

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).

Description

The Accuryn Monitor Mounts and Accuryn Monitor Floor Stands are accessories to the Accuryn Monitoring System that are used to mount/place the Accuryn Monitor on an IV pole or near the patient's bed on the floor during stationary use or transport.



Please read carefully.



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

Background

This manual covers the function and proper use of the Accuryn Monitor Mounts and Accuryn Monitor Floor Stand Accessories for 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 and Monitor have their own accompanying Instructions for Use (IFU), which is provided with the Accuryn Monitor.** 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.

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, core body temperature, and intra-abdominal pressure.
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).

Overview

The Accuryn Monitor Mount (Figure 1), Accuryn Monitor High Mount (Figure 5), Accuryn Monitor Floor Stand (Figure 2) (AKA "Tall Floor Stand"), and Accuryn Monitor Short Floor Stand (Figure 9, 10) (AKA "Short Floor Stand"), are accessories to the Accuryn Monitoring System. This set of accessories provides several options to mount/place the Accuryn Monitor near the patient while using the Accuryn Monitoring System.

Set up procedures

1. Attach either the Accuryn Monitor Mount or High Mount mounting point (Figure 1, F1) to the back of the Accuryn Monitor at the mounting interface located on the back of the Monitor (Figure 8, M7) by first aligning the mounting point with the Monitor's mounting interface, and then **firmly** press the mounting point into the Monitor and **firmly** pull the Mount up. The mounting point should "click" into the Monitor when it is fully engaged.
2. Several options for placing the Accuryn Monitor when attached to the Accuryn Monitor Mount are described below:
 - a. IV Pole: Use the pole-clamp and knob to attach the back of the Accuryn Monitor Mount (Figure 1, F3) to an IV pole (Figure 3). If the Accuryn Monitor High Mount is used, the pole-mount feature is not available.
 - b. Floor: Use the Handle (Figure 1, F2) to lower the Monitor into the center of the Floor Stand (Figure 2). The Floor Stand is designed to provide a platform to mount the Accuryn Monitor by use of the Accuryn Monitor Mount (Figure 4) or Accuryn Monitor High Mount.
 - c. High Mount: When emptying the drainage bag, grasp the purple hook-shaped Handle and lift the Monitor to the top of the Floor Stand (Figure 7). The High Mount will slide on top of the Floor Stand, enabling hands-free bag drainage. The Monitor may then be placed back in the normal, lower position on the Floor Stand (Fig 6).

Cleaning and Disinfecting

Visually inspect the 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.

If the Monitor is connected to any of the accessories, turn the Monitor off and unplug the 18V Power Supply from AC power before cleaning. To thoroughly clean and disinfect the Monitor Mount or Accuryn Monitor High Mount, disconnect either Mount from Monitor prior to cleaning.

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.

Warnings

Do not attempt to open, repair, or modify the Accuryn Monitor 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 Monitor Mounts, High Mounts and Floor Stands have no serviceable parts.

The Accuryn Monitor Mounts, Monitor Floor Stands, and 18V Power Supply are MR Unsafe. Do not take the Accuryn Monitor Mount, High Mount, Monitor Floor Stand (Tall), or 18V Power Supply into an MRI unit. (However, the Accuryn Urinary Catheter Kit is MR Conditional. Follow guidance in "MRI Safety Information" section in the Catheter Kit IFU).

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.

The Accuryn Monitor Mounts and Accuryn Monitor Floor Stands are designed to hold the Monitor level with the floor. Do not place Monitor Floor Stands on a surface that excessively tilts the Monitor. See Setup section above for proper hanging procedure.

Do not position the Monitor so that it is difficult to disconnect the 18V Power Supply from the Monitor. Only use the provided 18V Power Supply cable for the Monitor. Attempting to plug in any non-approved cables or devices may compromise the function of the Monitor or the external device.

Handle the Monitor Floor Stands carefully. Do not drop.

Do not lower or rest any other equipment on or from the Monitor Floor Stands such as hospital beds or other drainage systems. Doing so could cause damage to equipment, injury or improper operation of the equipment. Always keep the Monitor Floor Stands clear of other equipment to prevent damage to the Accuryn Monitoring System and Monitor Floor Stands.

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).

Note: Prior to transport, it is recommended that the drainage line be clamped, and the Monitor paused. See Accuryn Monitoring System Operator's Manual for additional details.

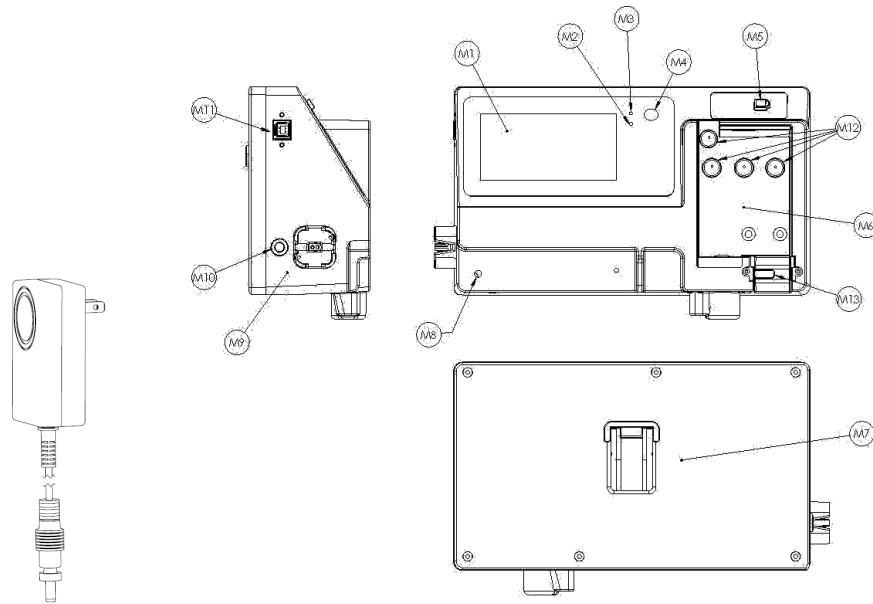


Figure 8. 18V Power Supply that attaches to Power Connector (M10) on the Accuryn Monitor.

Accuryn Monitor Mount Features:

F1. Mounting Point for Monitor

F2. Handle for Transport

F3. Pole-clamp and knob

Accessories Images:

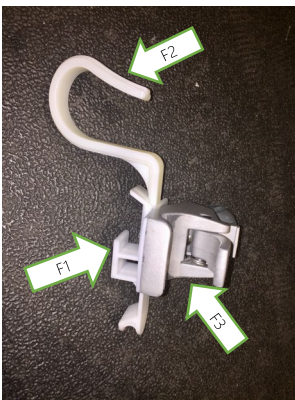


Figure 1: Accuryn Monitor Mount



Figure 2: Accuryn Monitor Floor Stand – Tall (19.5in tall)

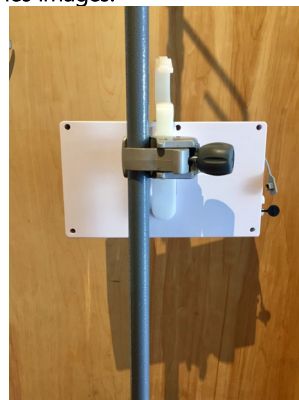


Figure 3: IV Pole mount



Figure 4: Accuryn Monitor mounted to Monitor Floor

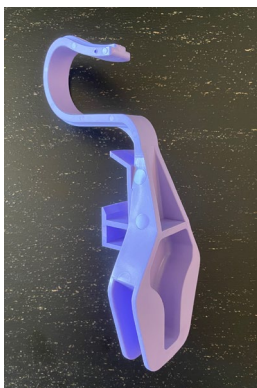


Figure 5: Accuryn Monitor High Mount



Figure 6: Accuryn Monitor High Mount in low position



Figure 7: Accuryn Monitor High Mount in high position



Figure 9: Accuryn Monitor Short Floor Stand (16 in tall)

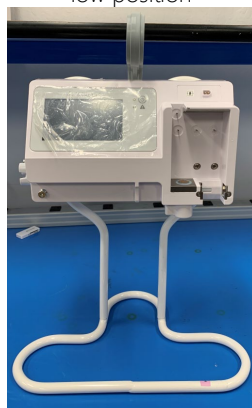


Figure 10: Accuryn Monitor Short Floor Stand with Monitor

Technical Support

For technical support, please call **Potrero Medical Customer Service at +1 833 ACCURYN (1 833 222-8796)**.

Accuryn® is a registered trademark of Potrero Medical, Inc.

Patent: www.potreromed.com/patents © 2021 Potrero Medical, Inc. (all rights reserved). Printed in U.S.A.



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

Issue Date: April 2023