Accuryn® Monitoring System

Operator's Manual

IFU-06-2845 Rev U

Introduction

NOTE: Refer to Accuryn Urinary Catheter Kit IFU for information specifically for catheter and drainage tubing. If connecting to an AccuTab tablet, refer to the AccuTab IFU for additional information.


Please read carefully.

This manual covers the function and proper use of the Accuryn Monitoring System. The Accuryn Monitoring System refers to the combined use of the Accuryn Monitor and the Accuryn Urinary Catheter Kit. **NOTE: The Catheter Kit has its own accompanying instructions for use, which is found inside the Kit assembly.** Both IFUs must be referenced for proper usage of the Accuryn Monitoring System. Refer also to the separate IFUs for additional warnings, precautions, and contraindications.

Do not use or operate the Accuryn Monitor until you have read and understood this manual and the separate instructions included with the disposable kit.

Report any serious incident that has occurred in relation to the use of Accuryn Monitoring System to **Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796) and the corresponding health authority.**

CAUTION: The Accuryn Monitoring System is only intended for use by a physician, or on the order of a physician.

Potrero Medical, Inc.
26142 Eden Landing Road
Hayward, CA 94545
www.potreromed.com

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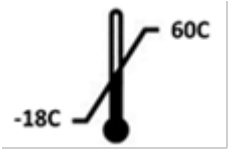
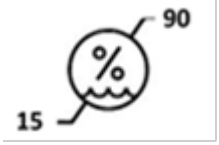
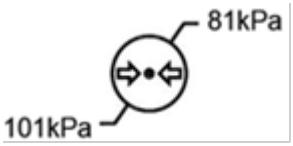
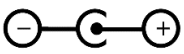
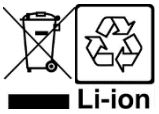
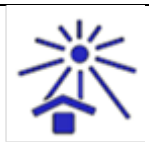
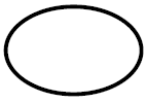
Symbols Glossary

The required symbols below relate to the labeling for the Accuryn Monitoring System. Explanations of the symbols are included in this glossary.

Symbol	Description
	Refer to Instruction Manual Indicates a requirement to read and understand the Operator's Manual and other accompanying instructions before use of the device. ISO 7010-M002
	General Warning General caution or warning sign. Also indicates referral to accompanying documents. ISO 7010-W001
	Defibrillation Proof Type BF Applied Part Indicates low risk conductive contact between device and body. Also indicates that device is defibrillation-proof. IEC 60417-5334
	Direct Current Indicates a direct current connection. IEC 60417-5031
	Power Plug Identifies connecting means (e.g. plug or cord) to the power source (mains). IEC 60417-5534
	USB Type B Indicates a type B slave USB port. Symbol applies only to Accuryn Monitors with Serial Numbers beginning with "E" or a numerical value.
	Universal Serial Bus (USB), port/plug Identifies a port or plug as meeting the generic requirements of the Universal Serial Bus (USB). Symbol applies only to Accuryn Monitors with Serial Numbers beginning with "P". ISO 7000-3650
	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed: temperatures between -18ºC to 60ºC. ISO 7000-0632
	Humidity Limitation Indicates the range of humidity to which the medical device can be safely exposed: range of humidity between 15% and 90%. ISO 7000-2620

	Atmospheric Pressure Limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed: range of atmospheric pressure from 81 kPa to 101 kPa. ISO 7000-2621
	Keep Dry Indicates the device needs to be protected from moisture. ISO 7000-0626
	Fragile, Handle with Care Indicates the device can be broken or damaged if not handled carefully. ISO 7000-0621
	Do Not Use if Package is Damaged and Consult Instructions for Use Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. ISO 7000-2606
	Non-Sterile Indicates the device has not been subjected to a sterilization process. ISO 7000-2609
	Positive Polarity Indicates that the center (tip) of the output plug is Positive (+) and the barrel (ring) of the output plug is Negative (-). IEC 60417-5926
INPUT: 18VDC	Power supply specific Indicates that only power supply cable provided with the Monitor can be used to provide power to the Monitor.
	Power ON/OFF Press this button to turn the Monitor on and off. IEC 60417-5009
	Waste, and Li-ion Battery inside Indicates that unit cannot be thrown away, and that there is a lithium-ion battery inside. Return unit to manufacturer for disposal. BS EN 50419, ISO 60417-1135
Temperature pass-thru connector	Temperature pass-thru connector Plug the temperature pass-through connector into this port. Symbol applies only to Accuryn Monitors with Serial Numbers beginning with "E" or a numerical value.
	Temperature pass-thru connector Plug the temperature pass-through connector into this port. Symbol applies only to Accuryn Monitors with Serial Numbers beginning with "P".

	Thermistor Input Port Plug the thermistor cable into this port. Symbol applies only to Accuryn Monitors with Serial Numbers beginning with "P".
	Serial Number Indicates serial number of the Accuryn Monitor. ISO 7000-2498
	Lot Number (Batch code) Indicates lot number of the Accuryn Urinary Catheter Kit. ISO 7000-2492
	Catalog Number Indicates the model number of the Kit or the Monitor. ISO 7000-2493
	Rx Only Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner). 21 CFR Part 801 § 801.109(b)(1)
	MR Unsafe Indicates that a component may be hazardous if introduced into magnetic resonance (MR) environments. ASTM F 2503
	MR Conditional Indicates that the device may be introduced into magnetic resonance (MR) environments under certain conditions. ASTM F 2503
	Keep away from sunlight Indicates the device needs protection from light sources. ISO 7000-0624
	Do Not Re-Use Indicates the device is intended for one use ISO 7000-1051
	Do Not Resterilize Indicates that the device must not be resterilized. ISO 7000-2608
	Sterilized using Ethylene Oxide Indicates that the device has been sterilized using ethylene oxide. ISO 60417-2501
	Single sterile barrier system Indicates a single sterile barrier system. ISO 7000-3707
	Use-By date Indicates the use-by date. ISO 7000-2607

	Date of manufacture Indicates the date when the medical device was manufactured. ISO 7000-2497
	Country of manufacture To identify the country of manufacture of products. ISO 60417-6049
	Manufacturer Indicates the manufacturer of the device. ISO 7000-3082
	Medical device Indicates the item is a medical device.
	Unique device identifier Indicates a carrier that contains unique device identifier information.
IP22	Protection against solid particle Indicates that the Monitor is protected against object size of >12.5 mm. Protection against ingress of liquid Indicates that the Monitor is protected against dripping water when tilted up to 15°. IEC60529
	Distributor To indicate the entity distributing the medical device into the locale. ISO 7000-3724
	Coin cell; coin battery To provide information on packaging that it contains a small round cell or battery where the overall height is less than the diameter, and which contains non-aqueous electrolyte, for example a lithium cell or battery. IEC 60417-6367
	Do not use power supply with damaged plug To indicate that the power supply unit shall not be used, if pins of the plug part are damaged. IEC 60417-6352
	Maximum altitude To indicate that the appliance is intended to be usable up to the maximum altitude 2,000 m. IEC 60417-6343

Background

Operator Manual Scope

This manual covers the function and proper use of the Accuryn Monitoring System. The Accuryn Monitoring System refers to the combined use of the Accuryn Monitor and the Accuryn Urinary Catheter Kit. **NOTE: The Catheter Kit has its own accompanying instructions for use, which is found inside the Kit assembly.** Both IFUs must be referenced for proper usage of the Accuryn Monitoring System.

Definitions

Accuryn Monitoring System	Combined usage of the Accuryn Monitor with the Accuryn Urinary Catheter Kit.
Accuryn Monitor	Portable electronic device which, when used with the Accuryn Urinary Catheter Kit, measures urine output (U/O or UO), core body temperature (Temp), and intra-abdominal pressure (IAP).
Accuryn Urinary Catheter Kit	Disposable, single-use, sterile kit consisting of the Accuryn Sensing Urinary Catheter, the Accuryn Insertion Kit, and the Accuryn Urine Collection Set. The Kit has been sterilized using Ethylene Oxide (EO).
Accuryn Sensing Urinary Catheter – U/O, Temp, IAP	Urinary catheter with lumens for urine drainage, retention balloon inflation/deflation, balloon pressure measurement, and temperature measurement. Provided permanently connected to the Accuryn Urine Collection Set. Includes temperature cable, which can connect to the Accuryn Monitor using the Accuryn Temperature Cable. The catheter (applied part) comes into physical contact with the patient and is connected to the Monitor to perform its function.

Accuryn Sensing Urinary Catheter – U/O, Temp	An alternative Catheter that connects to the Urine Collection Set and is compatible with the Accuryn Monitor. The U/O, Temp Catheter contains the same functionality as the U/O, Temp, IAP Catheter without balloon pressure measurement functionality.
Accuryn Foley Adapter (formerly "SmartCath")	A universal adapter to any Foley catheter from 6Fr to 24Fr. The Accuryn Foley Adapter is an Accuryn disposable with no Foley catheter or thermistor.
Accuryn Temperature Cable	A reusable 75in cable with standard 2-pin temperature connector that connects the Accuryn Sensing Urinary Catheter directly to the Accuryn Monitor.
Accuryn Temperature Cable Adapter	A reusable short cable adapter that adapts Foleys with 3.5mm round connectors to Accuryn Temperature Cable.
Accuryn Insertion Kit	Off-the-shelf components intended to facilitate placement of the Accuryn Sensing Urinary Catheter.
Accuryn Urine Collection Set	Urine collection system comprised of a drainage tube, measurement cassette, and urine collection bag. Provided permanently connected to the Accuryn Sensing Urinary Catheter. An indicator for "U/O, Temp" or "U/O, Temp, IAP" is provided on the cassette.
AccuTab	Medically rated tablet, running Windows 10 Professional in kiosk mode, which connects to the Accuryn Monitor via USB cable and runs AccuData.
AccuData	AccuData is a software application that displays the data generated by the Accuryn Monitor.

Overview

Intended Use

The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System with the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for short term use (less than 30 days).

Functional Description

The Accuryn Monitor is a standalone monitoring unit and includes a power supply. The use of the Monitor is restricted to one patient at a time and is to be used exclusively with the Accuryn Urinary Catheter Kit. The two components together are known as the Accuryn Monitoring System.

The Accuryn Sensing Urinary Catheter is a single use device intended for short term use (less than 30 days). The Accuryn Sensing Urinary Catheter drains urine from the patient's bladder into the drainage tube and finally the measurement cassette of the Urine Collection Set, which is placed into a cassette interface on the Monitor. The Monitor clears airlocks in the drainage tube on a time interval and measures urine output volume and rate. When the cassette is full, the Monitor activates a pinch valve to empty the urine from the cassette into the urine collection bag. A thermistor is incorporated into the catheter. Connecting the thermistor to the Accuryn Monitor using the Temperature Cable allows for continuous temperature measurement. Temperature is sampled once per minute in direct mode (i.e. the output temperature is an unadjusted temperature that represents the temperature of the bladder, which corresponds to core body temperature). The Monitor can also detect IAP via a small balloon located at the end of the catheter (when used with the Accuryn Urinary Catheter Kit - U/O, Temp, IAP).

The Accuryn System is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator. The Monitor stays in the current operating mode without loss of any stored data. The Accuryn System has no electrodes or transducers and therefore the hazards of burns are not expected from our system.

Contraindications

This device is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

Patient Risks

Per FDA Guidance, general urological catheters for short-term use (<30 days) are considered non-significant risk (NSR) devices. The device is not intended as an implant, nor is it purported or represented to be for use supporting or sustaining human life, nor is it of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health.

The Accuryn Urinary Sensing Catheter Kit is single use only. It has not been tested or designed for cleaning and re-sterilization.

The potential risks associated with using or re-using this device are:

- urinary tract infection
- systemic infection
- peritonitis
- urinary retention
- bladder perforation/tear/rupture/injury
- urethral perforation/tear/rupture/injury
- renal dysfunction
- skin infection
- skin irritation
- hypothermia
- hyperthermia
- elevated intra-abdominal pressure
- dehydration
- fluid overload
- allergic reaction
- electrical injury
- body trauma due to fall
- prostatic injury
- intestinal injury
- pressure ulcer

Warnings

WARNING: No modification of any kind is allowed for this equipment. Do not attempt to open, repair, or modify the unit or replace broken parts. Attempting to do so could result in bodily injury or harm. If the unit or any parts are not working, please contact Potrero Medical Customer Service at +1-833-ACCURYN (1-833-222-8796). Repairs should only be made by Potrero Medical trained personnel. The Accuryn Monitoring System has no serviceable parts.

Do not touch connector ports and the patient simultaneously. Doing so could result in bodily injury or harm to you and/or the patient.

Avoid contact between Monitor and water and/or fluids. Do not immerse or submerge Monitor in water and/or fluids.

A hazard can exist if different alarm presets are used for the same or similar equipment in any single clinical area, e.g. an intensive care unit (ICU) or a cardiac operating theatre.

Connection of the Accuryn Monitor to a network/data coupling that includes other equipment could result in previously unidentified risks to patients or operators. The responsible organization (hospital, clinic, etc.) should identify, analyze, and control such risks. Subsequent changes to the EMR system may introduce new risks (i.e. no longer compatible with Accuryn Monitor, cannot write data to EMR system) and may require a new analysis. Changes to the EMR system include configuration, connection of additional items to the EMR system, disconnecting items from EMR, update of equipment connected to EMR, and upgrade of equipment connected to the EMR system.

Do not steam autoclave, EO sterilize, immerse the Monitor, or allow fluids to enter the housing.

Do not spray fluids directly into the Monitor, especially into any connector.

Accuryn Monitor is MR unsafe. Do not take the Monitor into an MRI unit. (However, Accuryn Urinary Catheter Kit is MR conditional. Follow guidance in "MRI Safety Information" section in this manual and in Catheter Kit IFU).

Use the cables and accessories provided with the Accuryn system to provide protection against the effect of the discharge of a cardiac defibrillator.

Do not use Monitor with a multiple socket system.

The Monitor uses a Lithium-ion battery. Leakage of the Lithium-ion batteries can occur. Discontinue use if leakage occurs.

Cautions

The Accuryn Monitoring System, along with any accessory mounting option, must always remain below the level of the patient's bladder. Do not raise the Accuryn Monitor above the level of the patient's bladder.

Proper protocols for whether a urinary drainage catheter should be placed should be followed. Proper aseptic procedure for inserting a urinary drainage catheter should be followed to prevent infection.

The Accuryn Monitor requires special precautions regarding electromagnetic compatibility. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Potrero Medical as replacement parts for internal components, may result in increased emissions or decreased immunity of the Accuryn Monitor or the Accuryn Monitoring System.

The Accuryn Monitor or the Accuryn Monitoring System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Accuryn Monitor or the Accuryn Monitoring System should be observed to verify normal operation in the configuration in which it will be used.

Handle the Accuryn Monitor carefully. Do not drop.

Only plug cables provided with the Monitor into the power and temperature port. Only plug thermistor cable on Accuryn Urine Collection Set or the reusable Temperature Cable into the thermistor port on the top front of the Monitor. Attempting to plug in non-approved cables or devices may compromise the function of the Monitor or the external device.

As with all temperature probes, in the presence of RF energy sources, local heating, temperature errors, and probe damage may occur.

Do not excessively tilt the Monitor. Do not invert the Monitor during cleaning.

Unplug 18V Power Supply and USB Type B cable before moving the Monitor. Failure to do so could damage the cord, the Monitor, or the external device(s) to which the Monitor is attached.

During cleaning, do not use strong solvents such as acetone or trichloroethylene and do not use abrasive materials (such as steel wool or silver polish).

When connected to the Accuryn Sensing Urinary Catheter – U/O, Temp, IAP, readings for IAP are affected by patient positioning, breathing and movement. IAP values may not be clinically relevant if patient is not supine. Patients with elevated head of the bed will exhibit higher IAP. Refer to the Setup and Operation instructions for measuring IAP.

Do not position the Monitor so that it is difficult to disconnect the 18V Power Supply from the Monitor.

Cybersecurity and Network

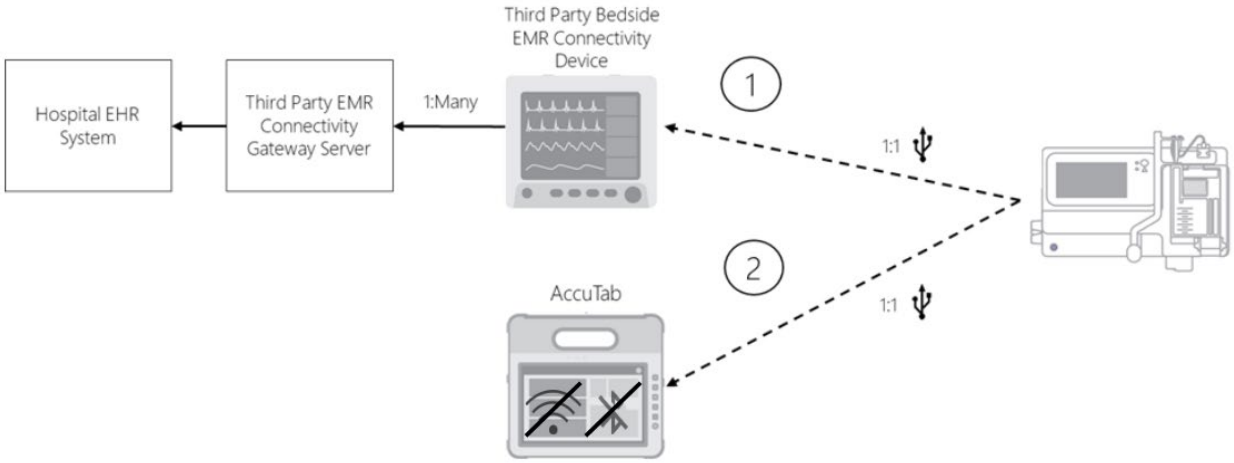


Diagram 1: Optional Monitor Connections Overview

The above diagram illustrates the optional Accuryn Monitoring System external communication connections to the (1) institution's EMR system or (2) the AccuTab tablet. The Accuryn Monitor can support one USB Type B connection at any given time. For an EMR system connection, the Monitor is connected to a third party EMR integration hardware and software via a wired USB Type B connection. For an AccuTab connection, the Monitor is directly connected to the AccuTab through a wired USB connection.

Security of the Accuryn Monitoring System is a shared responsibility between Potrero Medical and the hospital. Hospitals are responsible for establishing controls to protect network and networked devices and should adhere to the following general cybersecurity best practices (which are not meant to be an exhaustive list) to maintain the hospital's overall security posture:

- Prevent unauthorized physical access to medical devices or network access points at the hospital site
- When connecting the Accuryn Monitor to a networked device such as a third-party bedside EMR connectivity device, ensure the network is secure with protections against viruses (e.g., firewall, virus scanners, etc.)

Accuryn Monitor and AccuTab product security information:

- The Monitor does not have any networking or wireless hardware.
- The Monitor serial port is configured such that a connecting device must have the custom Potrero Medical driver installed.

- No PII or PHI data is saved to the Monitor.
- Data stored on the Monitor and AccuTab is encrypted using AES-256.
- Network connectivity (Wi-Fi/Bluetooth/Ethernet) for AccuTab is deactivated by default.
- The AccuTab operates in kiosk mode where the user is limited to the main application only.
- The AccuTab has a separate Administrator login that requires a password unique to each device, which is controlled by Potrero Medical personnel only.
- Any upgrades or servicing activities are performed by Potrero Medical personnel only.
- User or third-party updates can only be performed manually by Potrero Medical personnel.
- All software for the Monitor and AccuTab is completely built and integrated by Potrero Medical.

If a cybersecurity event is detected or suspected, disconnect the Accuryn Monitor, AccuTab, and any EMR middleware connection. Contact Potrero Medical Customer Support at cs@potreromed.com or +1-833-ACCURYN (1-833-222-8796).

Contact Potrero Medical Customer Service for additional information on EMR compatible characteristics and set up at +1 833 ACCURYN (1-833-222-8796) or online: www.potreromed.com.

Package Contents

Each Accuryn® Monitor package contains:

1 Accuryn® Monitor
1 18V Power Supply
1 Maintenance Kit

Monitor Features

M1. Touch screen display
M2. Error Indicator Light
M3. Power Indicator Light
M4. Power Button
M5. Temperature Port
M6. Cassette Interface
M7. Mounting Interface
M8. Urine Collection Bag Hook
M9. Temperature Pass-through Connector
M10. Power Connector
M11. USB Type B Connector
M12. Cassette Ports
M13. Pinch Valve

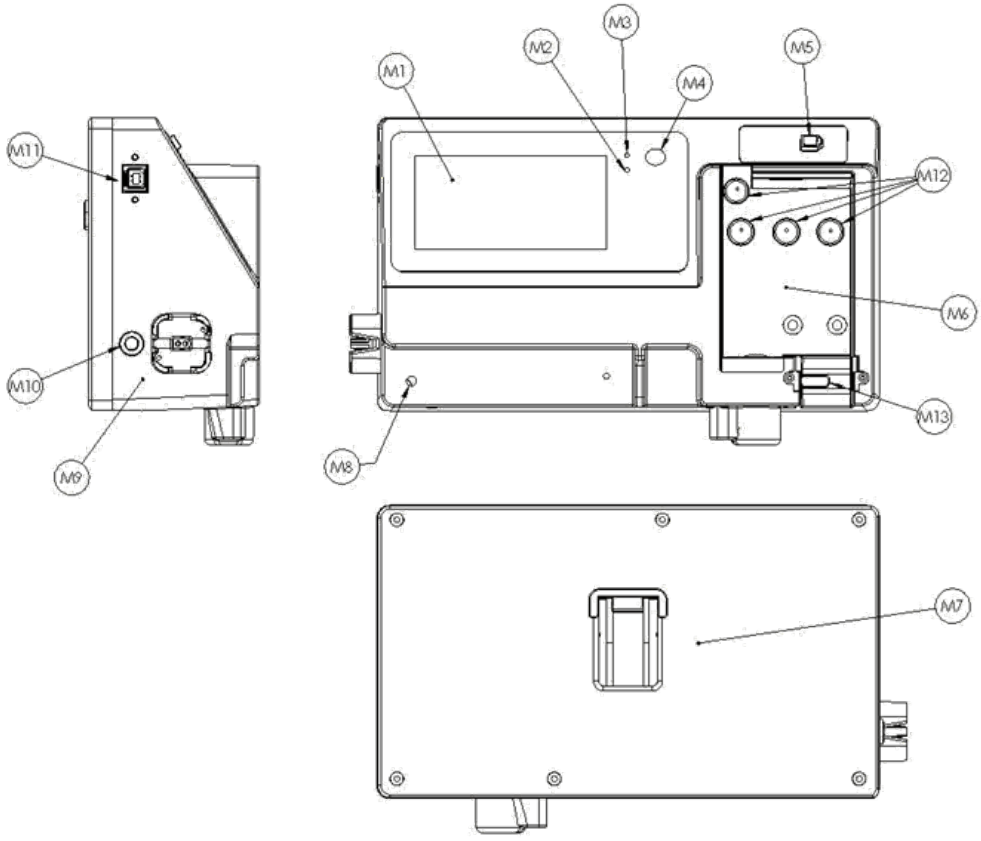


Figure 1 Accuryn Monitor Diagram

Referenced Features in Urinary Catheter Kit

D1. Accuryn Sensing Balloon (only with U/O, Temp, IAP Catheter)
D2. Urine drainage holes
D3. Retention Balloon
D4. Retention Balloon Valve
D5. Sampling Port
D6. Drainage Tubing
D7. Thermistor Plug
D8. Measurement Cassette
D9. Hanger Notch
D10. Monitor Eyelets
D11. Urine Collection Bag
D12. Drainage Bag Valve
D13. Drainage Bag Hanger

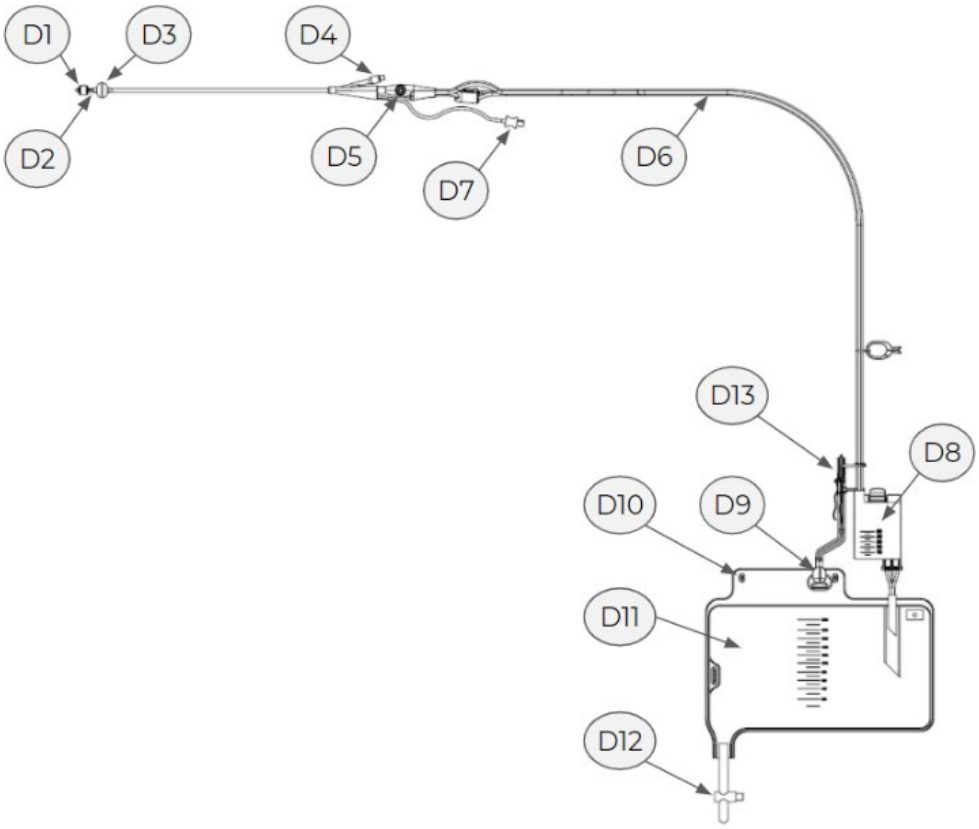


Figure 2 Accuryn Sensing Urinary Catheter and Urine Collection Set Assembly

Referenced Features in Reusable Temperature Cable

T1. Foley Connector End (white)
T2. Accuryn Monitor Connector End (purple)

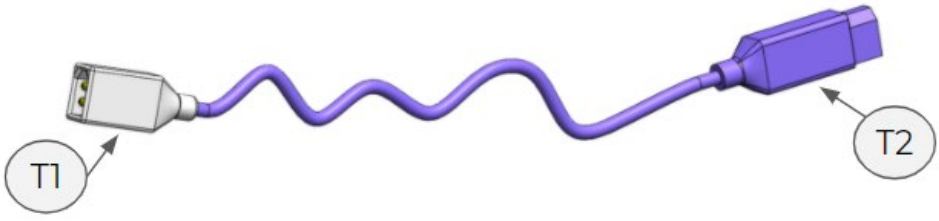


Figure 3 Reusable Temperature Cable

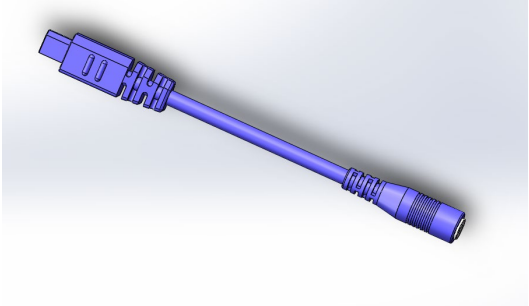


Figure 3a Temperature Cable Adapter

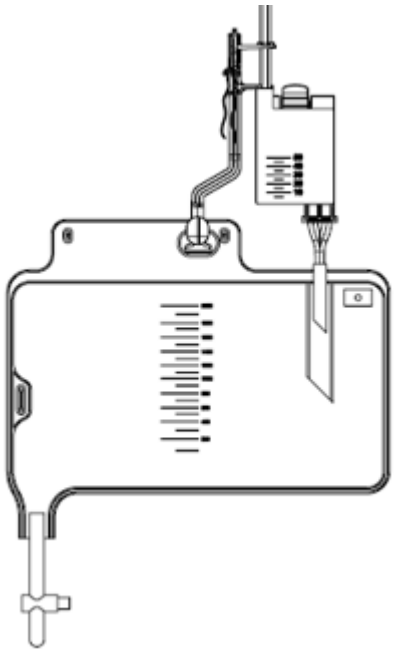


Figure 4 Drainage Bag and Hanger (use when not connected to Monitor)

Figure 5 18V Power Supply that attaches to Power Connector M10 in Figure 1

Setup and Operation

Setup

The Monitor should be mounted on an appropriate Accuryn mount obtained from Potrero Medical. The operator may stand by the Monitor while powering up or changing settings on the device, but for normal use the operator does not need to remain next to the device. The Monitor runs on either wall power or internal battery. Interruption of wall power exceeding 30 seconds is not an issue since the Monitor will switch to internal battery power.

1. Set up the Accuryn Sensing Urinary Catheter according to the IFU packaged with the Accuryn Urinary Catheter Kit.
2. Ensure that the Drainage Tubing (D6) extends from the catheter to the Measurement Cassette (D8) in a smooth, unkinked path.
3. Mount the Monitor by aligning the provided Accuryn Mount with the Mounting Interface (M7). Firmly push down on the Monitor for a press-fit.
4. Connect the Monitor to wall power via the provided 18V Power Supply and the Power Connector (M10). Make sure to secure the plug by tightening the screw casing, otherwise the electrical connection could be compromised. Verify that the AC cable is fully inserted into the 18V Power Supply brick.
5. Attach the Cassette (D8) to the Cassette Interface (M6) on the Monitor, as depicted in the lower right panel of Figure 6. Ensure that the latch on top of the cassette engages with the Monitor.

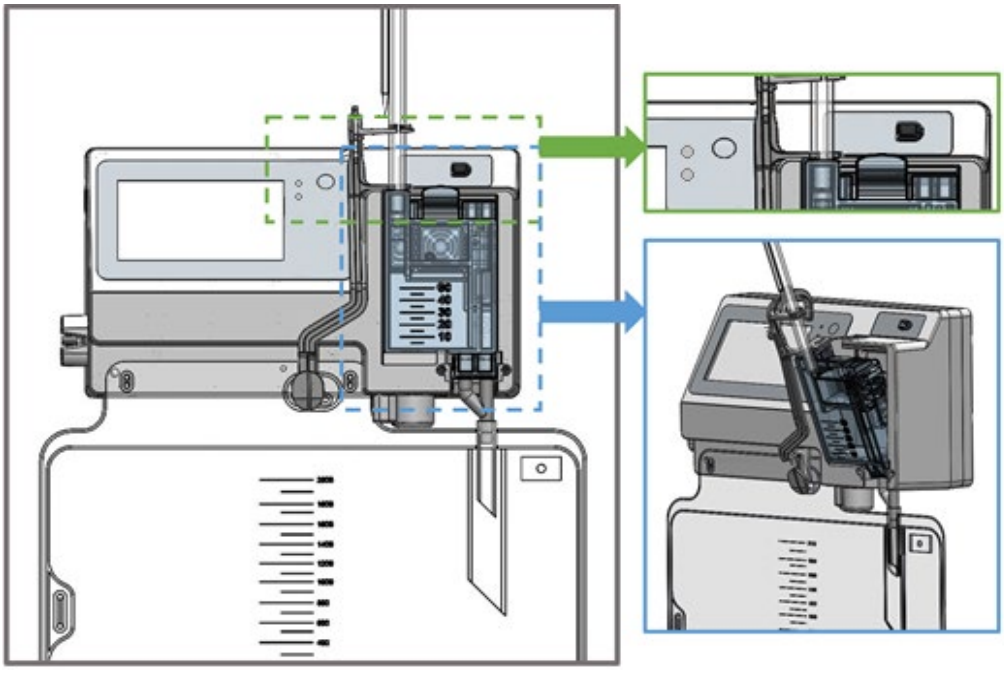


Figure 6 Monitor Setup Diagram

6. Hang urine collection bag on the Bag Hook (M8) as depicted in the left panel of Figure 6. Ensure that the bag hangs freely.
7. Connect the Temperature Connector (D7) to the Foley Connector Side of the Temperature Cable (T1), then connect the Monitor Connector Side of the Temperature Cable (T2) to the Temperature Port (M5) as depicted in the top right panel of Figure 6.
8. If using a third-party Foley with a round 3.5mm temperature connector, use the Accuryn Temperature Cable Adapter (Figure 3a) to adapt this Foley to the Accuryn Temperature Cable.

External Overhead Monitor

If desired, connect the institution's overhead monitor to the Temperature Pass-through connector on the side of the Monitor.

Electronic Medical Record (EMR) System Connection

If desired, connect a USB Type B cable to the port labeled "Type B" on the side of the Accuryn Monitor. Connect the opposite end of the USB Type B cable to the institution's EMR system. Contact Potrero Medical regarding EMR system set up.

The Accuryn Monitor is EMR-capable. Contact Potrero Medical for additional information on EMR compatible characteristics and set up.

Operation

To Turn on Monitor

Press the Power Button (M4). The display screen will turn on and the Power Indicator Light (M3) will illuminate.

If the monitor is turned on within 8 hours after being used previously, it will prompt the operator to choose if the monitor will be used on a NEW PATIENT or SAME PATIENT. If NEW PATIENT is chosen, the monitor will proceed to the Patient Settings screen. If SAME PATIENT is chosen, the monitor will confirm the last patient connected to the monitor by asking the operator to confirm the MRN number and/or the last time the monitor was connected to the same patient.

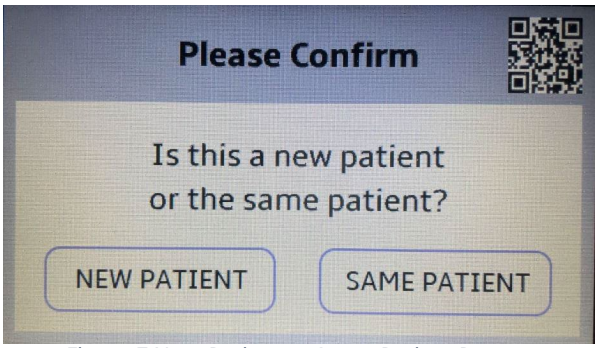


Figure 7 New Patient or Same Patient Prompt

Patient Identification Prompt

The Patient Settings screen allows the operator to enter patient identification information: patient weight (in kg), KDIGO setting (in mL/kg/hr) and medical record number (MRN). To complete this:

1. The Patient Settings menu can be accessed from the Home Screen by tapping the Settings button (gear) in the right column of the screen.
2. Tap on "WEIGHT (kg)" to enter the patient's weight. Tap the green checkmark to lock in the patient's weight.
3. If "KDIGO LINE" is not already selected as demarcated by a box around "KDIGO LINE", tap "KDIGO LINE" to enter the desired KDIGO urine output per weight per hour threshold value to be drawn on the UO graphs. The default is 0.5 ml/kg/hr. NOTE: This value will only determine the horizontal line drawn on the UO graph as a visual aid and will not change the values used to determine AKI Staging. A popup will appear after saving a non-default KDIGO Line value to instruct the user that this value will not change AKI Staging Criteria.
4. If "PATIENT MRN" is not already selected as demarcated by a box around "PATIENT MRN", tap on "PATIENT MRN".
5. Use the keypad to enter the patient's MRN. If a mistake is entered, use the yellow back arrow to delete the last entry. When complete, tap the green checkmark to "lock in" the patient's MRN (the entered number will turn from red to green).
6. Tap the right arrow button in the top right corner to proceed to the Monitor Settings screen. Alternatively, tap on the Home button in the top left to navigate to the Home screen. NOTE: The home and right arrow buttons will not be accessible if the entries have not been saved (by tapping on the checkmark).

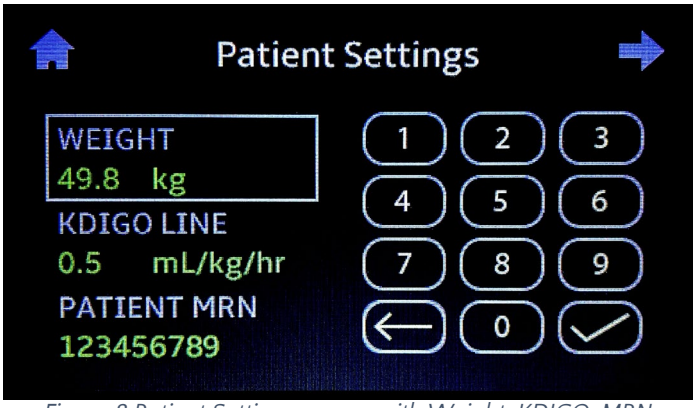


Figure 8 Patient Settings screen with Weight, KDIGO, MRN

Changing Monitor Settings

Settings for Total or Hourly Urine Output (UO), time, screen brightness and Global Mute may be changed.

1. From the Home screen, tap the Settings symbol. Then, tap the right arrow button in the top right corner once to navigate to the "Monitor Settings" screen.

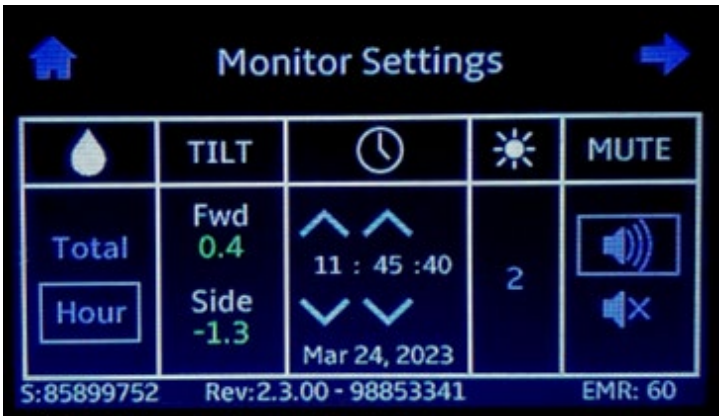


Figure 9 Monitor Settings screen

2. Tap the UO droplet symbol to change the main UO display between Total and Hourly. The Total UO will display the total volume of urine measured since the Total UO setting was reset. The Hourly UO will display the current hour UO measurement.
3. TILT will display the current tilt axis of the monitor in respect to gravity. Adjust the monitor tilt until both "Fwd" and "Side" change to green and are as near to zero as possible.
4. To set the time: tap the Up and Down arrows to change the hour and minute of the time.
5. To set brightness: tap the digit under the sun symbol. You may scroll through settings 1 through 5 to adjust the brightness.
6. To set Global Mute: tap the speaker symbol to allow audio alerts. Tap the speaker with an "X" symbol to mute ALL audio alerts. If Global Mute is chosen, alert messages will continue to be displayed on the screen, but all audio will be disabled. The Global Mute selection will be reflected on the Home screen, as the speaker symbol with an "X" in the lower right. If the Monitor is rebooted and Global Mute had previously been engaged (audio was disabled), a popup will appear asking the user whether the audio should now be enabled or not (See Figure 10).
7. Global Mute can be turned off from the Monitor Settings screen, or from the Home screen by tapping on the speaker symbol on the bottom right.

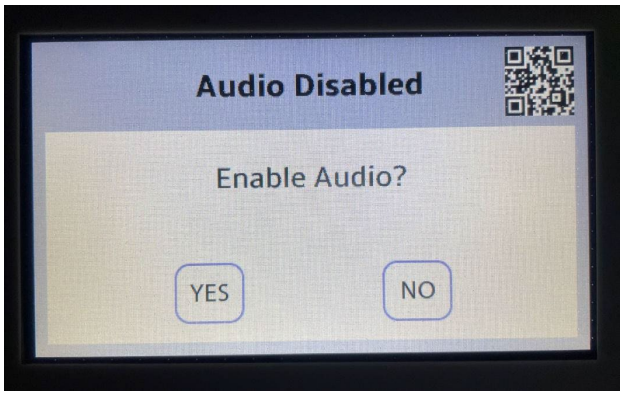


Figure 10 Global Mute Quick Prompt

8. A Temporary Mute is also available if the Global Mute is not set. The Temporary Mute can be accessed by tapping the speaker icon on the Home screen and selecting the desired time interval for the Temporary Mute. Once a time interval is selected, the remaining time will be shown on the Home screen under the triangle icon. The Temporary Mute can be turned off by tapping on the speaker icon on the Home screen and then tapping Enable.

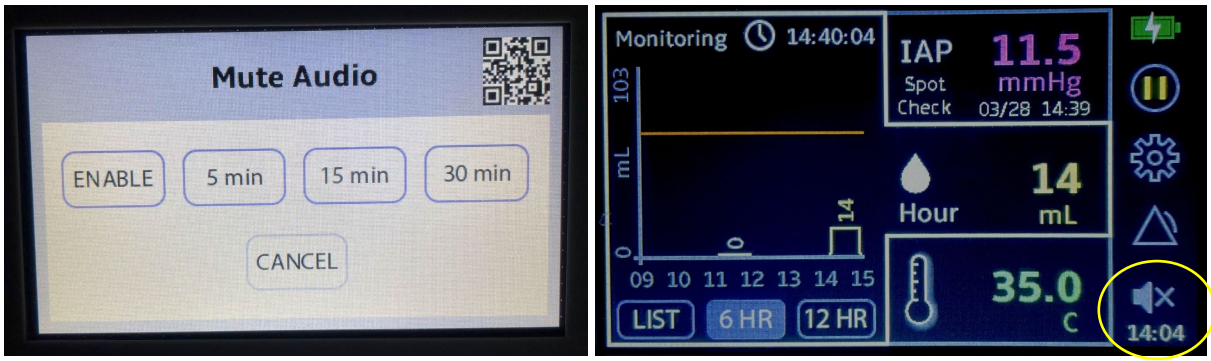


Figure 11 Temporary Mute Menu and Home Screen with Temporary Mute countdown

Programming Alarm Settings for Temperature, IAP, and Urine Output

The Accuryn Monitor is designed to alarm the operator to abnormal IAP, urine output, and temperature readings, as defined by an acceptable range set by the operator. If any value falls outside its associated range, the system will alert the operator with visual and auditory cues. If the ranges are not defined by the operator, manufacturer's default values will be used:

Table 1 Default Alert Settings

	State	Low Alert	High Alert
Temperature	Enabled	35° C	38° C
IAP	Enabled	--	19 mmHg
Urine Output Rate	Enabled	15 mL/hr	2000 mL/hr
AKI	Enabled	N/A	

Note: The Accuryn monitor can also notify the operator if the patient meets Acute Kidney Injury (AKI) conditions as defined by KDIGO UO guidelines. AKI Staging Status is Non-Device Clinical Decision Support (CDS) software. There are no user-configurable low/high settings for AKI notifications, but AKI notifications can be enabled/disabled in the same manner as UO/Temp/IAP alerts. See AKI Status section for more information.

Rationale for Default Alarm Settings

Temperature: The default temperature alarm levels are <=35 and >=38° C. Hypothermia is usually defined as a temperature at or below 35° C, and fever is generally defined as a temperature of 38° C or greater. Temperatures between these levels are generally considered to be within normal limits, however some patients may require tighter temperature boundaries, which can be managed by changing the device alert settings.

Intra-abdominal Pressure: There is no intra-abdominal pressure that is considered too low, and therefore there is no lower default alert setting. Pressures at or above 12mmHg are considered abnormal for a supine patient, however an upper boundary alert pressure of 15mmHg is solidly within the abnormal range and is a reasonable warning threshold. It should also be noted that the current guidelines recommend all patients in the ICU will be kept with the head of the bed at 30 degrees. A 30 degree elevation causes an average of 3.7mmHg IAP elevation up to a maximum of 4mmHg elevation, so the preset warning threshold will be placed at 19mmHg to take this practical measure of patient care into account. Users can set their own threshold based on patient positioning. If the UO, Temp Catheter is being used, no alert will sound.

Urine Output: Urine output at or below 15mL/hr is generally considered low. The definition of oliguria may be different for patients of different weights, however a lower boundary of 15mL should be relevant for nearly all patients. The Accuryn Monitor defaults to 2,000 mL/hr as the high alert. This is the highest UO rate setting on the Accuryn Monitor.

It is recommended that the alarm settings are kept at default ranges while monitoring patients that are not continuously attended by a clinical operator. However, alarm levels should be adjusted to particular clinical situations accordingly.

Every time the Monitor is powered off and restarted, the settings will revert to the default values.

There are minimum and maximum values below and above which the range limits cannot be set, as well as increments by which each bound can be changed. These are:

Table 2 Maximum and minimum alert settings

	Minimum	Maximum	Increment
Temperature	9° C	45° C	0.5° C
IAP	1 mmHg	50 mmHg	1 mmHg
Urine Output	0 mL/hr	2000 mL/hr	0-20 mL: Increment by 1 mL 20-100 mL: Increment by 5 mL 100-1000 mL: Increment by 10 mL 1000-2000 mL: Increment by 100 mL

Changing the Alarm Settings

1. The Alert Settings menu can be accessed from the Home Screen by tapping the triangle button in the right column of the screen.

2. Select a value you would like to change by pressing the number. If the value is selected, a box will surround the number.

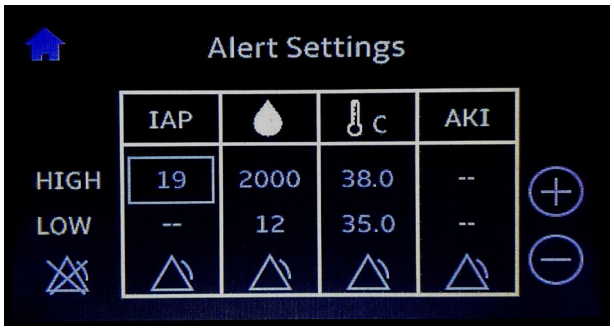


Figure 12 Alert Settings screen

3. Use the "plus" and "minus" keys on the right side of the screen to either increase or decrease the number. Changes will be automatically saved.
4. To remove an alert sound, tap a triangle to toggle back and forth between audible alert and mute. The triangle image will be crossed out if an alert is removed (mute). If any alert sound is removed (muted), the triangle on the home screen will be crossed out.
5. When you are satisfied with your changes, tap the Home button in the top left corner.

Home Screen

Once in the Home Screen, the monitor will be in PAUSED mode. After 60 seconds of PAUSED mode, the monitor will automatically show the "Insert Cassette & Press Play" screen to remind the operator that the monitor will only begin monitoring once the Cassette is inserted and Play is pressed. The operator may cancel out of this screen if desired.

Figure 13 Screen indicating Monitor is PAUSED

Figure 14 Screen indicating Insert Cassette & Press Play

The Home screen depicts IAP, UO, and temperature values on the right side. On the left side, the screen shows a trend graph of the parameter which is selected. The water droplet symbol denotes urine output (choice of current hour mL or Total mL, which are chosen in Settings), and the thermometer symbol represents temperature. The graphed parameter can be changed by tapping once on the desired parameter. In addition, the time axis of the graph can be changed between 6 hours and 12 hours by tapping on the 6HR and 12HR buttons below the graph. For IAP, LIST will display the past 24 Spot Check IAP readings whereas for UO and temperature, LIST will display the past 24 hours of data at the top of each hour. The selected time axis is highlighted. The temperature unit of measure can be changed between degrees Celsius and Fahrenheit by tapping twice on the thermometer symbol. If the U/O, Temp Catheter is in use, the IAP parameter will display "- -" on the Monitor.

The Urine Output 6-hour and 12-hour graphs display a horizontal line at the KDIGO oliguria threshold (*0.5ml/kg/hr is the default. This threshold may be customized in the Patient Settings screen*). This KDIGO line is displayed ONLY if the patient weight has been entered into the Patient Settings screen.

The UO Box will display the patient's AKI Stage, if applicable, above the current hourly or total UO value as shown in Figure 15.

Figure 15 Home screen appearance with KDIGO line

Obtaining Temperature, Urine Output, and IAP Readings

Verify that setup instructions have been followed properly. Verify that the drainage tubing clamp has been released so that urine can flow. If any parameters are unable to be measured, "--" will display next to their symbol on the Home screen.

1. On the Home screen, press the green play button on the right side of the screen.
2. Message "Is Catheter in Bladder?" appears. Confirm that the catheter is in the bladder. Tap the YES button.

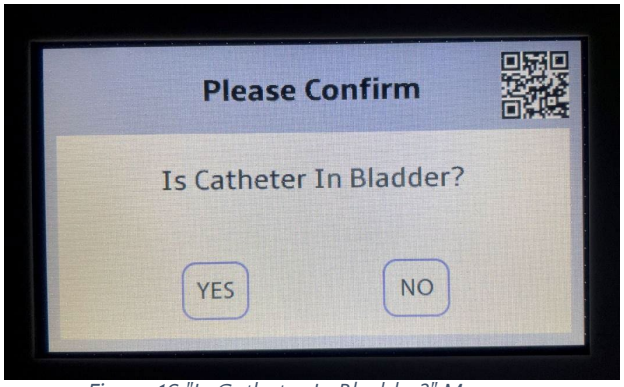


Figure 16 "Is Catheter In Bladder?" Message

3. After data collection has been initiated by pressing the play button (The word "Monitoring" will appear in top left of Home screen), the play button will turn into a yellow pause button. You may press the pause button to stop data collection ("Monitoring" will then be replaced with "PAUSED" in the top left corner).
4. Once the play button has been pressed and data collection has been initiated, both temperature and urine output will be displayed on the screen. Further action is required to obtain a Spot Check IAP reading. To obtain a Spot Check IAP reading (if using the U/O, Temp, IAP kit):

4.1. Tap on the IAP button twice. A message will pop up reading "Is patient supine and resting?" Verify that the patient is supine and resting, and then tap YES.

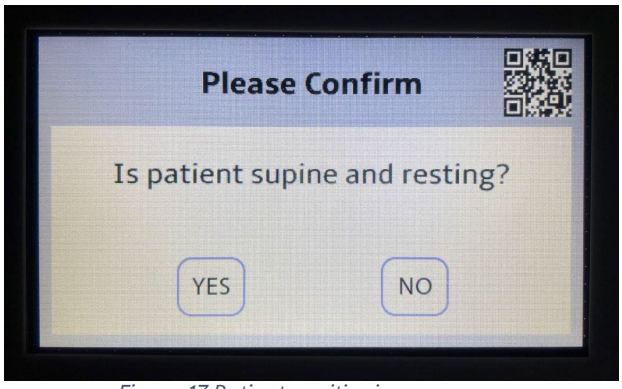


Figure 17 Patient positioning message

4.2. A rotating hourglass symbol will indicate that the system is measuring IAP. This will take approximately one minute. *Note*: This measurement can be canceled at any time by pressing on the hourglass and confirming the cancellation.
4.3. After obtaining a measurement, the system will prompt the operator to confirm the Spot Check IAP reading.

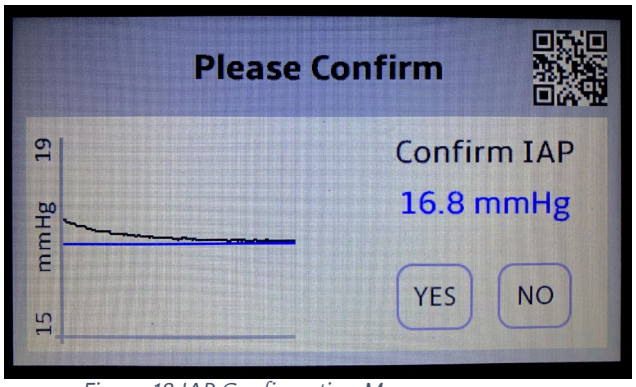


Figure 18 IAP Confirmation Message

4.4. Both "YES" and "NO" entries will make the message disappear. If "YES" is tapped, the measured IAP value will appear in the Spot Check IAP box with a timestamp of when that reading was measured. If "NO" is tapped, then this IAP reading will not be recorded.

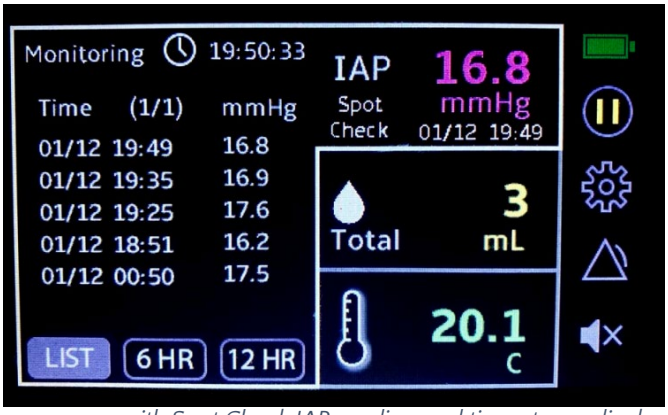


Figure 19 Home screen with Spot Check IAP reading and time stamp displayed

4.5. The IAP trend graph screen displays List, 6HR or 12 HR. The List button displays the past 24 Spot Check IAP readings. The 6HR and 12HR buttons display trending IAP over 6 hours or 12 hours. When pressing 6HR or 12HR, a Caution screen will appear: "Caution: Raised head of bed will increase IAP, Refer to IFU".

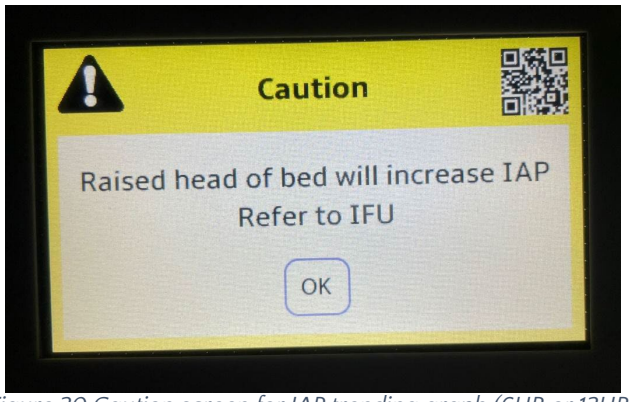


Figure 20 Caution screen for IAP trending graph (6HR or 12HR)

4.6. Once the OK button is pressed on the Caution screen, the appropriate trending IAP screen will be displayed. The Trending value currently being drawn on the graph will be labeled.

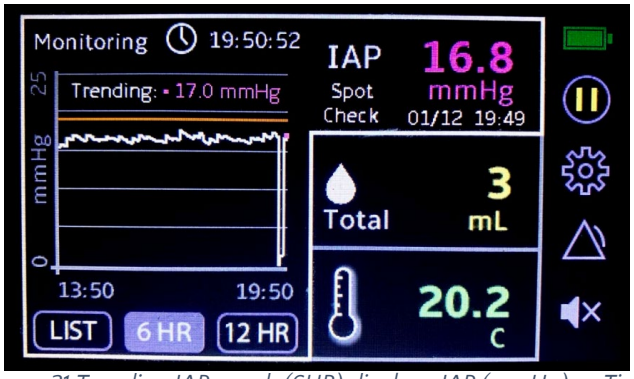


Figure 21 Trending IAP graph (6HR) displays IAP (mmHg) vs Time

4.7. If using the Accuryn Sensing Urinary Catheter - U/O, Temp model (without IAP) or the Accuryn Foley Adapter (without IAP), attempting to measure IAP will not yield a value.

4.8 NOTE: If more than 4 hours have elapsed since the last Spot Check IAP request, the Spot Check IAP value will not be shown in the IAP field anymore; instead, the IAP field will change to "- -" if the current Trending IAP value is below the user-configured IAP alert threshold, or it will flash "CHECK IAP/HIGH" if Trending IAP is above the alert threshold.

Draining the Urine Collection Bag

1. An alert message will appear on the screen when it is time to drain the urine collection bag (when it is getting too full).
2. Close the blue drainage tubing clamp and allow any fluid in tubing to drain into the measurement chamber. Empty the bag per hospital protocol. Open blue drainage tubing clamp to resume normal use. NOTE: the drainage spout on the bag slides back and forth to open and close.

UO Menu

Reset Total Urine Output Volume

1. Document Urine Output.
2. Tap "UO" Symbol until UO Menu is displayed.
3. Select "RESET".
4. Confirm message to reset the Total UO volume back to zero.

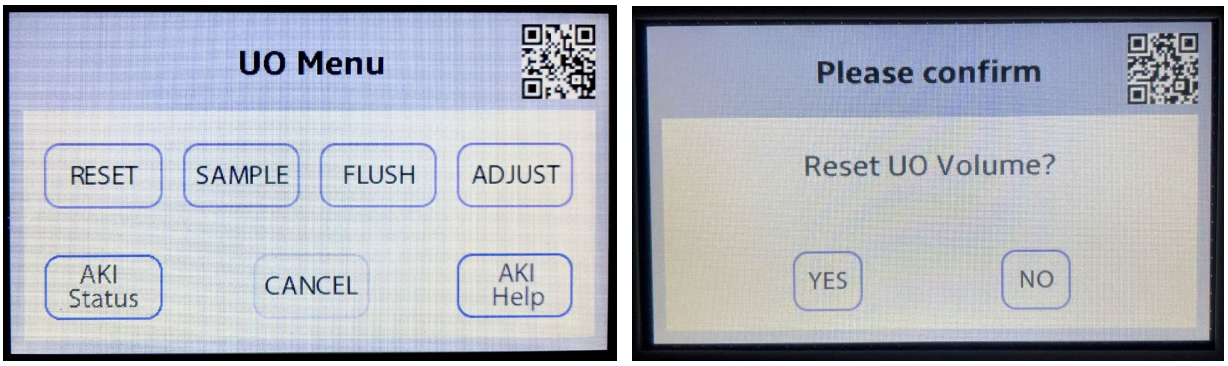


Figure 22 "UO Menu" and "Reset UO Volume?" message

Urine Sampling

1. Clamp the drainage line. Wait 1-2 minutes.
2. Swab surface of sampling port with antiseptic wipe.
3. Using aseptic technique, position a luer-lock syringe in the center of the sampling port. Press the syringe in firmly and twist gently to lock the syringe into the sampling port.
4. Aspirate desired volume of urine, then twist to disengage syringe from sampling port.
5. On the Monitor, tap the "UO" symbol. Select "SAMPLE" from the menu. Using the number pad, select volume of urine aspirated and then press the green check mark. Confirm on the next screen.
6. The urine output number will automatically be adjusted to account for the sample taken.

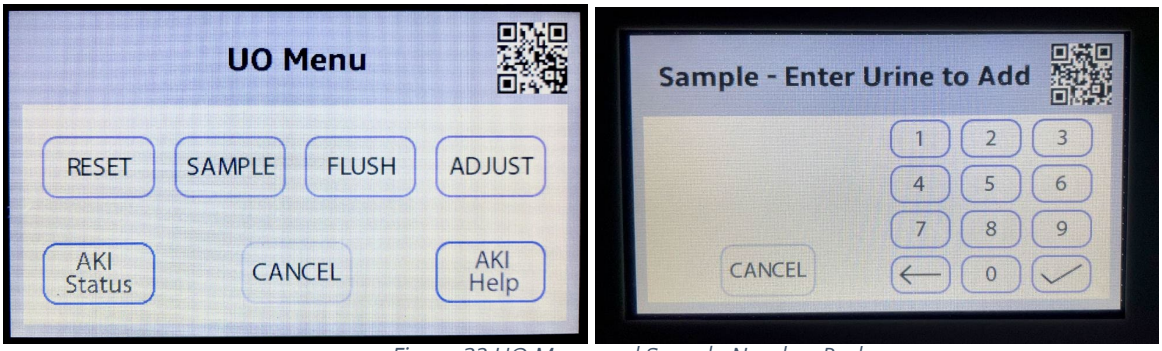


Figure 23 UO Menu and Sample Number Pad

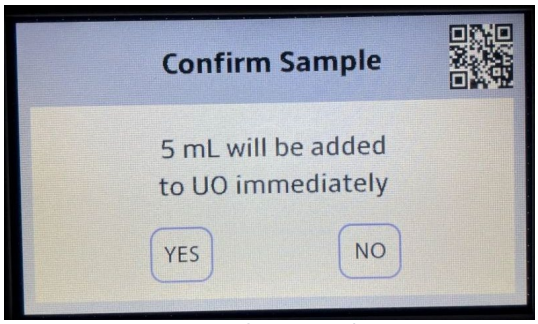


Figure 24 "Confirm Sample" screen

Flushing

1. On the monitor, tap the UO symbol. Select "FLUSH" from the menu.
2. Using the number pad, select volume of fluid that will be flushed and then press the green check mark. Confirm on the next screen.
3. If there is flush volume remaining from a previous flush, the amount of the flush remaining will be indicated on both the Flush Volume selection screen and the Flush Confirmation screen.
4. The UO box on the main screen will flash "FLUSH" until the flush volume remaining is accounted for.
5. Swab surface of Sampling Port (D5) with antiseptic wipe.
6. Using aseptic technique, position a luer-lock syringe in the center of the sampling port. Press the syringe in firmly and twist gently to lock the syringe into the sampling port.
7. Flush the catheter per facility protocol and disengage the syringe.

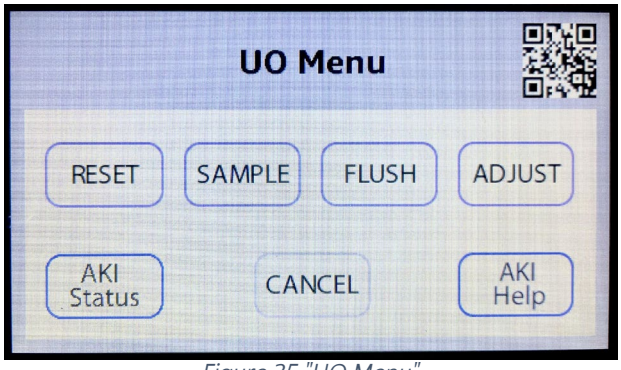


Figure 25 "UO Menu"

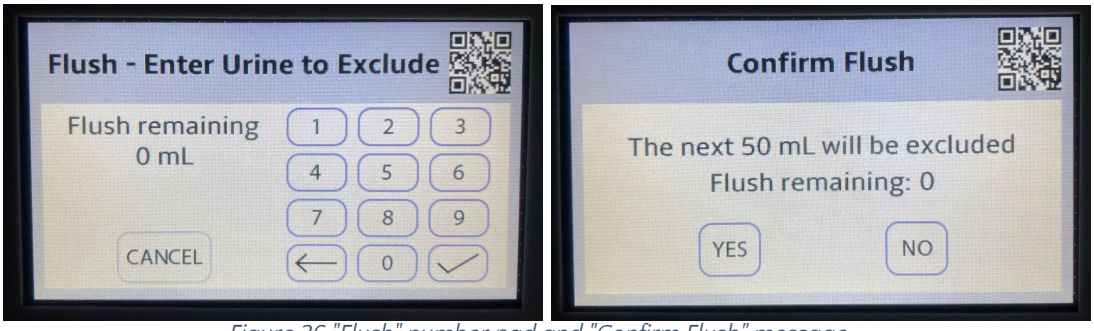


Figure 26 "Flush" number pad and "Confirm Flush" message

Adjust UO

In the instance where the operator needs to adjust the UO volume, tap the UO symbol. Choose "ADJUST". Using the number pad, adjust the urine output volume by the desired amount, and tap the green check mark.

NOTE: Adjust only adds to the urine output, there is not an option to subtract urine output.

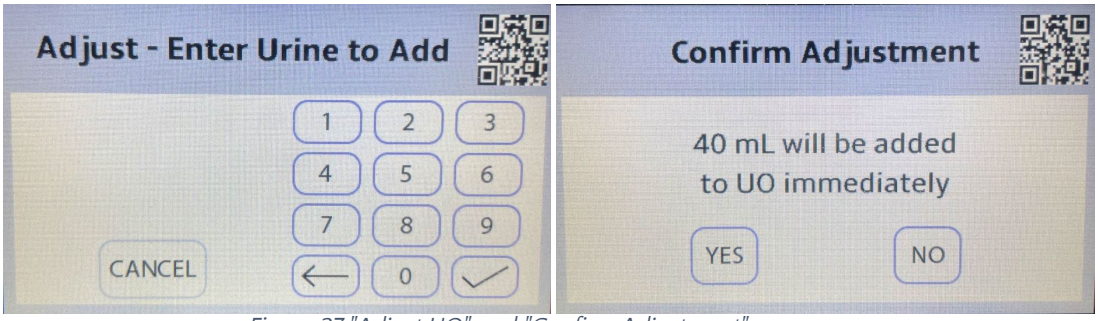


Figure 27 "Adjust UO" and "Confirm Adjustment" message

AKI Status

AKI Staging Status is considered Non-Device Clinical Decision Support software. It is provided for informational purposes only and for the purpose of supporting the user. It does not determine a patient's treatment or provide a definitive diagnosis of a patient's disease or condition. AKI Staging Status is shown for 6 hour, 12 hour, or 24 hour durations, correlating with the three AKI Stages per KDIGO Clinical Practice Guideline for Acute Kidney Injury[1] using the urine output criteria.

The value shown is a calculated weight-normalized urine output average (mL/kg/hr) over the stated time interval. The calculation requires sufficient urine output data for each time duration (e.g., enough time in Monitoring mode has elapsed) and for patient weight to be entered. The UO mL/kg/hr thresholds for AKI determination follow the KDIGO guidelines and can be accessed in the AKI Help screen (Figure 29).

To check the patient's AKI status, tap on the UO symbol to access the UO Menu screen and tap on the "AKI Status" button. This screen will provide the AKI Stage the patient is in if applicable, the relevant time period's total UO, the calculated weight-normalized urine output average (mL/kg/hr) if the patient's weight has been entered on the Patient Settings screen, and the amount of time the monitor has been paused in the relevant staging time if applicable. If the patient's weight has not yet been entered on the Patient Settings screen, the AKI Status screen will advise the user to enter the patient's weight. Figure 28 shows several variations of the AKI Notification that pops up when a

[1] Kellum, J. A., Lameire, N., Aspelin, P., Barsoum, R. S., Burdmann, E. A., Goldstein, S. L., Herzog, C. A., Joannidis, M., Kribben, A., Levey, A. S., MacLeod, A. M., Mehta, R. L., Murray, P. T., Naicker, S., Opal, S. M., Schaefer, F., Schetz, M., & Uchino, S. (2012). Kidney disease: Improving global outcomes (KDIGO) acute kidney injury work group. KDIGO clinical practice guideline for acute kidney injury. Kidney International Supplements, 2(1), 1-138. https://doi.org/10.1038/kisup.2012.1

patient has met the AKI Staging criteria. The AKI Status screen, when accessed through the UO Menu, will display the same information as the AKI notifications.

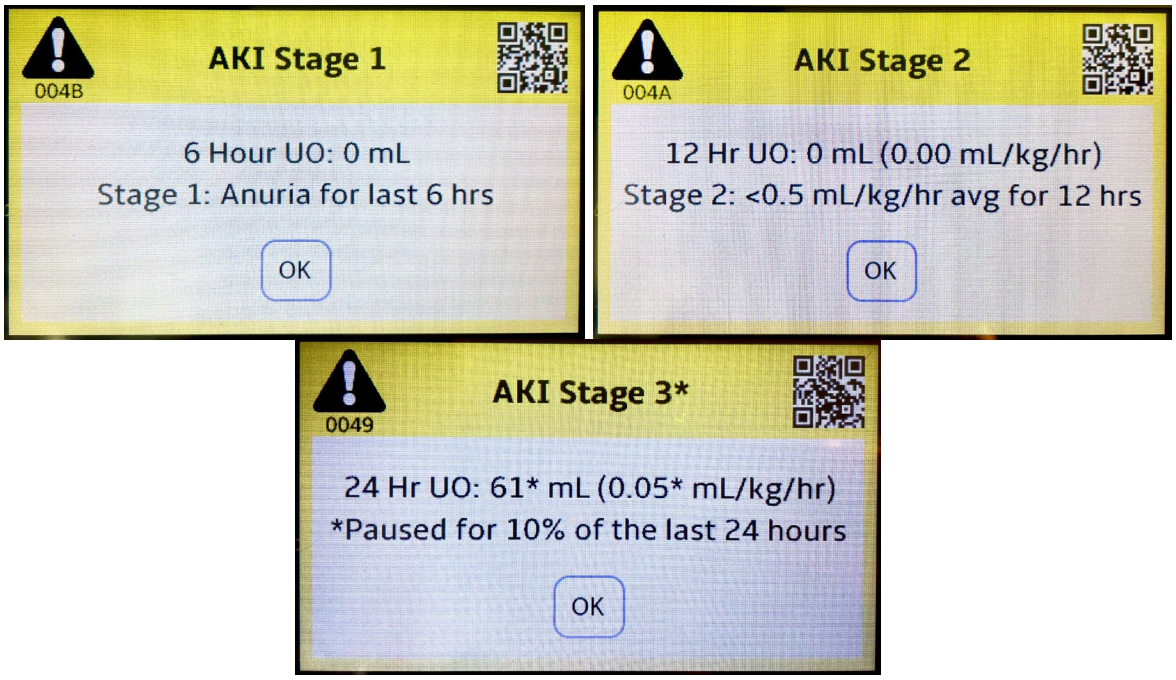


Figure 28 Variations of the AKI Status Notification

AKI Help

The AKI Staging Criteria used for determining the patient's AKI Status is defined in the AKI Help screen which is accessed through the UO Menu. The staging criteria follows KDIGO AKI guidelines for Urine Output.

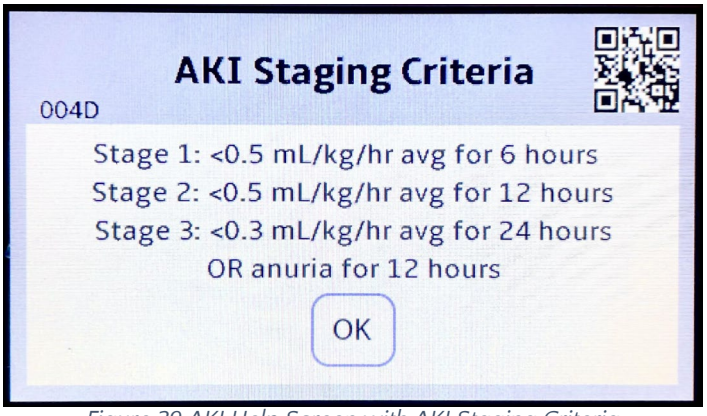


Figure 29 AKI Help Screen with AKI Staging Criteria

Additional details for AKI stage determination:

- If weight is not entered, Stage 1 can still be determined after 6 hours of anuria and Stage 3 can be determined after 12 hours of anuria, provided that minimum monitoring times have

been met (i.e., Accuryn was in Monitoring mode for at least 92% of the time interval in question).

- Non-anuric Stage 1 AKI determination requires a minimum of 6 hours since Monitoring began for the current patient, with at least 2 hours of time in Monitoring mode during the last 6 hours.
- Stage 2 AKI determination requires a minimum of 12 hours since Monitoring began for the current patient, with at least 8 hours of time in Monitoring mode during the last 12 hours.
- Non-anuric Stage 3 AKI determination requires a minimum of 24 hours since Monitoring began for the current patient, with at least 16 hours of time in Monitoring mode during the last 24 hours.
- If 6-Hour UO >= 0.5 mL/kg/hr, the 12-Hour and 24-Hour UO data is not evaluated for AKI.
- Entering a different value for the KDIGO Line field on the Accuryn Patient Settings screen does not affect the AKI stage determination. It will only change where the orange line is drawn on the UO graphs (on both Accuryn and AccuTab). If the Monitor was in Monitoring mode for less than 92% of any given time interval (equivalent of 5 minutes of missing data per 1-hour period), an asterisk is appended to the UO value for that time interval. If an AKI stage is displayed based on this time interval, then the stage number will also have an asterisk appended. In this scenario, the clinician should conduct further review to determine whether any UO may not have been recorded and whether this may have affected the AKI staging.

Urine Output Display – Incomplete Hours

UO is displayed in List mode and in 6HR and 12HR mode (bar graphs). If the monitor did not measure urine for a full hour (for instance, if monitor was in PAUSE mode for part of an hour), then the UO display will show an asterisk (*) next to that hour's urine output data. If using the 6HR or 12HR mode, the bar for that hour will be hollow. *A partial hour is defined as missing 5 minutes or more of UO measurement.* See two screenshots below:

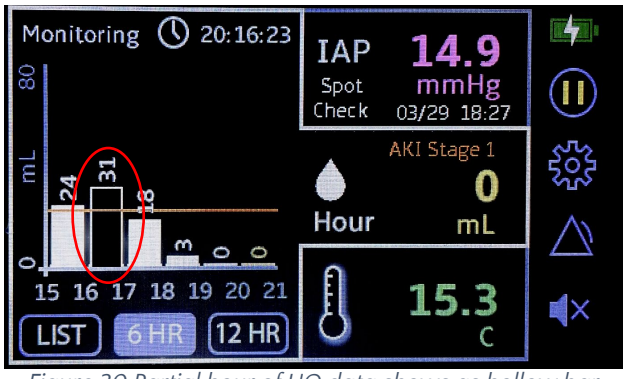


Figure 30 Partial hour of UO data shows as hollow bar

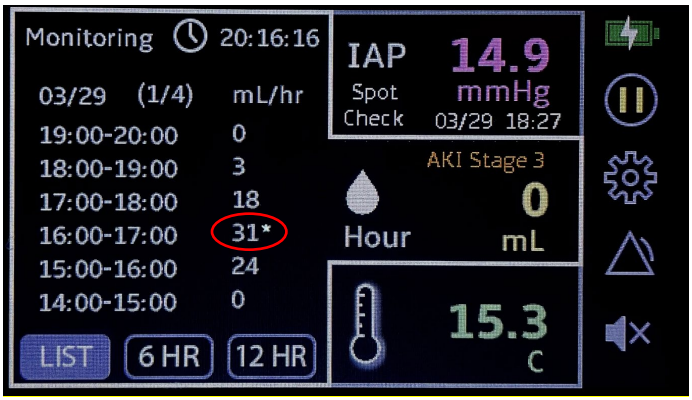


Figure 31 Partial hour of UO data shows with asterisk in List Mode

Charging the Internal Battery

Plug the Accuryn Monitor into wall power according to the setup instructions. Only use the provided 18V Power Supply unit. If the Monitor is charging, a lightning symbol will appear within the battery symbol on the right side of the Home screen.

Preparing for Patient Transport

Prior to transport it is recommended that the drainage line be clamped, and the Monitor paused. There are several options for transporting a patient with the Accuryn Monitoring System:

Transport of the entire Accuryn Monitoring System:
When the catheter and urine collection set is connected to the Monitor, use the mount accessories provided to attach the Monitor to the bed or IV pole for transport. See Accuryn Monitoring System Accessories Manual for additional detail.

Transport of the Accuryn Urinary Catheter Kit Only:
After disconnecting the Accuryn Urinary Catheter Kit from the Monitor (see Step 3. in Section "Turning Off and Removing the Monitor from the Accuryn Mount" below), use the white, pre-attached hanger to suspend the urine collection bag from a bedframe. See Figure 4 and Accuryn Urinary Catheter Kit IFU for more information.

Note: During transport, the "MONITOR TILTED" alert will occur if the Accuryn Monitor is not paused and is tilted too far from its normal, upright position. To avoid this alert while in transport, it is recommended to pause the Monitor and clamp the drainage line.

WARNING: The Accuryn Monitor is MR Unsafe. Do not transport the Monitor into an MRI unit. However, the Accuryn Urinary Catheter Kit is MR conditional. Follow guidance in the "MRI Safety Information" section in this Manual and in the Catheter Kit IFU.

Note: After transport, unclamp the blue drainage line clamp, and press Play to resume monitoring.

Turning Off the Monitor

The Monitor may be powered off and disconnected from certain components if monitoring is no longer required. NOTE: Refer to Urinary Catheter Kit instructions for use for removing the catheter.

1. From the Home screen, press the Power Button (M4) until the Power Off Confirmation screen is shown, and then follow the prompt to confirm the power off.

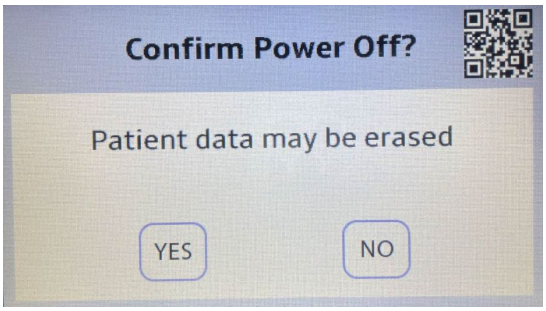


Figure 32 Power Off Confirmation screen

Pressing and holding the Power Button (M4) will bypass the confirmation and proceed to shutdown. A message "Confirm Power Off – Patient Data may be Erased" appears on the screen. The operator may choose Yes or No for this message. If the operator chooses Yes, the monitor will power off. If the operator chooses No, the monitor will return to the main screen.
2. If desired, disconnect all connections from the Monitor including: reusable temperature cable (if used), Temperature Cable Adapter (if used), 18V Power Supply, EMR cable (if used), and temperature pass-through cable (if used).
3. Remove the disposable by removing the cassette from the cassette interface by pressing and holding the tab at the top of the cassette while tilting and pulling the cassette out of the space. Unplug the temperature connector from the monitor. Unhook the urine collection bag from its hook. Use the hanger provided with Accuryn Urinary Catheter Kit to suspend the urine collection bag from bedframe. Refer to the instructions with the Accuryn Urinary Catheter Kit for further details.

Environment and Cleaning

Use and Storage Environment

The Monitor is intended to be used and stored in a hospital environment between 50°F and 104°F (10°C to 40°C), relative humidity of 10-90%, non-condensing, altitude within 0 to 2000 meters, and pressure of 101 kPa to 81 kPa. Please refer to Appendix C for guidance on conditions impacting electromagnetic performance of the device.

MRI Safety Information

The *Accuryn Monitor* is MR unsafe. Do not take the Monitor into an MRI unit.

Refer to SmartFoley IFU for Accuryn Urinary Catheter MRI Safety information.

Maintenance

At least once every 3 months, perform the following maintenance:

1. Visually inspect the transducer dome for damage and/or delamination located at the bottom of the cassette interface (Figure 1, M6). If damage is observed, please contact **Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796)** for assistance.
2. Clean the Monitor with the provided Maintenance Kit. With the brush, clean the interior and exterior of the 4 hollow pins in the Monitor (where the Cassette normally resides). Only insert the Nylon Brush to the end of the bristles. Wipe the brush clean for the next use.
3. Use the Temperature Tool to confirm temperature functionality. Insert the Temperature Tool into the top-right port of the Monitor (where the thermistor normally inserts). Compare the temperature reading of the Temperature Tool with the Monitor. If it is not within ±0.3°C/±0.5°F, please contact **Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796)** for assistance.
4. Check the activation of both the alarm indicator and audio function:
    a. Ensure audio is enabled. From the Home screen, ensure the speaker symbol in the bottom right does not have an "X". To enable audio, tap on the speaker symbol and tap "Enable".
    b. Ensure no temperature cable is connected to the Monitor and press Play. Confirm an audible alarm is activated and an error message is displayed for Error 0036 "Temp disconnected". This indicates that the visible and audible alarm indicators are functioning correctly. If no audible alarm and/or no error message is displayed, please contact **Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796)** for assistance.

Cleaning and Disinfecting

Visually inspect the monitor and reusable accessories for damage and/or signs of degradation prior to cleaning and disinfecting. If damage and/or degradation is observed, please contact Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796) for assistance.

The monitor and reusable accessories should be cleaned and disinfected prior to their first use and prior to subsequent uses.

Turn the Accuryn Monitor off and unplug the Power Supply from AC power before cleaning. The exterior surface of Accuryn Monitor may be cleaned and disinfected.

Super Sani-Cloth® Germicidal wipes have been tested and qualified for cleaning and disinfecting the Accuryn Monitoring System and associated cables. Follow the instructions below for manual cleaning and disinfection. In addition, follow your institution's guidelines for cleaning and disinfecting of devices.

Manual Cleaning

1. Using Super Sani-Cloth® Germicidal wipes, wipe the articles to remove soil.

2. The monitor and reusable accessories should be thoroughly cleaned. If after cleaning, the reusable articles are not visually clean, repeat the cleaning process. Use additional wipes as necessary.

3. Allow the articles to air dry.

Manual Disinfection

1. Using Super Sani-Cloth® Germicidal wipes, wipe the articles to remove soil.

2. Use additional wipes as necessary.

3. Once gross soil has been removed, use more wipes to thoroughly wet the surfaces of the articles and ensure that they remain wet for 4 minutes.

4. Allow the articles to air dry.

Servicing, Troubleshooting, and Technical Support

Servicing and Periodic Maintenance

All servicing and/or repairs are to be completed by Potrero Medical trained personnel only. Periodic maintenance, as described in Environment and Cleaning (above), may be performed by a clinical operator or hospital personnel.

Troubleshooting

A list of common problems and possible solutions is below. **Please consult Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796)** if the problem cannot be resolved even after referring to the list below.

Problem	Potential Solution
No parameter readings are displayed	Ensure that the temperature connector of the Urinary Catheter Kit is firmly connected to the Monitor. Ensure that the Play button was tapped to begin monitoring. The Monitor will not function without a Urinary Catheter Kit.
IAP not functional or IAP reading shows "--" on Monitor	Check that an Accuryn Urinary Catheter – [U/O, Temp, IAP] is being used. If a [U/O, Temp] Catheter is in use, there is no IAP functionality. (Look for "IAP" label on front of cassette – this indicates an IAP Foley is present)
Cannot press buttons or select parameters (touch screen non-responsive)	Press the desired button firmly a few times. If this does not work, refer to the Setup and Operation section of this manual to check if the button is one that the user can press and/or select.
Unit is plugged into wall power but is not charging	Firmly insert the power plug into the Monitor until a hard stop is felt. Tighten the screw collar of the power plug over the power port. Ensure that the 18V Power Supply is plugged into a functioning wall outlet, with the AC power cable fully inserted into the power supply brick.
UO not counting urine	Check Foley & drainage line for kinks or clots. Is blue pinch clamp on drainage line clamped? If so, unclamp. Is monitor in UO Pause mode? If so, press the Pause button and then the Play button. If patient is making little urine & there is <20mL of urine in the Cassette, there may be a delay in UO count until the Cassette fills above 20mL.
UO momentarily not accurate	Especially in low & high UO situations, the Accuryn Monitor will occasionally update the UO count as the Cassette fills.

Urine not draining while connected to Monitor	Note: During normal operation, the Cassette will fill to 45mL and drain to 15mL, then repeat. Is blue pinch clamp on drainage line clamped? If so, unclamp. Check Foley & drainage line for kinks or clots. Follow institution guidelines for possible blocked Foley. Check for clots/sediment from Foley to drainage bag entrance. Examine the top-right of the collection bag for any creases that are preventing urine flow. Correct if found. Is monitor in UO Pause mode? If so, press the Pause button and then the Play button.
Urine not draining while NOT connected to Monitor	Note: The Cassette will have some amount of urine in it during normal operation. Confirm collection bag is placed properly for gravity collection to function. Is blue pinch clamp on drainage line clamped? If so, unclamp. Check Foley & drainage line for kinks or clots. Follow institution guidelines for possible blocked Foley. Check for clots/sediment from Foley to drainage bag entrance. Examine the top-right of the collection bag for any creases that are preventing urine flow. Correct if found.
Collection bag inflating with air	Empty air from bag by opening drainage spout & gently squeezing bag. The bag's air vent may have gotten wet during transport or use, and the problem may resolve once the air vent dries.
Urine leaking from collection bag drainage spout	Slide valve on collection bag drainage spout is NOT designed to be rotated/twisted. If slide valve was rotated or twisted, gently rotate it back into its original position. Fold the spout up and place it in the slot in the collection bag. If slide valve was rotated/twisted, more frequent emptying of the bag will be necessary.

IAP Error when press IAP button for a measurement	Inspect label on front of Cassette. Is the disposable a UO/Temp/IAP version? If not, then do not attempt to measure IAP. If the disposable is UO/Temp/IAP, then check tubing for kinks. Re-try IAP measurement. If error persists, please contact Potrero Medical Customer Service.
Urine leakage at peri-urethral area	Is blue pinch clamp on drainage line clamped? If so, unclamp. Was a non-standard securement device such as a StatLock used? If so, inspect for a pinched drain line or Foley lumen as a result. Check Foley & drainage line for kinks or clots. Follow institution guidelines for possible blocked Foley.
Clock not accurate	Clock may be adjusted in the Settings menu. Record software version number. The software version number is displayed on the bottom-left of the Monitor Settings screen (accessed in the Settings menu). The software version number is also displayed at Monitor startup. Software version 2.0.13 or greater has improved clock drift. If hospital has 2.0.12 or earlier and is experiencing more clock drift than satisfactory the Monitor may be returned for servicing.

Temperature not accurate or displays "ERROR"	Note: If Accuryn reading is higher than other readings, note that Core temperature is usually higher than Peripheral temperature (oral, temporal, etc.). Note: The temperature reading from the Accuryn Monitor pass-through to other sources may differ by 0.1 – 0.2° Celsius. Check temperature with the Temperature Tool provided in the Maintenance Kit. Remove the temperature connector of the Urinary Catheter Kit (top-right corner). Insert the Temperature Tool into the same top-right port of the Monitor. Compare the temperature reading of the Temperature Tool with the Monitor. If they are within ±0.3°C/0.5°F, the Monitor reading is accurate. If accurate, disconnect the Temperature Tool, and reattach the temperature connector of the Urinary Catheter Kit with the Monitor. If the temperature reading is inaccurate, a hardware error has likely occurred. Call Potrero Medical Customer to return the Monitor for servicing. If the temperature reading is physiologically unlikely, the issue may be with the disposable, temperature cable, or temperature cable adapter. Call Potrero Medical Customer Service to return the disposable for engineering evaluation.

Alarm sound is annoying	If silencing the alarm is desired, go the triangle alarm button for the desired alarm to be changed. Choose the specific triangle for the parameter to silence, then tap the "+" or "-" to turn the alarm sound on or off. You may also tap the triangle itself to toggle on/off. The Global Mute or Temporary Mute may also be used to silence the alarms. Global Mute can be found in the Monitor Settings screen, which is accessible by tapping the Settings ("gears") button, then the top right arrow. Temporary Mute will temporarily mute audio for a specific duration. Access Temporary Mute by tapping the speaker icon (lower right). Temporary Mute will mute audio for 5, 15 or 30min. If desired, the IAP, UO and Temp alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alert level and changing it using the "+" or "-" buttons.
The numbers on the main screen are flashing	The numbers flash when the value is outside of the alert limits. You may adjust the alert limits in the Settings (gear-shaped button) menu, even when the audible alarm is silenced. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alert level and changing it using the "+" or "-" buttons.

Technical Support

For technical support, please call Potrero Medical Customer Service at +1 833 ACCURYN (1-833-222-8796) Online: www.potreromed.com

Appendix A: Alarms and Alerts

The Accuryn Monitor has several types of cues for system errors, including a display message on the screen, an LED error indicator, and an auditory cue. In normal operation, the LED error indicator will be off and there should be no auditory cue. Alarms are checked on a 10ms periodic loop.

Medium level alarms are denoted by a flashing yellow bar in the popup message box. For a medium level alarm, after pressing the OK button to acknowledge the alarm, if the condition persists another alarm will be triggered 20 seconds later.

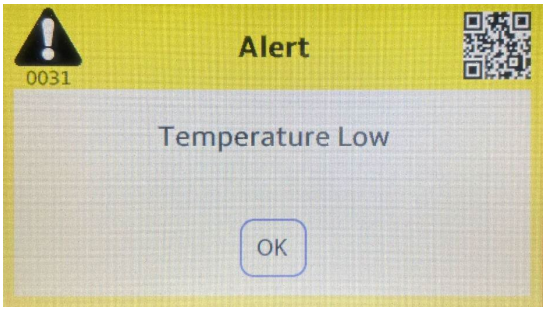


Figure 33 Medium priority alarm example

Low level alarms are denoted by a blue bar in the popup message box. For a low level alarm, after pressing the OK button to acknowledge the alarm, if the condition persists another alarm will be triggered 30 seconds later.

Visual Alarms/Alerts – Technical and Physiological Alarm Conditions

Displayed Message	Description	Audio/Alarm Level	What to Do
Errors at Startup			
Error 0001 Monitor Error Please restart	An exception or software error has occurred.	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0002 Monitor Error Please restart	Firmware CRC checksum failed	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0003 Monitor Error Please restart	Graphics Monitor communication failed	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0004 Monitor Error Please restart	Graphics flash CRC checksum failed	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0005 Monitor Error Please restart	Touch Monitor initialization and self-test failed	Low	Note the error number. Restart the Monitor, ensuring that nothing is touching the touch screen. If the message persists, please contact Potrero Medical Customer Service.
Error 0006 Monitor Error Please restart	Watchdog expires; relates to microprocessor	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0008 Monitor Error Please restart	Clock time not incrementing	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 0009 Monitor Error Please restart	Pinch valve error	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.
Error 000A Monitor Error Please restart	Ultrasonic error	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service.

Displayed Message	Description	Audio/Alarm Level	What to Do
Error 000B Monitor Error Please restart	Loop time exceeds 10ms	Low	Note the error number. Restart the Monitor. If the message persists, please contact Potrero Medical Customer Service. If message does not reoccur, it is still recommended the Monitor be returned for servicing at the earliest convenience.
Error 000C Monitor Error SD Card Error Contact Customer Support	SD card error	Low	Note the error number. Restart the Monitor. Monitor still functional for user needs, but error will still show on startup when viewing the Home screen. No data will be stored on internal SD card, so no patient data will be permanently saved. Please contact Potrero Medical Customer Service.
Error 000E	I2C Error	Low	If restart does not resolve the error, Contact Potrero Medical Customer Service.
Error 0039 Monitor Error Please restart	Manufacturing settings erased	Low	If restart does not resolve the error, Contact Potrero Medical Customer Service.
Error 0040 Monitor Error Please restart	UO pump 1 power on test	Low	Check Cassette for blockages/clots/sediment at the tubes to drainage bag. Disconnect the Cassette, and remove fully from the Monitor. If blockages were observed, agitate the Cassette and collection bag vigorously to clear. Reconnect the Cassette, then restart the Monitor. If restart does not resolve the error, Contact Potrero Medical Customer Service.

Displayed Message	Description	Audio/Alarm Level	What to Do
Error 0041 Monitor Error Please restart	UO pump 2 power on test	Low	Disconnect and reconnect the cassette, then restart the monitor. If restart does not resolve the error, Contact Potrero Medical Customer Service.
Error 0042 Monitor Error Please restart	UO pump 3 power on test	Low	Disconnect and reconnect the cassette, then restart the monitor. If restart does not resolve the error, Contact Potrero Medical Customer Service.

Errors During Use			
Error 0020 Monitor Tilted - Fix Tilt Fwd Tilt: X.X Side Tilt: X.X UO Draining Not Recorded	The Monitor is tilted too far from the horizontal.	Low	Check and adjust the Monitor so that it is as parallel to the floor as possible. Check handle mount is fully inserted in the Monitor. Is Monitor on floor stand? Check that mount is fully seated in the floor stand. Check that the floor stand is level, and not on cables or uneven surfaces. Is monitor hanging from handle on the bed? If so, place Monitor either on floor stand or IV pole. If message persists after corrective attempts, contact Potrero Medical Customer Service.

Error 0021 Bag Full Empty Urine & Air From Bag	The urine collection bag is full.	Low	Empty the urine collection bag according to instructions provided with the Accuryn Urinary Catheter Kit. If collection bag is filled with air, empty air from bag by opening drainage spout & gently squeezing bag. If error persists, examine the collection bag to make sure the collection bag or drainage tubing is not kinked or clogged. If the Monitor is resting on a surface, that could cause the collection bag to kink. To clean: Press Pause. Disconnect and remove the Cassette from the Monitor and examine the 4 hollow pins in the Monitor where the Cassette was. Examine for any clogs, and clean out any obstructions with the provided Maintenance Kit. Wipe the tools clean for the next use. Afterwards, reinsert the Cassette into the Monitor. Press Play to resume urine output measurements.

Error 0044 - Bag Full Empty Urine & Air UO not recording Call Biomed if Recurs	The urine collection bag is full	Low	Empty the urine collection bag according to instructions provided with the Accuryn Urinary Catheter Kit. If collection bag if filled with air, empty air from bag by opening drainage spout & gently squeezing bag. Monitor has entered "UO Pause" mode (see top-left of display). No urine output data is currently being collected. After emptying the collection bag, press Pause and then Play to resume urine output measurements. If error persists, examine the collection bag to make sure the collection bag or drainage tubing is not kinked or clogged. If the Monitor is resting on a surface, that could cause the collection bag to kink. To clean: Press Pause. Disconnect and remove the Cassette from the Monitor and examine the 4 hollow pins in the Monitor where the Cassette was. Examine for any clogs, and clean out any obstructions with the provided Maintenance Kit. Wipe the tools clean for the next use. Afterwards, reinsert the Cassette into the Monitor. Press Play to resume urine output measurements.

Error 0022 Battery Low (~3 hours) Charge Battery	The battery has 50% capacity remaining	Low	Plug the device into wall power. Firmly insert the power plug into the Monitor until a hard stop is felt. Tighten the screw collar of the power plug over the power port. Ensure that the 18V Power Supply is plugged into a functioning wall outlet, with the AC cable fully inserted into the power supply brick. The charging battery symbol should appear on the Home screen. Approximately 3 hours of charge remaining when this alarm appears.
Error 0023 Battery Critically Low (~1 hour) Charge Battery	The battery has 20% capacity remaining	Low	Plug the device in to wall power. Firmly insert the power plug into the Monitor until a hard stop is felt. Tighten the screw collar of the power plug over the power port. Ensure that the 18V Power Supply is plugged into a functioning wall outlet, with the AC cable fully inserted into the power supply brick. The charging battery symbol should appear on the Home screen. Approximately 1 hour of charge remaining when this alarm appears.
Error 0025 Monitor Error Press Pause then Play or Call Technical Support	Pinch valve error	Medium	Note: Monitor has entered "UO Pause" mode (see top-left of display). No urine output data is currently being collected. Press Pause and then Play to resume urine output measurements. Note the error number. If error 0025 occurs more than once during operation, switch to another Accuryn Monitor and contact Potrero Medical Customer Service.

Error 0047 Cassette Error Reconnect to Monitor Call Biomed If Recurs	"Cassette Error - Reconnect", shown once *[Cassette Installation animation displayed]*	Medium	Check that the Cassette is placed in the Monitor correctly (rotated in and lever firmly secured). Also check that there are no kinks or clogs in the drainage tubing. Press Pause and then Play following any correction to Cassette/drainage tube. If error persists, press Pause, then remove the Cassette fully and reinsert into the Monitor. Press Play to resume. To clean: Press Pause. Disconnect and remove the Cassette from the Monitor and examine the 4 hollow pins in the Monitor where the Cassette was. Examine for any clogs, and clean out any obstructions with the provided Maintenance Kit. Wipe the tools clean for the next use. Afterwards, reinsert the Cassette into the Monitor. Press Play to resume urine output measurements. If error persists, switch to another Accuryn Monitor and continue use. If Error 0047 <u>does not</u> occur again, a hardware error has likely occurred with the <u>original</u> Monitor. Return the original Monitor for servicing. If Error 0047 <u>does</u> occur again, it is recommended the disposable be hung in standard Foley/drainage mode for duration of patient use. The issue may be with the

			disposable. Return the disposable for engineering evaluation.

Error 0045 Cassette Error Reconnect to Monitor Call Biomed If Recurs	"Cassette Error - Reconnect", shown once *[Cassette Installation animation displayed]*	Medium	Check that the Cassette is placed in the Monitor correctly (rotated in and lever firmly secured). Also check that there are no kinks or clogs in the drainage tubing. Press Pause and then Play following any correction to Cassette/drainage tube. If error persists, press Pause, then remove the Cassette fully and reinsert into the Monitor. Press Play to resume. To clean: Press Pause. Disconnect and remove the Cassette from the Monitor and examine the 4 hollow pins in the Monitor where the Cassette was. Examine for any clogs, and clean out any obstructions with the provided Maintenance Kit. Wipe the tools clean for the next use. Afterwards, reinsert the Cassette into the Monitor. Press Play to resume urine output measurements. If error persists, switch to another Accuryn Monitor and continue use. If Error 0045 <u>does not</u> occur again, a hardware error has likely occurred with the <u>original</u> Monitor. Return the original Monitor for servicing. If Error 0045 <u>does</u> occur again, it is recommended the disposable be hung in standard Foley/drainage mode for duration of patient use. The issue may be with the

			disposable. Return the disposable for engineering evaluation.
Error 002D Balloon Deflation Error - Remove Cassette from Monitor	Unable to pull a vacuum on the Sensing balloon	Medium	Prior to catheter removal, disconnect the Cassette from the Monitor. If message persists when Cassette is fully removed from the Monitor, call Potrero Medical Customer Service.
Error 0036 Temp Disconnected – Connect Temperature	The temperature cable is disconnected	Low	Ensure the temperature cable is connected securely to the temperature port of the Monitor and the temperature connector on the Foley. If error persists, switch to another Accuryn Monitor and continue use. If Error 0036 does not occur again, a hardware error has likely occurred with the original Monitor. Return the Monitor for servicing. If Error 0036 does occur again, the issue may be with the disposable. Silence the thermistor alarm. Use of an alternate temperature device is recommended. Return the disposable for engineering evaluation.

Error 0038 Cassette Drain Blocked Remove/Reinstall Cassette Call Biomed if Recurs	Blockage at Cassette outflow (junction between cassette and collection bag)	Low	Check Cassette for possible blockages at Cassette outflow tubing into collection bag. If possible blockage seen, press Pause. Disconnect the Cassette, and remove fully from the Monitor. Agitate the Cassette and collection bag vigorously to clear. Reconnect the Cassette, then press Play. Make sure the Monitor is not sitting on the collection bag, causing the outflow tubing to be closed off. Examine the top-right of the collection bag for any creases that are preventing urine flow past the outflow tubing. Manually correct if found. If the error message persists, please contact Potrero Medical Customer Service.

IAP Error	IAP sensor recorded invalid reading	Off	Only can occur after pressing IAP button for a Spot Check reading. Inspect label on front of Cassette. Is the disposable a [UO/Temp/IAP] version? If not, then do not attempt to measure IAP. IF the disposable is [UO/Temp/IAP], high signal noise can cause error message. Confirm patient is supine and resting before re-trying Spot Check IAP measurement. Check tubing for kinks. If found and corrected, re-try IAP measurement. Press Pause, then remove the Cassette fully and reinsert into the Monitor. Press Play to resume. Reattempt Spot Check IAP measurement. If error persists, switch to another Accuryn Monitor and continue use. If error message does not occur again, a hardware error has likely occurred with the original Monitor. Return the Monitor for servicing. If error message does occur again, the issue may be with the disposable. Return the disposable for engineering evaluation.
Error 0046 UO Leak – Check Monitor and Disposable	A leak is detected through the outflow tubing of the cassette.	Medium	Pause monitor. Remove cassette and inspect for leaks.

Caution - Raised head of bed will increase IAP - Refer to IFU	Alert displayed if the IAP 6 hour or 12 hour graph is selected for the first time	Medium	Acknowledge alert and continue use.
Error 0026 - Ultrasonic Error	Error in the ultrasonic UO measurement system	Medium	Visually inspect the transducer dome for damage and/or delamination located at the bottom of the cassette interface, as described in the Maintenance section.

Physiological Alerts			
Alert 0030 Temperature High	The patient's measured temperature is above the user-set temperature range.	Medium	Address the issue per standard medical practice. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alarm level and changing it using the "+" or "-" buttons.
Alert 0031 Temperature Low	The patient's measured temperature is below the user-set temperature range.	Medium	Address the issue per standard medical practice. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alarm level and changing it using the "+" or "-" buttons.
0032 Check IAP	The patient's measured IAP is above the user-set IAP range.	Medium	Take a Spot Check IAP reading with patient supine and resting to confirm high IAP. Address the issue per standard medical practice. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alarm level and changing it using the "+" or "-" buttons.

0034 UO High	The patient's measured UO is above the user-set UO range.	Medium	Visually confirm that urine output is high by examining approximate volume in Cassette and collection bag (note that the Accuryn Monitor retains a minimum 15mL of urine in the Cassette at all times). If high urine output is confirmed, address the issue per standard medical practice. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alarm level and changing it using the "+" or "-" buttons.
0035 UO Low	The patient's measured UO is below the user-set UO range.	Medium	Visually confirm that urine output is low by examining approximate volume in Cassette and collection bag (note that the Accuryn Monitor retains a minimum 15mL of urine in the Cassette at all times). Check the drainage tubing for kinks or clogs, and make sure the clamp is not engaged. If low urine output is confirmed, address the issue per standard medical practice. If desired, the alert limits may alternatively be changed to a more relevant range in the same Settings menu, pressing the desired alarm level and changing it using the "+" or "-" buttons.

AKI Notifications			
Code – 004B AKI Stage 1	Patient's UO meets the KDIGO AKI Criteria for AKI Stage 1 based on the user-entered patient weight	Medium	Health Care Provider to independently review and address issue per standard medical practice. If desired, the AKI Alerts can be muted in the Alert Settings screen by tapping the triangle in the AKI column to put an X through it.
Code – 004A AKI Stage 2	Patient's UO meets the KDIGO AKI Criteria for AKI Stage 2 based on the user-entered patient weight	Medium	Health Care Provider to independently review and address issue per standard medical practice. If desired, the AKI Alerts can be muted in the Alert Settings screen by tapping the triangle in the AKI column to put an X through it.
Code – 0049 AKI Stage 3	Patient's UO meets the KDIGO AKI Criteria for AKI Stage 3 based on the user-entered patient weight	Medium	Health Care Provider to independently review and address issue per standard medical practice. If desired, the AKI Alerts can be muted in the Alert Settings screen by tapping the triangle in the AKI column to put an X through it.
Code – 0048 AKI Stage 3 - Anuria	Patient's UO meets the KDIGO AKI Criteria for AKI Stage 3 Anuria	Medium	Health Care Provider to independently review and address issue per standard medical practice. If desired, the AKI Alerts can be muted in the Alert Settings screen by tapping the triangle in the AKI column to put an X through it.

Appendix B: Technical Specifications

Performance Specifications

Component	Specification
Power Supply	18V±1.8V, DC, 2.2A EN55011, Class B FCC Part 15, Class B EN61000
Full battery	8 hours capacity
Battery	Type: Li-Ion Voltage: 10.8V
Pneumatic Pumps	3V, 10 inHg vacuum
Urine Volume Measurement	Range: 0 to 2000 mL / hour
Urine Volume Measurement: Ultrasonic Transducer Accuracy	±1% at level
System Temperature (Rated output range)	Range: 32°C to 42°C System Accuracy: ±0.3°C
Rated extended output range	9°C to 32°C, 42°C to 45°C System Accuracy: ±0.4°C
Pressure Sensor	Analog Accuracy: ±1 psi
IAP Measurement	Range: 0 to 45 mmHg Accuracy: ± 2.0 mmHg

General Characteristics

Parameter	Specification
Dimensions	10 in L x 3.5 in W x 6 in H (Monitor only)
Weight	3.1 lbs.
Mobility	Portable
Protection against ingress of liquid	IP22
System Environmental Use Conditions / Transport Conditions	Ambient temperature: 50°F to 104°F (10°C to 40°C) Relative humidity: 10%-90%, non-condensing Altitude: 0 to 2000 meters Pressure: 101 kPa to 81 kPa
Electrical Utility Requirements	100-240V~

	50-60 Hz 0.5A (0.5-0.3A)
Electromagnetic Compatibility	Complies with IEC 60601-1-2. See Appendix C
Patient Connected Circuits	Type BF (IEC 60601-1) classification, Defibrillator Proof
Electrical Safety	Designations: Type BF-Defib Proof Applied Parts Complies with IEC 60601-1
Mains of isolation	Disconnect power supply
Alarms, Alerts	See Appendix A
Alarm Sound Level	62.9 to 71.6 dB
Alarm Details	Meets IEC 60601-1-8 requirements Volume: 80 dB at 10cm Frequency: 795 Hz ± 24 Hz Voltage Range: 5.0 ± 0.5 V DC Max Current: <250 mA
Data Recording	Data written to internal SD card
Sampling	Temperature: 1x every second Urine Output: 1x every 10ms IAP: 1x every 10 ms
Calculation	Temperature: N/A Urine Output: N/A IAP: averaged every 10ms
Screen Update (Numbers)	Temperature: 1x every second Urine Output: 1x every second Spot Check IAP: As requested by user. Continuous Trending IAP: displays last value on the trending graph
Screen Update (Graphs)	Temperature: Redrawn every 20 seconds Urine Output: 1x every 20 seconds Continuous Trending IAP: Redrawn every 20 seconds.

Appendix C: Guidance and Manufacturer's Declaration

Essential Performance

The Accuryn Monitoring System complies with the requirements of IEC 60601-1-2. The system was tested to the standards listed in this Appendix.

The limits are designed to provide reasonable protection against harmful interference in a typical hospital environment. To maintain proper functioning of the Accuryn Monitoring System as it pertains to EMC, all the instructions in this manual should be followed.

Loss or degradation of essential performance may result in no or inaccurate urine output, temperature, or intra-abdominal pressure data during the presence of electromagnetic disturbances if used outside of the specified electromagnetic guidance in this Appendix.

The Accuryn Monitoring System essential performance functions are:

- Clear airlocks
- Display and update urine output
- Display and update temperature
- Display and update intra-abdominal pressure

C.1. Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The FGN-06-2687 (Accuryn Monitor) is intended for use in the electromagnetic environment specified below. The customer or the user of the FGN-06-2687 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The FGN-06-2687 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The FGN-06-2687 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Complies	

C.2. Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The FGN-06-2687 is intended for use in the electromagnetic environment specified below. The customer or the user of the FGN-06-2687 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The FGN-06-2687 is intended for use in the electromagnetic environment specified below. The customer or the user of the FGN-06-2687 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV to line(s) ± 2kV to earth	± 1kV to line(s) ± 2kV to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FGN-06-2687 requires continued operation during power mains interruptions, it is recommended that the FGN-06-2687 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The FGN-06-2687 is intended for use in the electromagnetic environment specified below. The customer or the user of the FGN-06-2687 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the FGN-06-2687, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (1.2)\sqrt{P}$ $d = (1.2)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.3)\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due			

to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FGN-06-2687 is used exceeds the applicable RF compliance level above, the FGN-06-2687 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FGN-06-2687.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

C.3. Separation Distance

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the FGN-06-2687

The FGN-06-2687 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FGN-06-2687 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FGN-06-2687 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = (\frac{3.5}{V1})\sqrt{P}$	**80 MHz to 800 MHz** $d = (\frac{3.5}{E1})\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (\frac{7}{E1})\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.