medi® pcs genius

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 genius. 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 3.6 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 genius, 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 genius.

The medi pcs genius 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 General questions contact

For questions regarding your medi pcs genius system that cannot be answered in Chapter 8: Troubleshooting, please contact your point of purchase. If you have medical questions, please contact your clinician or other health care provider.

1.3 Indications & contraindications

The medi pneumatic compression system (pcs) genius 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 health care 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 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

2 The medi pcs genius system

Components 2.1

2.1. (a) *pressure control unit (PCU)*

2.1. (b) *blocking plate*

2.1. (c) *garment connector*

2.1. (d) *power supply & wall outlet cord*

1) Pressure Control Unit (PCU)
The PCU 2.1. (a) 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 ten air chambers in the garments, or twenty 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. (b) 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. (c) 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 and wall outlet cord
The power supply 2.1. (d) connects the PCU to an electrical outlet.

System assembly 2.2

Step 1: When your medi pcs genius 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. (a) 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. (b) 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. (c).

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. (a)

2.2. (b)

2.2. (c)

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 genius 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.

NOTE: Use the navigational and setting selection buttons to navigate menus and adjust settings. Navigation to a new screen saves the new setting as changes are applied.When adjusting any of the settings, hold + or − for several seconds continuously to adjust values more quickly.

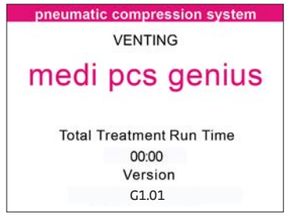
CYCLE TIMES

Fill-to-fit and treatment cycle times are dependent on the number of garments attached, garment/limb size, and pressure settings.

3.1 Powering on

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

3.1. (a)



3.1. (b)

3.2 Unlocking access to settings

Unlocking the PCU allows access to the user adjusted software settings. When locked, the user adjusted software setting access is limited.

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 3.2. (a). 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. The PCU will remain unlocked until the access level is changed back to locked. If no further action is taken to change the settings, the screen will automatically redirect to the Treatment Summary screen after 10 seconds.

3.2. (a)

Administrative system settings 3.3

Step 1: From the Treatment Summary screen 3.3. (a), and with access unlocked, press the ⚙ button to access the main setting menu.

Step 2: From the main settings menu 3.3. (b), select Admin.

Step 3: Use the menus described below to adjust administrative settings as needed.

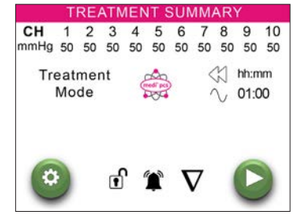
Language Selection From the Admin menu 3.3. (c), select Language 3.3. (d), then select one of the four language options, English, French, Spanish, or Portuguese by pressing ● until the desired language is selected.

Beeper Options 3.3. (e). From the Admin menu, select Beeper, then 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

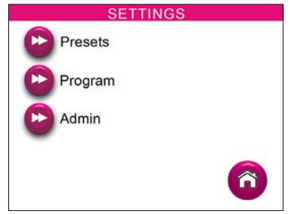
When turned off, the beeper sounds in these situations:
- When an error occurs

Settings Access 3.3. (f). From the Admin menu, select Access, then select 🔒 to lock access to the settings 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 health care professional.

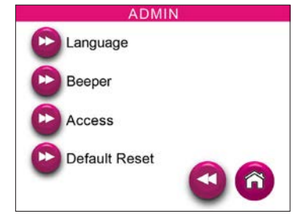
System Default Reset 3.3. (g)**.** From the Admin menu, select Default Reset. When prompted by the warning screen, select yes to reset all software settings to the indexed manufacturer defaults. Select no to return to the Admin menu without losing current system settings.



3.3. (a)



3.3. (b)

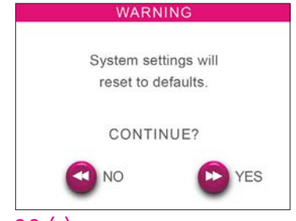


3.3. (c)

3.3. (d)

3.3. (e)

3.3. (f)



3.3. (g)

3.4 Preset Programming Mode

The Preset menu settings offer a simplified approach to quickly program and adjust therapy outputs based on commonly utilized treatment protocols. Changes to settings under the Preset menu overwrite Program menu settings.

•**Step 1** From the Treatment Summary screen 3.4. (a), and with access unlocked, press the ⚙ button to access the main setting menu.

•**Step 2** From the main settings menu 3.4. (b), select Presets.

•**Step 3** From the Presets menu 3.4. (c), select Sleeve & Zone.

•**Step 4** From the Sleeve menu 3.4. (d), select your sleeve type: Arm & Hand or Leg & Foot.

•**Step 5** From the Treatment Zone menu 3.4. (e,f), select the desired area to apply treatment, then press ⏩. If a partial area is selected, only that zone of the sleeve will apply compression during treatment, while the other areas of the sleeve will remain inactive.

•**Step 6** From the Treatment Mode menu 3.4. (g), select the desired mode: Peristaltic or Sequential, then press ⏩.

Peristaltic treatment mode creates traveling pressure waves through the sleeve, while sequential mode fills each chamber of the sleeve sequentially before venting all chambers to complete the cycle.

•**Step 7** From the Pressure Level menu 3.4. (h), select the desired compression level: Low, Normal, or High; then press ⌂ to return to the Treatment Summary screen.

The low and high pressure level settings decrease or increase the normal pressure level setting by 10mmHg respectively.

•**Step 8** From the Treatment Summary screen 3.4. (i), review and confirm your settings. The selected Treatment Zone icon will display on the center of the screen indicating the Preset programmed.

3.4. (a)

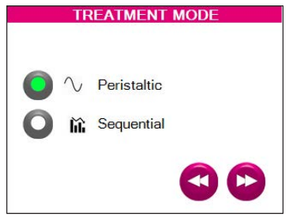
3.4. (b)

3.4. (c)

3.4. (d)

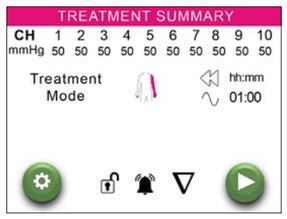
3.4. (e)

3.4. (f)



3.4. (g)

3.4. (h)



3.4. (i)

genius Programming Mode 3.5

The genius program menu settings allow for comprehensive therapy output adjustments and activation of supplemental treatment modes described in this section. Changes to treatment settings under the genius program menus are saved upon navigation to a new screen and append and overwrite settings made using Preset programming mode. The treatment icon displayed on the center of the treatment summary screen signals whether the current therapy settings are a preset program or a custom-tailored genius program.

Tip: Preset programming is recommended for quickly creating a baseline therapy program. Genius programming mode is then best used to tailor the baseline settings to the users needs, e.g., changing treatment time, skipping chambers, and activating supplemental modes.

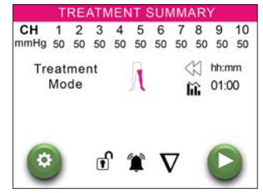
Example:
3.5. (a) The whole leg highlight icon in the center of the screen indicates preset programming for whole leg therapy is active.

3.5. (b) The genius icon in the center of the screen indicates a custom-tailored therapy program, e.g. the whole leg preset program of the prior example was altered to a 30 minute treatment time and chambers 5&6 in the knee area were set to skip to avoid user sensitiuities.

Accessing genius Treatment Settings

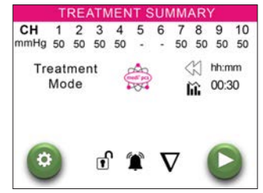
3.5. (c) From the Treatment Summary screen, and with access unlocked, press the ⚙ button to access the main setting menu.

3.5. (d) From the main settings menu, select Program for complete access to genius treatment settings.



3.5. (a)

3.5. (b)

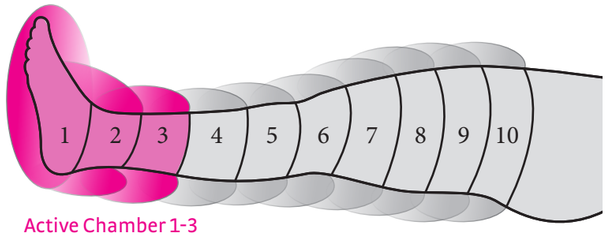


3.5. (c)

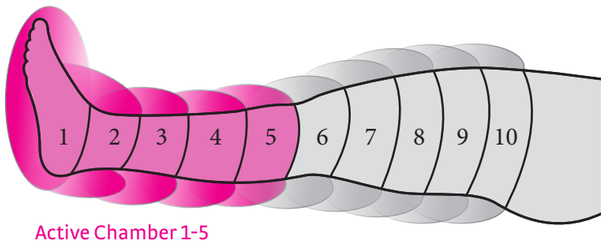
3.5. (d)

Active Chambers

The Active Chambers setting establishes the range of chambers subject to inflation/deflation during decongest and standard treatment mode cycling. Adjustable in 1 chamber increments starting from the most distal chamber 1, this setting is useful to limit the treatment zone within the sleeve. For example, a whole leg sleeve with 10 chambers and the Active Chamber setting set to 1–3, would only apply pressure cycling to the first 3 distal chambers of the sleeve, which aligns with treating only the foot and ankle region. Extending the Active Chamber setting adjustment to 1–5, would extend the treatment zone from the foot and ankle to the knee region to treat the lower leg, while chambers 6–10 would remain inactive and deflated during therapy.



Active Chamber 1-3



Active Chamber 1-5

Tip: The Active Chamber setting does not need to be adjusted to match the sleeve configuration. The medi pcs genius autodetects if a 6, 8, or 10 chamber sleeve is connected and adjusts the therapy output accordingly. For example, in clinical use this allows for switching between whole leg 10-chamber garments and half leg 6-chamber garments effortlessly without having to modify the program settings.

3.5. (e) From the Program menu, select Sleeve to access the active chamber sleeve settings.

3.5. (e)

3.5. (f) The Active Chambers default setting is 1-10 to activate all chambers.

3.5. (f)

Treatment Settings

3.5. (g) From the Program menu, select Treatment to access the treatment settings.

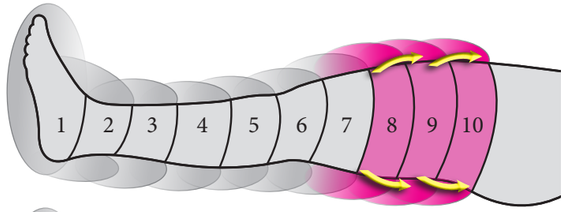
Treatment Modes

3.5. (h) From the Treatment menu, select Modes to access the Modes menu.

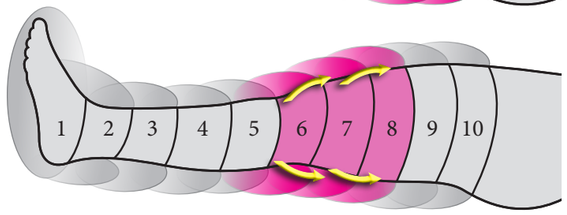
Decongest Mode

3.5. (i) From the Modes menu, select Decongest to access the Decongest Period setting.

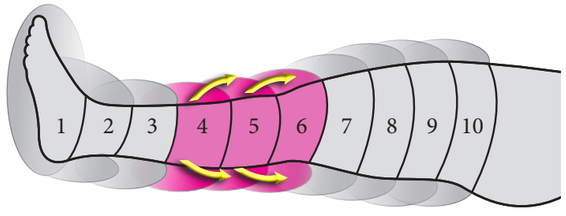
Decongest mode is used to clear proximal pathways in preparation for fluid movement from distal area treatment. Decongest mode consists of a peristaltic inflation/deflation sequence, starting in the last three proximal active chambers and then progressing distally by chamber groups as pre-determined by the Active Chamber setting, see page 10.



Decongest Sequence 1



Decongest Sequence 2



Decongest Sequence 3

3.5. (j) The Decongest Period default setting is Pre-Treatment. Use the ● to change the setting.

When Decongest Period is set to Pre-treatment, the Decongest therapy cycle completes first and then continues to the standard treatment therapy cycles. When Decongest Period is set to Continuous, the Decongest therapy cycle sequences repeats until the expiration of the Treatment Time timer, bypassing standard treatment & focus mode treatment therapy cycles, see page 13. When Decongest Period is set to Off, the Decongest therapy cycle is bypassed and therapy immediately progresses to the standard treatment and/or focus mode therapy cycles. The pressure settings for Decongest mode are shared with the standard treatment cycle pressure settings and cannot be independently adjusted.

Tip: For convenience, the default and full limb Preset programs include Pre-treatment Decongest cycling. If Decongest therapy is not desired, it can be disabled after completing preset setting selections.

3.5. (g)

3.5. (h)

3.5. (i)

3.5. (j)

Treatment

3.5. (k) From the Modes menu, select Treatment to access the Treatment Mode setting.

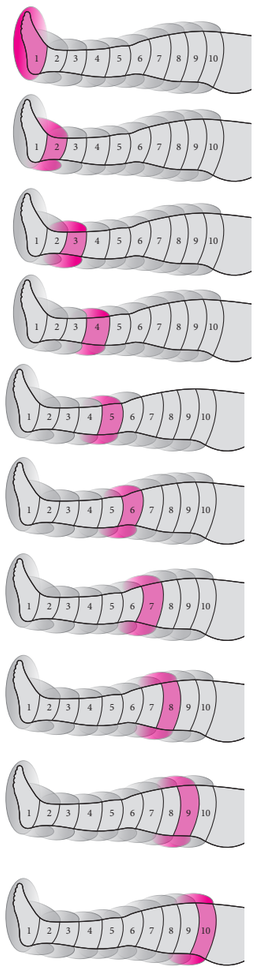
The Treatment Mode setting determines the standard treatment therapy cycle inflation/deflation sequence type, peristaltic or sequential. Peristaltic sequences create traveling pressure wave(s) through the sleeve, while sequential sequences fill all chambers of the sleeve sequentially before venting all chambers to complete the cycle. In both Peristaltic and Sequential modes, inflation/deflation standard treatment cycles repeat for the duration of the Treatment Time setting, dependent on decongest mode (page 11) and/or focus mode (page 14) settings.

3.5. (l) The Treatment Mode default setting is peristaltic single wave. Use the  to change the setting.

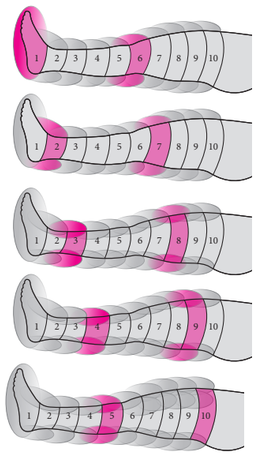
3.5. (k)

3.5. (l)

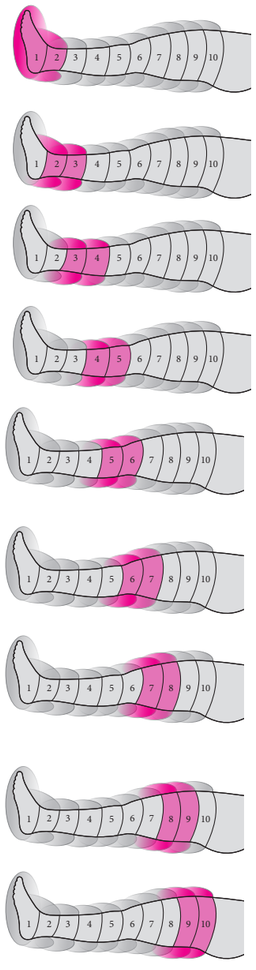
Peristaltic Single Wave *(Default)*



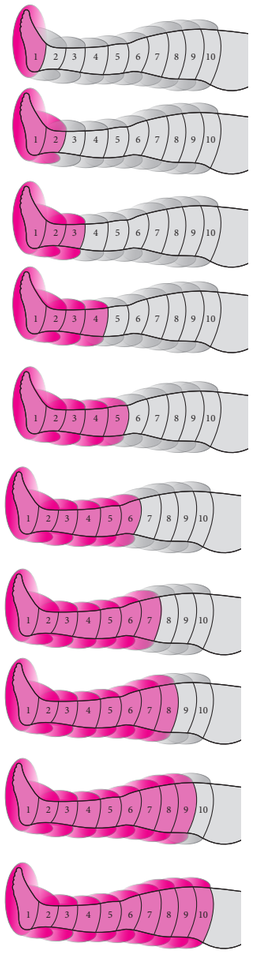
Peristaltic Dual Wave



Peristaltic Power Wave



Sequential



Peristaltic Single Wave (Default)

Single wave peristaltic mode inflates and deflates a single chamber to form a narrow pressure wave as the sequence progresses through the Active Chamber range, starting at chamber 1 distally and sequentially progressing through the last proximal chamber as determined by the Active Chamber setting.

Peristaltic Dual Wave

Dual wave peristaltic mode inflates and deflates a leading and trailing chamber simultaneously to form two separated narrow pressure waves as the sequence progresses through the Active Chamber range, starting at chamber 1 distally and sequentially progressing through the last proximal chamber as determined by the Active Chamber setting.

Peristaltic Power Wave

Power wave peristaltic mode inflates and deflates an adjacent leading and trailing chamber simultaneously to form a wide pressure wave as the sequence progresses through the Active Chamber range, starting at chamber 1 distally and sequentially progressing through the last proximal chamber as determined by the Active Chamber setting.

Sequential

Sequential mode inflates each chamber starting at chamber 1 distally and sequentially progressing until the last proximal chamber is inflated as determined by the Active Chamber setting. In Sequential mode all chambers vent simultaneously between inflation cycles.

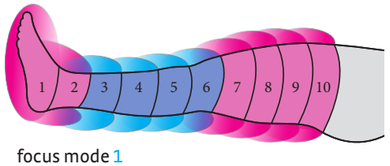
Focus Mode Programming

3.5. (m) From the Modes menu, select Focus to access the Focus menu.

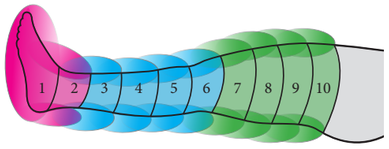
Supplemental Focus Modes 1 & 2 are independently programmed therapy cycles consisting of focused 4-chamber sequences that output in the same manner as standard treatment cycles. These focused 4-chamber programs run between standard treatment cycles, continuously, or at the end of treatment dependent on the Focus settings detailed further in this section.

Focus modes are useful for adding compression therapy cycles in areas of the body that require more attention, such as fibrotic areas. Focus modes can also be used to output decongest sequences between standard treatment cycles to ensure proximal pathways remain clear for continued distal fluid movement.

3.5. (n) Use the Focus menu to activate and program supplemental Focus Modes 1 & 2



focus mode 1



focus mode 1 & 2

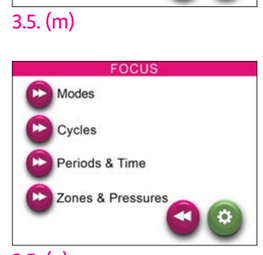
Focus Mode Setting

3.5. (o) The Focus Mode 1 & 2 default settings are Off. Use the to change the settings to sequential therapy output or peristaltic single wave output.

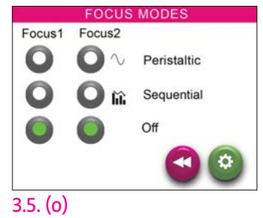
When set to Off, the Focus Mode is not active and will not be integrated into treatment. When set to Peristaltic or Sequential, the Focus mode inflation/deflation pressure cycling sequence is activated and integrated into treatment per the Focus settings detailed further in this section.

Tip: For convenience, the default and Preset program settings includes pre-programmed Focus Modes 1 & 2 to run a single decongest cycle pattern between standard treatment cycles to intermittently clear proximal pathways. Selecting the peristaltic setting for both Focus Mode 1 and 2 will activate this sequence without need for adjusting any other Focus settings. By default, these preprogrammed Focus Modes are set to Off.

3.5. (m)



3.5. (n)

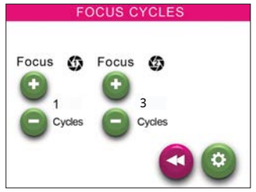


3.5. (o)

Focus Cycles Setting

3.5. (p) The Focus Cycles default setting is 1 cycle. Use the buttons to change the number of times each Focus Cycle repeats before moving to the next focus or treatment cycle.

The Focus Cycles setting; 1,2 or 3 cycles, determines the number of repeated inflation/deflation pressure cycling sequences that will be executed by each focus mode before transitioning to the next focus mode or standard treatment cycle sequence. For example, Focus Mode 1 will cycle once before progressing to Focus Mode 2, which will repeat 3 cycles before progressing.



3.5. (p)

Focus Period & Time Settings

3.5. (q) The Focus Period default setting is Treatment Cycle. Use the to change the setting. Selecting the Post-Treatment setting allows navigation to the Post-Treatment Time setting screen by pressing .

3.5. (q)

3.5. (r) The Focus Post-Treatment Time default setting is 10 minutes. Use the buttons to change the setting.

3.5. (r)

When the Focus Period is set to Treatment Cycle and a Focus Mode is activated to Sequential or Peristaltic, the Focus Mode will run the supplemental 4-chamber sequence after each standard treatment cycle for the number of cycles as determined by the Focus Cycles setting. If both Focus Mode 1 & 2 are activated, following each standard treatment cycle, the Focus Mode 1 cycling sequence will run to completion followed by the Focus Mode 2 cycling sequence.

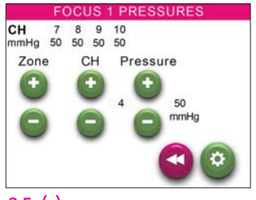
When the Focus Period is set to post-treatment, each activated Focus Mode will continuously run in sequence after the last standard treatment cycle completes when the remaining treatment time timer has reached the Focus Post-Treatment time setting. The activated Focus modes will then continue to run until the Treatment Time timer expires and may extend slightly beyond the timer expiration to fully complete the focus cycle sequence(s). The Focus Post-Treatment time setting range is limited to a maximum time of the Treatment Time setting less 10 minutes. This provides at least 10 minutes of decongest and/or standard treatment cycling prior to running the post-treatment focus mode(s).

When the Focus Period is set to Continuous, Decongest and standard treatment cycles are bypassed, and Focus Mode cycling continues to run for the duration of the Treatment Time setting until the timer expires.

Note: Focus Modes and Decongest Mode cannot both be activated to run continuously. Setting an active Focus Mode period to continuous, while the Decongest Period setting is continuous will result in the Decongest Period switching to Off. Likewise, setting the Decongest Period to continuous while an active Focus Mode period is set to continuous will result in the Focus Mode setting switching to Off.

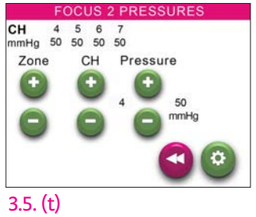
Focus Zones & Pressures

3.5. (s) Focus Mode 1 & 2 default zone and pressure settings are pre-configured to run a decongest pattern progression to clear proximal pathways. Use the buttons to change Focus 1 settings and the button to navigate to Focus 2 zone & pressure settings.



3.5. (s)

3.5. (t) When Focus Mode 2 zone & pressure programming is complete, use the button to quickly navigate to the main settings menu and return to the Treatment Summary screen.



3.5. (t)

Focus Mode zones & pressures are programmed by selecting any group of 4 adjacent chambers and individually adjusting each associated chamber pressure between 20-100mmHg or to Skip (–). The Gradient Lock setting, when set to On, limits pressure setting programming to reducing gradient or static equivalent pressure profiles only, meaning the distal chamber pressure settings will always be greater or equal to the next proximal chamber pressure settings. Gradient Lock does not restrict setting chambers to Skip (–) to allow for avoiding compressing areas with sensitivities. Gradient Lock also does not control or limit pressure differences between the standard treatment cycle program and Focus Mode programs.

To expedite Focus pressure programming, initial Focus Pressure settings are inherited from the current standard treatment pressure settings when the Focus Mode setting is set to Off. If the Focus Mode setting is active, i.e., set to Sequential or Peristaltic, standard treatment pressure setting changes will not affect the Focus Mode pressure settings. Focus Mode pressure settings are also inherited from Preset setting selections. Increasing or decreasing the Preset Pressure Level setting will also increase or decrease Focus Mode pressure settings by 10mmHg accordingly. Relative pressure changes must remain within the pump output range (20-100mmHg) or the setting adjustments are applied at the pump output range limits. See the Preset Menu Pressure Level in section 3.4 for further information.

Treatment time

3.5. (u) From the Treatment menu, select Time to access the Treatment Time settings.

3.5. (u)

3.5. (v) The treatment time default setting is 1 hour. The total treatment therapy time may be adjusted between 10 minutes and 3 hours using the buttons. Actual treatment times may extend slightly beyond the timer expiration to fully complete the final inflation sequence.

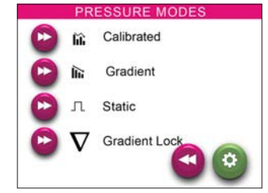
3.5. (v)

Treatment Pressures

3.5. (u) From the Treatment menu, select Pressures to access the Pressure Modes menu.

Pressure Settings

3.5. (x)From the Pressure Modes menu, select Calibrated, Gradient, and/or Static to make pressure setting changes.

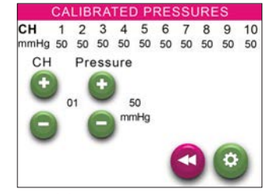


3.5. (x)

Different modes for adjusting the decongest and standard treatment cycle pressure settings are provided to simplify programming and expedite tailoring treatment. Single or combined methods, explained below, may be utilized to set the desired pressure profile. Decongest and standard treatment cycle pressures are always the same and cannot be adjusted independently.

Calibrated Pressures

3.5. (y) Use the buttons to select each active chamber and adjust the pressure setting or set to Skip (–). Inactive chambers, per the Active Chamber setting, see page 10, are automatically set to Skip (-) and will not change.



3.5. (y)

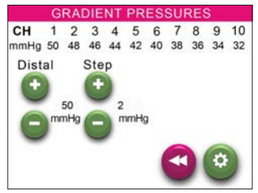
The Calibrated Pressure setting mode allows for individual pressure setting adjustments of active chambers between 20-100mmhg. Alternatively, any chamber(s) can be set to Skip (–) which removes the chamber(s) from the cycling sequence. When the Gradient Lock setting is set to On, see page 16, pressure setting programming is limited to reducing gradient or static equivalent pressure profiles only, meaning the distal chamber pressure settings will always be greater or equal to the next proximal chamber pressure settings. Gradient Lock does not restrict setting chambers to Skip (–).

The Skip (–) setting is useful for avoiding sensitive areas of the body where compression is not desired. Setting multiple chambers to Skip (–) can also be used to create unique compression zone(s). For example, distal and proximal chambers can be set to Skip, leaving only the middle zone of the sleeve active. This can be useful for tailoring targeted compression therapy in areas such as the knee or elbow only.

Tip: Use the Gradient or Static Pressure setting mode to quickly program a pressure profile for all active chambers. Then use the Calibrated Pressure setting mode to tailor specific chamber settings as needed. The Preset Pressure Level setting: Low, Normal, or High, may also be used to quickly increase or decrease the custom programmed pressure profile by 10mmHg respectively.

Gradient Pressures

3.5. (z) Use the buttons to adjust the distal pressure setting of chamber 1, and the gradient pressure step setting increment for the remaining active chambers. Inactive chambers, per the Active Chamber setting, see page 10, are automatically set to Skip(-) and will not change.



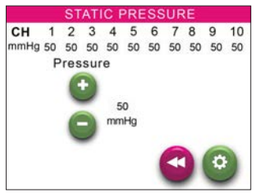
3.5. (z)

The Gradient Pressure setting mode allows for simultaneous pressure setting adjustments to all active chambers by first setting the Distal Pressure chamber 1 setting between 20-100mmHg, and then setting a gradient pressure step setting between 0-80mmHg to apply a uniform pressure drop gradient between successive chambers thereafter. For example, if the Distal Pressure is set to 50mmHg and the Step value is set to 2mmHg, the resulting pressure settings are shown in 3.5. (z). This pressure setting approach is useful for efficiently establishing Sequential Treatment mode therapies where a graduated compression profile at complete sleeve inflation is desired.

Tip: Use Gradient Pressure setting mode to quickly establish pressure profiles for sequential mode treatments. Then use Calibrated mode to adjust individual chamber settings as needed.

Static Pressure

3.5. (aa) Use the buttons to adjust the pressure for all active chambers to the same setting. Inactive chambers, per the Active Chamber setting, see page 10, are automatically set to Skip (-) and will not change.



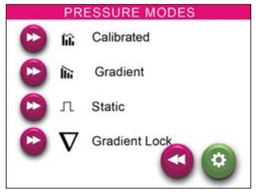
3.5. (aa)

The Static Pressure setting mode allows for simultaneous adjustment of all active chambers to a singular pressure between 20-100mHg. This pressure setting approach is useful for establishing Peristaltic Treatment mode therapies where a singular static pressure wave level is often desired.

Tip: Use Static Pressure setting mode to quickly establish a singular pressure profile for peristaltic mode treatments. Then use Calibrated mode to adjust individual chamber settings as needed.

Gradient Lock

3.5. (ab) From the Pressure Modes menu, select Gradient Lock to access the pressure gradient control setting.

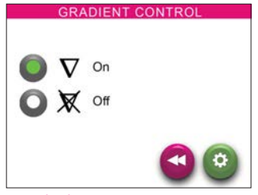


3.5. (ab)

By default, Gradient Lock is set to On. This limits pressure setting programming to reducing gradient or static equivalent pressure profiles only, meaning the distal chamber pressure settings will always be greater or equal to the next proximal chamber pressure settings. Gradient Lock does not restrict setting chambers to Skip (–) to allow for avoiding compressing areas with sensitivities.

When Gradient Lock is set to Off, the chamber pressure setting profiles are not limited in any way and may be set to any value between the full 20-100mmHg setting range. Changing the Gradient Lock setting requires treatment settings resetting to defaults overwriting current treatment settings. Admin settings are retained and not affected by the Gradient Lock setting change.

3.5. (ac) The default Gradient Lock setting is On.



3.5. (ac)

3.5. (ad) Changing the Gradient Lock setting requires that treatment settings are reset to defaults. Select Yes to continue with the Gradient Lock setting change or No to keep the current setting and avoid loss of current treatment settings.

3.5. (ad)

Patient settings

3.6

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

Admin

- o Language: English, Spanish, French, Portuguese
- o Beeper: On, Off
- o Access: Locked, Unlocked

Preset Setting

- o Treatment Zone: Full Leg, Half Leg, Foot, Full Arm, Half Arm, Hand
- o Treatment Mode: Peristaltic, Sequential
- o Pressure Level: Low, Normal, High

Program Settings

- o Active Chambers: 1– __
- o Decongest Mode: Pre-treatment, Continuous, Off
- o Treatment Mode: Single Wave, Dual Wave, Power Wave, Sequential
- o Treatment Time(HH:MM): __:__

CH	1	2	3	4	5	6	7	8	9	10
mmHg										

- o Gradient Lock: On, Off
- o Focus Mode 1: Peristaltic, Sequential, Off
- o Focus Mode 2: Peristaltic, Sequential, Off
- o Focus 1 Cycles: 1, 2, 3
- o Focus 2 Cycles: 1, 2, 3
- o Focus Period: Treatment, Post-Treatment, Continuous
- o Post-Treatment Time (HH:MM): __:__
- o Focus 1 Chambers & Pressures:

CH				
mmHg				

Focus 2 Chambers & Pressures:

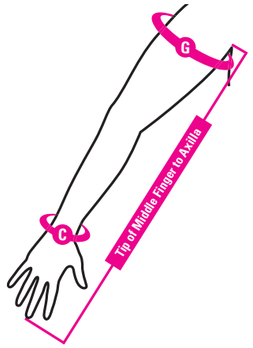
CH				
mmHg				

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	CSAR105M22	50-57	14-42	21-57
Regular	CSAR105M26	58-66		
Long	CSAR105M29	66-74		

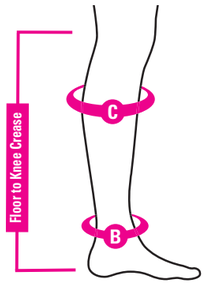


Arm Garment Sizing Measurements

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		

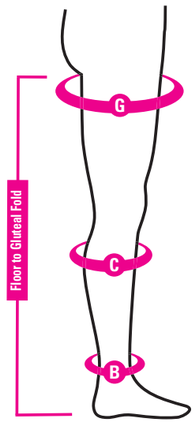


Lower Leg Sizing Measurements

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	CSWL105S28	64-70	18-56	24-61	41-79
Small-Regular	CSWL105S31	71-77			
Small-Long	CSWL105S34	78-85			
Medium-Short	CSWL105M28	64-70	36-74	39-76	52-89
Medium-Regular	CSWL105M31	71-77			
Medium-Long	CSWL105M34	78-85			
Large-Short	CSWL105L28	64-70	48-85	51-88	61-98
Large-Regular	CSWL105L31	71-77			
Large-Long	CSWL105L34	78-85			



Whole Leg Sizing Measurements

4.2 Introduction

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) or ten (10) chambers
- **Lower leg garments** contain six (6) chambers
- **Whole leg garments** contain eight (8) or ten (10) chambers

Six, eight, or ten chamber garments can be used with the medi pcs genius.

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

4.3 Application & Removal

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 4.3 (a).

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 4.3 (b)) or upper thigh (for whole leg, shown in 4.3 (c)).
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 4.3 (d). 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.

4.3 (a)

4.3 (b)

4.3 (c)

4.3 (d)

Leg garments

Method B:

Step 1: While sitting or lying down, undo the hook and loop material of the garment and open the it 4.3 (d).

Step 2: Place your foot in the foot section of the garment with your heel comfortably positioned in the heel pocket 4.3 (e).

Step 3: Starting at the ankle, secure the garment in place around your leg using the hook and loop materia 4.3 (f). 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 4.3 (g). When applied, the garment should be comfortably secured, but not so tight that it applies compression. Fully applied whole leg shown in 4.3 (h). **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.


4.3 (d)


4.3 (e)


4.3 (f)


4.3 (g)


4.3 (h)

Arm garments

Step 1: Loosely form the garment to your arm's shape and fasten the hook tabs 4.3 (i). 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 4.3 (j).

Step 3: Ensure that the curved top edge of the garment is positioned on the outer side of your shoulder 4.3 (k). 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.

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.


4.3 (i)


4.3 (j)


4.3 (k)

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 (a). 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 5.1 (b). 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 5.1 (c). 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 (a)


5.1 (b)


5.1 (c)

Bilateral treatment (treatment with two garments) 5.2

Step 1: Locate the garment connectors at the end of the hoses attached to the garments 5.2 (a).

Step 2: Insert the garment connector into the open port on the front of the PCU 5.2 (b). 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 5.2 (c).

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.


5.2 (a)


5.2 (b)


5.2 (c)

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 genius by pressing the power switch on the back of the PCU 6.1 (a). Once on, the Startup Venting screen will be displayed while the air chambers vent 6.1 (b).

Step 3: The Treatment Summary screen will appear 6.1 (c). It provides an overview of the programmed treatment. After confirming all treatment settings are correct, press to begin treatment. See the Symbol Glossary in Section 8.4 for meanings of the setting symbols.

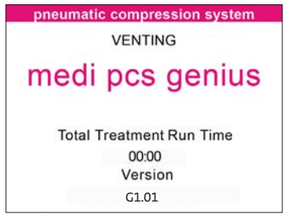
Step 4: The Treatment Running screen will appear 6.1 (d) and the programmed treatment cycle will begin. The Treatment Running screen will show treatment time remaining,

What is the fill-to-fit process?
The default treatment mode is single wave peristaltic. If the sequential treatment mode is selected, the fill to the fill-to-fit process is activated. In this 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.

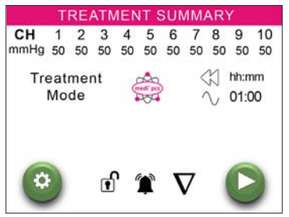
Each following cycle will complete more quickly and will gradually build to the programmed compression settings.

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.

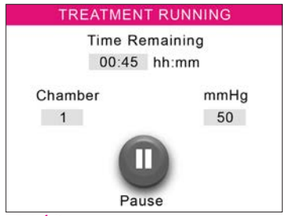
6.1 (a)



6.1 (b)



6.1 (c)



6.1 (d)

Pausing a session 6.2

Press on the Treatment Running screen to pause treatment. The Treatment Paused screen will appear 6.2 (a) 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.

6.2 (a)

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 6.3 (a) after completing the active treatment cycle. All air chambers will vent completely and the beeper will sound if the beeper is set to On. Press the continue button to return to the Treatment Summary screen to start a new treatment session.

6.3 (a)

Turning off the PCU 6.4

Press the power switch on the back of the PCU to turn off the medi pcs genius. 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. 6.5 (a) It will include the chamber number that caused the error. Please note the chamber number and see **Section 8. Troubleshooting & Technical Information** on resolving errors.

Pressing the continue button will end the beeper and return to Treatment Summary Screen.

6.5 (a)

7 Caring for your medi pcs genius 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.

8 Troubleshooting & technical information

8.1 Troubleshooting

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 the point of purchase.
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 the point of purchase. 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 the point of purchase.
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 the point of purchase.
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 health care 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 health care professional. 7. Contact the point of purchase 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.
Error screen appears and air chambers remain inflated (e.g., vent failure error).	1. Disconnect the garment connectors from the PCU. 2. Contact the point of purchase.
PCU runs treatment for shorter or longer than expected	1. Verify that the Treatment Time selected is that recommended by a health care 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 the point of purchase.
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 the point of purchase.
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 the point of purchase.
Graphical User Interface (GUI) becomes non-responsive.	Power off the PCU and disconnect the sleeve(s) to deflate. Reconnect the sleeve(s) and power on the PCU. Restart treatment. If GUI remains non-responsive, contact the point of purchase.

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 the authorized reseller from the point of purchase.

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.

Symbol Glossary 8.4

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.
MR	MR Unsafe	ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.4.9	To indicate the device is unsafe to use in the Magnetic Resonance Environment
	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 electromagnetic 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 andElectronic 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	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.
REF	Catalogue number	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2493	To identify the manufacturer of a product.
SN	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.

8.4 Symbol Glossary

Symbol	Title	Standard	Reference No.	Function
	Access Locked	NA	NA	Indicates access to the settings menu is disabled
	Access Unlocked	NA	NA	Indicates access to the settings menu is enabled
	Beeper On	NA	NA	Indicates that beeper will sound upon error, end of treatment, and button activation.
	Beeper Off	NA	NA	Indicates that beeper will sound upon error only.
	Gradient Lock On	NA	NA	Indicates that pressure setting profiles are restricted to static or decreasing gradients only.
	Gradient Lock Off	NA	NA	Indicates that pressure setting profiles are unrestricted.
	Static Gradient			Indicates pressure setting menu used to create a uniform pressure profile.
	Sequential Gradient	NA	NA	Indicates pressure setting menu used to create a constant gradient pressure profile.
	Sequential Calibrated	NA	NA	Indicates sequential therapy output and pressure setting menu used to create a calibrated gradient pressure profile.
	Peristaltic	NA	NA	Indicates single wave, dual wave, or power wave persitaltic therapy output.
	Focus Mode	NA	NA	Indicates focus mode therapy setting menu.
	Focus Mode 1	NA	NA	Indicates Focus Mode 1 therapy output is active.
	Focus Mode 2	NA	NA	Indicates Focus Mode 2 therapy output is active.
	Continuous	NA	NA	Indicates that decongest or focus mode treatment has be set to output continuously for the duration of treatment.
	Post-Treatment	NA	NA	Indicates that decongest mode is active and will run before the treatment mode cycles.
	Treatment	NA	NA	Indicates that focus mode(s) will run between treatment cycles.
	Pre-Treatment	NA	NA	Indicates that focus mode(s) will run after the treatment mode cycles.
	Settings	NA	NA	Navigates to the administrative, presets, and programming settings menus.
	Home	NA	NA	Navigates to Treatment Summary screen.
	Start	NA	NA	Begins or resumes the treatment program.
	Pause	NA	NA	Pauses the treatment program
	Stop	NA	NA	Ends the treatment program.
	Back	NA	NA	Navigates to the next menu screen.
	Next	NA	NA	Navigates to the prior menu screen.
	Decrease Setting	NA	NA	Decreases the setting value.
	Increase Setting	NA	NA	Increases the setting value.

Symbol Glossary 8.4

Symbol	Title	Standard	Reference No.	Function
	Selected	NA	NA	Indicates setting is activated.
	Unselected	NA	NA	Indicates setting is deactivated.
	Genius Mode	NA	NA	Indicates default or customized programmed therapy mode.
	Preset Mode - Whole Arm	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the whole arm.
	Preset Mode - Half Arm	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the half arm.
	Preset Mode - Hand	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the hand.
	Preset Mode - Whole Leg	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the whole leg.
	Preset Mode - Half Leg	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the half leg.
	Preset Mode - Foot	NA	NA	Indicates preset therapy mode and active chamber treatment zone for the foot.

General Equipment Specifications 8.5

MODEL: genius
IEC PROTECTION CLASSIFICATION: Class II
DIMENSION: 8.75” (W) x 13” (D) × 4.5” (H)
WEIGHT: 6.6 lbs
PRESSURE RANGE: 20-100 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 Compatibility

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 ensure 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 not 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 ensure 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 ensure 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] √P d = [6/E] √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.

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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.

8.8 MRI Safety Information

The medi pcs genius is MR Unsafe. The medi pcs genius is an electrically active device and is not intended for use in the Magnetic Resonance (MR) environment.

8.9 Cybersecurity Information

The medi pcs genius is a software driven device. It does not have external wired or wireless connectivity capability and does not request or store user information. Device firmware updates are serviceable only by the manufacturer or an authorized service provider. If you suspect someone has tampered with your device or if it is operating outside the scope of this manual, please contact medi USA customer service at 1-800-633-6334.

FDA Adverse Event Reporting Information 8.10

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

Call FDA at 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

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

medi USA
6481 Franz Warner Parkway
Whitsett, NC 27377
info@mediusa.com
T 800-633-6334
F 888-570-4554
mediusa.com

PBO158