Attachment on IIPV

Table of Contents

1 OVERFILL GUIDANCE FOR PATIENTS

1.1 What is IIPV?

Increased Intraperitoneal Volume (IIPV), also commonly referred to as overfill, is a condition where excess fluid is present in the peritoneal cavity from overfilling or not draining enough effluent (fluid) during a peritoneal dialysis (PD) exchange.

1.2 What are the most common signs and symptoms of IIPV?

While some people may not exhibit symptoms, most commonly observed symptoms include:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting or spitting-up
- Difficulties feeding
- Localized swelling around the PD catheter exit site, belly button, groin region, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- A child complaining of a "funny feeling" in the abdomen
- A child crying
- Unexpected increase in blood pressure

1.3 What are the possible causes of IIPV when using the HomeChoice device?

*** IIPV can occur because one or more of the following causes.**

Please review all possible causes described here*

- The INITIAL DRAIN ALARM is programmed too low. The system may move on to the first Fill before you are completely drained if:
  - Your last therapy left you with more than your normal Last Fill Volume
  - You did not perform a manual drain
  - A slow flow condition occurs before you are completely drained

Temporarily increase your I-Drain Alarm setting or perform a Manual Drain to make sure that your Initial Drain is complete. Talk to your PD center or nephrologist if you have further questions regarding your I-Drain Alarm setting.

- LAST MANUAL DRAIN is programmed to No, or the UF Target for the Last Manual Drain is programmed too low. This can cause an incomplete last Drain. Talk to your PD center or nephrologist if you have further questions regarding Last Manual Drain UF Target Volume settings.
- A MANUAL DRAIN performed during Fill is stopped or bypassed. This can cause the system to deliver a full Fill in addition to any fluid left in the peritoneal cavity.
- Any Drain phase is bypassed, including INITIAL DRAIN, DAY DRAIN, OR NIGHT DRAIN. This can cause the system to deliver a full Fill in addition to any fluid left in the peritoneal cavity.
- DRAIN NOT FINISHED, LOW UF, LOW DRAIN VOLUME, or CAUTION: NEGATIVE UF alarms are bypassed. This can cause the system to deliver a full Fill in addition to any fluid left in the peritoneal cavity.
- DAY FILL VOLUME, NIGHT FILL VOLUME, or LAST FILL VOLUME is programmed too high. This can cause you to be overfilled if the volume is not appropriate for your body's size. Please discuss with your PD center and nephrologist if you think your Maximum Fill Volume is set too high. See Maximum Fill Volume Table in section 1.5 for further guidance.
- The Minimum Drain Volume % is programmed too low. This can cause your Drain cycles to end early. Please discuss with your PD center and nephrologist if you think your Minimum Drain Volume % is set too low.

Additional possible causes of IIPV in patients receiving fill volumes less than 1000 mL:

- Low Fill Mode is not programmed for patients whose fill volumes are less than 1000 mL. These patients typically weigh less than 44 lbs (20 kg).
- In this group of patients, the Negative UF Limit should not be raised above 50% and the Minimum Drain Volume % should not be lowered below 85% (the default values).

Additional possible causes of IIPV in patients receiving Tidal Therapies:

- Total UF volume is programmed too low. This can cause a gradual buildup of UF volume during the therapy. Discuss with your PD center and nephrologist if you have further questions regarding your Tidal Total UF settings.

Other possible causes of IIPV:

- The patient line length is greater than 12 feet (3.6 meters) and Initial Drain Alarm is set below 30 mL. This can cause your Initial Drain to end early.
- The Stop button, then Go button are pressed during Tidal dwells over multiple dwell cycles. This can reduce the volumetric accuracy of the device over the course of successive Tidal Dwell cycles.
- After a power failure during Prime, the Go button is pressed to start therapy without closing all clamps first. This can cause a free flow of fluid from one bag to another and/or to the patient during the time when LOAD THE SET is displayed.
- The door is opened during an alarm or System Error without closing all clamps first. This can cause a free flow of fluid from one bag to another and/or to the patient.
- The transfer set is connected to the patient line before CONNECT YOURSELF appears on the display screen. This can cause air to be delivered to your peritoneal cavity, which can cause IIPV if you had fluid in your peritoneal cavity prior to the Initial Drain.
- At the start of Fill 1, the patient line clamp is opened after a Check Patient Line alarm or Check Your Position alarm appears on the display screen without first initiating a manual drain. This can cause air to be delivered to your peritoneal cavity, which can cause IIPV if you had fluid in your peritoneal cavity prior to the Initial Drain.
- The Go button is pressed at the end of therapy before all clamps are closed when CLOSE ALL CLAMPS appears on the display screen. This can cause a free flow of fluid to the patient.
- The door is opened at the end of therapy before all clamps are closed. This can cause a free flow of fluid to the patient.

IIPV could result in a feeling of abdominal discomfort, serious injury, or death.

1.4 What should you do if IIPV is suspected?

1. Press STOP immediately, then press the DOWN ARROW and initiate a Manual Drain. The Manual Drain procedure is located below.

2. Once the fluid is completely drained from the abdomen, call your nephrologist.

3. Call your nephrologist immediately if you have ANY complaints or symptoms of IIPV including those listed above.

4. For assistance in performing the above steps, call the Baxter Clinical Hotline, available 24 hours a day, 7 days a week at 017-722 9837.

Steps to perform a Manual Drain (Confirm locally)

The current FILL phase appears on the display screen, for instance, FILL 3 OF 5.

1. Press STOP. The display indicates that your fill phase has stopped.

2. Press DOWN ARROW. The display indicates the fill volume that has been delivered thus far.

3. Press DOWN ARROW. The display indicates the option to bypass. (Do not select this option).

4. Press DOWN ARROW. The display indicates the option to change programmed therapy settings.

5. Press DOWN ARROW. The display indicates the option to make adjustments to other settings.

6. Press DOWN ARROW. The display indicates the option to perform a manual drain.

7. Press ENTER to select the manual drain option. The display indicates that it is now draining. The display screen also shows the volume that has been drained. The system continues to drain until flow is no longer detected.

8. Press GO to return to therapy.

9. Reinitiate a Manual Drain if it is stopped during Fill

1.5 What is the Maximum Fill Volume that I should receive?

The following Table is to be used as guidance to help reduce IIPV incidents due to programming a fill volume which may be too high for you. **Most patients will be prescribed a fill volume which is lower than the values shown in this Table. Never rely on this Table alone to determine your fill volume. Your clinician should determine what fill volume is appropriate for you.** For a given patient weight, this Table provides a corresponding fill volume which typically should not be exceeded. To use the maximum fill volume Table, find the row with your weight in pounds (or kilograms) and read across to find the corresponding Fill Volume Limit.

- EXAMPLE: If dry weight is 120 pounds (convert to metric if desired), the Fill Volume Limit is 2500 mL.

If your weight is between the values listed in two adjacent rows, choose the row with lower weight and read across to find the corresponding Fill Volume Limit.

- EXAMPLE: If dry weight is 137 pounds, the Fill Volume Limit for 135 pounds is 2800 mL.

Use a Fill Volume Limit of 3000 mL if your weight is 145 pounds or greater.

If any of your programmed per-cycle fill volumes (day fill, night fill, last fill) exceed the value in the Table for your weight, please contact your clinician before continuing your therapy. They might have accidentally programmed, or asked you to program, a fill volume which may be too high for you. **Do not simply program the fill volume listed next to your weight. Most patients will be prescribed a fill volume which is lower than the values shown in this Table. Never rely on this Table alone to determine your fill volume. Your clinician should determine what fill volume is appropriate for you.**

Weight		**Fill Volume Limit**
Pounds (lbs)	**Kilograms (kg)**	**Milliliters (mL)**
5	2	100
10	5	250
15	7	350
20	9	450
25	11	550
30	14	700
35	16	800
40	18	900
45	20	1000
50	23	1100
55	25	1200
60	27	1300
65	30	1400
70	32	1500
75	34	1600
Continued in next column		

Weight		**Fill Volume Limit**
Pounds (lbs)	**Kilograms (kg)**	**Milliliters (mL)**
Continued from first column		
80	36	1700
85	39	1800
90	41	1900
95	43	2000
100	45	2100
105	48	2200
110	50	2300
115	52	2400
120	55	2500
125	57	2600
130	59	2700
135	61	2800
140	64	2900
145 or more	66 or more	3000

2 INCREASED INTRAPERITONEAL VOLUME (IIPV) GUIDANCE FOR CLINICIANS

Clinicians should first read the Overfill Guidance for Patients section to understand the patient actions that can contribute to an increased risk of Increased Intraperitoneal Volume (IIPV). It is important to note that several programmable therapy parameters can increase the risk of IIPV if used incorrectly.

2.1 What programmable parameters influence the risk of IIPV?

Desirable therapy outcomes can best be achieved on the HomeChoice APD System if you properly program the therapy prescription parameters. The guidance in this document should never overrule good clinical practice. This is presented to help the clinician program proper fill and drain volumes to reduce the likelihood of unintended outcomes due to therapy programming. Peritoneal dialysis prescriptions must be tailored to the individual's needs, as determined by the clinician.

2.1.1 How can the programmable FILL parameters influence the risk of IIPV?

Several programmable parameters affect the amount of fluid delivered to the patient. These parameters include Fill Volume, Day Fill Volume, Night Fill Volume, and Last Fill Volume. In order to ensure the HomeChoice APD System delivers the desired volume of fluid during fill cycles, you must take care to properly program these parameters. Programming a fill volume that is excessive for a given patient could lead to an IIPV situation. Therefore, proper precaution is necessary to ensure that your patient receives the correct fill volume. The terms and definitions for these fill parameters are as follows:

2.1.1.1 FILL VOLUME

Fill Volume refers to the per-cycle volume desired to be in the peritoneal cavity at the beginning of each night dwell cycle, in milliliters (mL). For CCPD therapies, this is the amount of fluid to be filled in each cycle. For Tidal therapies, the Fill Volume is the target volume to remain in the peritoneal cavity at the beginning of each night dwell. The first fill cycle of a Tidal therapy delivers the full programmed Fill Volume. After the first Tidal (partial) drain, the subsequent fill cycles deliver a percentage of the Fill Volume such that the sum of the residual volume left from the previous cycle and the partial fill totaled together equal the programmed Fill Volume. See Section 2.4 for more information on Tidal Therapy.

2.1.1.2 DAY FILL VOLUME

Day Fill Volume refers to the volume of fluid to be delivered in each Day Fill cycle, in milliliters (mL). This may be programmed to a value that does or does not match the Fill Volume. This parameter is only applicable to Hi-Dose therapies.

2.1.1.3 NIGHT FILL VOLUME

Night Fill Volume is the same as Fill Volume described above. For Hi-Dose therapies, the HomeChoice APD System distinguishes between Day Fill and Night Fill cycles. For therapies with no Day Fill Cycles, the HomeChoice APD System only shows Fill Volume to represent the night fill cycles.

2.1.1.4 LAST FILL VOLUME

Last Fill Volume is the volume of fluid to be delivered in the last night fill prior to disconnecting from the HomeChoice APD System. This may or may not be programmed to be the same volume as the Fill Volume setting. For patients who remain dry during the day, the Last Fill Volume can be set to zero. You should make sure the I-Drain Alarm setting

reflects the residual volume in the peritoneal cavity due to the Last Fill Volume setting, as described in the following programmable Drain Parameters Associated with IIPV section.

2.1.2 How can the programmable DRAIN parameters influence the risk of IIPV?

During APD drain phases, the HomeChoice APD System attempts to drain the patient until it reaches the necessary conditions to move on to the next fill cycle. There are several programmable parameters which may impact how long the system continues attempting to drain the patient before moving on to the next cycle. In order to ensure the HomeChoice APD System removes the desired volume of fluid during drain cycles, you must take care to properly program these parameters.

The HomeChoice APD System keeps an estimate of the amount of fluid in the patient's peritoneal cavity at any given time in therapy. The system assumes that no fluid remains in the peritoneal cavity when certain conditions are reached, usually at the end of Initial Drain and at the end of each full drain. However, the system also assumes that no fluid remains in the peritoneal cavity if a drain phase is bypassed during an alarm condition, which results in delivering a full fill volume to the patient on the next fill cycle. Bypassing drain phase alarms if the patient is not empty can lead to IIPV. The system assumes any undrained volume has been absorbed by the body unless the drain was bypassed without an alarm condition.

The following programmable parameters must be set properly to ensure the system maintains an accurate accounting of volume in the patient's peritoneal cavity. The terms as they appear on the programming screen and their definitions are as follows:

2.1.2.1 INITIAL DRAIN ALARM

Initial Drain Alarm, or I-Drain alarm, is the threshold for determining when to sound an alarm to the patient due to insufficient amount of fluid drained during their initial drain. Similarly, it is the threshold for beginning the first fill phase without alarming. When the HomeChoice APD System reaches an empty detection condition during Initial Drain, it determines whether it has drained a volume greater or equal to the Initial Drain Alarm setting. If the I-Drain Alarm volume has drained, it automatically assumes that no fluid remains in the peritoneal cavity and begins the first fill phase. If it reaches an empty detection condition during Initial Drain, and the volume drained is less than the programmed Initial Drain Alarm setting, the system displays LOW DRAIN VOLUME. If the Initial Drain Alarm is set to OFF, the Initial Drain phase ends as soon as a No Flow condition exists, regardless of the volume of fluid drained. The HomeChoice APD System always sets the estimated patient volume to zero at the end of Initial Drain, even if Initial Drain is bypassed.

> NOTE: If the patient has fluid in their peritoneal cavity at the beginning of a therapy, either due to the previous therapy's Last Fill Volume, or an off-cycler exchange, their I-Drain Alarm should not be set to zero (0) or Off. Recommended practice is to set the I-Drain Alarm to at least 70% to 95% of the Last Fill or 70% to 95% of the last off-cycler fill volume, depending on the last fill solution type delivered. See I-Drain Table for assistance calculating the appropriate I-Drain Alarm setting. If you set the I-Drain Alarm setting to zero (0) or Off, it can be associated with a higher risk of IIPV due to the possibility of an incomplete drain followed by a full fill volume.

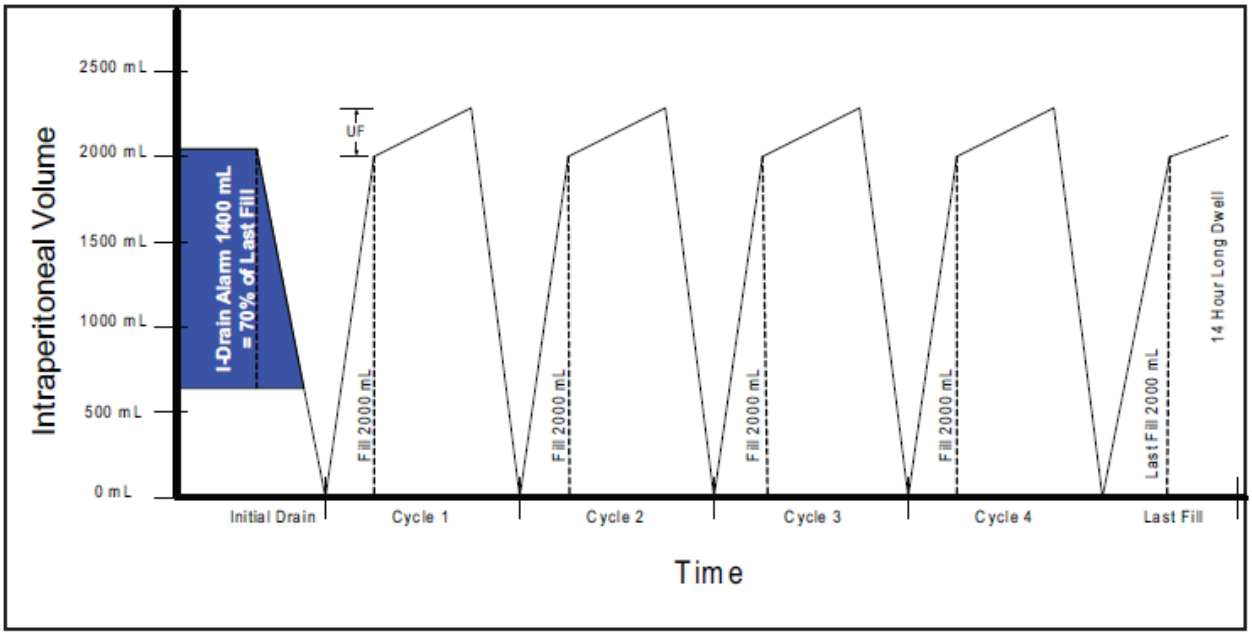

Figure 1: Determining Starting I-Drain Alarm

In the graph shown in Figure 1 above for a CCPD therapy, the starting I-Drain Alarm is calculated as follows:

Assume this patient uses Dianeal for the last fill. The long dwell period is shown as 14 hours. The Last Fill Volume is shown as 2000 mL. The I-Drain Table shows that for a Last Fill Dwell time of 8 to 16 hours using Dianeal, the recommended starting point for I-Drain Alarm Setting is 70% of the Last Fill Volume. Seventy percent of 2000 mL is 1400 mL. The I-Drain Alarm setting is programmed as 1400 mL.

2.1.2.2 MINIMUM DRAIN VOLUME

Minimum Drain Volume % is the threshold for determining when to sound an alarm to the patient due to insufficient amount of fluid drained during all drains except Initial Drain. Similarly, it is the threshold for moving on to the next therapy phase without alarming.

> NOTE: The default value for Minimum Drain Volume % is 85%. If the patient typically has ultrafiltrate in each drain cycle, consider changing this parameter to a higher value. If you set Minimum Drain Volume % less than 85%, it can be associated with a higher risk of IIPV due to residual volume building up over the course of several drain cycles.

When the HomeChoice APD System reaches an empty detection condition during Drain, it determines whether it has drained a volume greater or equal to the Minimum Drain Volume % of the fill volume (plus UF Per Cycle for Tidal therapy). If it reaches an empty detection condition during Drain, and the percentage drained is less than the programmed Minimum Drain Volume % setting, the HomeChoice APD System displays LOW DRAIN VOLUME. If it reaches an empty detection condition during Drain, and the percentage drained is more than the programmed Minimum Drain Volume % setting, the HomeChoice APD System automatically sets the estimated patient volume to zero (0) and continues to the next phase of therapy.

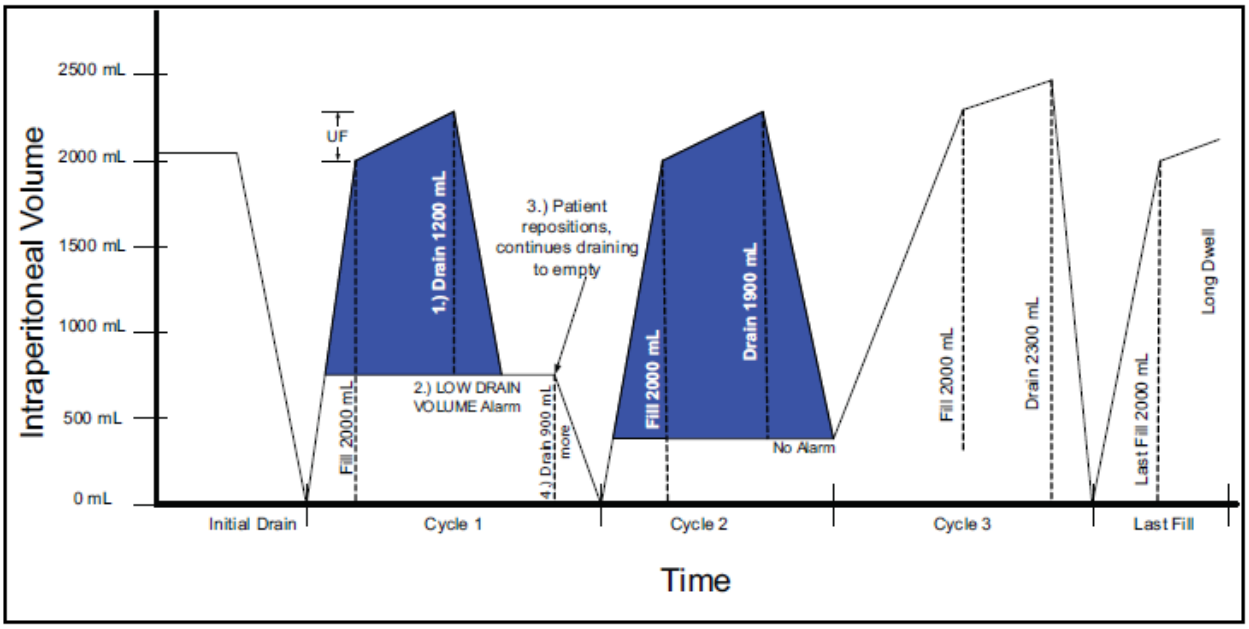

Figure 2: Effects of MIN DRAIN VOL% Setting

In Figure 2 shown above for a CCPD therapy, the Minimum Drain Volume % is programmed to 85%. The Fill Volume is 2000 mL. The calculated volume that must be drained in each drain cycle is 85% of 2000 mL, which is 1700 mL. The graph shows that during Drain 1, only 1200 mL drained before the flow rates began to reduce due to a partially occluded patient line.

Since the amount drained, 1200 mL, was less than 1700 mL, a Low Drain Volume Alarm occurred. The patient changed the position and continued draining to empty.

In Drain 2, the HomeChoice APD System drained 1900 mL before detecting an empty condition, even though a small residual volume still remained. Since 1900 mL is greater than the minimum of 1700 mL, the system transitioned to Fill 3 with no alarm.

Note that the intraperitoneal volume is higher than 2000 mL in Cycle 3, since 2000 mL was delivered in Fill 3 in addition to the UF volume and the residual volume. If the Minimum Drain Volume % is set lower than 85%, the potential exists for even greater intraperitoneal volume due to a greater residual volume. This could lead to an IIPV situation.

2.1.2.3 LAST MANUAL DRAIN and UF TARGET

Last Manual Drain and UF Target are related parameters designed to ensure that the patient is more fully drained before their Last Fill Volume is delivered. These are applicable to all therapy types. On any given drain cycle, it is possible for the system to assume the peritoneal cavity is empty when fluid still remains, due to a variety of reasons (catheter blockage, a partially kinked patient line, patient position, or other conditions), which could lead to IIPV. The Last Manual Drain setting allows the patient another opportunity to more fully drain in the event that insufficient UF volume has been achieved. Once you set Last Manual Drain to Yes, there are two additional settings to program: UF Target (mL) and Alarm (YES/NO). If you set Last Manual Drain to Yes, the HomeChoice APD System stops therapy and sounds a Low UF alarm at the end of the last drain if the UF Target volume has not been achieved. The UF Target should be programmed based on the minimum expected UF volume for the entire therapy. The UF Target alarm can be silenced (displayed only) by setting ALARM NO, or it can be turned on by setting ALARM YES.

This allows the patient to perform a Last Manual Drain to attempt to drain more fluid before delivering the Last Fill Vol, based on the UF Target setting. **If Last Manual Drain is set to No, there is an increased risk of IIPV.**

2.1.2.4 TIDAL VOLUME %

Tidal Volume % refers to the percentage of the programmed night fill volume to be filled in each Tidal (partial) fill cycle after the first full fill cycle is complete. It also represents the percentage of the night fill volume to be drained in each Tidal drain cycle. In addition to draining the Tidal Volume percentage of the Fill Volume, the HomeChoice APD System also drains the UF in each drain cycle. The amount of UF per cycle is calculated by dividing Total UF goal with number of cycles. A higher value for Tidal Volume % means the system drains more fluid in each partial drain cycle, and subsequently fills more fluid in the next partial fill cycle. The closer the Tidal Volume % is to 100%, the more similar a Tidal therapy is to a CCPD therapy. A 5% Tidal setting (the default setting) does not provide adequate PD therapy if programmed over long period of time, therefore it is desirable for only limited number of patients. , In this case only a small amount of fresh dialysate is exchanged with each cycle.

Tidal therapies may be associated with higher risk of IIPV in certain circumstances due to the fact that the patient's cumulative therapy UF may be allowed to build up over the course of many cycles, especially if full drains are not enabled. A more detailed explanation of Tidal therapies is shown in the Tidal Therapy section of this letter.

2.1.2.5 TIDAL TOTAL UF

Total UF is only applicable to Tidal therapies. Total UF represents the expected UF for the entire therapy, not the expected UF for one cycle. When Total UF is divided by the number of cycles, it represents the extra volume to be drained off in addition to the Tidal portion of the Fill Volume that must be drained based on the Tidal Volume % prescribed. Recommended practice is to set Total UF to at least 70% to 100% of the typical average daily UF value, based on an average of the UF from at least the prior 7 consecutive days. See Tidal Therapy section of this letter for a detailed worksheet and discussion of Tidal parameters. It is important to set a Total UF value that is similar to the patient's average daily UF. If the patient greatly exceeds their recommended daily fluid intake on a given day, they may need to increase their Total UF or program one or more Full Drains in their Tidal Therapy to reduce the risk of IIPV.

> NOTE: Setting Total UF too low, or to zero (0), may be attributed to a higher risk of IIPV. If Total UF is set to zero (0), and the actual UF for the Tidal therapy is much higher, the patient's intraperitoneal volume continues to increase with each Tidal fill cycle, and accumulates over time.

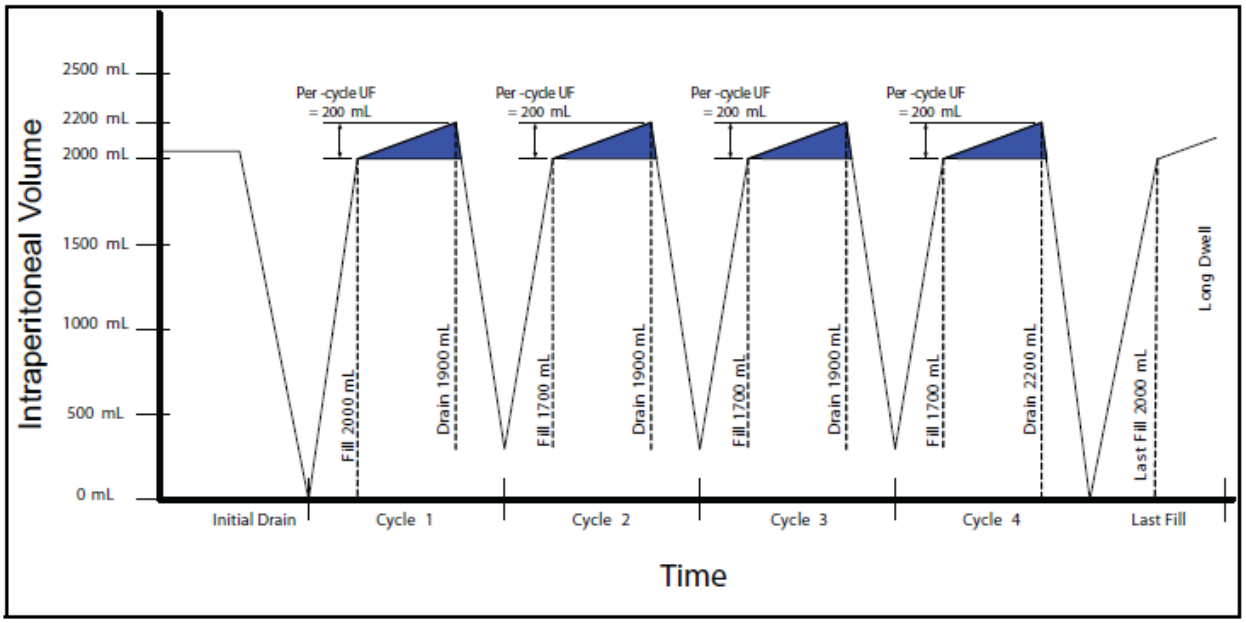

Figure 3: Effects of TIDAL VOL% and Total UF

In Figure 3 for a Tidal therapy, the Tidal Volume % is programmed to 85%. The Fill Volume is 2000 mL. The Total UF is programmed to 800 mL. Given that there are 4 cycles, the calculated per-cycle UF is 800 ÷ 4 = 200 mL per cycle.

The first Fill cycle delivers the full Fill Volume of 2000 mL. Each Tidal fill cycle delivers the Tidal Volume of 85% of the programmed Fill Volume, which is 1700 mL.

Each Tidal drain cycle drains the Tidal Volume of 1700 mL plus the calculated per-cycle UF of 200 mL, for a total of 1900 mL.

The last drain cycle is a full drain, which drains the entire 2200 mL in the patient.

Note that for the same patient in Figure 3 above, if the Total UF was programmed to zero (0) while the actual Total UF was 800 mL, each drain cycle would drain only the Tidal Volume of 1700 mL. The patient would accumulate an extra 200 mL of UF volume in each of the 4 cycles while the intraperitoneal volume continued to increase. At the end of Dwells 1, 2, 3, and 4, the patient would have 2200 mL, 2400 mL, 2600 mL, and 2800 mL, respectively, remaining in the peritoneal cavity. This could lead to an IIPV situation. This is shown in Figure 4.

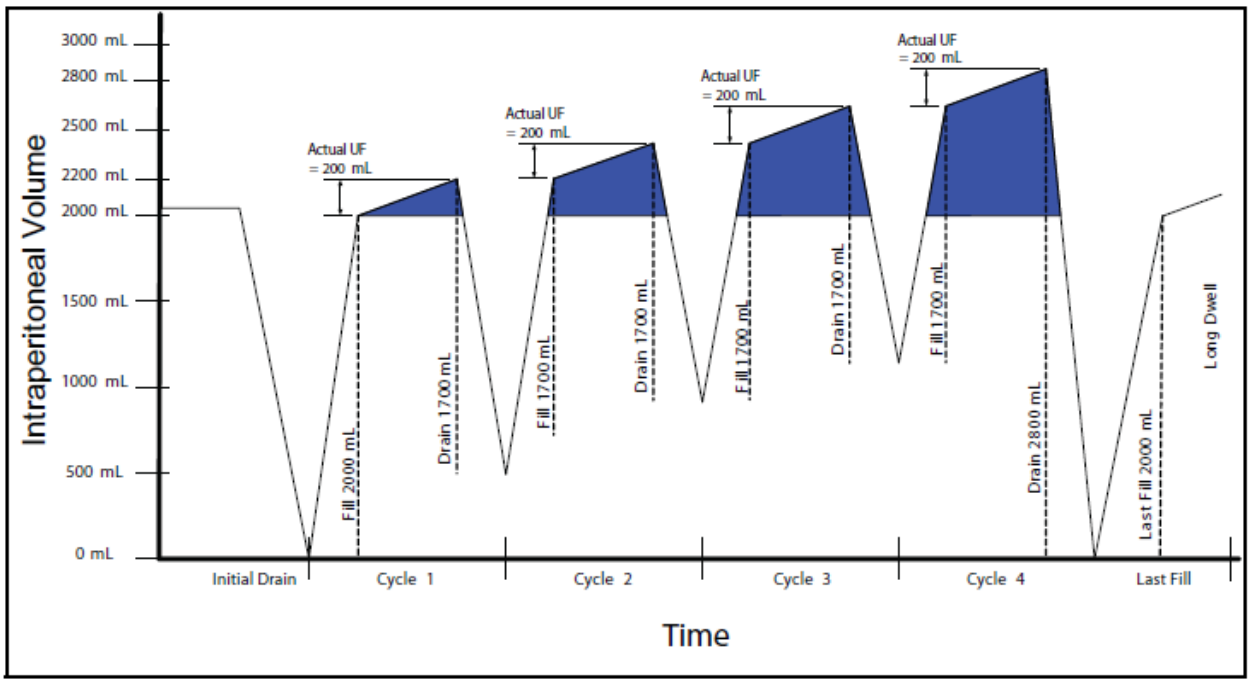

Figure 4: Effect of Tidal Total UF Set to 0; Actual UF is 800 mL

2.1.2.6 TIDAL FULL DRAINS

Programming TIDAL FULL DRAINS can reduce the risk of IIPV. If Full Drains are disabled and Total UF is set too low or to zero (0), near the end of the last dwell cycle, the patient's intraperitoneal volume contains the Fill Volume in addition to a UF volume that could be as much as the actual total UF amount for the entire therapy, which could lead to an IIPV situation, as seen in Figure 4. To reduce the likelihood of IIPV, set Tidal Full Drains to YES. This instructs the system to perform one full (non-Tidal) drain every X cycles, where X is the number from Full Drains Every X cycles. This allows the patient to receive one or more full drains in the middle of their Tidal therapy to reduce the accumulation of UF throughout the duration of the Tidal therapy.

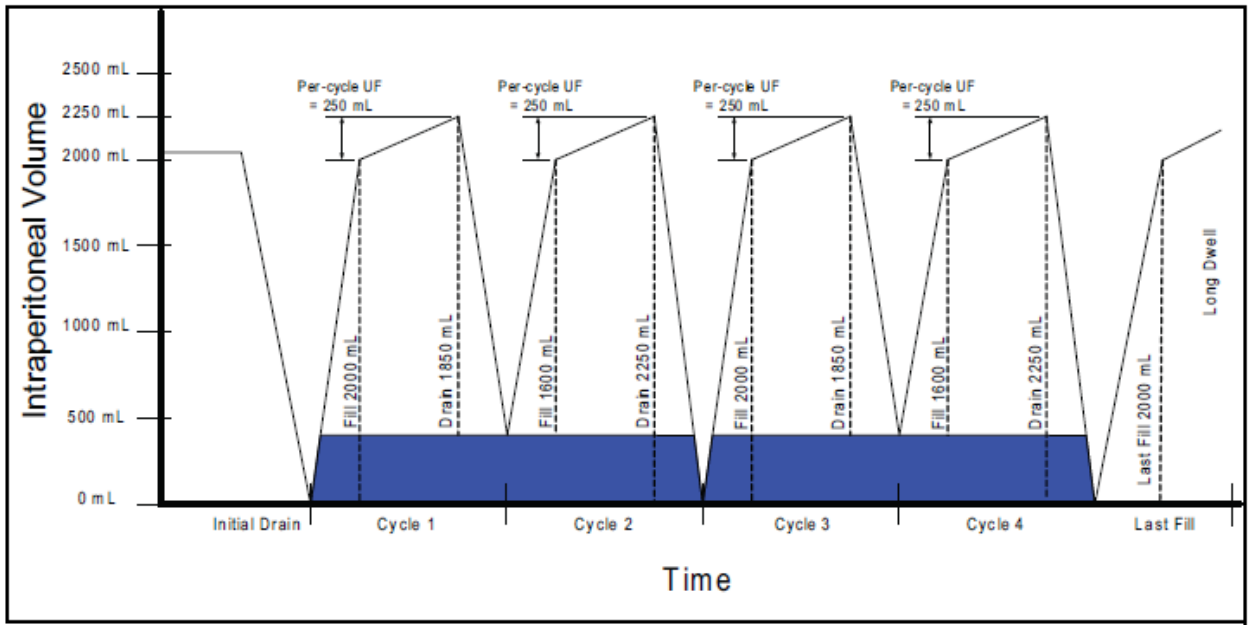

Figure 5: Effect of Tidal Full Drains

In the graph shown in Figure 5 for a Tidal therapy, the Tidal Volume % is programmed to 80%. The Fill Volume is 2000 mL. The Total UF is programmed to 1000 mL. Tidal Full Drains is set to YES and programmed to Full Drains Every 2 cycles. Given that there are 4 cycles, the calculated per-cycle UF is 1000 ÷ 4 = 250 mL per cycle.

The first Fill cycle delivers the full Fill Volume of 2000 mL.

Each Tidal fill cycle delivers the Tidal Volume of 80% of the programmed Fill Volume, which is 1600 mL.

Each Tidal drain cycle drains the Tidal Volume of 1600 mL plus the calculated per-cycle UF of 250 mL, for a total of 1850 mL. However, with Full Drains enabled (YES) and set to perform a full drain every 2 cycles, every 2nd cycle drains the patient to empty. For this reason, cycle 1 is a partial drain, cycle 2 is a full drain, cycle 3 is a partial drain, cycle 4 is a full drain.

Since both Drain 2 and the last drain cycle are full drains, the entire 2250 mL is drained from the patient in these cycles.

2.1.3 How can the LOW FILL MODE programmable parameters influence the risk of IIPV?

2.1.3.1 INITIAL DRAIN TIME

Programming the correct INITIAL DRAIN TIME can reduce the risk of IIPV. Initial Drain Time, or I-Drain Time, is only applicable to Low Fill Mode therapies. This is the minimum amount of time that must be spent in Initial Drain before transitioning to the next therapy phase due to an empty detection condition. Both the I-Drain Time and the I-Drain Alarm conditions must be met before the HomeChoice APD System exits Initial Drain.

2.1.3.2 MINIMUM DRAIN TIME

Programming the correct MINIMUM DRAIN TIME can reduce the risk of IIPV. Minimum Drain Time is only applicable to Low Fill Mode therapies. This is the minimum amount of time that must be spent in each Drain phase, except Initial Drain, before transitioning to the next therapy phase due to an empty detection condition. Both the Minimum Drain Time and the Minimum Drain Volume % conditions must be met before the HomeChoice APD System exits a drain phase other than Initial Drain.

2.1.3.3 NEGATIVE UF LIMIT %

Negative UF Limit % is only applicable to Low Fill Mode therapies. (For Standard Mode therapies, the Negative UF Limit is always 50% of the fill volume and is not programmable.) This parameter determines how much cumulative negative ultrafiltration is allowed at the end of a therapy drain phase before triggering an alarm. A negative UF condition exists when the cumulative amount drained is less than the cumulative amount filled. It is similar to Minimum Drain Volume %, except that Minimum Drain Volume % is the alarm threshold for the minimum percentage that must be drained in each cycle, while Negative UF Limit % is the maximum percentage of the fill volume that is allowed to be retained over the course of the entire therapy. It is possible to drain the default 85% of the fill volume in each cycle over the course of several cycles before a Negative UF Alarm is posted. For Low Fill Mode therapies, Negative UF Limit can be set from 20-60% of the fill volume. In general, lower settings are recommended since the system posts a Negative UF Alarm when the peritoneal cavity contains a smaller retained volume. If you set a Negative UF Limit greater than 50%, it can be associated with a higher risk of IIPV due to a larger residual volume building up over the course of several drain cycles before the Negative UF alarm is posted.

2.2 How do I determine the Initial Drain Alarm setting?

The following Table is to be used as guidance to help reduce the occurrence of an IIPV situation due to programming an Initial Drain Volume which may be too low.

Baxter recommends setting your patient's Initial Drain Alarm to at least 70% to 95% of the last volume filled into the patient's peritoneal cavity, which is often the Last Fill Volume programmed in the device. If the patient's most recent fill was performed as a gravity-filled exchange prior to starting the HomeChoice APD system therapy, the recommended Initial Drain Alarm setting is at least 70% to 95% of the gravity-filled solution volume.

Never rely on this Table alone to determine your patient's initial drain alarm volume. You as a clinician should determine what initial drain alarm is appropriate for your patient.

Table of Initial Drain Alarm Based on % of Last Fill Volume

Last Fill Volume (mL)	70%	75%	80%	85%	90%	95%
60	40	50	50	50	50	60
80	60	60	60	70	70	80
100	70	80	80	90	90	100
120	80	90	100	100	110	110
140	100	110	110	120	130	130
160	110	120	130	140	140	150
180	130	140	140	150	160	170
200	140	150	160	170	180	190
220	150	170	180	190	200	210
240	170	180	190	200	220	230
260	180	200	210	220	230	250
280	200	210	220	240	250	270
300	210	230	240	260	270	290
320	220	240	260	270	290	300
340	240	260	270	290	310	320
360	250	270	290	310	320	340
380	270	290	300	320	340	360
400	280	300	320	340	360	380
420	290	320	340	360	380	400
440	310	330	350	370	400	420
460	320	350	370	390	410	440
480	340	360	380	410	430	460
500	350	380	400	430	450	480
600	420	450	480	500	550	550
continued in next column						

Last Fill Volume (mL)	70%	75%	80%	85%	90%	95%
continued from first column						
700	490	550	550	600	650	650
800	550	600	650	700	700	750
900	650	700	700	750	800	850
1000	700	750	800	850	900	950
1100	750	850	900	950	1000	1000
1200	850	900	950	1000	1100	1100
1300	900	1000	1000	1100	1200	1200
1400	1000	1100	1100	1200	1300	1300
1500	1100	1100	1200	1300	1400	1400
1600	1100	1200	1300	1400	1400	1500
1700	1200	1300	1400	1400	1500	1600
1800	1300	1400	1400	1500	1600	1700
1900	1300	1400	1500	1600	1700	1800
2000	1400	1500	1600	1700	1800	1900
2100	1500	1600	1700	1800	1900	2000
2200	1500	1700	1800	1900	2000	2100
2300	1600	1700	1800	2000	2100	2200
2400	1700	1800	1900	2000	2200	2300
2500	1800	1900	2000	2100	2300	2400
2600	1800	2000	2100	2200	2300	2500
2700	1900	2000	2200	2300	2400	2600
2800	2000	2100	2200	2400	2500	2700
2900	2000	2200	2300	2500	2600	2800
3000	2100	2300	2400	2600	2700	2900

2.3 How do I determine the Tidal Total UF and Last Manual Drain UF Target Volume settings?

The following Tables are to be used as guidance to help reduce the occurrence of an IIPV situation due to programming a Total UF (Tidal therapies) or Last Manual Drain UF Target volume which may be too low for your patient.

When the Therapy type is changed from CCPD to Tidal, the Total UF reverts to the default setting of zero (0) which could result in an IIPV situation. The following provides guidance with regards to setting your patient's Tidal Total UF:

- A Total UF volume set too high can result in an increased number of LOW DRAIN VOLUME alarms.
- Seventy percent (70%) of your patient's normal Night UF is a good starting point for determining the optimal Total UF. For help in converting 70% of the expected total therapy UF into a value that can be programmed as the Total UF for a Tidal therapy, see the Table below.

  If your patient uses a solution for Tidal therapy that is different from the solution used in his or her previous therapy, he or she may need to adjust the Total UF based on the concentration of the new solution.

The Last Manual Drain UF Target volume setting can be used for any therapy type to ensure your patient achieves a complete drain before delivering the last fill or ending therapy. Baxter recommends YES be selected for the LAST MANUAL DRAINIf a LAST MANUAL DRAIN is set to YES, a UF Target and a UF Alarm must be set. The UF TARGET allows you to set a minimum amount of UF that must be drained before the Last Manual Drain option is enabled.

- A good starting point for setting your patient's Last Manual Drain UF Target is 70% of the expected Total UF. If the UF is less than the UF Target at the end of the last Drain of the therapy, the system stops and a LOW UF alarm appears on the display screen.

Occasionally, the location of the catheter tip can be in a less-than-optimal position. This can lead to an incomplete Drain of the dialysis solution when lying down. With the Last Manual Drain option, your patient may want to change position before the Last Fill is performed by the system.

The Tables below allow you to determine the:

- Total UF volume setting for a Tidal therapy, or
- UF Target volume setting for the Last Manual Drain

based on different percentages of the estimated Total UF volume.

To use the Tables, identify the row with your patient's expected Total UF volume and read across to the column with the desired Total UF volume percentage (%) to find the recommended Total UF volume setting.

- EXAMPLE 1: If the expected Total UF volume for the therapy is 1300 mL and you desire to program your patient's Tidal Total UF volume at 70%, use a Total UF volume setting of 910 mL.

If the expected Total UF volume is between the values listed in two adjacent rows, choose the row with the lower Total UF volume and read across to find the corresponding UF Target volume setting.

- EXAMPLE 2: If the expected Total UF volume for the therapy is 1300 mL and you desire to program your patient's UF Target volume for the Last Manual Drain at 70%, the UF Target volume setting is 900 mL.

Tidal Total UF and Last Manual Drain UF Target Volume Settings based upon % of Expected Total UF Volume

	Tidal Total UF Volume Settings (mL)					
Expected Total UF (mL)	**70%**	**75%**	**80%**	**85%**	**90%**	**95%**
20	10	20	20	20	20	20
40	30	30	30	30	40	40
60	40	50	50	50	50	60
80	60	60	60	70	70	80
100	70	80	80	90	90	100
120	80	90	100	100	110	110
140	100	110	110	120	130	130
160	110	120	130	140	140	150
180	130	140	140	150	160	170
200	140	150	160	170	180	190
220	150	170	180	190	200	210
240	170	180	190	200	220	230
260	180	200	210	220	230	250
280	200	210	220	240	250	270
300	210	230	240	260	270	290
320	220	240	260	270	290	300
340	240	260	270	290	310	320
360	250	270	290	310	320	340
380	270	290	300	320	340	360
400	280	300	320	340	360	380
420	290	320	340	360	380	400
440	310	330	350	370	400	420
460	320	350	370	390	410	440
480	340	360	380	410	430	460
500	350	380	400	430	450	480
600	420	450	480	510	540	570
700	490	530	560	600	630	670
800	560	600	640	680	720	760
900	630	680	720	770	810	860
1000	700	750	800	850	900	950
1100	770	830	880	940	990	1000
1200	840	900	960	1000	1100	1100
1300	910	980	1000	1100	1200	1200
1400	980	1100	1100	1200	1300	1300
1500	1100	1100	1200	1300	1400	1400
1600	1100	1200	1300	1400	1400	1500
1700	1200	1300	1400	1400	1500	1600
1800	1300	1400	1400	1500	1600	1700
1900	1300	1400	1500	1600	1700	1800

	Last Manual Drain UF TARGET Volume Settings (mL)					
Expected Total UF (mL)	**70%**	**75%**	**80%**	**85%**	**90%**	**95%**
20	0	0	0	0	0	0
40	50	50	50	50	50	50
60	50	50	50	50	50	50
80	50	50	50	50	50	100
100	50	100	100	100	100	100
120	100	100	100	100	100	100
140	100	100	100	100	150	150
160	100	100	150	150	150	150
180	150	150	150	150	150	150
200	150	150	150	150	200	200
220	150	150	200	200	200	200
240	150	200	200	200	200	250
260	200	200	200	200	250	250
280	200	200	200	250	250	250
300	200	250	250	250	250	300
320	200	250	250	250	300	300
340	250	250	250	300	300	300
360	250	250	300	300	300	350
380	250	300	300	300	350	350
400	300	300	300	350	350	400
420	300	300	350	350	400	400
440	300	350	350	350	400	400
460	300	350	350	400	400	450
480	350	350	400	400	450	450
500	350	400	400	450	450	500
600	400	450	500	500	550	550
700	500	550	550	600	650	650
800	550	600	650	700	700	750
900	650	700	700	750	800	850
1000	700	750	800	850	900	950
1100	750	850	900	950	1000	1050
1200	850	900	950	1000	1100	1150
1300	900	1000	1050	1100	1150	1250
1400	1000	1050	1100	1200	1250	1350
1500	1050	1150	1200	1300	1350	1450
1600	1100	1200	1300	1350	1450	1500
1700	1200	1300	1350	1450	1550	1600
1800	1250	1350	1450	1550	1600	1700
1900	1350	1450	1500	1600	1700	1800

Tidal Total UF and Last Manual Drain UF Target Volume Settings based upon % of Expected Total UF Volume (continued)

	Tidal Total UF Volume Settings (mL)					
Expected Total UF (mL)	**70%**	**75%**	**80%**	**85%**	**90%**	**95%**
2000	1400	1500	1600	1700	1800	1900
2100	1500	1600	1700	1800	1900	2000
2200	1500	1700	1800	1900	2000	2100
2300	1600	1700	1800	2000	2100	2200
2400	1700	1800	1900	2000	2200	2300
2500	1800	1900	2000	2100	2300	2400
2600	1800	2000	2100	2200	2300	2500
2700	1900	2000	2200	2300	2400	2600
2800	2000	2100	2200	2400	2500	2700
2900	2000	2200	2300	2500	2600	2800
3000	2100	2300	2400	2600	2700	2900

	Last Manual Drain UF TARGET Volume Settings (mL)					
Expected Total UF (mL)	**70%**	**75%**	**80%**	**85%**	**90%**	**95%**
2000	1400	1500	1600	1700	1800	1900
2100	1450	1600	1700	1800	1900	2000
2200	1550	1650	1750	1850	2000	2100
2300	1600	1750	1850	1950	2050	2200
2400	1700	1800	1900	2050	2150	2300
2500	1750	1900	2000	2150	2250	2400
2600	1800	1950	2100	2200	2350	2450
2700	1900	2050	2150	2300	2450	2550
2800	1950	2100	2250	2400	2500	2650
2900	2050	2200	2300	2450	2600	2750
3000	2100	2250	2400	2550	2700	2850

2.4 What is Tidal Therapy?

Tidal Peritoneal Dialysis (TPD) is an automated therapy that allows a partial drain and replenishment of the fill volume. TPD maintains a residual (reserve) volume in the peritoneal cavity throughout the dialysis treatment by exchanging only a portion of the dialysate. One form of TPD (50%-60% range) utilizes larger therapy volumes and more frequent cycles in an attempt to increase PD adequacy. However, this form of TPD has not been found to increase small solute clearances above those obtained with other APD therapies[1]. Typically, Tidal therapy is identified by the percentage of the fill volume to be drained from the patient. 60% TPD means only 60% of the fill volume is exchanged each cycle and a 40% reserve volume or residual volume is left in the peritoneal cavity.

2.4.1 What is Low Reserve Volume Tidal Peritoneal Dialysis (TPD)?

More common use of Tidal therapy is Low Reserve Volume TPD, which is a form of TPD whereby the reserve volume in the peritoneal cavity is low. A much smaller reserve volume remains in the cavity (usually 200-300 mL). Low Reserve Volume TPD may be beneficial for patients experiencing pain at the end of drain. It may also minimize slow drain time, hence optimizing cycle dwell time.

A typical Low Reserve Volume TPD prescription is 85-90% which creates a reserve volume of 10-15% (200-300 mL based upon a fill volume of 2000 mL). As shown in the example of 85% Tidal (Figure 6) the first cycle fill volume is 2000 mL. Subsequently, 1700 mL plus estimated per-cycle UF volume for the first exchange is then drained at cycle 1. The patient is then left with 300 mL reserve volume. The cycle 2 fill volume and subsequent fill volumes are 1700 mL and this volume combined with the reserve volume yields a net volume of 2000 mL.

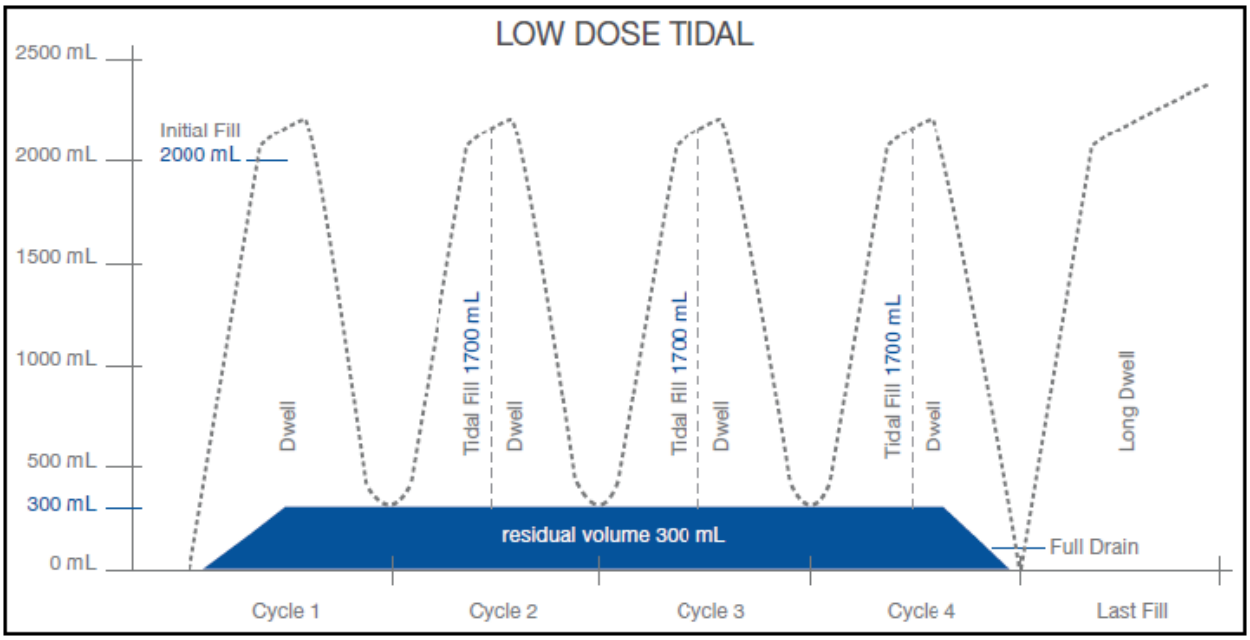

Figure 6: Low Reserve Volume Tidal

NOTE: When TPD is desired, two additional prescription parameters need to be determined and programmed: a Tidal volume percent and total UF goal.

[1] Khanna, R. Krediet R. Nolph and Gokal's Textbook of Peritoneal Dialysis. Third Edition. New York, NY: Springer Science+ Business Media, LLC 2009

2.4.2 What are typical Low Reserve Volume Tidal Volume Percent settings?

To determine a Low Reserve Volume Tidal volume percent, first determine the volume of fluid to remain in the peritoneal cavity. The Table below lists some common Low Reserve Volume Tidal volume percents, fill and reserve volumes:

Low Reserve Volume Tidal Volume Percent Table

Fill Volume	1500 mL Night Fill Volume		2000 mL Night Fill Volume		2500 mL Night Fill Volume		3000 mL Night Fill Volume	
Tidal %	Tidal	Reserve	Tidal	Reserve	Tidal	Reserve	Tidal	Reserve
95%	1425 mL	75 mL	1900 mL	100 mL	2375 mL	125 mL	2850 mL	150 mL
90%	1350 mL	150 mL	1800 mL	200 mL	2250 mL	250 mL	2700 mL	300 mL
85%	1275 mL	225 mL	1700 mL	300 mL	2125 mL	375 mL	2550 mL	450 mL
80%	1200 mL	300 mL	1600 mL	400 mL	2000 mL	500 mL	2400 mL	600 mL

2.4.3 How can I determine the Tidal UF Settings?

A total UF goal setting is necessary to ensure ultrafiltration is included in every cycle and not retained until therapy completion. This is programmed as Total UF on the HomeChoice APD System in the Change Program Menu. If the Total UF is set too low, a substantial residual UF volume may occur towards the end of the therapy. If the total UF is set higher than the actual UF, the patient may experience pain on drain Evaluation of previous treatments, including drain history is essential in determining an adequate total UF.

A good starting point would be, at a minimum, to review a drain history over the previous seven treatment days. The total amount of UF over the seven days should be added and then divided by seven to obtain an average daily UF (See the worksheet).

For example, if the patient's average cycler UF is 600 mL, then the UF goal is 600 mL. To obtain UF per cycle the 600 mL goal is divided by the number of cycles. At each cycle a set amount of UF is drained from the patient (See Table at right).

UF Goal	600 mL ÷ 4 cycles
Cycle 1	150 mL
Cycle 2	150 mL
Cycle 3	150 mL
Cycle 4	Full Drain

Some clinicians prefer to set the Total UF slightly less than the average daily UF. See Total UF Table in section 2.3 to calculate 70-95% of the average daily UF.

The total UF setting should be routinely assessed since overestimation may cause the Tidal volume to be depleted during the therapy. For example, if the patient is still experiencing drain pain after programming a Low Reserve Volume TPD, there may be a need to adjust the therapy. The total UF may need to be lower, the Tidal volume percent may need to be decreased (i.e. increase reserve volume), or both adjustments may need to be made.

The opposite is true if the total UF is set too low. The patient will retain excess UF volume in the peritoneal cavity and may complain of feeling full. In this case, the total UF setting should be reassessed. ,

2.4.4 Is there an example for programming a Low Reserve Volume Tidal Therapy?

Low Reserve Volume TPD prescriptions require a therapy time, therapy volume, therapy fill volume, Tidal volume % and Total UF. See Table below for a sample prescription.

Sample Low Reserve Volume TPD Prescription Table

Total Therapy Time:	9 hours
Total Therapy Volume:	10000 mL[2]
Fill Volume:	2000 mL
Tidal Volume Percent:	85%
Total UF:	600 mL
Last Fill Volume:	2000 mL

Fill 1 = 2000 mL Fill 2, 3 and 4 = 1700 mL Last Fill = 2000 mL Total delivered volume = 9100 mL

NOTE: As with any prescription change, the therapy should be monitored for PD adequacy. Additionally, the patient UF should be continuously re-evaluated to avoid "underestimation" or "overestimation" that could result in overfill [3] or drain pain. If the patient experiences inflow or outflow pain, or feelings of fullness, the therapy modifications should be re-evaluated.

[2] Delivered therapy volume with low dose TPD will be only 9100 mL.

[3] This can be associated with an increase in the intraperitoneal volume.

2.4.5 Tidal Total UF Worksheet

Determining a Low Reserve Volume Tidal Therapy Total UF

1. Review patient's home records and record the last seven treatment days of cycler UF:

Day One	Day Two	Day Three	Day Four	Day Five	Day Six	Day Seven
mL	mL	mL	mL	mL	mL	mL

2. Add the seven day cycler UF to obtain a weekly cycler UF total:

Weekly Cycler UF Total:_____mL

3. Divide weekly cycler UF total by seven to obtain the average daily cycler UF:

Weekly Cycler UF Total: _____mL ÷ 7 = Average Cycler UF Per Day: _____mL

4. Program Total UF on the HomeChoice APD System with average cycler UF per day. If less than 100% of the average cycler UF is desired, program Total UF to 70-95% of the average cycler UF as shown in the Total UF Table.

5. Perform the following calculation to determine the UF volume drained at each cycle:

Total Number of Cycles Prescribed: _____

Average Cycler UF Per Day: _____mL ÷ Number of Cycles: _____= UF Per Cycle: _____mL