



January 2021

Homechoice Claria with Updated Software Shipping Soon

Dear Healthcare Provider,

Baxter is committed to supporting your patients every step of the way on their PD journey. In the spirit of constant improvement, new upgraded version 12.002 Homechoice Claria APD systems will be shipping soon from Baxter with an updated Patient At-Home Guide (PATIENT GUIDE). The included leaflet provides an overview of the 12.002 software changes.

The latest update is consistent with international standards for Peritoneal Dialysis and Alarms¹. Under the new standard, Baxter has redefined lower priority alarms, which will be called information Notices starting in version 12.002. Rest assured, the handling of alarms will not change. The changes are focused on naming convention, visuals, and sound only.

Version 12.002 Included Products


Product Code	Description	Serial Numbers
5C6M40	Homechoice Claria APD system	All

Now Introducing: Notice vs. Alarm

While Alarms require a patient's attention when something has happened during therapy that might affect the patient or system, the new Notices that Baxter is now introducing occur when Homechoice Claria needs to communicate with your patients at certain occasions.

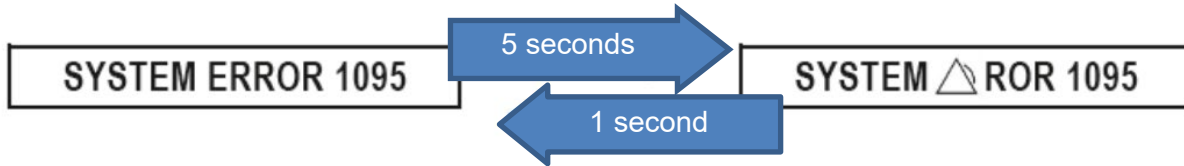
Your patients are now empowered with more control over the sounds their cyclor makes throughout the night. Unlike Alarms, Notices have the benefit of lower sound level overall. Patients are even able to choose the sound level for Notices within a specified range to further customize their PD experience. Please note that patients can choose not to respond to a notice which could possibly lead to discomfort.

Here is an overview of the types of sounds the cyclor will make for Alarms and Notices (Refer to Section 15.1 of your PATIENT GUIDE for a list of alarms and notices):

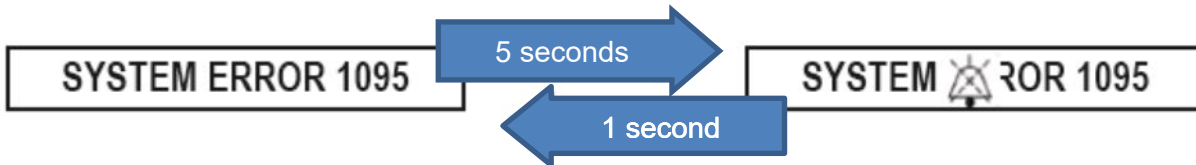
Name of the message	Loudness	Sound pattern	Urgency
System Error Alarm	Non-adjustable: 75 ± 10 dBA	0.5 second Beep, repeating every 0.5 second	Highest
Manually Recoverable Alarm		1 second Beep, repeating every second	
Manually Recoverable Notice	User Adjustable: 35 dBA to 65 dBA	2 second Beep, repeating every 2 seconds	
Auto Recoverable Notice		1 second Beep repeating every 30 seconds	
One-Time Notice		Single Beep	Lowest



For an alarm, the cyclor displays the alarm message with an alarm symbol in a flashing pattern that overlays the alarm message. Refer to the figure for an example of the system display during an alarm.



During an audible alarm silence period, the cyclor displays the alarm message with Audio Paused symbol in a flashing pattern that overlays the alarm text. Refer to the figure for an example of the display during the Audio Paused Period.



Sincerely,

Alexandra Duffy
PD Products
Baxter Healthcare Corporation

Homechoice Claria APD system is intended for automated dialysis solution exchanges in patients with renal failure undergoing peritoneal dialysis, at home.

Rx Only. For the safe and proper use of the devices mentioned herein, refer to the Instructions for Use.

¹The new software is compliant with the requirements from the latest Industry Standards for Peritoneal Dialysis equipment IEC 60601 2-39 (3rd Edition) and the specific Industry Standard for Alarms IEC 60601-1-8 (2.1 Edition).

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