

Accuryn[®] Monitoring System

SmartCath Instructions for Use

IFU-06-101677 Rev A

Introduction



Please read carefully.

This manual covers the function and proper use of the Accuryn Monitoring System with SmartCath.

NOTE: The Accuryn Monitor has its own accompanying Operator's Manual, which is provided with the Monitor. All 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 Monitor.

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

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Patent: www.potreromed.com/patents

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Background

Definitions

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| SmartCath | An alternative Urine Collection Set that is provided without a catheter . It is compatible with the Accuryrn Monitor. Once connected to a catheter, the Collection Set has the same functionality as the U/O, Temp catheter. The kit pairs with an external temperature cable to connect the catheter to the Accuryrn Monitor. |
| Reusable Temperature Cable | Reusable external cable that connects to a temperature sensing Foley and to the Accuryrn Monitor. The cable uses the same port which the Accuryrn Sensing Urinary Catheter – U/O, Temp uses |

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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 is capable of additional functions. Refer to the Operator's Manual for the complete Intended Use.

Functional Description

The Accuryn Monitor is a standalone monitoring unit and includes a power supply. The Monitor is to be used exclusively with SmartCath. These components together are known as the Accuryn Monitoring System.

A Foley catheter drains urine from the patient's bladder into the drainage tube and finally the measurement cassette of the Urine Collection Set (SmartCath), 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. An external temperature cable is connected to a temperature sensing foley and when attached to the Monitor, 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).

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 Technical Support 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 or Reusable Temperature Cable and water and/or fluids. Do not immerse or submerge Monitor or Reusable Temperature Cable in water and/or fluids.

Do not steam autoclave or EO sterilize the Monitor or Reusable Temperature Cable

SmartCath has been tested with 6-24 Fr Foleys.

SmartCath is compatible with most Foley catheters including those from Bard and Medline.

Cautions

When using the Accuryn Monitoring System with a patient producing 10ml/hr or less, flush 10cc of sterile saline upon insertion of the foley and after anytime the monitor has been tilted or paused.

Only plug cables provided with the Monitor into the power and temperature port. Only plug 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. In medical use, disconnect all connections between the SmartCath and the Accuryn Monitor before activating electrosurgical or other types of directly-coupled RF energy sources.

When using a Foley catheter without temperature capabilities, the Accuryn Monitor will alert once that there is no temperature connected. Press "OK" to clear alarm away and continue normal use.

Insertion Kit

SmartCath is provided with a catheter insertion kit which contains the following:

- 10cc syringe of Sterile Water
- Waterproof Drape
- Fenestrated Drape
- Alcohol Preparation Pad
- Specimen Container
- Nitrile Gloves (Size 8)
- Lubricating Jelly
- Povidone-Iodine Swabs
- Catheter Securement Device
- Skin Protectant Pad
- Soap Towelette
- Hand Sanitizer

Sterile: Contents of inner wrap are sterile unless package has been opened or damaged.

Referenced Features in SmartCath

B1. Foley Connector
B2. Sampling Port
B3. Drainage Tubing

B4. Drainage Bag Hanger
B5. Measurement Cassette
B6. Hanger Notch

B7. Monitor Eyelets
B8. Urine Collection Bag
B9. Drainage Bag Valve

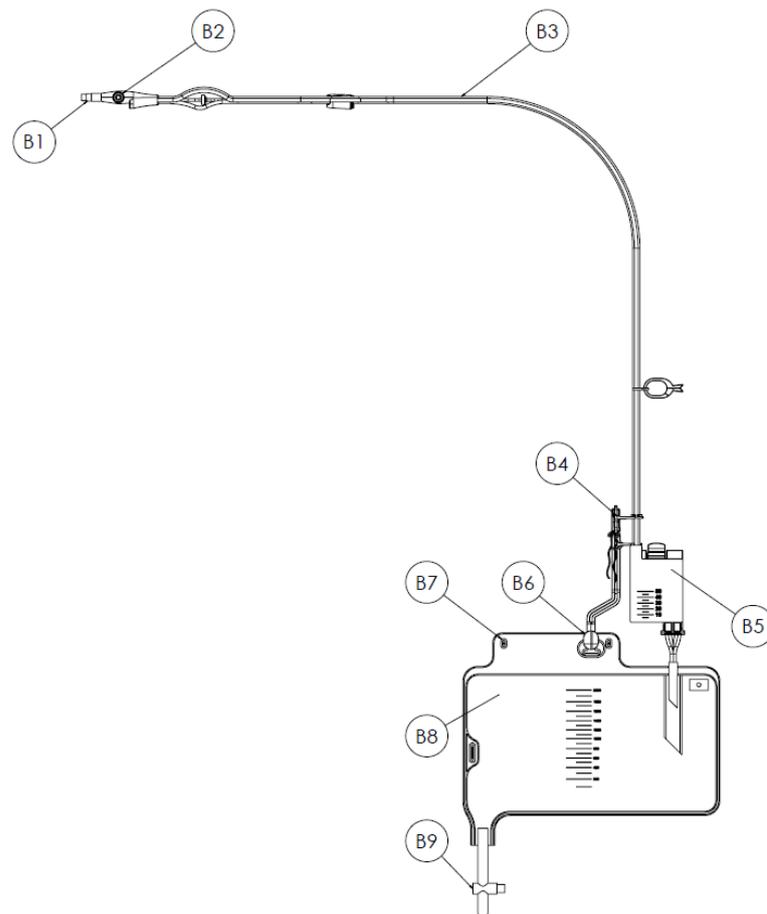


Figure 1: SmartCath

Referenced Features in Reusable Temperature Cable

- T1. Connector for Foley (to A3)
- T2. Connector for Monitor (to M5)



Figure 2: Reusable Temperature Cable

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.

Urinary Catheter Set up

1. Perform hand hygiene and put on non-sterile gloves provided by your institution.
2. Prior to use, visually inspect kit packaging to ensure no breaches. If there are breaches, dispose of product per institution guidelines and obtain a new package.
3. To open, pinch tabs on packaging and pull apart.
4. Pull tray out of pouch and place in field.
5. Using aseptic technique, unfold outer wrap to form sterile field in front of patient's perineal area.
6. Pinch the drainage tube closed using the attached blue drainage tubing clamp.
7. Use soap towelettes to perform perineal cleansing per facility guidelines.
8. Pick up waterproof drape by edge without contaminating contents and place with shiny side down under buttocks.
9. Use hand sanitizer provided.
10. Put on nitrile sterile gloves.
11. Lift tray top to reveal lower tray components.
12. Attach 10cc sterile water filled syringe to catheter.
13. Open lubricating jelly packet and squeeze into tray well to lubricate the catheter tip.
14. Place fenestrated drape on patient without contaminating gloves.
15. Open Povidone-Iodine swabs packet.

16. For female patient, use Povidone-Iodine swabs to clean patient's meatus from top going down. For male patients, use swabs to clean the patient's meatus per facility's guidelines. Each swab is for single use.

17. Attach a Foley catheter to SmartCath and proceed with catheterization according to facility guidelines.

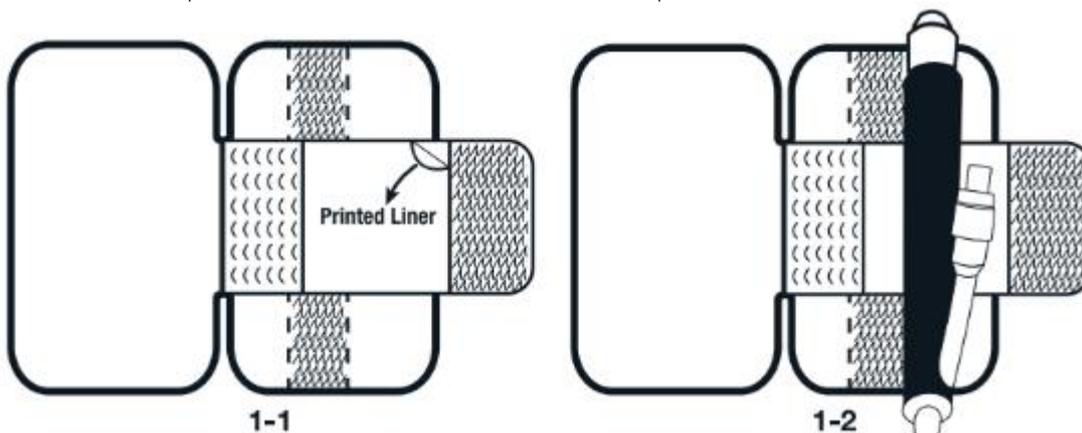
18. Inflate the catheter retention balloon using the syringe provided. Instill entire amount of sterile water (10cc).

19. Confirm urine drainage by briefly opening the blue drainage tubing clamp so that urine can flow through the closed system toward the collection bag. Note: any urine collected prior to connecting to the Monitor and powering on will not be measured electronically, so re-close the blue drainage tubing clamp as soon as possible after confirmation of flow. **CAUTION: Do not use an external clamp on the drainage tubing assembly, as it may damage the catheter.**

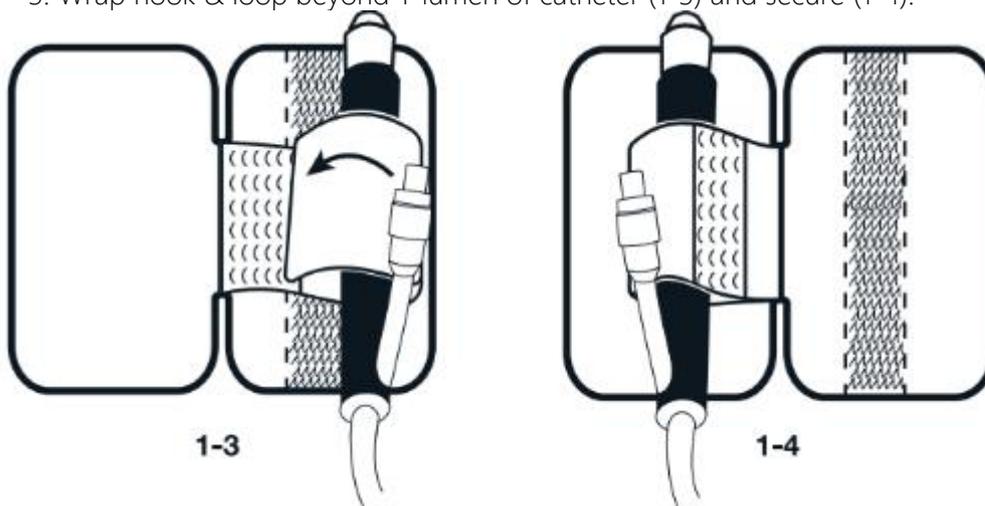
Application Instructions for Foley Catheter Securement

WARNING: Do not use catheter securement device on patients with known tape or adhesive allergies.

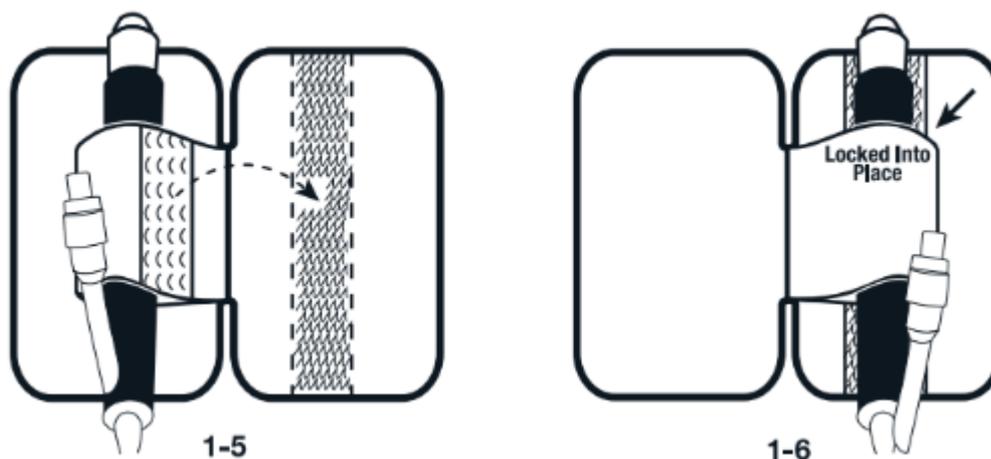
1. Clean application area with alcohol, let dry. After insertion of catheter, fully extend patient's leg.
2. Peel back printed liner (1-1). Place catheter on exposed adhesive (1-2).



3. Wrap hook & loop beyond Y lumen of catheter (1-3) and secure (1-4).



4. Locate securement site allowing for one inch of tubing slack between securement site and urinary meatus to prevent undue traction.
5. Fasten secured tab to strip on device base (1-5), locking tube in place (1-6).



6. Peel off back liner and apply catheter securement device to patient.
7. To remove: release hook and loop tab, remove Foley. Gently peel edge of securement device until completely removed. Alcohol may be used if necessary.

SmartCath Set Up

1. Ensure that the Drainage Tubing (A6) extends from the catheter to the Measurement Cassette (A8) in a smooth, unkinked path.
2. Mount the Monitor by aligning the provided Accuryn Mount with the Mounting Interface (M7). Firmly push down on the Monitor for a press-fit. Adjust the Monitor position to be parallel with the floor as close as possible.
3. 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.
4. Attach the Cassette (A8) to the Cassette Interface (M6) on the Monitor, as depicted in the lower right panel of Figure 3. Ensure that the latch on top of the cassette engages with the Monitor.

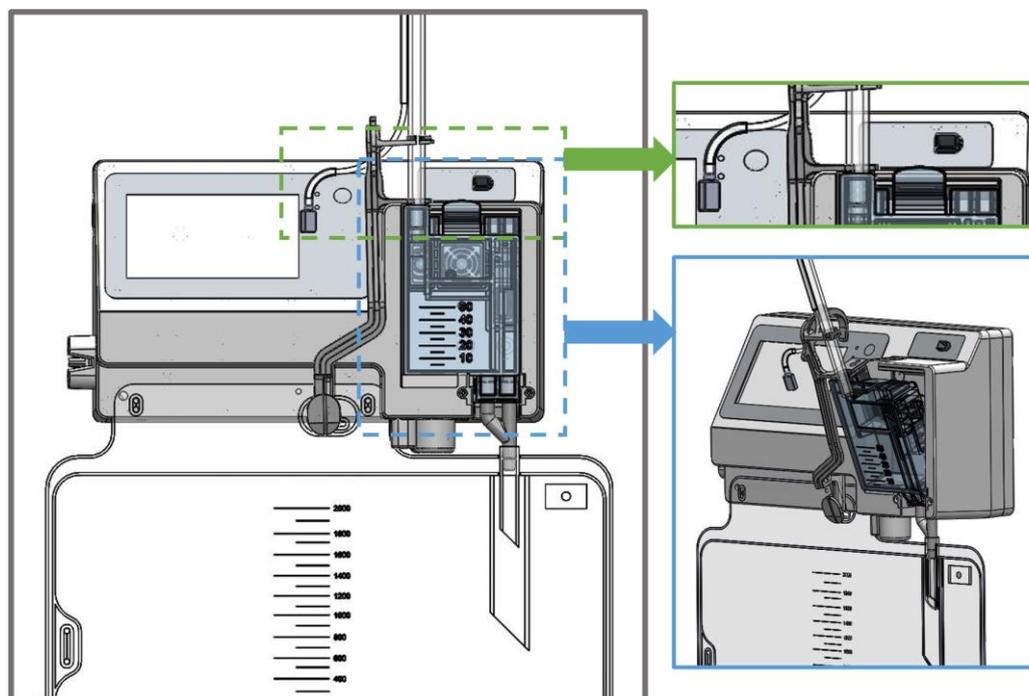


Figure 3: Monitor Setup Diagram

5. Hang urine collection bag on the Bag Hook (M8) as depicted in the left panel of Figure 3. Ensure that the bag hangs freely.
6. If using a temperature-sensing Foley catheter, connect the Temperature Connector (T2) of the Temperature Cable to the Temperature Port (M5) as depicted in the top right panel of Figure 3.
7. Connect the temperature cable (T1) to the Foley.

Removal Procedure

CAUTION: Disconnect Measurement Cassette (D8) from the Monitor prior to removing catheter.

Failure to do so may result in urethral trauma.

1. Ensure all data has been recorded before removal of the device.
2. Pause the monitor (upper right corner of the display screen M1). Wait approximately 5 seconds until the monitor is flashing "PAUSED."
3. Disconnect the Thermistor Plug (D7) from the Temperature Port (M5).
4. Disconnect the Measurement Cassette (D8) from the Monitor.
5. Remove Drainage Bag from Bag Hanger (B4).
6. Hang disposable from the bed by the Bag Hanger.
7. **Deflate retention balloon:** Gently insert a luer slip tip syringe into the Retention Balloon Valve (D4). Allow the pressure within the balloon to force the plunger back and fill the syringe with water. Use only gentle aspiration to encourage deflation if needed.

CAUTION: Do not remove urinary catheter if resistance is felt. Check balloon status.

8. Slowly remove catheter from the bladder.
9. At end of device use, dispose of all materials in accordance with facility protocol.
10. Power down the Accuryn Monitor (M4) by pressing and holding power button.

11. Clean the monitor and accessories thoroughly. Follow cleaning instructions for the monitor in the Accuryn Monitoring System Operator's Manual.

Environment and Cleaning

MRI Safety Information

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

Non-clinical testing has demonstrated the *SmartCath* is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3 T;
- Maximum spatial gradient field of 8,100 gauss/cm (81 T/m);
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

The position of the thermistor wire of the Foley Catheter with temperature sensor has an important effect on the amount of heating that may develop during an MRI procedure. Accordingly, the Foley catheter with temperature sensor must be positioned in a straight configuration down the center of the patient table (i.e. down the center of the MR system without any loop) to prevent possible excessive heating associated with an MRI procedure. If using a Reusable Temperature Cable, disconnect cable from Foley before MRI.

Cleaning and Disinfecting

Turn the Monitor off and unplug the 18V Power Supply from AC power before cleaning. The exterior surfaces of the Reusable Temperature Cable may be cleaned and disinfected.

Super Sani-Cloth® Germicidal wipes have been tested and qualified for cleaning and disinfecting the Accuryn Monitoring System, including the reusable temperature cable. 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. 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.