

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/reportsmanualsforms/forms/ucm163919.pdf

For information on care and maintenance of your system, system assembly, programming treatment, troubleshooting, or technical information, please refer to the Operator's Manual. For other language translations, please visit www.mediusa.com

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PB0159 REV A

medi

medi pcs

pneumatic compression system Patient Quick Start Guide

Components included with your medi pcs system



pressure control unit (PCU)



blocking plate



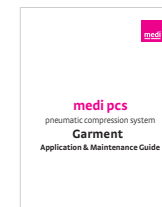
garments (will vary)



power supply



garment application guide

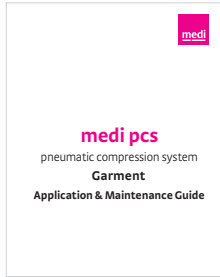


operator's manual

Before you get started

- Consult your healthcare professional prior to using your medi pcs if the treatment settings have not been preset to your prescribed settings.
- Ensure that your medi pcs pressure control unit (PCU) is placed on a flat, stable surface where you can easily reach it during treatment.
- During treatment, you should be seated or in a reclining position. You should never attempt to walk or move vigorously while connected to the PCU, as this could cause the PCU to be damaged and/or cause injury to you.
- Please read all Safety Warnings & precautions in the Operator's Manual prior to using the system.

Refer to the **Garment Application & Maintenance** for instructions on applying your arm or leg garment(s).



garment application guide



whole leg garment



arm garment

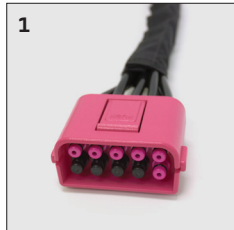
2 Connect your garment(s) to the PCU

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

2. Insert the garment connector into either of the two open ports on the front of the PCU. The latching mechanism on the 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.

3. If using only **one** garment, insert the blocking plate into the remaining open port on the front of the PCU. 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.

4. If using **two** garments, insert the second garment connector into the remaining open port using the same method applied for the first garment connector.




Run your treatment program

1. Ensure that the compression garment(s) are applied and properly connected to the PCU.

2. Turn on the PCU by pressing the power switch on the back of the unit **(A)**. Once on, the Startup Venting screen will be displayed while the air chambers vent.


3. The Treatment Summary Screen will appear **(B)**. It provides an overview of the programmed treatment.


After confirming all treatment settings are correct, press  to begin treatment.

4. The PCU will begin the programmed treatment cycle and the Treatment Running screen will appear **(C)**. The Treatment Running screen will show the treatment time remaining, current active chamber in use, and the pressure setting for the active chamber.

Pausing treatment: Press  to pause treatment.

The Treatment Paused screen will appear **(D)** after the garment(s) have vented. After venting, press

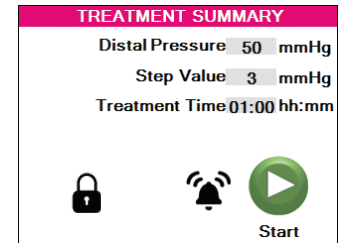
 to resume treatment. Treatment will restart, continuing treatment for the remaining amount of time. If treatment is not resumed within one hour,

the treatment session will be ended. Press  to end treatment entirely. The Treatment Summary screen will automatically reappear.

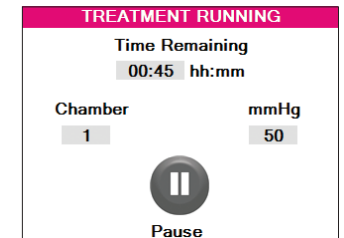
After treatment: When the Time Remaining on the Treatment Running screen reaches 00:00, the PCU will automatically proceed to the Treatment Complete screen after completing the active treatment cycle. All air chambers will vent completely and the beeper will sound if the beeper is set to on. Press the power switch on the back of the PCU to turn it off. Disconnect and remove your garment(s).



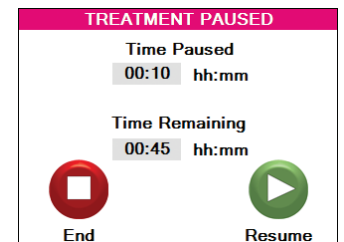
A



B



C



D