



CloudCath System

Instructions for Use/User Guide

00121-110424

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PRODUCT OVERVIEW

CloudCath Peritoneal Dialysis Drain Set Monitoring System
(CloudCath System)

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INTENDED USE

The CloudCath System is intended for patients undergoing acute and chronic peritoneal dialysis.

THE CLOUDCATH SYSTEM IS TO BE USED ONLY WITH...

- Baxter Healthcare Homechoice PRO
- Baxter Healthcare Homechoice Claria
- Baxter Healthcare Amia Automated PD System
- Fresenius Liberty Select Cyclor

The most current CloudCath System User Guide/Instructions for Use and related Technical Bulletins can be obtained from the CloudCath website: www.cloudcath.com or by contacting your healthcare professional for more information. If you have any questions, please contact CloudCath Product Technical Support at 877-664-6555 (toll-free) or 415-484-4896.

INDICATIONS FOR USE

The Cloudcath System enables drainage and measures turbidity, reported as a numeric score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The System is indicated for use by patients undergoing continuous cycling peritoneal dialysis (CCPD) in a healthcare facility or at home. The Optical Sensor has associated hardware and software components to allow for data transmission to a healthcare professional.

This System is not intended to provide diagnostic information and is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

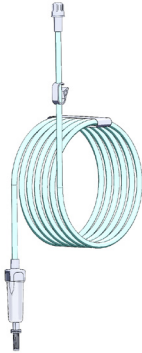
PRODUCT DESCRIPTION: CLOUDCATH SYSTEM

The CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) is tabletop passive drainage system used as an attachment during peritoneal dialysis (PD) treatment and indicated for use by patients with acute and chronic end stage renal disease undergoing PD. The CloudCath System connects directly to the end of the cyclor tubing set drain line in order to enable draining and contains an optical sensor that measures turbidity, reported as a turbidity score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The System is indicated for use with validated peritoneal dialysis cyclers in healthcare facilities or home use environments. The optical sensor has associated hardware and software components to allow for remote data transmission by healthcare providers.

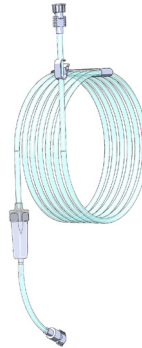
The CloudCath System consists of two components for the patient:

- Drain Set, Baxter or Fresenius Configuration (*provided separately*)
- Sensor

CloudCath Drain Set (Single-Use Disposable 20 ft. Drain Line Extension)



*CloudCath Drain Set -
Baxter Configuration*



*CloudCath Drain Set -
Fresenius Configuration*

Figure 1: System Components

CloudCath Sensor



System Workflow

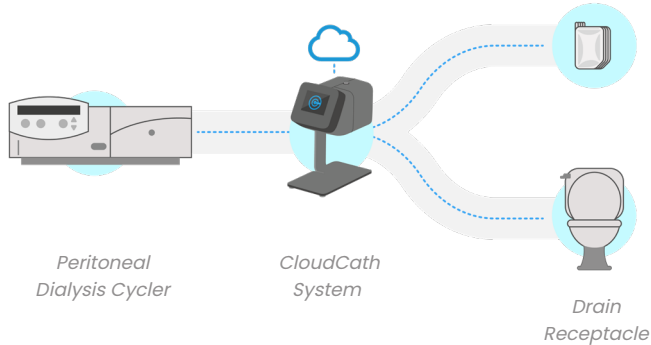


Figure 2: System Workflow

CLOUDCATH DRAIN SET AND SENSOR

With the CloudCath System, patients connect the drain line of the PD automatic cycler tubing set to the CloudCath Drain Set (which includes a 20 ft. length of extension tubing) before routing the fluid to the drainage receptacle, as shown in Figure 2.

The CloudCath Sensor, when assembled with the CloudCath Drain Set, monitors the effluent drainage from the patient through non-fluid contacting optical sensors during each dialysis exchange cycle and provides information on the fluid turbidity for the Healthcare Provider to aid in management of PD patients. The optical sensor performs turbidity measurements during each drainage cycle. Data from the optical sensors is processed and stored until the data for each drainage cycle is successfully transmitted to the cloud-based Patient Monitoring Software database via wireless communication.

Note: The CloudCath System does not utilize Bluetooth or Wi-Fi connections. The CloudCath System transmits data via wireless communications similar to a cellular phone.



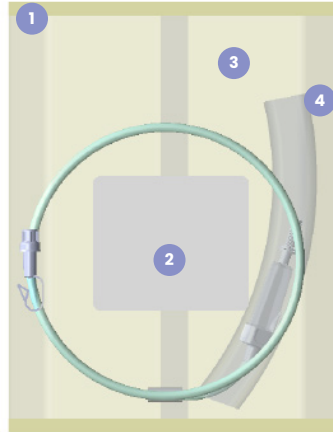
Section 1.1

CLOUDCATH DRAIN SET COMPONENTS

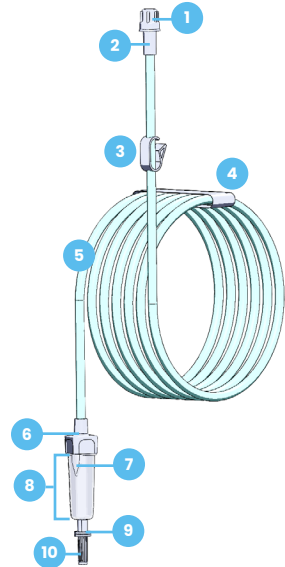
Figure 3: Detailed Diagram: CloudCath Drain Set Components

CloudCath Drain Set - Baxter Configuration

Packaged

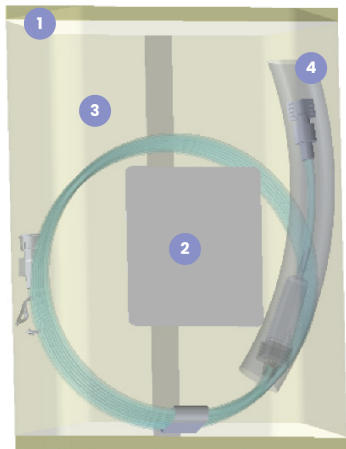


Unpackaged

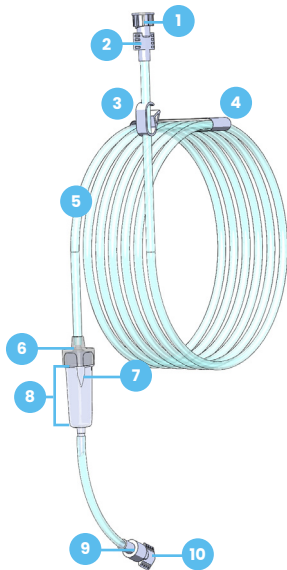


CloudCath Drain Set - Fresenius Configuration

Packaged



Unpackaged



Packaged

- ① Tear Notch
- ② Product Label
- ③ Packaging Pouch
- ④ Protective Sleeve

Unpackaged

- ① End Cap (Drain End)
- ② Drain / Exit Connection Port
- ③ Tubing Clamp
- ④ Tape
- ⑤ Drain Tubing
- ⑥ Sensing Window Cap
- ⑦ Window Notch Tab
- ⑧ Sensing Window
- ⑨ Inlet Connection Port
- ⑩ End Cap (Cycler End)

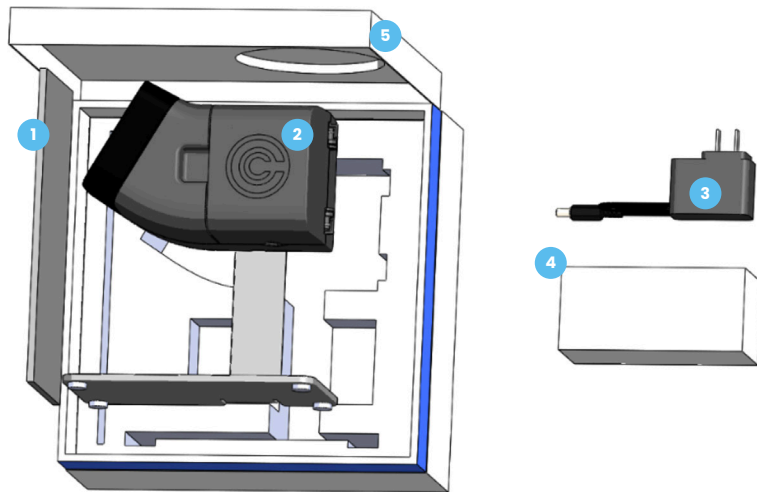
Sensor Packaging and Components

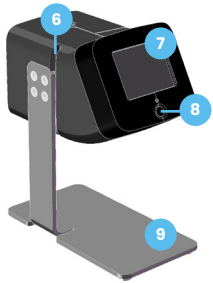


Section 1.2

SENSOR COMPONENTS

Figure 4: Detailed Diagram: CloudCath Sensor Components

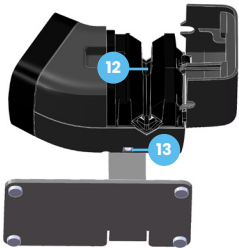




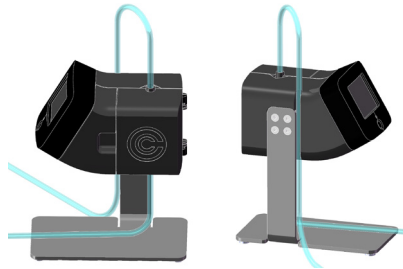
Sensor (Left Side View)



Sensor (Right Side View)



Sensor (Bottom View)



Sensor Assembled with Drain Set

- ① Instructions for Use
- ② Sensor
- ③ Power Supply
- ④ Power Supply Box
- ⑤ Sensor Storage Box
- ⑥ Tubing Holder
- ⑦ Display Screen
- ⑧ Display Button
- ⑨ Stand
- ⑩ Thumb Groove
- ⑪ Door
- ⑫ Sensing Area
- ⑬ Power Inlet



Section 1.3

DEFINITIONS & DESCRIPTIONS

Drain/Exit Connection Port

Connect this port to the drainage receptacle or drain bag, if applicable

End Cap (Cycler End)

Remove this cap to connect to the cycler

End Cap (Drain End)

Remove this cap to drain into receptacle

Inlet Connection Port

Use this port to complete connection to cycler

Sensing Window Cap

Top component of Sensing Window which is utilized to hold the Sensing Window during setup

Sensing Window

Component that will be inserted into the CloudCath Sensor to allow for monitoring

Tubing Clamp

Utilize during and after setup to manage fluid

Window Notch Tab

Verifies correct orientation upon insertion into the CloudCath Sensor by using the notch tab as a guide

Display Button

Pressed to exit standby mode

Display Screen

Interface where Sensor will display instructions, modes and errors

Instructions for Use

User Guide that explains proper setup, use, cleaning, maintenance, storage and operating conditions, and technical specifications

Power Inlet

The connection port to the Power Supply

Power Supply

Connects Sensor to a standard wall outlet for power

Power Supply Box

Used to store or transport the Power Supply

Stand

Supports Sensor and allows Sensor to be placed on flat surface

Sensing Area

Interface to the Drain Set Sensing Window where turbidity sensing will be performed

Sensor Packaging and Components

Packaged assembly that will include Sensor, Instructions for Use, Power Supply, Sensor Storage Box, and Power Supply Box

Sensor Storage Box

Used to store or transport the Sensor and accessories

Tubing Holder

Area to secure tubing to assist with managing tubing

Thumb Groove

Allows access to open the door



Section 1.4

SENSOR MONITORING MODES

MONITORING MODES

Monitoring modes will indicate whether dialysate fluid has normal turbidity, or if the fluid turbidity has exceeded the notification threshold set by the Healthcare Provider.

- The logo will appear in blue with text stating “**Monitoring**” and remain steady when fluid turbidity is normal.
- If the turbidity notification threshold is exceeded, the logo will switch from blue to orange, and the text “**Contact Healthcare Provider**” will flash continuously.
- After contact with Healthcare Provider is completed, the screen will remain orange and the text will state “**Monitoring Under Treatment.**”
- The logo only switches from orange back to blue when the notification is resolved by the Healthcare Provider.

Figure 5: Active Monitoring mode graphics



Fluid Turbidity is Normal
NO ACTION NEEDED



Fluid Turbidity has exceeded notification
threshold
CONTACT HEALTHCARE PROVIDER



Healthcare Provider Has Acknowledged
Notification
**MAINTAIN CONTACT WITH HEALTHCARE
PROVIDER DURING TREATMENT**

1

2

3



GENERAL WARNINGS & CAUTIONS

COMPATIBILITY

The CloudCath System is to be used only with...

- Baxter Healthcare Homechoice PRO
- Baxter Healthcare Homechoice Claria
- Baxter Healthcare Amia Automated PD System
- Fresenius Liberty Select Cyclor

Consult the peritoneal dialysis cyclers Instructions for Use as needed.

CAUTION

- Federal (USA) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

Do NOT use the CloudCath Drain Set extension with low recirculation sets and fill volume of less than 1000 ml.

NOTES

Under normal operating and storage conditions, the expected useful life of the CloudCath Sensor is five years.



GENERAL WARNINGS

The **CloudCath System** could be potentially affected by optically active agents/medications, foods and supplements including but not limited to indocyanine green.

Do NOT attempt to disassemble or service the **CloudCath Sensor**. For technical service, contact the Healthcare Provider or CloudCath.

Do NOT service or maintain any part of the **CloudCath System** while in use with a patient. For technical service, contact the Healthcare Provider or CloudCath.

Do NOT operate the **CloudCath System** where the following are in use:

- Flammable anesthetic agents
- Nitrous oxide
- Oxygen-enriched environment (for example, oxygen tent)

Do NOT operate the **CloudCath System** if it:

- Is visibly damaged
- Has a damaged **Power Supply**
- Is not working properly
- Has been dropped or damaged
- Has been dropped into water

Do NOT use attachments, accessories, or supplies not recommended by CloudCath. Always ensure adequate supplies which are compatible with the peritoneal dialysis cyclers have been ordered with oversight provided by a Healthcare Provider.

Do NOT use the **CloudCath Drain Set** after expiration date.

Keep the **Power Supply** away from heated surfaces. Only use the CloudCath provided **Power Supply**.

When handling the **CloudCath Drain Set**, use aseptic techniques. Contamination of any portion of the fluid path may result in peritonitis. If contamination is suspected, follow the instructions supplied by the Healthcare Provider for proper procedure.

Do NOT use the **CloudCath Drain Set** if package is damaged or **End Caps** are not in place.

Do NOT place or store **CloudCath System** where it can fall or be pulled into a tub or sink.

Do NOT place or drop the **CloudCath System** into water or other liquid.

Do NOT use the **CloudCath Drain Set** more than once. Discard after each use. Reusing the disposable **CloudCath Drain Set** may increase the risk of contamination, which may result in peritonitis.

Ensure all connections to the **CloudCath Drain Set** remain secure during treatment. Prevent the **CloudCath Drain Set** from being pulled on while installed in the **CloudCath Sensor**. Failure to do so may result in damage to **CloudCath Sensor**, peritoneal dialysis cyclor, or serious patient injury.

Use caution when handling the **CloudCath Sensor Power Supply** or **CloudCath Drain Set** as they may cause strangulation. Coil and maintain extra wire and tubing when not in use.



GENERAL WARNINGS

Continued

Use caution when handling the **CloudCath Sensor Power Supply**, **CloudCath Drain Set**, and peritoneal dialysis cyclor tubing set since they can be a trip hazard and may result in falls.

Do NOT reach for the **CloudCath System** if it has fallen into water. Unplug it from the wall outlet right away.

Keep the **CloudCath System** away from water. Do not store or operate the **CloudCath System** in a wet or moist place.

Wipe up spills on or near the **CloudCath Sensor** right away. This reduces the chance of moisture entering the **CloudCath Sensor** and causing a malfunction or contamination.

Do NOT submerge the **CloudCath Drain Set** drain end in liquid such as in the toilet. If not using a drain bag, maintain an air gap between the end of the **CloudCath Drain Set (Drain/Exit End Connection Port)** and any fluid in the drain or container.





GENERAL CAUTIONS

Do NOT operate the **CloudCath System** until training is completed by a qualified medical professional on its safe and effective use. Read the entire contents of the **Instructions for Use** that explains how to setup the system.

Use caution to not disrupt the **CloudCath System** during setup of the peritoneal dialysis cyclor.

Use only accessories approved by CloudCath for use with the system and ensure **Instructions for Use** provided with the accessory are followed. CloudCath cannot ensure that unapproved accessories, when connected with the **CloudCath System** will function in a safe and satisfactory manner.

Do NOT use additional drain line extensions with the **CloudCath Drain Set**.

Do NOT disconnect power during monitoring. Failure to follow these instructions could result in interruption of monitoring.

The **CloudCath Sensor** is not intended to be a hand-held system. Ensure the **CloudCath Sensor** is placed on flat surface during operation. Do not operate while holding in hand.

Do NOT store or operate the **CloudCath System** in direct sunlight.

Ensure a safe operating distance from users. Do not operate **CloudCath Sensor** within 1 meter of users.

To prevent the **CloudCath Sensor** from falling, place it on a sturdy, dry surface. Falling can damage the System or cause personal injury.

Avoid proximity to equipment with high electrical noise. Portable Radio Frequency (RF) communications equipment (including items like antenna cables and external antennas) should not be closer than 30 cm (12 inches) to any part of the **CloudCath Sensor**. Otherwise, degradation of the performance of the **CloudCath Sensor** could result.

Keep the **Power Supply** away from heated surfaces. Only use the CloudCath provided **Power Supply**.

Do not place the **CloudCath Sensor** on top of the peritoneal dialysis cyclor, near fluid bags, metal beams, or other medical equipment or electronics that could potentially block network signal. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The use of the **CloudCath Sensor** in home or hospital environments may result in interference with some types of broadcast receivers such as televisions, radios or other medical equipment. If such interference were to occur, it could result in a delay/inability to monitor and premature or late notifications.

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SYSTEM SETUP

4

CLOUDCATH SENSOR PREPARATION AND INSPECTION:

1. Open the **Sensor Storage Box** and remove the **CloudCath Sensor** by lifting it out of the foam insert. Keep the **Sensor Storage Box** to use as protective packaging for storage or transport of the Sensor.
2. Remove the **Power Supply** from the **Power Supply Box**.
3. Inspect the **CloudCath Sensor** and **Power Supply** for any damage.

Warning: Do not use a CloudCath Sensor if the Sensor is found to be damaged.

CLOUDCATH DRAIN SET PREPARATION AND INSPECTION:

1. Inspect **Packaging Pouch** and confirm that Drain Set is not past the expiration date.
Warning: Do not use a CloudCath Drain Set if past the expiration date.
2. Open the **Packaging Pouch** of the CloudCath Drain Set using the **Tear notch**.
*Warning: Do not use a CloudCath Drain Set if the **Packaging Pouch** is found to be opened or damaged.*
3. Inspect the CloudCath Drain Set for any damage.
*Warning: Do not use a CloudCath Drain Set that has physical damage.
Remove the **Protective Sleeve** covering the **Sensing Window**.*
4. Inspect the **Sensing Window** of the CloudCath Drain Set for any marks or damage.
*Warning: Do not use a CloudCath Drain Set that has visual marks or damage on the **Sensing Window**. NEVER touch the **Sensing Window** while handling to avoid marking or damaging the **Sensing Window**.*
3. Uncoil the Drain Set by removing the **Tape** and verify that there are no kinks in the **Drain Tubing**.



CLOUDCATH SENSOR SETUP AND DRAIN LINE INSERTION

Use the following sequence DAILY at the time that the cyclor instructs you to connect the cassette drain line to the drain bag or drain receptacle.



1

Plug the **Power Supply** connector into the bottom of the CloudCath Sensor **Power Inlet**.



2

Plug the **Power Supply** power plug into a standard AC power outlet, and wait for the Sensor **Display Screen** to turn on.

Note: Upon powering on or restarting the CloudCath Sensor, ensure that initialization, as detailed below, is completed without interruption.



3

The Sensor will initialize and connect to the cellular network, when starting up. Initialization may take 2-3 minutes.

*Note: During the Sensor initialization, do not have anything inserted in the **Sensing Area**, and the **Door** must be closed.*



Once initialization is complete, the Sensor **Display Screen** will indicate "Device Ready for Use!"



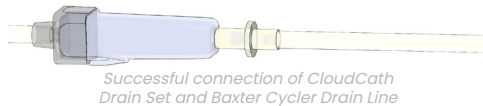
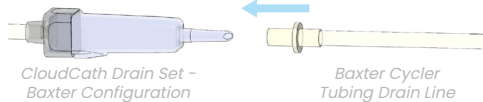
Connect Drain Set



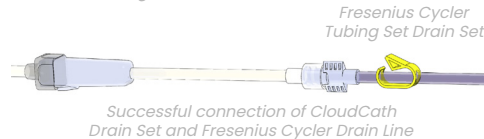
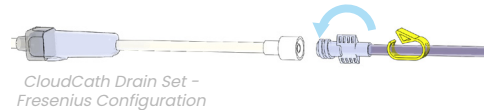
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When the **Sensor Display Screen** prompts to “Connect Drain Set”, verify the protective sleeve has been removed from the Drain Set, and connect Baxter or Fresenius peritoneal dialysis cyclor tubing set drain line to the CloudCath Drain Set:

Baxter Configuration



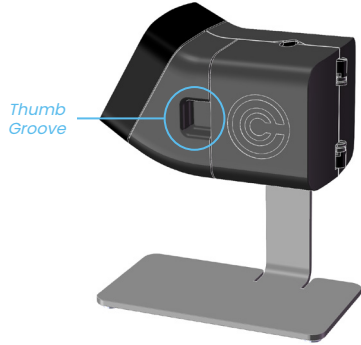
Fresenius Configuration



- Uncoil the peritoneal dialysis cyclor tubing set drain line to reduce the chance of introducing air bubbles.
- NEVER touch the **Sensing Window**. Hold the Drain Set by the **Sensing Window Cap** to avoid damage to the **Sensing Window**.
- Remove the **End Cap (cyclor end)** from the **Inlet Connection Port** of the Drain Set.
- Connect the drain line connector of the cyclor tubing set to the **Inlet Connection Port** of the **CloudCath Drain Set**.

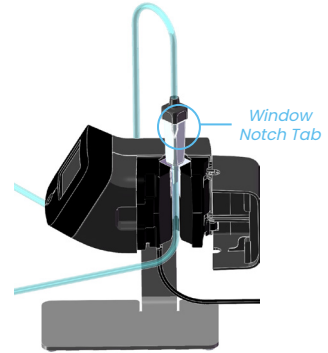
*Note: For the **Baxter configuration**, push the drain line connector to the **Inlet Connection Port** until they are firmly seated. The drain line connector should be flush with the shoulder of the **Inlet Connection Port**.*

*Note: For the **Fresenius configuration**, rotate the connectors until secure.*



5

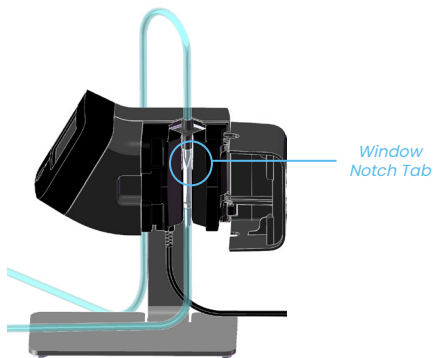
Use the **Thumb Groove** to open the CloudCath Sensor Door.



6

Insert CloudCath Drain Set **Sensing Window** by sliding it into the **Sensing Area** in the CloudCath Sensor.

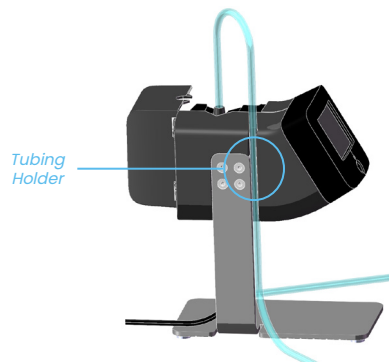
Verify that the CloudCath Drain Set **Inlet Connection Port** is on the bottom and **Exit Connection Port** is on the top.



7

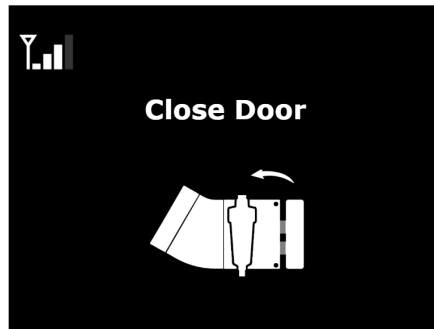
Push the CloudCath Drain Set **Sensing Window** all the way down to fully seat the **Sensing Window** into the **Sensing Area**.

Verify the **Window Notch Tab** is in the correct rotational orientation.



8

Loop the **Drain Tubing** on the opposite side of the CloudCath Sensor and press tubing into the **Tubing Holder** to secure the CloudCath Drain Set.



9

Once the Drain Set is inserted properly, the **Sensor Display Screen** will prompt you to “Close Door”. Close the **Sensor Door** until completely closed.

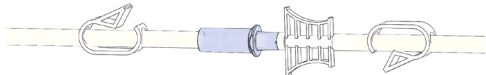


Baxter Configuration



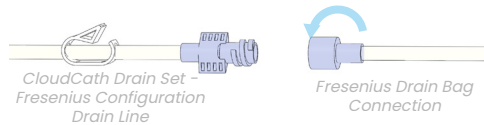
CloudCath Drain Set -
Baxter Configuration
Draining Line

Baxter Drain Bag
Connection



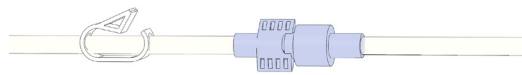
Successful connection of CloudCath
Drain Set - Baxter Configuration and
Baxter Drain Bag Connection

Fresenius Configuration



CloudCath Drain Set -
Fresenius Configuration
Drain Line

Fresenius Drain Bag
Connection



Successful connection of CloudCath
Drain Set - Fresenius Configuration and
Fresenius Drain Bag Connection

10

Remove the **End Cap** of the **Drain/Exit Connection Port**.

If not using a drain bag, place the end of the CloudCath Drain Set into the toilet or other receptacle, ensuring an air gap is maintained between the end of the **Drain/Exit Connection Port** and any fluid. Do NOT submerge the **Drain/Exit Connection Port** in any fluid.

If using a drain bag, connect the **Drain/Exit End Connection Port** to the bag as noted:

- For a Baxter drain bag, connect the **Drain/Exit End Connection Port** to the spiked connector of the drain bag by pushing the **Drain/Exit End Connection Port** until they are firmly seated. The **Drain/Exit End Connection Port** should be flush with the shoulder of the drain bag spike connector.
- For a Fresenius drain bag, connect the **Drain/Exit End Connection Port** to the connector of the drain bag by rotating the connectors until secure



11

Verify the **Tubing Clamp** is in the open position.

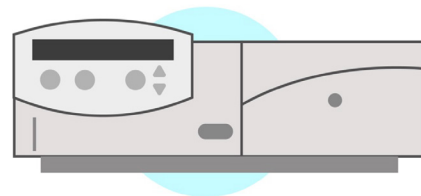


Note: Monitoring Mode display may vary. See Section 4.

12

When the CloudCath Sensor and CloudCath Drain Set setup is complete, the **Display Screen** will be updated to indicate the device is in monitoring mode.

At this point, the CloudCath System is ready to monitor and will automatically measure the effluent fluid during each peritoneal dialysis drain cycle.



Peritoneal Dialysis Cyclor

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Proceed with remaining setup instructions for the cyclor per the manufacturer's Instructions for Use to perform dialysis.

Note: Coil and manage any unused Drain Set tubing.

3

4



MONITORING MODES

After Sensor setup is complete, the Sensor will enter Monitoring Mode. During all Monitoring Modes, the device will continue measuring dialysate fluid turbidity, and must be set up properly.

5

4.1 NORMAL MODE



Figure 6: Normal Monitoring mode display

Normal Monitoring mode will indicate when patient turbidity is under the notification threshold. The CloudCath logo will appear in blue and the text will state "Monitoring."

Fluid Turbidity is under notification threshold.
NO ACTION NEEDED AT THIS TIME

4.2 CONTACT HEALTHCARE PROVIDER MODE



Figure 7: Contact Healthcare Provider Monitoring mode display

If the turbidity notification threshold is exceeded, the logo will switch from blue to orange, and the text “Contact Healthcare Provider” will flash. This indicates when an increase in fluid turbidity occurs.

Fluid Turbidity has exceeded notification threshold.
CONTACT HEALTHCARE PROVIDER IMMEDIATELY

4.3 MONITORING UNDER TREATMENT MODE



Figure 8: Monitoring Under Treatment mode display

During an escalation in which effluent fluid has exceeded the notification levels, and after contact is made with your Healthcare Provider, the logo will remain orange and the text will state “Monitoring Under Treatment.” This indicates that you have contacted your Healthcare Provider and they are currently monitoring your medical treatment. The CloudCath System will remain in this mode until your Healthcare Provider has resolved the notification.

Fluid Turbidity has exceeded a notification threshold and patient is under the care of Healthcare Provider.

CONTINUE CONTACT WITH YOUR HEALTHCARE PROVIDER UNTIL YOUR TREATMENT IS COMPLETE

4

5



DRAIN SET REMOVAL/DISPOSAL

Session Completion and Drain Set Removal:

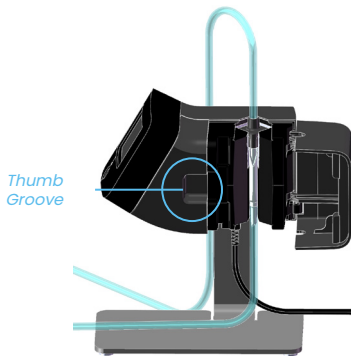
When the cyclor indicates that the dialysis treatment is complete or the cyclor instructs you to disconnect the patient catheter, use the following sequence for each DAILY disconnection of the system.

6



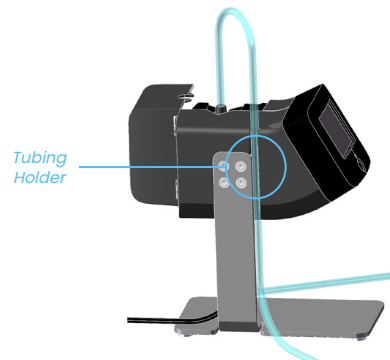
1

Close the **Tubing Clamp**.



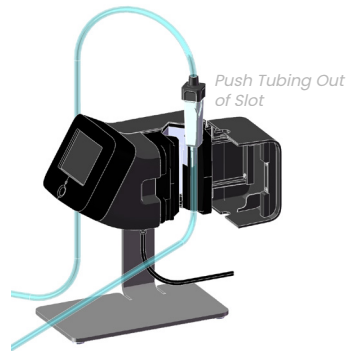
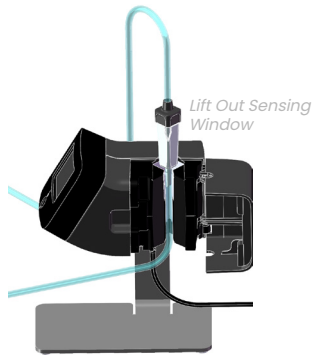
2

Use the **Thumb Groove** to open the Sensor door.



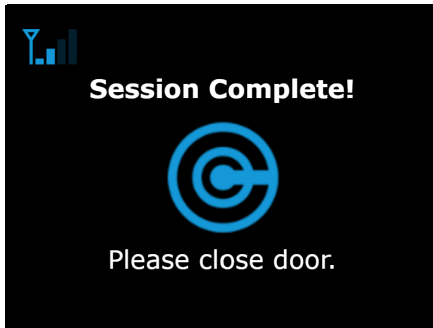
3

Remove the **Drain Tubing** from the **Tubing Holder**.

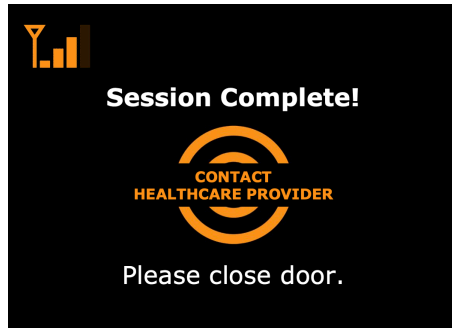


4

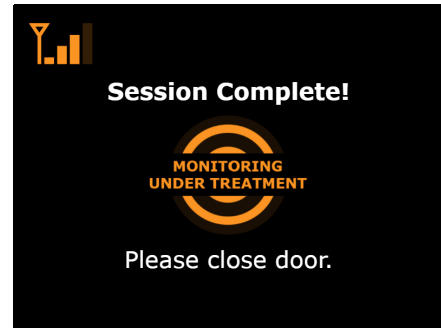
Lift the **Sensing Window** out of the **Sensing Area**. Next, push the tubing out of the slot.



Session Complete Display A



Session Complete Display B



Session Complete Display C

5

Upon successful use of the system and completion of the session, the **Display Screen** will indicate "Session Complete!".

Close the **Sensor Door**.



Ensure door is completely closed

6

Dispose of the cyclor tubing set and CloudCath Drain Set per local guidelines for dialysis waste disposal. Do NOT dispose of the CloudCath Sensor.

7

Proceed with existing manufacturer cyclor disconnect instructions.



8

After each use, the Sensor may be left on and plugged in. After 5 minutes of no activity, the sensor will enter Standby mode and the **Display Screen** will dim.



9

To exit Standby mode when the Sensor is ready for the next use, push the **Display Button** or open the **Sensor Door**.

Warning: Do NOT leave a CloudCath Drain Set assembled to the CloudCath Sensor while the Sensor is not in use. The Sensor will continue measuring the fluid and may provide incorrect monitoring results.

5.1: DRAIN SET DISPOSAL

Disposal of CloudCath Drain Set:

Dispose of the cyclor tubing set and CloudCath Drain Set as a single piece per local guidelines for dialysis waste disposal. Do NOT dispose of the CloudCath Sensor.

5.2: SENSOR RETURN

Disposal/Return of CloudCath Sensor:

Do NOT dispose of the CloudCath Sensor in a waste disposal. Return to Healthcare Provider or CloudCath.



5

6

7



SENSOR DISPLAYS

CloudCath Sensor Displays:

When the Sensor is powering on, the **Display Screen** information will appear in the following sequence.



1

Power connection indicated by **Display Screen** back light.



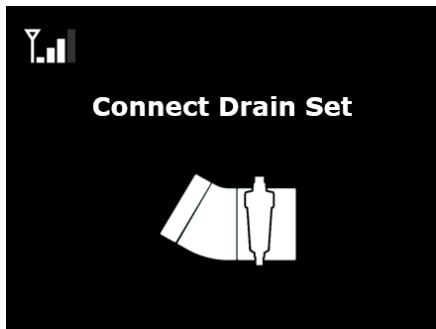
2

Sensor initialization starts including cellular network connection.



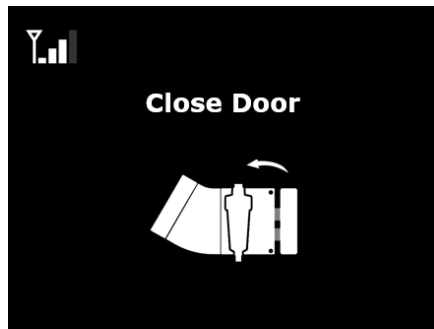
3

CloudCath Sensor has completed initialization and is ready for use.



4

Prompt to connect the CloudCath Drain Set to the cyclor tubing set and insert Drain Set **Sensing Window** into the CloudCath **Sensor**.



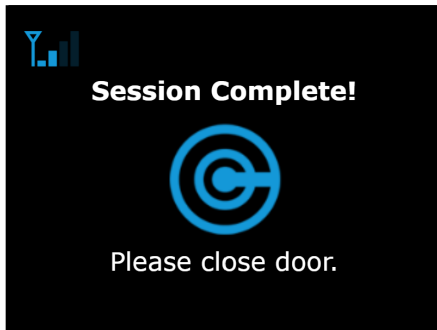
5

Prompt to close the CloudCath Sensor **door**.

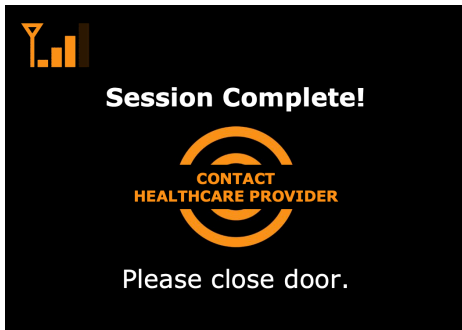


6

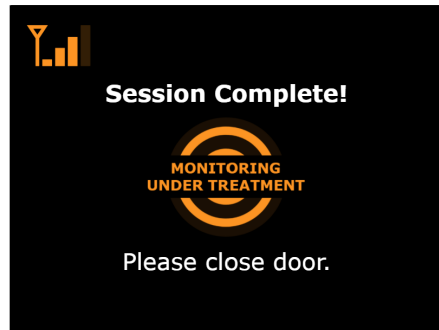
When all setup steps are complete, indicates the Sensor is in Monitoring mode. (May display Normal Monitoring Mode, Contact Healthcare Provider Monitoring Mode or Monitoring Under Treatment Mode.)



Session Complete Display A



Session Complete Display B



Session Complete Display C

7

Upon completion of a peritoneal dialysis treatment, indicates session is complete. (Display dependent based on most recent Monitoring Mode.)

Display A indicates Fluid Turbidity is under the notification threshold.

Display B indicates Fluid Turbidity has exceeded threshold. Contact Healthcare Provider.

Display C indicates Fluid Turbidity has exceeded notification threshold and patient is under the care of the Healthcare Provider. Maintain contact with the Healthcare Provider until the treatment is complete.



7



STANDBY MODE

Standby Mode:

When the Sensor has completed Monitoring mode and has not been used for over 5 minutes, the **Display Screen** will indicate that the system is in Standby mode as shown below by the display of the CloudCath logo. If the **Display Screen** does not show any active notifications, the **Display Screen** will appear blue. If a notification is active, the **Display Screen** will appear orange as shown in **Figure 9** on the next page.

Figure 9: Standby modes



8



ERROR MESSAGES & TROUBLESHOOTING

Error Messages and Troubleshooting:

Error messages and icons will appear in the following cases

Remove Drain Set for System Initialization



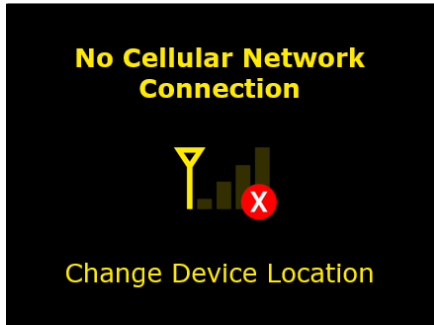
If a CloudCath Drain Set or other object is placed inside the CloudCath Sensor during initialization, the “Remove Drain Set for System Initialization” error will display. During Sensor Initialization, the CloudCath Drain Set must be removed from the Sensor.

Close Door for System Initialization



If the CloudCath Sensor door is open during initialization, the “Close Door for System Initialization” error will display. During System Initialization, the Sensor door must be closed.

Error Display During Initialization



Error Display During Monitoring Mode



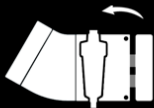
If there is cellular network coverage loss during initialization or after using the system in Monitoring mode for more than 12 hours without network connection, the “No Cellular Network Connection” error will display.

Note: No notifications can be triggered without cellular network connection.

- Move the CloudCath Sensor to see if cellular network strength improves and the error disappears. Avoid close proximity to large metal objects or structures.
- If the error does not disappear, try to reset the CloudCath Sensor by unplugging and re-plugging the **Power Supply**.
- If error still does not disappear and cellular network connection cannot be made, contact CloudCath support.



Close Door



If the door is not closed completely or is opened during Monitoring mode, the “Close Door” error will display.

- Attempt to re-insert the **CloudCath Drain Set**, ensure there is no door blockage, and open/close the door again.

Patient Not Assigned to Device



Contact CloudCath Support

Each CloudCath Sensor is specifically assigned to an individual patient. If the CloudCath Sensor has not been activated, the “Patient Not Assigned to Device” error will display.

- Ensure the CloudCath Sensor is in a location with sufficient cellular network connection. If error remains, contact CloudCath support.
- Once successfully assigned, the **Display Screen** will update as shown.

Success!



Patient Assigned to Device

Device Error



**Servicing Required
Contact CloudCath Support**

ERROR CODE: -####, -####, -####

If the system has a critical error during initialization, the “Device Error” will display.

- First, clean the **Sensing Area** per the Cleaning and Disinfection Instructions provided in this **User Guide** in Section 9, then reset the CloudCath Sensor by unplugging and re-plugging the **Power Supply**.
- If the Sensor error is not resolved, contact CloudCath Support to replace the Sensor. CloudCath Support may request the displayed error code.

Temperature is too low



**Move device to location
where temperature is above
41F**

If the temperature of the Sensor (Device) is lower than the minimum temperature allowed.

- Move the device to a place where the temperature is within range of the temperature range outlined in the Operating Conditions in Section 10.2 below.

Temperature is too high



Move device to location where temperature is below 104F

If the temperature of the Sensor (Device) is higher than the maximum temperature allowed.

- Move the device to a place where the temperature is within range of the temperature range outlined in the Operating Conditions in Section 10.2 below.

Clean Sensing Area



Close door when complete

If the **Sensing Area** is not clean enough to perform monitoring, the “Clean Sensing Area” error will display.

- Clean the **Sensing Area** per the Cleaning and Disinfection Instructions provided in this **User Guide** in Section 9. After cleaning, close the CloudCath Sensor door. If cleaning was performed successfully, the **Display Screen** will update
- If the error screen remains, reset the CloudCath Sensor by unplugging and re-plugging the **Power Supply**.
- You may reattempt cleaning multiple times. If the error message remains, contact CloudCath support to replace the Sensor.

Clean Sensing Area Complete



Place Device Upright on Flat Surface



If the CloudCath Sensor is not upright on the **Stand**, the “Place Device Upright on Flat Surface” error will display.

- Ensure the CloudCath Sensor is placed upright with the **Stand** on a flat, stable surface.

System Update

Update in progress
Don't turn off device



Downloading...

25%

[SWS # FIELD]
[FIRMWARE VERSION FIELD]

A CloudCath Sensor software update is being performed when this screen is present. This screen will only display when a CloudCath Sensor software update is required.

DO NOT POWER OFF the CloudCath Sensor when this screen is displayed.



If the Sensing Hardware Display appears frozen, blank, or non-functional, reset the CloudCath Sensor by unplugging and replugging the power supply.

8

9



CLEANING & DISINFECTION INSTRUCTIONS

10



CLEANING INSTRUCTIONS

Perform cleaning weekly or immediately upon a spill of fluid on or near the CloudCath Sensor.

*NOTE: During cleaning, ensure the **power supply** is removed to prevent electrical shock.*

1

Prepare a detergent solution using 1/4 to 1/2 teaspoon of dish soap in 1 quart of warm (room temperature) tap water.

2

Dampen (i.e. wet but not dripping) a non-linting wipe (e.g., Read Right Data Wipe or equivalent 6" x 6" wipe) in the detergent solution and use to wipe the exterior **Sensor** surfaces including the **stand** a minimum of one (1) wipe per side of **Sensor**, and **stand** (except the **stand** bottom) and until visibly clean. Pay particular attention to seams, recessed areas and buttons. Replace wipes if they become visibly soiled or damaged.

3

Use a clean soft-bristled brush (i.e. toothbrush) wetted with detergent solution (wet, but not dripping) and brush the exterior **Sensor** seams, hinges, display and housing interface, logo, screws and other hard to clean areas for a minimum of 30 seconds in total. Refer to Figure A. Re-wet the brush with detergent solution as necessary during brushing.

Use the **thumb groove** to open the **door** and continue brushing the **thumb groove**, ridges and other hard to clean areas for a minimum of 15 seconds in total and until visibly clean. Refer to Figure B.

Continue cleaning until no visible soil remains.

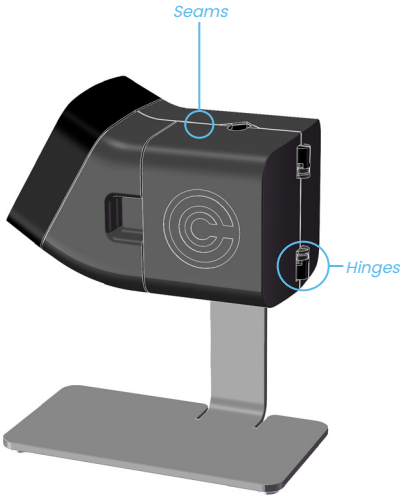


Figure A. Seams and Hinges

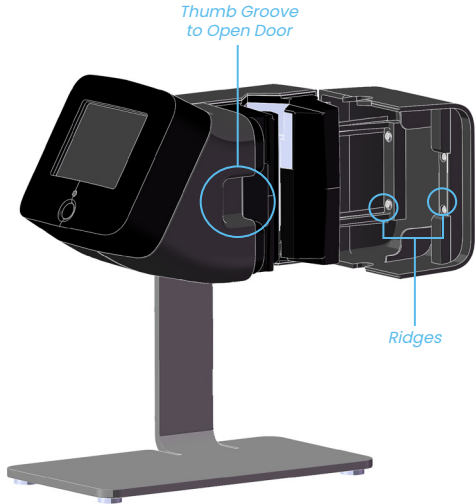


Figure B. Interior Surfaces Door



Figure C. Folded Non-Linting Wipe

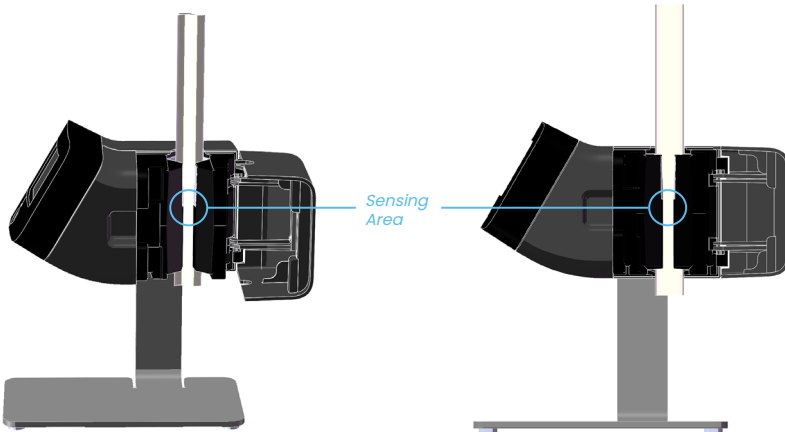


Figure D. Non-Linting Wipe in Sensing Area

Figure E. Flossing of Sensing Area

4

Dampen a non-linting wipe with the prepared detergent solution (wet but not dripping) and fold to fit inside the **Sensing Area**. Refer to Figure C and Figure D.

Grasping each side of the wipe, floss the **Sensing Area** for a minimum of 30 seconds and until visibly clean ensuring that each of the four (4) sides have been wiped and visibly clean. Refer to Figure E.

5

Dampen (wet but not dripping) a non-linting wipe with warm (room temperature) water and fold to fit inside the **Sensing Area**. Refer to Figure C and Figure D.

Grasping each side of the wipe, floss the **Sensing Area** for 30 seconds until visibly clean ensuring that each of the four (4) sides have been wiped and visibly clean. Refer to Figure E.

Replace wipes if they become visibly soiled or damaged.

6

Dampen (i.e. wet but not dripping) a non-linting wipe with warm tap water and use to wipe the door interior surfaces a minimum of one (1) time per surface and until visibly clean. Pay particular attention to seams, ridges and hard to clean areas.

Replace wipes if they become visibly soiled or damaged.

7

Close the door and using a new clean non-linting wipe (dampened but not dripping) with warm tap water (room temperature) rinse all exterior surfaces of the CloudCath Sensor and **stand** (except **stand** bottom), ensuring all surfaces are wiped a minimum of one (1) time.

If detergent residue is still visible, continue wiping surfaces (each surface one (1) time until no detergent is visible).

8

Thoroughly dry the **Sensing Area** by folding a non-linting wipe neatly and floss it through the **Sensing Area** to dry the **Sensing Area** surfaces (reference Figures D and E). Allow the CloudCath Sensor to air dry.

9

Inspect the CloudCath Sensor in a well-lit area to ensure all Sensor surfaces are clean. If visible soil is still observed, repeat cleaning steps.



DISINFECTION INSTRUCTIONS

Perform disinfection weekly or immediately upon a spill of fluid on or near the CloudCath Sensor.

*NOTE: During cleaning, ensure the **power supply** is removed to prevent electrical shock.*

1

Use non-linting wipe (e.g., Read Right Data Wipe or equivalent 6" x 6" wipe) dampened (wet but not dripping) with 70% Isopropyl Alcohol (IPA) or commercially available pre-saturated 70% IPA wipes to thoroughly wipe all external surfaces including the **stand**.

Wipe all external surfaces of the CloudCath Sensor. Open door and wipe all internal surfaces of the Sensor.



Figure F. Folded Non-Linting Wipe

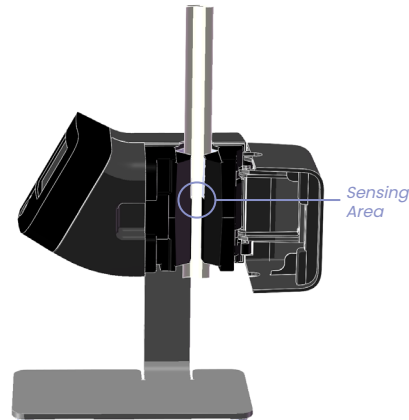


Figure G. Non-Linting Wipe in Sensing Area

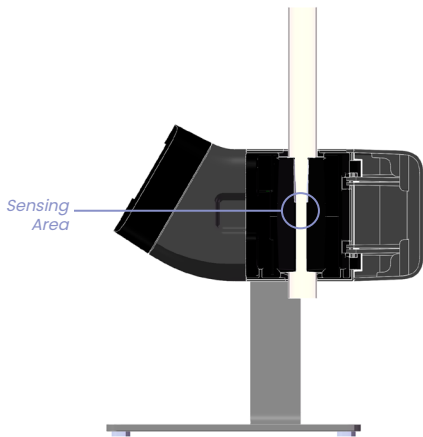


Figure H. Flossing of Sensing Area

2

Continue to thoroughly wipe all surfaces of the CloudCath Sensor to ensure the surfaces to remain visibly wet for a minimum of ten (10) minutes.

- During the ten (10) minute contact time, use additional wipes to thoroughly wipe crevices and hard-to-disinfect areas such as seams, hinges, display and housing interface, logo, screws.
- For the **Sensing Area**, fold the wipe neatly and floss it through the **Sensing Area** to wet the interior. Reference Figures F through H.
- If needed, use additional wipes to ensure the surface remains wet for the ten (10) minute wet contact time.

3

Allow the CloudCath Sensor to thoroughly air dry before using.

9

10



SPECIFICATIONS

10.1: STORAGE & TRANSPORT CONDITIONS

The CloudCath System is designed to be portable and to allow you to travel. The following guidelines allow safe operation of the CloudCath System during your travel.

Please store and transport the CloudCath Sensor in its original packaging. The original packaging is intended to be used for transport.

The CloudCath System should be stored and transported in the following conditions:

Storage Temperature

-30°C to 60°C
(-22°F and 140°F)

Storage Humidity

15% to 90%

Caution: Allow the CloudCath System to acclimate to room temperature for at least 4 hours before use, if it is moved between temperatures that are more than 20°C (36°F) different. Failure to allow the CloudCath System to acclimate may cause incorrect readings.

10.2: OPERATING CONDITIONS

Operating Temperature Limits

5°C to 40°C
(41°F to 104°F)

Operating Humidity

15% to 90%, non-condensing

Operating Atmospheric Pressure range:

700 hPa to 1060 hPa
(2908 m to -415 m)
(9539 ft to -1362 ft)

10.3: KEY OF SYMBOLS



Warning: This symbol indicates the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

IP21

This symbol indicates that the medical device is protected against solid objects over 12.5mm (e.g., a finger) and protected against vertically falling drops of water or condensation.



This symbol indicates a medical device that needs protection from direct sunlight sources.



This symbol indicates when the medical device was manufactured.

R ONLY

This symbol indicates that the product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician.



This symbol indicates the manufacturer's catalogue number so that the medical device can be identified.



This symbol indicates the date after which the medical device is not to be used.



This symbol indicates the temperature limits to which the medical device can be safely exposed.



This symbol indicates the range of humidity to which the medical device can be safely exposed.



This symbol indicates the medical device manufacturer.



This symbol indicates the manufacturer's serial number so that a specific medical device can be identified.



This symbol indicates the manufacturer's batch code so that the batch or lot can be identified.



This symbol indicates a medical device that has been sterilized using ethylene oxide.



This symbol indicates a medical device that is intended for one use, or for use on a single patient.



This symbol indicates a medical device that should not be used if the package has been damaged or opened.

10.4: MODEL AND CONTACT INFORMATION

Model:



CloudCath Sensor

01PD001

CloudCath Drain Set – Baxter Configuration

02PD001

CloudCath Drain Set – Fresenius Configuration

03PD001

Manufacturer:



CloudCath

665 3rd St, Suite 250
San Francisco, CA 94107
(415) 484-4896
www.cloudcath.com

10.5: SENSOR MATERIALS

- Glass
- Polycarbonate-Acrylonitrile butadiene styrene
- Polycarbonate
- Acrylonitrile butadiene styrene
- Nylon
- Ethylene propylene diene monomer rubber
- Anodized Aluminum
- Vinyl
- Stainless Steel
- Polyester

10.6: SENSOR – ELECTRICAL SPECIFICATIONS

Mode of Operation	Continuous
Type of Protection Against Electrical Shock	Class II equipment
Applied Parts	None
IP Rating	IP21
AC Input	100-240VAC±10%, 50-60Hz
Input Current	100-240VAC: 0.6- 0.3A
Output Voltage	12.0V
Output Current	0.5A
Highest Frequency	80 MHz (2.2 GHz for LTE)

10.7: POWER SUPPLY SPECIFICATIONS

Safety Approvals	medical: UL/cUL 60601 ITE: PSE
EMI/EMC	FCC Part 15B Class B
MTBF	as per MIL-HDBK-217F, 100,000 hours
RoHS	2011/65/EU

10.8: MODEM SPECIFICATIONS

Contains: FCC ID: XMR201707BG96

Serial Number starting with C:

Serial Number starting with A:

Cellular Frequency Band Used

Band 2: 1850.7 - 1909.3 Mhz
Band 4: 1711.5 - 1753.5 Mhz
Band 12: 699.7 - 715.3 Mhz

Band 2: 1850.7 - 1909.3 Mhz
Band 4: 1711.5 - 1753.5 Mhz
Band 12: 699.7 - 715.3 Mhz

Peak gain for the frequency band used

Band 4 : 3.5 dBi
Band 2: 3.2 dBi
Band 12: 0.8 dBi

Band 12 : 1.33 dBi
Band 4: -1.42 dBi
Band 2: 0.52 dBi

Average gain for the frequency band used:

Band 2: -2.86dBi
Band 4: -2.58dBi
Band 12: -3.64dBi

Band 12: -4.1dBi
Band 4: -5.5dBi
Band 2: -2.7dBi

Average efficiency for all the frequency band used:

>45%

>55%

Maximum return loss for the frequency band used

-7.1 dB

-7.3 dB

Maximum VSWR for the frequency band used

2.58:1 MAX

2.5:1 MAX



10.9: EMC DECLARATION

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CloudCath System is intended for use in the electromagnetic environment specified below. The customer or the user of the CloudCath System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CloudCath System 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 B	The CloudCath System is suitable for use in all establishments, including domestic establishments 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	Complies	



Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CloudCath System is intended for use in the electromagnetic environment specified below. The customer or the user of the CloudCath System 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines ¹	±2 kV for power supply lines	Mains power quality should be that of a typical residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical residential environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>Voltage Dips 30% reduction, 25/30 periods At 0°</p> <p>Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>Voltage Dips > 95% reduction, 1 period At 0°</p> <p>Voltage Interruptions > 95% reduction, 250/300 periods</p>	<p>Voltage Dips 30% reduction, 25/30 periods At 0°</p> <p>Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>Voltage Dips > 95% reduction, 1 period At 0°</p> <p>Voltage Interruptions > 95% reduction, 250/300 periods</p>	<p>Mains power quality should be that of a typical residential environment. If the user of the CloudCath System requires continued operation during power mains interruptions, it is recommended that the CloudCath System be powered from an uninterruptible power supply or a battery.</p>
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>

Immunity test**IEC 60601
test level****Compliance level****Electromagnetic environment –
guidance**

Conducted RF
IEC 61000-4-6

3 Vrms
150 kHz to 80 MHz
(6 Vrms in ISM and amateur
radio Bands within 150kHz –
80MHz)

3Vrms

Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Radiated RF
IEC 61000-4-3

10 V/m
80 MHz to 2.7 GHz

10 V/m

Recommended separation distance

$$d = 1.2\sqrt{P}$$

$$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$$

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

¹The CloudCath System does not contain signal input/output lines longer than 3 m in length.

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.

^aField 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Recommended separation distances between portable and mobile RF communications equipment and the CloudCath System

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

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.

**Rated maximum
output power of
transmitter (W)**

Separation distance according to frequency of transmitter (m)

	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
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

Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band ^a (MHz)	Service ^a	Modulation ^b	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse Modulation 18 Hz ^b	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine ^c	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz ^b	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz ^b	2	0.3	28

Test Frequency (MHz)	Band ^a (MHz)	Service ^a	Modulation ^b	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz ^b	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz ^b	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz ^b	0.2	0.3	9

^a For some services, only the uplink frequencies are included.

^b The carrier shall be modulated using a 50% duty cycle square wave signal.

^c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case



This product and/or the use of this product in a method
may be covered by one or more patents or patent
applications, available at
<https://www.cloudcath.com/patents/patent-1/>

