medi pcs brio

pneumatic compression system

Operator’s Manual

Table of Contents

1 Before you get started

Read the entire operator's manual before using the pneumatic compression system (pcs) for the first time. Keep the manual for reference purposes. Keep all packaging materials in in the event that you must transport the medi pcs brio. The packaging materials have been specifically designed and fitted to protect the system from damage during transport.

Health care professionals: It is recommended that you assemble, program, and lock the treatment settings of the Pressure Control Unit (PCU) prior to initial patient use. The patient's settings should be recorded in 3.4 Patient Settings in the event that the PCU needs to be re-programmed.

Patients: Consult your health care professional prior to use if treatment settings have not been preset to your prescribed settings. You may refer to the Patient Quick Start Guide included with your system for easy set-up and use instructions.

1.1 Introduction

This manual contains important information regarding your medi pcs brio, including: product components, features & capabilities, operation, maintenance, and repairs. The information contained in this manual will guide you in easily setting up and using your medi pcs brio.

The medi pcs brio is a non-invasive intermittent sequential pneumatic compression therapy system meant for external use on the lower leg, whole leg, or arm. It assists in the management and treatment of lymphedema, venous stasis ulcers, venous insufficiency and peripheral edema. The system is safe for both hospital and home use. Caution: Federal law restricts this device to sale by or on the order of a clinician.

1.2 How to contact medi USA

For questions regarding your medi pcs brio system that cannot be answered in Chapter 8: Troubleshooting, please contact medi USA Customer Service. medi USA Customer Service is available Monday through Friday from 8:00 am to 6:00pm EST at (800)633-6334 or info@mediusa.com. If you have medical questions, please contact your clinician or other healthcare provider.

1.3 Indications & contraindications

The medi pneumatic compression system (pcs) brio is a compression device based on sequential pneumatic compression technique which is intended for the treatment of the following conditions: Lymphedema; Venous stasis ulcers; Venous insufficiency; Peripheral edema. The device is intended for home and hospital use.

Absolute Contraindications: use while ambulatory; use while sleeping; the presence of lymphangiosarcoma; suspected or known acute deep vein thrombosis; existing pulmonary edema; existing pulmonary embolism; inflammatory phlebitis; severe congestive cardiac failure; severe atherosclerosis or other ischemic vascular diseases; any circumstance where increased venous and lymphatic return is undesirable; extreme musculoskeletal deformity of limb intended for treatment; any local skin or tissue condition which the device would interfere such as gangrene, untreated or infected wounds, recent skin graft, and dermatitis; known presence of malignancy in the limb intended for treatment; limb infections, including cellulitis, that have not received antibiotic coverage.

Relative Contraindications: unsupervised children use under the age of 18; allergy or intolerance to garment material (100% Nylon)

Caution should be used when treating patients with heart disease or peripheral occlusion disease as the increased movement of fluids may pose additional health risks.

1.4 Guidelines for use

Do not use the system in the following situations or under these conditions:

- Power supply cord or plug is damaged or not working
- PCU is wet or has been dropped into water
- PCU or connectors are damaged and/or exposing internal components
- Graphical User Interface (GUI) is damaged or not functioning properly
- Alarm fails to sound during error mode

Should any of these situations occur, please do the following:

- Return pump for inspection or repair by qualified personnel
- Do not modify the PCU, garments, or power supply
- Service to the system should be conducted by qualified personnel only

Intended Operators include Qualified Medical Professionals and Non-Medical Operators. A Qualified Medical Professional is a licensed or non-licensed healthcare professional with sufficient skills and experience with the use of an intermittent pneumatic compression and/or other compression modalities commonly utilized for the intended use of the device and is able to aid or train someone in the use and maintenance of the device such as or technicians or equivalent and caregivers.

A Non-Medical Operator includes patients who operate devices on themselves to provide self-care and family members or friends who serve as lay caregivers to people receiving care in the home.

To qualify as a Non-Medical Operator, an individual must be:

- Alert and mentally competent
- Able to read and understand written instructions and symbols
- Able to understand and maintain good hygiene
- Capable of operating the device, donning the garment(s), and interacting with the display

The medi pcs brio system

Components 2.1

(2.1.1) *pressure control unit (PCU)*

(2.1.2) *blocking plate*

(2.1.3) *garment connector*

(2.1.4) *power supply*

1) Pressure Control Unit (PCU)
The PCU (2.1.1) is a programmable pneumatic compressor with two connector outlets. Each connector has ten outflow ports into which the garment hoses plug. Air passes through the hoses, delivering treatment through the sequential inflation and deflation of up to eight air chambers in the garments, or sixteen chambers total if two garments are being used. By programming a treatment program using the touchscreen Graphical User Interface (GUI), targeted pressure is delivered to the chambers and assists in moving excess fluid out of affected limb(s).

2) Blocking Plate
The blocking plate (2.1.2) is used to cover an open connector outlet. If the patient is using only one garment, you must install the blocking plate in the open connector outlet. The PCU will not operate properly if there is an uncovered, open connector outlet, resulting in an error. If the patient is using two garments at the same time during treatment, the blocking plate can be set aside but should not be discarded.

3) garment Connector
The garment connector (2.1.3) attaches the garment to the PCU. The number of open/closed ports will vary based on compression garment model. See Chapter 4 for compression garment sizing and application information.

4) Power Supply
The power supply (2.1.4) connects the PCU to an electrical outlet.

System assembly 2.2

Step 1: When your medi pcs brio arrives, carefully unpack the contents and ensure that all equipment required to begin operation is present.

Components:
- Operator's Manual
- Garment Application & Maintenance Guide
- Patient Quick Start Guide
- Pressure Control Unit (PCU)
- Blocking Plate
- Power Supply
- Garment(s) (the garment(s) received will vary depending on individual patient orders)

Step 2: Place the PCU on a flat, stable surface where the patient will easily be able to operate the controls during treatment. (2.2.1) The surface should be free of miscellaneous items such as loose paper, fabric, or tablecloths that could cause the air outflow ports to become blocked during treatment.

Step 3: Attach the two parts of the power supply to each other. (2.2.2) Locate the power supply jack on the back of the PCU and plug the circular end of the power supply into the PCU (2.2.3).

Step 4: Plug the opposite end of the power supply into an outlet.

NOTE: Garments should not be connected to the PCU until after garments have been applied to the appropriate limbs to reduce the risk of accidentally pulling the PCU off its resting surface.

(2.2.1)

(2.2.2)

(2.2.3)

3 Programming treatment settings

Treatment settings should only be programmed by Qualified Medical Professionals. Patients should refer to the separate **Patient Quick Start Guide** for instructions on running a treatment session.

Before using the medi pcs brio for the first time, ensure that a treatment area has been established for the patient so that he or she can easily access the PCU Graphical User Interface (GUI) at all times.

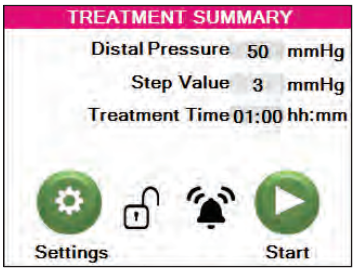
3.1 Powering on

Turn on the PCU by pressing the power switch on the back side of the PCU. Once on, the Startup Venting screen will be displayed while the chambers vent (3.1).

(3.1)

3.2 Initial setup

NOTE: When programming treatment settings, press ◀◀ to save your settings and return to the previous treatment setting. Press ▶▶ to save your settings and move onto the next treatment setting. When adjusting any of the settings, hold + or − for several seconds continuously to adjust values more quickly.



(3.2)

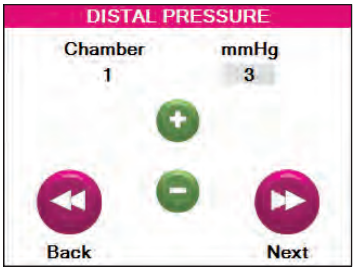
(3.3)

Step 1: Treatment Summary Screen (3.2)
This screen shows all the treatment parameters for the program currently stored in memory. There are two buttons on the Treatment Summary screen:

⚙ : This will take you to the main settings screen where you can adjust all the PCU settings. If the Settings button is not visible, proceed to Section 3.3 to unlock the PCU.

▶ : This will run the current treatment settings.

Press ⚙ to begin programming treatment settings.



(3.4)

Step 2: Select Language (3.3)**.** Select one of the four language options, English, French, Spanish, or Portuguese by pressing ● until the desired language is selected.

Step 3: Set Distal Pressure (3.4)**.** The Distal Pressure is the amount of compression that will be applied by the most distal chamber of the garment (at the hand or foot, depending on the limb being treated). The Distal Pressure can be set from 20-80 mmHg. Press + to increase the distal pressure in increments of 1 mmHg. Press − to decrease the distal pressure in increments of 1 mmHg.

Step 4: Set Step Value (3.5)**.** The step value is the increment by which the compression level will decrease between each chamber of the garment going up the garment from distal to proximal. The step value setting can be changed in 1 mmHg increments ranging from 1–60 mmHg. However, the step value range is limited such that no chamber will ever allow a pressure of less than 20 mmHg. All subsequent chambers will also be filled to the 20 mmHg minimum pressure level. (See Example 2.)

The PCU is preloaded with default settings of a distal pressure of 50 mmHg and a step value of 3 mmHg, regardless of garment type. This compression profile is shown below in Example 1.

(3.5)

Example 1: A 6-chamber garment (lower leg) where the distal pressure is set to 50 mmHg with a step value of 3 mmHg.

Chamber	1	2	3	4	5	6
mmHg	50	47	44	41	38	35

Example 2: An 8-chamber garment (whole leg or arm) where the distal pressure is set to 80 mmHg with a step value of 15 mmHg.

Chamber	1	2	3	4	5	6	7	8
mmHg	80	65	50	35	20	20	20	20

(3.6)

Step 5: Set Treatment Time (3.6)**.** The treatment time is the complete session time, including the initial garment fill-to-fit (see p.14) and treatment cycles. The treatment time can be set in 5 minute increments ranging from 10 minutes to 3 hours. Touch  to increase the treatment time in 5 minute increments or  to decrease the time in 5 minute increments. Regardless of the treatment time setting, the fill-to-fit process will always complete along with at least one treatment cycle. If treatment time expires during a treatment cycle, the session will end at the completion of the treatment cycle.

CYCLE TIMES

Fill-to-fit and treatment cycle times are dependent on the number of garments attached, garment/limb size, and pressure settings. At default settings (50 mmHg distal pressure, 3 mmHg step), fill-to-fit times range between 5-9 minutes, and average treatment cycle times range between 33-46 seconds. The minimum cycle times for six and eight chamber garments are 18 seconds and 24 seconds, respectively.

Step 6: Set Access Level (3.7). Select to lock the unit and only allow the patient to start and stop the unit with the current treatment settings. This is the recommended setting for patient use. Select to unlock the unit and allow access and modification to all treatment settings. This setting is recommended only when used under the guidance of a healthcare professional.

(3.7)

Step 7: Set Beeper Options (3.8). Select to turn the beeper on.

Select to turn the beeper off.

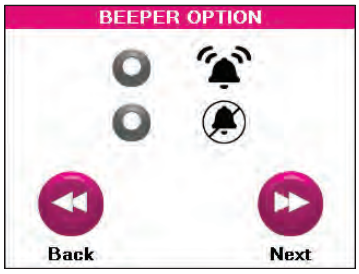
When turned on, the beeper sounds in these situations:

- When buttons are touched
- When an error occurs
- At the end of treatment

When turned off, the beeper sounds in these situations:

- When an error occurs

Note: Pressing the CONTINUE button will silence the button upon error or the end of treatment.



(3.8)

Step 8: Set up complete. Press after selecting beeper option to return to the Treatment Summary screen. The medi pcs brio is now ready to operate. Please review the settings displayed in the Treatment Summary screen to ensure that all settings have been entered correctly.

3.3 Unlocking settings

If you must unlock or change the treatment settings after initial programming, the PCU contains a hidden feature that allows the user to unlock the PCU and change the access level, thus enabling them to change the treatment settings.

To access this feature, first turn off the PCU by pressing the power switch. Then, turn the PCU back on and immediately press and hold the upper left corner of the screen for approximately five seconds. A small rectangle will display in the upper left corner of the startup screen when pressed correctly (3.9). You will be redirected to the language settings screen. From there, you can now navigate to all settings, including access level, to unlock the PCU. If no further action is taken to change the settings, the screen will automatically redirect to the Treatment Summary screen after 10 seconds.


(3.9)

Patient settings

Record the patient's settings here in the event that they must be reprogrammed:

Patient Name: _____

Language: _____ Treatment time: _____

Distal pressure: _____ Access level: _____

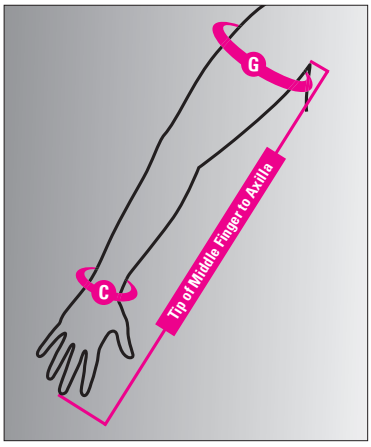
Step value: _____ Beeper: _____

4.1 Sizing

Arm

Sizing Chart: Use to select the appropriate garment based on body measurements. All measurements in cm.

Size	Item #	Arm Length	Circumferences	
			Wrist (C)	Axilla (G)
Short	CSAR085M22	50-57	14-42	21-57
Regular	CSAR085M26	58-66		
Long	CSAR085M29	66-64		

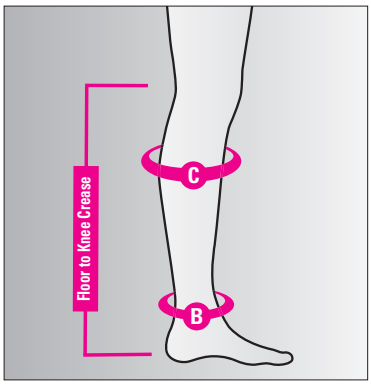


Arm Garment Sizing Measurements

Lower Leg

Sizing Chart: Use to select the appropriate garment based on body measurements. All measurements in cm.

Size	Item #	Leg Length	Circumferences	
			Ankle (B)	Calf (C)
Regular	CSLL065S17	34-43	18-56	24-61
Long	CSLL065S20	43-51		

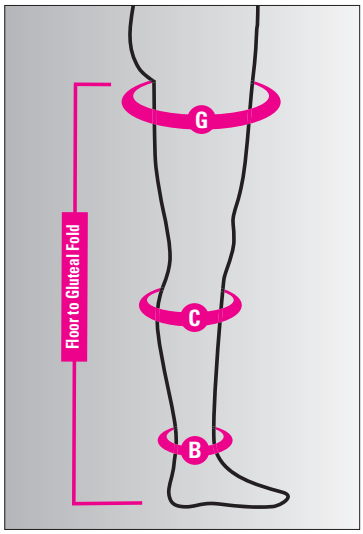


Lower Leg Sizing Measurements

Whole Leg

Sizing Chart: Use to select the appropriate garment based on body measurements. All measurements in cm.

Size	Item #	Leg Length	Circumferences		
			Ankle (B)	Calf (C)	Thigh (G)
Small-Short	CSWL085S28	64-70	18-56	24-61	41-79
Small-Regular	CSWL085S31	71-77			
Small-Long	CSWL085S34	78-85			
Medium-Short	CSWL085M28	64-70	36-74	39-76	52-89
Medium-Regular	CSWL085M31	71-77			
Medium-Long	CSWL085M34	78-85			
Large-Short	CSWL085L28	64-70	48-85	51-88	61-98
Large-Regular	CSWL085L31	71-77			
Large-Long	CSWL085L34	78-85			



Whole Leg Sizing Measurements

Introduction 4.2

The garments are air-chambered garments that are made of smooth, pliable fabric (100% nylon). They are designed to fit the contours of the body by wrapping around the limb(s) and attaching with hook and loop fasteners. They contain overlapping air chambers that inflate and deflate sequentially.

- **Arm garments** contain eight (8) chambers
- **Lower leg garments** contain six (6) chambers
- **Whole leg garments** contain eight (8) chambers

Six or eight chamber garments can be used with the medi pcs brio.

Undersleeves for wear underneath the garments are available for purchase separately, but are not required.

Application 4.3

Do not connect the garments to the PCU until after the garments have been applied to the appropriate limbs to avoid accidental pulling or movement of the PCU.

Remove any jewelry, watches, or other items that may cause damage to the garment before applying.

If desired, apply a liner over the limb before applying the garment. This will help keep the garment clean during use. Loose, unrestrictive clothing such as sweatpants or cotton t-shirts may also be used, so long as the clothing is safe to be compressed against the skin and will not cause damage to the garment.

Leg garments

There are two methods of application:

Method A:

Step 1: Loosely form the garment to your leg's shape and fasten the hook tabs (4.1).

Step 2: With the foot piece of the garment furthest from you, slide your leg into the garment until it reaches your knee (for lower leg, shown in 4.2) or upper thigh (for whole leg, shown in 4.3).
Note: do not stand or walk while wearing leg garments. Photo is for illustration purposes only.

Step 3: Readjust the hook and loop material of the garment if necessary so that it fits securely but comfortably on your leg (4.4). As the garment inflates it will intelligently apply compression based on your limb size so it is not necessary that the garment have a snug fit or apply compression from donning.

(4.1)

(4.2)

(4.3)

(4.4)

Leg garments

Method B:

Step 1: While sitting or lying down, undo the hook and loop material of the garment and open the it (4.5).

Step 2: Place your foot in the foot section of the garment with your heel comfortably positioned in the heel pocket (4.6).

Step 3: Starting at the ankle, secure the garment in place around your leg using the hook and loop material (4.7). As the garment inflates it will apply compression so it is not necessary that the garment have a snug fit or apply compression from donning.

Step 4: Continue securing the garment up your leg until the entire garment is fastened (4.8). When applied, the garment should be comfortably secured, but not so tight that it applies compression. Fully applied whole leg shown in (4.9). **Note:** Do not stand or walk while wearing leg garments. Photo is for illustration purposes only.

Your toes may or may not extend from the end of the garment, depending on your foot size. The garment should not be applied so tightly that it applies compression without inflation, and it should never hurt. The garment connector should extend from the end of the garment closest to the heel.


(4.5)


(4.6)


(4.7)


(4.8)


(4.9)

Arm garments

Step 1: Loosely form the garment to your arm's shape and fasten the hook tabs (4.10). Use the outermost hook panel for larger circumference arms. Fold the panel under itself and use the inner hook panel for smaller circumference arms.

Step 2: With the curved end of the garment closest to you, slide your arm into the garment until it reaches your armpit (4.11).

Step 3: Ensure that the curved top edge of the garment is positioned on the outer side of your shoulder (4.12). The straight end of the garment should be positioned over the hand. Readjust the hook and loop material of the garment, if necessary, so that it fits securely but comfortably on your arm. As the garment inflates it will intelligently apply compression based on your limb size so it is not necessary that the garment have a snug fit or apply compression from donning.

Your fingers may or may not extend from the end of the garment depending on the length of your arm. When applied, the garment should not be so tight that it applies compression and it should never hurt. The garment connector should extend from the end of the garment closest to the wrist.


(4.10)


(4.11)

Garment removal

Disconnect the garment from the PCU and deflate as necessary. To remove the garment, either slide your limb out of the garment or undo the hook and loop material and remove your limb. It is recommended to keep the hook and loop material fastened even when the compression garment is not in use to avoid it snagging on clothes, linens, or other materials.


(4.12)

Connecting the garments to the pressure control unit (PCU)

Unilateral treatment (treatment with one garment) 5.1

Step 1: Locate the garment connector at the end of the hoses attached to the garment (5.1). The number of open ports will vary based on the garment model.

Step 2: Insert the garment connector into the open port on the front of the PCU (5.2). The latching mechanism on top of the garment connector should face up and will firmly lock into position when inserted properly into the PCU port. The garment connector connects with minimal amount of force and should never be jammed or forced into the PCU port. The garment connector will not connect if inserted upside down or sideways.

Step 3: Insert the blocking plate into the remaining open port on the front of the PCU and ensure that it is secure (5.3). If needed, the garment connector and blocking plate can be switched between ports. The compression output is the same for both ports and is not left- or right-dependent.

After treatment, disconnect the garment connector from the PCU by pressing down on the latch mechanism and pulling the connector out. The blocking port can remain in place for future treatment sessions.

(5.1)

(5.2)

(5.3)

Bilateral treatment (treatment with two garments) 5.2

Step 1: Locate the garment connectors at the end of the hoses attached to the garments (5.4).

Step 2: Insert the garment connector into the open port on the front of the PCU (5.5). The latching mechanism on top of the garment connector should face up and will firmly lock into position when inserted properly into the PCU port. The garment connector connects with minimal amount of force and should never be jammed or forced into the PCU port. The garment connector will not be able to connect if inserted upside down or sideways.

Step 3: Insert the second garment connector into the second port of the PCU using the same method applied for the first garment connector (5.6).

The blocking plate is not needed and can be set aside for later use if running unilateral treatment.

After treatment, disconnect the garment connectors from the PCU by pressing down on the latch mechanism and pulling the connectors out.

(5.4)

(5.5)

(5.6)

6 Conducting a treatment session

6.1 Starting a session

During treatment, the patient should be in a seated or reclining position and should never attempt to walk or move vigorously while connected to the PCU as this could cause the PCU to be pulled from the surface and damaged and/or cause injury to the patient.

Step 1: Ensure that the garment(s) are properly connected to the PCU before beginning treatment.

Step 2: Turn on the medi pcs brio by pressing the power switch on the back of the PCU (6.1). Once on, the Startup Venting screen will be displayed while the air chambers vent (6.2).

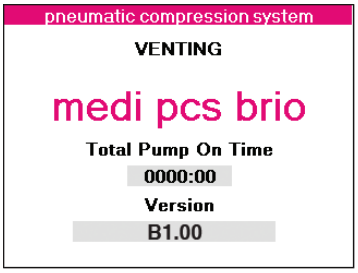
Step 3: The Treatment Summary screen will appear (6.3). It provides an overview of the programmed treatment. After confirming all treatment settings are correct, press  to begin treatment.

Step 4: The Treatment Running screen will appear (6.4). The PCU will begin the fill-to-fit process, after which the programmed treatment cycle will begin. The Treatment Running screen will show treatment time remaining, current active chamber in use, and the pressure setting for the active chamber.

What is the fill-to-fit process?
During the fill-to-fit process, each of the air chambers is gradually filled to a greater pressure over the course of several inflation cycles to acclimate the limb for treatment. The first inflation cycles will take the longest amount of time and will have the least amount of compression. Each following cycle will complete more quickly and will gradually build to the programmed compression settings.

For optimal results, remain in a relaxed position, avoid rapid movements and changes in posture during the first 5-10 minutes of treatment running the fill-to-fit process. In the event of an error or if you feel the garment has not filled properly, pause and end the current treatment session and start a new session to begin the process again.


(6.1)



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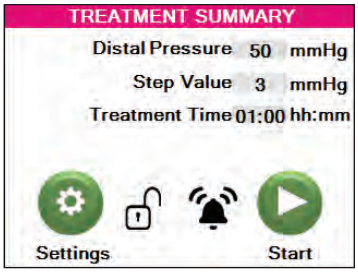

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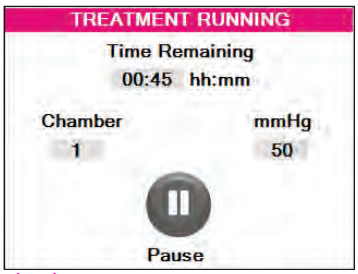
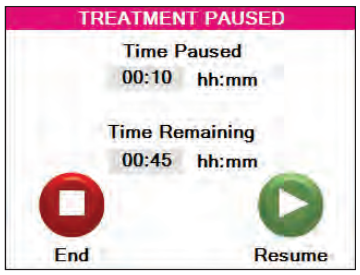


(6.4)

Pausing a session 6.2

Press on the Treatment Running screen to pause treatment. The Treatment Paused screen will appear (Fig. 6.5) after the garment(s) have vented. After venting, press to resume treatment. Treatment will restart, continuing treatment for the remaining amount of time. If treatment is not resumed within one hour, the treatment session will be ended.

Press to end treatment entirely. The Treatment Summary screen will automatically reappear.



(6.5)

Completing a session 6.3

When the Time Remaining on the Treatment Running screen reaches 00:00, the PCU will automatically proceed to the Treatment Complete screen (6.6) after completing the active treatment cycle. All air chambers will vent completely and the beeper will sound if the beeper is set to On.

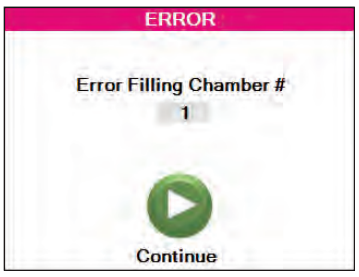
(6.6)

Turning off the PCU 6.4

Press the power switch on the back of the PCU to turn off the medi pcs brio. Please note that the PCU inflation & deflation valves close while the PCU is turned off. If a garment is connected it will not be able to be deflated further until it is disconnected from the PCU or the PCU is turned on.

Error screen 6.5

If an inflation issue is encountered the beeper will sound and the Error screen will display. (6.7) It will include the chamber number that caused the error. Please note the chamber number and see **8. Troubleshooting & Technical Information** on resolving errors. Pressing the continue button will end the beeper and return to Treatment Summary Screen.



(6.7)

7 Caring for your medi pcs brio system

7.1 Storing your system

After treatment is complete and the PCU is turned off, unplug the power supply cord from the power outlet and from the PCU. Disconnect the garments from the PCU.

Store the garments by first loosely coiling the hoses and garment connectors. Avoid kinking or crushing the hoses. Lay the garments flat in a cool, dry place for storage.

Store the PCU in a cool, dry place, avoiding direct sunlight. Keep it away from excessive heat or cold, and keep away from children and pets.

7.2 Cleaning your system

PCU: Ensure that the power supply is unplugged before cleaning the PCU. Gently wipe the PCU with a slightly damp cloth. Do not allow any moisture or liquid to enter the device. If additional cleaning is required, the PCU can be wiped with a light application of hospital-grade disinfectant, such as 70% Isopropyl Alcohol solution.

Garments: Ensure that the garments are disconnected from the PCU before cleaning them. Gently wipe the garment using a slightly damp cloth, moistened with a mild anti-bacterial soap or 70% Isopropyl Alcohol solution. Do not allow any moisture or liquid to enter the air inlets of the garment connectors. After wiping with a damp cloth, thoroughly dry the garment using a soft towel or cloth and allow to air dry fully. Do not bleach, iron, or machine wash or machine dry the garments.

Troubleshooting & technical information

Troubleshooting 8.1

Issue	Recommended Solutions
Pressure Control Unit (PCU) does not turn on	1. Ensure that the power supply is correctly assembled and correctly connected to both the PCU and wall outlet. 2. Ensure that the power switch has been turned on. 3. If PCU still does not turn on, please contact medi USA Customer Service.
Error screen appears after prolonged duration attempting to fill chamber (e.g. leak)	1. Check garment connection. Disconnect and reconnect garment entirely. 2. Check hoses and garments for leaks. If any component is found to have a leak, contact medi USA Customer Service. 3. If Blocking Plate is not connected during unilateral treatment, connect Blocking Plate to PCU.
Error screen appears at the start of the treatment (e.g. blocked port)	1. Check the the PCU & garment connector ports for blockages. 2. Verify that garment connectors are correctly connected to PCU and that hoses are not kinked or twisted. 3. Run treatment. 4. If error continues contact medi USA for service.
Error screen appears after 5-10 minutes after start of treatment (e.g. fill-to-fit error)	1. Check garment and/or blocking plate for proper connection and leaks. 2. Re-run treatment ensuring to avoid any rapid movements or drastic posture changes during fill-to-fit process. 3. If error repeats, recheck garment for leaks or contact medi USA.
Air chambers do not fill with air	1. Verify that the Start button has been pressed to begin treatment. 2. Verify that garment connectors are correctly connected to PCU and that hoses are not kinked or twisted. Disconnect and reconnect garment connectors. 3. If the chambers still do not fill, turn the PCU off, detach connectors, and start the PCU again. Press the Start button to begin a treatment session. If you feel air coming out of the connectors, reattach the garment connectors and try again. 4. Verify the blocking plate is correctly installed if conducting unilateral treatment.
Cannot change treatment settings	Treatment settings should only be configured by a trained healthcare professional. See section 3.3 Unlocking settings for instructions on changing treatment settings.
Air chamber pressures are higher or lower than expected	1. If you believe the fill-to-fit process may not have been performed correctly, pause and end the treatment session immediately and restart a new session ensuring to avoid any rapid movements or drastic posture changes during the first 5-10 minutes of treatment. 2. Verify that the correct treatment settings have been selected by referring to the Treatment Summary screen. 3. Adjust the fit of the garment, ensuring there are no folds or kinds in the fabric. 4. Ensure that the garment connectors are correctly attached to the PCU. 5. Ensure that the PCU ports are free from obstruction. 6. Verify the pressure settings with your healthcare professional. 7. Contact medi USA if you believe the system is not working properly.
Air chambers remain inflated	It is normal for a small amount of air to remain in the air chambers between inflations, which gives the garment a slightly puffy appearance. However, if the chambers remain fully inflated: 1. Ensure that the hoses are not kinked, twisted, or pinched. 2. Disconnect the garment connectors from the PCU.
PCU runs treatment for shorter or longer than expected	1. Verify that the Treatment Time selected is that recommended by a healthcare professional. 2. If the PCU continues to operate beyond the appearance of the Treatment Complete screen or discontinues treatment prematurely, contact medi USA Customer Service. Regardless of the treatment time setting at least one treatment cycle will always run after the fill-to-fit process to complete the session. If the treatment timer expires during treatment the current active cycle will run to completion.
garment connectors, hoses, garments, or PCU buttons have broken or become defective	Contact medi USA Customer Service.
PCU makes an abnormal or loud noise	The PCU will make a light clicking noise during the fill-to-fit process. This is normal and will cease 5-10 minutes after treatment has started. 1. Verify that the PCU is placed on a stable surface. 2. Ensure that the system is correctly assembled. 3. Turn the system off and restart. Begin treatment again. 4. If the noise persists, contact medi USA Customer Service.
PCU makes a clicking sound at the end of the inflation cycle before venting.	This is normal pressure fill-to-fit functionality. This will cease during treatment cycles.
Other problem or defect with system	Contact medi USA Customer Service.

8

8.2 Warranty & return policy

The Manufacturer's Warranty states that products are warranted to be free from defects in material and workmanship for a defined period. The Manufacturer's sole obligation in the event of a breach of this warranty is expressly limited to the replacement of defective parts that, in the sole discretion of the Manufacturer, cannot be repaired. Replacement parts may be new or refurbished parts as solely determined by the Manufacturer. This warranty is available only to the original user and is not transferable. Repairs or alterations to the product not conducted by the Manufacturer shall void these warranties. These warranties do not cover failures due to improper or negligent use of the product. The Pressure Control Unit (PCU) is covered by warranty for 3 years. The garments are covered by warranty for 1 year.

For questions regarding the Manufacturer's Warranty and technical support, please contact:
Medi USA, LP
6481 Franz Warner Parkway
Whitsett, NC 27377
(800)633.6334
info@mediusa.com

8.3 Safety warnings

Warning: Explosion Hazard
Do not use in the presence of flammable gases, including flammable anesthetics.

Warning: Electrical Shock Hazard
Do not allow liquid to enter any part of the system.

Warning: Electric Shock Hazard
Never attempt to perform maintenance or service the device while in use. To completely eliminate power, disconnect the power supply from the Pressure Control Unit or from the wall outlet.

Warning:Electric Shock Hazard
Unplug power supply from source and do not use medi pcs during electrical storms.

Warning: Electric Shock Hazard
To prevent electric shock, do not open the Pressure Control Unit. Do not attempt to service the pressure control unit yourself. All maintenance tasks should be performed only by the manufacturer or by authorized service personnel. Service by unauthorized personnel shall void the warranty.

Warning: Ventilation Hazards
Always place the pump on a solid surface free of objects that may block ventilation openings. Never lock the ventilation openings. Keep the ventilation opening free of debris such as lint and hair. Never operate the pump on a soft surface, such as a bed, couch, or pillow, where the ventilation opening may be blocked. Never drop or insert any object into any opening of the pump.

Warning: Environmental Hazards
Keep the pump, garments, and power supply cord and plug away from sharp objects, flames, and heated surfaces.

Warning: Proper Inspection Required
Prior to using always inspect pressure control unit, power supply, garments, and connectors for damage.

Warning: Tripping
Never operate the controller where the cord or tubing harness shall present a tripping hazard.

Warning: Strangulation
The power supply and hoses of this product may pose a strangulation hazard. Keep power supply and hoses out of the reach of children at all times.

Warning: Contact Injuries
Pressure Control Unit should be placed at same height or below patient to prevent possible injury from device falling on patient.

Warning: Treatment Should Never Hurt
The garment compression should never hurt. If you experience pain or notice your condition worsening, contact your physician. Do not change your treatment settings without consulting your physician.

Warning: Parental Supervision
Children under the age of 18 should only use the system under adult supervision and direction of a physician.

Caution: Single Patient Use
Garments are intended for single patient non-ambulatory use only.

Caution: Compatibility
Use only the medi pcs power supply (GSM60B24), garments, and accessories with the medi pcs system.

8.4 Symbol Glossary

Symbol	Title	Standard	Reference No.	Function
	Caution	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	0434A	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Caution, risk of electric shock	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	6042	To identify equipment, for example, the welding power source, that has risk of electric shock.
	Warning; Explosive material	ISO 7010 — Graphical symbols -- Safety colours and safety signs -- Registered safety signs	W002	To warn of explosive materials
	Keep away from rain	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	0626	To indicate that the transport package shall be kept away from rain and in dry conditions.
	Read Operator's Manual	ISO 7010 — Graphical symbols -- Safety colours and safety signs -- Registered safety signs	M002	To signify that the instruction manual/booklet must be read
	Operator's manual; operating instructions	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	1641	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	Type BF applied part	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5333	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	Class II equipment	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5172	To identify a type BF applied part complying with IEC 60601-1.
	Direct current	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5031	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Non-ionizing electro-magnetic radiation	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5140	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	Symbol for the Marking of Electrical and Electronic Equipment	DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)	NA	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	SGS North America Listed Mark	NA	NA	To indicate separate collection for electrical and electronic equipment (EEE)
	Manufacturer Symbol	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3082	To identify the Nationally Recognized Testing Laboratory responsible for the certification of safety standards.
	Catalogue number	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2493	To identify the manufacturer of a product.
	Serial Number	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2498	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
	Do not bleach	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3124	To indicate that bleaching the textile article is not allowed.
	Do not iron	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3113	To indicate that ironing is not allowed.
	Do not dry clean	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3114	To indicate that dry cleaning is not allowed.
	Do not wring	ASTM D5489-18 Standard Guide for Care Symbols for Care Instructions on Textile Products	NA	To indicate that wringing is not allowed.
	Do not wash	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3123	To indicate that washing the textile article is not allowed during the cleaning process.
	Flat drying	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	3080	To indicate that flat drying is allowed in the natural drying process.

Specifications

General Equipment Specifications 8.5

MODEL: brio
IEC PROTECTION CLASSIFICATION: Class II
DIMENSION: 8.75" (W) x 13" (D) × 4.5" (H)
WEIGHT: 6.5 lbs
PRESSURE RANGE: 20-80 mmHg
ELECTRICAL: 100 - 240vac, 50/60Hz, 1.4 -0 .7 amps
POWER: 60 Watts
IP2X: Protected against ingress of solid objects over 12.5 mm
e.g. accidental touch by a person's hand.
No protection against ingress of liquids.
APPLIED PART: Type BF
APPLIED STANDARDS: ANSI/AAMI ES60601-1, AAMI HA60601-1-11, CSA C22.2 No. 60601-1, CSA C22.2 No. 60601-1-11, ISO 13485, ISO 14971, IEC 62304 IEC/EN 60601-1-2, IEC/EN61000-3-2, IEC/EN 61000-3-3, FCC CFR 47; Part15; Subpart B, ICES 001; ISSUE 4, AS/NZS CISPR 11, JIS T 0601-1-2, ABNT NBR IEC 60601-1-2
LEGAL MANUFACTURER: medi USA, LP, 6481 Franz Warner Parkway, Whitsett, NC 27377,
www.mediusa.com Made in USA

Environmental Conditions 8.6

Temperature: Operating Temperature: 41°F (5°C) – 104°F (40°C); Storage Temperature: -13°F (-25°C) – 158°F (70°C)

Humidity: Operating Humidity: 15% – 93%; Storage Humidity: < 93%

Atmospheric Pressure: Operating Pressure: 70 kPa – 106 kPa; Storage Pressure: 50 kPa – 106 kPa

Disposal: The PCU should be discarded in accordance with proper electronic waste disposal regulations. There are no disposal restrictions on the garments and they can be disposed with normal household waste.

8.7 Electromagnetic Compatability

The medi pcs requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medi pcs, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: 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.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

1	**Guidance and Manufacturer's Declaration – Electromagnetic Emissions**		
2	**The medi pcs is intended for use in the electromagnetic environment specified below. The customer or the user of the medi pcs should assure that it is used in such an environment.**		
3	Emissions Test	Compliance	Electromagnetic Environment - Guidance
4	RF emissions CISPR 11	Group 1	The medi pcs uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class B	The medi pcs 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.
7	Harmonic emissions IEC 61000-3-2	Class A	
	Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The medi pcs is intended for use in the electromagnetic environment specified below. The customer or the user of the medi pcs should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ELECTROSTATIC DISCHARGE (ESD)	RF emissions CISPR 11	Group 1	The medi pcs uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in nearby electronic equipment.
ELECTRICAL FAST TRANSIENT/BURST IEC 610004-4	+2kV for power supply lines	+2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+1kV line(s) to line(2) +2kV line(s) to earth	1kV line(s) to line(2) +2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the medi pcs requires continued operation during power mains interruptions, it is recommended that the medi pcs be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The medi pcs is intended for use in the electromagnetic environment specified below. The customer or the user of the medi pcs should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ECONDUCTED RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the medi pcs, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/10] √P 80 MHz to 800 MHz d = [7/10] √P 800 MHz to 2.7 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
RADIATED RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

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.

• Field 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 medi pcs is used exceeds the applicable RF compliance level above, the medi pcs should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the medi pcs.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

IMMUNITY TEST	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V	Portable and mobile RF communications equipment should be used no closer to any part of the medi pcs, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment the medi pcs

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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz d = [3.5/10] √P	800 MHz to 2.7 GHz d = [7/10] √P	710, 745, 780, 5240, 5500, 5785 d = [6/9] √P	240, 5500, 5785 d = [6/9] √P
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	6.670	2.143

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.

For other language translations,
please visit www.mediusa.com.

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