passio™

Pump Drainage System

Instructions for Use

Product Description:

The Passio Pump Drainage System provides patients with a convenient way to relieve pleural effusion symptoms at home.

The Passio Pump Drainage System consists of the Passio Catheter, Handheld Control Unit (pump) and the Disposable Collection Kit, which includes a redressing kit, for drainage of recurrent and symptomatic pleural effusions.

The Passio Handheld Control Unit is attached to the implanted Passio catheter using the disposable collection kit and is activated to begin the evacuation of fluid into the collection bag. The Passio catheter is a silicone catheter with a polyester cuff and eyelets to drain accumulated fluid from the pleural cavity. This cuffed catheter is implanted to allow for intermittent external draining of excess fluid in the pleural cavity. There is a valve on the catheter that prevents air and/or fluid from being evacuated from the pleural space until drainage is activated with the Handheld Control Unit. The Passio catheter is exclusively designed for use with the Passio collection system but can be connected to a water seal chest drain or vacuum pump at the discretion of a physician.

Indication for Use:

The Passio Pump Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The Passio Pleural Catheter is intended for long-term access of the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions and other recurrent effusions.

Contraindications:

None known when using with the Passio Pump Drainage System.

Warnings:

- The Passio Handheld Control Unit is intended as a single patient use device (Do not reuse). Reuse and repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device which may lead to device failure and/or lead to injury, illness or death of the patient.
- Do not use excessive force on the valve or catheter. Excessive force or incorrect usage may damage the device.
- Accessing the catheter valve with anything other than an approved Passio Pump Drainage System adaptor may damage the valve.
- Dispose of used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.
- Do not reuse on another patient, reprocess or resterilize. Reuse, reprocessing or resterilizing may compromise the device and/or lead to device failure.
- Do not use if package is damaged.

Precautions:

- Do not drain more than 1000 ml from the chest in any one drainage session.
- Follow a clean procedure when accessing the catheter.
- Check the package for damage before opening. Use of the device if package is damaged could result in patient injury, illness or death.
- Inspect kit to ensure all components are included.
- Ensure the drainage system is securely connected to the valve before initiating drainage.
- Do not drain fluid through a damaged catheter.
- Do not use scissors or any sharp instruments on the catheter as that may damage the catheter.
- If damage to the catheter does occur, place the supplied slide clamp between the catheter damage and exit site and contact the patient's physician.
- Access the catheter valve using only the Passio Pump Drainage system.
- A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop and restart the Passio Handheld Control Unit to restart flow.
- Potential complications of draining the pleural space include, but not limited to:
  - Pneumothorax; failure of lung to re-expand
  - Re-expansion pulmonary edema (swelling or fluid build-up in the lung due to rapid re-expansion of the lung)

  - Hypotension (low blood pressure)
  - Circulatory collapse
  - Infection
- The patient should be instructed to contact their physician if:
  - Patient develops a fever (body temperature above 100.5°F (38°C), redness, swelling, oozing, drainage or discomfort around catheter exit site. These may be signs of infection that may require treatment.
  - Shortness of breath isn't relieved after draining 1000 ml from the chest at one time.
  - The patient continues to experience symptoms, but little or no fluid drains from the catheter.
  - Less than 50 ml drains in 3 drainage procedures in a row.
  - The appearance of fluid (color, thickness, etc.) changes significantly between drainages.
- Users should be familiar with pleural drainage procedures before using the Passio Pump Drainage System.
- Radiofrequency emissions from RF emitters such as RFID or security systems might interfere with the Handheld Control Unit operation. Please note these RF emitters might not be visible. If you suspect your Handheld Control Unit is experiencing interference, move the patient away from the source before resuming therapy.

Possible Complications:

Pleural fluid drainage may result in any of the following complications:

- Infection
- Exposure to bodily fluids
- Discomfort during fluid removal
- Skin irritation
- Hypotension subsequent to drainage
- Accidental catheter dislodgement, breakage or removal
- Leakage around catheter
- Occlusion around catheter
- Fluid path blockage
- Low flow rate/prolonged drainage
- Re-expansion pulmonary edema

Passio Pump Drainage System components:

- 1 Passio Handheld Control Unit (pump)
- 1 Passio Pleural Catheter
- 1 Collection bag with attached pump head
- 1 Redressing Kit containing:
  - 1 pair latex free gloves
  - 3 ea. alcohol prep pads
  - 1 ea. catheter valve cap
  - 4 ea. 4" x 4" gauze pads
  - 2 ea. split gauze pads
  - 1 ea. adhesive dressing
  - 1 ea. removable blue slide clamp
  - 1 ea. skin prep wipe
- 2 AA batteries

Component Sterility:

The Passio Handheld Control Unit (non-sterile) is reusable on a single patient. All other components of the Passio Pump Drainage System are single-use, sterilized using Ethylene Oxide. The Passio Catheter is sterilized using Ethylene Oxide as part of the Passio Pleural Catheter Insertion Kit.

Battery Replacement:

Two (2) AA batteries are included in the Disposable Collection Kit 10 pack. Replace the 2 batteries in the Passio Handheld Control Unit prior to using the disposable collection systems in the 10 pack. Remove the battery compartment cover on the back of the Handheld Control Unit. Place the new batteries in the same position as the batteries that are removed and replace the battery compartment cover.

Storage:

Event	Temp.	Rel. Humidity
Operating	5° to 40° C	15% - 90%
Storage & Transport	-20° to 40° C	35% - 70%

Drainage Instructions:

NOTE: Before beginning this procedure, ensure that a Passio Catheter has been placed in the patient. Read the “Contraindications”, “Warnings”, “Precautions” and “Possible Complications” sections of these instructions for use.

1. Prepare a clean working area to perform the drainage therapy.
2. Thoroughly wash your hands with soap and water for at least 1 minute.
3. Open the pouch with the Passio Pump Drainage System. Remove and separate the redressing kit (blue wrapped pouch) from the drainage system.
4. Remove the adhesive dressing from the catheter site and discard. Do not pull on catheter. Press on skin while slowly pulling dressing away from site. Inspect the catheter valve for signs of damage.
5. Open the redressing kit using sterile technique by carefully unfolding the sterile blue wrap to create a working area. Leave all of the contents of the kit on the blue area. Do not touch any of the contents with ungloved hands.
6. Thoroughly wash your hands again with soap and water for at least 1 minute.
7. Pick up gloves by the cuffed fold and put them on, being careful not to touch the outside of the gloves on anything outside of the blue wrap.
8. Open the 3 alcohol pads, but do not remove them from the pouch. Place them back on the blue wrap.
9. Remove catheter valve cap by pulling away from catheter valve. Dispose of cap. (Figure 1)

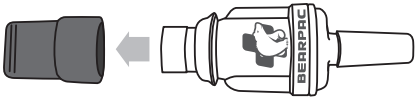


Fig. 1

10. Wipe the catheter valve with an alcohol pad.
11. Remove the plastic sheath from the catheter connector. While holding the catheter firmly, insert the (blue) male catheter connector on the end of the drainage line into the catheter valve until you hear or feel a connection (click). Gently pull back on drainage line to confirm the connection is secure. (Figure 2)

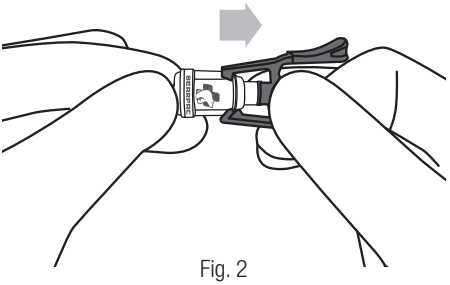


Fig. 2

12. Attach the pump head to the Passio Handheld Control Unit. (Figure 3) Place the Passio Handheld Control Unit and collection bag at or below the level of the chest for draining.

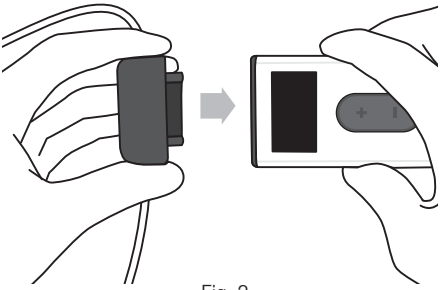


Fig. 3

13. Press the Power button ⏻ on the Passio Handheld Control Unit to activate the system. The system will cycle through the following screens: (Figures 4a, 4b, 4c).

Fig. 4a

Fig. 4b

Fig. 4c

NOTE: The system must be primed before initial therapy

14. Press the "+" button once to initiate the priming process and to begin fluid flow. (Figures 5a, 5b, 5c)
    – The Handheld Control Unit will automatically prime the tubing with fluid and then shift to SPEED 1 to continue flow of fluid. *If the system does not prime with fluid, remove pump head and restart the Passio Handheld Control Unit.*

Fig. 5a

Fig. 5b

Fig. 5c

15. To *bypass* the priming process, press the "–" button which will start the Passio Handheld Control Unit at SPEED 1
16. Continue to press "+" button to increase fluid flow as can be tolerated by patient. (Figures 6a, 6b, 6c)

Fig. 6a

Fig. 6b

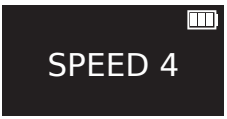


Fig. 6c

17. Press the "–" button to slow the fluid flow rate.
18. When the collection bag is full or fluid flow has stopped, press pause ("II") button to complete therapy. The system will automatically pause/stop when the volume indicator reaches 1000 ml.

19. Disconnect the drainage line by holding the catheter valve firmly with one hand and squeezing both sides of the (blue) male catheter connector clip with your other hand. (Figure 7) This will allow the catheter connector clip to separate from the catheter valve.

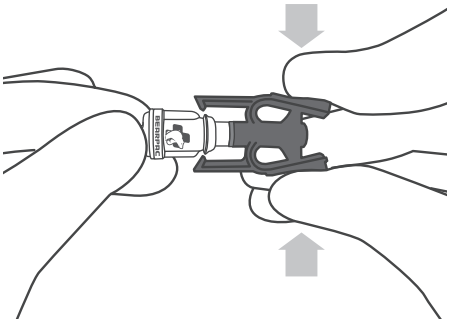


Fig. 7

20. Clamp off the collection bag tubing with the blue clamp to prevent fluid leakage. Set drainage collection system aside.
21. Wipe the catheter valve with a new alcohol pad and place a new catheter valve cap onto the catheter valve.
22. Open and remove the skin prep wipe from its pouch and apply protectant to area of adhesive dressing site. Allow to dry for approximately 30 seconds.
23. Coil catheter and redress the catheter insertion site in the following manner:
    – Place split gauze around catheter exit site and place up against skin. (Figure 8a)
    – Coil catheter and place up to 4 pieces of gauze over coiled catheter (Figure 8b) and carefully cover with adhesive dressing (Figure 8c), covering entire catheter site and gauze.
    – Remove gloves

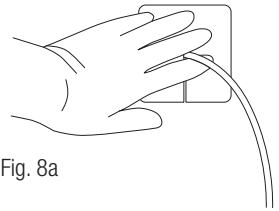


Fig. 8a

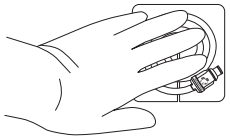


Fig. 8b

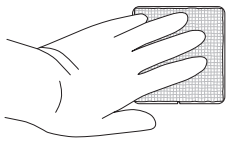


Fig. 8c

Apply adhesive dressing in the following manner:

- Remove printed layer – exposing adhesive layer (Figure 9a)
- Center dressing over the gauze and apply to skin (Figure 9b)
- Remove and dispose of center layer from dressing (Figure 9c)
- Slowly remove the frame while pressing on self-adhesive dressing. (Figure 9d)

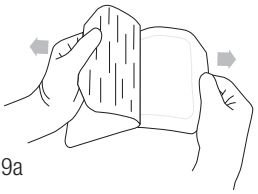


Fig. 9a

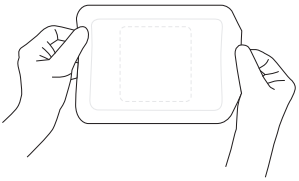


Fig. 9b

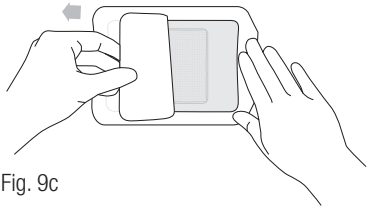


Fig. 9c

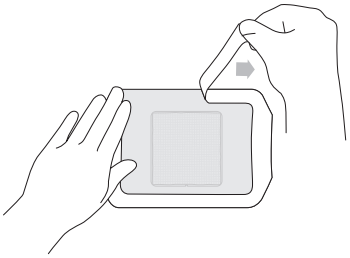


Fig. 9d

24. Record the amount of drainage displayed on the Handheld Control Unit screen.
25. Press and hold the Power button for 2 seconds to turn off the power to the unit and store until next drainage therapy.
26. Remove pump head from Passio Handheld Control Unit. (Figure 10)

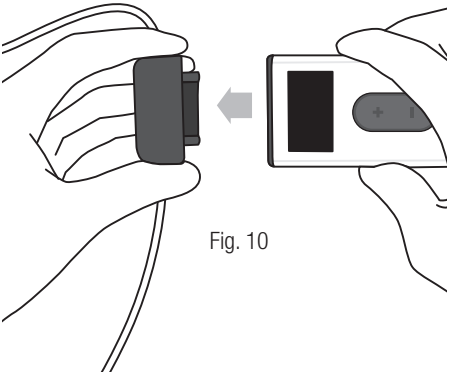


Fig. 10

27. Dispose of collection system in accordance with all applicable regulations.
28. If the Passio Handheld Control Unit is dirty or soiled, wash exterior with mild soap and water and wipe dry immediately. Do not immerse Passio Handheld Control Unit in water.

NOTICE: If a serious incident occurs during use of this device, please report to the manufacturer.

Maximum Pressure: Maximum negative pressure generated is less than 49 kPa (500 cmH_2O).

Note: The Passio Pump Drainage System does not contain DEHP and is not made with natural rubber latex.

Electromagnetic Compatibility Tables - RF Emissions Class B

Guidance and manufacturer's declaration - electromagnetic immunity		
The Passio Handheld Control Unit is in compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.		
IMMUNITY test	**IEC 60601-1-2 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz	10V/m 80MHz-2.7GHz 80% AM at 1kHz

Guidance and manufacturer's declaration - electromagnetic emissions		
The Passio Handheld Control Unit is in compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS glass and group.		
Emissions	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B	The Passio Handheld Control Unit 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test Frequency (MHz)	Band (Mhz)	Service [a]	Modulation [b]	Max. Power (W)	Distance (m)	ImmunityTest Level (V/m)	Compliance level
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM [c] ±5kHz deviation 1 kHz sine	2	0.3	28	28
710	704-787	LTE-Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	GSM 800/900, TRETRA 800, Iden 820, CMDA 850, LTE B and 5	Pulse Modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE B and 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

NOTE:
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.

LCD Display glossary

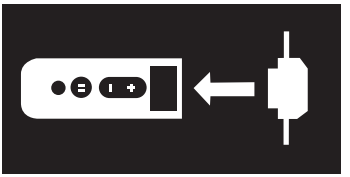
Device Ready Indicator Screen - Indicates the device is ready to use.

Priming Indicator Screen - Indicates the device is in priming mode.

Motor Speed Indicator Screens - Indicate the flow speed of the device (1 to 4).

Pause Screen indicates the Handheld Control Unit is currently paused.

Fluid Volume Indicator Screen - Indicates the fluid volume collected in milliliters. The number of filled circles indicate the currently selected speed (1 to 4).



Pump Disconnected Indicator Screen will be shown after the device startup sequence is completed and no pump head is connected, or the user tries to activate the pump motor (pressing '+' button) but the pump head has been disconnected from the Handheld Control Unit.

Low Battery Indicator - Indicates the Handheld Control Unit will power off in 5 seconds and new batteries should be inserted into the device.

Device failure indicator - Indicates a device failure has occurred and the device will power off in 5 seconds.

Device usage indicator - Indicates the current number of uses up to the maximum 100, and the phone number to call for reorder.

Troubleshooting

What do I do if the Passio Pump Drainage System does not prime with fluid?
If the system does not prime with fluid, remove the pump head, then place it back onto the Handheld Control Unit and restart by pressing the Power button.

What do I do if the catheter appears to be clogged?
If the catheter becomes plugged, gently squeeze the catheter where it joins the catheter valve, then gently squeeze the drainage line near the access tip. This may loosen the material lodged at the connection. If this does not cause flow to resume, contact the patient's physician.

What do I do if the Pause button doesn't pause the Handheld Control Unit?
If the Pause button does not pause the flow of fluid, press the Power button to power down the system and stop the flow of fluid.

Symbols Used on Product Labels

 Manufacturer

 Date of Manufacture

LOT Batch Code REF Model Number

STERILE EO Sterilized Using Ethylene Oxide

 Use-by Date

 Caution

 Do Not Re-use

 Do Not Re-sterilize

 MR Conditional

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

IP21 Protected against solid foreign objects of 12.5 mm dia. and greater; Protected against vertically falling water drops

 Compliance with international requirements for protection from electric shock (Type BF Applied Part)

 Refer to Instructions for Use (This symbol is blue on the product)

 Conforms to AAMI Std. ES60601-1, IEC Std 60601-1-11, IEC Std. 60601-1-6 Certified to CSA Std. C22.2 No. 60601-1, 60601-1-11, 60601-1-6

 Keep the device dry.

 Keep the device away from sunlight

 Temperature limitation for operation, transport and storage

 Handle the fragile device with care

 Humidity limitation for operation, transport and storage

BEARPAC
MEDICAL

Bearpac Medical, LLC
1-833-BEARPAC
(1-833-232-7722)

bearpac.com

Manufacturer
Bearpac Medical, LLC
124 West Point Road
Moultonborough, NH 03254 USA
Tel. 1-833-232-7722

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

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