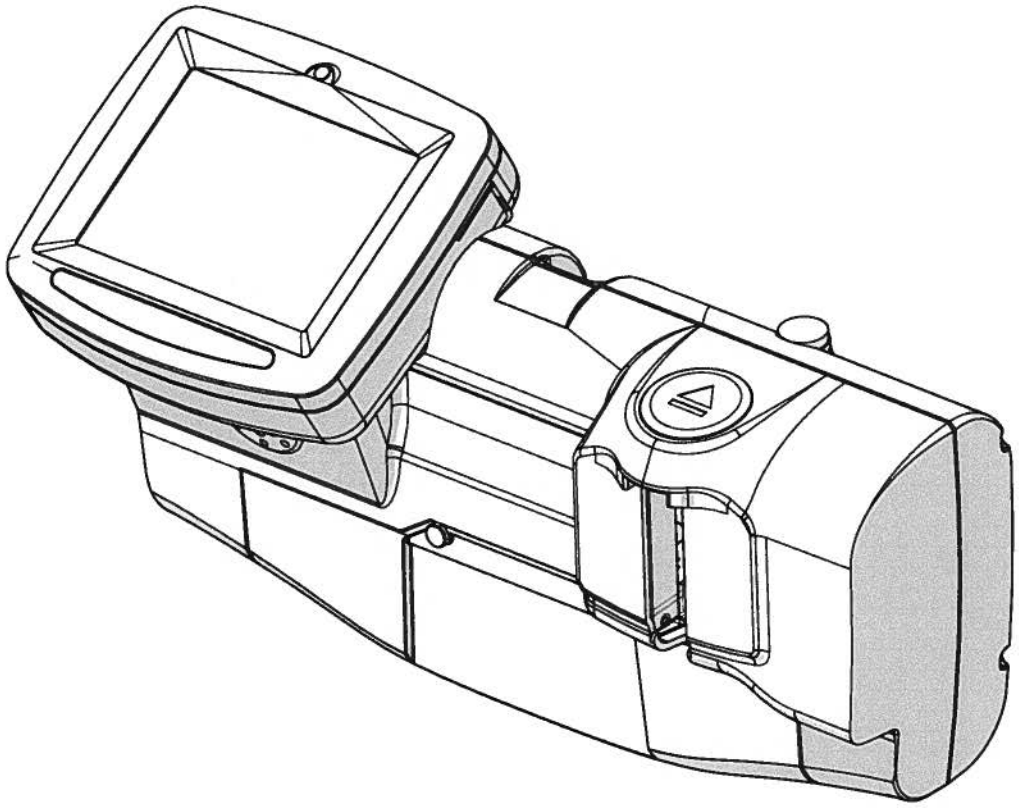
BARD® UROS™

AUTOMATED URINE OUTPUT TEMPERATURE MONITOR



OPERATOR'S MANUAL

MODEL: BK

BARD | MEDICAL

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Section 1 - Indications for Use, Contraindications, Warnings and Cautions

Indications for Use

The UROS™ Automated Urine Output and Temperature Monitor is indicated to monitor urine output and core bladder temperature.

Contraindications

There are no known contraindications for the use of the UROS™ Automated Urine Output and Temperature Monitor.

Warnings

- The UROS™ Automated Urine Output and Temperature Monitor requires special precautions regarding EMC and needs to be installed and put into service accordingly. Portable and mobile RF communications equipment may affect the operations of UROS™ Automated Urine Output and Temperature Monitor.
- The UROS™ Automated Urine Output and Temperature Monitor should not be used adjacent to or stacked with other equipment. If it is absolutely necessary to use the UROS™ Automated Urine Output and Temperature Monitor in close proximity with other equipment, the UROS™ Automated Urine Output and Temperature Monitor should be observed to verify normal operation in the configuration in which it will be used.
- Do not immerse or submerge the UROS™ Automated Urine Output and Temperature Monitor or turn it upside down when cleaning.
- During long-term storage, remove primary batteries to prevent battery leakage.
- When shipping the UROS™ Automated Urine Output and Temperature Monitor for service or repair:
    - Remove battery pack from device to prevent battery leakage.
    - Package battery pack separately in a non-conductive bag.
    - Place warning label on the outside of the shipping package (See Section 8, Shipping Lithium Batteries).
- To avoid the risk of electric shock this equipment must only be connected to a supply mains with protective earth.
- User shall not place the UROS™ Automated Urine Output and Temperature Monitor within the sterile field.

Cautions

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Use only a UROS™ Automated Urine Output and Temperature Monitor compatible battery. Do not incinerate batteries. Recycle or dispose of them properly. Contact BARD® for disposal information.
- State and Federal regulations govern the packaging necessary for return of medical product which may have been contaminated. Refer to local, state and Federal regulations when packaging the UROS™ Automated Urine Output and Temperature Monitor for return.
- There are no user serviceable components inside the UROS™ Automated Urine Output and Temperature Monitor. The user should not attempt to repair the UROS™ Automated Urine Output and Temperature Monitor. To do so may void the warranty and could result in erroneous monitor readings. For Service and/or Repair, call BARD® Customer Service at: 1-800-526-4455, U.S. only.
- Use of cables or sensors and other accessories other than those specified for use with the UROS™ Automated Urine Output and Temperature Monitor, except those sold by BARD® for use as a replacement part or repair components, may result in increased emissions or decreased immunity (more susceptible to equipment interference) of the UROS™ Automated Urine Output and Temperature Monitor to electromagnetic interference.
- The UROS™ Automated Urine Output and Temperature Monitor should be recycled properly per European Union directive 2012/19/EU on Waste Electronic and Electrical Equipment, July 4, 2012. Do not dispose with ordinary municipal waste.
- Regulations and laws pertaining to the recycling and disposal of lithium ion batteries and battery packs vary widely from country to country, as well as by state and local governments which may have additional requirements. Please dispose of in accordance with state and local procedures.

- UROS™ Battery Module
  - Do not open, crush, or heat the battery pack above 50°C or incinerate.
  - Risk of fire and burns.
  - Store pack at -20°C to 50°C.
- Avoid kicking or knocking over the monitor with Foley bag attached.
- Avoid placing the UROS™ Automated Urine Output and Temperature Monitor on the bed.
- Always pause the UROS™ Automated Urine Output and Temperature Monitor utilizing the user interface when transporting the patient or replacing the bag.
- The UROS™ Automated Urine Output and Temperature Monitor shall be used with the provided mounting options. The mounting options shall only be used with the UROS™ Automated Urine Output and Temperature Monitor.
- It is recommended that the UROS™ Automated Urine Output and Temperature Monitor receive a maintenance inspection annually or more frequently as dictated by hospital protocol. The inspection must be performed at an authorized BARD® Service Facility. To arrange for service from BARD®, call 1-800-526-4455.
- Always perform a functional checkout of the UROS™ Automated Urine Output and Temperature Monitor prior to putting the monitor into service after repair.
- The UROS™ Automated Urine Output and Temperature Monitor is designed for use with only BARD® products (SURESTEP™ Foley Tray Systems and the UROS™ Precision Urine Output Meter).
- The UROS™ Automated Urine Output and Temperature Monitor is designed for use only with the provided external power supply (See Section 9: Replacement / Spare Parts).
- Medical electrical equipment needs special precautions to minimize electromagnetic interference. The following are manufacturer's guidance:
  - The use of accessories or cables other than those specified or sold by BARD® is not recommended.
  - Use of unapproved accessories or cables may result in increased emissions or in decreased immunity of the UROS™ Automated Urine Output and Temperature Monitor to electromagnetic interference.
  - If the UROS™ Automated Urine Output and Temperature Monitor is used directly adjacent to other equipment, the user should periodically observe the UROS™ Automated Urine Output and Temperature Monitor to verify it operates normally in that environment.
  - Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- The UROS™ Automated Urine Output and Temperature Monitor contains a Class 3R laser. Class 3R lasers are considered safe when handled carefully.
  - A Class 3R laser is low powered.
  - There is only a small hazard potential for accidental exposure.
  - It normally would not harm eyes during a momentary exposure of less than ¼ second. This is within the aversion response, where a person turns away and/or blinks to avoid bright light.
  - Do not deliberately look or stare into the laser beam.
  - Laser protective eyewear is normally not necessary.

Federal Communications Commission Declaration of Conformity

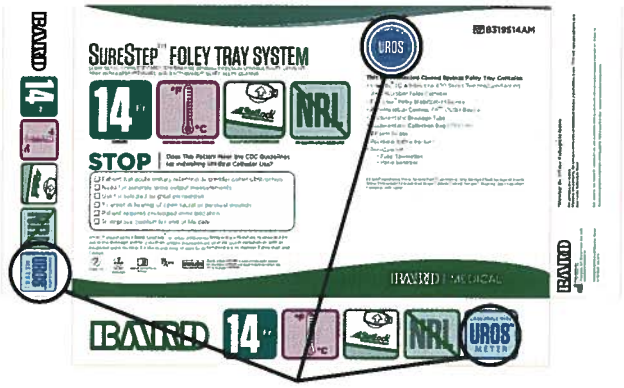
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with the instruction manual it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference, which can be determined by turning the medical device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - o Reorient or relocate the medical device.
  - o Increase the separation between the medical device and receiver.
  - o Connect the medical device into an outlet on a circuit different from that to which the receiver is connected, if operating on mains power.
  - o Consult an authorized dealer or service representative for help.
- BARD® is not responsible for any equipment interference caused by using other than specified or recommended cables and connectors, or by unauthorized changes or modifications to this medical device.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This manual is intended for use by qualified personnel who are familiar with electromechanical medical devices. The manual can also be used as a learning tool for those persons who will be using the BARD® UROS™ Automated Urine Output and Temperature Monitor (hereinafter referred to as "UROS™ Monitor").

Section 2 - Quick Start Guide

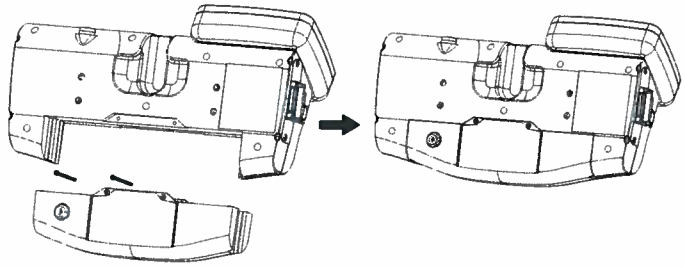
Preparing Monitor

1. Unpack monitor

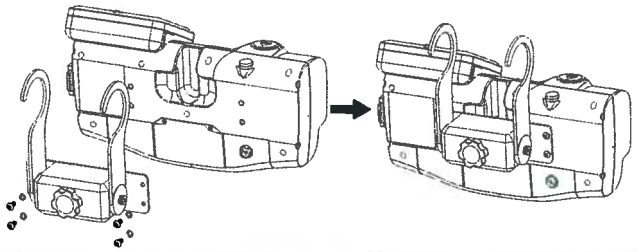


Note: Only UROS™ Compatible SURESTEP™ Foley Tray Systems will work with the UROS™ Monitor and UROS™ Meter.

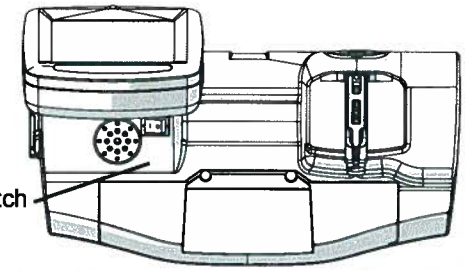
2. Install battery (Charge for 12 hours)



3. Attach to floor stand.

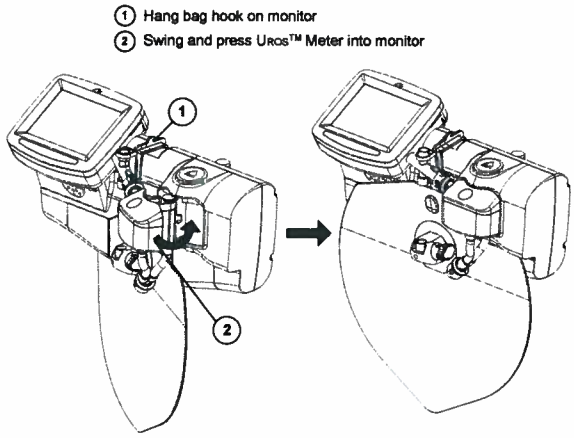


4. Power system On

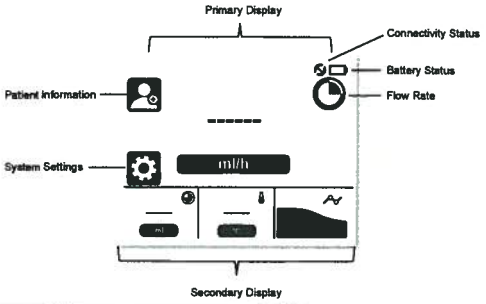


Start Monitoring

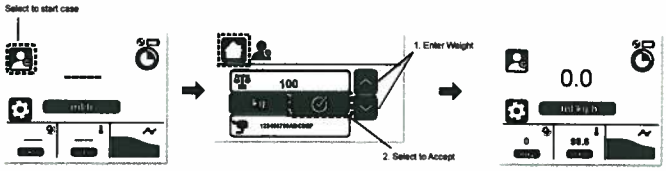
5. Attach UROS™ Meter/Bag assembly to monitor



6. Home Screen



7. Begin Patient Case



8. Default Alarm Settings

Alarm	Default Threshold	Audible Alarm	Visible Alarm Color	Blink Rate
Level 1	<0.5 ml/kg/h for 6hr OR 50 ml/hr for 6hr	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec)
Level 2	<0.5 ml/kg/h for ≥ 12 hours OR 50 ml/hr for 6hr	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec) Repeats 2X
Level 3	<0.3 ml/kg/h for X24 hours OR 30 ml/hr for 24hr	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec) Repeats 3X
Level 4	Anuria for ≥ 12 hours	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec) Repeats 4X
Level 5	>15 ml/kg/hr at any time OR 1500ml/hr at any time	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec) Repeats 5X

Foley catheters are intended for use in drainage and/or collection and/or measurement of urine. Temperature sensing Foley catheters provide a measure of core bladder temperature and are intended for use with compatible 400-series temperature sensing monitors. Please consult product label and insert for any indications, contraindications, hazards, warnings, cautions and directions for use. The Foley catheters included in the Bardex® I.C. and Lubri-Sil® I.C. System contain Bacti-Guard® silver alloy coating licensed from Bactiguard A.B. Bacti-Guard is a registered trademark of Bactiguard A.B.

Section 3 - Product Description

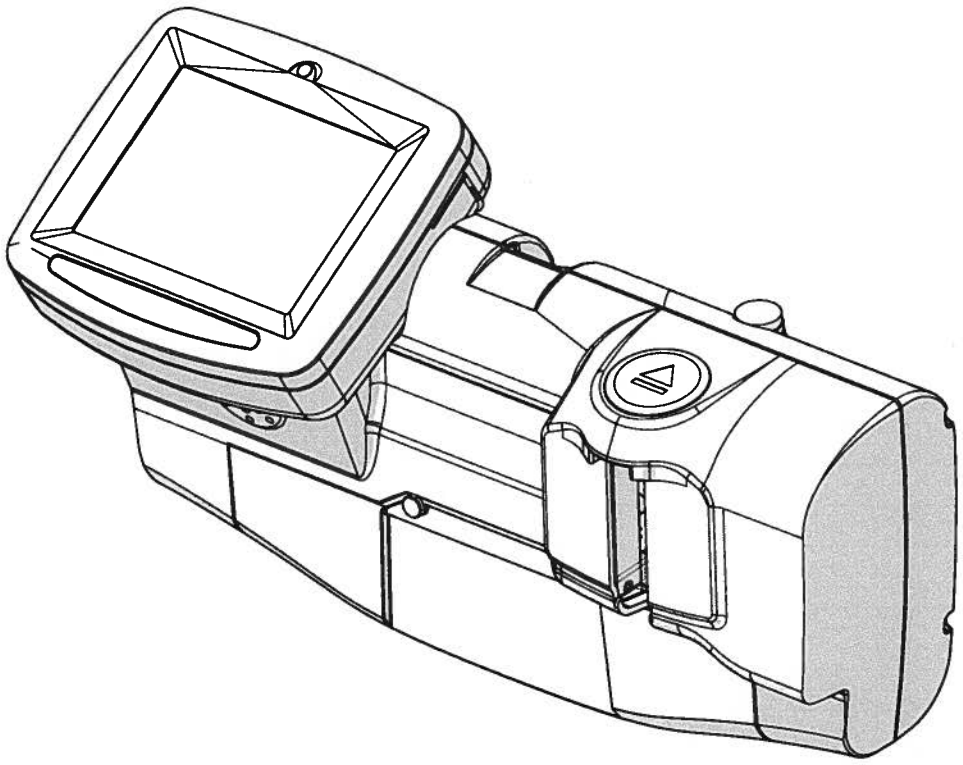
System Overview

The BARD® UROS™ System is composed of three primary components. (1) The UROS™ Monitor measures urine output and core bladder temperature. (2) The SURESTEP™ UROS™ Foley Tray System includes all necessary components for the placement of an indwelling temperature-sensing Foley catheter. The tray also incorporates connections for the UROS™ Precision Urine Output Meter. (3) The UROS™ Precision Urine Output Meter, when attached to the SURESTEP™ UROS™ compatible Foley Tray system, will enable precision electronic urine output monitoring.

UROS™ Monitor Description

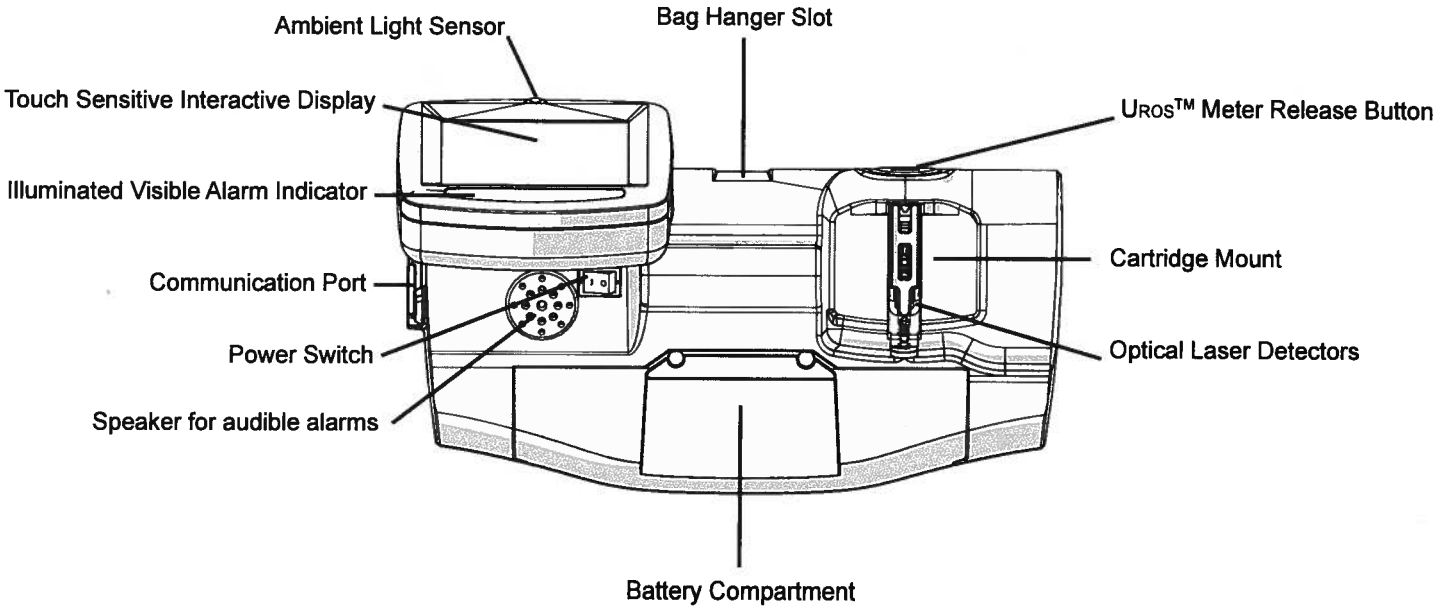
The UROS™ Monitor enables electronic urine output monitoring for patients requiring accurate urine output and temperature monitoring. The UROS™ Monitor is capable of communicating real-time data by connecting to electronic medical record systems. Both thresholds and alarms are user definable allowing users to customize the system to their specific requirements.

UROS™ Monitor

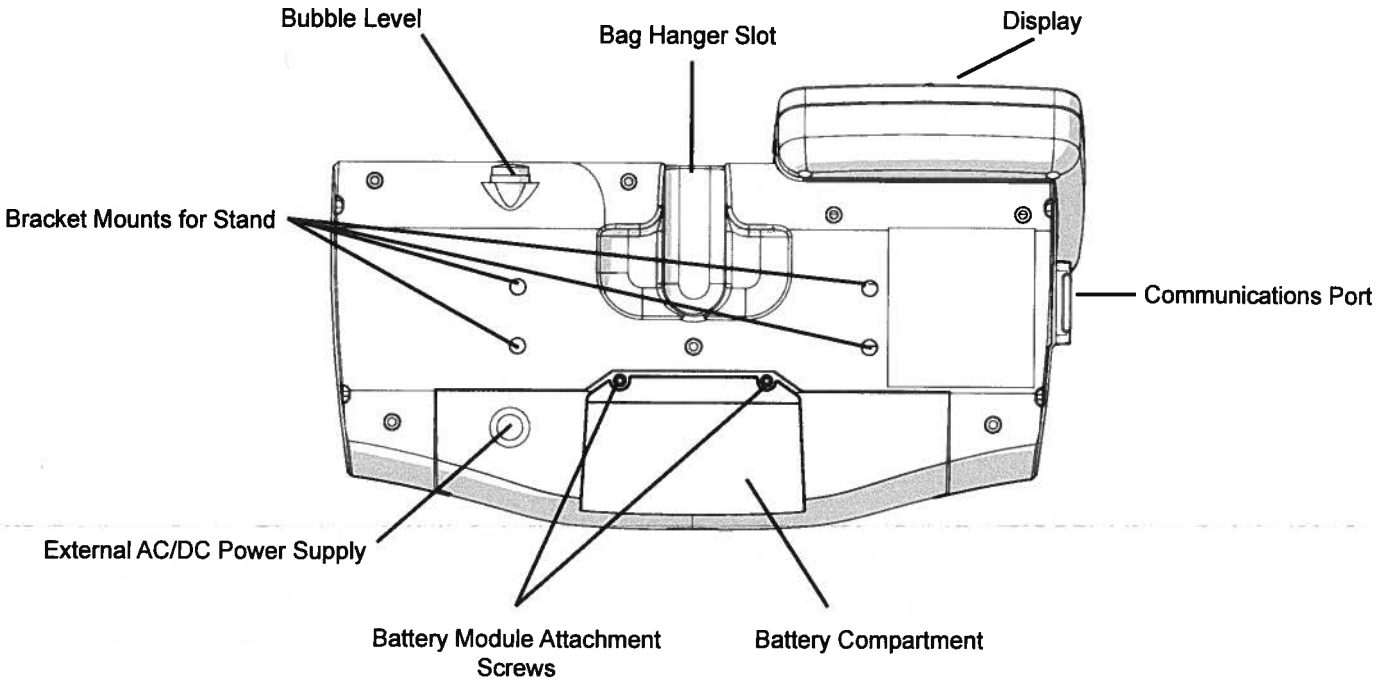


User Hardware

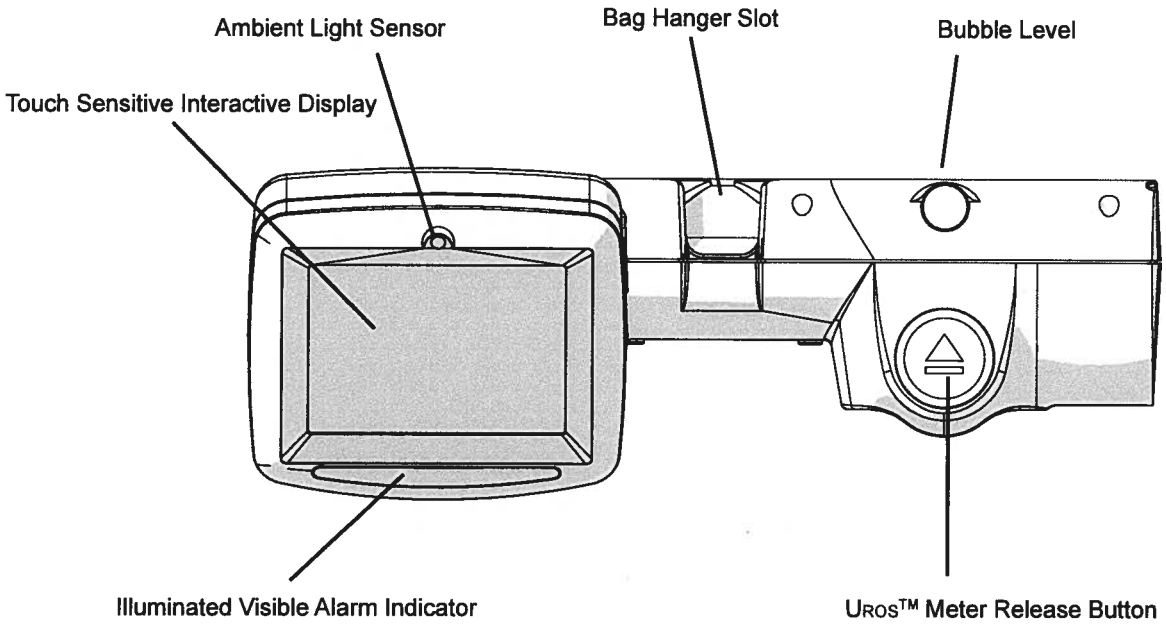
UROS™ Monitor - Front View



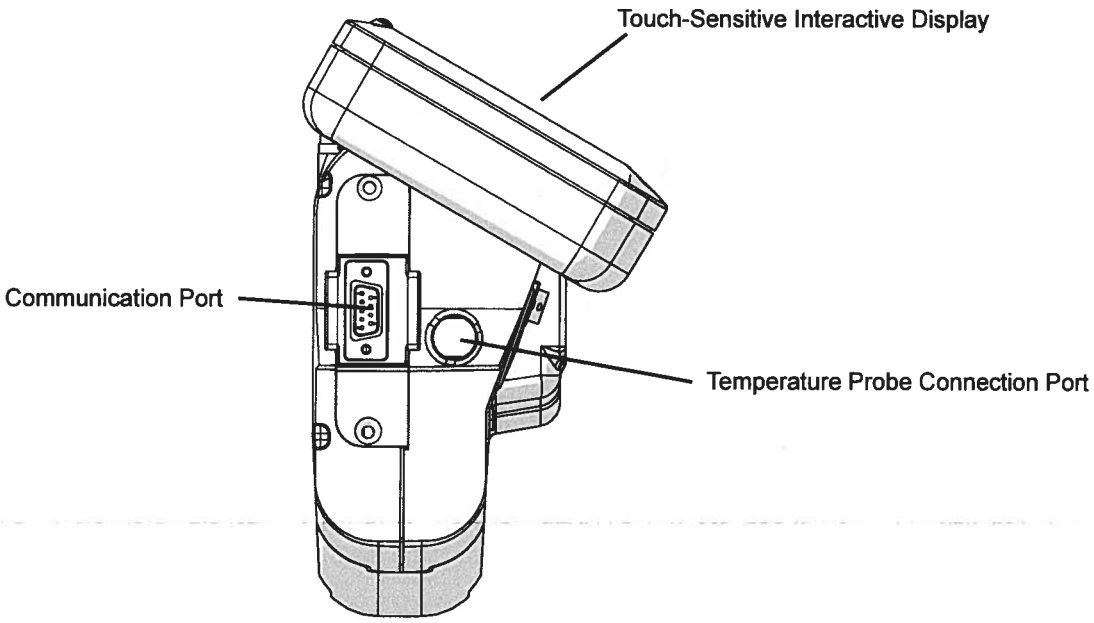
UROS™ Monitor - Rear View



UROS™ Monitor - Top View

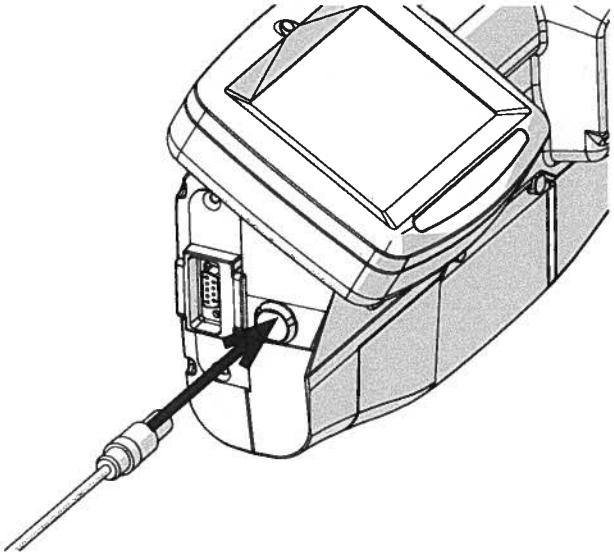


UROS™ Monitor - Left Side View



BARD® UROS™ Monitor – Temperature Monitoring

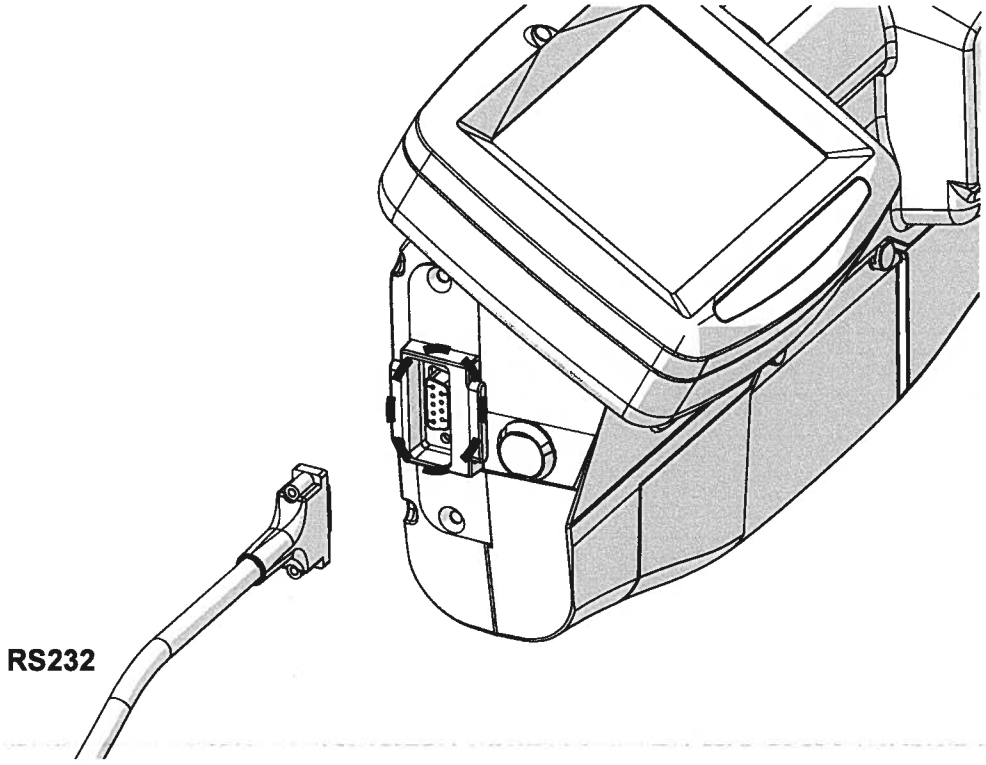
Connecting the Patient Temperature Probe Adapter Cable to the UROS™ MONITOR



To monitor core bladder temperature with Bard Temperature Sensing Foley Catheter, insert the Uros two pin adapter cable to the monitor.

BARD® UROS™ Monitor – RS232 Connection

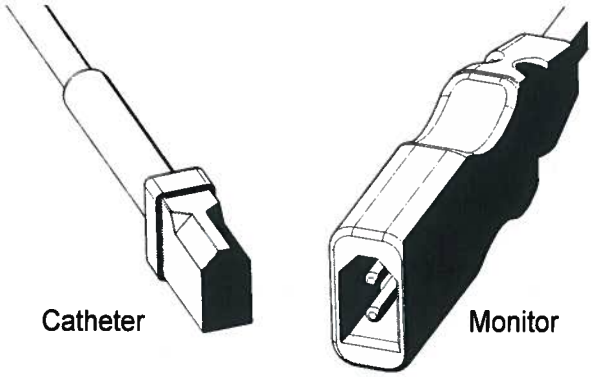
Connecting the RS232 Serial Communication Cable to the UROS™ Monitor



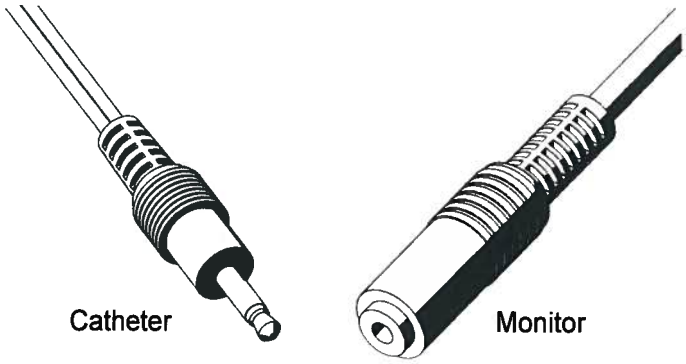
To monitor core bladder temperature with Bard Temperature Sensing Foley Catheter, insert the Uros two pin adapter cable to the monitor.

Connecting the Foley Temperature Sensing Cable to the Patient Temperature Probe Adapter Cable

Molex Style Termination



1/8 inch Mono Plug Termination



Connect the catheter side of the adapter cable to the temperature lead on the third port of the catheter. Depending on the catheter temperature lead, either a Molex or a 1/8 inch style adapter cable will be required.

BARD® SURESTEP™ Foley Tray System

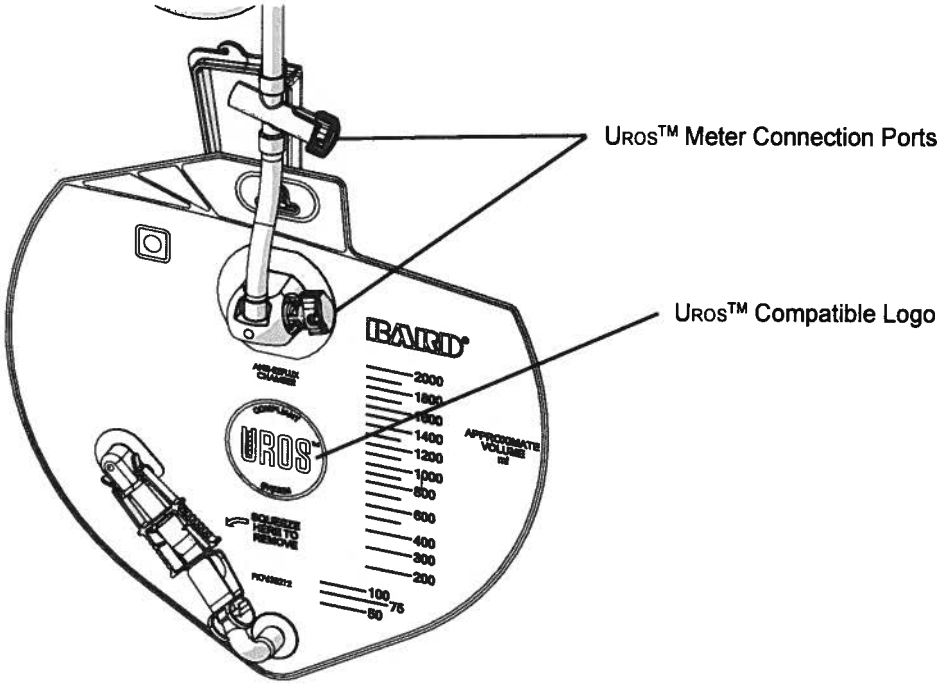
The BARD® SURESTEP™ Foley Tray System provides closed system trays that are available in a wide variety of configurations to meet critical needs of patients. Please call 1-800-526-4455 or contact your local sales manager for the most current list of available configurations.

BARD® SURESTEP™ Foley Tray System are UROS™ Compatible

UROS™ compatible trays can be identified by the blue UROS™ markings identified above.

NOTE: ONLY "UROS™ Compatible" trays will work with the UROS™ Monitor.

The SureStep™ Foley Tray System is configured in a Uros™ compatible configuration, which provides a monitoring enabled closed Foley system.



The Uros™ compatible Foley tray systems incorporate Uros™ Meter connection ports. Otherwise, they are identical to standard SureStep™ Foley trays in design.

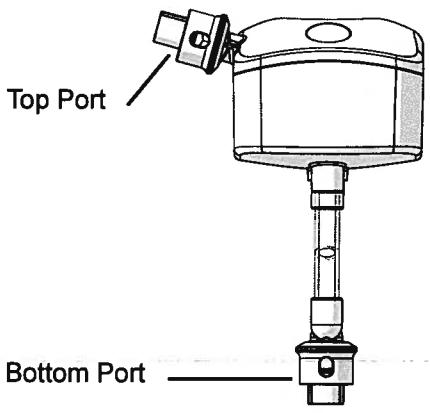
Uros™ Precision Urine Output Meter

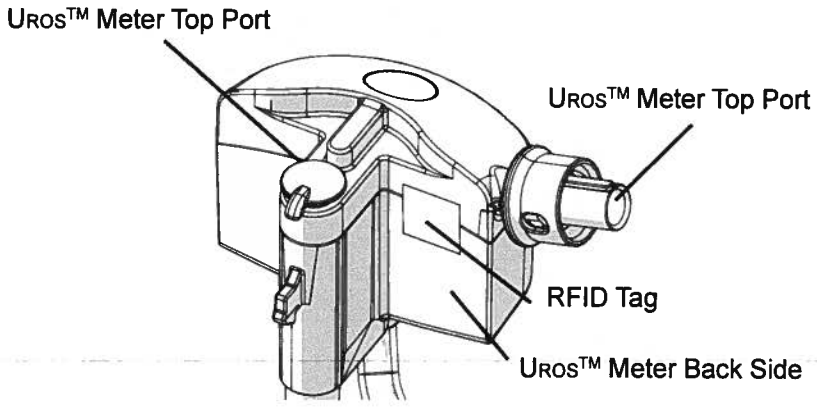
When precision electronic monitoring of urine output and temperature is required, a Uros™ Meter can be inserted into the connection ports on the SureStep™ Foley Tray System.

The Uros™ Meter has been specifically designed to easily attach to SureStep™ Foley Tray System while maintaining a closed system. The meter is designed for single patient use. Once attached, the meter cannot be removed. If monitoring is no longer required, the meter does not interfere with non-electronically monitored urine output.

Uros™ Meter

The Uros™ Meter allows the addition of metering capabilities for electronic monitoring of urine output.

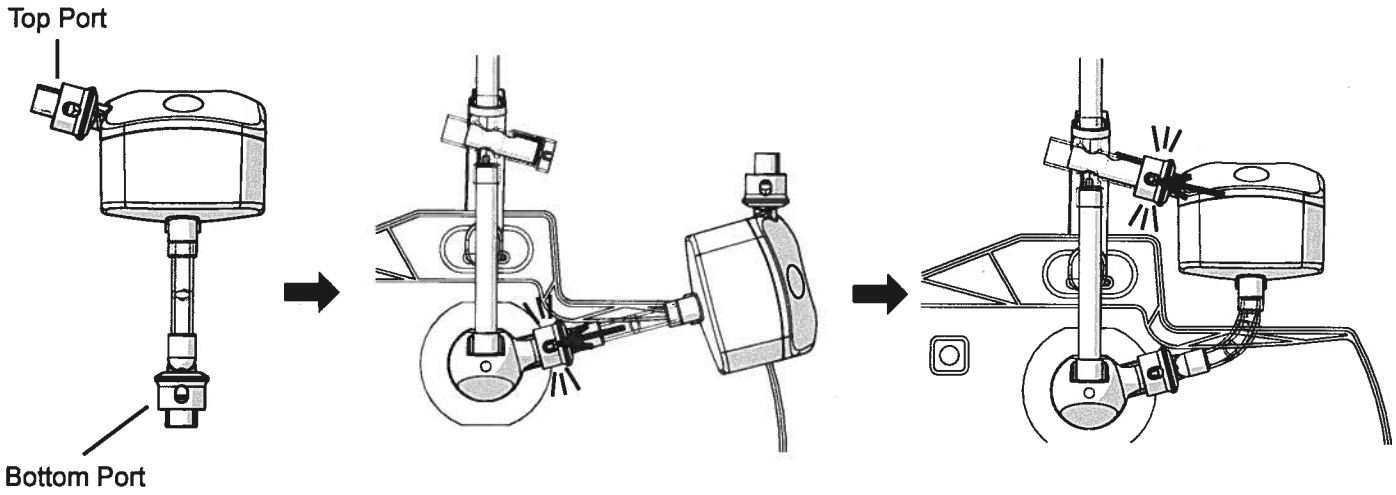




The Uros™ Meter has a unique identifier which authenticates the meter to the Uros™ Monitor. The identifier can be used to create the Positive Patient Identification within Electronic Medical Record systems.

Attaching the UROS™ Meter

The UROS™ Meter allows the addition of metering capabilities for electronic monitoring of urine output.



To attach the UROS™ Meter to the UROS™ compatible urinary drainage system, simply attach the bottom port, followed by the top port and the assembly is ready for use in the UROS™ Monitor.

Please refer to the "UROS™ Precision Urine Output Meter" Instructions for Use for further information.

Section 4 – Installation, Setup, Operation

Unpacking

Contents in package:

- UROS™ Monitor
- UROS™ Battery Module
- External AC/DC Power Supply
- Temperature Probe Adapter Cable
- Operator's Manual

System Battery Charging

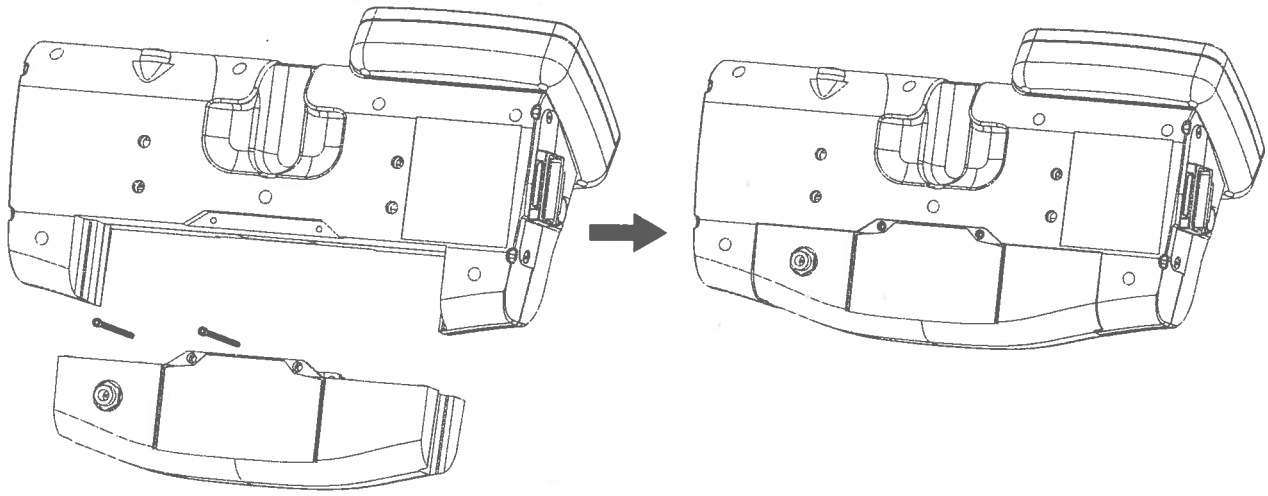
The UROS™ Monitor uses a high capacity lithium ion battery designed to allow continuous operation for approximately 12 days of typical usage between charging. An on-screen indicator of battery life remaining is located on the display and is visible at all times.

The system will alarm the user in the event the battery power is at or below 3% of full charge capacity.

The system battery is designed to be charged with the battery in place. To charge, simply plug in the power supply. During the charging process, the small battery icon seen at the top of the screen will increment from empty to full indicating the battery is currently charging. A new battery will take approximately 12 hours to become fully charged from a completely discharged state. The battery is designed to charge-cycle approximately 250 cycles while retaining 50% capacity before requiring replacement.

If the system battery does not maintain a charge, cannot be charged fully or has a significantly reduced run time, a replacement battery may be necessary. Replacement batteries can be purchased by calling 1-800-526-4455 or contact your local sales manager for replacement.

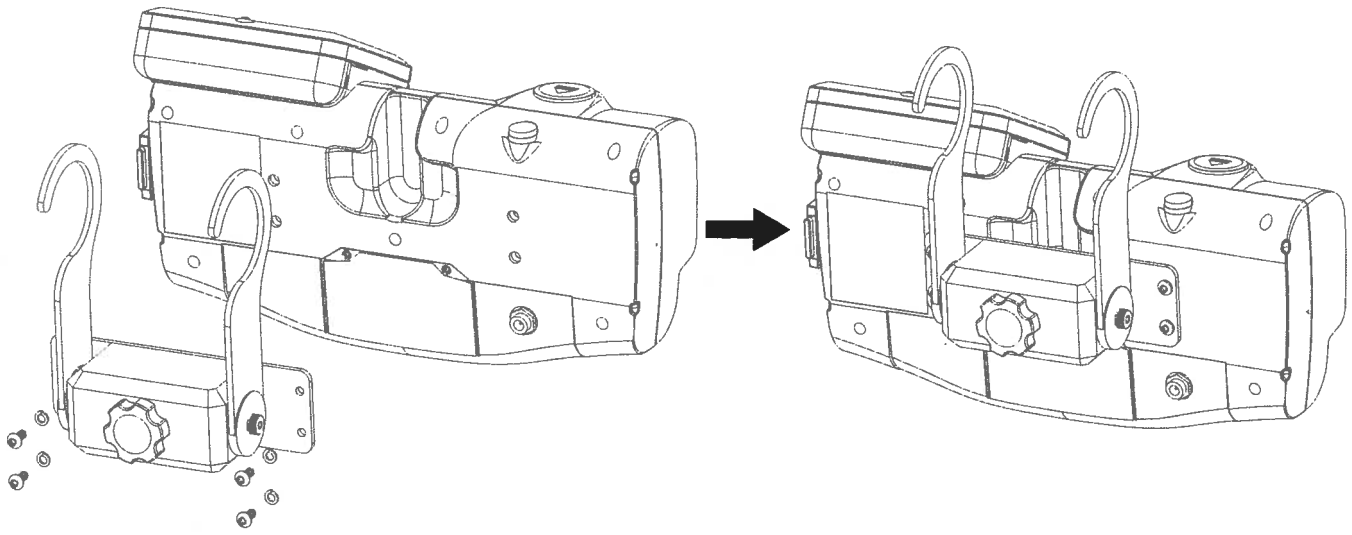
Directions for installing or replacing system battery



1. Upon unpacking and prior to use, the battery module must be installed and charged.
2. To install battery module, slide into place as illustrated above.
3. Tighten two bolts (pre-attached to battery)
4. Mount to monitor stand (please refer to stand instructions for use for mounting)
5. Charge with supplied external power supply until fully charged
6. Your system is ready to use

Mount Stand Bracket to Monitor

Directions for mounting Stand Bracket to Monitor



Attach Stand Bracket

1. Align mounting holes of Stand Bracket to the back of the monitor as pictured above
2. Fasten Stand Bracket by using the included 4 sets of washers and screws

Hardware and Software Operation

General Overview

The Uros™ Monitor is designed to be intuitive and easy to use. The interface has been designed to maximize the use of icons to simplify user interaction.

Screen Backlight

The Uros™ Monitor has a backlit display providing visibility in low light conditions. The backlight is optimized to maximize battery usage. The system will automatically adjust brightness levels depending on ambient light conditions.

The backlight will automatically activate in low ambient light conditions. In low ambient light conditions, the backlight will automatically turn off after 30 seconds of inactivity. Reactivating the backlight can be accomplished by touching anywhere on the display. The initial touch will only reactivate the backlight regardless of where touched. To select a new function a second touch on that function will be required.

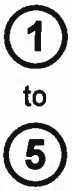
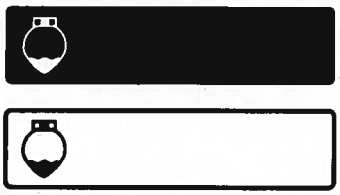
Alarming

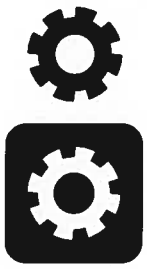
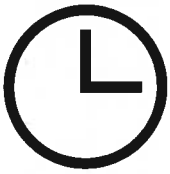
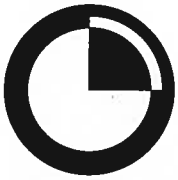
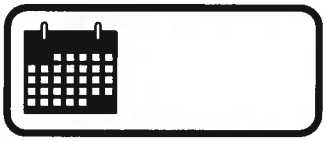
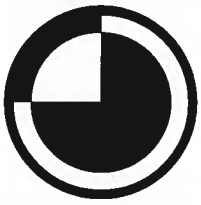
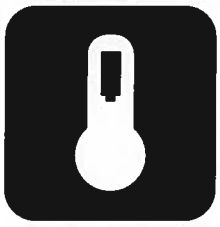
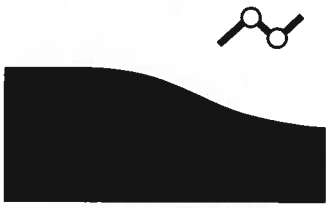
Only system critical alarms will produce audible alarms in addition to a white blinking visible alarm.

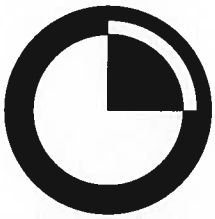
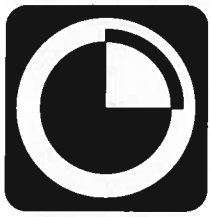
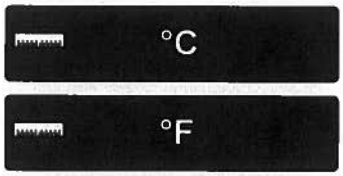
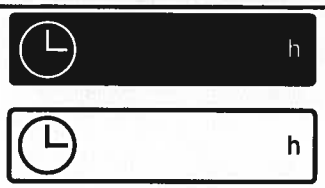
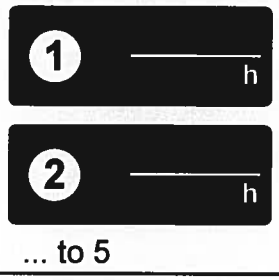
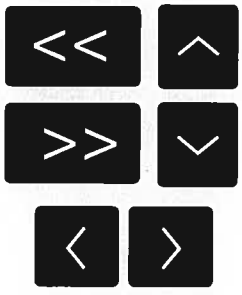
Urine output and temperature related alarms are silent, but visible and color coded to indicate patient status. They have been designed to easily observe patient status from a distance without disturbing the patient. These alarms also include on-screen icons that work in conjunction with the color coded visible alarms.

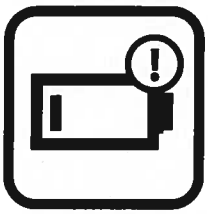
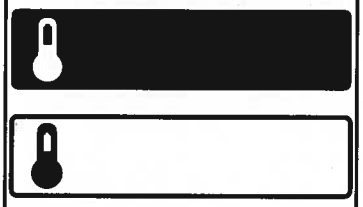
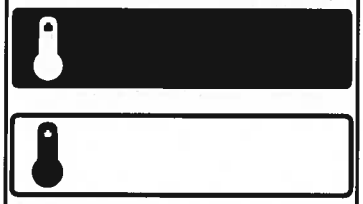
Uros™ Monitor User Interface Icons

Many system icons will be found in the graphical display. Below is a list of icons with their description and function. Most active icons will have a black background to indicate it has been selected unless otherwise noted.

Primary Functions Buttons and Icons			
	Home screen button. Select to return to the home screen and primary display		Data history (black is selected.)
	Start Case Icon		Meter ID
	Select to view, change current patient information.		Alarm icons indicating which stage alarm the patient is currently experiencing. The system alarm thresholds can be modified to user preference.
	Select to view, change current patient information.		Flow Rate threshold button. White button is selected.
	Patient Case Stop confirmation button. Select to confirm end of patient case.		Kilogram selection button. Black is selected.

	Device Configuration. Select to configure system options. Black is selected.		Pound Selection button. Black is selected.
	Clock Icon – appears on the time date settings screen.		Weight Field. Enter patient weight.
	Flow RateIcon – appears in the secondary field of the main display.		Factory Reset to factory default values. Found in Device Configuration settings.
	Monitoring Duration of patient. Appears in the Case Info screen.		Factory Reset icon.
	Cancel button. Appears in confirmation screen and allows user to cancel previous input.		Confirmation/Accept button. Select to confirm entry.
	Timed Interval Volume. 12 hour interval is available.		Timed Interval Volume icon.
	Patient Temperature button – found on Data History screen. Select to retrieve temperature history.		Graphing View button. Select to display urine output and temperature graphing.

Information Status Buttons and Icons			
	Flow Rate – Found on Primary and in Units and Alarm Setting screen.		Toggle between Flow Rate displayed as ml/kg/h and weight normalized flow rate displayed as ml/h.
	Flow Rate History button – Found on Graphing screen and Data History screen.		Toggle between milliliter and milliliter/kg selection button.
	Data Output Icon – Found in Device Configuration screen. Turns data I/O on or off.		°C and °F selection button. Toggles between options.
	Data Connected – Found on main screen if Data Output has been enabled.		Time entry button. Used to set Flow Rate Alarm duration. White is selected.
	Data Not Connected - Found on main screen if Data Output has been enabled.		Alarm Threshold settings. Select each of 5 levels to customize.
	Found on Device Configuration screen. Enabled Mode.		Directional button selections. Additional information will be displayed when selected.
	Found on Device Configuration screen. Disabled Mode.		

Alarm Buttons and Icons			
	Alarm Code Icon Status. Found on relevant alarm screens with relevant alarm code number.		Patient Temperature Alarm Button Found on primary screen. If present, the system is notifying user of a temperature alarm
	Battery Alarm. Found on primary screen. If present, the system is notifying user the battery has less than 3% power remaining.		Tilt Alarm. If present, the monitor is tilted off-level by more than 10%. Return monitor to level to disable the alarm.
	Battery Alarm icon.		Tilt Alarm Icon
	Battery Icon found on primary screen. As battery power is depleted, the battery indicator will show a depleting charge. When battery has less than 3% charge, an empty battery will be displayed and the battery alarm will activate.		Patient Temperature lower limit setting. White is selected. Found in the Patient Temperature Alarm Settings screen.
	Flow Rate Alarm. Found on primary screen. If present, the system is notifying user of a Flow Rate alarm.		Patient Temperature upper limit setting. White is selected. Found in the Patient Temperature Alarm Settings screen.
	Flow Rate Icon		Alarm button. Select to confirm acknowledgment of changes for alarm settings. Found on Patient Temperature. Allows toggling temperature alarm ON.
			Alarm button. Select to confirm acknowledgment of changes for alarm settings. Found on Patient Temperature. Allows toggling temperature alarm OFF.

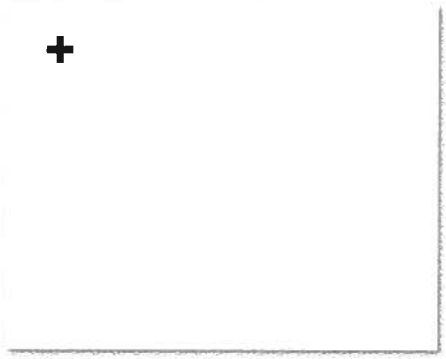
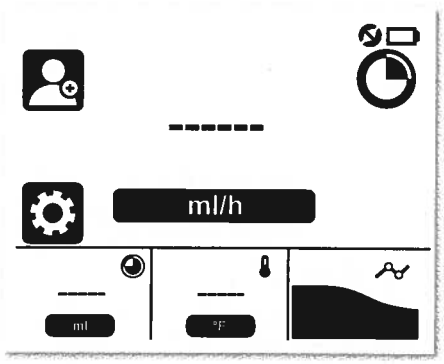
System Units of Measure		
lb = pounds	kg = kilogram	ml = milliliter
h = hour	ml/h = milliliter per hour	°F = degrees Fahrenheit
°C = degrees Celsius	ml/kg = milliliter per kilogram	ml/kg/h = milliliter per kilogram per hour

UROS™ Monitor User Interface

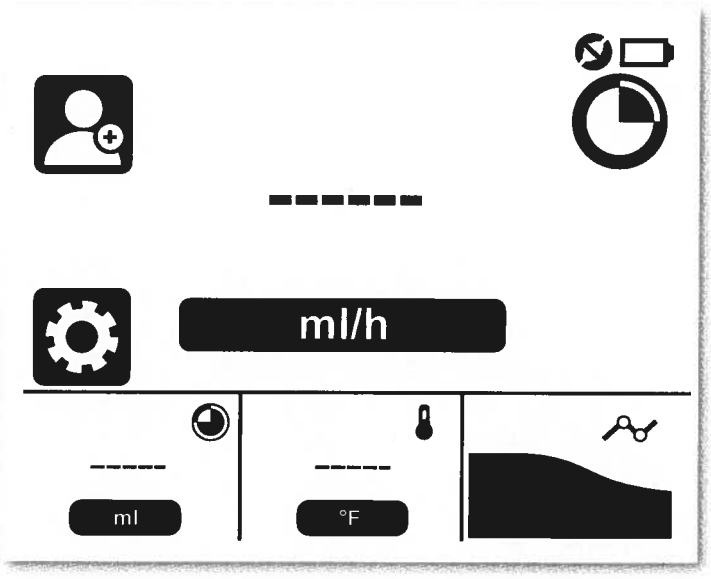
Boot Display

Upon boot up, the splash screen will be displayed for a short time. Below the Bard logo, the current software version and system serial number will be displayed. (The top number on the splash screen indicates the software version. The lower number indicates the monitor serial number.)

Screen Calibration Instructions

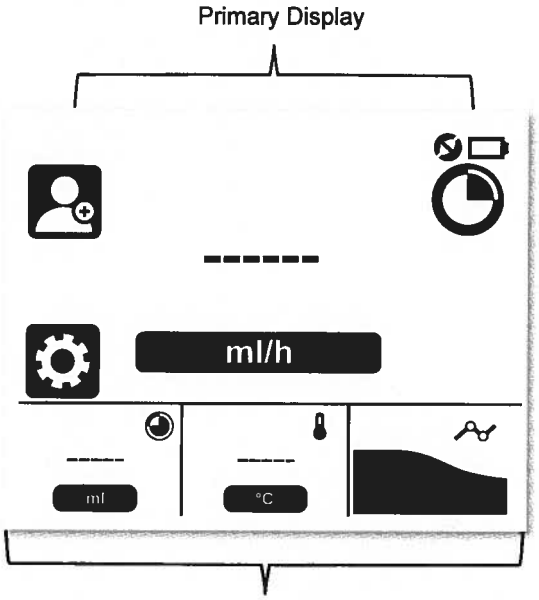
Power on the Uros™ Monitor and wait for the splash screen to appear as shown below.	As soon as the Splash screen appears press and hold the monitor screen for approx. 3 seconds until the corner image appears on the upper left hand corner of the screen as shown in the below image.	Press the Image in the upper left corner and as it moves to the remaining 3 corners of the screen and continue pressing the image until the calibration process is completed and the Main screen appears as shown in the image below.
		

Startup Display



Following display of the Boot Screen, the system will display the Startup Screen. Initial data values will be reported as dashes until the system is set up to monitor a patient.

Primary Secondary Display

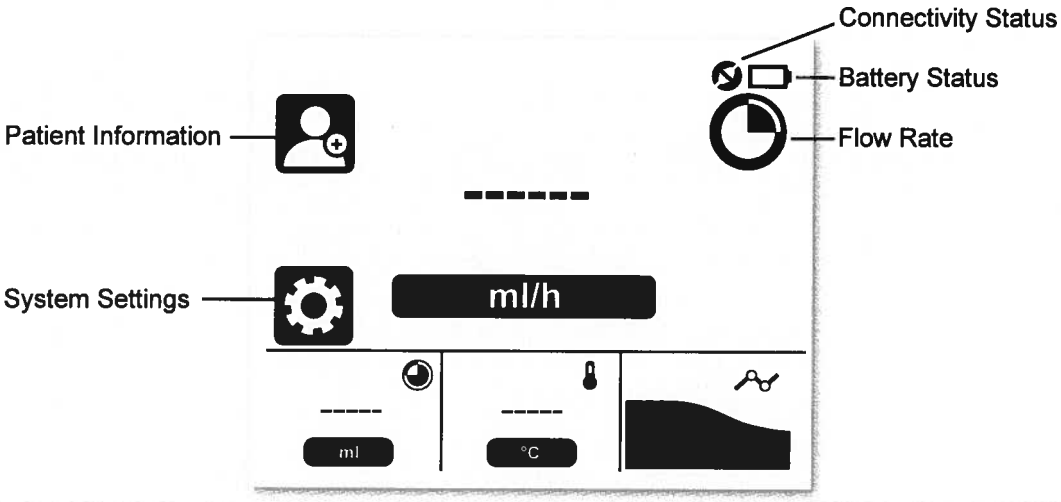


The UROS™ Monitor user interface is flexible and customizable to prominently display whichever parameter is preferred in the primary display.

Secondary parameters are found in the secondary display area across the bottom and are presented in a smaller font size. The primary display is considered the "active" parameter. Touching the primary display area will allow for additional settings to be made for the active parameter.

To enable a secondary parameter to become "active" in the primary display area, simply select any of the secondary display parameters and it will be swapped into the primary display area.

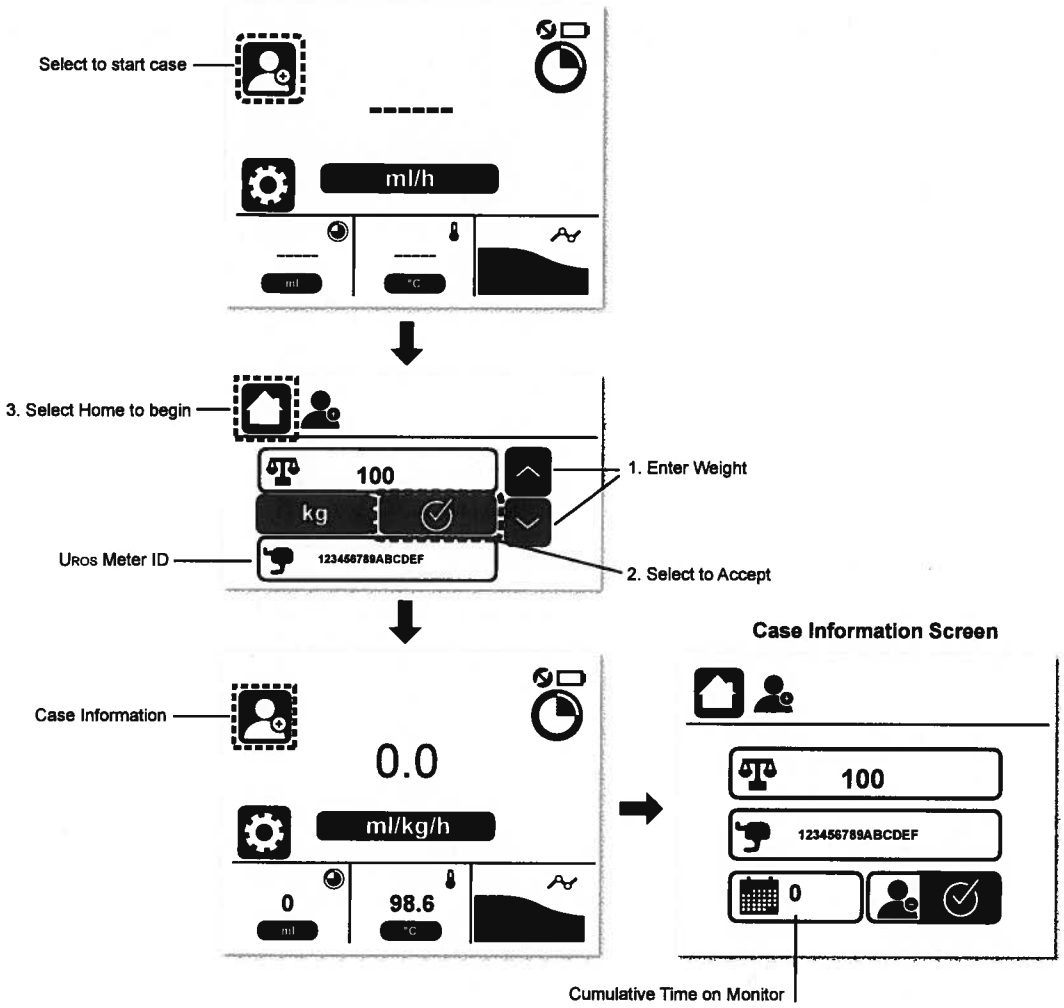
Display Information



Additional functions are displayed on either side of the primary display area. Some functions will remain constant in all screens, while other functions are context sensitive and will change depending on the current screen or settings selected.

Status indicators across the top of the primary display such as the battery and connectivity status will remain present at all times in the primary display mode.

Starting a New Patient Case



1. To start a case (e.g. Add Patient), Select "Add Patient" icon.
2. Next, enter weight using toggle buttons and accept entry to begin case.
3. The Uros™ Meter ID will be displayed at the bottom of the screen. This ID is unique to the Uros™ Meter and will never be duplicated. The Uros™ Meter ID will be transmitted in the data stream and can be used to establish Positive Patient Identification (PPID) within Electronic Medical Record (EMR).
4. The Uros™ Meter ID can be retrieved by accessing the ongoing case via selecting the Case Information Screen.
5. The Cumulative Time on Monitor will be displayed.

NOTE: If the active case is terminated or the patient is switched between monitors, the Cumulative Time on Monitor will reset to zero. If system is connected to an Electronic Medical Record system, depending on the integration, the data may be retained and re-associated with the Uros™ Meter ID Since the Uros™ Meter ID does not change unless the Foley catheter is discontinued and a new Uros™ Meter is used.

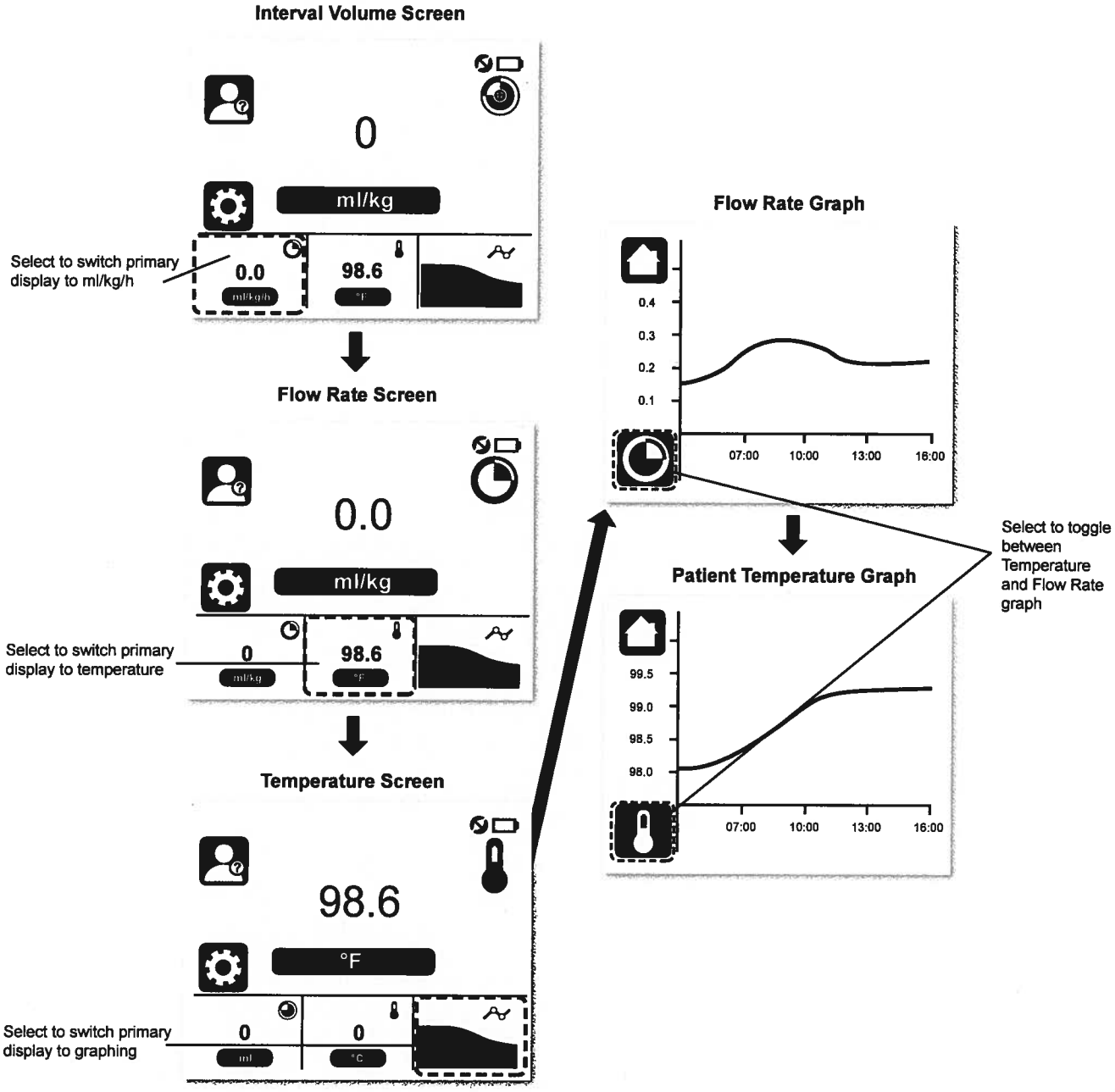
NOTE: Flow Rate can be reported in ml/kg/hr (default) or ml/hr. Entry of the patient's weight will determine the global setting and calculations. Once set, the system will adjust all reported values to correspond to the user's selection.

NOTE: The Uros™ Monitor begins monitoring as soon as the Uros™ Meter is plugged in. Any urine collecting in the Uros™ Meter that has not been lost in the overflow will be accounted for while user is starting the case.

NOTE: Repeatedly press the down arrow until "---" is displayed to disable the weight normalized calculations.

NOTE: Uros™ Meter RFID Operation
Each Meter will display a unique identifier, which is contained in the RFID tag located on the back of the meter. This unique identification number can be accessed via the patient settings screen.

Switching Primary Display



Three parameters are displayed on the screen at all times:

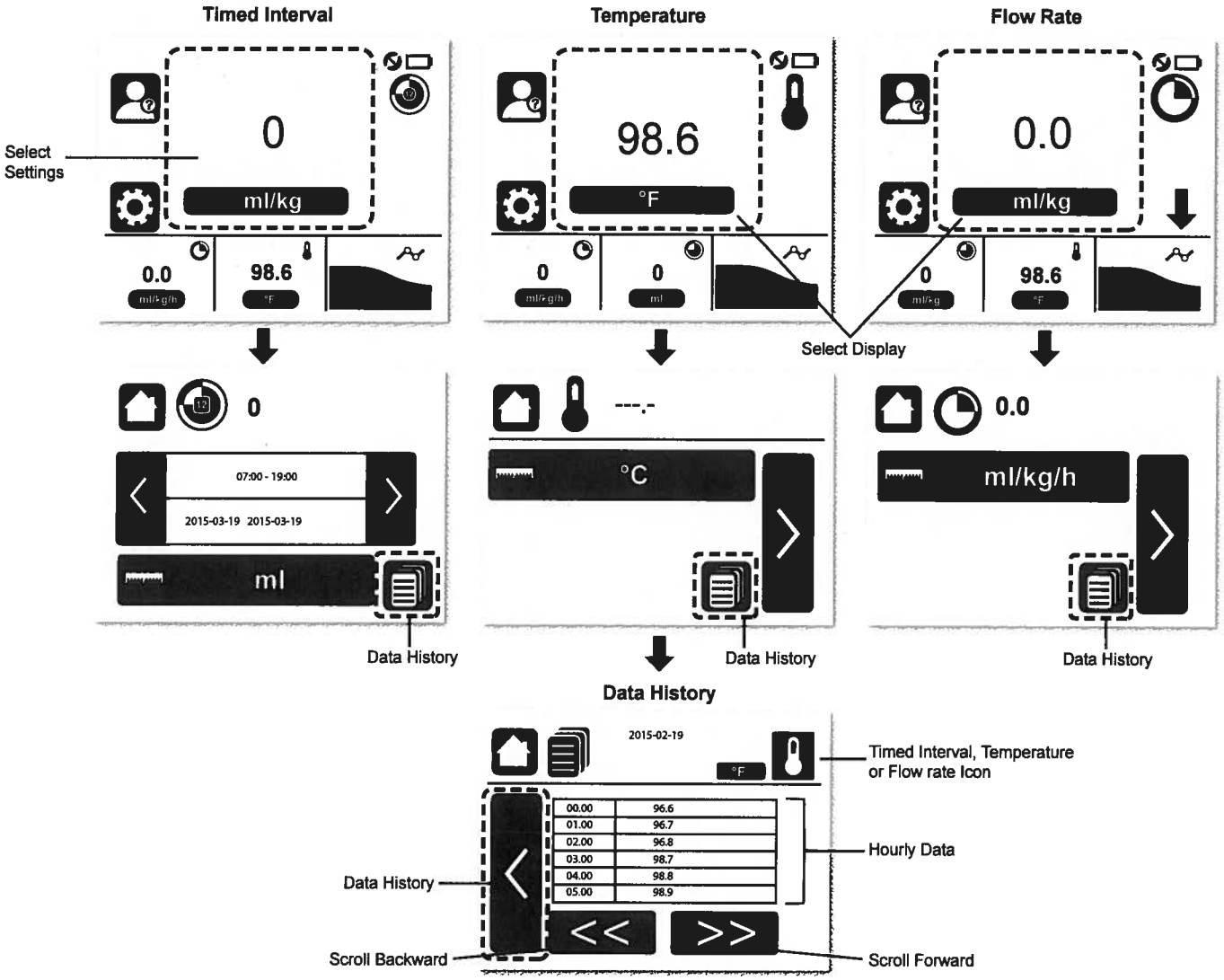
1. **Interval Volume** – provides immediate view of accumulated volume during the 12 hour timed interval
2. **Flow Rate** – provides current flow rate (normalized by patient weight if selected)
3. **Temperature** – provides current patient temperature (either °C or °F)

Trended graphing of either Flow Rate or Temperature can also be displayed in the primary screen, but is not actively displayed or updated until selected as the primary screen.

Select any Secondary Display area to switch it to the Primary Display.

Selecting the graph will display either trended Flow Rate or Temperature. Selecting the button on the bottom left of the graph display will toggle between the Flow Rate and Temperature graph.

Accessing Patient History



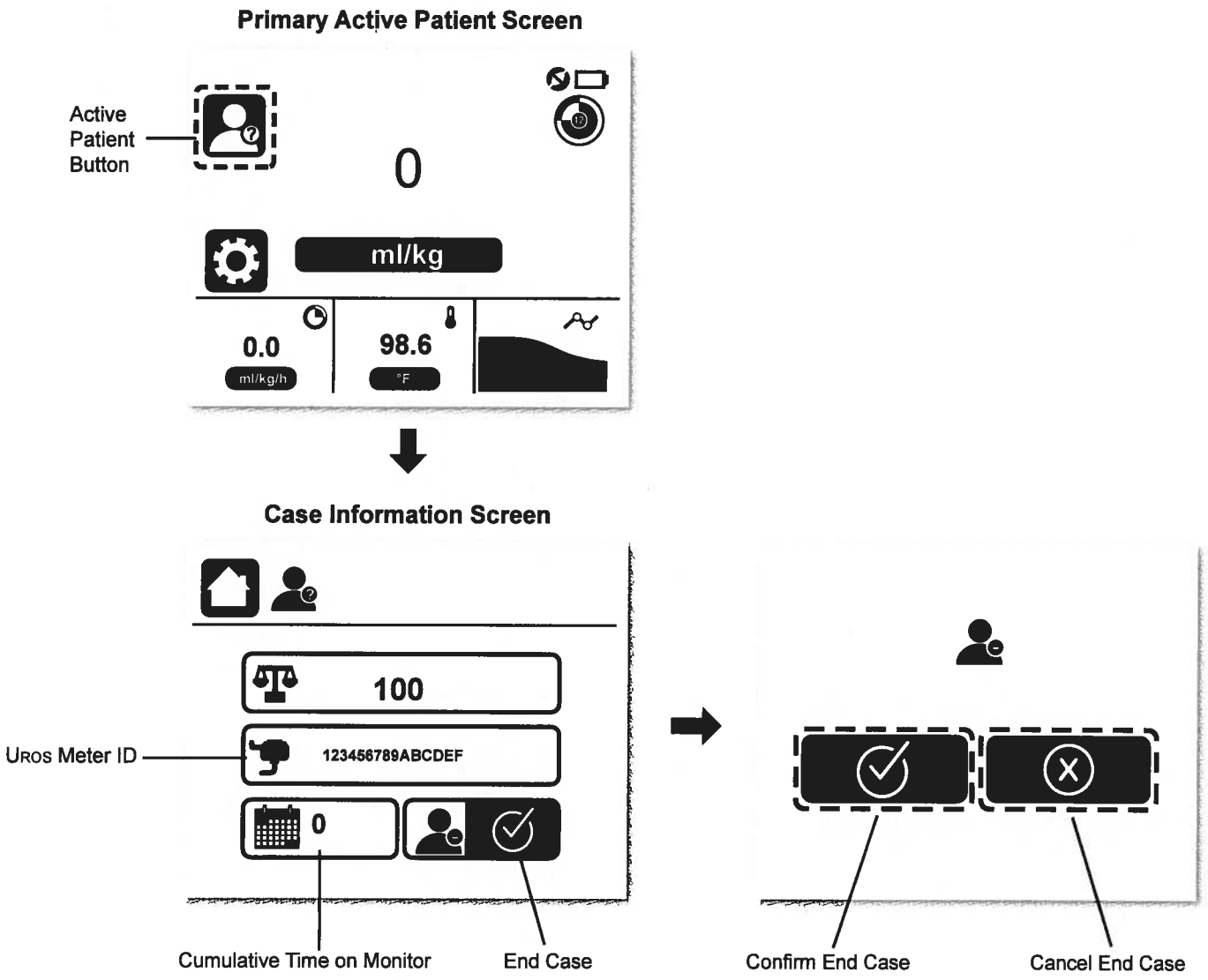
Patient Data History can be accessed through Timed Interval, Temperature or Flow Rate screens.

1. Once these screens are selected, a Data History button will appear
2. Selecting Data History button will open the Patient Data History
3. An icon at the top of the screen will identify which data set (Timed Interval, Temperature or Flow Rate) is displayed
4. Scroll backward or forward to access hourly Patient History data
5. Go back to the previous settings page by selecting the Left Arrow button
6. Go to the Home Screen by selecting the home button

NOTE: Pressing the  icon will toggle between "Timed Interval," "Temperature," and "Flow Rate."

NOTE: Once a patient case has ended, all data in history will be lost.

Ending Patient Case



To end a case or access the active Case Information Screen from the Home Screen:

1. Select the Active Patient button from the Home Screen
   - The UROS™ Meter ID will be displayed
   - The Cumulative Time on the UROS™ Monitor will be displayed
2. To end active case, select the End Case button
3. Either Confirm or Cancel Confirmation and the system will return to the Home Screen

NOTE: If the active case is terminated or the patient is switched between monitors, the Cumulative Time on Monitor will reset to zero. If system is connected to an Electronic Medical Record system, depending on the integration, the data may be retained and re-associated with the UROS™ Meter ID Since the UROS™ Meter ID does not change unless the Foley catheter is discontinued and a new UROS™ Meter is used.

Urine Output Threshold Alarms

The UROS™ Monitor has been designed to monitor patient urine output and core temperature.

Urine output will be displayed in several user selectable values: Volume, Shift Volume and Flow Rate.

Timed Interval Volume – The total volume output by patient during the timed interval. The length of the Timed Interval Volume calculation is **fixed at 12 hours.** Upon starting a new case, a new Timed Interval Volume will begin. The initial volume will accumulate until either **0700** or **1900** hours is reached, whichever time point is reached first. From this point forward, the Timed Interval Volume will reset to zero volume at both **0700** and **1900** hours until the case is ended.

Flow Rate – Is a calculated value that is based on volume output over time.

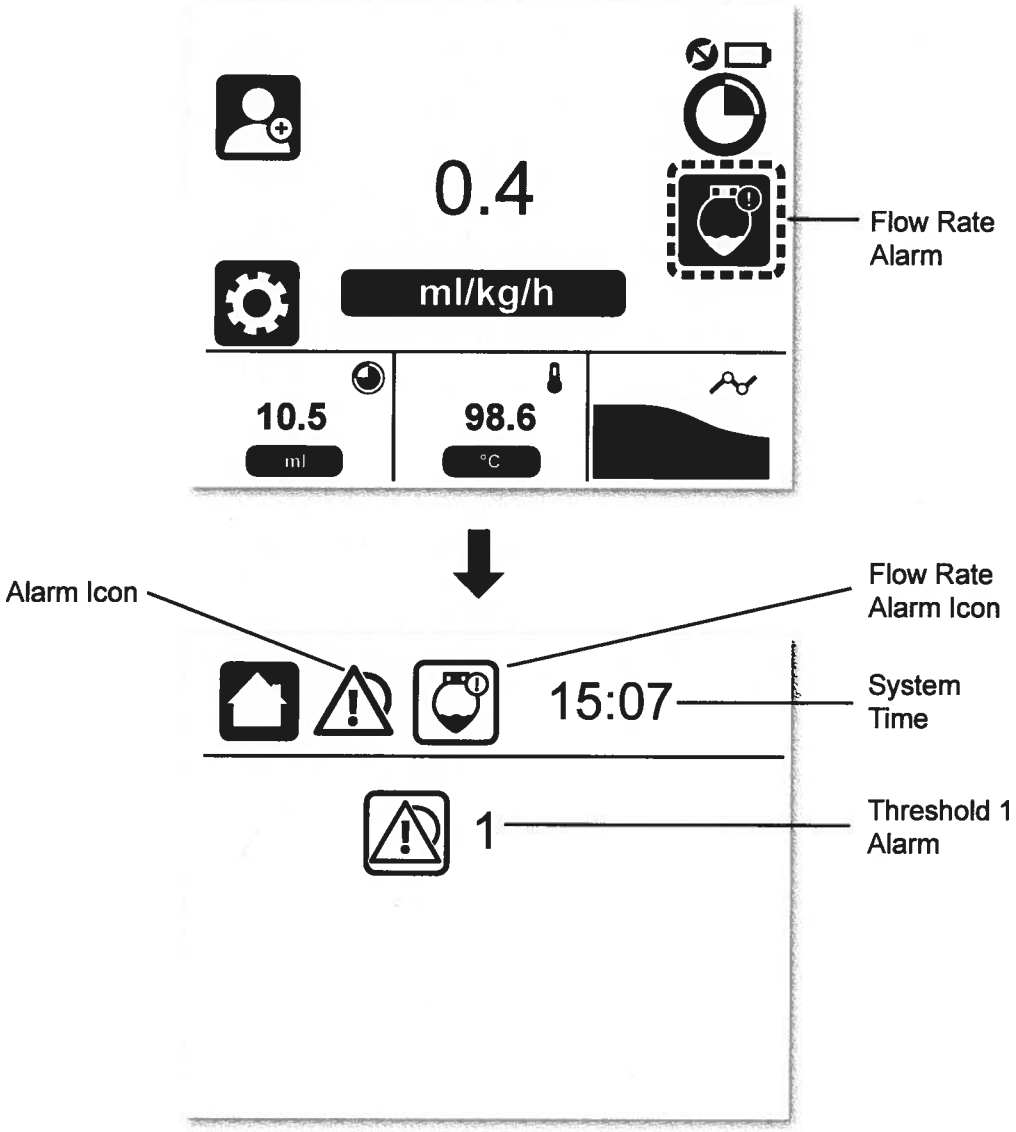
- The Flow Rate can be displayed as ml/h or ml/kg/h depending on whether the weight has been entered and normalization by weight has been activated.

Urine volume is continuously monitored at 10 second intervals and posted via communication protocols every 5 minutes. (The UROS™ Monitor must be integrated into an Electronic Medical Record (EMR) system before information can be visualized off monitor.)

Factory Default Urine Output (Flow Rate) Threshold Alarm settings are:

Alarm	Default Threshold	Audible Alarm	Visible Alarm Color	Blink Rate
Level 1	<0.5 ml/kg/h for 6 hours OR 50 ml/h for 6h	None	Yellow	Blinks 1 X every 5 seconds (illumination period ~0.1 sec)
Level 2	<0.5 ml/kg/h for ≥ 12 hours OR 50 ml/h for 6h	None	Yellow	Blinks 2x in rapid succession every 5 seconds.
Level 3	<0.3 ml/kg/h for X24 hours OR 30 ml/h for 24h	None	Yellow	Blinks 3x in rapid succession every 5 seconds.
Level 4	Anuria for ≥ 12 hours	None	Yellow	Blinks 4x in rapid succession every 5 seconds.
Level 5	>15 ml/kg/h at any time OR 1500 ml/h at any time	None	Yellow	Blinks 5x in rapid succession every 5 seconds.

Example Flow Rate Alarm

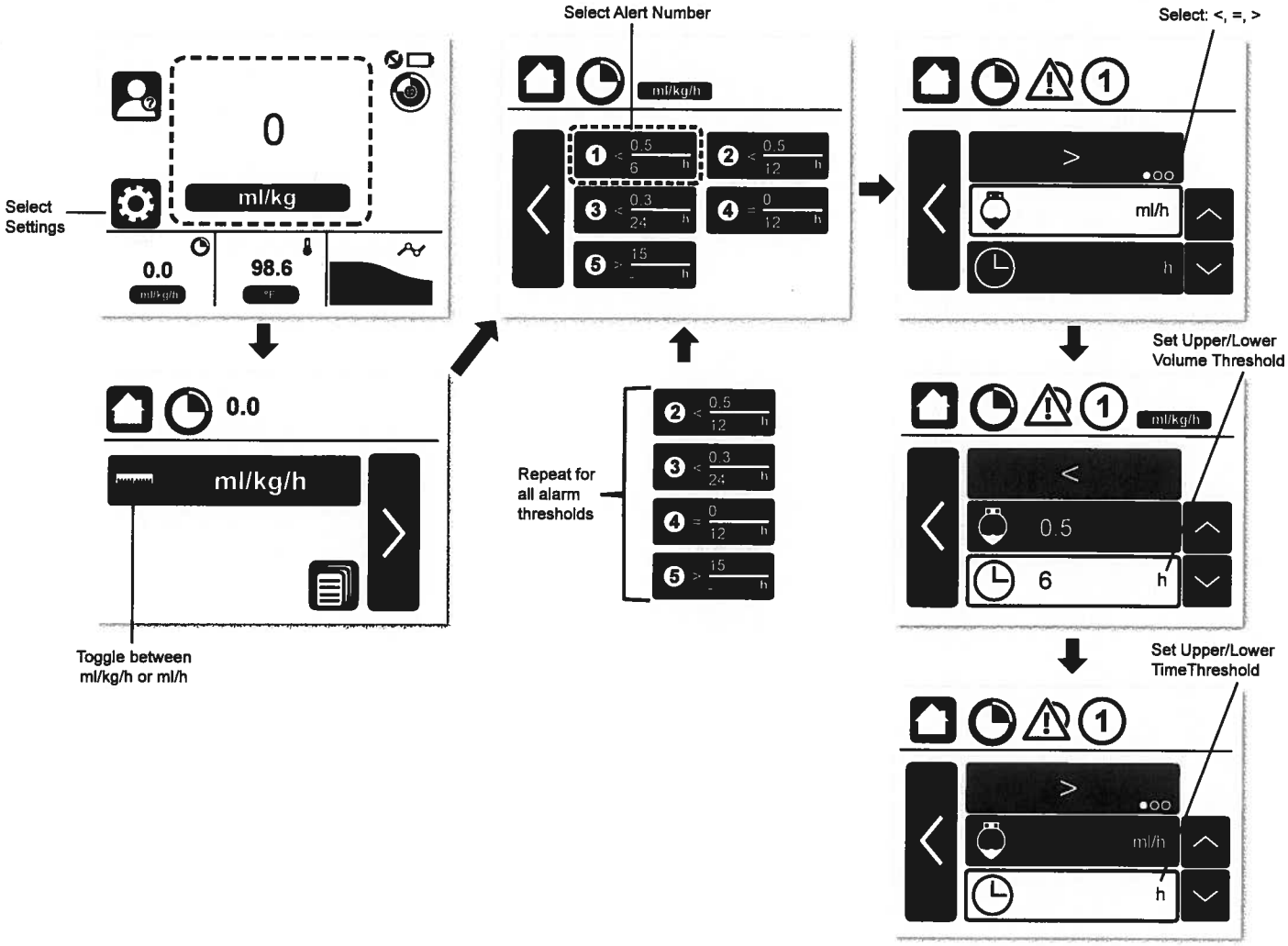


If the patient flow rate drops to the defined alarm threshold, a Flow Rate alarm will activate. The Flow Rate alarm button will appear on the right side of the primary display.

1. Selecting the Flow Rate alarm button will open the alarm specific display. Specific alarm information can be found on this display.
2. Select the Home button to return to the Primary Display.

The Alarm Icon on the Primary Display in addition to the visible blinking alarm will continue to alert while the patient meets the alarm threshold requirements.

Customizing Urine Output Threshold Alarm



Setting the urine output thresholds begins on the primary display. A total of 5 alarms are available to customize.

1. Select the Settings icon
2. Select the units of measure (ml/hr or ml/kg/h) (if weight is entered)
3. Select a threshold alarm number 1-5
4. Select a logic identifier (<, =, >)
5. Select upper or lower volume/rate threshold limit
6. Select a length of time the threshold must be in violation before alarm will notify user

Core Bladder Temperature Measurement

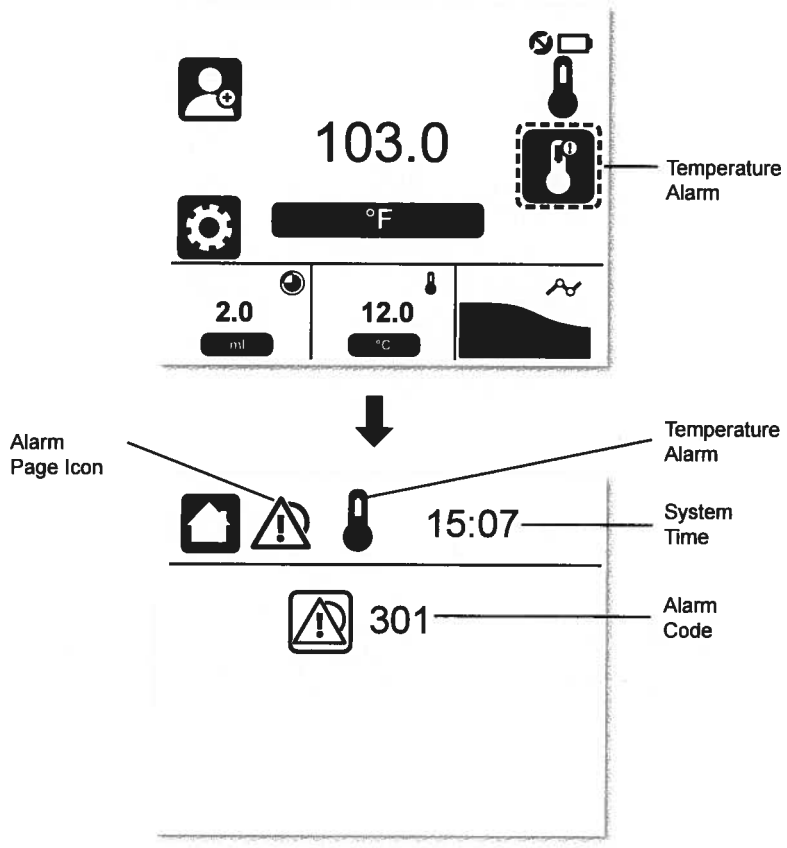
The UROS™ Monitor has been designed to monitor bladder core temperature when used in conjunction with a BARD® 400-Series bladder temperature sensing catheter.

Core bladder temperature display shows the bladder temperature in °F or °C, as determined by the user. If the temperature cannot be determined or is out of range, "---" will be displayed.

Default temperature threshold alarm settings are:

Alarm	Default Threshold	Audible Alarm	Visible Alarm Color	Blink Rate
High Temperature	>38.3°C	None	Magenta	Blinks 1 X every 3 seconds (illumination period ~0.1 sec)
Low Temperature	<36°C	None	Blue	Blinks 1 X every 3 seconds (illumination period ~0.1 sec)

Temperature Alarm Example

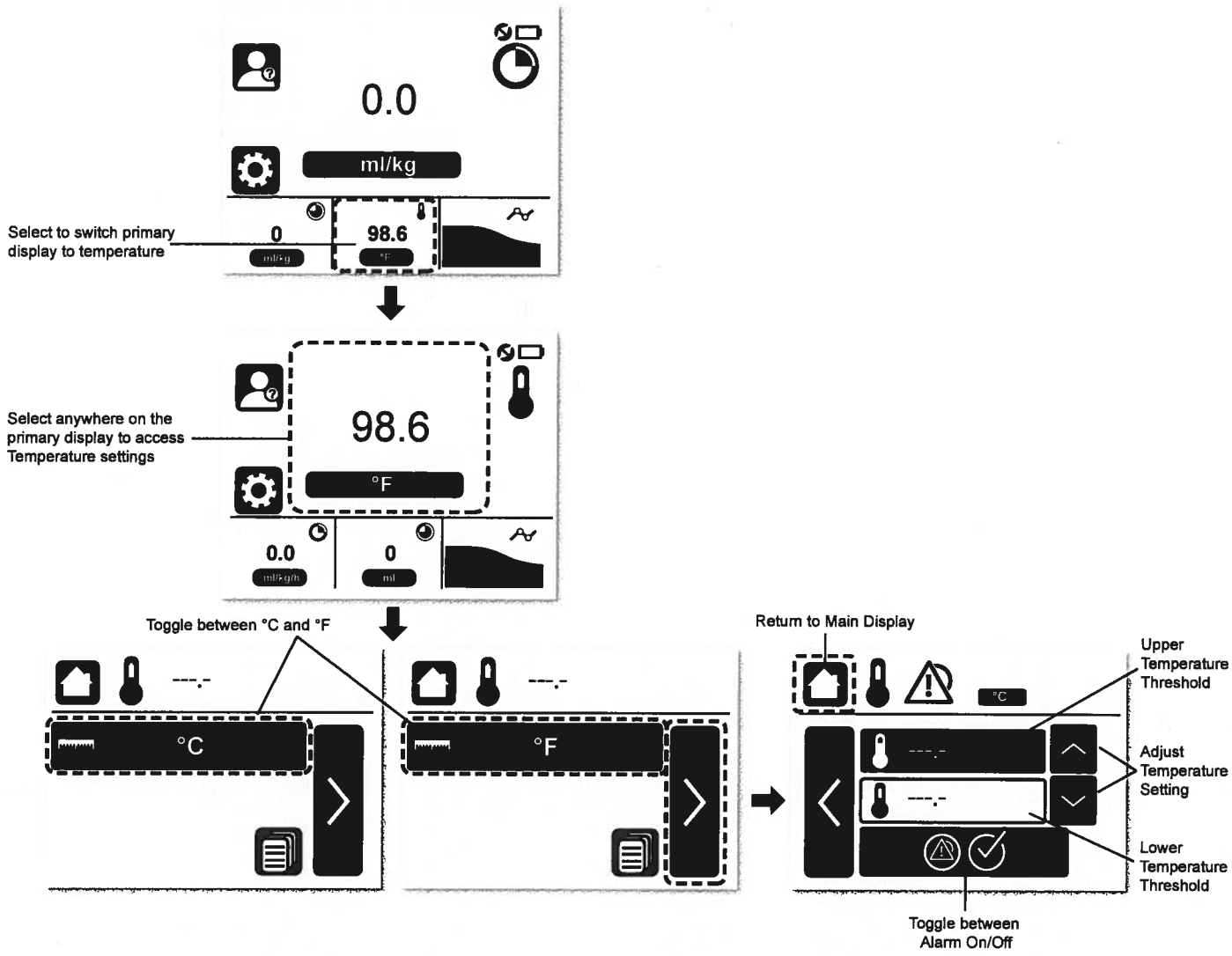


If the patient temperature is above or below the defined alarm threshold, a Temperature Alarm will activate. The Temperature Alarm button will appear on the right side of the Primary Display.

1. Selecting the Temperature Alarm button will open the alarm specific display. Specific alarm information can be found on this display.
2. Select the Home button to return to the Primary Display.

The alarm icon on the primary display in addition to the visible blinking alarm will continue to alert while the patient meets the alarm threshold requirements.

Customizing Temperature Threshold Alarms



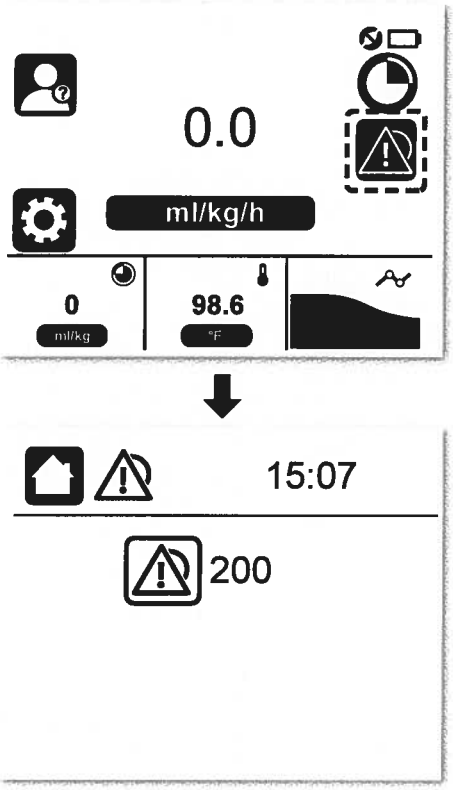
Temperature for both upper and lower alarm thresholds is user definable. To adjust:

1. Select Temperature so it is displayed in the Primary Display
2. Select Temperature anywhere on the Primary Display
3. Toggle between °C and °F
4. Select the "Right" button to display the Threshold Settings screen
5. Select the Upper or Lower alarm button
6. Adjust Temperature Threshold Alarm using toggle buttons (Set to "---.-" to disable alarm)
7. Confirm Entry to return to Home Page

System Alarms

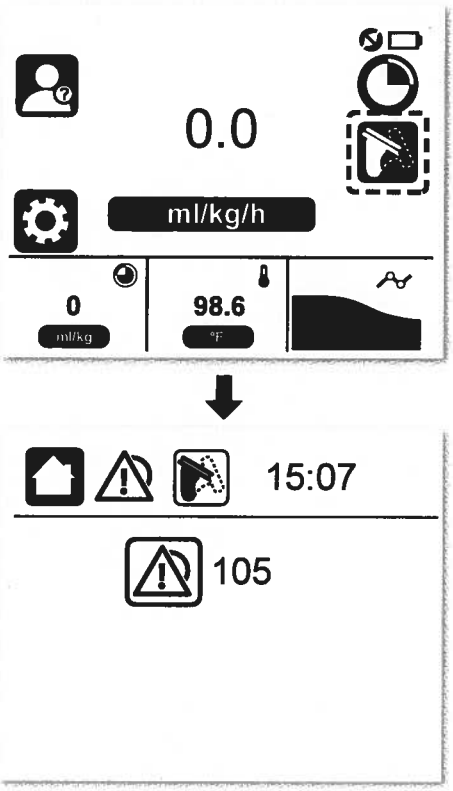
Customizing Temperature Threshold Alarms

Generic Alarm



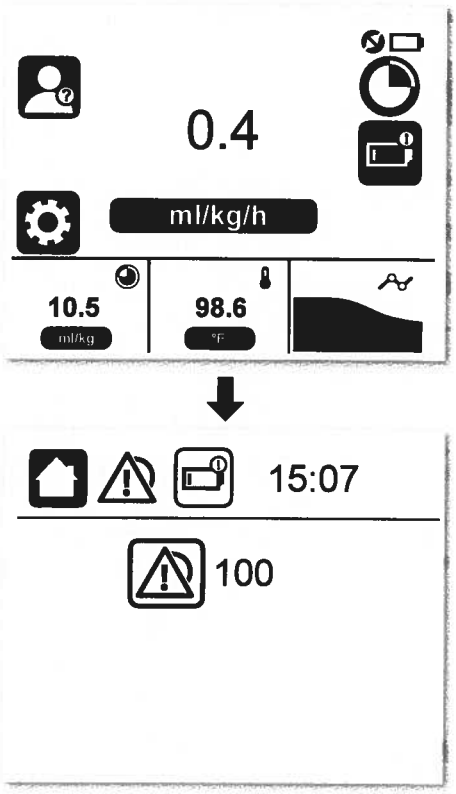
If generic fault alarm is alerting, reference the General Systems Alarms table on page 35, for resetting instructions.

Tilt Alarm



If Tilt Alarm is alerting, level system to reset alarm.

Low Battery Alarm



Battery Alarm will activate when charge is at or below 3% and device is not charging. Charge battery to reset alarm.

The UROS™ Monitor has several audible alarms. All audible alarms will have a highly visible white blinking indicator light below the display.

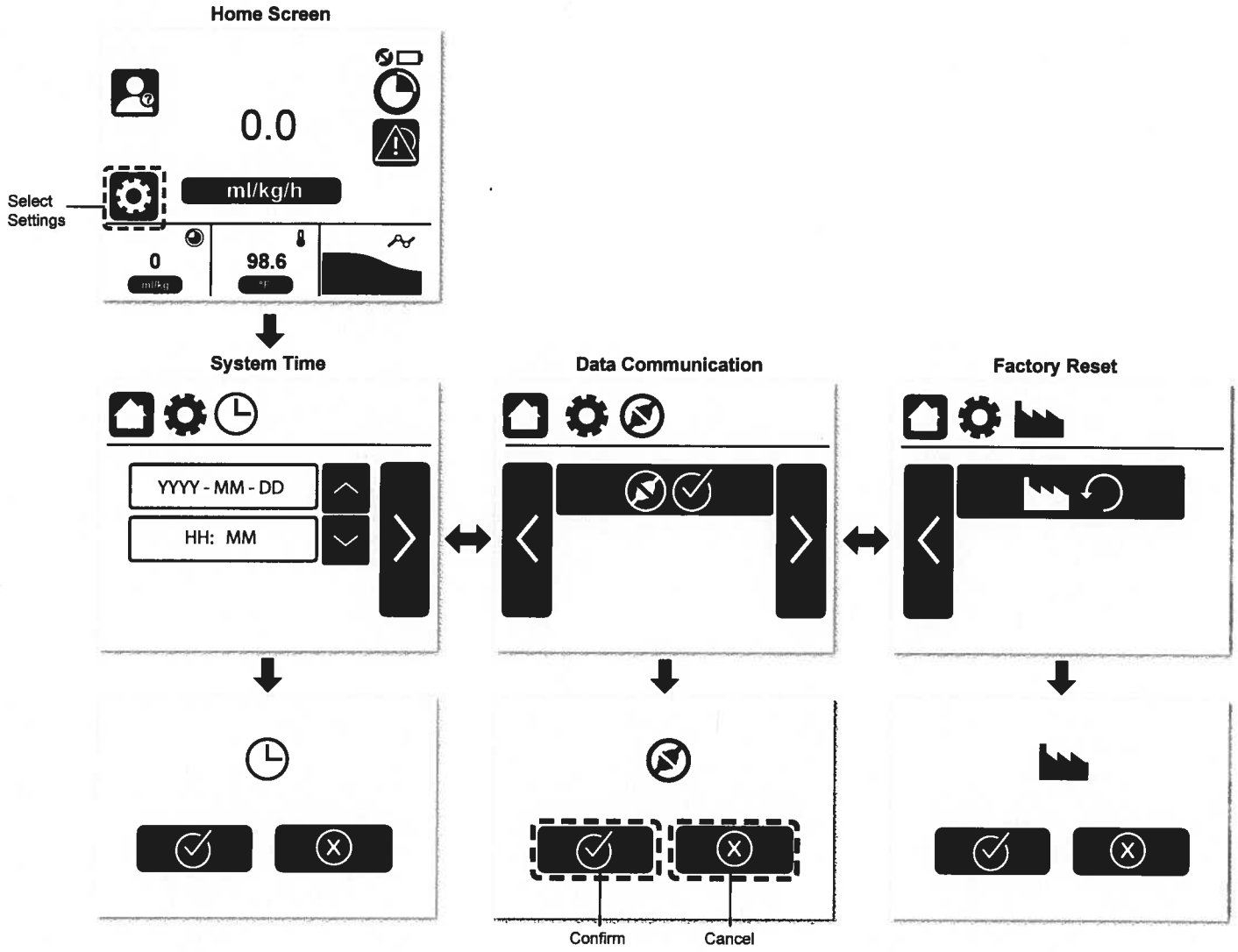
There are three types of audible alarms. When active, the display will also identify which type of alarm is active with a specific button along the right side of the display. When selected, additional alarm information will be presented.

NOTE: The Tilt Alarm can easily be resolved by leveling the monitor using the bubble level indicator.

NOTE: The Low Battery Alarm can easily be resolved by charging the unit with the supplied external AC Power Supply.

NOTE: If your system has an active General Alarm, please refer to the alarm code reference in this manual for further information. Most general alarms can be reset by simply rebooting the system. If the alarm persists, please contact BARD® Customer Service at: 1-800-526-4455.

System Settings



System Settings allows the UROS™ Monitor to be configured for your hospital environment.

1. **System Time** – Set system time in Years, Month, Day, Hours and Minutes. Select each field and adjust up or down until the system time matches your local time. Press the right arrow button to activate the confirmation screen (If a case is in progress then the time and date cannot be modified).
2. **Data Communication** – Toggle Data Stream on or off.
3. **Factory Reset** – Selecting Factory Reset will reset all settings to factory defaults described in this manual.

NOTE: System Time will be reported in Data Stream. If System Time is not accurately set, data being reported to the hospital Electronic Medical Record (EMR) system may not be accurate if UROS™ Monitor time takes priority over other EMR time inputs.

NOTE: If Factory Reset is selected, all patient data will be deleted and will not be recoverable.

NOTE: Selecting the Confirm button will accept changes and open the Home Screen. Selecting the Cancel button will return to the previous screen.

General System Alarms Table:

Alarm	Default Threshold or Activation	Audible Alarm	Visible Alarm Color	Blink Rate	Resolution
Tilt Alarm	Activates when device tilt angle is greater than 10 degrees from level.	Yes Sounds at 10 second intervals	White	Blinks every 2 seconds (illumination period ~0.1 sec)	Level system
Meter ID Failure	Activates when system reports cartridge ID failure.	Yes Sounds at 10 second intervals	White	Blinks every 5 seconds (illumination period ~0.1 sec)	Re-read Meter
System Fault	Activates when system fault occurs.	Yes (If Possible)	White	Blinks every 5 seconds (illumination period ~0.1 sec)	Power cycle system
Fluid Measurement Communication Timeout	Active when fluid measurement communications exceed the Fluid Measurement Maximum Read Time.	Yes Sounds at 10 second intervals	White	Blinks every 5 seconds (illumination period ~0.1 sec)	Power cycle system

Section 5 - Troubleshooting

Description	Recommendation
Power	
System does not power on.	Plug system into AC power source. • If system turns on, battery may be undercharged, defective or beyond usable life. • If system does not turn on, call Service Center for further support.
Battery does not hold charge.	A new battery will take approximately 12 hours to become fully charged from a completely discharged state. The battery is designed to charge-cycle approximately 250 cycles while retaining 50% capacity before requiring replacement. If battery does not meet these requirements, replacement of battery is recommended.
Accuracy	
System does not appear to measure urine output accurately.	• Verify the Uros meter is plugged in and seated firmly. • Verify the Uros meter window area is clean and clear of any physical blemishes or defect. • Verify Uros meter receptacle on the Uros monitor is clear of any debris or physical blemishes or interface defect. • Verify the Uros meter can properly drain stored urine within the meter.
System does not appear to measure temperature accurately.	• System has only been tested to be compatible with Bard 400-Series thermister bladder temperature sensing catheter. • Ensure temperature cable is firmly plugged in at the monitor and catheter end. • Ensure connections are clean and dry. • Ensure connections are not damaged. • Replace any cables that appear worn or are loose when connected.
Connectivity	
System does not connect to EMR.	Identify connectivity icon on main screen is present. Ensure the system Data Communication is enabled in system settings.

Section 6 - Specifications

Environmental Requirements

Operating environment:

Temperature:	50°F to 80°F
	10°C to 27°C
Relative humidity:	5 to 70%, non-condensing
Atmospheric pressure:	70-110 kPa

Shipping and storage environment:

Temperature:	-20°F to 120°F
	-30°C to 49°C
Relative humidity:	5 to 95%, non-condensing
Atmospheric pressure:	70-110 kPa

UROS™ Battery Module

Technology:	Lithium-ion
Operating Temperature:	50°F to 80°F
	10°C to 27°C
Total Cells:	8 cells
Battery Cell:	
Voltage	3.60 VDC
Capacity	25.60 Ah
Energy	92.16 Wh
Output:	3.30 VDC / 2.0 A
Input:	9.0 VDC / 30 W

Section 7 - Care and Maintenance

Cleaning and Maintenance

The monitor should be cleaned periodically and between patients as per your facility infection control protocols. The system does offer limited water intrusion protection IPX1- Protection against water drops falling vertically. Water drops falling at a rate of 3 to 5 mm/minute from a height of 7.87 inches (200 mm) for 10 minutes and should not be submersed or have heavy amounts of liquid cleaners applied to the surface. The system has been designed to be compatible with common cleaning agents 70% Isopropyl alcohol, 0.6% Bleach (hypochlorite), 4.25% hydrogen peroxide, quaternary ammonium solutions, and glutaraldehyde cleaning agents.

First, unplug the monitor from any AC source prior to cleaning.

Use either a pre-moistened towel or apply cleaner to a towel first, then wipe the monitor temperature cables, communication cable, power cords and external power module with towel. Avoid spraying or pouring cleaner directly onto the monitor as this may damage the unit and will void the warranty.

Device Inspection

Periodically inspect the external areas of the device for damaged, loose or missing parts, and frayed or twisted power cords and cables.

Discontinue using the device displaying one or more of the above conditions until the problem is corrected and has been verified to be operating correctly and safely.

Section 8 - Shipping

Shipping Lithium Batteries – without electronic equipment

1. **Short Circuit Protection**
   a. As they are packed, batteries must be protected against short circuits.
   b. Place single battery pack into a plastic bag (without other contents), putting non-conductive tape over battery terminals.
   c. Never pack metal objects or other conductive items into the same package with battery pack if there is an opportunity for those objects or items to come into contact with the batteries' terminals.
   d. If it is necessary to send tools or other items with the batteries, separately contain properly protected batteries in a small box within a larger package that you use for the other items.
2. **Warning Label**
   a. It is important to provide the necessary warnings on the outside of a package containing lithium batteries. Any package containing lithium metal batteries must display a distinctive handling label (110 mm x 120 mm):

   b. Where the packages are of dimensions such that they can only bear smaller labels, label dimensions of (74 mm x 105 mm) may be used in place.

Shipping Lithium Batteries – packed with or contained in equipment

1. **Packed with equipment**

   a. The battery pack must be fully protected against short circuit.

   b. Must be placed into a rugged inner package that fully contains the battery pack, separate from the equipment.

   c. It is important to provide the necessary warnings on the outside of a package containing lithium batteries. Any package containing lithium metal batteries must display a distinctive handling label (110 mm x 120 mm):

   d. Where the packages are of dimensions such that they can only bear smaller labels, label dimensions of (74 mm x 105 mm) may be used in place.

2. **Contained in equipment**

   a. The battery pack must be removed from the equipment prior to packaging and shipping.

   b. Must be placed into a rugged inner package that fully contains the battery pack, separate from the equipment.

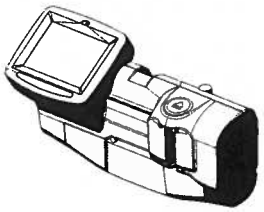
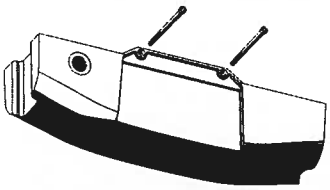
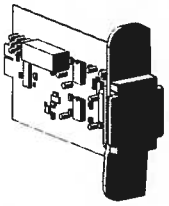
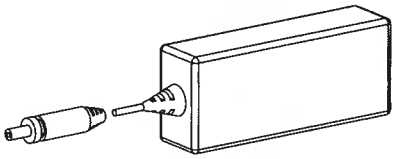
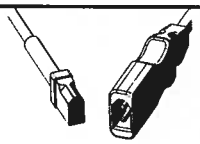
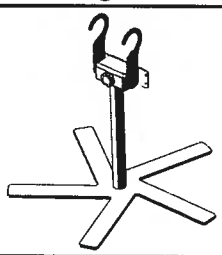
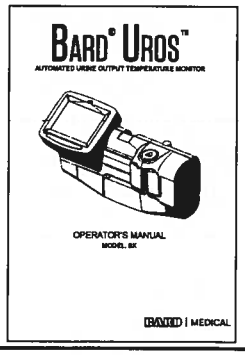
   c. It is important to provide the necessary warnings on the outside of a package containing lithium batteries. Any package containing lithium metal batteries must display a distinctive handling label (110 mm x 120 mm):

   d. Where the packages are of dimensions such that they can only bear smaller labels, label dimensions of (74 mm x 105 mm) may be used in place.

Battery disposal

Regulations and laws pertaining to the recycling and disposal of lithium ion batteries and battery packs vary widely from country to country, as well as by state and local governments which may have additional requirements. Please check the applicable laws and regulations where you live.

Section 9 - BARD® UROS™ Monitor Replacement / Spare Parts

Part Number	Description	
BK10001M	Bard UROS™ Monitor, RS232, US	
BK00103A	Bard UROS™ Battery Pack	
BK00001S	RS232 Serial Communication Card	
BK00104A	External AC/DC Power Supply	
BK00105A	Patient Temperature Probe Adapter Cable, Molex	
BK00106A	Patient Temperature Probe Adapter Cable, 1/8 inch mono plug	
BK00100A	UROS™ Monitor Floor Stand	
BK00200A	UROS™ Operator Manual	

Section 10 - BARD® UROS™ Monitor Warranty / Service

BARD

LIMITED WARRANTY

ON NEW UROS™ MONITORS

Bard Medical Division, C. R. Bard, Inc. ("Bard") warrants to the original purchaser that the UROS™ Monitor will be free from defects in material and workmanship for a period of 90 days from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard for repair, replacement, refund or credit at Bard's option. All returns must be authorized in advance in accordance with Bard's Returned Goods Policy found in its then current Price List. The liability of Bard under this limited product warranty does not extend to any abuse, misuse, improper storage, alteration, further manufacture, packaging or processing of this product or its repair by anyone other than an authorized Bard representative.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD MEDICAL DIVISION, C. R. BARD, INC. AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD MEDICAL DIVISION, C. R. BARD, INC. WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

Section 11 - Appendix

Classification

The unit is classified, according to IEC 60601-1, as:

Type of protection against electrical shock	a) Class II when unit is powered by external power supply (only for external power supply provided with the unit) • Input: 100 – 240 VAC, 1.1A, 50-60 Hz • Output: 9.0 VDC, 3.33A b) Internal powered equipment (use only battery pack provided with the unit) • Li-ion battery pack • Input: 9.0 VDC, 30 W • Output: 3.3 VDC, 2A
Degree of protection against electrical shock	Type BF defibrillation-proof applied part
Degree of protection against ingress of water	IPX1: Equipment protected against vertically falling drops of water. Do not immerse or excessively wet the monitor.
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Mode of operation	Continuous operation

System Error Codes

Name	Number	Alarm Priority*
System Fault	220	1
Cartridge ID Failure	200	2
Tilt Alarm	105	3
High Temperature Alarm	301	4
Low Temperature Alarm	302	5
Flow Rate Alarm 4	4	6
Flow Rate Alarm 3	3	7
Flow Rate Alarm 2	2	8
Flow Rate Alarm 1	1	9
Flow Rate Alarm 5	5	10
Flow Rate Alarm 6	6	11
Low Battery Alarm	100	12

* Alarm priority determines the order of which alarm will be identified on the primary display. The alarm priority does not interfere with the visible color light alarms.

Data Stream Output Definition

The data stream output will be in a "pipe-delimited" structure. The data will be communicated at 5 minute frequency.

Specifications:

- Data output shall be in an ASCII text format
- Data output shall start with # (pound) character
- Data output shall end with (carriage return, CR, 13 dec, 0xD hex) character
- Data output fields shall be separated by | (pipe) character
- During an active case the communications module shall send a record every 5 minutes +- 5 seconds, if enabled
- Data output shall contain the following parameters:
  - o Packet version: format will be X.Y.Z
  - o Date and time: format will be DD-MM-YYYY HH:mm
  - o Device UID: format will be 10 digits
  - o Patient temperature: format will be NNN.N, units will be the user selected units, 10ths of degree
  - o Patient temperature units: will be either C or F, user selected units
  - o Urine flow rate: format will be NNN.N for ml/kg/h or NNNN for ml/h
  - o Urine flow rate units: will be either ml/kg/h or ml/h, user selected units
  - o Current timed interval volume: format will be NNN.N for ml/kg or NNNNN for ml
  - o Current timed interval volume units: will be either ml/kg or ml, user selected units
  - o Cartridge UID: format will be 16 hexadecimal digits
  - o Application version: format will be N.X.Y.Z
  - o Patient Weight: format will be NNNN in the user selected units, will be 0000 if disabled
  - o Patient Weight units: will be either kg or lb, user selected units
  - o Number of Days on Monitor: format will be NNN in days
  - o Sequence Number: format will be NNNNN
  - o Current alarm(s)
    - – System Alarm Number (000 if not active): format is NNN
    - – Patient Related Alarm Number (000 if not active): format is NNN
  - o Note(s) List
    - – Number of Notes (000 if none): format is NNN
    - – Notes (if any): format is NNN
  - o -CRC16: format will be HHHH, hexadecimal characters
- Acknowledge shall be data output start character followed by '$'

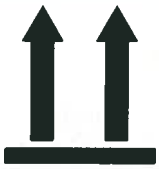
  Example transaction: #0.0.1\|27-02-2015 17:28\|0123456789ABCDEF\|037.0\|C\|005.0\|ml/kg/h\|123.4\|ml/kg \|FEDCBA0123456789\|0.9.0\|0100\|kg\|001\|00100\|000000\|000\|455A
- Factory reset shall be data output on
- Power on reset shall retain user settings for data output on/off
- The first send shall be the field names
- Data output shall time out after 15 +- 1 seconds if no response is received

Header:

#VERSION|DATETIME|DEV UID|PAT TEMP|UNITS|FLOW RATE|UNITS|INTERVAL VOLUME|UNITS|CART UID|APP

Section 12 - Symbols

	For the safe and effective use of this device, the operator must consult the accompanying documents prior to use.
	Models of the BARD® UROS™ Automated Urine Output and Temperature Monitor that bear the ETL Monogram have been Certified for Safety by ETL Intertek in accordance with CAN/CSA C22.2 STD 601.1- M90 and UL STD 60601-1
	Models of the BARD® UROS™ Automated Urine Output and Temperature Monitor that bear the FCC logo have been certified and approved for safe operation in accordance with Part 15 of the FCC rules.
	This symbol adjacent to the patient connections means that the thermal probe connection is a "Defibrillator-Proof, Type BF Applied Part," per standard IEC 60601-1 and affords the degree of patient protection defined in that standard for this type of applied part.
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Catalog number
	Serial number
FCC ID:	FCC identification indicating that the device has received a grant of authorization from the FCC, and that it meets the FCC technical requirements for safe operations.
	Do not use in presence of flammable agents.
	To reduce the risk of electric shock, DO NOT remove cover (enclosure). There are no user serviceable components inside the UROS™ Automated Urine Output and Temperature Monitor. Refer servicing to qualified personnel.

	Date of manufacture
	Manufacturer
	Fragile. Handle with care.
	Keep dry
	This side up
	Humidity Limitation
	Temperature Limit
 Units	Unit
	Shipping package warning label indicating content of Li-ion batteries.

 Li-ion	UROS™ Battery Module must be recycled, and disposed of properly.
	UROS™ Battery Module must be disposed of properly. DO NOT dispose of the battery into the garbage.
	BARD® UROS™ Automated Urine Output and Temperature Monitor is classified as Class 1 laser product per IEC 60825-1: 2014.
	Presence of Class 3R laser when device is opened as classified per IEC 60825-1: 2014.

Manufacturer

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Covington, GA 30014 USA

1-800-526-4455

www.bardmedical.com

BK00200A

PK0396648 8/2015