] to mute the audible alarm, to clear the DRAIN ALARM screen, and to display the HELP screen as follows:
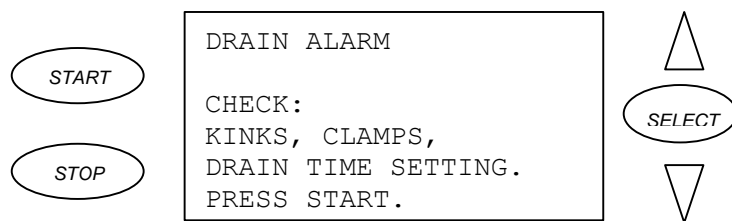
```
        DRAIN ALARM      ╱╲
START
        CHECK:           SELECT
        KINKS, CLAMPS,
STOP    DRAIN TIME SETTING.
        PRESS START.      ╲╱
```

Make any adjustments needed and press [START] to continue the treatment.

When you restart the treatment, the Drain is repeated from the beginning of the DRAIN TIME. If you have FAST FILL/DRAIN set to "YES", once you have drained enough, the treatment will automatically advance to the Fill even if there is still time remaining in the repeated Drain phase. You can BYPASS a DRAIN ALARM if there is no chance of you being overfilled during the next Fill. (See OVERFILL ALARM).

If you have many DRAIN ALARMS, the most important thing to make sure of is that you have programmed enough DRAIN TIME to meet the minimum Drain requirement of 85%. In addition, a DRAIN ALARM may occur because of a kink (bend) in the Patient Line caused when you roll over in your bed onto the Patient Line. Lastly, a DRAIN ALARM may occur if your body is not positioned above the level of the Drain Bag hanging on the Cycler Drain Hook. Simply repositioning yourself when either of these conditions occurs may correct the problem.

If you continue to have unexplained DRAIN ALARMS, consult with your clinic.

d. Emptying Alarm

An EMPTYING ALARM occurs if the cycler is unable to successfully pump out the fluid from the Cycler Drain Bag to your waste site.

An EMPTYING ALARM will appear as follows:

```
            ┌─────────────────────┐      △
  ( START )  │      EMPTYING       │
            │       ALARM         │    ( SELECT )
            │  PRESS STOP TO MUTE  │
  ( STOP )   └─────────────────────┘      ▽
```

Press [STOP] to mute the audible alarm, to clear the EMPTYING ALARM screen, and to display the HELP screen as follows:

```
            ┌─────────────────────────┐      △
  ( START )  │ EMPTYING ALARM          │
            │ CHECK:                  │    ( SELECT )
            │ PUMP-TO-DRAIN TUBING    │
  ( STOP )   │ KINKS AND CLAMP.        │
            │ PRESS START TO          │      ▽
            │ CONTINUE.               │
            └─────────────────────────┘
```
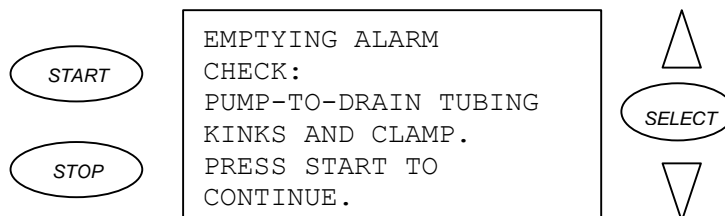
Check for kinks (bends) in the waste tubing leading to your waste site. Also, check to see that all appropriate clamps on the waste tubing are open. After making needed adjustments, press [START] to continue the treatment.

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ALARMS (cont'd)

If you continue to have unexplained EMPTYING ALARMS, call Technical Service.

e. Fill Alarm

A FILL ALARM occurs when your programmed FILL TIME has run out during a Fill, and you have not been filled with the complete programmed Fill Volume.

A FILL ALARM will appear as follows:

```
         ┌─────────────────────────┐
  START  │         FILL            │      △
         │                         │
         │        ALARM            │   SELECT
         │   PRESS STOP TO MUTE     │
   STOP  │                         │      ▽
         └─────────────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the FILL ALARM screen, and to display the HELP screen as follows:
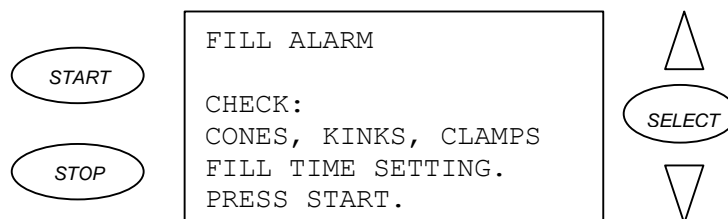
```
         ┌─────────────────────────┐
         │  FILL ALARM              │      △
  START  │                         │
         │  CHECK:                  │   SELECT
         │  CONES, KINKS, CLAMPS    │
   STOP  │  FILL TIME SETTING.      │      ▽
         │  PRESS START.            │
         └─────────────────────────┘
```

Make any adjustments needed and press [START] to continue the treatment.

When you restart the treatment, the Fill is repeated from the beginning of the FILL TIME. When the correct amount of solution has filled you, the treatment will advance to the Pause or Dwell phase (depending on your program) even if there is time remaining in the repeated Fill phase.

If you have many FILL ALARMS, the most important thing to make sure of is that you have programmed enough FILL TIME to allow you to fill with your programmed fill volume. In addition, a FILL ALARM may occur because of a kink (bend) in the Patient Line caused when you roll over in your bed onto the Patient Line. Lastly, a FILL ALARM may occur if your body is not positioned below the level of the solution bags on the cycler Heater Tray. Simply repositioning yourself when either of these conditions occurs may correct the problem.

If you continue to have unexplained FILL ALARMS, consult your clinic.

f. Interrupt Too Long

An INTERRUPTED TOO LONG alarm will occur, if you have pressed [STOP] to INTERRUPT the treatment and have not restarted the treatment within 10 minutes.

An INTERRUPTED TOO LONG alarm will appear as follows:


```
INTERRUPT
TOO LONG
PRESS STOP TO MUTE
```
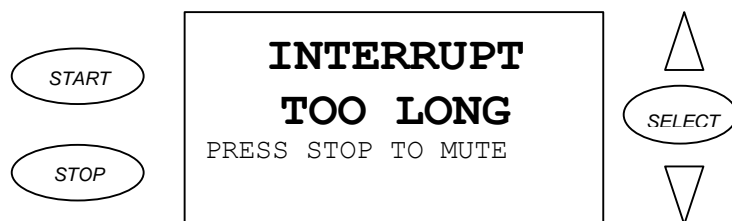
Press [STOP] to mute the audible alarm, to clear the INTERRUPT TOO LONG screen, and to display the HELP screen as follows:


```
INTERRUPT
TOO LONG
PRESS START TO
CONTINUE.
```
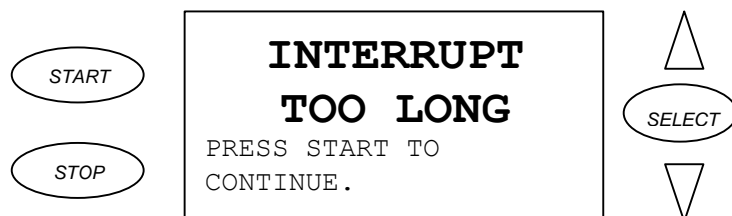
You can press [STOP] to INTERRUPT the treatment again, but be aware that an INTERRUPTED TOO LONG alarm will occur again if you have not restarted the treatment within another 10 minutes.

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g. IQcard Batt Dead

An IQCARD BATT DEAD alarm occurs when the battery in the IQcard is completely dead.

An IQCARD BATT DEAD alarm will appear as follows:

```
  START          ┌─────────────────────┐        △
                 │      IQCARD         │
                 │    BATT DEAD        │     SELECT
  STOP           │ PRESS STOP TO MUTE  │
                 └─────────────────────┘        ▽
```
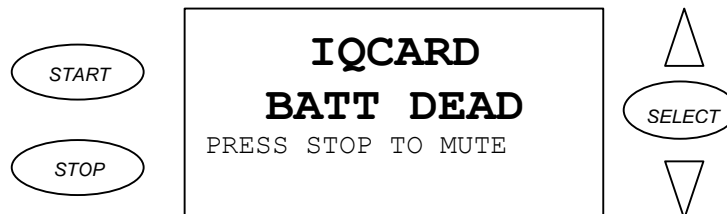
Press [STOP] to mute the audible alarm, to clear the IQCARD BATT DEAD alarm screen, and to display the HELP screen as follows:

```
  START          ┌─────────────────────────┐        △
                 │ IQCARD BATTERY DEAD.    │
                 │ REMOVE THE IQCARD,      │
                 │ INSTALL A NEW BATTERY.  │     SELECT
                 │ INSTALL THE IQCARD.     │
  STOP           │ PRESS START TO          │
                 │ CONTINUE.               │        ▽
                 └─────────────────────────┘
```
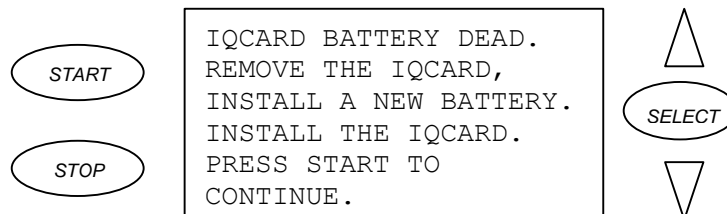
Make any adjustments needed and press [START] to continue the treatment.

If you can not replace the dead battery immediately, replace the battery as soon as you are able to do so, because the cycler will not send information to an IQcard with a dead battery. Since the cycler stores up to seven treatments in its internal memory, any of these seven treatments not recorded on the IQcard while it had a dead battery will be transferred to the IQcard once it contains a good battery.

h. IQcard Batt Low

An IQCARD BATT LOW alarm occurs when the battery is weak and needs replacing.

ALARMS (cont'd)

An IQCARD BATT LOW alarm will appear as follows:

```
        START          IQCARD              △
                       BATT LOW          SELECT
        STOP        PRESS STOP TO MUTE      ▽
```
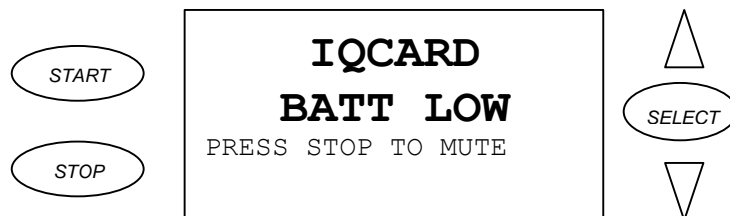
Press [STOP] to mute the audible alarm, to clear the IQCARD BATT LOW
alarm screen, and to display the HELP screen as follows:

```
        START       IQCARD BATTERY WEAK.    △
                    INSTALL A NEW BATTERY
                    SOON. DATA RETENTION   SELECT
                    IS UNCERTAIN. PRESS
        STOP        START TO CONTINUE.      ▽
```
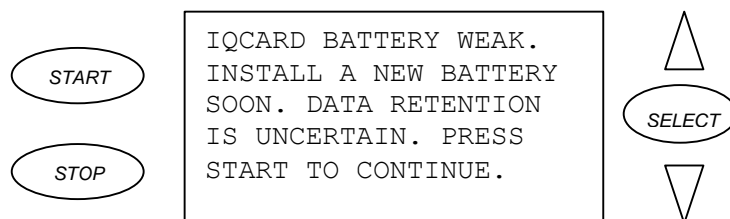
Make any adjustments needed and press [START] to continue the treatment.

You will need to return the IQcard to your clinic and get another card to use.
The treatment will be able to continue, and because the cycler records data
for up to 7 days, the treatment data will be saved and then transferred to the
card once it is inserted.

i. IQcard Is In

An IQCARD IS IN alarm occurs if you place an IQcard into the cycler
IQcard slot when IQCARD USED? is set to "NO".

An IQCARD IS IN alarm will appear as follows:

```
        START          IQCARD              △
                        IS IN             SELECT
        STOP        PRESS STOP TO MUTE      ▽
```

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ALARMS (cont'd)

Press [STOP] to mute the audible alarm, to clear the IQCARD IS IN alarm screen, and to display the HELP screen as follows:

```
         ┌─────────────────────────┐        △
 ╭───────╮│ IQCARD IS PRESENT.      │
 │ START ││ CHANGE OPTIONS TO       │     ╭────────╮
 ╰───────╯│ USE IQCARD.             │     │ SELECT │
          │ OTHERWISE, THE IQCARD   │     ╰────────╯
 ╭───────╮│ WILL BE IGNORED. PRESS  │
 │ STOP  ││ START TO CONTINUE.      │        ▽
 ╰───────╯└─────────────────────────┘
```
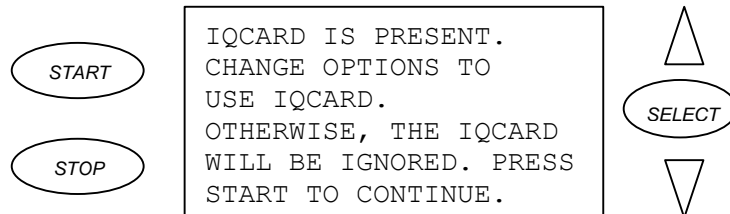
Make any adjustments needed and press [START] to continue the treatment.

If you plan to use the IQCARD to record your treatments, change IQCARD USED? to "YES". (See the "ADDITIONAL OPTIONS" section of these operating instructions for programming IQCARD USED?).

j. IQcard Not In

An IQCARD NOT IN alarm occurs if no IQcard is inserted into the Cycler IQcard Slot when IQCARD USED? is set to "YES".

An IQCARD NOT IN alarm will appear as follows:

```
         ┌─────────────────────────┐        △
 ╭───────╮│                         │
 │ START ││      IQCARD             │     ╭────────╮
 ╰───────╯│                         │     │ SELECT │
          │      NOT  IN            │     ╰────────╯
 ╭───────╮│ PRESS STOP TO MUTE      │
 │ STOP  ││                         │        ▽
 ╰───────╯└─────────────────────────┘
```
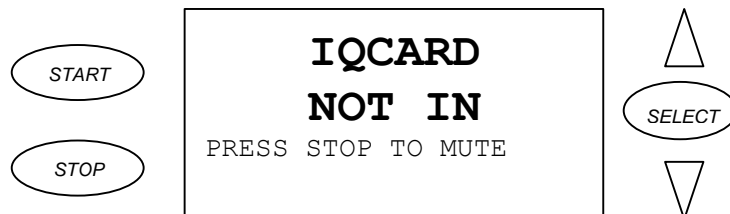
Press [STOP] to mute the audible alarm, to clear the IQCARD NOT IN alarm screen, and to display the HELP screen as follows:
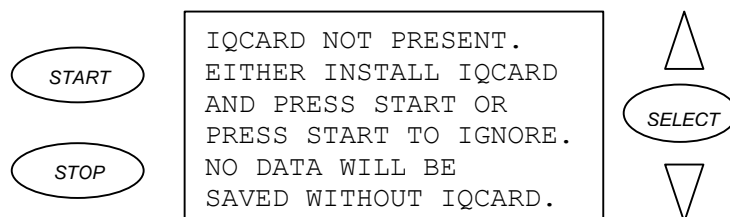
```
         ┌─────────────────────────┐        △
 ╭───────╮│ IQCARD NOT PRESENT.     │
 │ START ││ EITHER INSTALL IQCARD   │     ╭────────╮
 ╰───────╯│ AND PRESS START OR      │     │ SELECT │
          │ PRESS START TO IGNORE.  │     ╰────────╯
 ╭───────╮│ NO DATA WILL BE         │
 │ STOP  ││ SAVED WITHOUT IQCARD.   │        ▽
 ╰───────╯└─────────────────────────┘
```

Make any adjustments needed and press [START] to continue the treatment.

If you do <u>not</u> plan to use the IQCARD to record your treatments, change IQCARD USED? to "NO". (See the "ADDITIONAL OPTIONS" section of these operating instructions for programming IQCARD USED?).

k. IQcard Not Initialized

An IQCARD NOT INIT'ED alarm occurs if the cycler senses that there is a problem with the IQcard.

You will need to return the IQcard to your clinic and get another card to use. The treatment will be able to continue, and because the cycler records data for up to 7 days, the treatment data will be saved in the cycler's memory and then downloaded when you insert a new card.

An IQCARD NOT INIT'ED alarm will appear as follows:

```
┌─────────────────────────────┐
│     IQCARD NOT              │
│     INIT'ED                 │
│ PRESS STOP TO MUTE          │
└─────────────────────────────┘
```
START   STOP   SELECT
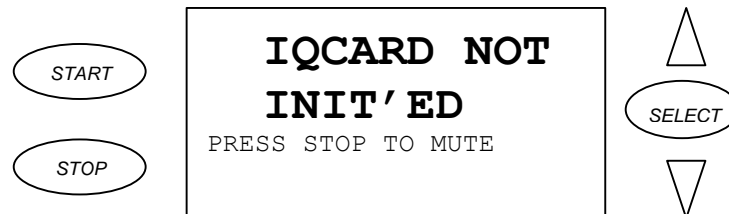
Press [STOP] to mute the audible alarm, to clear the IQCARD NOT INIT'ED alarm screen, and to display the HELP screen as follows:

```
┌─────────────────────────────┐
│ IQCARD NOT INIT'ED.         │
│ REMOVE IQCARD AND           │
│ RETURN IT TO CLINIC         │
│ FOR REPLACEMENT.            │
│ PRESS START TO              │
│ CONTINUE.                   │
└─────────────────────────────┘
```
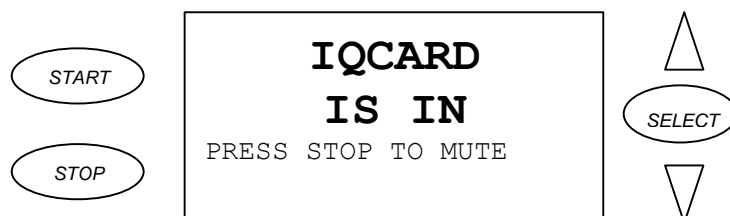START   STOP   SELECT
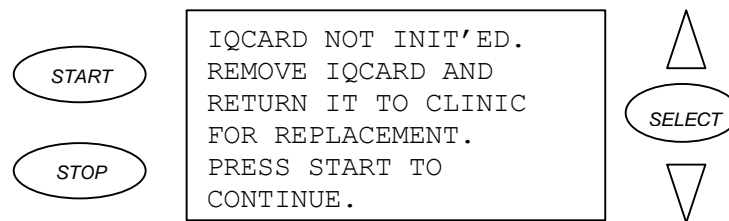
Remove the card, and press [START] to continue the treatment.

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l. IQcard Write Protected

An IQCARD WRITE PROTECTED alarm occurs if the cycler senses that the Write Protect switch on the IQcard is in the "LOCK" position. The cycler can not write to the IQcard when the IQcard is "locked" (Write Protected).

An IQCARD WRITE PROTECTED alarm will appear as follows:

```
   START        IQCARD WRITE          △
                 PROTECTED          SELECT
   STOP      PRESS STOP TO MUTE        ▽
```

Press [STOP] to mute the audible alarm, to clear the IQCARD WRITE PROTECTED alarm screen, and to display the HELP screen as follows:

```
              IQCARD WRITE               △
   START      PROTECTED. REMOVE THE
              IQCARD. DISABLE THE      SELECT
              WRITE PROTECTION,
   STOP       INSTALL THE CARD.          ▽
              PRESS START.
```
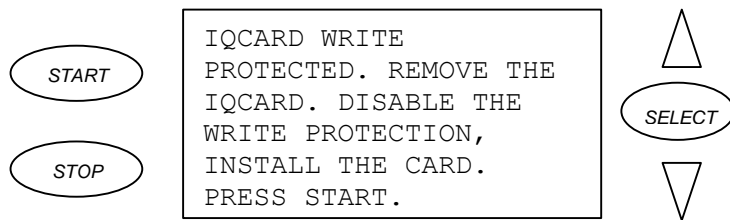
Contact Fresenius USA Technical Service for instructions to make any adjustments needed. Press [START] to continue the treatment.

m. Last Bag Alarm

The LAST BAG ALARM sounds just prior to the Last Fill of the treatment to alert you that it is time to prepare for your Last Fill.

A LAST BAG ALARM will appear as follows:

```
START                  LAST  BAG            △
                        ALARM          SELECT
STOP              PRESS START TO MUTE        ▽
```

Press [STOP] to mute the audible alarm, to clear the LAST BAG ALARM screen, and to display the HELP screen as follows:

```
                  LAST BAG ALARM.            △
START             CLOSE CLAMPS ON
                  SOLUTION LINES.       SELECT
                  OPEN CLAMP ON LAST
STOP              BAG LINE. PRESS START.      ▽
```
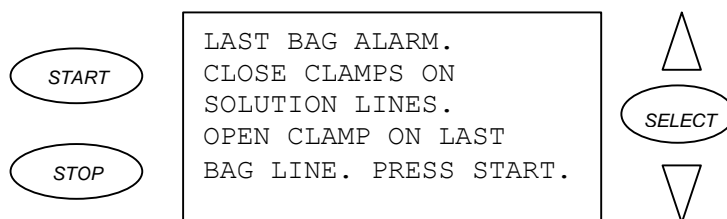
Follow the HELP screen instructions and press [START] to continue the treatment.

n. Valve Cover Open

A VALVE COVER OPEN alarm occurs if the cycler senses that the Pump-to-Drain valve cover is open when it should not be.

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ALARMS (cont'd)

A VALVE COVER OPEN alarm will appear as follows:

```
  ( START )        ┌──────────────────────┐          △
                   │       VALVE          │
                   │    COVER OPEN        │      ( SELECT )
  ( STOP )         │  PRESS STOP TO MUTE  │
                   └──────────────────────┘          ▽
```

Press [STOP] to mute the audible alarm, to clear the VALVE COVER
OPEN alarm screen, and to display the HELP screen as follows:

```
  ( START )        ┌──────────────────────┐          △
                   │       VALVE          │
                   │    COVER OPEN        │      ( SELECT )
  ( STOP )         │  PRESS START TO      │
                   │  CONTINUE.           │          ▽
                   └──────────────────────┘
```

Close the Pump-to-Drain valve cover and press [START] to continue the
treatment.

If you continue to have VALVE COVER OPEN alarms when the Pump-to-
Drain valve cover is closed, call Technical Service.

o. Mid-Drain Alarm

A MID-DRAIN ALARM occurs if you haven't drained at least one half of
the expected Drain amount prior to one-half of the programmed DRAIN
TIME. For example, if you filled with 2000ml of Solution and your
programmed DRAIN TIME is 20 minutes, you must drain at least 1000ml of
Solution within the first 10 minutes of the Drain phase or a MID-DRAIN
ALARM will occur.

A MID-DRAIN ALARM will appear as follows:

```
          ┌─────────────────────┐     △
  START   │     MID-DRAIN       │
          │      ALARM          │   SELECT
  STOP    │  PRESS STOP TO MUTE.│
          └─────────────────────┘     ▽
```

Press [STOP] to mute the audible alarm, to clear the MID-DRAIN ALARM screen, and to display the HELP screen as follows:
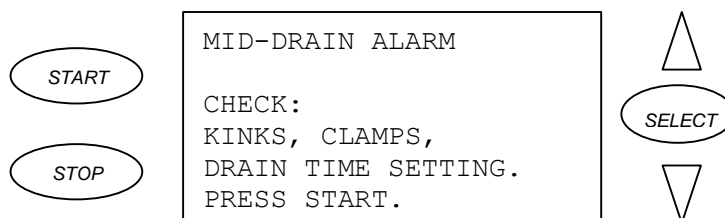
```
          ┌─────────────────────┐     △
  START   │ MID-DRAIN ALARM     │
          │                     │   SELECT
          │ CHECK:              │
  STOP    │ KINKS, CLAMPS,      │
          │ DRAIN TIME SETTING. │     ▽
          │ PRESS START.        │
          └─────────────────────┘
```

Make any adjustments needed and press [START] to continue the treatment.

When you restart the treatment, the Drain is repeated from the beginning of the DRAIN TIME. If you have FAST FILL/DRAIN set to "YES", once you have drained enough, the treatment will automatically advance to the Fill even if there is still time remaining in the repeated Drain phase. You can BYPASS a MID-DRAIN ALARM if there is no chance of you being overfilled during the next Fill. (See OVERFILL ALARM).

If you have many MID-DRAIN ALARMS, the most important thing to make sure of is that you have programmed enough DRAIN TIME to meet the minimum Drain requirement of 85%. In addition, a MID-DRAIN ALARM may occur because of a kink (bend) in the Patient Line caused when you roll over in your bed onto the Patient Line. Lastly, a MID-DRAIN ALARM may occur if your body is not positioned above the level of the Drain Bag hanging on the Cycler Drain Hook.. Simply repositioning yourself when either of these conditions occurs may correct the problem.

If you continue to have unexplained MID-DRAIN ALARMS, consult with your clinic.

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p. Mid-Fill Alarm

A MID-FILL ALARM occurs if you haven't filled with at least one half of your Fill Volume prior to one-half of the programmed FILL TIME. For example, if you are programmed to Fill with 2000ml of Solution and your programmed FILL TIME is 10 minutes, you must fill with at least 1000ml of Solution within the first 5 minutes of the Fill phase or a MID-FILL ALARM will occur.

A MID-FILL ALARM will appear as follows:

```
                          ┌─────────────────────┐
   ( START )              │      MID-FILL       │         △
                          │       ALARM         │    ( SELECT )
   ( STOP )               │  PRESS STOP TO MUTE │         ▽
                          └─────────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the MID-FILL ALARM screen, and to display the HELP screen as follows:

```
                          ┌─────────────────────┐
                          │ MID-FILL ALARM.     │
   ( START )              │                     │         △
                          │ CHECK:              │    ( SELECT )
                          │ CONES, KINKS, CLAMPS,│
   ( STOP )               │ FILL TIME SETTING.  │         ▽
                          │ PRESS START.        │
                          └─────────────────────┘
```

Make any adjustments needed and press [START] to continue the treatment.

When you restart the treatment, the Fill is repeated from the beginning of the FILL TIME. When the correct amount of solution has filled your peritoneal cavity, the treatment will advance to the Pause or Dwell phase (depending on your program) even if there is still time remaining in the repeated Fill phase.

If you have many MID-FILL ALARMS, the most important thing to make sure of is that you have programmed enough FILL TIME to allow you to fill with your programmed fill volume. In addition, a MID-FILL ALARM may occur because of a kink (bend) in the Patient Line caused when you roll over in your bed onto the Patient Line. Lastly, a MID-FILL ALARM may occur

if your body is not positioned below the level of the Solution Bags on the Cycler Heater Tray. Simply repositioning yourself when either of these conditions occurs may correct the problem.

If you continue to have unexplained MID-FILL ALARMS, consult your clinic.

q. Not Flushing Alarm
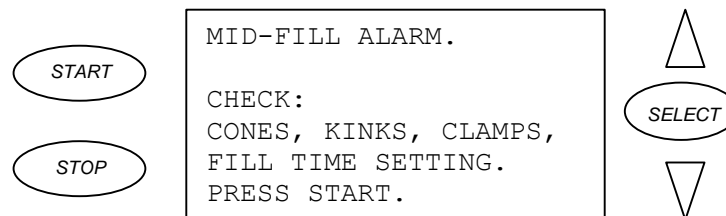
A NOT FLUSHING alarm occurs if the cycler senses a problem during the Flush Procedure of the treatment set-up phase.

A NOT FLUSHING alarm will appear as follows:

```
        START            NOT             SELECT
                      FLUSHING
        STOP       PRESS STOP TO MUTE
```
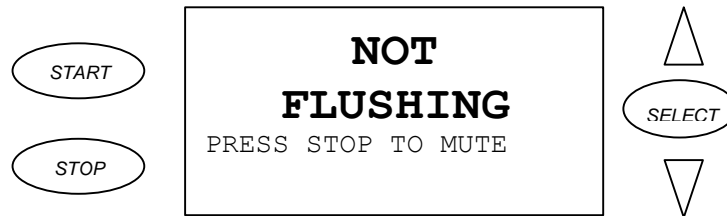
Press [STOP] to mute the audible alarm, to clear the NOT FLUSHING alarm screen, and to display the HELP screen as follows:

```
        START      CHECK: CONES BROKEN,    SELECT
                   WHITE CLAMPS OPEN,
                   RED CLAMPS CLOSED.
                   CORRECT TUBING.
        STOP       INSTALLATION PRESS
                   START TO CONTINUE
```
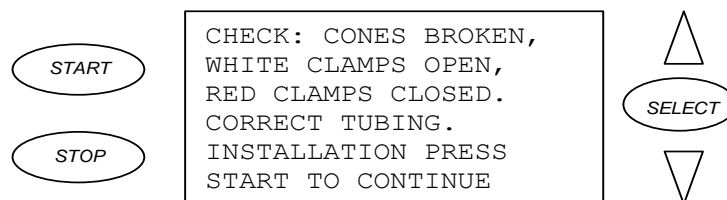
Make sure that all of the white clamps are open and the cones are fully broken on the connected Solution Bag. Also, make sure that there are no kinks (bends) in the Pump-to-Drain tubing. Lastly, make sure that the yellow clamp on the pump tubing is fully open and both red clamps are closed. After you make any needed adjustments, press [START] to continue the treatment setup.

If you continue to have unexplained NOT FLUSHING alarms, call Technical Service.

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r. No Upload During Treatment

A NO UPLOAD DURING TX alarm will occur if the IQcard is put into the Cycler after the treatment has started. The treatment has started after the set-up screen that reads "PLACE BAGS ON SCALE…"

A NO UPLOAD DURING TX alarm screen will appear as follows:

```
        START          ┌─────────────────────┐           △
                       │   NO UPLOAD         │
                       │   DURING TX         │        SELECT
        STOP           │ PRESS STOP TO MUTE  │
                       └─────────────────────┘           ▽
```

Press [STOP] to mute the audible alarm, to clear the NO UPLOAD DURING TX alarm screen, and to display the HELP screen as follows:
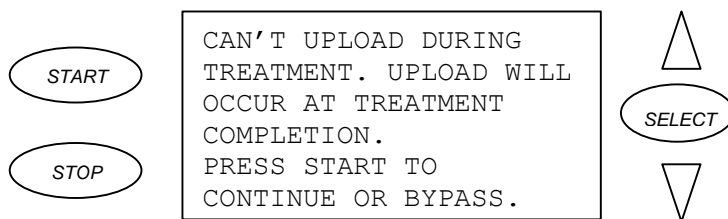
```
        START          ┌─────────────────────────┐        △
                       │ CAN'T UPLOAD DURING     │
                       │ TREATMENT. UPLOAD WILL  │
                       │ OCCUR AT TREATMENT      │     SELECT
                       │ COMPLETION.             │
        STOP           │ PRESS START TO          │
                       │ CONTINUE OR BYPASS.     │        ▽
                       └─────────────────────────┘
```

You may leave the IQcard in the Cycler and your treatment will continue with your current settings. After the treatment is complete, you will be asked to accept the new treatment settings at that time.

s. Overfill Alarm

An OVERFILL ALARM will occur if the Volume left in your peritoneum plus the next Fill Volume will be more than 150% (1 ½) of your programmed CCPD (or FIRST FILL when in Tidal Therapy) Volume. For example, if your programmed CCPD Volume is 2000ml, an OVERFILL ALARM will occur if the Volume left in your peritoneum up to the current point in the treatment, plus the next Fill Volume, is more than 3000ml.

An OVERFILL ALARM will appear as follows:

```
  START         OVERFILL            △
                 ALARM           SELECT
   STOP      PRESS STOP TO MUTE      ▽
```

Press [STOP] to mute the audible alarm, to clear the OVERFILL ALARM screen, and to display the HELP screen as follows:
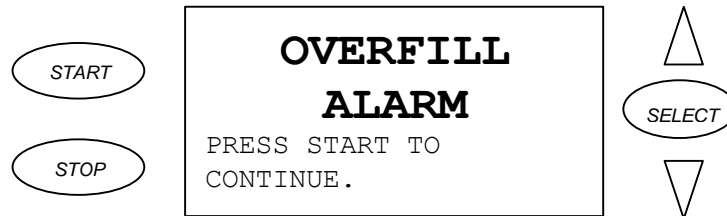
```
  START         OVERFILL            △
                 ALARM           SELECT
   STOP      PRESS START TO         ▽
             CONTINUE.
```

Press [START] to continue the treatment.

When you restart the treatment, the Drain is repeated with the full-programmed DRAIN TIME. **The treatment will not advance to the next Fill until an adequate amount of additional fluid has been drained from your peritoneum**.

An OVERFILL ALARM can not be BYPASSED.
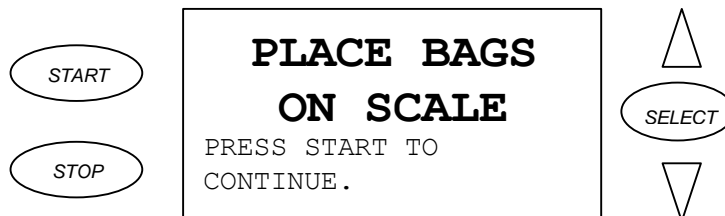
t. Place Bags on Scale

A PLACE BAGS ON SCALE alarm occurs if you have forgotten to put your Solution Bags on the Cycler Scale during setup.

A PLACE BAGS ON SCALE alarm will appear as follows:

```
  START        PLACE BAGS           △
               ON SCALE          SELECT
   STOP      PRESS STOP TO MUTE      ▽
```

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Press [STOP] to mute the audible alarm, to clear the PLACE BAGS ON SCALE alarm screen, and to display the HELP screen as follows:

```
  ┌─────────┐    ┌───────────────────────┐       △
  │  START  │    │     PLACE BAGS        │
  └─────────┘    │      ON SCALE         │    ┌─────────┐
                 │  PRESS START TO       │    │ SELECT  │
  ┌─────────┐    │  CONTINUE.            │    └─────────┘
  │  STOP   │    │                       │       ▽
  └─────────┘    └───────────────────────┘
```

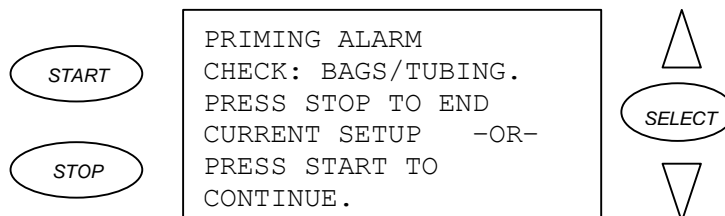Place Solution Bags on the Cycler Scale and press [START] to continue the setup.

u. Priming Alarm

A PRIMING ALARM occurs if the more than 250 ml of fluid loss occurs during the priming process. This may indicate that there is a fluid leak at the Solution Bags or the tubing set, or that you connected to the Patient Line when you shouldn't have.

A PRIMING ALARM will appear as follows:

```
  ┌─────────┐    ┌───────────────────────┐       △
  │  START  │    │       PRIMING         │
  └─────────┘    │        ALARM          │    ┌─────────┐
                 │  PRESS STOP TO MUTE   │    │ SELECT  │
  ┌─────────┐    │                       │    └─────────┘
  │  STOP   │    │                       │       ▽
  └─────────┘    └───────────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the PRIMING ALARM screen, and to display the HELP screen as follows:

```
  ┌─────────┐    ┌───────────────────────┐       △
  │  START  │    │ PRIMING ALARM         │
  └─────────┘    │ CHECK: BAGS/TUBING.   │    ┌─────────┐
                 │ PRESS STOP TO END     │    │ SELECT  │
  ┌─────────┐    │ CURRENT SETUP   -OR-  │    └─────────┘
  │  STOP   │    │ PRESS START TO        │       ▽
  └─────────┘    │ CONTINUE.             │
                 └───────────────────────┘
```

Check the Solution Bags and tubing set for leaks. If you see any leaks, press [STOP] to end the current setup. You must use new Solution Bags and a new tubing set to prepare for your treatment.

If you mistakenly connected yourself to the Patient Line, close the blue clamp on the Patient Line firmly and press [START] to advance to the next setup screen.

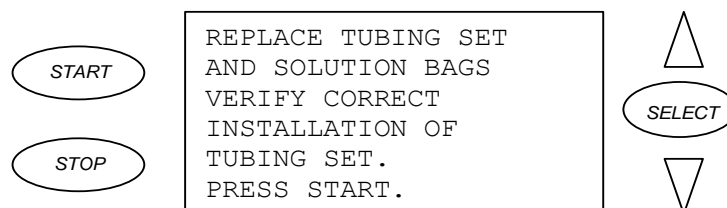If you continue to have unexplained PRIMING ALARMS, call Technical Service.

v. Pump Error

A PUMP ERROR alarm occurs if the cycler senses a problem during the Flush Procedure of the treatment set-up phase.

A PUMP ERROR alarm will appear as follows:
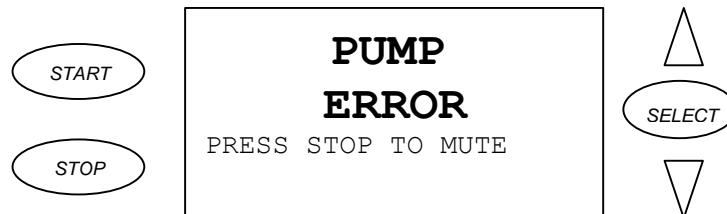
Press [STOP] to mute the audible alarm, to clear the PUMP ERROR alarm screen, and to display the HELP screen as follows:

Make sure that the pump segment tubing is installed correctly. Also, make sure that there are no kinks (bends) in the Pump-to-Drain tubing. Lastly, make sure that the yellow clamp on the pump tubing is fully open and both red clamps are closed. After you replace the tubing set and the solution bags, press [START] to continue the treatment setup.
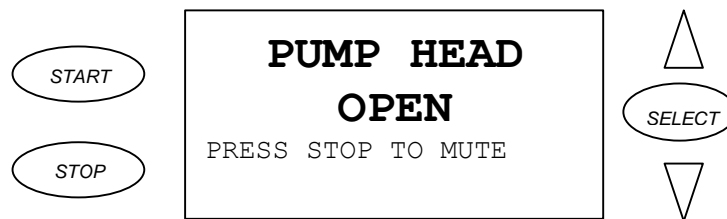
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If you continue to have unexplained PUMP ERROR alarms, call Technical Service.
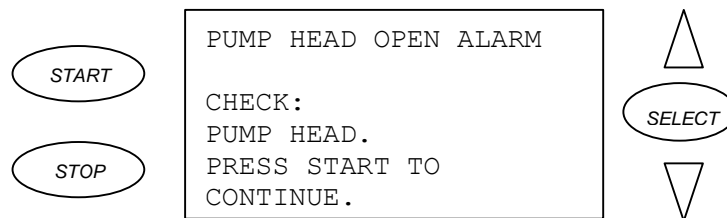
w. Pump Head Open

A PUMP HEAD OPEN alarm occurs if the cycler senses that the Pump-to-Drain pump head is open when it should not be.

A PUMP HEAD OPEN alarm will appear as follows:

```
  START      ┌─────────────────────────┐        △
             │      PUMP  HEAD          │
             │        OPEN              │     SELECT
  STOP       │  PRESS STOP TO MUTE      │
             └─────────────────────────┘        ▽
```

Press [STOP] to mute the audible alarm, to clear the PUMP HEAD OPEN alarm screen, and to display the HELP screen as follows:

```
  START      ┌─────────────────────────┐        △
             │ PUMP HEAD OPEN ALARM     │
             │                          │
             │ CHECK:                   │     SELECT
             │ PUMP HEAD.               │
  STOP       │ PRESS START TO           │
             │ CONTINUE.                │        ▽
             └─────────────────────────┘
```

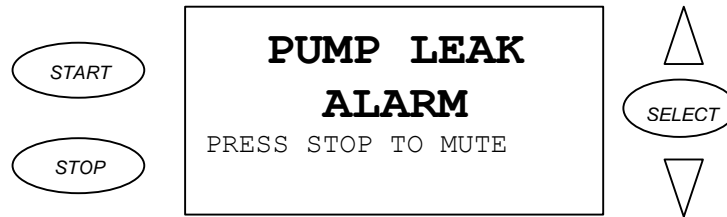Close the Pump-to-Drain pump head and press [START] to continue the treatment.

If you continue to have PUMP HEAD OPEN alarms when the Pump-to-Drain pump head is closed, call Technical Service.

x. Pump Leak Alarm

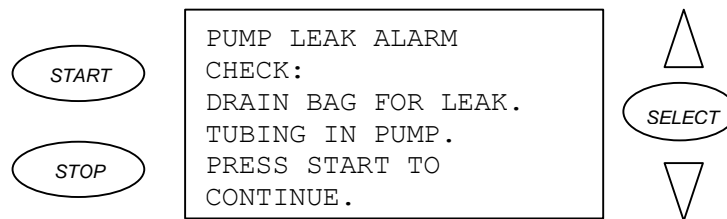A PUMP LEAK ALARM occurs if the cycler senses unexpected fluid movement in the drain or waste tubing.

A PUMP LEAK ALARM will appear as follows:

```
                    ┌──────────────────────┐      △
        START       │     PUMP LEAK        │
                    │     ALARM            │   SELECT
        STOP        │ PRESS STOP TO MUTE   │
                    │                      │      ▽
                    └──────────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the PUMP LEAK ALARM screen, and to display the HELP screen as follows:

```
                    ┌──────────────────────┐      △
        START       │ PUMP LEAK ALARM      │
                    │ CHECK:               │
                    │ DRAIN BAG FOR LEAK.  │   SELECT
                    │ TUBING IN PUMP.      │
        STOP        │ PRESS START TO       │
                    │ CONTINUE.            │      ▽
                    └──────────────────────┘
```

Close the blue clamp on your Patient Line and check for leaks in the Drain Bag, Drain tubing, or Waste Tubing. If you find a leak, power the cycler off then on and follow the Help screens to properly end the treatment.

If you do not find any leaks in the Drain Bag, Drain tubing, or Waste Tubing, check to make sure that the tubing is properly placed in the Pump-to-Drain assembly. After you make any needed adjustments, open the blue clamp on your Patient Line and press [START] to continue the treatment.

If you continue to have unexplained PUMP LEAK ALARMS, call Technical Service.

y. Scale Alarm

The cycler has one internal Scale that measures fluid movement to and from the cycler. The cycler Heater Tray and Drain Hook are connected to this Scale. The cycler continually monitors the Scale and if it detects that fluid is flowing in the wrong direction or too rapidly, a SCALE ALARM will occur.
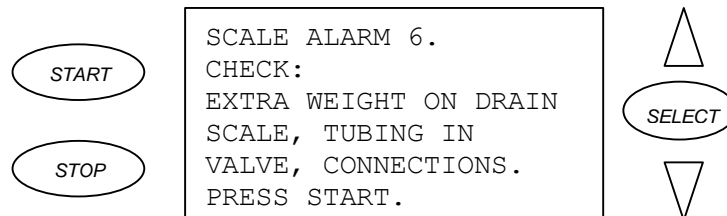
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A SCALE ALARM is followed by a number (for example, SCALE ALARM 3) which indicates the specific error that the cycler detected. A Scale 2 or 3 alarm indicates a flow error during a Fill. A Scale 5 or 6 alarm indicates a flow error during a Drain. A Scale 9 alarm indicates a flow error during Setup, a Pause, or a Dwell.

As an example, a SCALE ALARM 6 will appear as follows:

```
            SCALE
  START
           ALARM 6                    SELECT
           PRESS STOP TO MUTE
  STOP
```
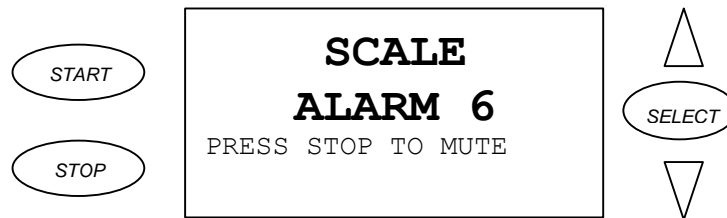
Press [STOP] to mute the audible alarm, to clear the SCALE ALARM 6 screen, and to display the HELP screen as follows:

```
           SCALE ALARM 6.
           CHECK:
  START    EXTRA WEIGHT ON DRAIN
           SCALE, TUBING IN           SELECT
           VALVE, CONNECTIONS.
  STOP     PRESS START.
```

Make any adjustments as needed and press [START] to continue the treatment.

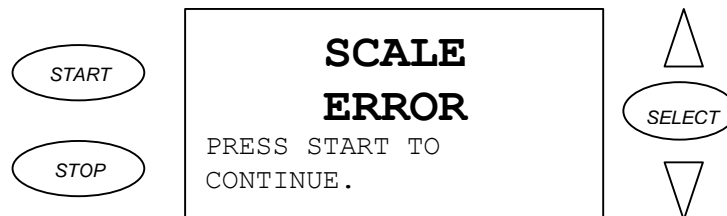If repeated SCALE ALARMS occur, call Technical Service for assistance.

z. Scale Error

A SCALE ERROR will occur during the cycler power-up if the cycler detects an abnormal scale condition during it self-test.

A SCALE ERROR alarm will appear as follows:

```
  START          SCALE              △
                 ERROR            SELECT
  STOP      PRESS STOP TO MUTE      ▽
```

Press [STOP] to mute the audible alarm, to clear the SCALE ERROR alarm screen, and to display the HELP screen as follows:

```
  START          SCALE              △
                 ERROR            SELECT
  STOP      PRESS START TO          ▽
           CONTINUE.
```

Most of the time, simply powering the cycler off and then back on will correct the error.

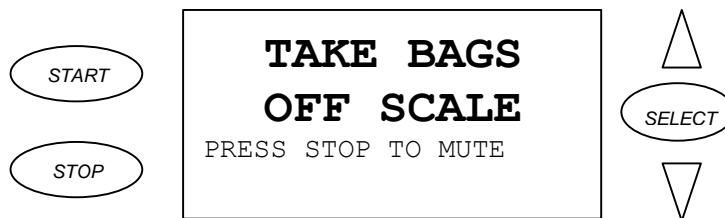If repeated SCALE ERROR alarms occur, call Technical Service for assistance.

aa. Take Bags off Scale

A TAKE BAGS OFF SCALE alarm occurs in most cases if you powered-on the cycler with full Solution Bags on the Cycler Bag Organizer or Drain Hook. The Cycler Scale must not have any weight on it during the cycler power-on self-test.
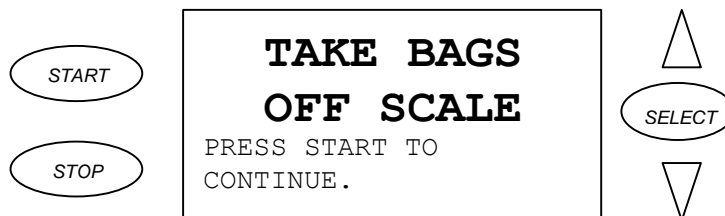
There are power-on situations when this alarm may not occur, such as after an electrical power failure in your home. Refer to the IN THE EVENT OF A POWER FAILURE section of these Operator Instructions for an explanation of how the cycler functions in an electrical power failure situation.

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ALARMS (cont'd)

A TAKE BAGS OFF SCALE alarm will appear as follows:

```
  ( START )      ┌──────────────────┐       △
                 │   TAKE  BAGS      │    ( SELECT )
  ( STOP )       │   OFF  SCALE      │
                 │ PRESS STOP TO MUTE│       ▽
                 └──────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the TAKE BAGS OFF SCALE alarm screen, and to display the HELP screen as follows:

```
  ( START )      ┌──────────────────┐       △
                 │   TAKE  BAGS      │    ( SELECT )
  ( STOP )       │   OFF  SCALE      │
                 │ PRESS START TO    │       ▽
                 │ CONTINUE.         │
                 └──────────────────┘
```

Remove all bags from the Cycler Bag Organizer and Drain Hook. Press [START] to continue the cycler power-on self-test.

If repeated TAKE BAGS OFF SCALE alarms occur and all bags are off the Cycler Scale, call Technical Service for assistance.
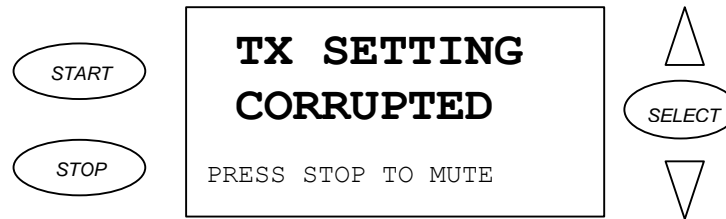
bb. Treatment Setting Corrupted

A TX SETTING CORRUPTED alarm will occur if there is a problem sensed when the cycler is uploading (reading) the prescription from the IQcard. Typically when this alarm occurs, you must replace the card.

NOTE: You may see this alarm if your prescription fill volume has been set for over 3 liters on your IQcard but you did not set ALLOW > 3 LITERS to "YES" in the cycler DIAGNOSTICS OPTIONS screen. See the "ADDITIONAL OPTIONS" section of these Operator Instructions for information on setting your cycler to deliver volumes greater than 3 liters.

A TX SETTING CORRUPTED alarm will appear as follows:

Press [STOP] to mute the audible alarm, to clear the TX SETTING CORRUPTED alarm screen, and to display the HELP screen as follows:
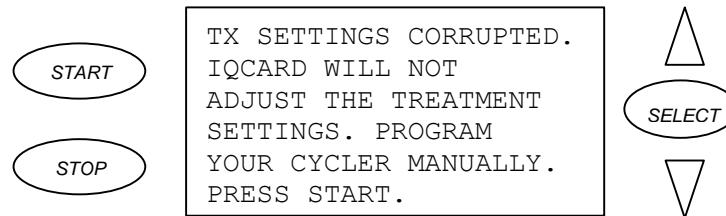
Using the prescription sheet your clinic nurse gave to you, manually program your cycler and go on with your treatment.

If you leave the card in and press [START], the cycler will attempt to write to your card. If the card can be written to, then at the end of your treatment your treatment data will be written to the IQcard.
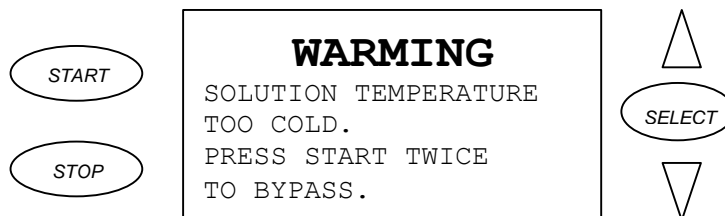
Replace the corrupted IQcard as soon as possible.

cc. Warming Alarm

A WARMING alarm will occur just prior to your first Fill if the cycler detects that the Dialysis Solution is not warm enough. The Solution may not be warm enough because adequate Solution PREWARMING time did not occur, or because the cycler Heater Switch is off.

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A WARMING alarm will appear as follows:

```
              ┌──────────────────────────┐      △
  ( START )   │         WARMING          │
              │  SOLUTION TEMPERATURE    │   ( SELECT )
              │  TOO COLD.               │
  ( STOP )    │  PRESS START TWICE       │      ▽
              │  TO BYPASS.              │
              └──────────────────────────┘
```

If you decide to continue with cool Solution, you will have to BYPASS this alarm. If you would rather continue when the Solution is warmer, turn on the cycler Heater Switch if it is off, and leave the cycler at the WARMING alarm screen. BYPASS the alarm when you are ready to continue your treatment.
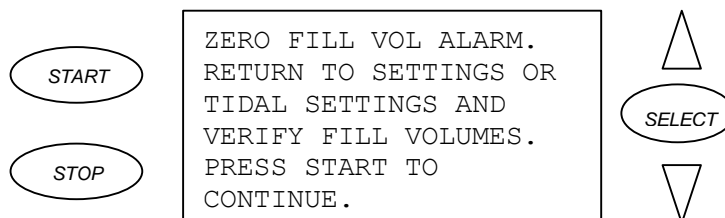
dd. Zero Fill Volume Alarm

A 0 FILL VOL ALARM occurs when you have exited the SETTINGS screen with one or more of the Fill Volumes set to "0" (with the exception of LAST FILL).

A 0 FILL VOL ALARM will appear as follows:

```
              ┌──────────────────────────┐      △
  ( START )   │       0  FILL VOL        │
              │          ALARM           │   ( SELECT )
              │  PRESS STOP TO MUTE      │
  ( STOP )    │                          │      ▽
              └──────────────────────────┘
```

Press [STOP] to mute the audible alarm, to clear the 0 FILL VOL ALARM screen, and to display the HELP screen as follows:

```
              ┌──────────────────────────┐      △
  ( START )   │  ZERO FILL VOL ALARM.    │
              │  RETURN TO SETTINGS OR   │   ( SELECT )
              │  TIDAL SETTINGS AND      │
              │  VERIFY FILL VOLUMES.    │      ▽
  ( STOP )    │  PRESS START TO          │
              │  CONTINUE.               │
              └──────────────────────────┘
```

ALARMS (cont'd)

Press [START] then [SELECT] to enter the SETTINGS screen. Review the
TIDAL SETTINGS menu to make sure that the correct therapy and volumes
are programmed.

Press [START] to return to the SETTINGS screen and review the PAUSE,
CCPD (or FILL), and LAST FILL Volumes to make sure that they are
correct. Once you make all needed corrections, press [START] to return to
the STANDBY screen.

16. ABANDON TREATMENT ALARMS

Abandon Treatment alarms occur when the cycler detects a condition that requires you to stop the treatment and to power off the cycler. An Abandon Treatment alarm will specify the condition that the cycler detected and display a message requiring you to "TURN MACHINE OFF".

The Abandon Treatment alarms are:

BAT RAM ALARM	**THERM 2B ALARM**
EPROM ERROR	**THERM 3 ALARM**
HEATER ALARM	**THERM 3B ALARM**
PTD ALARM	**VOLTAGE ALARMS**
SCALE OUT OF RANGE	**VALVE ERROR**
THERM 2 ALARM	**WATCHDOG ALARM**

If an Abandon Treatment alarm occurs you should:

- clamp the temporary blue clamp on the Newton IQ Set Patient Line,
- write down all the information displayed on the alarm screen,
- power off the cycler and,
- call Fresenius USA Technical Service for assistance.

There are two preventable Abandon Treatment alarms. By taking the following steps, you might be able to prevent these alarms:

Therm 2, 2b, 3, Or 3b Alarm (Temperature Alarms) – make sure that there are no heating or air conditioning vents, or fans directly over the Solution Bags resting on the Cycler Bag Organizer. Also, if you need only one Solution Bag for your treatment, place the single bag in the center of the Cycler Bag Organizer.

ABANDON TREATMENT ALARMS (cont'd)

Scale Out Of Range Alarm – the maximum allowable combined weight on the Newton IQ Cycler scale is 39,500 grams (39.5 liters). The combined weight on the Scale consists of the cycler Heater Tray, Bag Organizer, Dialysis Solution Bags, Drain Hook, and Drain Bags. You can avoid causing a SCALE OUT OF RANGE ALARM by:

- placing only the amount of Dialysis Solution necessary to perform your treatment on the Heater Tray/Bag Organizer at the start of the treatment

- not leaning or placing any foreign article(s) on the Heater Tray/Bag Organizer and,

- not pulling down forcefully on the Drain Hook.

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17. IN THE EVENT OF A POWER FAILURE

If a power failure occurs (or if the power switch is turned off) while the Newton IQ Cycler is at the Standby screen, the cycler will perform its normal power-up routine when power is restored.

If a power failure occurs (or if the power switch is turned off) while the Newton IQ Cycler is at any screen other than the Standby screen, the cycler will close any open valve, stop the pump if it is rotating, and turn off the display. When power is restored, the Newton IQ Cycler will sound an alarm. Pressing the [STOP] key will mute the alarm and display a Help screen allowing you to choose to resume the current treatment from where it was interrupted, or start an entirely new treatment.

If a power failure occurs during the setup, the screen will prompt the user to restart the procedure. Be sure to read and follow the screen prompts carefully.

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18. DESCRIPTION

The Newton IQ Cycler consists of a Control Unit, a Pump-to-Drain assembly, and a Stand.

Control Unit - The Control Unit consists of a Heater/Scale assembly and a Front Control Panel.

> **Heater/Scale Assembly** – The cycler Heater holds, and warms Dialysate Solution Bag(s). **Up to 20 liters of Solution can be placed on the Heater surface.** The cycler contains a single Scale that weighs fluid delivered to and drained from the patient. The Scale monitors weight placed on the Heater Surface located at the top of the cycler and on the Drain Hook located at the underside of the cycler.

> **Front Control Panel** – The cycler Front Panel has a Display Screen and five Control Buttons. The Screen displays text providing cycler setup, treatment, and alarm instructions/information. The five Control Buttons are used for programming and operating the cycler. The five Control Buttons function as follows:

> - **[START]** – is used to advance through the normal exchange sequence. It also permits bypassing, when pressed twice in rapid succession.
> - **[STOP]** – is used to mute an alarm or interrupt the treatment.
> - **[SELECT], the [UP] arrow, and the [DOWN] arrow** – are used to program the cycler.

Pump-to-Drain Assembly – The Pump-to-Drain Assembly plugs into the Cycler Control Unit and mounts to the middle of the Cycler Stand. The Pump-to-Drain consists of two adjacent solenoid valves. The front solenoid valve opens to permit fluid to flow from the Cycler Fresh Dialysis Solution Bags to the patient. The rear solenoid valve opens to permit fluid to flow from the patient to the Cycler Drain Bags. The Pump-to-Drain also contains a peristaltic pump that rotates to empty effluent from the patient drain bag to a waste site. The Pump-to-Drain is controlled electronically by the Cycler Control Unit.

Cycler Stand – The Cycler Stand consists of a Base with locking castors, a two-part vertical Support Pole, a Pump-to-Drain mounting bracket, a horizontal Cycler Hanger Rod, and a manifold holder. The Cycler Stand serves as a support frame for the Cycler Control Unit and Pump-to-Drain Assembly.

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19. GLOSSARY OF TERMS

Diurnal- Daytime

Flush- Procedure to remove air and potential contaminates from bag lines and connections

Manifold- Round white disk on the cycler tubing

Manifold Holder- Used to hold the tubing during the flush procedure, tubing is placed with single-line up, 4 lines hanging down

Prime- Procedure to remove air from the tubing line that connects to the patient's catheter

Pump-to-Drain- This pumps the used fluid from the bag hanging below the cycler to a drain receptacle

20. SPECIFICATIONS

Dimensions: Control Unit: 10"H x 12"D x 15"W
                             Stand: 45"H x 22.5"D x 20"W

Weight: Control Unit: 25 pounds (14kG) Approx.
                             Stand: 5 pounds (2.2kG) Approx.

Power Requirements: 117V ±10%, 60Hz

Electrical Requirements: 3 Amp Grounded Plug and Receptacle
Current Leakage: Under 100 microamperes

Number of Fills: 1 – 20 (Exchanges)

Fill Volume: 500 – 4000ml

Last Fill Volume: 0 and 50 – 4000ml

Fill Time: Variable from 1 – 59 minutes

Dwell Time: Variable from 5 minutes to 9 hours 55 minutes

Drain Time: Variable from 1 – 59 minutes

Temperature: Fixed at 37°C ±2°C

Product Improvement Policy
The Newton IQ machine was designed and built to comply with these product specifications. It is the
intention of Fresenius Medical Care to continuously engage in product development that may result in
modifications or improvements to specifications or equipment produced in the future. Such product
improvements shall not incur any obligation to make similar changes or improvements to equipment
previously produced. These changes or improvements may or may not be applicable or usable with
previously produced equipment. Where possible, improvements will be made available at reasonable
prices. Any such improvement shall not be construed as corrections of any deficiency in previously
produced equipment.

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21. MAINTENANCE

Service and maintenance must be performed by a qualified person.

Surface cleaning of all Cycler components should be carried out on a per-treatment basis using a damp cloth and a dilute (1:100) bleach solution (1 part bleach to 100 parts water) or other surface disinfectant.

Do NOT use any disinfectant containing alcohol.

Do NOT use spray bottles.

Do NOT use foaming type cleaners on surfaces of the machine.

Clean up spills immediately.

The condition of the Cycler Stand should be checked periodically for:

- binding or damaged wheels,
- loose wheel fasteners,
- cracked base or welds,
- bent or dented legs or poles,
- loose or missing plastic leg end caps, and
- pole joints that are wobbly or can be rotated with the hitch pin inserted.

If any of these problems are found, do not use the Cycler Stand or attempt to repair it.

For further maintenance questions, please contact:

Fresenius USA
   4040 Nelson Avenue   Concord, CA 94520
Telephone:
(800) 227-2572 or (925) 288-4218

WARNINGS AND PRECAUTIONS

WARNING! Check the Heater Tray and Bag Organizer to be sure they are free of obstructions and do not touch the top of the Cycler Cabinet or the Stand Pole. Interference with the Heater Tray may result in inaccurate weighing of Dialysis Solution, and possibly result in patient injury. Check again when all Solution bags are on the scale.

WARNING! If the screen on your machine displays "T & C Mode" do <u>not</u> use the machine and call Technical Service for a replacement of the machine.

WARNING! Check and make sure the Manifold Holder does not come in contact with the Bag Organizer, this may result in inaccurate weighing of Dialysis Solution, and may possibly result in injury

WARNING! It is possible to program the Cycler to fill with more than 3,000 ml. Do not fill with more than instructed by your physician.

WARNING! Check the new prescription to be transferred from the IQcard to the Cycler carefully. If <u>your</u> name is not displayed, or the proposed prescription is not correct, do not accept the settings.

WARNING! The Cycler Stand could potentially tip over and cause injury to the patient or bystanders if a Cycler and Stand is used in a tilted position or if moved without appropriate care. **Never place objects under the Cycler Stand wheels to level the stand!**

WARNING! When the bags are in the Bag Organizer, check the Heater Tray and Bag Organizer to be sure they are free of obstructions and do not touch the top of the Cycler Cabinet or the Stand Pole. Interference with the Heater Tray may result in inaccurate weighing of Dialysis Solution, and possibly result in patient injury.

WARNING! The peritoneal dialysis Cycler may be subject to electromagnetic or electrostatic interference (EMI or ESD), causing false alarms and/or shutdown of the machine. Devices emitting electromagnetic radiation such as microwave ovens, portable phones, radio equipment (walkie talkies, etc.), radio transmitters, and like equipment should not be used close to this equipment. The operator should monitor the function of the machine and remove unnecessary equipment from the treatment area should the Cycler be affected. Home patient should be aware of large overhead power lines or electrical substations that may generate large electromagnetic fields.

CAUTION! Do not lift the Cycler with the Heater Tray/Scale. Doing this may damage the Cycler Scale.

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WARNINGS AND PRECAUTIONS (cont'd)

CAUTION! The Newton IQ Cycler is a computer controlled electromechanical medical device. The Newton IQ Cycler should be installed in an appropriate environment (indoors) free from extremes of temperature and humidity reasonably protected from dust and dirt contamination or liquid splashes. Failure to install the Newton IQ Cycler according to these guidelines may result in improper operation or early failure of the device or its components.

CAUTION! Use only Cycler tubing sets intended for Fresenius Newton IQ Cycler.

CAUTION! Maximum total weight on the Cycler load cell Scale is 39,500 grams (39.5 liters).

CAUTION! Overloading the Scale can cause damage to the Cycler load cell.

CAUTION! The Fresenius Newton IQ Cycler should be moved by pulling on the Cycler Stand vertical Pole, or the Cycler Stand horizontal Hanger Rod, **not the Control Unit**.

WARNINGS AND PRECAUTIONS (cont'd)

Precautions:

Federal (USA) law restricts this device to sale only by or on the order of a physician. Frequency, duration, and treatment parameters are to be determined by the prescribing physician.

Warnings:

These instructions are for the Fresenius USA, Inc. Newton IQ Cycler peritoneal dialysis exchange device. The machine must be operated in accordance with these instructions. All operators of this machine must be thoroughly trained and must read this entire manual and any applicable appendices before using the Newton IQ Cycler.

The Newton IQ Cycler is not intended for pediatric use, or for use with patients requiring fill volumes of less than 500ml.

Aseptic technique to prevent infection is required with all peritoneal dialysis procedures.

The electrical source must be a single phase, three conductor type plug. The proper polarity and ground integrity must be initially checked and thereafter maintained. Failure to do so may result in electrical shock to the patient or operator.

Shock hazard. Do not remove the cover. Refer servicing to qualified personnel.

Replace fuses only with the same type and rating.

Indications:

The Fresenius Newton IQ Cycler is indicated for acute and chronic peritoneal dialysis. The following therapies are supported: continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD), tidal peritoneal dialysis (TPD), and PD Plus peritoneal dialysis (CCPD + daytime exchange delivered from the Cycler).

Contraindications:

CAPD and CCPD are effective and attractive choices for many ESRD patients; however, no one dialysis therapy is intended for all patients. When assessing peritoneal dialysis as a therapy in such situations, the benefits to the patient must be weighed against the possible complications.

Transdiaphramatic leakage, hypercatabolism, and insufficient surface area are generally considered to be contraindications to automatic cycling therapy.

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WARNINGS AND PRECAUTIONS (cont'd)

Side Effects:

Peritoneal dialysis therapy occasionally causes adverse patient reactions. Abdominal pain, bleeding, peritonitis and catheter obstruction can cause problems with the treatment. Hypovolemia, hypervolemia, hypotension, edema or muscle cramping can occur if improper dialysate solutions are used. The patient's weight and general physical status, including serum chemistry levels, must be routinely monitored as part of the dialysis treatment in order to maintain correct fluid removal and prevent such complications as congestive heart failure, volume depletion, shock, and inadequate therapy. Strict adherence to physician prescription for therapy is required to help prevent many of the physiological reactions to dialysis treatment.

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22. <u>LIMITED WARRANTY</u>

SALE of the machine or parts described or referenced herein is expressly conditioned upon the terms and conditions set forth below. Any additional or different terms or conditions set forth by the Purchaser to Fresenius USA, Inc., (herein called "the Company") shall not be effective or binding, and the terms set forth herein shall not be modified or amended, unless assented to in writing by an authorized official of the Company located in California.

                              Concord,

LIMITED WARRANTY: The Company warrants to the Purchaser that the equipment delivered is free from defects in material or workmanship for the periods specified below, provided the equipment is used and maintained in accordance with the original manufacturer's operating instructions:

      A. Mainframe chassis, and electronic components, lamps, etc. shall be warranted for ninety (90) days from the date of initial installation or one hundred and eighty (180) days from the shipment, whichever is first.

      B. Consumables shall not be warranted.

The Company will repair or replace, at its option, using new or reconditioned parts and/or assemblies, any parts subject to this warranty which are proven defective in materials or workmanship. Such repair and replacement will be made without cost to the Purchaser, and the Company reserves the right to determine the location at which the repair or replacement will be accomplished. The Warranty does not apply to any equipment which is misused, abused, neglected, tampered with, damaged by accident, flood, fire, or other hazard, subjected to abnormal or unusual electrical or fluid stress, improperly installed or operated, or not maintained in accordance with the routine maintenance schedule set forth in the operating manual for the equipment.

THE FOREGOING WARRANTY SHALL BE IN LIEU OF ANY OTHER WARRANTIES, EXPRESSED, IMPLIED, OR STATUTORY, RESPECTING THE EQUIPMENT OR ANY PARTS OR COMPONENTS THEREOF, AND THE COMPANY MAKES NO IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY IN CONTRACT, TORT, OR UNDER ANY OTHER THEORY AGAINST THE COMPANY RESPECTING THE EQUIPMENT AND ITS USE SHALL BE THE REPLACEMENT OR REPAIR OF THE EQUIPMENT AND ITS PARTS AS DESCRIBED ABOVE, AND NO OTHER REMEDY (INCLUDING, WITHOUT LIMITATION, CONSEQUENTIAL DAMAGES) SHALL BE AVAILABLE TO THE PURCHASER. The company shall have no further obligation or liability with respect to the equipment or its sale, operation and use, and the Company neither assumes, nor authorizes the assumption of, any obligation or liability in connection with such equipment.

TERMS: Net 30 days, FOB shipping point plus sales and similar taxes. The Company's prices do not include sales, use, excise, or similar taxes. Consequently, in addition to the prices specified herein, the amount of any present or future sales, use, excise, or other similar tax applicable to the or use of the equipment hereunder shall be paid by the Purchaser, or in lieu thereof, the Purchaser shall provide the Company with a tax exemption certificate acceptable to the taxing authorities.

REFER ALL SERVICING AND INFORMATION REQUESTS TO:
Fresenius USA, Inc.
   4040 Nelson Avenue Concord, CA 94520 Telephone: (800) 227-2572

FRESENIUS MEDICAL CARE

NEWTON IQ®
putting science to work for you