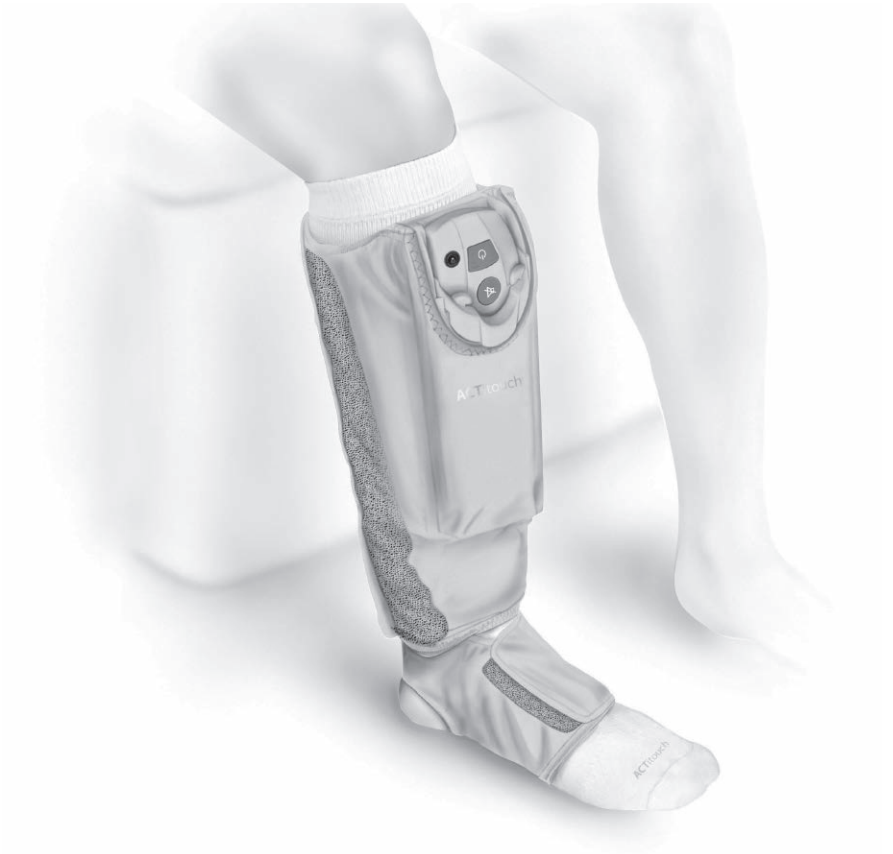
ACTITOUCH® SYSTEM USER GUIDE

—

Adaptive Compression Therapy



Tactile MEDICAL™

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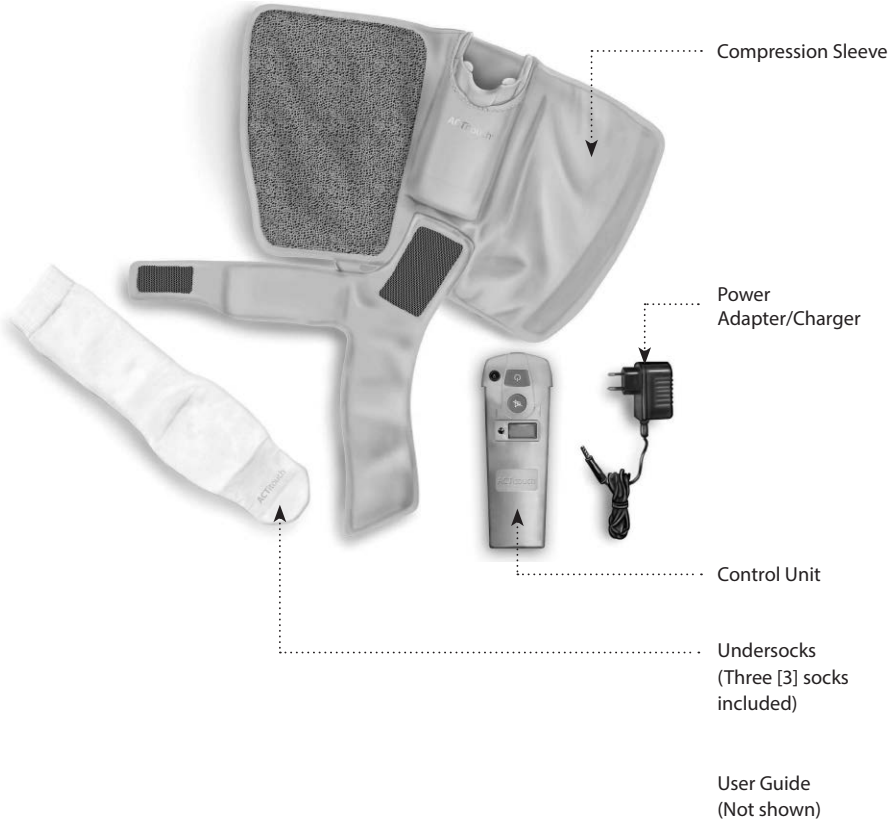
Component List

Before first use, ensure that the following ACTitouch® System components are accessible:



Product Description

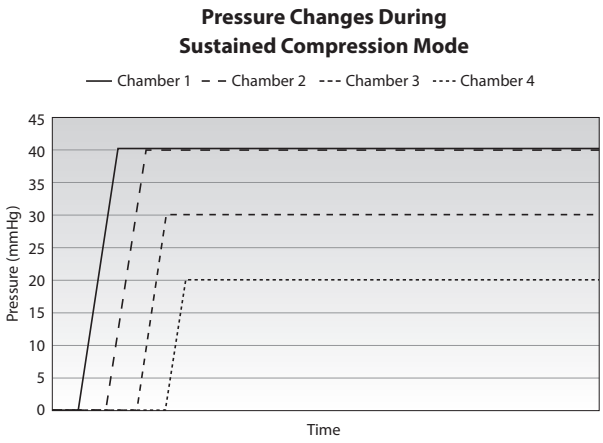
The ACTitouch System applies pneumatic compression to the lower leg, ankle, and foot. It consists of four (4) main parts:

1. The Compression Sleeve consists of four (4) chambers that inflate with air to apply pressure to the leg. Its simple wrap-around design with hook and loop fasteners means the Compression Sleeve can be fitted to many differently shaped legs and can be applied and removed with ease.
2. The control unit fits into the Compression Sleeve during device use. It monitors and adjusts the air pressure to ensure the correct level of compression is applied to the leg.
3. The Undersock is designed to draw perspiration and moisture away from the skin and has padding in key areas to provide additional comfort.
4. The Power Adapter/Charger is used to power the device directly or to charge the battery for ambulatory use.

The device has two (2) modes of operation: Sustained Compression Mode and Intermittent Pneumatic Compression Mode.

2.1 Sustained Compression Mode

In this mode, the device provides sustained, graduated pneumatic compression to the leg at preset pressures, while powered by its own rechargeable battery. When it is first switched on, the device gradually inflates, starting at the foot and working up toward the knee. Each chamber will stop inflating



when the correct pressures are achieved and will hold these pressures until the device is turned off. Every half hour, the pressures are automatically checked and readjusted, if necessary. The patient may hear the pump running for a few seconds while the pressure is being checked. In this mode, the patient is free to move around and carry out normal activities *(See Chapter 3 Warnings and Cautions)*.

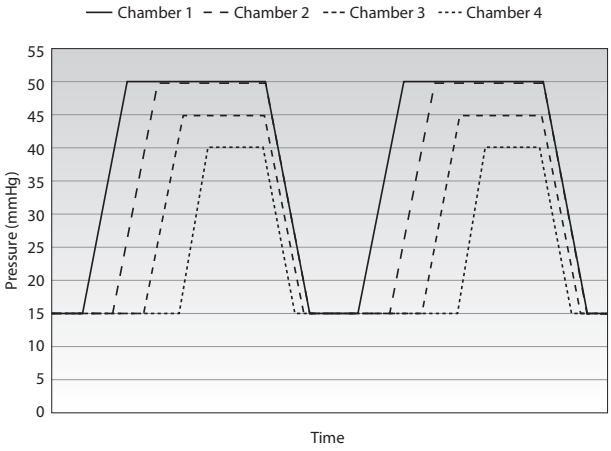
When operating in Sustained Compression Mode, and absolute quiet is necessary (e.g., at the theater), a MUTE or PAUSE button can be used to pause the pump *(See Section 5.6 Muted Operation in Sustained Compression Mode)*. While muted or paused, the device will remain inflated to apply pressure to the leg but will no longer adjust the pressure.

IMPORTANT: The device will automatically reset to normal operation after two (2) hours of muted or paused use.

2.2 Intermittent Pneumatic Compression Mode

When in Intermittent Pneumatic Compression Mode, the device will perform cyclic inflation/deflation sequences to preset gradient pressures. To operate in this mode, the control unit requires power from the Power Adapter/Charger. When the device is first plugged in and switched on, it will initially inflate to a low pressure in each chamber. Once the starting pressure is reached, each chamber will inflate in sequence, starting at the foot and working up toward the knee until all of the chambers reach the intended pressure levels. All four (4) chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is either unplugged from the Power Adapter/Charger or after two (2) hours of use. When the device is operating in Intermittent Pneumatic Compression Mode, the patient should remain lying down, reclined, or seated with leg elevated.

Pressure Changes During Intermittent Pneumatic Compression Mode



CHAPTER 3

Warnings and Cautions

3.1 Warnings

- Please read all of the information provided before use and ensure that all instructions are followed.
- Do not use the device on patients with medical conditions where an increase in venous and lymphatic return is undesirable.
- Electrical equipment may be hazardous if misused. Do not open or take apart the ACTitouch control unit for any reason or the warranty will be voided. There are no customer serviceable parts in this device.
- Prior to use, the patient should be fully assessed by a healthcare professional for treatment suitability, trained on the use of the device, and advised on optimal wear time in each mode.
- Failure to wear the device as recommended, even for short periods, may delay ulcer healing or may negatively impact treatment outcomes.
- Use the ACTitouch control unit or ACTitouch Compression Sleeve only with the ACTitouch Undersock and Power Adapter/Charger. Do not use the ACTitouch System while wearing other compression products.
- Treatment should be stopped if additional pain, tingling or numbness of the limb occurs during, or as a result of treatment.
- The Undersock should not be placed in direct contact with an open wound. It is recommended that this device be used in conjunction with an appropriate absorptive moisture retentive wound dressing, applied before the ACTitouch System.
- Caution should be taken when using the ACTitouch System on fragile skin.
- Do not operate motor vehicles or other machinery while wearing the ACTitouch System. Consult with your healthcare provider about compression options when not wearing the ACTitouch System.
- Ensure the electrical supply to the device is switched off by disconnecting it from the Power Adapter/Charger before cleaning or disinfecting.
- The ACTitouch System should be removed before bathing or showering. Reapply the device immediately afterward, ensuring the skin is dried prior to application.
- Do not walk with the Power Adapter/Charger attached to the device.

3.2 Cautions ⚠

- Regularly check the status indicator located at the top of the control unit while using ACTitouch. The green light on the control unit indicates the control unit is charged and on. A flashing red status light (and periodic audible alarm) indicates that battery power is low. No light indicates the power is off.
- Ensure that the device is clean and dry prior to storage.
- Do not immerse the ACTitouch System in water, or spill liquid on the control unit. The device is not waterproof, and exposure to liquid may damage the control unit or Compression Sleeve. If the device becomes soaked with fluid, discontinue use of the device.
- Do not allow the Compression Sleeve to come into contact with sharp objects.
- Do not expose the Undersock, Compression Sleeve or control unit to excessive heat or open flames, such as cigarettes, portable heaters, etc.

CHAPTER 4

Indications and Contraindications

Rx Only
U.S. Federal law restricts this device to sale by, or on the order of, a licensed healthcare professional.

4.1 Indications

The ACTitouch System provides graduated compression in both sustained and intermittent settings for use in:

- Enhancing venous return;
- Reducing venous leg ulcer healing time;
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers;
- Treatment of chronic venous insufficiency;
- Reducing edema due to venous stasis;
- Treatment of lymphedema.

4.2 Contraindications

The ACTitouch System is contraindicated if the patient has:

- An Ankle Brachial Pressure Index of less than 0.6 or ankle systolic pressure less than 60 mmHg;
- Diagnosed or suspected acute Deep Vein Thrombosis (DVT) or pulmonary embolism;
- Pulmonary edema;
- Leg gangrene;
- Acute thrombophlebitis;
- Decompensated/Congestive Cardiac Failure;
- Severe arteriosclerosis or other ischemic vascular disease;
- Diabetes in association with peripheral arterial disease;
- Acute infections of the skin such as cellulitis;
- Any lower limb malignancy.

CHAPTER 5

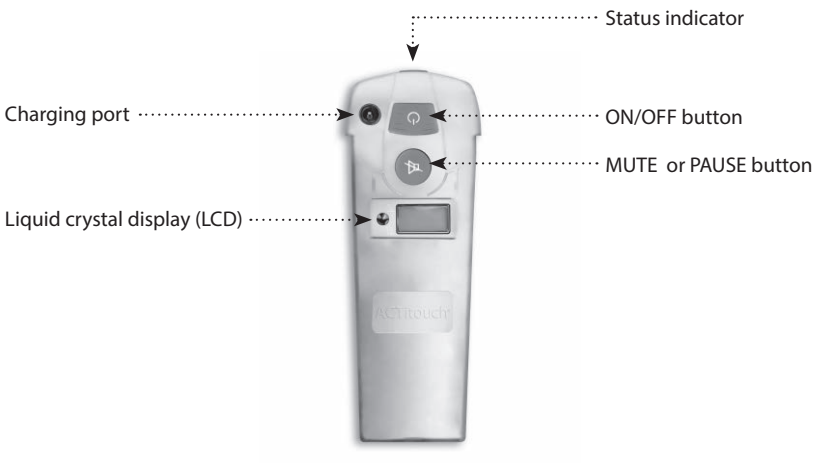
Directions for Use

- The ACTitouch System should be worn as recommended and prescribed by the physician. The usual prescribed duration of use will range from 10 to 14 hours per day, including both Sustained Compression and Intermittent Pneumatic Compression Modes.
- The device should be applied immediately upon waking and worn throughout the day. The ACTitouch System should be removed for bathing or showering, and when driving or operating machinery. Reapply the device immediately after these activities.
- The device should be removed just prior to going to bed and recharged *(See Section 5.3 Charging the Device)*. Consult with your healthcare provider about other compression options during sleep.

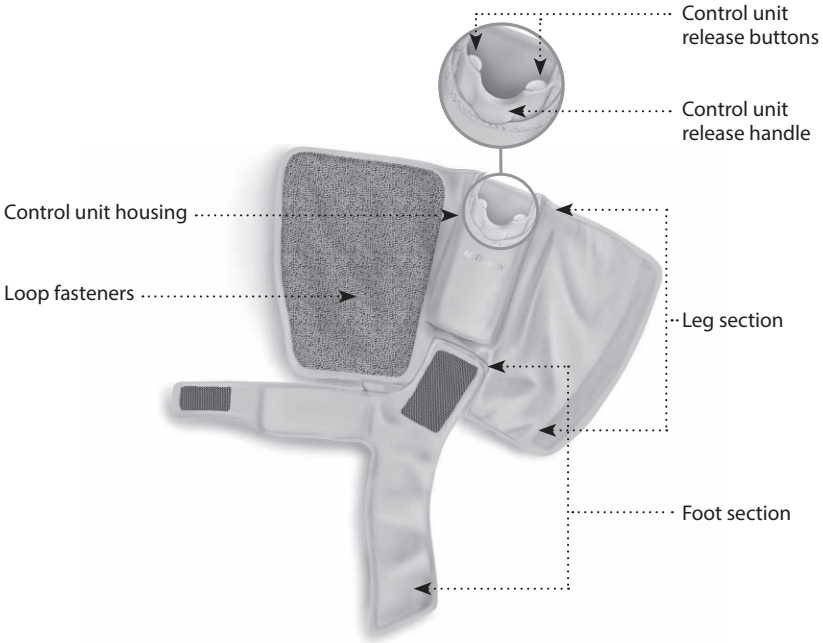
IMPORTANT: Failure to wear the device as recommended, even for short periods, may delay ulcer healing or may negatively impact treatment outcomes.

5.1 Functional Controls

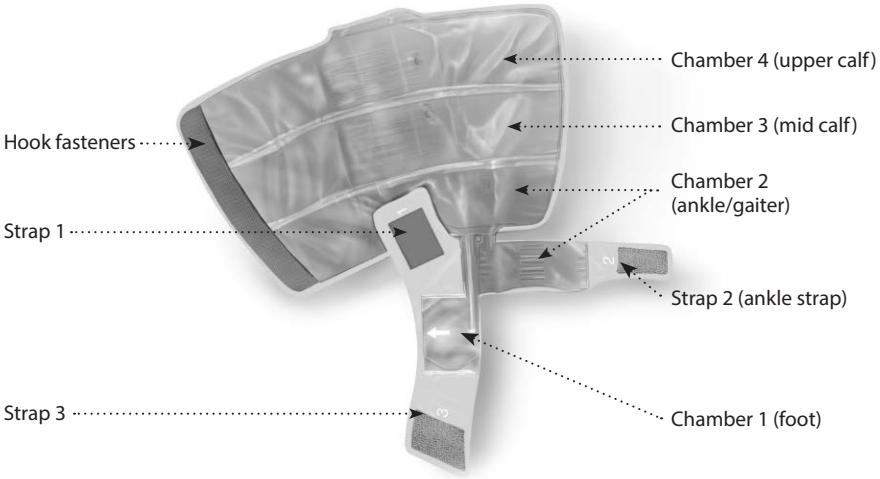
ACTitouch Control Unit



ACTitouch Compression Sleeve (Outer Face Up)



ACTitouch Compression Sleeve (Outer Face Down)



5.2 First Use

Remove all device components from the packaging and fully charge the device as indicated in *Section 5.3 Charging the Device*.

5.3 Charging the Device

Before each daily use, the ACTitouch System should be fully charged. It is recommended that the device be charged every night for a minimum of four (4) hours. The control unit should remain inserted in the Compression Sleeve while charging.

- Ensure that the Power Adapter/Charger is connected to a working AC power outlet. A green light will illuminate on the Power Adapter/Charger when it is correctly connected.
- Plug the supplied Power Adapter/Charger into the charging port on the control unit. If this is done correctly, and the battery was low, the control unit status indicator will flash red until fully charged. Otherwise, the green status indicator on the control unit will illuminate. Charge the unit for a minimum of four (4) hours, even if the status indicator on the control unit is showing green
- The status indicator flashes red when the battery charge is low. Immediate charging is required. The normal battery life between charges is sixteen (16) hours.

- The device will be fully charged after four (4) hours. Nightly charging is recommended.

If the control unit is stored unused for prolonged periods of time, the control unit should be fully charged at least once every six (6) months. This will ensure that a good battery life is maintained.

IMPORTANT: To ensure an adequate supply of power while wearing the device, please ensure that you charge the device at the end of each day. Charge whether the status indicator is showing green or flashing red.

Use only the Power Adapter/Charger provided with your ACTitouch System for charging the control unit and for Intermittent Pneumatic Compression Mode operation.

The batteries are not user replaceable.

5.4 Applying the ACTitouch System

CAUTION: The ACTitouch Undersock should not be placed in direct contact with an open wound. It is recommended that this device be used in conjunction with an appropriate wound dressing before the device is applied (See Chapter 6 Wound Dressings).

IMPORTANT: Patients are advised to apply the device before putting on clothing over the leg and foot.

5.4.1 Applying the ACTitouch Undersock

For correct positioning of the Undersock, ensure that the word "ACTitouch" is positioned on the top of the foot and the padded areas are positioned over the shin and around the heel and ankle.

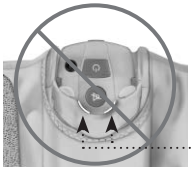
Apply the Undersock over the foot, and then pull it up to just below the knee, taking care not to displace any wound dressing.

5.4.2 Inserting the Control Unit into the Compression Sleeve

Slide the control unit into its housing on the Compression Sleeve until a click is felt and heard; the control unit is then secured correctly within the sleeve.

Correct placement

Verify the control unit is correctly assembled by checking to see if the blue markings are visible on the front of the control unit. If they are visible, the control unit is not fully secure.

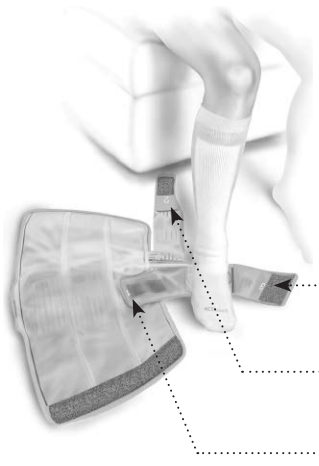


Incorrect placement

IMPORTANT: For correct functioning of the device, ensure that the control unit is correctly inserted in the Compression Sleeve.

The patient should leave the control unit inserted into the Compression Sleeve at all times. The battery can be charged without removing the control unit from the Compression Sleeve.

5.4.3 Applying the Compression Sleeve



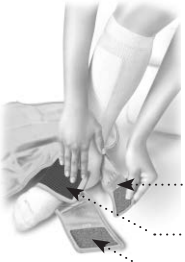
Place the Compression Sleeve on the floor, outer face downward so that the chambers can be seen, with strap 2 (ankle strap) pointing toward the wearer, regardless of whether the Compression Sleeve is to be applied to the right or left leg.

Place the arch of the foot over chamber 1 (marked with an arrow on the Compression Sleeve) with the toes pointing in the direction of the arrow.

Strap 3

Strap 2 (ankle strap)

Strap 1

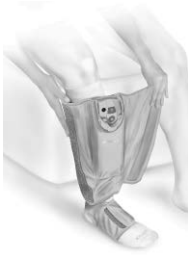


Wrap strap 1 over the top of the foot and secure in place by wrapping strap 2 (ankle strap) around the ankle and placing over strap 1.

Wrap strap 3 over the top of the foot and secure in place over straps 1 and 2.

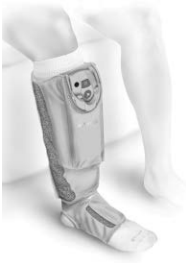
The correctly applied foot section will appear as shown.

Once the foot section is fastened, lift the leg section of the Compression Sleeve and drape over the leg with the control unit and "ACTitouch" logo positioned over the shin.



Wrap the loop fasteners around the back of the calf.

Fix the loop fasteners securely in place with the hook fasteners.



Ensure that fasteners are adjusted to give a close fit between the Compression Sleeve and the leg and foot.

The correctly applied ACTitouch System will appear as shown.

WARNING: When applied, the top of the Compression Sleeve should be at least 2.5cm below the crease of the knee when seated.

IMPORTANT: Always ensure that the Compression Sleeve is applied in the correct position with the control unit on the front of the leg over the shin.

Applying the sleeve too loosely may result in the unit switching off.

5.5 Switching On the ACTitouch System in Sustained Compression Mode

IMPORTANT: If footwear is to be worn during the treatment session, it is advisable for the wearer to put on footwear prior to switching on the ACTitouch System.

Do not switch on the device in Sustained Compression Mode unless it is applied to the leg.

- Ensure that the control unit is correctly inserted in the Compression Sleeve, that the Compression Sleeve is correctly applied to the leg, and that the Power Adapter/Charger is not connected.
- While seated, press and hold the ON/OFF button until the status indicator illuminates (approximately two [2] seconds). The ON/OFF button can then be released.

- The Compression Sleeve will now inflate. It may take up to five (5) minutes to completely inflate the Compression Sleeve. Remain seated during inflation. To ensure a better fit, pull up and support the Compression Sleeve in place while the chambers inflate.
- The control unit is programmed to inflate the chambers of the Compression Sleeve to preset pressures. When the correct pressures are reached, the control unit will stop pumping.
- When the Compression Sleeve is fully inflated, the patient may stand up and resume normal activities. *(See Chapter 3 Warnings and Cautions.)*
- The MUTE button may be used in Sustained Compression Mode once the Compression Sleeve is fully inflated. *(See Section 5.6 Muted Operation in Sustained Compression Mode for details.)*

5.6 Muted Operation in Sustained Compression Mode

- To activate muted or paused operation during Sustained Compression Mode, press the MUTE button and hold for at least two (2) seconds. Upon release of the MUTE button, the control unit will make a subtle beep sound.

IMPORTANT: While muted, the device will remain inflated to apply pressure to the leg but will no longer adjust the pressure.

- To deactivate muted operation, press the MUTE button again (for at least two [2] seconds). Upon release of the MUTE button, the control unit will make a subtle beep sound. The pump will now restart and, if necessary, readjust all chambers back to the correct pressures.
- If muted operation is not manually deactivated, then the device will automatically switch back to Sustained Compression Mode operation after two (2) hours.

5.7 Intermittent Pneumatic Compression Mode

In Intermittent Pneumatic Compression Mode, the device will operate a cyclic pulsed inflation/deflation sequence until either it is unplugged from the Power Adapter/Charger, or two (2) hours have elapsed, at which point the device will switch back to Sustained Compression Mode operation.

It is recommended that the Intermittent Pneumatic Compression Mode be used for at least two (2) hours per day. When using in Intermittent Pneumatic Compression Mode, the user should be either seated or lying down with the foot elevated and ankle relaxed; not standing. This can be for:

- One (1) session of two (2) hours OR
- Two (2) one-hour (1-hour) sessions.
- Any session should be a minimum of 30 minutes.

It is recommended that the Intermittent Pneumatic Compression Mode be used late in the user's day when swelling would be the greatest, and when the user is less active and can sit, recline, or lie down.

To operate in Intermittent Pneumatic Compression Mode for longer than two (2) hours in succession, the Intermittent Pneumatic Compression Mode may be re-activated after the device automatically switches back into Sustained Compression Mode. For advice on optimal wear time in Intermittent Pneumatic Compression Mode, please consult a healthcare professional. Failure to use the device as recommended may delay ulcer healing or may negatively impact treatment outcomes.

CAUTION: Do not walk while the device is operating in Intermittent Pneumatic Compression Mode.

5.7.1 To Activate Intermittent Pneumatic Compression Mode from Sustained Compression Mode Operation

- Plug the supplied Power Adapter/Charger into the charging port on the control unit.
- Ensure that the Power Adapter/Charger is connected to an AC power outlet. A green light will illuminate on the Power Adapter/Charger if it is correctly connected to the power supply.
- Press the ON/OFF button for at least two (2) seconds. Upon release of the ON/OFF button, Intermittent Pneumatic Compression Mode will be activated and the pump will start.

IMPORTANT: Do not switch the device into Intermittent Pneumatic Compression Mode unless the Compression Sleeve is applied to the leg.

5.7.2 To Activate Intermittent Pneumatic Compression Mode from Off:

- Apply the Compression Sleeve *(See Section 5.4.3 Applying the Compression Sleeve)*.
- Plug the supplied Power Adapter/Charger into the charging port on the control unit.
- Ensure that the Power Adapter/Charger is connected to a working AC power outlet. A green light will illuminate on the Power Adapter/Charger if it is correctly connected to the power supply.
- Press the ON/OFF button for at least two (2) seconds. Upon release of the ON/OFF button Intermittent Pneumatic Compression Mode will be activated and the pump will start.

5.8 Switching Off the ACTitouch System

- Ensure that the Power Adapter/Charger is not attached to the charging port.
- Press and hold the ON/OFF button for at least two (2) seconds. On release of the ON/OFF button, the device will now deflate all chambers and automatically switch itself off.

IMPORTANT: The ACTitouch System device may automatically switch off on rare occasions if prolonged high pressure is detected by the device. This could occur if high pressure is applied externally to the sleeve. This is a safety feature of the device, which may be restarted in the normal way (See Section 5.5 Switching On the ACTitouch System in Sustained Compression Mode). If the device switches off repeatedly, refer to Chapter 8 Troubleshooting Guide.

5.9 Removing the ACTitouch System

- To remove the device, reverse the procedure outlined in *Section 5.4 Applying the ACTitouch System*.
- If required, clean the Compression Sleeve according to the cleaning instructions in *Chapter 7 Cleaning, Care and Maintenance*.
- Wash the Undersock according to the cleaning instructions in *Chapter 7 Cleaning, Care and Maintenance*.

IMPORTANT: The patient should leave the control unit inserted into the Compression Sleeve at all times.

The battery can be charged without removing the control unit from the Compression Sleeve.

CHAPTER 6

Wound Dressings

The ACTitouch System should be used in conjunction with an appropriate wound dressing as recommended by your clinician. Apply the dressing to the wound before applying the ACTitouch Undersock.

Please follow the dressing manufacturer's instructions for use. Appropriate tape or a light retention stocking may aid dressing retention.

The primary dressing over the ulcer should be changed when clinically indicated. Typically dressings will require changing when they are moistened, as can occur if your wound is leaking any fluid or if the dressing becomes wet after bathing or showering.

Remove the ACTitouch System prior to showering. If you do not wish to change the dressing when showering, cover the dressing with a waterproof outer layer.

Cleaning, Care and Maintenance

Please refer to *Chapter 3 Warnings and Cautions*. Switch off and disconnect the Power Adapter/Charger before cleaning or disinfecting.

7.1 Cleaning and Disinfecting

7.1.1 Cleaning the ACTitouch Undersock

IMPORTANT: The ACTitouch Undersock is intended for single patient use only.

It is recommended that the ACTitouch Undersock be replaced after a maximum of 60 washes. To purchase additional socks please contact Customer Service at 866.435.3948.

	Machine wash hot on a gentle cycle
	Air dry or tumble dry on a low-temperature setting
	Do not iron
	Do not use chlorine-based bleach
	Do not dry clean

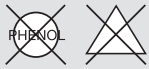
7.1.2 Cleaning and Disinfecting the ACTitouch Compression Sleeve

WARNING: Switch off and disconnect the Power Adapter/Charger before inspecting, cleaning or disinfecting. Failure to comply could result in electric shock.

	To clean, wipe down with a soft cloth dampened with mild soap and water. Do not immerse in fluids. Air dry thoroughly.
	Do not machine wash
	Do not tumble dry
	Do not iron
	Do not dry clean

DisCide® ULTRA Spray Disinfectant has been demonstrated to effectively disinfect the ACTitouch System. Use DisCide ULTRA Spray or similar disinfectant compliant with OSHA's Bloodborne Pathogen Standard (29 CFR 1910.1030) and/or registered with EPA. To disinfect the ACTitouch Compression Sleeve between patient use, or if there are visible biological contaminants or visible stains, the following steps are recommended:

1. Clean any visible blood or body fluids from the surface of the sleeve.
2. Thoroughly wet surface with DisCide ULTRA Disinfecting Spray.
3. Allow surfaces to remain wet for one minute and then allow to air dry.

	Do not clean or disinfect with household detergents, abrasive cleaners, scourers, degreasers, solvents, bleach or phenol-based agents, such as trichlorophenol (TCP).

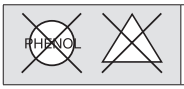
7.1.3 Cleaning and Disinfecting the ACTitouch Control Unit

WARNING: Switch off and disconnect the Power Adapter/Charger before inspecting, cleaning or disinfecting. Failure to comply could result in electric shock.

	To clean, wipe down with a soft cloth dampened with mild soap and water. Do not immerse in fluids. Air dry thoroughly.

DisCide® ULTRA Spray Disinfectant has been demonstrated to effectively disinfect the ACTitouch System. Use DisCide ULTRA Spray or similar disinfectant compliant with OSHA's Bloodborne Pathogen Standard (29 CFR 1910.1030) and/or registered with EPA. To disinfect the ACTitouch control unit between patient use, or if there are visible biological contaminants or visible stains, the following steps are recommended:

1. Clean any visible blood or body fluids from the surface of the controller.
2. Thoroughly wet surface with DisCide ULTRA Disinfecting Spray.
3. Allow surfaces to remain wet for one minute and then allow to air dry.



Do not clean or disinfect with household detergents, abrasive cleaners, scourers, degreasers, solvents, bleach or phenol-based agents, such as trichlorophenol (TCP).

7.2 Storage and Handling

It is recommended that the ACTitouch System be stored at room temperature. Avoid excessive heat and cold. Do not store device in direct sunlight. Ensure that the device is clean and dry prior to storage.

Reasonable care should be taken when handling and using the ACTitouch System. Although the device has been designed for everyday use, heavy impacts, contact with sharp objects and rough handling should be avoided. Do not immerse the device in fluid. If either the Compression Sleeve or control unit become soaked with fluid or otherwise damaged, do not use the device.

7.3 Maintenance and Service

The ACTitouch System is designed to be maintenance free; routine service is not required.

CAUTION: Do not open or take apart the ACTitouch control unit for any reason. There are no customer serviceable parts in the ACTitouch System.

7.4 Disposal

For disposal of any components of the ACTitouch System, please follow local waste regulations or consult your local institutional waste-management service or municipal waste authority.

Troubleshooting Guide

The following table provides a troubleshooting guide for the ACTitouch System in the unlikely event of a malfunction. Please refer to *Section 8.2 Obtaining Replacement Products and Service* for additional information.

Problem	Possible Cause	Corrective Action
The Compression Sleeve is not inflating or deflating as expected.	1. The control unit has not been securely inserted into the Compression Sleeve. 2. The control unit needs to be charged. 3. The control unit has not been switched on. 4. The MUTE button has been activated while operating in sustained mode. 5. Device fault.	1. *Refer to Section 5.4.2 Inserting the Control Unit into the Compression Sleeve.* 2. Charge the control unit. *Refer to Section 5.3 Charging the Device.* 3. Switch the control unit on. *Refer to Section 5.5 Switching On the ACTitouch System in Sustained Compression Mode.* 4. Deactivate muted operation. *Refer to Section 5.6 Muted Operation in Sustained Compression Mode Operation.* 5. Please call customer service at (toll-free) 866.435.3948.*
The Compression Sleeve is difficult to fasten securely.	1. An incorrectly sized Compression Sleeve has been selected. 2. The Compression Sleeve is already partially inflated prior to application to the limb. 3. The Compression Sleeve hook or loop fastening areas have been contaminated with foreign bodies (debris, such as lint or hair.) 4. Device fault.	1. Please call customer service at (toll-free) 866.435.3948.* 2. Switch the control unit on. Prior to full inflation of the Compression Sleeve, switch the control unit off again to evacuate any air present in the sleeve. 3. Inspect the Compression Sleeve fastening areas and remove any fluff or similar foreign bodies. 4. Please call customer service at (toll-free) 866.435.3948.*

***Customer service can be contacted at 866.435.3948 (toll-free) between 7:00 am – 7:00 pm CT, Monday through Friday.**

Problem	Possible Cause	Corrective Action
The control unit will not operate in Sustained Compression Mode.	1. The control unit has not been securely inserted into the Compression Sleeve. 2. The control unit needs to be charged. 3. The control unit has not been switched on. 4. The MUTE button has been activated. 5. The event log needs to be reset. 6. Device fault.	1. *Refer to Section 5.4.2 Inserting the Control Unit into the Compression Sleeve.* 2. Charge the control unit. *Refer to Section 5.3 Charging the Device.* 3. Switch the control unit on. *Refer to Section 5.5 Switching On the ACTitouch System in Sustained Compression Mode.* 4. Deactivate muted operation. *Refer to Section 5.6 Muted Operation in Sustained Compression Mode Operation.* 5. Remove the control unit from the Compression Sleeve. Reset the device by pressing and holding the MUTE button for ten (10) seconds. The LCD will flash "–––" to indicate a successful event log reset, and the unit will switch off. The control unit may now be reinserted into the Compression Sleeve and used as normal. 6. Please call customer service at (toll-free) 866.435.3948.*
The control unit does not respond to buttons being pressed.	1. The control unit needs to be charged. 2. The control unit has not been switched on. 3. The event log needs to be reset. 4. Device fault. 5. Control unit does not respond to the button being pressed.	1. Charge the control unit. *Refer to Chapter 5.3 Charging the Device.* 2. Switch the control unit on. *Refer to Chapter 5.5 Switching On the ACTitouch System in Sustained Compression Mode.* 3. Remove the control unit from the Compression Sleeve. Reset the device by pressing and holding the MUTE button for ten (10) seconds. The LCD will flash "–––" to indicate a successful event log reset, and the unit will switch off. The control unit may now be reinserted into the Compression Sleeve and used as normal. 4. Please call customer service at (toll-free) 866.435.3948.* 5. Hold button down for a longer period of time (e.g., Two [2] seconds)

***Customer service can be contacted at 866.435.3948 (toll-free) between 7:00 am – 7:00 pm CT, Monday through Friday.**

Problem	Possible Cause	Corrective Action
The control unit will not operate in Intermittent Pneumatic Compression Mode.	1. The control unit has not been securely inserted into the Compression Sleeve.	1. *Refer to Section 5.4.2 Inserting the Control Unit into the Compression Sleeve.*
	2. The Power Adapter/Charger is not securely connected to the charging port and an AC power outlet.	2. Ensure the Power Adapter/Charger is securely connected to the charging port and power supply. A green light will illuminate on the Power Adapter/ Charger if it is correctly connected to an AC power outlet.
	3. The control unit has not been switched on.	3. Switch the control unit on. *Refer to Section 5.7.1 To Activate Intermittent Pneumatic Compression Mode from Sustained Compression Mode Operation* and *Section 5.7.2 To Activate Intermittent Pneumatic Compression Mode from Off.*
	4. The event log needs to be reset.	4. Remove the control unit from the Compression Sleeve. Reset the device by pressing and holding the MUTE button for ten (10) seconds. The LCD will flash "–––" to indicate a successful event log reset, and the unit will switch off. The control unit may now be reinserted into the Compression Sleeve and used as normal.
	5. Device fault.	5. Please call customer service at (toll-free) 866.435.3948.*
The Compression Sleeve appears to be leaking air.	1. The control unit has not been securely inserted into the Compression Sleeve.	1. *Refer to Section 5.4.2 Inserting the Control Unit into the Compression Sleeve.*
	2. Device fault.	2. If sleeve is damaged, call customer service at (toll-free) 866.435.3948* for replacement.
The device is frequently "locking out."	1. The event log needs to be reset.	1. Remove the control unit from the Compression Sleeve. Reset the device by pressing and holding the MUTE button for ten (10) seconds. The LCD will flash "–––" to indicate a successful event log reset, and the unit will switch off. The control unit may now be reinserted into the Compression Sleeve and used as normal.
	2. Multiple "lockouts" may be a device fault.	2. Please call customer service at (toll-free) 866.435.3948.*

***Customer service can be contacted at 866.435.3948 (toll-free) between 7:00 am – 7:00 pm CT, Monday through Friday.**

Problem	Possible Cause	Corrective Action
The control unit power does not last a full day.	1. The control unit needs to be charged. 2. Device fault.	1. Charge the control unit. *Refer to Section 5.3 Charging the Device.* 2. Please call customer service at (toll-free) 866.435.3948.*
There is a change in performance of the device.	1. The control unit has not been securely inserted into the Compression Sleeve. 2. Device fault.	1. *Refer to Section 5.4.2 Inserting the Control Unit into the Compression Sleeve.* 2. Please call customer service at (toll-free) 866.435.3948.*
The device turns off unexpectedly.	1. Automatic shutdown due to temporary event. 2. The control unit needs to be charged. 3. Auto shutdown and lock out. 4. Device fault.	1. Switch the control unit back on. *Refer to Section 5.5 Switching On the ACTitouch System in Sustained Compression Mode.* 2. Charge the control unit. *Refer to Section 5.3 Charging the Device.* 3. Remove the control unit from the Compression Sleeve. Reset the device by pressing and holding the MUTE button for ten (10) seconds. The LCD will flash "–––" to indicate a successful event log reset, and the unit will switch off. The control unit may now be reinserted into the Compression Sleeve and used as normal. 4. Please call customer service at (toll-free) 866.435.3948.*

***Customer service can be contacted at 866.435.3948 (toll-free) between 7:00 am – 7:00 pm CT, Monday through Friday.**

8.1 Limited Warranty for Home Use

Tactile Medical provides a warranty for the ACTitouch System. The ACTitouch control unit, sleeve and power adapter are warranted to be free from defects in material and workmanship for a period of one (1) year from the date of purchase. All other accessories and supplies related to the use of the ACTitouch System are warranted to be free from defects in material and workmanship for their first use. Tactile Medical's sole obligation in the event of a breach of this warranty is expressly limited to the replacement of defective parts that cannot, in the sole discretion of Tactile Medical, be repaired. Replacement parts may be new or refurbished parts as solely determined by Tactile Medical. No representation or other affirmation of fact set forth in this agreement, including but not limited to statements regarding suitability for use or performance of the ACTitouch System, shall be deemed to be a warranty or representation by Tactile Medical for any purpose, nor give rise to any liability or obligation of Tactile Medical. EXCEPT FOR THE FOREGOING, TACTILE MEDICAL MAKES NO OTHER WARRANTY. THE WARRANTIES SET FORTH HERE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY THE MANUFACTURER, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE AND ALL

OBLIGATIONS OR LIABILITIES ON THE PART OF TACTILE MEDICAL FOR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE, REPAIR OR PERFORMANCE OF THE ACTITOUCH SYSTEM. IN NO EVENT SHALL TACTILE MEDICAL BE LIABLE FOR ANY SPECIAL, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES. Some states, provinces or countries do not allow exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply. This warranty is available only to the original user and is not transferable. Repairs or alterations to the product not conducted by Tactile Medical shall void these warranties. These warranties do not cover failures due to improper or negligent use of the product.

These warranties provide specific legal rights; there may be other available rights, which may vary by state, province or country.

8.2 Obtaining Replacement Products and Service

For information about replacement products and service, contact customer service: 866.435.3948.

8.3 Limited Warranty and Service for Facility Use

Contact Tactile Medical for information regarding the service agreements available to facilities.

8.4 Return Policy

Returns are not accepted nor are refunds issued for these products; this includes the wraps, sleeves, controller, or any accessories, once opened.

8.5 Patents

The ACTitouch® System is protected by the following United States patents*:

7,741,966 7,909,786 7,947,003

8,075,507 D578,652

*Additional patents pending.

8.6 Product Development and Quality Improvement

Tactile Medical reserves the right to modify product specifications as part of its continuing program of product development and quality improvement.

The ACTitouch System is not made with natural rubber latex.

Technical Information

Equipment Classifications and Standards	
The ACTitouch System is tested to/complies with the following equipment classifications and standards:	
U.S. Medical Equipment Classification	Class II
Degree of Protection Against Electric Shock	Class II
Classification According to Directive 93/42/EEC	IIA
Safety	UL60601-1 and CAN/CSA C22.2 No.601.1–M90
Electromagnetic Compatibility (EMC)	EN60601-1-2
Software	EN60601-1-4
Internal Power Source	Lithium Ion Battery
External PSU Input	100–240Vac, 200mA, 50–60Hz, Class II
External PSU Output	7.5Vdc, 900mA

Dimensions and Weights		
Component	**Size cm (inches)**	**Weight kg (lbs)**
Control Unit	18.7 x 6.9 x 3.2 (7.4 x 2.7 x 1.3)	0.22 kg (0.49 lbs)

Pressure Parameters				
Mode	**Foot (± 5 mmHg)**	**Lower Calf (± 5 mmHg)**	**Middle Calf (± 5 mmHg)**	**Upper Calf (± 5 mmHg)**
Sustained Compression	40	40	30	20
Intermittent Pneumatic Compression	50	50	45	40

Operating Conditions	
Temperature	+10°C to +40°C (+50°F to +104°F)
Humidity	0 to 75% RH
Pressure	0.7 to 1.3 Bar (70 kPa to 130 kPa)

Storage Conditions
Store at room temperature. Avoid excessive heat and cold.

9.1 Symbols

	ON/OFF button		Class II equipment (Protection)
	MUTE/PAUSE button		Friwo AC/DC adaptor type: FW7333M/08
	Sustained Compression Mode		Caution
	Intermittent Pneumatic Compression Mode		Manufacturer's part number
	Direct current		Keep dry. Avoid high humidity.
	AC/DC Adapter polarity – center positive		Operating temperature limits
	Type BF Applied part		Lot number
	Refer to User Guide for Instructions for Use.		MEDICAL EQUIPMENT with respect to electrical shock, fire, and mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1 43MH
	Manufactured after August 2005 Do not dispose of this product — special collection only — EU only.		Recycle

9.2 Device Label

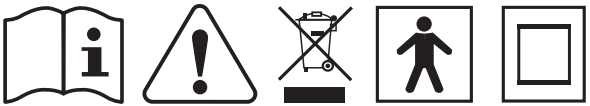
The device label is found on the back of your control unit. To read the label, place the control unit facing away from you at eye level at a distance that maximizes character clarity — generally 20 inches (50 cm) to 40 inches (100 cm) with an illumination of 500 lx minimum.

- Call Tactile Medical Customer Service if issues reading the label remain.
- Device label not to scale.
- Device label depiction may be different than that on your device.
- See User Guide for symbol definitions.

ACT999999

ACTitouch™

MEDICAL EQUIPMENT

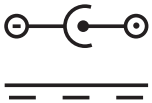


Tactile Medical

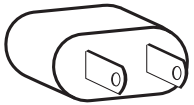
Minneapolis, Minnesota 55413

Rx Only REF **500234-000-00**

7.5V



Friwo AC/DC adaptor type FW7333M/08



UL 60601-1
CAN/CSA C22.2
No. 601.1 43MH

MADE IN TAIWAN

500233-000-01

9.3 Electromagnetic Interference

This device has been tested and found to comply with the limits for medical devices in accordance with EN60601-1-2:2001. These limits are designed to provide reasonable protection to assure the safety of medical devices from interference from other electrical equipment and devices. This equipment can be affected by radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ACTitouch System is intended for use in the electromagnetic environment specified below. The customer or the user of the ACTitouch System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group 1	The ACTitouch System 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.
RF emissions CISPR 11	Class B	The ACTitouch System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ACTitouch System is intended for use in the electromagnetic environment specified below. The customer or the user of the ACTitouch System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV for common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U^T (>95 % dip in U^T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U^T (60 % dip in U^T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ACTitouch System is intended for use in the electromagnetic environment specified below. The customer or the user of the ACTitouch System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ACTitouch System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 0.35 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	$d = 0.29 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.58 \sqrt{P}$ 800 MHz to 2.5 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 metres (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: 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects, and people.

NOTE A 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 ACTitouch device is used exceeds the applicable RF compliance level above, the ACTitouch System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating ACTitouch System.

NOTE B Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ACTitouch System

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

Rated maximum output power of transmitterW	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d = 1.2√P	**80 MHz to 800 MHz d = 1.2√P**	**800 MHz to 2.5 GHz d = 2.3√P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

For Additional Questions

If you have any questions that are not covered by this user guide, contact:

Tactile Medical
1331 Tyler Street NE, Suite 200
Minneapolis, MN 55413

Telephone: 612.355.5100
Toll-free Telephone: 866.435.3948 (U.S. only)
Fax: 612.355.5101
Toll-free Fax: 866.435.3949 (U.S. only)

Hours of Operation: Monday–Friday 7 a.m. to 7 p.m. CT

Email: info@tactilemedical.com

www.tactilemedical.com

Tactile MEDICAL™

Tactile Medical
1331 Tyler Street NE, Suite 200
Minneapolis, MN 55413 USA
T: 612.355.5100
F: 612.355.5101

Customer Service
Toll-Free Tel: 866.435.3948
Toll-Free Fax: 866.435.3949
Hours: Monday through Friday, 7 a.m. – 7 p.m. CT
www.tactilemedical.com

D/N: 500220-000-00 Rev. F 01/2017