ActiveCare®
SAFE DVT PREVENTION

ActiveCare+S.F.T.® and ActiveCare+DTx®

Operation and Service Manual

(for healthcare providers)

MCS
Medical Compression Systems Inc.

activecare.mcsmed.com

Rx only

NOTE: The figures in this User Manual are for illustration purposes only, and are applicable for ActiveCare+S.F.T.®, HomeCare ActiveCare+S.F.T.®, ActiveCare+DTx® and HomeCare ActiveCare+DTx®, unless specified differently.

Document Symbols, Definitions and Abbreviations

This manual contains different typefaces designed to improve readability and increase understanding of its content. Note the following examples:

- ⚠ **WARNING** - Identifies situations or actions which, if not avoided, may result in death or serious injury.
- **CAUTION** - Identifies situations or actions which, if not avoided may result in minor injury, or damage to the equipment or other property.
- **NOTE** - Sets apart special information or important instruction clarification.
- **ActiveCare+S.F.T.®** - Is a registered trademark of Medical Compression Systems, Ltd.
- **ActiveCare+DTx®** - Is a trademark of Medical Compression Systems, Ltd.
- **MCS** - Medical Compression Systems
- **C.E.C.T.** - Continuous Enhanced Circulation Therapy
- **DVT** - Deep Vein Thrombosis
- **S.F.T.** - Synchronized Flow Technology

Table of Contents

Introduction

This guide is designated for **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems.

A full understanding of the technical principles and clinical applications related to **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems is necessary before use. Please read this entire manual before activating the system.

Indications for Use

The **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems are portable, ambulatory, sequential, intermittent pneumatic compression devices (IPCDs) prescribed by healthcare professionals. The systems include a rechargeable battery powered option allowing patient mobility and ease of use. These devices simulate muscle contractions in order to treat or enhance blood flow velocity in individuals experiencing venous impairment or reduced pulsatility (dysfunction of the muscle pump) when blood flow may become challenged or compromised, such as during and after major orthopedic surgery procedures e.g total joint (hip and knee) arthroplasty. They are intended for use in the clinical setting or home environment and can be provided directly to the patient for home use.

These devices are indicated for use in:

- Preventing Deep Vein Thrombosis (DVT)
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Patients at risk for Deep Vein Thrombosis (DVT) and related Pulmonary Embolism (PE) (Venous Thromboembolism (VTE))
- Treatment of venous stasis
- Treatment and assistance in healing: Stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers
- Enhancing blood circulation
- Treatment of chronic venous insufficiency
- Reducing edema

The **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems are intended to provide external compression in synchrony with the specific patient's natural venous blood flow return profile in order to achieve a high pulsatile venous blood flow.

In addition, the **ActiveCare+DTx®** System can detect hemodynamic changes in venous blood flow.

Contraindications

Do not use the **ActiveCare+S.F.T.®** or **ActiveCare+DTx®** System in the following cases:

- Fresh, pre-existing Deep Vein Thrombosis (DVT)
- Pulmonary Embolism (PE)
- Leg gangrene

- Recent skin graft
- Acute thrombophlebitis
- Medical situations where increased venous and lymphatic return are undesirable

System Advantages

- Full patient mobility – The device is lightweight and portable
- Higher compliance – as demonstrated by a clinical study[1]
- The compact sleeve design enables user to easily move about
- Systems can work either with the AC/DC adapter connected to applicable power source (wall outlet) or built-in rechargeable battery power
- Unique hemodynamic profile - System operation is in synchronization with the natural, respiratory related venous phasic flow

In addition, the **ActiveCare+DTx®** System is designed for:

- DVT prevention on a 24/7 basis, together with real time detection of possible impairment in the leg's venous flow. The **ActiveCare+DTx®** is not a diagnostic tool.

1 *Froimson, M. I., et al. Venous thromboembolic disease reduction with a portable pneumatic compression device. J. Arthroplasty 24, 310–6 (2009).*

General Warnings and Cautions

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

⚠ **WARNING: ActiveCare+S.F.T.®** or **ActiveCare+DTx®** system is not intended for use in close proximity to flammable anesthetics or within oxygen rich environment.

CAUTION: Although the device is durable, it is advised to avoid high impact, rough handling or dropping to prevent device damage.

CAUTION: Inspect patient's leg(s) under treatment at least once a day for signs of pathological skin changes.

CAUTION: Inspect legs of high-risk patients at least three times a day. Double check the positioning and proper adjustment of the sleeve before and during device operation. High-risk patients included - elderly; debilitated; paralyzed; unconscious; with diffuse malignancy; with severe peripheral neuropathies; known severe arterial vasculopathy or patients with continuous epidural analgesia.

CAUTION: Inappropriate conditions (e.g. leaving the device in the trunk of a car or exposing it to direct sunlight) may damage the equipment.
Store or transport the device and its accessories according to the storage conditions listed at the end of this manual.

NOTE: None of the system components is made with natural rubber latex.

Section 1: System Description

1.1 Unpacking and Parts Identification

CAUTION: Do not use any broken or damaged device or accessories, since this may delay the treatment. Notify your service provider of any defects.

Before use, make sure you have the following parts, and verify their propriety:

① Device with removable carrying strap: **ActiveCare+S.F.T.®** (1A) or **HomeCare ActiveCare+S.F.T.®** (1B) **or ActiveCare+DTx®** (1C) or **HomeCare ActiveCare+DTx®** (1D).

② Medical grade AC/DC adapter with 14.76 ft/4.5 m electric cord

③ One pair of 3.9 ft /1.2 m extension tubes

④ Cradle for hanging the system (optional)

⑤ Operation and Service Manual

- Final Quality Control Form (not shown)

The Patient Instructions for Use Manual (for outpatients) will be provided by the healthcare provider (refer to Section 7).

It is recommended to save the original box for storage of the **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems.

NOTE: The sleeves are supplied separately.

①A

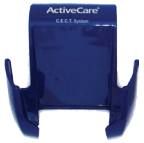
①B

②

①C

①D

③

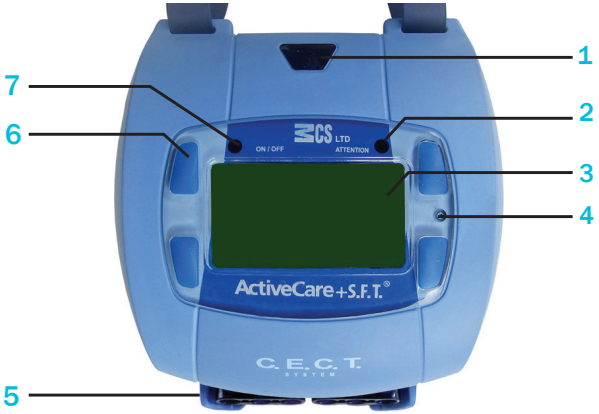


④

⑤

1.2 Device View

Frontal View



1. Infrared communication (for MCS technical support internal use)
2. Attention indicator
3. LCD screen
4. Buzzer (opening)
5. Manifold port (x2)
6. Operation push button (x4)
7. ON/OFF indicator - Green light indicates power on

Rear View

1. DC power jack
2. Device label. Refer to section 5.3 for the full definitions of the symbols.
3. Serial number label
4. ON/OFF power switch
5. Battery cover

1.3 Sleeves

⚠ **WARNING:** Sleeves are intended for single patient use in order to avoid cross-contamination.

Dispose of used sleeves according to established procedures.

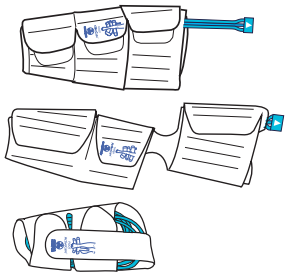
1.3.1 Sleeve Description

The **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems use three types of sleeves, available in different sizes:

Calf Sleeve
Small/Medium/Large/
Extra large

Thigh Sleeve
Small/Medium/Large

Foot Sleeve
Single size



Sleeves bags are marked by different colors (purple, blue, green or orange) for easy identification of sleeves sizes. Same color code is used for both calf and thigh sleeves.

1.3.2 Treatment Options

The versatile **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems have numerous treatment options; each mode is automatically selected according to the combination of sleeves being used (single sleeve or any combination of two sleeves).

Section 2: System Operation

For additional information consult the Training Video for professionals at: activecare.mcsmed.com

2.1 Preparations for Use

Before applying the system to a patient, please take the following steps:

1. Make sure all the systems' parts (device, sleeves, AC/DC adapter, etc.) are clean, intact and working correctly (refer to sections 2.8, 2.9).
2. Make sure the device's battery is fully charged (refer to section 2.9).
3. Select the sleeves type (according to the physician's instruction), and match their size to the patient's legs (refer to section 2.2).

2.2 Sleeve Selection

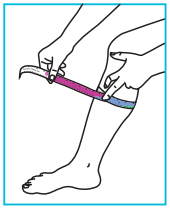
In order to select the most appropriate sleeve for a specific patient:

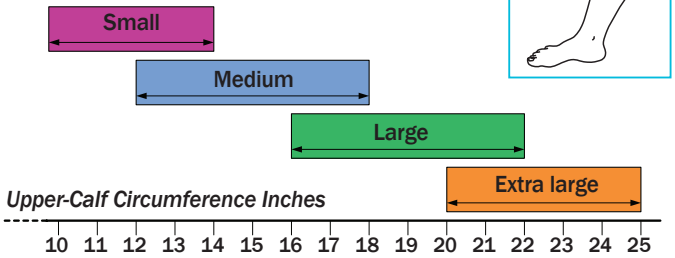
- Measure the height and circumference as described below.
- Identify the sleeve size according to the relevant diagram or the Calf Sleeve Selection (CSS) tool.

NOTE: If the specific patient's maximal circumference is within the range of two different sleeve sizes, choose either one of them (according to the medical team preference).

2.2.1 Calf Sleeve Selection

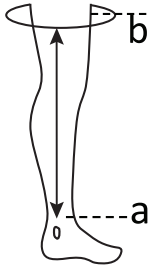
- Make sure that the calf height (the distance between the upper level of the Malleoli (a) and the lower level of the Tibial Tuberosity (b)) is at least 11.5"/ 29.2 cm.
- Measure the maximal circumference of the patient's calf using the colored Calf Sleeve Selection (CSS) tool or a measuring tape.
- CSS tool is designed to help matching calf circumference and calf-sleeve size with the sleeve bag color.



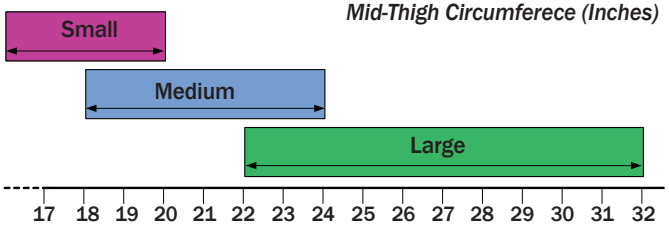


Bag Color	Sleeve Size	Calf Circumference		Part Number
		Inches	cm	
Purple	Small	<14	< 35.5	A201C-020S-10
Blue	Medium	12-18	30.5-45.5	A201C-120S-10
Green	Large	16-22	40.5-56	A201C-220S-10
Orange	Extra large	20-25	51-63.5	A201C-420S-10

2.2.2 Thigh Sleeve Selection



- Make sure that the thigh height (the distance between the upper level of the Malleoli (a) and the mid-thigh (b)) is at least 20" / 50.8 cm.
- Measure the circumference of the patient's mid-thigh (b).
- Identify the thigh sleeve size using the following fitting tool diagram.



Bag Color	Sleeve Size	Thigh Circumference		Part Number
		Inches	cm	
Purple	Small	< 20	< 51	A201T-0480-10
Blue	Medium	18-24	45.5–61	A201T-1480-10
Green	Large	22-32	56–81.5	A201T-2480-10

2.3 Sleeve Application

CAUTION: Do not attach the sleeve upside down as this may cause discomfort or swelling of the foot.

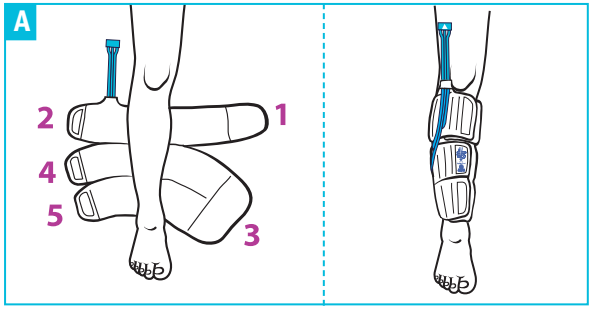
CAUTION: A loosely fastened sleeve can result in ineffective treatment, while an overly tight sleeve can cause discomfort.

NOTES:

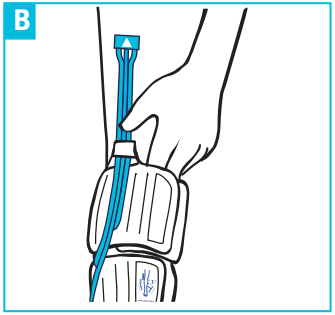
- For patient positioning and comfort, connectors can be adjusted by slightly rotating the sleeves.
- It is recommended to apply the sleeves over cotton stockings for patient's comfort.
- Sleeves and extension tubes are identical for both the right and left legs.

2.3.1 Calf Sleeve Application

Wrap the sleeve around the calf and fasten it according to the numbers in the drawing.

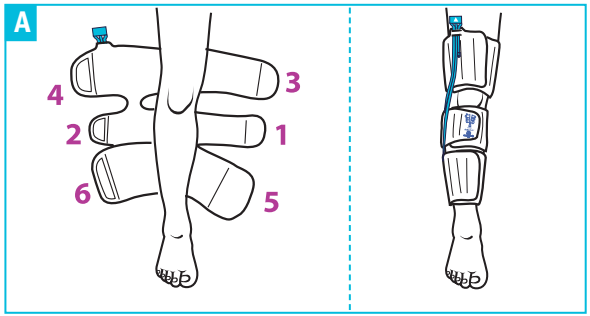


Check that the sleeve is snugly fit but still allows the insertion of two fingers.

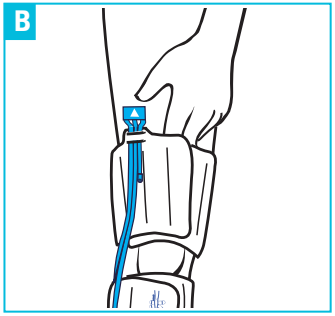


2.3.2 Thigh Sleeve Application

Wrap the sleeve around the leg and fasten it according to the numbers in the drawing.

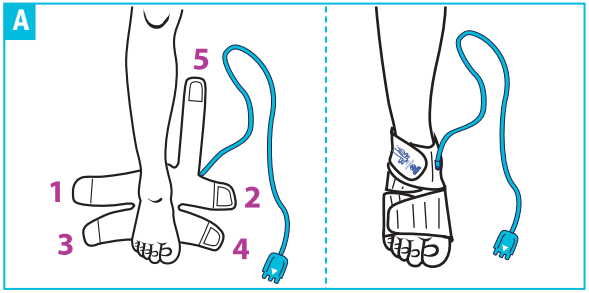


Check that the sleeve is snugly fit but still allows the insertion of two fingers.

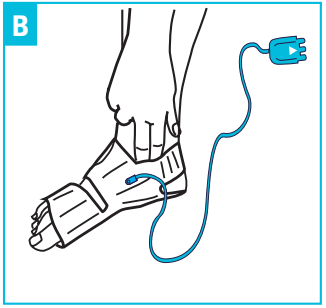


2.3.3 Foot Sleeve Application

Place the foot over the open sleeve and align the heel with the end of wide edge of the sleeve. Fasten it according to the numbers in the drawing.



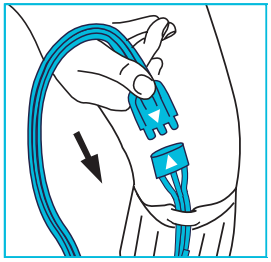
Check that the sleeve is snugly fit but still allows the insertion of two fingers.



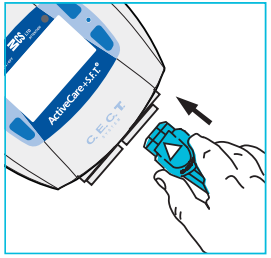
2.3.4 Sleeve to Device Connection

Connect the sleeves to the device before turning it on.

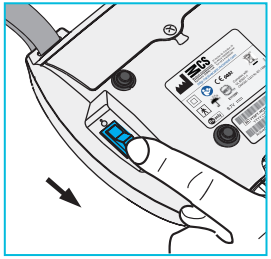
A. For thigh and calf sleeves only: connect one end of the extension tube to the sleeve connector. The white arrows should be pointed towards each other.



B. For all sleeves: connect the other end of the extension tube to the device. The white arrow should be facing upwards. Make sure the connectors are locked.



2.4 Device Operation

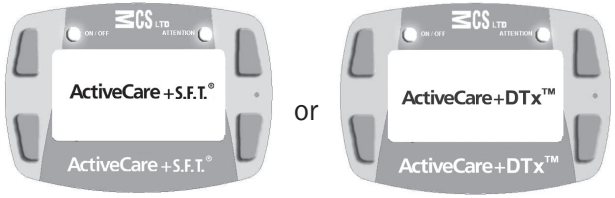


Turning the device on:

Press the power switch located on the back of the device to ON position.

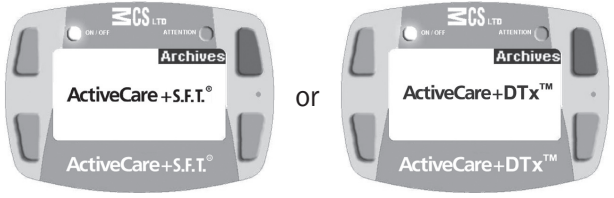
2.4.1 Getting Started

After turning the device on, the self-test mode is initiated. The ON/OFF and attention indicators flash while the auditory indicator beeps. The device logo is displayed.



Wait for the display of the Configuration Setup Screen (see next page).

To display patient's data select "Archives" (see section 2.4.2.4, for the medical team use).
This selection will terminate treatment initiation.

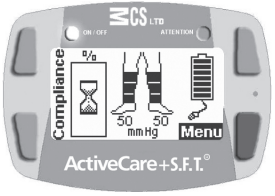


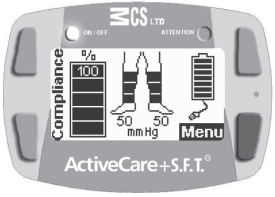
The system automatically activates the self-test mode and begins to inflate the sleeve sequentially, starting from the lowest sleeve cell. Sleeve inflation occurs one leg at a time. Sleeves types are automatically identified and treatment mode is selected accordingly. Treatment mode selection takes about one minute.

CAUTION: Visually examine that all cells in the sleeve inflate correctly.

Main screen (see next section) is displayed. Check that the treatment mode icon matches the sleeves that are being used.

If the device is assigned for a new patient, select ***Menu*** to set a New Patient within the first 3 minutes from the device startup (the time period that the hourglass icon is displayed on the main screen).



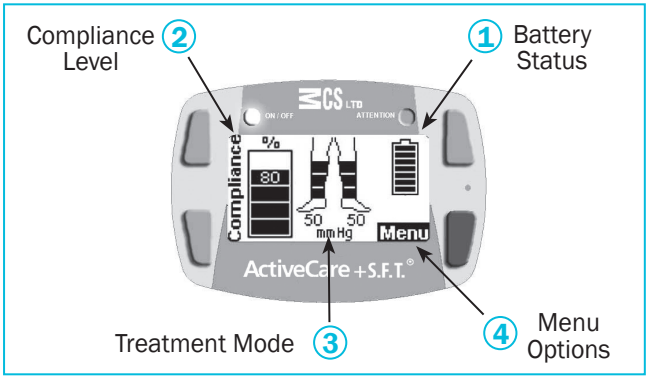


CAUTION: If removal or changing of sleeve type is needed: **Turn off the device,** connect or disconnect the applicable sleeve, and turn it on again.

NOTE: If auditory indicator sounds or attention indicator flashes or the attention screen is displayed - refer to the Troubleshooting (Section 3).

2.4.2 Main Screen Features

The four main screen features are:



2.4.2.1 Battery Status Indicator

The battery status indicator represents the battery charging level.

- For low or empty battery, see Troubleshooting in section 3.
- In **ActiveCare+DTx®** Device, the estimated battery operation time is displayed below the battery status indicator (only when the device is battery operated).

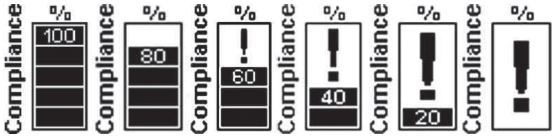
- The power cord is visible while the device is connected to the wall outlet. This indicates that the battery is being charged.

2.4.2.2 Compliance

Compliance percentage is calculated according to the following equation:

Total time the device was used / Total time from initial treatment X 100 = % Total Compliance

The compliance indicator represents compliance level:

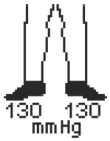


For exact compliance percentage, use patient code option (refer to section 2.4.2.4 -Compliance).

2.4.2.3 Treatment Mode

The Treatment Mode is automatically selected during start-up. The numbers below the icons indicate the average pressure applied to the limb (measured by millimeters of mercury (mmHg)).

*Calf-Calf**



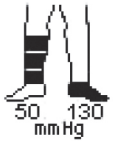
Foot-Foot

Thigh-Thigh

None-Calf

None-Foot

None-Thigh



Combined Calf-Foot

Combined Thigh-Foot

*** NOTE:** When the Calf-Thigh sleeves combination is being used, the icon of Calf-Calf is displayed.

2.4.2.4 Menu Screen

To display the menu screen, select "*Menu*" option in the main screen. The following options are displayed:

Compliance

DTx Mode (Only for **ActiveCare+DTx®**, while Calf-Calf is used.)

New Patient/Patient Code: New Patient option is available only for the first 3 minutes from the device startup (the time period that the hourglass icon is displayed on the main screen).

After three minutes, the *New Patient* option is replaced by the ***Patient Code*** option. In order to set a *New Patient* code after the first three minutes, turn off the device, turn it on again, and choose the *New Patient* option.

NOTE: While *Menu* screen is displayed, the system continues to operate as usual. If no option is selected, the system returns to main screen.

Setting New Patient:

Select **New Patient** on the Menu screen.

The following screen is displayed:

Back - return to the previous screen

No - the system will default to current patient.

Yes - a New Patient code will be assigned.

The Patient Code is a combination of the starting date and time.

To return to the main screen, press **Ok**.

Patient Code:

In the Menu screen, select **Patient Code** to display the Patient Code and treatment starting date (see above).

Compliance

Select **Compliance** to access the list of Patient Codes. Scroll up or down on the list of patients using the arrow buttons.

Select - choose the highlighted code to present the treated patients' data screen (see below).

Back - return to the previous screen.

Patient Data screen displays:

- Start date
- Total compliance
- Total days of treatment

Select **Data** to display detailed patient compliance. The information is available only for the current patient (first patient on the list):

- Overall total compliance (**Total**)
- Total days of treatment (**Days**)
- Compliance on any other date (scroll down the list)

NOTE: Compliance data is unavailable during the first three minutes after turning the device on.

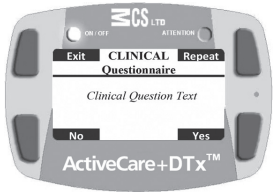
2.4.3 DTx Mode

Relevant for ActiveCare+DTx® Only

The **ActiveCare+DTx®** System can provide information regarding suspected proximal venous flow impairment. This situation can be caused by several patho-physiological mechanisms, and DVT is only one of them. The system is not intended for DVT diagnosis. Only a licensed physician can diagnose DVT based upon clinical judgment combined with standard DVT diagnostic procedures.

NOTE: The DTx mode can only be activated when Calf-Calf Sleeves are used.

Select **DTx Mode** in the Menu screen to start the Clinical Questionnaire.



Yes/No: To answer the questions.

Repeat: Start over the Questionnaire.

Exit: Return to the main screen.

If no selection is made within 10 minutes, the system will automatically return to prophylactic treatment mode.

At the end of the Clinical Questionnaire, the Detection Procedure shall begin:

Start: Start detection test.

Back: Re-answer the questions.

Exit: Return to the main screen.

Test performance:

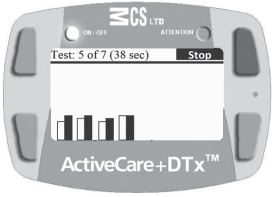
Maintain the following optimal conditions:

- Patient is lying in supine position with upper body elevated to about 30°.
- Patient is breathing normally, focusing on breath.
- Patient is avoiding unnecessary movements and talking. The patient should be informed about the length of the test.

The duration of the Detection Procedure is about 7 minutes. However, it can be stopped any time by pressing **Stop**.

NOTE: The prophylactic treatment mode will not be active during the detection test.

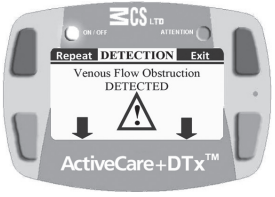
During the test, a graphical presentation of the collected data will be displayed about once a minute (white bars: left leg, black bars: right leg).



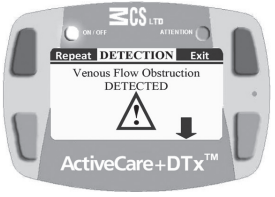
At the end of the test (or if **Stop** was pressed), the probability of the existence of proximal venous flow obstruction is displayed.

Venous flow obstruction was not detected

Venous flow obstruction is suspected in the leg treated by the device left port



Venous flow obstruction is suspected in both legs



Venous flow obstruction is suspected in the leg treated by the device right port

In case an obstruction was not suspected - press **Exit** to return to the prophylactic treatment mode. Otherwise the treatment mode will be automatically resumed within 10 minutes.

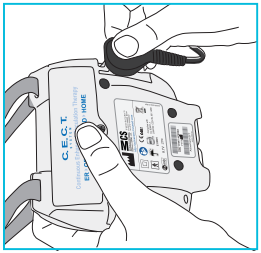
If venous flow obstruction was suspected – an auditory indicator alerts every minute. The system will not return to the prophylactic treatment mode unless **Exit** is selected.

2.5 Mobility and Portability

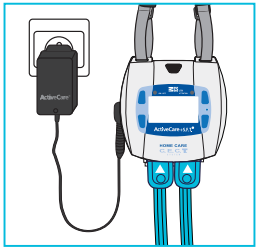
2.5.1 Charging the device:

⚠ **WARNING:** Use only the AC/DC adapter supplied by MCS. Using a non-original adapter may cause serious injury.

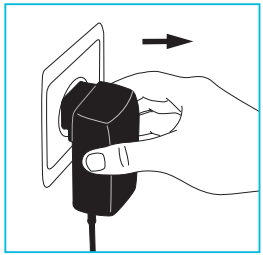
Connect the AC/DC adapter to the DC jack on the back of the device, and connect it to a wall outlet.



In order to disconnect the device from the main outlet, detach the AC/DC adapter from the wall outlet.



Grasp the body of it and pull it out in a straight direction. Do not pull the cord (as this might damage the wires) and do not pull the adapter at an angle (as this might bend the prongs).

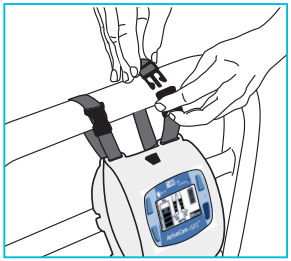


CAUTION: Improper removal may damage the AC/DC adapter.

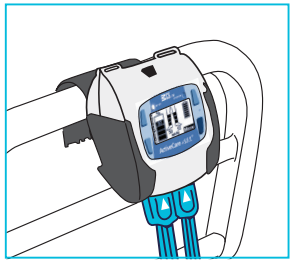
2.5.2 Hanging the Device

Hang the **ActiveCare+S.F.T.®** or **ActiveCare+DTx®** System on a patient assistive device (walker, wheelchair, etc.) or bed rail:

- Use the carrying straps clips, or
- Use the **ActiveCare®** Cradle



Hanging to bed with straps



Hanging to bed with cradle

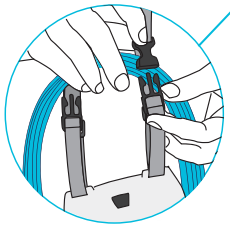
CAUTION: Do not cover the device while it is being used or charged since this might damage the device.

2.5.3 Carrying the Device

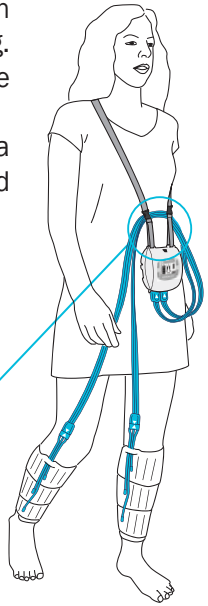
The **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems are lightweight and allow full patient mobility.
While walking with the system, disconnect the AC/DC

adapter from the system and shorten the extension tubes to prevent tripping. Loop and fasten the tubes using the clips on the carrying strap.
The device should be carried in a crossover shoulder fashion and should not be hanged loose around the neck.

⚠ **WARNING**: Extension tubes may become tangled when walking with the **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Systems. Adjust their length to avoid tripping injury or equipment damage.



Shorten the Extension Tubes



Over-the-Shoulder Use

2.6 Temporarily Stopping the Treatment

In order to remove the device for a limited time, to be used again by the same patient:

1. Turn off the device.
2. Disconnect the extension tubes from the sleeve.
3. Remove the sleeves.
4. Keep the sleeve(s) and the device with the extension tubes for continuation of treatment.

The patient may take the device off during self-care (i.e. showers) or for brief periods (such as to check the skin surface under the sleeves).

2.7 End of Treatment Period

Once the treatment is completed, disconnect the system as follows:

1. Turn the device off.
2. Disconnect the sleeve and the extension tubes.
3. Remove the sleeve(s) from the patient, and discard used sleeves. Keep the extension tubes, they are re-useable.

   ⚠ **WARNING**: Sleeves are intended for single patient use in order to avoid cross-contamination. Dispose of used sleeves according to established procedures.
4. Disconnect the AC/DC adapter from the device and from the main power outlet.

2.8 Cleaning the System

⚠ **WARNING**: Do not perform any maintenance while the device is in use.

CAUTION: The device is not waterproof. Liquid penetration might damage the device.

CAUTION: Do not use harsh cleaners or detergents, as this may damage the device or accessories.

CAUTION: Do not wash the sleeves, as this might damage the sleeves or the device.
Make sure that the equipment is completely dry before re-using it.

1. **Device cleaning**
   Make sure the device is off and is not connected to an external power outlet. Gently wipe the external surfaces of the device with a soft-cleaning pad, slightly dampened with 70% ethanol.
2. **Manifold cleaning**
   Wipe the exterior and the interior of the manifold with a damp cloth using 70% ethanol. Do not use soap and water. Do not allow liquid to penetrate the manifold itself.
3. **Extension Tubes cleaning**
   - Wipe the extension tube exterior with a damp cloth using 70% ethanol or soap and water. Do not immerse the tubes in liquid. Pay close attention to the tube's creases and areas around the connectors.
   - Visually inspect the extension tube after every cleaning. Ensure that the silicon O-rings on the connectors are present and in good condition.

   NOTE: It is recommended to replace the extension tubes every 4-6 months.
4. **Carrying straps cleaning**
   Wipe the carrying straps with a damp cloth using 70% ethanol or soap and water. Replace the straps if any sign of wear and tear is visible.
5. **AC/DC adapter cleaning**

   ⚠ **WARNING**: Ensure the AC/DC adapter is completely dry before using it. Failure to do so may result in injury or equipment damage.

   Wipe the exterior of the AC/DC adapter with a damp cloth using 70% ethanol or soap and water. Visually inspect the AC/DC adapter after every cleaning to ensure that the cord and AC/DC adapter connectors are in good condition.

2.9 Routine Checkup

Before handing the device to a new patient follow the instructions below:

1. Clean all parts of the system according to cleaning procedures (section 2.8).
2. Visually inspect the carrying strap, push buttons, LCD screen, plastic covers, ON/OFF switch, DC jack, manifold ports and battery door. If any part is damaged, contact your service supplier or biomedical engineer.

3. Make sure the device is off. Attach the AC/DC adapter and verify that the message: “Battery is Charging Device is OFF” is displayed.

4. Fully charge the battery until the “Charging Completed Device is OFF” message appears.

5. Connect a pair of Calf Sleeves to the device and turn it on. Verify that:
   - The ON indicator is steady green.
   - The ERR indicator turns on and then off.
   - Buzzer beeps once.
   - LCD display turns totally black and then lights up.
   - No error messages appear.
   - All cells in both sleeves are inflated correctly, from the bottom to the top, sequentially.
   - Calf-Calf mode is indicated after about 1 minute.

   NOTE: If calf sleeves are not applied on legs, the Thigh-Thigh mode indication might be presented.

6. Leave the device on for 10 minutes. Ensure that no error messages appear.

7. Disconnect the device from the AC/DC adapter and leave it on for 10 minutes (while using the battery). Ensure that no error messages appear.

It is recommended to operate the device by battery for at least 2 hours to ensure sufficient battery lifetime.

2.10 Device and Battery Storage

Fully charge the system. When the device is off and connected to the AC power source, the following screens will appear:

- Before storing, detach the accessories. Avoid folding the extension tubes to prevent kinks.
- Store the device according to the storage instructions (section 5.4).

If the device will not be used for 30 days or longer, have your service supplier or biomedical engineer:

1. Fully charge the battery pack.
2. Remove the battery pack.
3. Store the battery separately according to storage conditions.

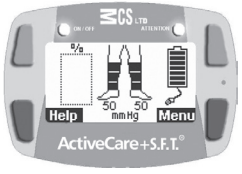
NOTE: A complete discharge and recharge of the battery pack (1 full cycle) should take place every six months.

Section 3: Troubleshooting

NOTE: When the device detects a problem, the auditory indicator is sounded, and the attention indicator flashes. The operation continues. Once the problem is fixed, the indicators switch off automatically and the main screen is displayed, unless specified differently in the following table.

Error	Problem Description	Steps to be taken
No treatment mode selected indication	 The device fails to identify the attached sleeves during start up. The Attention indicator flashes and an auditory indicator is sounded.	**1.** Check that the sleeves and the extension tubes are securely attached, and check for kinks in the tubing. **2.** If the problem persists, replace the sleeves and/or extension tubes. **3.** If the problem persists, replace the device.
Device fails to turn on	 Screen is blank, the indicators are off.	Turn the device off and allow the battery to recharge for at least 30 minutes before turning it on again.
Airway obstruction	 The attention indicator flashes and an auditory indicator is sounded. An arrow indicates the relevant port.	**1.** Check sleeves and tubes for kinks. **2.** If the problem persists, replace sleeves and/or extension tubes. **3.** If the problem persists, replace the device.
Air leakage	 The attention indicator flashes and an auditory indicator is sounded. An arrow indicates the relevant port.	**1.** Check connections of both sleeves and tubes. **2.** If the problem persists, replace sleeves and/or extension tubes. **3.** If the problem persists, replace the device.
Low battery	 The attention indicator flashes and an auditory indicator is sounded.	Connect the device to the wall outlet via an AC/DC adapter.

Error	Problem Description	Steps to be taken
Empty battery	 The device shuts down, the attention indicator flashes and an auditory indicator is sounded.	**1.** Connect the device to the wall outlet via an AC/DC adapter. **2.** Restart the device (the auditory indicator will continue to sound until restart).
Battery or its electrical connections are damaged	 Battery cannot be charged despite being connected to a wall outlet.	The device can still be operated by direct connection to the wall outlet via the AC/DC adapter. **1.** Replace the battery **2.** If the problem persists, replace the device.
Operation error	 System attempts to restart at regular intervals. The attention indicator flashes and an auditory indicator is sounded.	If restart fails, replace the device.

Error	Problem Description	Steps to be taken
Operation error	 Operation stops and the system attempts to restart at regular intervals. The attention indicator flashes and an auditory indicator is sounded.	If restart fails, replace the device.
No compliance display	 Compliance is not calculated.	Device should be replaced; However, the unit can still be used even though the compliance is not recorded. The device should be used according to the prescription.

Section 4: Parts Replacement

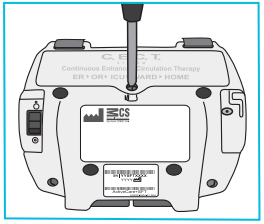
CAUTION: Do not attempt to repair the device. Only MCS authorized personnel may repair the device. Unauthorized service might cause equipment damage.

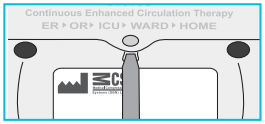
4.1 Battery Replacement

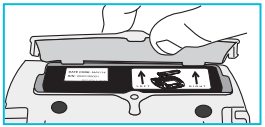
CAUTION: Use only the battery pack supplied by MCS. Alternative power source may cause permanent damage to the device.

If a fully charged battery is sufficient for less than three hours of calf-calf operation it is recommended to replace it.

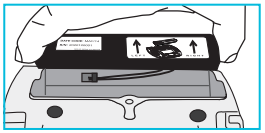
1. Turn the device off, and disconnect the AC/DC adapter.
2. Put the device upside down on a soft surface.
3. Remove the screw from the cover. Do not lose the screw.
4. You may use a tip of a small flat screwdriver to open the battery cover.
5. Remove the cover.



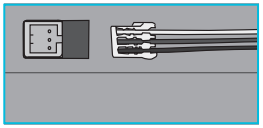




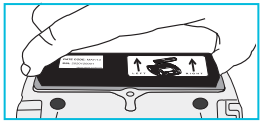
6. Lift and disconnect the battery.



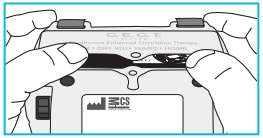
7. Connect the new battery according to the connectors alignment.



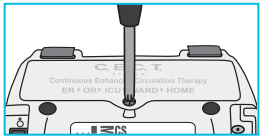
8. Fold the wires into the intended space and place the battery (labels facing up).



9. Align the cover with the slots and push it **in** until a “click” is heard. Then, push it **down** until another “click” is heard.



10. Secure the battery door with its screw.

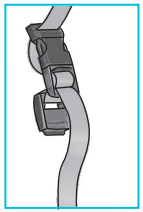


11. Fully charge the battery.

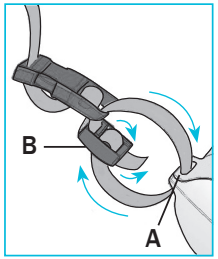
NOTE: Discard the old battery according to national standards, established practices and recycling plans.

4.2 Carrying Strap Replacement

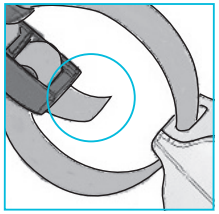
1. The carrying strap is supplied partially assembled.



2. Insert the strap through the opening in the device (A) from the top, and loop it through the clamp (B) from below.



3. Leave a 0.4'' / 1 cm edge and firmly secure the clamp on it.



Section 5: Technical Details

5.1 Classification and Standards

The **ActiveCare+S.F.T.®**, **HomeCare ActiveCare+S.F.T.®**, **HomeCare ActiveCare+DTx®** and **ActiveCare+DTx®** Systems are designed and manufactured according to the following equipment classification and standards:

Technical and Quality Assurance	ANSI/AAMI ES 60601-1:2005(R):2012+A1:2012+C1:2009+A2:2010 and CAN/CSA-C22.2 No. 60601-1:14, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and essential Performance. IEC 60601-1-2 Edition 3:2007-03 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests IEC 60601-1-6 Edition 3.0 2010-01, Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability). AAMI /ANSI /IEC 62366:2007 Medical Devices - Application Of Usability Engineering To Medical Devices. IEC 60601-1-11 Edition 1.0 2010-04, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment {Including Technical Corrigendum 1(2011)

Degree of Protection Against Electric Shock	Class II, Applied Part Type BF, Internally powered.
Classification According to Medical Device Directive 93/42/EEC	IIa

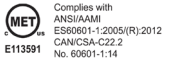
5.2 Electromagnetic Interference

This system has been tested and found to comply with the limits for medical devices according to the EN 60601-1-2:2007 and IEC 60601-1-2:2007 standards. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the distance between the equipment and other device(s).
- Connect the equipment into an outlet or circuit different from the one that the other device(s) are connected.

5.3 Product Symbols' Definition

Symbol	Definition
	Operation instructions
	Conforms to the European Medical Device Directive 93/42/EEC
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Accompanying the name community and the address of the authorized representative in Europe
	Sleeves and extension tubes are Type BF applied parts
	Class II equipment
	Not made with natural rubber latex
	Caution

	For single patient use
	A non-sterile item
	Keep dry
	NRTL approval mark, Canada and USA
	Manufacturer symbol
	Year of manufacture
	Catalog number
	Batch code
	Serial Number
	Device was put on the market after 13 August 2005. Conforms to the Directive 2003/108/EC on waste electrical and electronic equipment (WEEE) of the European Parliament.
	Direct current
	Alternating current (input, for AC/DC adapter only)
	Power switch ON

	Power switch OFF
	FRIWO trademark (for Friwo AC/DC adapters only)
	IEC60601-1 3rd ed (for Friwo AC/DC adapter only)
	CAN/CSA-C22.2 No.601.1-M90 (for Friwo AC/DC adapter only)
	IEC60601-1 3rd ed (for Megmeet AC/DC adapter only)
	Consult instructions for use (for the AC/DC adapter only)
	Storage or operation temperature range
	Storage and/or operation humidity range
	Package content: Device
	Package content: AC/DC adapter
	Package content: Extension tubes
	Package content: User Manual
	Keep away from sunlight
	Fragile, handle with care
	Package recycling information

5.4 Technical Specifications

Item	Specification
Dimensions (W x D x H)	5⅜" x 5⅜" x 2⅜"/ 13.5 x 13.5 x 6.0 cm
Weight	1.65 lb / 750 gr
Internally powered equipment requirements	7.2 VDC (NiMH rechargeable batteries)
AC/DC adapter	Medical grade transformer 100-240 VAC / 9.7 VDC, 50-60 Hz, 0.5A max
Calf Sleeve small	11½"x 17⅜" (29.2 cm x 44 cm)
Calf Sleeve medium	11½"x 21½" (29.2 cm x 55 cm)
Calf Sleeve large	11½"x 25½" (29.2 cm x 65 cm)
Calf Sleeve extra large	12" x 28½" (30.5 cm x 72.5 cm)
Thigh Sleeve small	20" x 22" (51 cm x 56 cm)
Thigh Sleeve medium	20" x 26½" (51 cm x 67.5 cm)
Thigh Sleeve large	20" x 34¾" (51 cm x 88 cm)
Average compression pressure applied to the limb	Thigh sleeve: 50 mmHg ±10%
	Calf sleeve: 50 mmHg ±10%
	Foot sleeve: 130 mmHg ±10%
Operation modes	Thigh sleeve - single/pair
	Calf sleeve - single/pair
	Foot sleeve - single/pair
	Combined (two sleeves)
Operating conditions	Temperature: +41°F to +104°F / +5°C to+40°C
	Relative humidity: 15% to 90%, non-condensing
	Atmospheric pressure range: 700-1060 hPA
Storage conditions (product with batteries)	Temperature: +14°F to +86°F / -10°C to +30°C
	Relative humidity: 10% to 85%, non-condensing
Storage conditions (product without batteries)	Temperature: +14°F to +158°F / -10°C to +70°C
	Relative humidity: 10% to 93%, non-condensing
Battery storage conditions (long-term)	Temperature: 14°F to +86°F / -10°C to +30°C
	Relative humidity: 10% to 85%, non-condensing
List of cables	Power supply low voltage cable

5.5 Accessories

Part Number	Description
A502B-0001-01 (US) A502B-0001-04 (EU) A502B-0001-06 (Kr) A502B-0001-08 (AU) A502B-0001-10 (UK)	ActiveCare+S.F.T.® System
A502B-0002-01 (US) A502B-0002-02 (EU) A502B-0002-03 (Kr) A502B-0002-04 (AU) A502B-0002-05 (UK)	ActiveCare+S.F.T.® HomeCare System
A502B-0004-01 (US) A502B-0004-02 (EU) A502B-0004-03 (Kr)	ActiveCare+DTx® System
A502B-0005-01 (US) A502B-0005-02 (EU) A502B-0005-03 (Kr)	ActiveCare+DTx® HomeCare System
A201C-020S-10	Calf Sleeve with Stockinette - small (5 pairs/box)
A201C-120S-10	Calf Sleeve with Stockinette - medium (5 pairs/box)
A201C-220S-10	Calf Sleeve with Stockinette - large (5 pairs/box)
A201C-420S-10	Calf Sleeve with Stockinette - extra large (5 pairs/box)
A201T-0480-10	Thigh Sleeve - small (5 pairs/box)
A201T-1480-10	Thigh Sleeve - medium (5 pairs/box)
A201T-2480-10	Thigh Sleeve - large (5 pairs/box)
A201F-1280-10	Foot Sleeve (5 pairs/box)
A501A-1201-10	Extension tubes - Standard 3.9ft /1.2 m (5 pairs/box)
A501A-2001-10	Extension tubes - Long 6.6 ft / 2.0 m (5 pairs/box)
A5010-2001-10	OR Extension Tubes 6.6 ft / 2.0 m (5 pairs/box)
H301H-0002-02 (US) A301A-0001-01 (EU) A301A-0003-03 (Kr) A301A-0004-02 (AU) A301A-0005-01 (UK)	Medical grade AC/DC adapter with 14.8 ft /4.5 m electric cord
503-A-0002-20	Rechargeable battery pack
A504A-1550-10	Carrying straps (10 units/box)
502-C-0004-01	ActiveCare® Cradle
380-A-0001-00	Calf Sleeve selection tool measuring tape

Section 6: Warranty and Returns

6.1 Warranty

This product is guaranteed by MCS for a period of one year after the date of purchase. The proper construction, workmanship and materials of this product are guaranteed by MCS. During this period of guarantee, MCS will repair or replace the defective product or any defective parts without charge for labor or parts.

The guarantee does not cover any of the following:

1. Damages of any kind caused accidentally or from misuse.
2. Transportation costs and risks.
3. Costs for repairs and/or defects resulting from repairs carried out by unauthorized persons.
4. Periodic check-ups, maintenance and repair.
5. Failure or wear of accessories or other attachments other than the operating unit itself and power supply, unless explicitly guaranteed above.
6. Costs arising from non-acceptance of a claim.

NOTE: In case guaranteed service is required, apply to an authorized MCS distributor or to your retailer (from whom the product was purchased).

Repair or replacement under the guarantee does not imply any extension or renewal of the guarantee period.

The retailer will grant the guarantee only if the complete product is returned together with the original invoice/ receipt issued to the consumer.

6.2 Returning the Device

Medical Compression Systems guarantees that your **ActiveCare+S.F.T.®** and **ActiveCare+DTx®** Devices are free from defective material and workmanship.

Our obligation under this warranty is limited to the repair of devices and transformers returned to the indicated service address, transportation charges prepaid, within one year of delivery to the original purchaser. Specifically, MCS agree to service and/or adjust any instrument as required if returned for that purpose, and to replace and repair any part that, upon our examination, is proven to have been defective. This warranty does not apply to the tube assembly or the individual disposable thigh, calf or foot sleeve or to equipment damaged through shipping, tampering, negligence and/or misuse, including liquid immersion, autoclaving, or ETO sterilization.

To replace the device during warranty period, or report about a malfunction please contact CustomerService@mcsmed.com or use MCS's website (https://returns.mcsmed.com).

Based on the submitted information MCS will issue a Return Goods Authorization (RGA) number and specific shipping instructions.

To qualify for credit, the **ActiveCare+S.F.T.®** or **ActiveCare+DTx®** Device must be tagged with the following information:

1. Invoice number.
2. Date of purchase.
3. Serial number.

Section 7: Discharge from Hospital

Before a patient is discharged from hospital to home or rehabilitation facility, with the **HomeCare ActiveCare+S.F.T.®**, **ActiveCare+S.F.T.®**, **HomeCare ActiveCare+DTx®** or **ActiveCare+DTx®** System, make sure that:

- The patient is aware of the length of use (compliance per day and overall duration of therapy)
- The patient knows how to operate the system
- The patient knows how to correctly apply the sleeves
- The patient receives a copy of the Patient Instruction for Use
- The patient is trained on troubleshooting
- The patient knows when to contact the physician
- The patient reviews the training video available on MCS's website (activecare.mcsmed.com)
- The patient has written contact details to call in case of technical problems

For US customers:

For any questions please contact ActiveCare® Customer Service:

(800) 377-5804

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ActiveCare+S.F.T.® and ActiveCare+DTx® Operation and Service Manual

For additional information visit our website
activecare.mcsmed.com

ActiveCare®
SAFE DVT PREVENTION

MCS Medical Compression Systems Inc.

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