

PRECAUTIONS AND OBSERVATIONS

1. The device must be inserted immediately after the patient has passed stool or after the rectum is confirmed to be void of stool.
2. In the event of expulsion of the device, rinse the receptacle and re-insert following instructions from the 'Insertion of Device' section and 'Receptacle Connection'.
3. The physician must use their discretion in using the device after having assessed the patient's medical history and size of hemorrhoid(s).
4. Caution must be exercised in patients with an inflammatory bowel condition or a previous history of anorectal surgery.
5. Care should be exercised while inserting as well as using the device on patients who tend to bleed from either anticoagulant/antiplatelet therapies or from an underlying condition/treatment.
6. Notify a physician immediately if any of the following occurs:
 - rectal pain
 - rectal bleeding
 - abdominal discomfort
7. If a patient appears to be having significant anal discomfort or if bleeding is visualized during the insertion of the device, the insertion procedure should be discontinued, and the physician should be notified.
8. The Qoromatic® Automated Stool Management uses systematic irrigation and suction to divert fecal exudate from the rectal vault. The patient may feel the sensation of "fullness" or foreign body sensation during use.
9. There is an inherent risk in handling fecal discharge and bodily secretions. Adequate precautions, per hospital guidelines, must be exercised while handling the device.
10. If the patient's bowel control, consistency, and frequency of stool begins to return to normal/formed stool or the patient becomes ambulatory, discontinue use of the device.
11. Some leakage of moisture or fecal discharge may be visible along the periphery of the device in patients with severe diarrhea or if the tube is obstructed.
12. The patient may involuntarily expel the device if any of the following happens:
 - stool consistency changes to normal/formed stool
 - device receptacle gets occluded with fecal material
 - rectum is not void of stool before device deployment
13. If any blood is visible along the periphery of the device or any wet redness of stool is observed in the transit tubing or drainage bag, discontinue the use of the device, and notify the physician.

POSSIBLE ADVERSE EVENTS

As with the use of any rectal device, the following adverse events could occur with the use of this device:

- rectal or anal bleed
- constipation or fecal impaction
- erythema of the rectal mucosa
- perforation of the anorectal region
- skin aggravation, pressure injury due to prolonged exposure with rigid portions of the device unless maneuvered regularly

In the event of any adverse events such as those listed above, please notify a physician immediately.

GENERAL GUIDELINES

1. If the product packaging is damaged, do not use.
2. The need for the drainage bag replacement should be assessed at least once in every 4-8 hours.
3. The uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.
4. The device may be removed as needed to perform patient assessment and reinserted after rinsing the receptacle.

INDICATIONS

The Qoromatic® Automated Stool Management is indicated for fecal management by diverting and collecting liquid or semi-formed stool in bedridden adult patients. Uninterrupted use of this device, including replacement with other same devices, should not exceed 29 days.

CONTRA-INDICATIONS

The Qoromatic® Automated Stool Management should NOT be used on individuals who:

- Have suspected or confirmed rectal mucosal impairment or pathology (i.e., severe proctitis, ischemic proctitis, mucosal ulcerations, etc.)
- Have had rectal surgery within the last year
- Have any GI bleeding, anal injury or have tendency to bleed
- Have hemorrhoids of significant size
- Have a rectal or anal stricture or stenosis
- Have or suspected to have tumor in the rectum or anal canal
- Have or suspected to have impacted stool
- Have or suspected to have constipation
- Have any indwelling rectal or anal device or delivery mechanism in place
- Are known to be sensitive or allergic to any components within the kit

INPUT: 100-240V, 50-60Hz, 1.5A AC

OUTPUT: 6V --- 2.0A DC

R ONLY
PRESCRIPTION
USE ONLY

TYPE B
APPLIED PART

TYPE B
APPLIED PART

NOT MADE WITH
NATURAL RUBBER
LATEX

DO NOT USE
IF PACKAGE IS
DAMAGED

CONSULT
INSTRUCTIONS
FOR USE

CONSULT
ACCOMPANYING
DOCUMENTS

IP20
PROTECTED AGAINST 12.5MM
Ø SOLID PARTICLES NOT
PROTECTED AGAINST WATER

UNIT

SINGLE USE

NON-STERILE

CLASS II
EQUIPMENT

conSure
MEDICAL

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IFU-12020-001-00

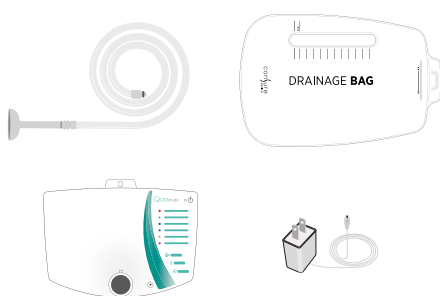
Qoromatic
Automated Stool Management

INSTRUCTIONS FOR USE

Read all Instructions for Use before using the product.

PRODUCT DESCRIPTION

The Qoromatic® Automated Stool Management (ASM) contains:
A. One receptacle attached to transit tube
B. One odor-barrier drainage bag
C. One Matic hub
D. One power adapter

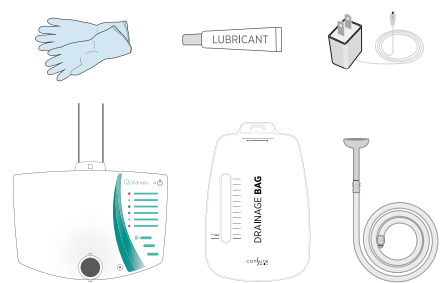


The Qoromatic® ASM is an automated and easy-to-use stool management device that requires minimal to no manual intervention to manage fecal incontinence or diarrhea in bedridden patients. This device employs a soft and pliable receptacle that rests inside the rectal vault and diverts fecal exudate into a drainage bag by systematically voiding the rectum using automated irrigation and suction.

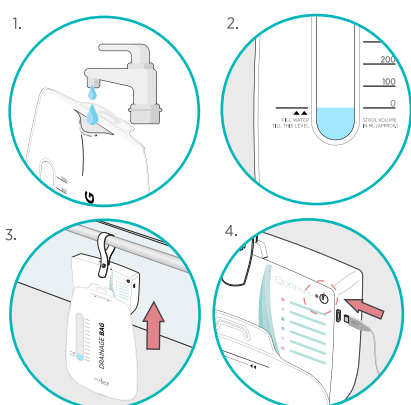
The indwelling receptacle is pre-assembled with a transit tube which connects to the matic hub at the other end. The disposable drainage bag connects to the matic hub and has two chambers. The irrigation fluid chamber is meant to be filled up till indication mark (approx. 500ml of distilled water/saline) and the stool collection chamber collects the fecal exudate diverted via the transit tube. The stool collection chamber negates the amount of irrigation fluid and accurately depicts the volume of stool output on a 1000 ml scale. The Matic hub has a one touch start/resume button and an indicator light at the front, and is hung at the bedside using integrated device strap.

PREPARATION OF DEVICE

1. In addition to Qoromatic® Automated Stool Management, lubricant, gloves, and approx. 500ml distilled water/saline will be required.
2. Ensure the nurse/trained hospital staff inserting the device is wearing gloves.

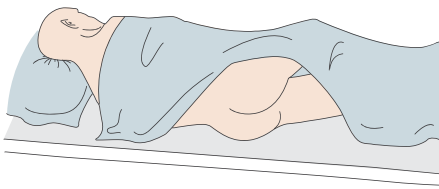


3. Fill the irrigation fluid chamber of the drainage bag with distilled water/saline, up till the indication mark.
4. Connect the bag to the Matic hub. Follow instructions mentioned under 'Replacement of Drainage Bag' section.
5. To hang the Matic hub, loop device strap over the bedside rail and secure. Ensure device is upright.
6. Plug in the Qoromatic® Automated Stool Management using power adapter provided in the box. A solid red indicator will appear on the device. DO NOT press the button yet.



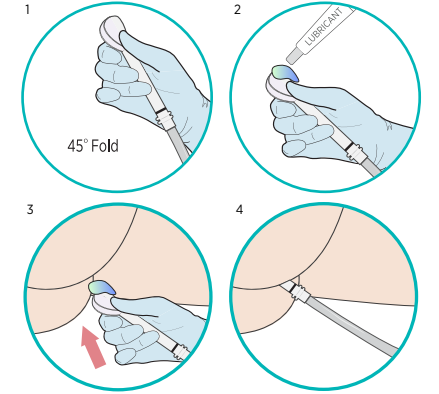
PREPARATION OF PATIENT

- 1. Position the patient in a left lateral Sims’ (side-lying) or a right lateral Sims’ position, depending on which the patient finds more comfortable. In the event the patient is not able to move, position the patient and the care provider such that the anal opening is visible and direct access is possible.
- 2. Ensure that the patient’s rectum is void of fecal matter prior to device deployment. If needed, at the discretion of a trained healthcare practitioner, institutional protocol can be followed to ensure the rectum is empty.



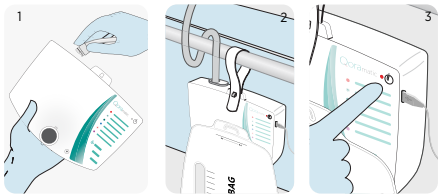
INSERTION OF DEVICE

- 1. Unfold the length of Receptacle unit to lay flat on the bed.
- 2. Hold the receptacle between the thumb and index finger, fold it twice, diagonally to create a smaller conical shape for easy insertion.
- 3. Generously coat the patient’s anal opening and the tip of the receptacle with lubricant.
- 4. Gently insert the receptacle through the anal orifice until it is past the anal canal and above the ano-rectal junction.
- 5. The black indicator on the receptacle assists in correct placement of the device. In most patients, black line immediately outside anal orifice indicates correct device placement.
- 6. Place the tube flat along the length of the bed and avoid any twists or kinks. No portion of the tube should be obstructed under the patient or other heavy objects on the bed.
- 7. Discard the contaminated gloves according to institutional protocol.



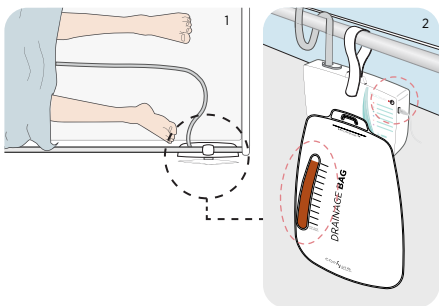
RECEPTACLE CONNECTION

- 1. Connect the tube connector on distal end of the transit tube to the Matic hub. Ensure snug fit. Looping the tube around the bed rail ensures it doesn’t get tugged off the Matic hub.
- 2. Press the power button once to turn on the Goramatic® Automated Stool Management. Previously red indicator will turn blinking green.



MAINTENANCE OF DEVICE

- 1. Ensure the transit tube is laid flat along the length of the bed with no twists or kinks. No portion of the tube should be obstructed under the patient or other heavy objects on the bed. Ensure the receptacle is adequately inserted inside the rectal vault and the other end of the transit tube is connected securely with the Matic hub.
- 2. Place the transit tube between the patient’s leg in supine and behind the patient in lateral position.
- 3. While repositioning or maneuvering the patient, relocate the matic hub at a location that avoids excessive tension.
- 4. Assess the volume of the collection bag at least once every 4-8 hours. Replace bag in case of blue Indicator light or stool output up till or over the 1000ml mark. Refer to ‘Replacement of Drainage Bag’ for more.
- 5. Check device indicator periodically to ensure consistent device operation. In case of indicator light other than green, device requires user intervention. Follow steps under ‘Indicator Light’.



REPLACEMENT OF DRAINAGE BAG

Drainage bag should be assessed at least once every 4-8 hours and replaced in either of these scenarios:

- 1. Blue indicator light (implies fluid in irrigation chamber is finished.)
- 2. Stool output over 1000ml mark in the bag (implies stool collection chamber is full.)

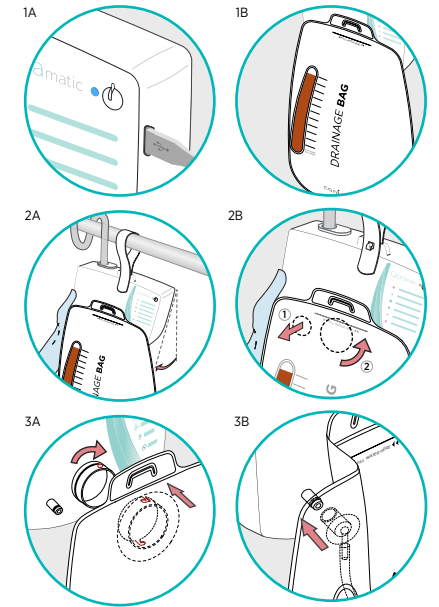
To remove a bag:

When replacing a bag, it is advised to get a fresh drainage bag and fill it with distilled water/ saline till indication, before unmatting the existing bag.

- 1. Turn OFF the device by unplugging power adapter
- 2. Tilt the bag and matic hub forward by 45 degrees to avoid any residue spillage while removing the drainage bag.
- 3. Carefully diconnect irrigation connector and then twist the bag connector counterclockwise from the matic hub to disengage bag.
- 4. Discard the used bag according to institutional protocol.

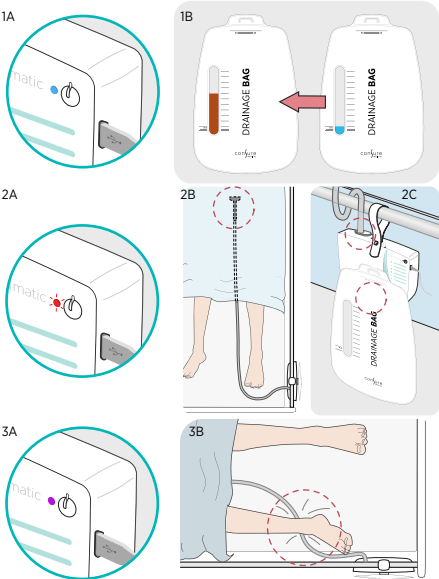
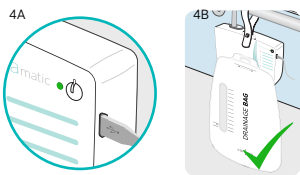
To mate a bag:

- 1. Mate the bag connector (filled with irrigation fluid) with the Matic hub and rotate it clockwise until they are locked together. Push fit irrigation connector on to irrigation port.
- 2. Turn the device ON by replugging the power adapter.



INDICATOR LIGHT

- 1. The light turns red when the device is plugged in. Turn on the device by pressing the start button.
- 2. Blinking green light indicates device operations such as irrigation or effluent diversion are currently ongoing. No intervention is required.
- 3. Solid green indicates device is operational and no intervention is required.
- 4. Blue light indicates water in the irrigation fluid chamber is finished. Follow instructions mentioned under ‘Replacement of Drainage Bag’ section to replace existing bag with a new one.
- 5. Blinking red light indicates vacuum error. Ensure the connections between receptacle connector, Matic hub, and the drainage bag are intact. Ensure receptacle is correctly placed in patient rectum. Press the start button to resume device functionality.
- 6. Solid magenta indicates tube block error. Ensure that no portion of the tube is obstructed under the patient or other heavy objects on the bed. Press the start button. If error persists, replace the device.



REMOVAL OF DEVICE

- 1. Turn OFF the device by disconnecting the adapter from the matic hub and the power socket.
- 2. Ensure the nurse/trained hospital staff removing the device is wearing gloves and the patient is in a left lateral Sims’ (side-lying) or right lateral Sims’ position. In the event the patient is not able to move, position the patient and the care provider such that the anal opening is visible and direct access is possible.
- 3. Hold the receptacle close to the anal canal and slowly retrieve the receptacle from the anal orifice.
- 4. Discard the device according to institutional protocol.

