TensCare Shockwave Therapy Device

REF: K-SHOCKWAVE

INSTRUCTIONS FOR USE

READ CAREFULLY BEFORE USE

Contents

1 Product Description

The TensCare Shockwave is a medical device produced for TensCare Ltd by Shenzhen Oceanus Medical Device Co., Ltd.

A solenoid drive activates a bullet body inside the therapeutic handle. When the bullet body collides with the therapeutic head, the impact energy is converted into a radial ballistic shock wave pulse, which is focussed to create the characteristics required to have a good therapeutic effect for musculoskeletal disorders.

The innovative technology has a compact design with no need for a compressor. The clear colour display shows all relevant treatment parameters and offers touch screen operation for ease of use during treatment.

Variable frequencies and various applicator heads allow treatment to be adapted to the particular condition of the patient.

2 Intended Use

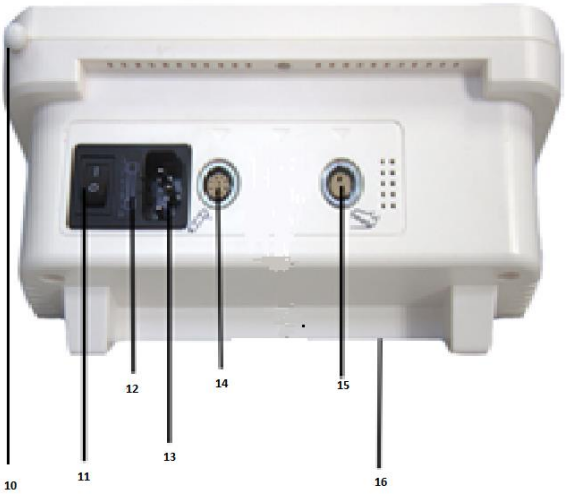
The TensCare Shockwave is for use in the area of adjuvant therapy of chronic joint pain and muscular pain.

It is intended to be used only by, or under the supervision of, suitably qualified medical staff (such as physicians, therapists and health paraprofessionals).

3 Product Components

The product mainly consists of a controller, therapeutic handle and footswitch.
The controller is comprised of upper and lower case, power supply, main board and touch screen. Accessories include power cable, stylus, handle stand, and aluminium alloy suitcase.
Replacement parts include silicone cap and therapeutic handle.
Therapeutic handle and footswitch are available as exchange components.

Products parts are identified as follows:



No.	Part Name
1	Controller
2	Display Screen
3	Frequency Adjustment Knob
4	Energy Adjustment Knob
5	Foot Switch
6	SD Card Slot
7	Air Intake and Fan
8	Therapeutic Handle
9	Air Outlet

No.	Part Name
10	Stylus
11	Power Switch
12	Fuse Wire
13	Power Socket
14	Handle Socket
15	Footswitch Socket
16	Product Nameplate
17	Silicone cap

4 Product Main Features

The main product features of TensCare Shockwave are as follows:

- The ergonomic design makes set-up and operation simple;
- 7-inch colour LCD touch screen design in Chinese and English is intuitive and clear;
- Mains powered, to ensure instant shock output effect;
- Adjustable energy and frequency.
- Range of professional probes;
- 7 adjustable pre-set Programs;
- Designed to be easily portable.

5 Environmental Requirements

Working power supply: 100-240VAC，frequency: 50/60Hz

Environmental requirements

Item	Temperature requirement	Humidity requirement	Atmospheric pressure
Operating environment	20℃-32℃	25%-75%RH	700hPa-1060hPa
Storage/ Transport environment	0℃-40℃	10%-93%RH	700hPa-1060hPa

6 Technical Description

Pulse energy levels:	10–185 mJ (at the applicator), adjustable in 10 mJ increments
	- at 22 Hz max. energy per pulse 90 mJ
	- at 16 Hz max. energy per pulse 120 mJ
	- at 10 Hz max. energy per pulse 185 mJ；
Output tolerance	±40mJ,
CV	±5%
Working frequency	1-22 Hz, adjustable in 1 Hz increments
Work pattern (Mode)	4 continuous capture modes 3 burst modes（shots /4/8/12 pulses）
Reference operating version	7 pre-set treatment Programs, with adjustable parameters.
Protocols	More than 30 illustrated pre-set treatment recommendations
Control functions	Touch screen controls
•	Rotary knobs control energy and frequency;
•	Multi-directional footswitch coordinates with therapeutic handle operation.
Product dimensions	290×240×130mm（length/width/height）
Product weight	2.22kg (not including therapeutic handle and footswitch)
Therapeutic handle	The therapeutic handle design conforms to human engineering, combines anodized aluminium shell with fan cooling, produces electromagnetic force drive projectile working by means of coil electrical over. Handle dimensions are 23cm length, 5cm diameter (maximum);
Minimum service life of therapeutic handle	4,000,000 pulses;
Maintenance	No maintenance required apart from daily cleaning. We recommend cleaning with medicinal alcohol;
Applicator head	Available in 3 sizes: 6/15/25mm (diameter);
Minimum service life of each applicator head	300,000 pulses
Power consumption	100/240VAC 50/60 Hz，300VA
Fuse (wire fuse) specification	250V/10A
Therapeutic head temperature	The external temperature of therapeutic head of the TensCare Shockwave is not greater than 48℃.
Electrical safety classification	Type BF applied parts 

7 Indications and Contraindications

7.1 Indications

7.1.1 Physiotherapy

- Radial and Ulnar Epicondylitis
- Shoulder Tendinitis
- Calcific Tendinitis of the Shoulder
- Patellar Tendinitis
- Patellar Tendinopathy
- Achillodynia
- Plantar Fasciitis
- Heel Spurs
- Myofascial Trigger Point Therapy – Nick; Back & Muscular pain)
- Trochanteric Bursitis
- Periostitis / Shin Splints
- Thumb Basal Joint Arthritis / Rhizarthrosis
- Status Post Muscular Injury

7.1.2 Aesthetics

- Cellulite
- Connective Tissue / Skin Tightening
- Stretchmarks
- In combination with Cryolipolyse, Radiofrequency or Ultrasonic Treatment

7.1.3 Erectile Dysfunction

7.2 Contraindications

Absolute Contraindications:

- Under 18 years of age (however, can be effective with Osgood-Schlatter Disease)
- Shockwave should not be applied to the surface area of the lungs and heart
- Shockwave should not be applied to major superficial blood vessels or nerves
- Heart or circulatory problems (including Pacemaker, High BP, Thrombosis, Diabetic Neuropathy)
- Implanted devices or hormones
- Pregnancy

Relative Contraindications:

- Infectious non-unions & skin infections or open wounds
- Blood thinning medications/coagulation disorders
- Synovial fluid leakage
- Joint replacements
- Cancer in or around the treatment area
- Corticosteroid injections within one month prior to the start of Shockwave Therapy

Care is required for patients with:

- Impaired sensitivity
- Severe autonomic disorders
- Or those under the influence of drugs and/or alcohol

As the excess strain on the circulatory system and inadequate responses to treatment cannot be excluded

8 Side Effects

Treatment with the TensCare Shockwave Device can occasionally cause irritation, petechiae, bruising, swelling or pain.

9 Warnings and Attention Before Use

9.1 Warnings

- Users of the TensCare Shockwave Therapy Device must be trained in how to use the system properly and have the appropriate skills.
- Any treatment instructions regarding treatment location, duration and strength require medical knowledge, and should only be given by authorised physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.
- The therapeutic apparatus cannot be used with HF apparatus to avoid burns or damaged apparatus.
- The patient should not be left unattended during therapy.
- Patients currently under treatment that reduces or alters blood clotting or extends the duration for blood to clot (such as aspirin treatments) should consult their therapist about the potential risks associated with this treatment. The application of radial shockwaves my result in increased haemorrhages and bruising.
- Shockwaves scatter in air pockets and create reflections, which may have negative effect. Therefore, treatment should never be applied over the lungs or gastrointestinal area.
- Applying shockwave close to the chest will increase the risk of heart fibrillation
- The Shockwave Therapy device will produce a small amount of heat when in use. The safe working temperature of the unit is set to 68˚C, as such, the therapeutic head's temperature will reach a maximum of 68˚C. Ensure the patient's condition is monitored, to avoid any adverse effects from the additional heat produced during use.
- DO NOT modify this equipment without authorization from the manufacturer. As unauthorised modifications can result in an increased risk of injury.

9.2 Attention Before Use

- Prior to using the device on a patient, the user should become acquainted with the operating instructions and individual treatment methods as well as the indications/contraindications, warnings and other instructions. Additional sources of information about types of therapy should be consulted.
- Before use, check that the device is connected with an earthed plug. The device may

only be operated with the supplied power cord. The power cord must be protected against mechanical stress.

- If the used simultaneously with HF apparatus, damage to the device or burns to the patient may result.
- If used in close proximity (1 meter) to short wave or microwave therapeutic apparatus, the output of the device may be unstable.
- Operating the device near strong electromagnetic fields (e.g. X-rays, diathermy devices or scanners) may interfere with the operation of the device. Please keep a safe distance of several meters.
- The TensCare Shockwave Therapy device is not suitable for operation in areas containing explosive, flammable, or combustible materials.
- Only accessories from Shenzhen Oceanus Medical Device Co., Ltd. and/or TensCare Ltd should be used.
- To prevent overheating of the therapeutic handle, ensure the air outlets on the top and bottom of the handle are not covered by the user's hand or anything else.
- The therapeutic handle should not be operated for extending continuous periods. Following a maximum of 6000 shots, allow for a 15-minute break. This will ensure that detrimental overheating does not occur.
- To avoid the risk of electric shock, the unit must be disconnected from the mains by unplugging the power supply before performing any maintenance or cleaning.

For further information please refer to the Safety Precautions on Page 25.

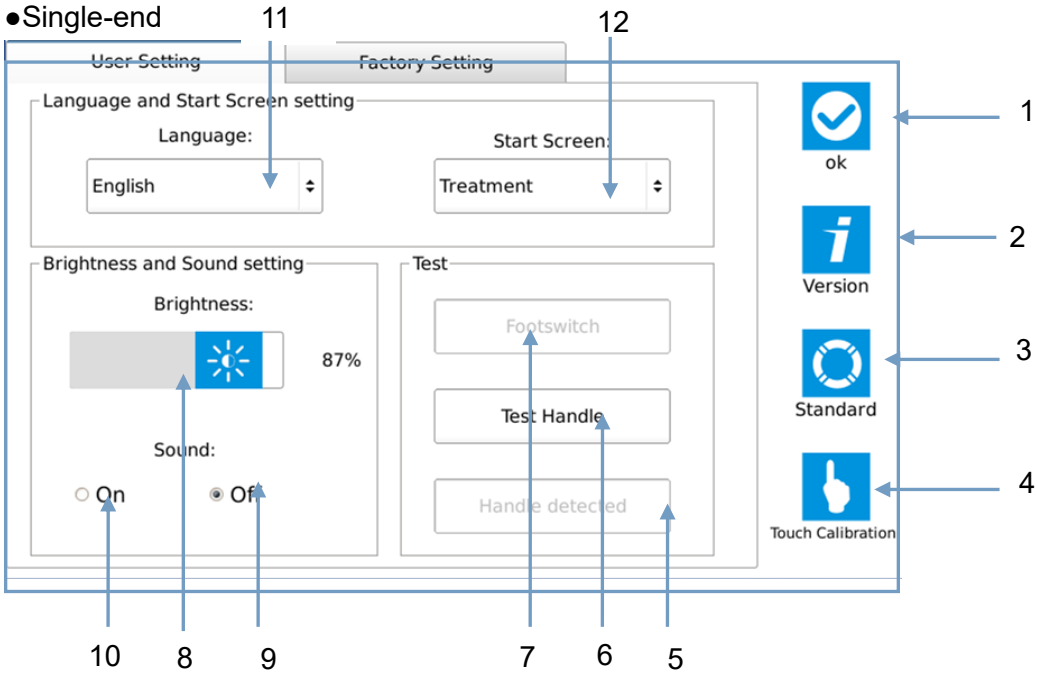
10 Instructions for Use

Read this manual carefully before using the product

10.1 Home Menu

1 **Setting** button: click on this icon to go to the Settings menu
2 **Start** button: click on this icon to go to the Treatment/Programme menu

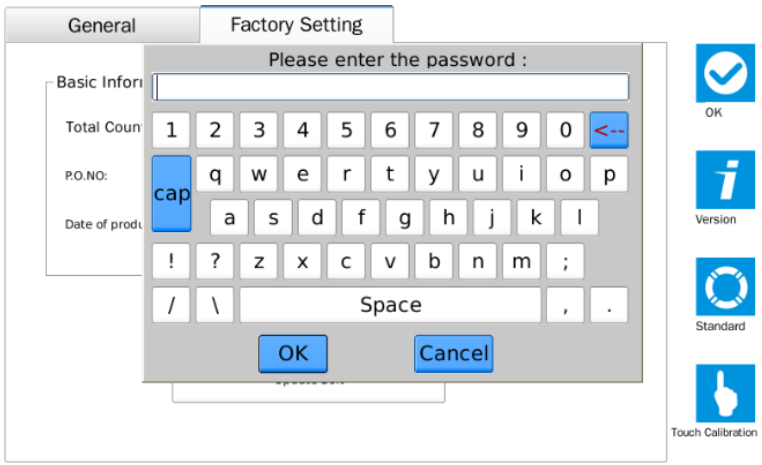
10.2 Settings Menu

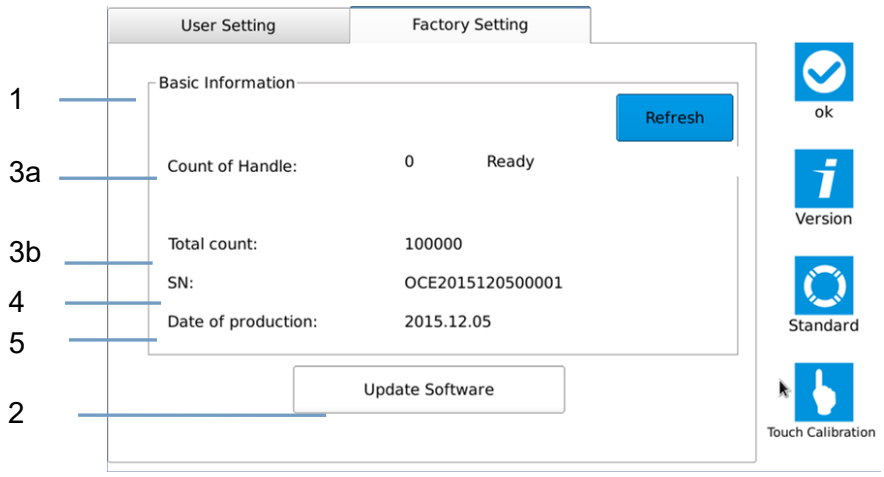


1. **“Confirm”** button: click on this icon to return to Home menu.
2. **“Versions**” button: click on this icon to display a Version dialog box showing product software information.
3. **“Standard”** button: click on this icon to return general settings to default.
4. **“Touch calibration”** button: click on this icon to open a Touch Screen Calibration dialog box, which will indicate whether you need to calibrate the touch screen.
5. **Handle status bar**: if the connection state is not normal, and the state bar turns blue, it means that the handle is not found.
6. **“Test handle”** button: click on this icon, the handle will fire once. This is used to test whether the handle is working normally.

7. **Footswitch status bar**: this displays the working state of the footswitch. When you operate the footswitch, the status bar will turn blue if it is operating correctly.
8. **Brightness display bar.** Touch either side of bar to increase or decrease brightness.
9. **Sound Off button:** click on this icon, the voice will stop.
10. **Sound ON button:** click on this icon, the voice will start.
11. **Start-up page selection**. Click on this to open a drop-down menu. Select the Mode that you wish to use as your start-up page.
    Choices are: Program/Therapy/Memory/Treatment
12. **Language drop-down menu:** click on this button to select your desired language.

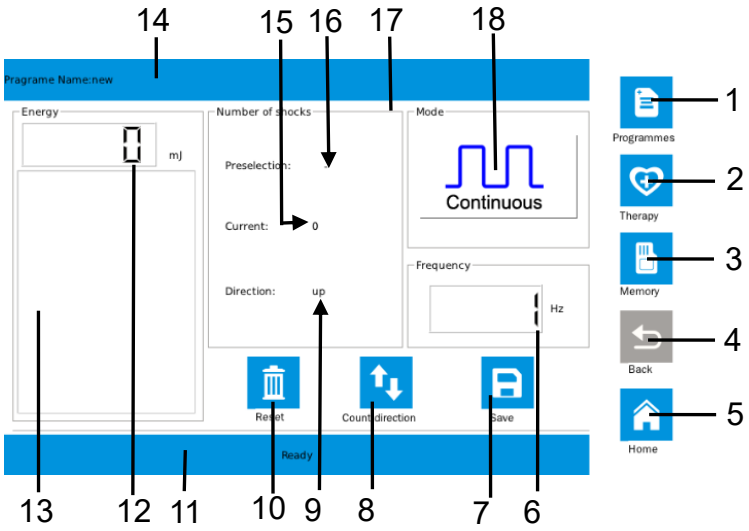
10.3 Factory Settings Menu





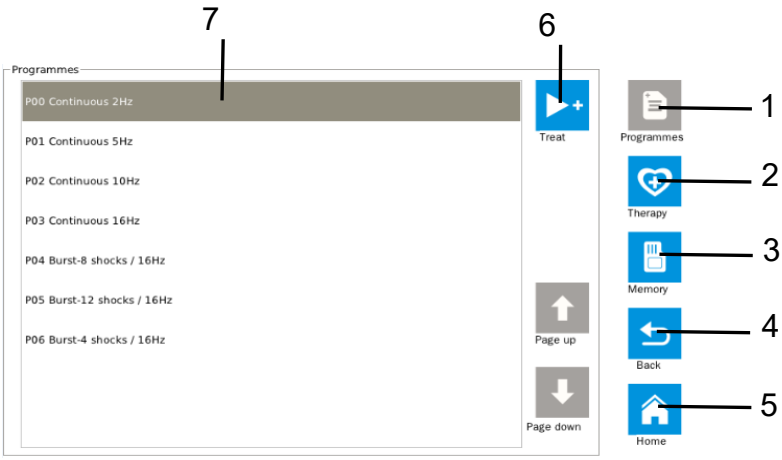
1 Basic information box: Displays some key information about this product.
2 "Update software" button, is used for updating software, usually for use by the manufacturer.
3a Count of Handle
3b Total Count, summarizing the working grand total data of the product.
4 SN number, the product serial number
5 Date of manufacture

10.4 Treatment Menu



1 **"Programs":** click on this icon to go to Programs menu.
2 **"Therapy":** click on this icon to go to the Treatment Recommendations menu.
3 **"Memory":** click on this icon to go to the Memory menu.
4 **"Back"** : click on this icon to go to the Treat menu.
5 **"Home"**: click on this icon, the display screen will jump to the Start menu.
6 **Frequency display bar:** as you adjust the knob on the front panel the displayed frequency value will change.
7 **"Save"**: click on this icon to save the current treatment settings.
8 **"Count direction"**: click on this icon to set the count value displayed to maximum or minimum.
9 **Count direction** display.
10 **"Reset"** button: click on this icon. When the count direction displays "up", the value will reset to 0; When the count direction is down it will reset to Set value.
12 **Digital Energy display**: as you adjust the knob on the front panel the digital display of current energy value will change. Device will not operate unless this is set to more than zero.
13 **Energy display bar:** as you adjust the knob on the front panel the analogue display of energy will change.
14 **Treatment programme name:** identifies currently selected treatment programme.
15 **Current count value:** Records the current number of strokes of the handle. If the number of strokes equal to the setting value, the handle will stop working, and the current count value will flash continuously.
16 **Preselection:** the maximum value is 10,000 strokes.
17 Click on this to open a dialog box to set the treatment energy level.
You can adjust the Number of Shocks in steps of 100 or 1000. See section 10.1
18 **Working mode:** Click on this box to open a dialog box to choose a working mode from choice of: Continuous/ Burst 4 pulse/ Burst 8 pulse/ Burst 12 pulse.

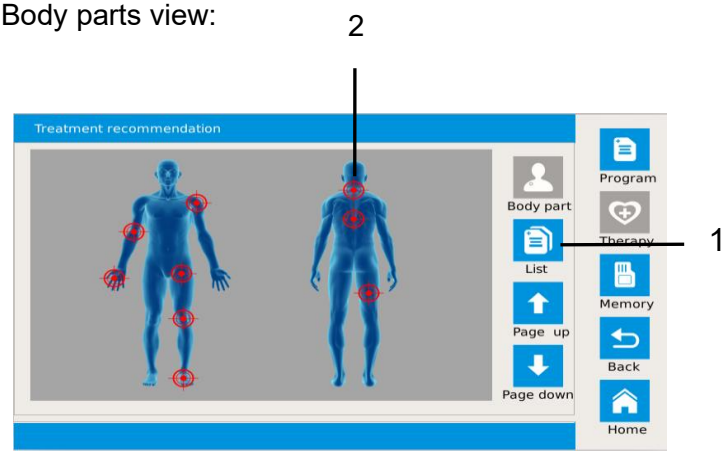
10.5 Programs Menu



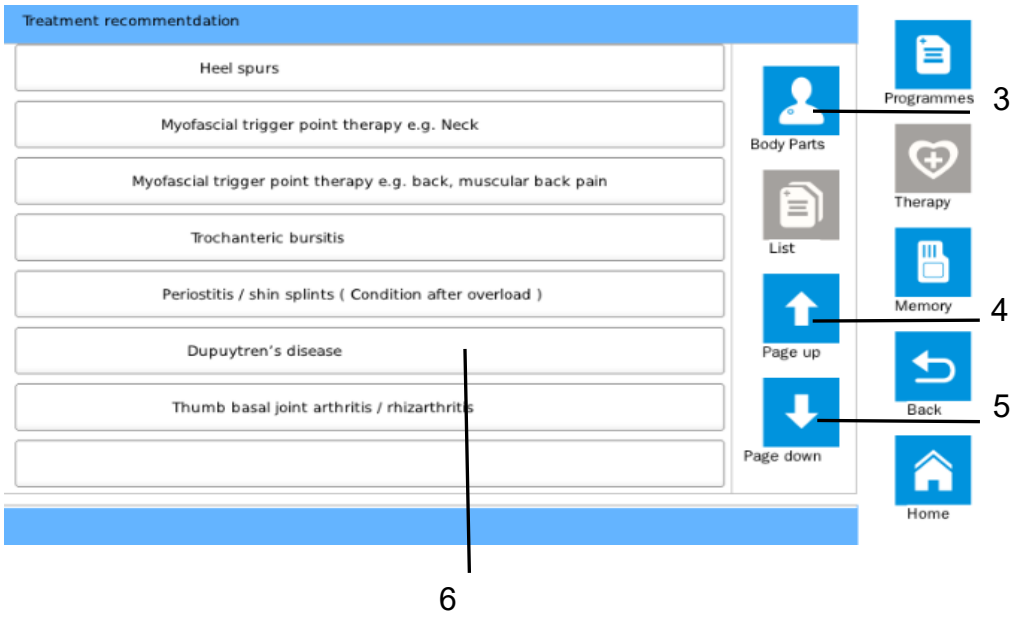
1 **“Programs”**: Click on this button to go to the Program menu. After entering the program menu, this button will automatically become grey and will not operate. If you select another menu in this column, the button will re-activate. The following items work in the same way.
2 **“Therapy”:** click on this button to go to the Treatment Recommendation menu.
3 “**Memory”** button: click on this button to go to the Memory menu.
4 **“Back”** button: click on this button to go to the Treatment menu.
5 **“Home**” button: click on this button to go to the Start menu.
6 **“Treat”** button: click on this button to go to the Treatment menu to adjust Setting value, Frequency, and Mode.
7 **Treatment Program selection menu**: available Treatment programs are listed. Click on the one you wish to use

10.6 Therapy Menu

Body parts view:



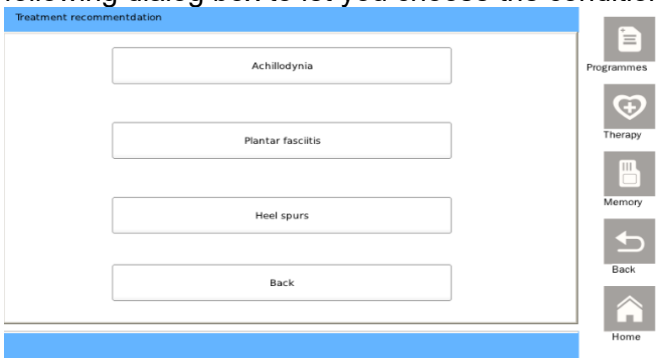
List view:



1 **"List"** : press this button to display a list of treatment recommendations.

Heel spurs	Radial & Ulnar Epicondylitis
Myofascial Trigger Point Therapy - Neck	Tendinitis of the shoulder
Myofascial Trigger Point Therapy - Back	Calcific Tendinitis of the shoulder
Trochanteric bursitis	Status post muscular injury
Periostitis/shin splints	Patellar Tendinitis
Dupuytren's disease	Achillodynia
Thumb basal joint arthritis	Plantar Fasciitis
Cellulite Stage I	In combination with Cryolipolyse
Cellulite Stage II	In combination with Radiofrequency
Cellulite Stage III	In combination with Ultrasonic
Connective Tissue / Skin Tightening	Erectile Dysfunction
Stretchmarks	

2 **Treatment Recommendation**: press this button to go to a menu displaying a detailed description of this treatment recommendation.
Since a region of the body may affected by several conditions, the screen will open the following dialog box to let you choose the condition to treat:



Click on the desired condition and the a menu will open. This menu will display the detailed description of this treatment recommendation. Press the "Return" button to close this dialog box.

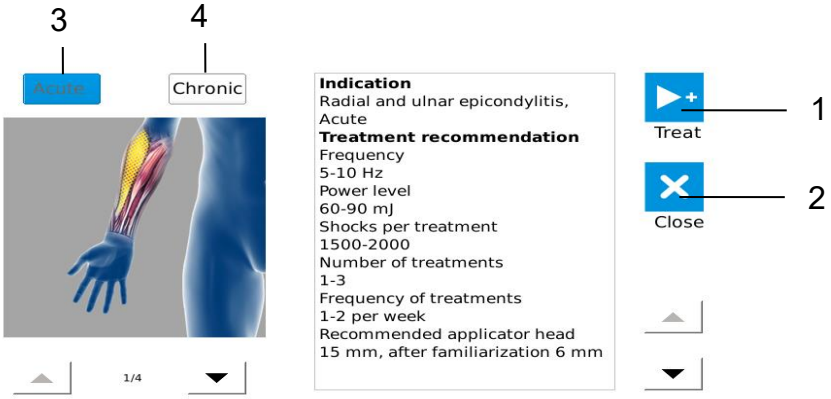
3 "**Body parts"**: Press this button to display a picture of the part of the body to be treated.

4 **"Previous page"**: Press this button to jump to the first page in the list.

5 **"Next page"**: Press this button to jump to the last page in the list.

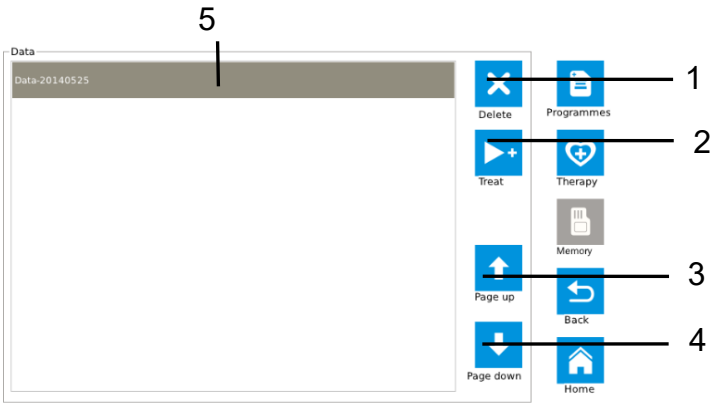
6 **Body parts/conditions list**: Select an item to jump to a menu which displays a detailed description of this treatment recommendation.

10.7 Treatment Description Menu



1. **“Treat”:** Press this button to open the treatment menu. Frequency, energy, setting value these will also be transfer to the working menu.
2. **“Close”:** Press this button to close the dialog box.
3. “**Acute disease”:** If you are a patient with acute disease, you can click on this button; this menu will give a particular treatment suggestion for you. If the button is blue this indicates that the button has been already selected.
4. “**Chronic disease”:** if you are a patient with chronic disease, you can click on this button; this menu will give a treatment suggestion for you. If the button is blue this indicates that the button has been already selected.

10.8 Memory Menu

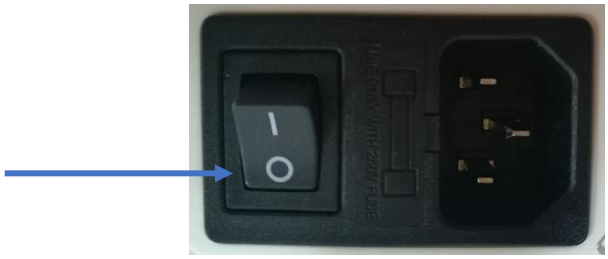


1 **“Delete”:** Press this button to delete the selected item.
2 **“Treat”:** Press this button to go to the Treatment menu, the data you saved will be selected and that will be read and transmitted to the working menu, including energy, setting value, mode and frequency.
3 **“Page Up”:** Press this button to go to the top of the list.
4 **“Page Down”:** Press this button to go to the end of the list.
5 **Option Item:** Your personalised treatment programs are stored in a list. Touch one to select it.

11 Using the Device

11.1 Setting Up

11.1.1 **Before** connecting the mains cable**, check** to ensure that **the** power **switch is off**



11.1.2 Connecting the handle and foot pedal connect

Line up the red dot on the plug with the red square on the socket.
Plugs are not interchangeable- it is not possible to insert them incorrectly

Controller unit:

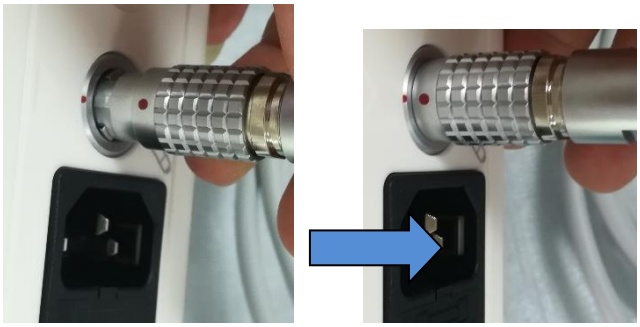
Identification area of handle's red squares

Identification area of foot pedal's red squares

Locking plug of handle and foot switch

Identification area of red dot

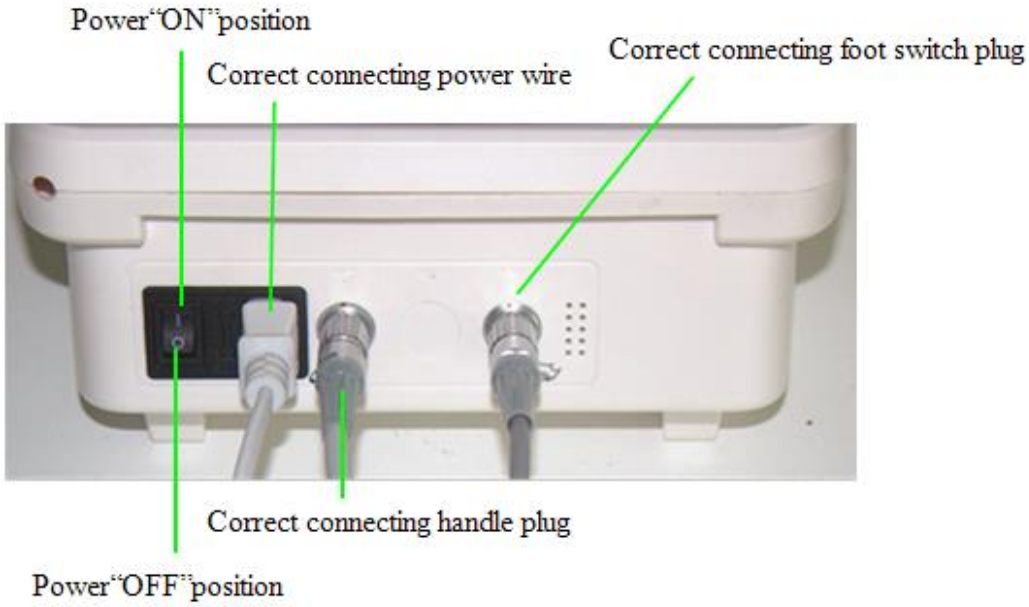
Plug/socket Alignment



Note: red dot of handle plug must be aimed at red dot of the device to connect.

11.2 Switching ON

After plugging in the power wire, footswitch and therapeutic handle, move the power switch to the “ON” position, the device will start booting. It takes about 17 seconds to open the Start menu.



11.3 Shutdown

Move the power switch to the "off" position. The device will enter power down mode.

⚠ **Do not remove the power lead until the power switch is OFF and the device is completely shut down (Display off).**

⚠ **Do not unplug accessories until the device is completely shut down (Display off).**

***** Unplugging while the device is active could result in damage *****

11.4 Normal Operation

Routine checks before starting operation.

Click on the Settings icon to enter the general settings menu, check the sound and brightness bar. Is the sound in the “open” mode? Is the display brightness suitable for operator? Adjust as required.

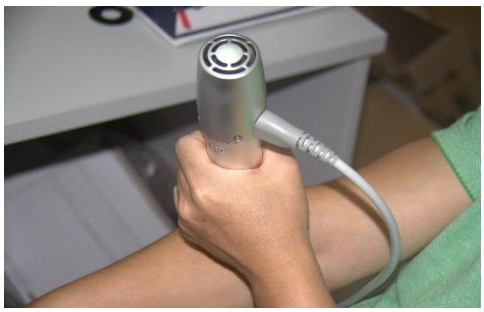
① Handle connection examination
The handle status bar is mainly used to displaying the connection state of handle, normal display is white, “handle not found” is shown in blue. If this shows, please check handle plug connection

② Footswitch and handle test
Click on the handle test button, frame colour will become dark, if the handle works once (heard as a “snap”), then the handle is in a normal working condition. If there is no sound, the handle is not working correctly. Depress the footswitch, footswitch test bar becomes blue, indicating that the footswitch is operating normally. If the colour does not change check the plug connection.

③ Into the Treatment menu
Click on the "Confirm" button to return to the Home menu, then click on the "Start" button to enter your selected start up menu.

④ Start work
If the energy value is 0, you need to adjust the energy knob on the left side of the panel to change its value, while clicking Count dialog box to set the number of treatments which you want and save it. As shown below:

Then bring the therapeutic head of the handle to the site in need of treatment, and depress the footswitch to begin treatment, as shown here:




⑤ User-defined choice
Before starting work, you can also change the settings value, frequency and mode to choose your favourite way for treatment. For detailed operation, please refer to the 7.2 Treatment settings menu description.

11.5 Menu Switching

There are 3 ways to change menus:

① Jump directly between menus
Click on the button associated with the menu. For example: in the treatment screen, click the "Programme" button to jump directly to the Programme menu.

② Jump from the beginning menu to the desired menu.
You can set the value of booting screen menu as the desired menu in the settings menu. For example, set the value of the booting screen is "Memory"; click on the "Start" button and display will go directly to the Memory menu. Of course, if do not make the above selection, clicking on the "Start" button will take you to the Home menu as in ① above.

③ Fixed direction Jump
You can change from the Settings menu to the other menus by pressing the "Confirm" button to return to the Home screen, and then selecting the next menu.
You can change from the Treatment description menu by pressing the "Cancel" button to return to the therapy menu, then go to the treatment menu by pressing the "Treatment" button.

11.6 Saving and Reading Data

You can only save data when you are in the Treatment menu.

1. Click on the "Save" button in the Working menu, the screen will pop up a dialog box in this dialog box. Enter a name for the data you want to save, and then click on "Save" and you will complete the preservation of data.
2. Go to the "Memory" menu. You can see the names of all the data you saved, select one you want to read out, click on the "treatment" button, the display screen will jump to the treatment menu, the energy, settings value, frequency, and mode will be transmitted to the treatment menu, now you can use them to work.

11.7 Using of the Programme Menu

1. In the Programme menu, select one you want, then click on the "treatment" button.
2. The display screen will go to the Treatment menu.
3. In the Treatment menu, if the energy value is 0, you must adjust the Energy knob to change its value, and then depress the footswitch.

11.8 View the Treatment Recommendations and Use for Treatment

1. Go to the Therapy menu.
2. Either select a button in the List view or click on Parts of the body.
    a. If a site has several conditions, the screen will open a dialog box that allows you to select one of them by clicking on the button.
3. After selecting the condition or treatment area, you will see a page with a detailed description of the treatment of selected conditions.
4. Finally, you can select the "Treat" button to jump to the Treatment Settings menu. Frequency, power, mode and setting values of these parameters will be passed to the Treatment menu.
5. The unit is now ready to begin treatment. Depress the footswitch to activate the handle.

12 Product Precautions for Use

12.1 Error Messages

- **Temp Error**

The temperature alarm appears that the current handle temperature exceeds the settings parameter of software, must be stopped until cooling fan stops running, and then starting up. The description of appeared position:

The picture is at the bottom of the treatment menu (handle work status bar).

- **Handle is not found**

The handle is not found. The alarm shows that the device cannot scan the handle. Pull out the handle plug, re-insert it and check whether you can easily pull out it. The message is shown on the screen in the same position as “Temp error”.

- **SD card+ not found**

NOTE- SD Card is used for software update only.
The occurrence of SD card is not found.
The alarm represents that the SD card is not inserted or is damaged.
If the card is in the slot but still has this problem, you can try rebooting the device.
If you cannot find the SD card after rebooting, it may mean this card is damaged.
It is recommended to replace it with another one to continue to use.
The message looks like this:

The message appears in the factory settings of Settings menu, and will only occur when upgrading the software.

- **New software cannot be found**

This alarm indicates that the software is not downloaded to the SD card or downloaded to an incorrect download path. Re-download the new software to the SD card. Images directory can solve this problem. Message is displayed in the same position as "NO SD-card found".

- **The service life of handle has expired**

This alarm indicates that the current life of the handle has expired.
You should replace with a new handle.
To avoid using a worn-out handle, the operator should check handle life regularly in use: Click the Settings button --- select Factory mode --- Check the total value. The message is shown on the screen in the same position as “Temp error”.

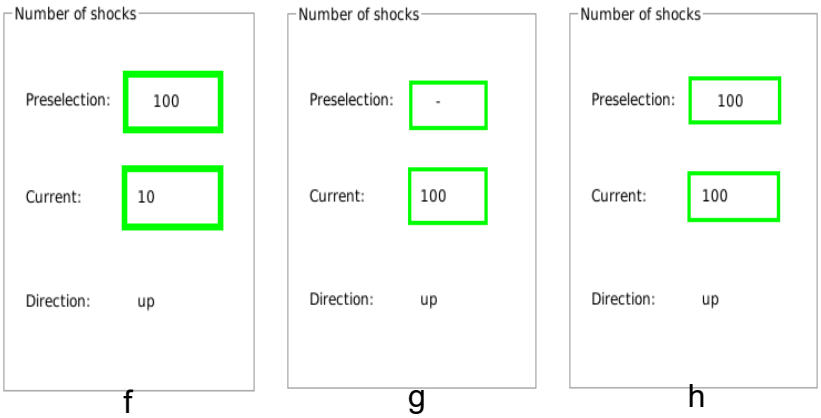
13 Operating Menu Icons

Icon	Introduction	Icon	Introduction	Icon	Introduction	Icon	Introduction
	Version information		Back to the previous level		Favourite treatment recommendations		Downward
	Save		Back to the Start menu		Treatment list		Settings
	Standard or default		Increase		Delete		Body parts
	Click and touch by hand		Decrease		Confirm		Up and down direction
	Memory management		Start up		Cancel		Selected work head 1
	Detailed programme description		Treatment		Upward		Selected work head 2

13.1 Explanation of Displayed Information

- **Working menu of count**

There are 3 situations in the working menu of count value; the following three pictures represent three cases:



f g h

f: The set value is 100, and the current count is 10, which means the current count before reaching 100, the handle can also be hit 90 times.

g: The set value displays "-" and indicates a value of 10,000, the current count displays 100, the handle can be worked until 9,900 of the current count is displayed.

h: The set value displays 100, and the current count displays 100, then the value of the count value will always blink. At this point the handle will not work, said that it has completed the designated. Release the footswitch, reset the data, or is cleared and then set the data.

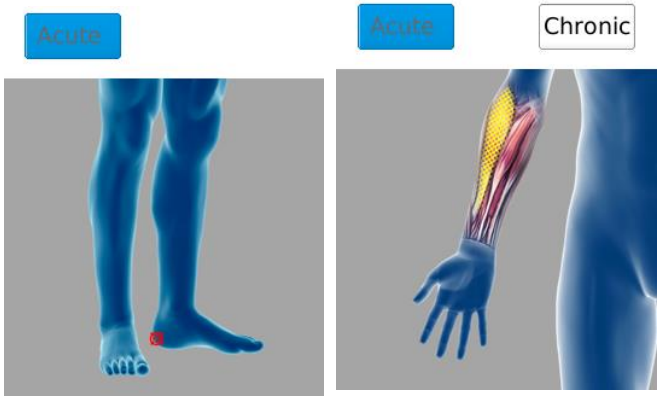
- **Count direction on the working menu**

If the value of the count direction is displayed as "up", the current count value will increase from zero to the set value. When it reaches the set value, the current count will flash, and the

handle will stop working.
If the value of the count direction is displayed as "down", the current count value from the set value will start decreasing until it is 0, when is 0, the current count will flash, and the handle will stop working.

- **Treatment description menu of button colours**

There are 3 colours on the treatment description menu of button colours: blue, grey and white. For example:



As shown in this background of the Acute menu icon is blue. The programme has defaulted to this treatment mode. If the background of this menu icon is grey that shows that this function cannot be used at the same time. If the background of the menu icon is white that shows that this function can be used to switch operation from the blue background icon.

- **Silk-screen labelling on case**

Silk-screen	Explanation	Silk-screen	Explanation
	Minus identification of frequency/energy adjusting knob on the TensCare Shockwave		Plus identification of frequency/energy adjusting knob on the TensCare Shockwave
	The Therapeutic Handle port label of TensCare Shockwave		Footswitch identification of footswitch on the TensCare Shockwave

14 Product Installation and Trouble Shooting

14.1 Product Installation

Please check that the power outlet has a good grounding wire before installing. It is strictly prohibited to use this machine without grounded power.
The machine requires installation away from water.
The instrument has its own embedded software, and the software has been installed at the factory. Machine installation does not require professionals at installation.

14.2 Common Trouble Shooting

Fault phenomenon:	Solution:
Unable to boot	Check whether the power wire has been properly connected, the connection is loose.
	Check the power switch whether is already selected in the "ON" position.
	Check whether the fuse has burned out and replace with the same specification as burned fuse.
	If still cannot boot after the above checks, please replace the power cable with one of the same specifications.
	Tip: After powering ON the device, you can see the logo information on the display screen at least 5~7 seconds
Touch screen inaccurate	Click on the "Touch Calibration" button on the Settings menu, and in once to recalibrate the touch screen.
Therapeutic handle does not work	If in the treatment menu, the therapeutic handle does not work after treading the footswitch, the solution is:
The therapeutic handle is not connected, or not operating.	You can see the blue state bar will show “therapeutic handle not found” at the bottom of working menu, check the connector to therapeutic handle connection. Unplug and reinstall. If the handle is still not found or the therapeutic handle has a problem, you may need to replace the handle.
Temperature	If the handle temperature is too high, the handle will not work. Blue status bar at the bottom of the working menu will show "temperature error", because the handle temperature exceeds the set temperature. Stop use until the fan automatically stops. Otherwise, the temperature is not the cause of the problem.
The energy on the working menu	In the working menu, if the energy is shown as "0", the handle cannot work. You must adjust the knob on the housing to change its value, and then depress the footswitch. If the handle can work, and the energy that is causing this problem, otherwise it is not.
The current count value on the working menu	In the working menu, if the current count keeps flashing, the handle also does not work. You can click the "Reset" button or change the setting value to solve this problem. Otherwise, it is not the cause of the problem.
Mode on the working menu	If you choose any mode other than “continuous” mode, the handle can only hit four times or 8 or 12 times after treading the footswitch. If you want the handle to continue firing, you must release the footswitch and press it again. Otherwise, it is not the reason.
Other reasons	If you have checked functions as described above and found no problems, please skip to the Settings menu and tread the footswitch and look at the colour of its information display bar to see whether turns it blue. If there is no change in colour, you will need to replace the footswitch.

15 Safety Precautions

■The purpose of warning signs and messages in the manual is to ensure that you use the product safely and properly, and to prevent harm to you and others.

■ Warning signs and messages, with their meanings are as follows:

Warning sign	Meaning
⚠ Contraindication for use	User error could result in death or serious injury
⚠ Warning	User error could possibly result in death or serious injury.
⚠ Attention	User error could possibly result in either personal injury or damage to the device

⚠ Contraindication	
●General factors: 1) Serious heart condition, arrhythmia and high blood pressure; 2) The patient with a cardiac pacemaker; 3) Chronic haemorrhagic disease or coagulation disorders of patient; 4) The use of immunosuppressants; 5) All kinds of cancer patients; 6) Patient with thrombosis; 7) Pregnant woman. 8) Growing children ●Local factors: 1) Patients with local infection and broken skin; 2) Acute injury of tendon and fascia; 3) Patients with synovial fluid leakage; 4) Specific parts in the brain/lung and spinal cord; 5) Atrophy and infectious non-unions; 6) Massive defective bone non-unions.	
⚠ Warning	
1 The therapeutic apparatus cannot be used with the HF apparatus to avoid burns or damaged apparatus 2 If the patient himself uses the therapeutic apparatus and HF apparatus at the same time, this may cause burns on massage plate of the device, it may also damage the device; If the device is used near (1 meter) short wave or microwave therapeutic apparatus, the output of device may become unstable. 3 It will increase a danger of heart fibrillation by using electrode close to the chest. 4 Do not modify this equipment without authorization of the manufacturer 5 Serious twist injury within 24 hours, prohibiting the use of treatment of shock wave. 6 The product will produce a certain amount of heat when used (when in the process of ultimate working the safe working temperature has a built-in 68C cut out and the therapeutic head's temperature will reach 68C). Please always pay attention to the patient's condition. 7 All accessories and replaceable parts of the products (silicone cap, therapeutic head/therapeutic handle and footswitch) are not interchangeable with other similar parts. To make any change you must	

contact the manufacturer to purchase correct spare parts. 8 When operating this product, the operators using the therapeutic handle to treat patients must be suitably qualified medical staff and must wear medical gloves.	
⚠ Precautions	
1) Before treatment, explain the sensation/feeling that the patient will experience during treatment, eliminating the patients' concerns and obtaining cooperation. 2) Before treatment, ask and check the skin of the treatment area(s) does not present with hypaesthesia, large scars or damage/infection. 3) Before treatment remove metal items from the area to be treated, such as wrist watch, jewellery, etc. 4) Please switch the power of the unit off when not in use. 5) The product cannot be used for treatment of the head/face area. 6) Please do not place the therapeutic head, without the silicone cover, in direct contact with the skin during treatment, as the metal therapeutic head will heat up during use. 7) The product will produce certain noise and heat during use, please be sure that the surroundings are suitable for use. 8) For safety reasons, the energy and frequency of the device cannot both be set to maximum at the same time. 9) The product will produce a low electromagnetic field during use, please keep away from a strong magnetic environment. 10) The device and therapeutic handle will wear in use. Long-term use of the handle can cause ballistic wear, which may wear out moving parts and cause an internal short circuit. The devices components will age in long term use. 11) Do not put weight on the device. Display screen may be broken if the device is dropped. The device does not receive any data input when in use. Damage could cause unintended operation during treatment which might cause harm to patients. 12) When connecting the device, the connector of work handle and the connector of footswitch are different (one is 2PIN, one/two are 10PIN), there will be no fault phenomena; the plug has a locking mechanism and cannot detach in use. 13) Please use the stylus provided when operating the touch screen. Do not click on the touch screen with any other sharp object. 14) If the device is not functioning correctly, and the customer cannot handle by themselves, please contact our after-sales service. It is not permitted to take open the case or modify the software- any resulting damage will be borne by the customers themselves.	

16 Product Maintenance and Care

Energy conservation	After treatment, please shutdown the power. This will, save the energy and protect the device.
Cleaning	Clean the controller case with a clean cloth and a 75% alcohol solution or warm water and soap. The interior does not require cleaning. At the same time clean the surface of the coupling with a paper or cloth. Clean or use a new silicone cap for each patient to prevent cross contamination. Please refer to "Cleaning Silicone Cap" section below OR use 75% medicinal alcohol solution to clean the surface of silicone caps between patients.
Cleaning Silicone Cap	1. Silicon Cap – Cleaning, manually: • Lukewarm tap/ drinking water • Container • Small Brush, e.g. medium hard toothbrush • Any alcohol cleaning product that is safe to use on plastic (e.g. cleaner for medical devices or soap and water) Remove the silicon protective cap from the applicator head before cleaning. Place the silicon cap into the container with the lukewarm water and cleaner solution. Clean the inner and outer surfaces of the protective cap by using a brush. Rinse the protection cap under clean running water before proceeding to step 2 (disinfection). 2. Silicon Cap -- Disinfection, manually: • Container • Commercially available alcohol disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties or wipes. Place the silicon protective cap into the container with the disinfectant ensuring that both the inner and outer surfaces of the cap are submerged. Leave the protective cape in the solution for the amount of time recommended by the manufacturer of the disinfection agent. Alternatively, when using disinfectant wipes ensure all inner and outer surfaces of the cap are wiped down thoroughly. Finally, rinse the protection cap under clean running water It is recommended that disinfection be completed once a week at a minimum. Additional disinfection may be required if there is any indication of contamination. Always perform cleaning prior to disinfection.
Cleaning Applicator head / handle	2. Applicator head / handle -- Cleaning, manually: • Disposable wipes • Any alcohol cleaning product (or warm water and soap) that is safe to use on plastic (e.g. cleaner for medical devices or soap and water) Handle must be cleaned when covered in visible contaminations or excess coupling gel lubricants. Remove the silicon protective cap from the applicator head before cleaning. The handle and the surface of the coupling can be cleaned with the commercially available alcohol cleaning product. Wipe the surface until the contamination is

	removed, using a soft damp cloth according to the specifications of the manufacturer of the cleaning agent.
Consumables	Accessories and replaceable parts of the product are not standard commodity parts. If you need to replace them, contact the manufacturer to buy the correct replacement parts.
Coupling Gel	Use a coupling gel during treatment, - medical coupling gel used for ultrasonic transducers is suitable.
	Caution: When using lubricants, the silicone cap must be placed over the applicator head in order to avoid contamination. If the device is used without the cap, lubricant may enter the interior of the applicator head and the handpiece, which can lead to permanent contamination and malfunction.
Calibration	The basic operation of the product is by means of touch screen, after long term operation the touch sensitivity may be impaired. You can recalibrate it with the touch calibration function in the Settings menu, and then continue to use.
Service life	The minimum service life of the complete machine is 4,000,000 times (calculation according to the number of strokes)
	The minimum service life of each therapeutic head is 300,000 times (calculation according to the number of strokes)
Scrap processing - WEEE	When the product has been taken out of use it should not be thrown away with general waste. Please comply with local Waste Electrical and Electronic Recycling regulations. In EU you may return items to be replaced to TensCare Ltd for recycling.

17 EMC Declarations

1. This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4. Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5. ⚠ Warning ⚠

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the AMBULATORY TensCare Shockwave as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the TensCare Shockwave.

Guidance and manufacture's declaration – electromagnetic emission		
The K-SHOCKWAVE TensCare Shockwave is intended for use in the electromagnetic environment specified below. The customer of the user of the K-SHOCKWAVE TensCare Shockwave should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions EN 55011	Group 1	The K-SHOCKWAVE TensCare Shockwave use 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 emission EN 55011	Class A	The K-SHOCKWAVE TensCare Shockwave is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity

The K-SHOCKWAVE TensCare Shockwave is intended for use in the electromagnetic environment specified below. The customer or the user of K-SHOCKWAVE TensCare Shockwave should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the K-SHOCKWAVE TensCare Shockwave requires continued operation during power mains interruptions, it is recommended that the K-SHOCKWAVE TensCare Shockwave be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The K-SHOCKWAVE TensCare Shockwave *is* intended for use in the electromagnetic environment specified below. The customer or the user of K-SHOCKWAVE TensCare Shockwave should assure that it is used in such an environment.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	Portableand mobile RF communications equipment should be used no closer to any part of the K-SHOCKWAVE TensCare Shockwave, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ z to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ MHz to 2.5 GHz Wh naximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] 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 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength 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 K-SHOCKWAVE TensCare Shockwave is used exceeds the applicable RF compliance level above, the K-SHOCKWAVE TensCare Shockwave should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the K-SHOCKWAVE TensCare Shockwave

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the K-SHOCKWAVE TensCare Shockwave.			
The K-SHOCKWAVE TensCare Shockwave *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the K-SHOCKWAVE TensCare Shockwave can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the K-SHOCKWAVE TensCare Shockwave as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
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.			

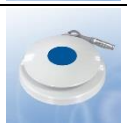
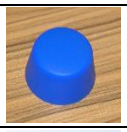
18Symbols Used

Label	Explanation	Label	Explanation
SN	Serial number		This symbol is used to direct the user to refer to documentation for additional information regarding t he system use or description.
	The name and address of the manufacturer		Keep dry
	Date of manufacture	CE 0120	CE identification + noticed code
	Contact its local authorities to d etermine the proper method of disposal of potentially bio hazar dous parts and accessories.		Anti-electromagnetic radiation
	Type BF anti-shake	EC REP	The name and address of the EU representative
	Fragile		

19 Applicable Standards

The product conforms to the following standards and laws:
EN 60601-1：2006/A1:2013 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
EN 60601-1-2：2007 /AC：2010 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

20 Accessories and Spare Parts

No.	Object	Material code	Quantity	Picture
01	Controller	OCE-ESWT-002-01	1	
02	Therapeutic handle	X-TCE101Z	1	
03	Footswitch	X-TCE20102	1	
04	Therapeutic head	X-TCE101Z-07 X-TCE101Z-08 X-TCE101Z-09	6MM 15MM 25MM	
05	Power line	OCE00102040401	1	
06	Handle pedestal	X-TCE101Z-04	1	
07	Handwriting pen	X-TCE10405	1	
08	Silicone cap	X-TCE101Z-06	10	
09	Aluminium alloy suitcase	X-TCE40101	1	
10	Product manual	OCE00103040402	1	Omit

21 Guarantee Card

Customer name: _____ Contact number:

Address:

Product name: _____ Product model:

Date of purchase: _____ year _____ month _____ day

Warranty Terms and Conditions:

1. First of all, thank you for choosing our products. For your convenience, please read these terms carefully.
2. The card is the warranty certificate, user is responsible for its safe keeping, if lost, it will not be returned.
3. The controller is covered by a one-year free warranty. If the controller goes wrong within a year, the product can be sent to the manufacturer who will repair free of charge, relying on this card. For all other parts please contact the manufacturer to purchase a replacement.
4. The Company does not assume warranty obligations if the controller failure is caused by man-made accidents, misuse, abuse or irresistible natural factors,
5. Before controller maintenance, please back up your data yourself, the Company has no obligation to you to back up your data. If data is lost in the process of maintenance, the company does not undertake any responsibility.
6. The company accepts no responsibility for damage resulting from unauthorized component change or disassembly.
7. Any other issues shall be negotiated between the parties, but the final interpretation shall lie with the Company.

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