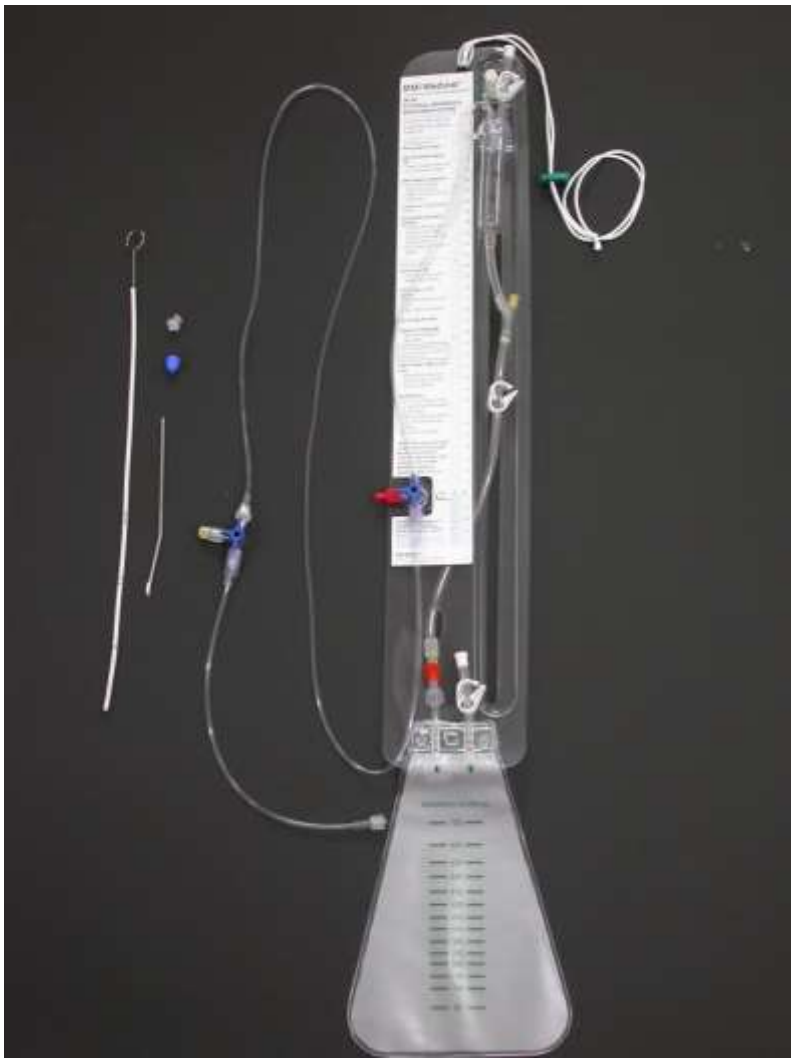
BMI® Medical

CSF Shunting System



Wellong Instruments Co., Ltd.

Company address:

2F, No.63,LinsenNorth Road, Taipei, Taiwan, R.O.C.

Factory address:

5th Floor, No.7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, R.O.C.

Tel: +886-2-2571-9829, +886-2-2541-2961

Fax:+886-2-2562-7884

E-mail: cctco@ms35.hinet.net

C012- E20230102

BMI MEDICAL - EXTERNAL DRAINAGE AND MONITORING SYSTEM

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❖LABELS

CE 2460	The device totally complies with European Directive 93/42/EEC
	Caution
	Use by
STERILE EO	Sterilization by Ethylene-Oxide Gas
	Do Not Reuse
REF	Model No.
LOT	Lot Number
	Manufactured at
	Date of manufacture
	Read and follow the instruction manual before use
	Temperature Limitation
	Do not use if package is damaged
	Do not resterilize
EC REP	Luana Med. B.V. 2627 AL, Abtswoudseweg 18, Delft, the Netherlands

WARNING

- **This device is sterile and non-pyrogenic unless package has been damaged or opened.**
- **The law restricts this device to sell by or on the order of a surgeon.**
- **Medical devices labelled as “single-use only” should never be reused. Reuse of these devices is strictly prohibited. Failure to do so may result in serious patient harm, including, but not limited to: cross-infection, contamination. It may cause significant degradation in device performance.**

❖DESCRIPTION

Thank you for purchasing BMI Medical product. The purpose of this manual is to provide detailed information for the BMI Medical External Drainage and Monitoring System (BMI EDMS). BMI EDMS allows physician to:

- Drainage cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space.
- Monitor cerebrospinal fluid (CSF) pressure and flow rate from the lateral ventricles of the brain or from the lumbar subarachnoid space.

❖CHECKLIST

Please check you have all the fittings listed below. If you find any missing parts or defects, please contact your distributor or manufacturer.

The BMI EDMS consists of the following components:

- Main system section: mounting panel
- A non-distensible patient connection line
- Patient line stopcock
- Two latex-free injection sites
- A removable drainage bag (with approximate volumetric graduation)
- Microbial filter

❖ INDICATIONS

Use BMI EDMS to drain and monitor CSF flow of the lateral ventricles or lumbar subarachnoid space in selected patients to:

- Reduce intracranial pressure (ICP)
- Monitor CSF chemistry, cytology and physiology
- Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts

Use BMI EDMS to monitor intracranial pressure (ICP) in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage graded III, IV or V preoperatively
- Reyes syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Miscellaneous problems when drainage is to be used as a therapeutic maneuver

❖INSTRUCTIONS FOR USE

NOTE: Prior to use of the BMI EDMS, it is important for the physician and attending personnel to familiarize themselves with the device. Physicians should review available literature on usage of BMI EDMS.

1. System Set-Up

1.1 To set up the system, first check BMI EDMS checklist to make sure that you have all the components.

1.2 Physician should wear a surgical face mask and sterile gloves when handling the system. Please check carefully to ensure that all components are assembled.

1.3 The system should be prepared under sterile conditions at least 30 minutes prior to the placement of the ventricular catheter or lumbar catheter.

CAUTION: Please ensure all connections and fittings are tight and leak free.

1.4 A pressure transducer adapter can be attached to the patient line stopcock or to the main system stopcock (see figure 4.2 and 4.3). If electronic pressure monitoring equipment is to be used please attach transducer adapter located to patient line or main system stopcock.

NOTE: Transducer adapter and transducer are not included in EDMS. Please contact your distributor or manufacturer to find out more.

1.5 Removing the end plug to attach a pressure transducer adapter to the main system stopcock. The plug may be used to cap a secondary inlet on the transducer adapter when needed. You should remove injection site cap to attach a transducer adapter at the patient line stopcock.

1.6 The system mounting panel incorporates a hanger hole and braided cord with lock for IV pole suspension and a panel bracket for manifold pole clamp mounting if more rigid mounting is desired. Locate the system mounting panel so that the main system stopcock is level with the patient foramen of Monro or at the level of the exit of the lumbar catheter.

NOTE: Please ensure that panel is properly aligned. The main system stopcock must be correctly aligned with the patient for accurate pressure monitoring. The pressure head scale found on the panel should be aligned with the scale zero of the main system stopcock.

2. Pre-Filling System

The system must be pre-filled to the flow chamber drip former with sterile isotonic saline solution before connecting to the patient.

2.1 Please use of 20 to 30 ml syringe with a 25-gauge needle to inject at patient line stopcock injection site until all air has been flushed from patient line stopcock, patient line, main system stop-cock and flow chamber connection line into drip chamber.

2.2 You may loosen the transducer adapter and patient line stopcock, end plug and injection site fitting to allow air to escape.

2.3 Please check system for any residual air bubbles. Air can be removed by combined injection of saline and aspiration of air through a 25-gaguge needled at injection site on the patient line stopcock.

2.4 Please ensure that fluid drains from the flow chamber into the drainage bag. It may be necessary to manipulate the drainage bag connection line or drainage bag one-way valve to establish drainage.

3. Connecting Catheter to System

After the catheter has been properly placed, the luer lock connector is inserted into the catheter.

NOTE: Care should be taken to allow only a minimal amount of CSF to escape. The catheter may be occluded at the scalp level or at lumbar catheter exit site by pinching or with an appropriate clamp to minimize fluid loss during the insertion of the connector.

NOTE: BMI also provides Ventricular Catheter and Lumber Catheter. The Ventricular Catheter, 20, 35, and 60cm in length, includes a separate end plug to allow temporary closure. The Lumber Catheter, 24, 30, 55, 80, and 85 cm in length, includes a catheter luerlock connector with an integral molded plug are available separately. This plug may be used to plug the catheter prior to connecting to the patient line.

3.1 To connect the catheter to the pre-filled system, set the patient line stopcock as in Fig 4.2(c).

3.2 Remove the end plug from the patient line.

3.3 The catheter should be occluded with an appropriate clamp to minimize CSF loss during connection to the system.

3.4 Attach luer lock connector to patient line. Care should be taken to ensure that the catheter and complete system is devoid of any air bubbles.

3.5 Set the patient line stopcock to the desired setting (see section 4. System Control for more details).

3.6 Remove the clamp from the catheter.

3.7 plug on the catheter luer lock connector should then be cut off.

4. System Control

4.1 To set pressure head, slide flow chamber to desired pressure setting (in cmH_2Oor mmHg) on system mounting panel. Then turn the thumb screw of locking bracket to unlock and lock sliding flow camber in place.

NOTE: An accurate pressure head is obtained only when the tubing from the patient to the flow chamber drip former is completely fluid-filled. If the tubing is not completely fluid-filled, the pressure head is equal to (in cmH_2O) the height of the meniscus of the fluid in the tubing, as referenced to the zero level of the system (see section 1. System Set-up).

CAUTION: The flow chamber of the BMI Medical can be positioned below 0cmH_2O. Such positioning will result in a negative pressure head, and may result in over drainage of CSF if not monitored vigilantly.

4.2 Patient Line Stopcock

The patient line stopcock is regularly positioned as depicted in the following figures:

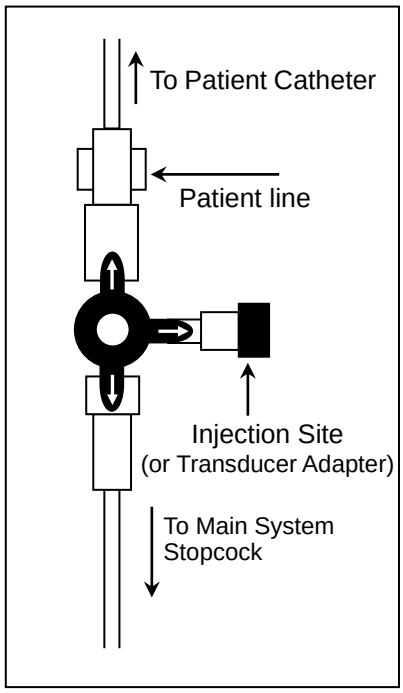

Fig4.2(a): Catheter communicates with patient line stopcock and patient line stopcock injection site (or transducer adapter). This is the regular setting for system.

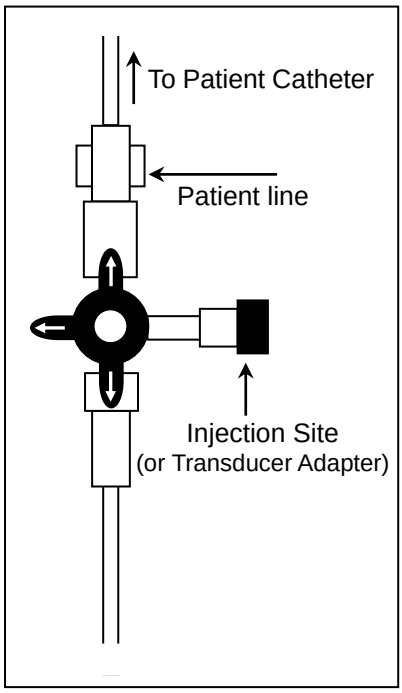

Fig4.2(b): Catheter communicates with the main system stopcock only. Catheter does not communicate with patient line stopcock injection site (or transducer adapter).

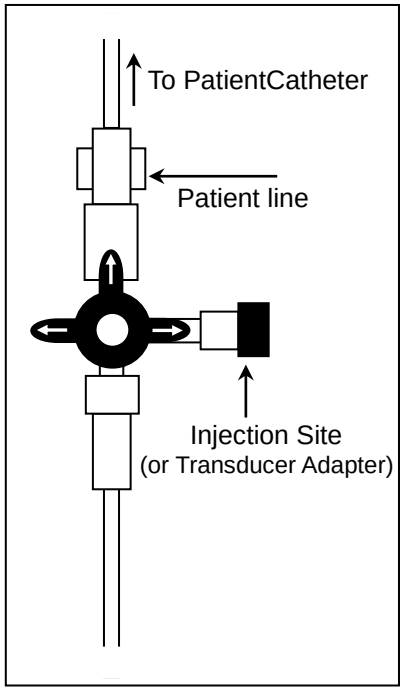

Fig4.2(c): Catheter communicates with patient line stopcock (or transducer adapter). Catheter does not communicate with main system stopcock.

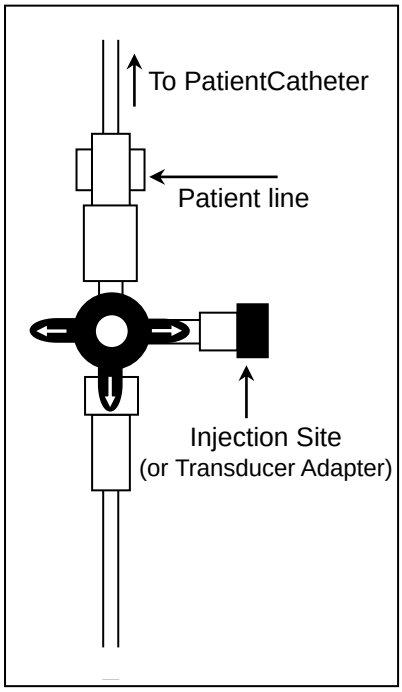

Fig4.2(d): Catheter does not communicate with patient line stopcock (or transducer adapter), or main system stopcock.

4.3 Main System Stopcock

The main system stopcock may be positioned as depicted in the following figures:

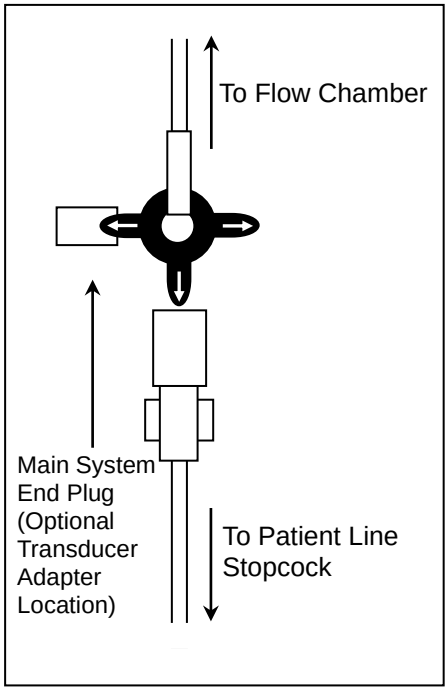

Fig4.3(a): Patient line communicates with transducer adapter (if connected). This is the regular setting for system use (drainage).

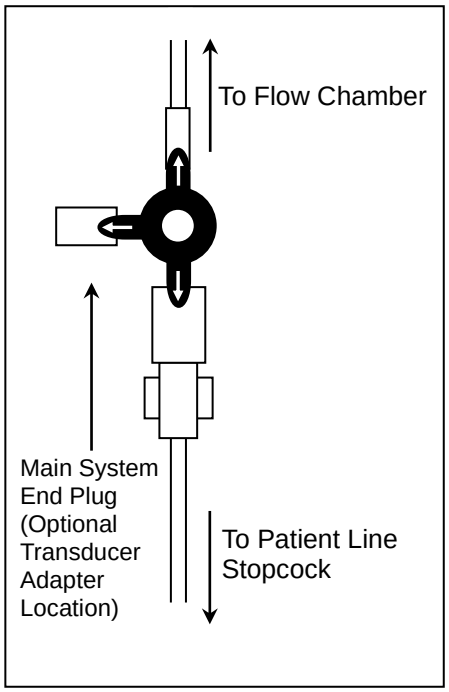

Fig4.3(b): Patient line communicates with flow chamber only. Patient line does communicate with transducer adapter.

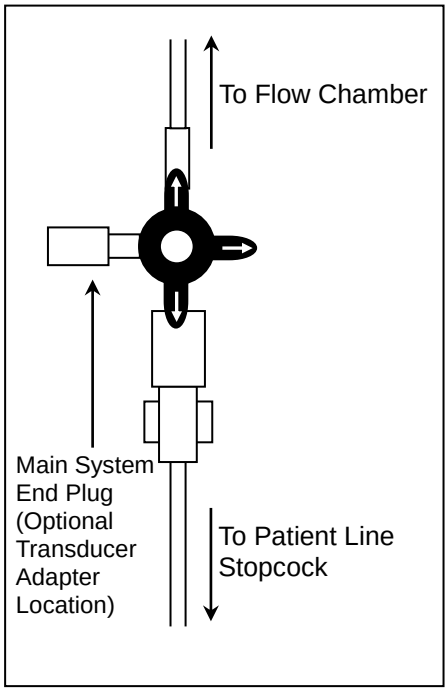

Fig4.3(c): Patient line communicates with flow chamber only. Patient line does not communicate with transducer adapter.

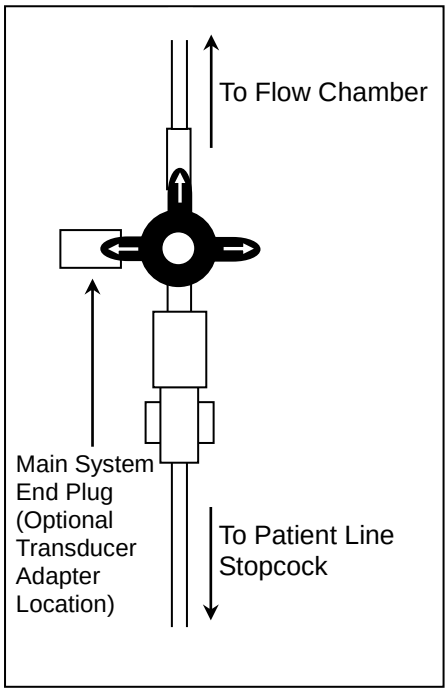

Fig4.3(d): Patient line does not communicate with main system stopcock. Patient line does not communicate with flow.

4.4 Flow Chamber Slide Clamp

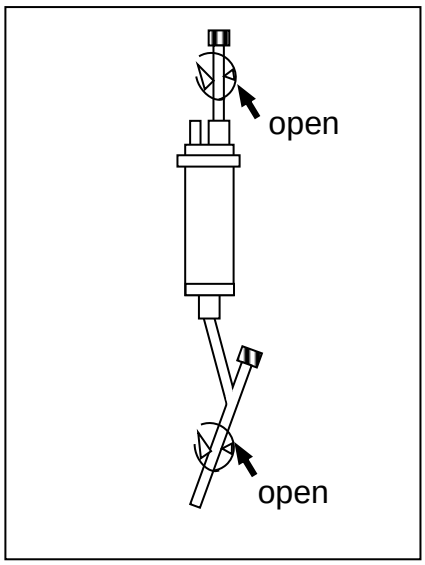

Fig 4.4(a): The flow chamber will communicate with the drainage bag when both side clamps are open or loosely positioned.

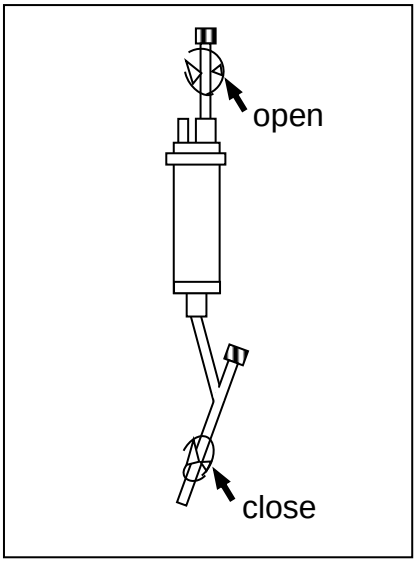

Fig 4.4(b):The flow chamber will not communicate with the drainage bag when either slide clamp is closed or positioned to compress and securely occlude drainage bag connection line (Fig 4.2 and 4.3). The slide clamp position shown in Fig 4.2 is used to sample CSF from the flow chamber

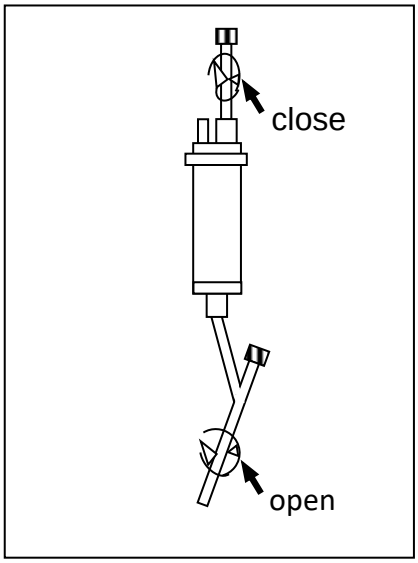

Fig 4.4(c): The slide clamp position is used to monitor the rate in the graduated chamber.

5. To Calibrate System

NOTE: Initial system calibration should be done prior to connecting system to patient.

5.1 The system provides several ways to perform the calibration. The transducer located on the patient line stopcock, or on main system stopcock, may be referenced to atmospheric pressure through the microbial filter on the flow chamber. This can be done to zero the transducer.

5.2 The flow chamber connection line can be used as a manometer tube. The transducer is then referenced to the saline solution filled connection line. The saline solution in the connection line can be maintained at constant height and provides a ready accessible standard pressure against which to calibrate the transducer.

5.3 To set the pressure, align the flow chamber inlet tube with the desired pressure setting on the cmH_2O or mmHg scale. The scale is located on the system mounting panel adjacent to the flow chamber slide. A pressure setting of 27.2cmH_2O or 20mmHg is recommended for transducer calibration.

6. To Drain CSF

6.1 Open patient line stopcock and main system stopcock to allow fluid to flow from the drainage catheter to the flow chamber.

6.2 Open the proximal drainage line slide clamp and the distal drainage line slide clamp to allow fluid to flow from chamber to the drainage bag.

CAUTION: The small filter vent slide clamp must be open to permit drainage of CSF.

6.3 The amount and rate of drainage will be partially dependent on the system pressure head setting (the height of the flow chamber red dot relative to the main system stopcock zero level).

CAUTION: During system use with the flow chamber slide clamp(s) open to allow flow into the drainage bag. Fluid may accumulate in the flow chamber before emptying. Flow must be carefully monitored to prevent complete filling of the flow chamber. It may be necessary to manipulate the drainage bag connection line to re-establish drainage from the flow chamber to the drainage bag. Complete filling of the flow chamber will preclude drainage of CSF due to wetting of filter vent.

NOTE: When the drainage line slide clamps are open, allowing flow into the drainage bag, a small accumulating of fluid may collect in the flow chamber before emptying. When the periodic fluid accumulation empties, a slight momentary reduction (0 to 4cmH_2O) in system may occur.

NOTE: When monitoring the CSF flow rate or flow volume with flow chamber, the drainage line slide clamp must be closed. If the CSF cannot smoothly flow into the drainage bag when the slide clamp is re-opened, the drainage line may be kinked. This

problem can be solved by moving down the slide clamp and straightening the kinked tube.

7. To Monitor Pressure

7.1 Position patient and main system stopcock so that the ventricular catheter or lumbar catheter communicates to transducer adapter.

NOTE: Simultaneous drainage and pressure monitoring may result in artifacts in measured pressure. If more accurate pressure monitoring is desired, the system should be temporarily closed to drainage by adjusting the patient line stopcock (Fig 4.2(c)) or main system stopcock (Fig 4.3(b)) so that the drainage catheter communicates only with the pressure transducer.

CAUTION: If system stopcocks are temporarily closed to allow for more accurate pressure monitoring, care must be taken to adjust the system and re-establish CSF drainage. Failure to read the system will preclude drainage of CSF.

8. To Monitor Flow

8.1 Set patient line stopcock and main system stopcock to allow fluid to communicate to flow chamber. Slide drip chamber up, aligning flow chamber red dot with the desired pressure setting.

8.2 Close drainage line proximal slide clamp to stop flow to the drainage bag. Record fluid accumulation over time per graduations (in ml) on flow chamber.

CAUTION: With the proximal drainage line slide clamp closed to monitor flow. There is no flow into the drainage bag. Flow must be carefully monitored to prevent complete filling of the flow chamber. Complete filling of flow chamber will preclude drainage of CSF.

8.3 To empty the flow chamber, set main system stopcock to “Off” (see Fig 4.3(d)) then open drainage line slide clamps (see Fig 4.1). When the flow chamber is emptied, reset main system stopcock to desired position (see Fig 4.3).

CAUTION: Failure to adjust main system stopcock to isolate patient from flow chamber during emptying may result in a momentary reduction in system pressure.

9. To Flush System

9.1 Injection site may be used to flush the system. Flush fluid into drainage bag.

CAUTION: Adjust patient line or main system stopcock to isolate patient and pressure transducer. Injury to patient and damage to the transducer may occur if the system is flushed with an open path to patient and/or transducer.

10. To Replace the Drainage Bag

10.1 Close distal drainage line slide clamp to prevent retrograde flow from the drainage bag connection line.

10.2 Remove the bag from the system mounting panel.

10.3 Using sterile handling technique to avoid contamination, disconnect the drainage bag connection line from the drainage bag.

10.4 Discard drainage bag in accordance with hospital medical waste guidelines.

10.5 Connect sterile BMI Medical Drainage Bag to the drainage bag connection line and attach to system mounting panel.

CAUTION: The drainage line slide clamp must be rest to open position to establish flow into the drainage bag. Complete filling of flow chamber will preclude drainage of CSF due to wetting of filter.

CAUTION: Avoid twisting flow chamber connection line during bag replacement. This may cause kinking.

11. To Empty Drainage Bag

Center for Disease Control (CDC) guidelines advocate minimizing exposure to body fluids. Therefore, replacement of the drainage bag is recommended by BMI Medical. However, should the physician choose to empty and reuse the drainage bag, the following method may be used:

11.1 Remove the bag from system mounting panel. Do not disconnect the drainage bag from flow chamber connection line.

11.2 Using sterile handling techniques, disconnect the vented port from the luer lock fitting.

11.3 With careful attention to avoid contamination of the open luer lock fitting, invert bag and empty.

11.4 Reattach bag to system mounting panel.

12. Irrigation, CSF Sampling and Intraventricular Medication

The system's latex-free injection site can be used for several purposes.

12.1 A25-gauge needle can be inserted through an injection site which had been cleaned and disinfected with alcohol.

12.2 A clogged ventricular catheter may be irrigated with 0.1 ml of sterile saline. Similarly, the injection site can be used to withdraw a sample of CSF for laboratory analysis or to inject intraventricular medication.

13. Volume/Pressure Relationship

A volume/pressure relationship (VPR) can be obtained using the following technique.

13.1 Fill a 1.0 ml syringe with an attached 25-gauge needle with sterile isotonic saline and insert the needle through the patient line injection site.

14. Moving an EDMS Patient

If it is desired to move a patient who is undergoing external drainage and/or monitoring with a BMI Medical EDMS, the system should be kept upright and correctly aligned with the patient. If it is not possible for the system to move in an upright manner, the following steps must be performed:

14.1 Ensure that the flow chamber has completely drained.

14.2 Isolate patient from communication with the flow chamber by:

a. Adjusting the patient line stopcock to “Off” (see Fig4.2(c) or (d))

b. Adjusting main system stopcock to “Off” (see Fig4.3(d))

14.3 Close small filter vent slide clamp

14.4 Move patient and system as required

14.5 Realign and readjust system and stopcocks to initiate drainage when patient reaches new location.

CAUTION: All stopcocks and slide clamps adjusted for patient transport must be returned to their normal position to re-established proper flow and drainage of CSF. Failure to properly re-adjust the stopcocks and slide clamps could result in under-or over-drainage of CSF.

CAUTION: Failure to perform steps 14.1- 14.5 above, may result in improper venting by flowing chamber microbial filter when drainage is re-established.

15. Brief Instructions

The following steps provide a visual aid in familiarizing responsible personnel with the use and function of the various components of the system. Always sterile technique in handling the BMI system.

15.1 To set up the system, first check all fittings on the BMI EDMS checklist.

15.2 Remove the end plug from the main system stopcocks.

15.3 Attach transducer to main system stopcock and cap open end with end plug.

15.4 Use preservative-free saline in either an IV bag or a 30cc syringe to fill the system to the drip former. Check all lines to ensure that no air bubbles are present.

Bleed air from transducer according to manufacturer’s instructions. Loosed end plug as required.

15.5 When the IV tubing or the syringe is disconnected, the open end of the stopcock port must be capped.

The date should be marked on the system panel after initial setup.

15.6 Lower the drip chamber so that the red dot on the drip chamber line up with the zero reference point on the system panel. Zero transducer and monitor according to manufacturer’s instructions.

15.7 Position the system mounting panel so that the main system stopcock is level with the patient’s foramen of Monro.

15.8 Connect a ventricular catheter to the BMI system. Set the patient line stopcock to the OFF position; then remove the end plug and attach the catheter to the luer adapter, being careful to avoid air bubbles.

15.9 Reset the drip chamber to the level prescribed by the physician and lock it into place by tightening the thumb-screw.

15.10 To drain CSF, position both main and patient line stopcocks as shown. To monitor ICP, rotate main system stopcock to communicate with transducer only. Position stopcock to

monitor or drain, never to both.

15.11 To sample CSF, clean the injection site with isopropyl alcohol and betadine solution. Allow the betadine to dry.

15.12 Use a 25-gauge needle for injection of medication into the ventricles, or for sampling of CSF.

15.13 Monitor flow rate of CSF by closing the slide clamp as close as possible to the drip chamber. Measure fluid accumulation in the chamber for the prescribed period of time. Never allow the drip chamber to overfill.

15.14 CSF can be sampled at the drainage line injection site using the method recommended for the patient line injection site. The slide clamp distal to the injection site can be closed to allow fluid sampling. After sampling, the slide clamp should be opened to allow fluid drainage.

15.15 During patient transport, if the system is to be laid down, the filter chamber slide clamp should be closed to prevent contamination of the filter. The slide clamp must always be open during CSF drainage when the BMI system is in the upright position.

15.16 The drainage bag can be either replaced when required, or emptied by removing the microbial filter cap assembly from the drainage bag port.

❖PATIENT EDUCATION

It is physician's responsibility to educate the patient and their representative(s) regarding external drainage and monitoring. This should include a description of associated complications, and an explanation of potential alternative product and treatments.

❖CONTRAINDICATIONS

- A patient undergoing external drainage and monitoring must be kept under continuous and close supervision. The use of "BMI" CSF Shunting System is contraindicated where trained personnelare not available to supervise on a 24-hour-a-day basis.
- Intracranial pressure monitoring with a ventricular or lumbar catheter is contraindicated in patients receiving anticoagulants or who are known to have ableeding diathesis.
- The use of a ventricular catheter is contraindicated if scalpinfection is present.
- If lumbar puncture will pose a danger to the patient, monitoring pressure from the lumbar subarachnoid space is contraindicated.
- The use of a lumbar catheter for CSF drainage and monitoring isnot recommended for patients with the following situations:
  1. large intracranial masslesions, hematomas, cysts, or tumors;
  2. non-communicating hydrocephalus;
  3. infections in thesurrounding area, including the subcutaneous tissue, skin, theepidural space and bone;
  4. blockage of cerebrospinal fluid to the subarachnoid space due to fracture, hematoma, trauma, or tumor;

5. and wherelumbar puncture is contraindicated.

The use of a lumbar catheter under these conditions for external drainage and monitoring is at the discretion of the physician.

❖WARNINGS AND PRECAUTION

- Patients undergoing external drainage and/or intracranial pressure monitoring must be kept under close and continuous supervision by trained professionals. Improper system setup or vigilance can result in over drainage or under drainage and potentially serious injury to the patient. Intracranial and lumbar pressure monitoring has been associated with intracranial infection, meningitis and ventriculitis. The risk of infection is probably influenced both by the duration of the monitoring and the number of times a system is opened. Prolonged use of steroid therapy can also increase the risk of infection.
- To minimize the possibility of infection, meningitis or ventriculitis, please follow the steps below.
  1. The injection sites should be cleaned with alcohol and the alcohol allowed to dry before a needle is inserted into them.
  2. Sterile technique should be observed in setting up the system and the placement of the catheter.
  3. Subgaleal tunneling of the ventricular catheter should be approximately one to two inches.
- After cleaning the luer connectors with alcohol or a disinfectant containing alcohol, it is necessary to fully air-dry the connectors prior to connecting the system to prevent it from cracking.
- To secure the ventricular or lumbar catheter to the connection fitting, a double suture tie with silk suture should be used. Check to ensure that the connection is tight prior to use.
- The puncture of the ventricle or the opening of the dura may lead to an intracranial hemorrhage.
- Failure to properly adjust the rate of CSF outflow through the Shunting System may cause serious injury to the patient.
- All connections should be finger tightened. Over tightening may result in cracks and leaks. Leakage could lead to complications such as underdrainage, overdrainage, patient infection, and user infection.
- Ensure that the line to the patient is not kinked and that all air bubbles, blood, or other debris are removed from the system.
- The monitoring system may give a false pressure reading either due to a pressure line becoming clogged or kinked or from an air bubble lodged in the system. An incorrect pressure reading may bring about the wrong therapy being given to the patient.
- Whenever irrigation of the catheter or the performance of the VPR is decided upon, great care must be taken so as not to initiate pressure waves. Only a small volume of saline is allowed to be injected into the ventricular system by, or on the order of, a physician.
- Check to ascertain that the transducer is on the same level as the patient’s ventricular

system to ensure the appropriate reference level in the manometer tube for use in calibration procedures. Pressure monitoring with the manometer may cause over drainage of the ventricles.

- In monitoring intracranial pressure, one should always be aware of the wave form on the oscilloscope. If the wave form starts to dampen out, the entire monitoring system should be examined.
- The ventricle may collapse and occlude the catheter if too much CSF is removed from the ventricles, either during a drainage procedure or when the ventricle is first punctured.
- To ensure against ventricular collapse and the possible consequence of tentorial herniation, please follow the points below.
  1. Please always perform a drainage maneuver against a positive pressure head on the order of 20 cmH_2O or 15mmHg.
  2. When the ventricle or lumbar subarachoid space is first punctured during the insertion of the catheter, care should be taken so as little CSF as possible is lost.

❖COMPLICATIONS

- The risk of infection, especially meningitis and ventriculitis, is one major complication related to ICP monitoring with a ventricular or lumbar catheter. To decrease the incidence of infection, care should be taken in inserting the ventricular catheter and stabilizing it by passing it through a subgaleal tunnel before it emerges. The lumbar catheter should be stabilized by using fixation tabs. Wound infections may occur but usually subside after the catheter is removed.
- Overdrainage, which may cause intracranial hemorrhage and permanent neurological deficit, is another major complication regarding ventricular or lumbar drainage of CSF. The cause of overdrainage may be improper system testing or setup (bringing about system leakage or inappropriate system pressure head heights) or the lack of enough fluid replacements to the patient.
- The result of ICP monitoring will be affected if the patient line, catheter, or other components of the system be clogged with brain tissue fragments, blood clots, or fibrinous debris.
- Intracerebral hemorrhage, edema, and a further rise in ICP may arise due to frequent punctures of the brain to insert the ventricular catheter.
- In patients with small ventricles, the ventricular walls may collapse around the tip of the catheter and lead to obstruction and predispose to tentorial herniation. Therefore, before the catheter is attached to the patient line, it is extremely important to prevent CSF from excessive release.