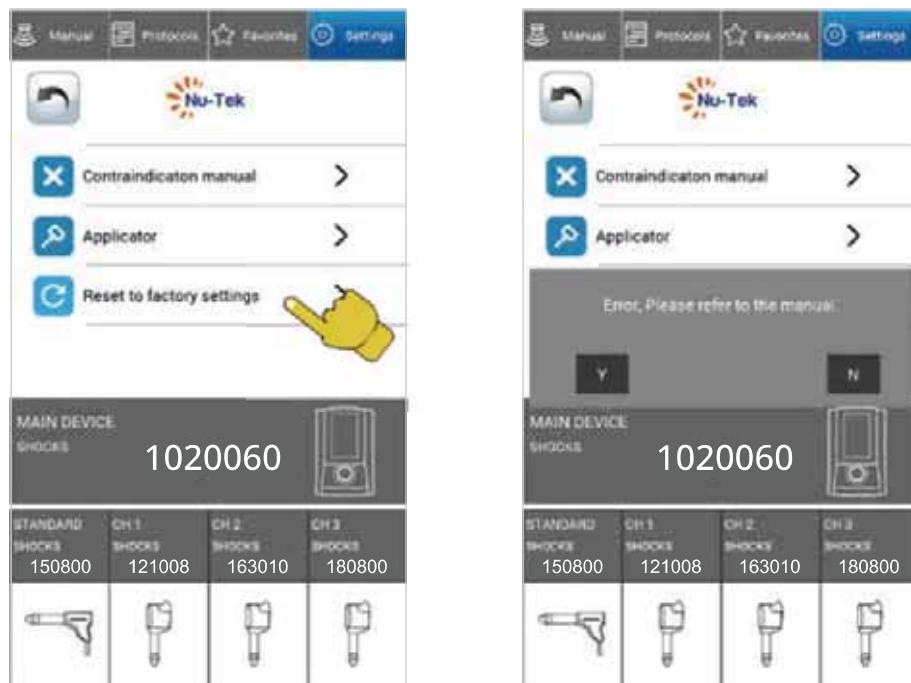


## Reset to factory settings:

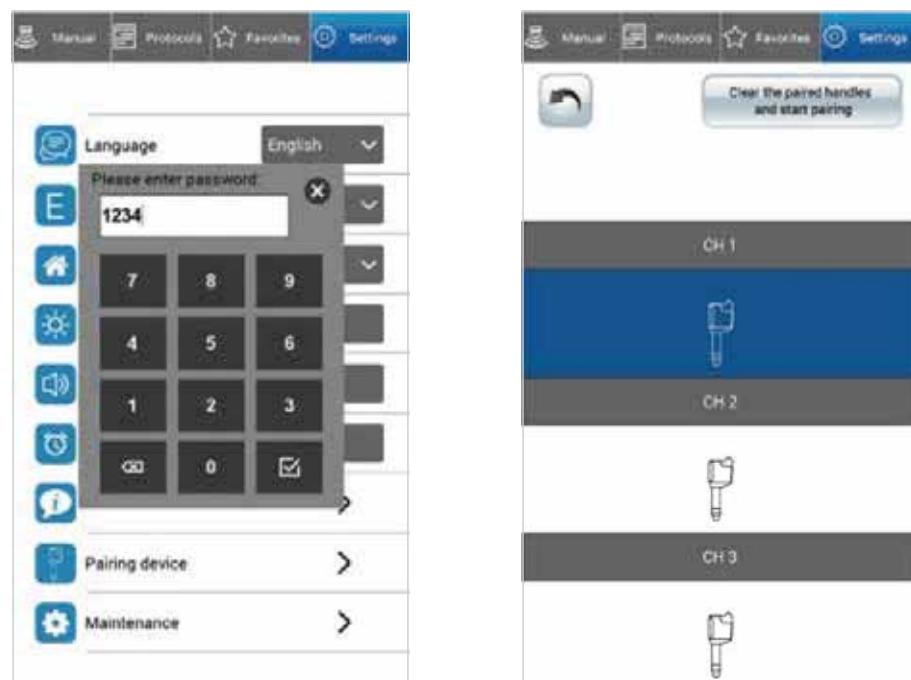
Reset to factory settings button is used to delete saved favorite programs and reset all settings parameters.



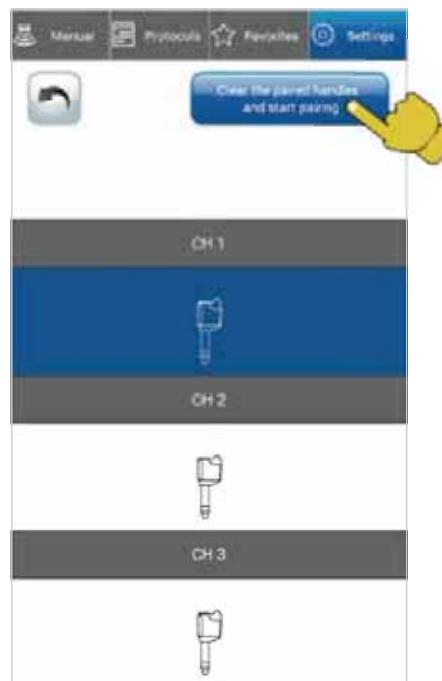
## Pairing device

Please turn off the wireless handpiece before entering the Pairing Interface.

Press the Pairing device Button, click and enter password "1234" to enter the Pairing Interface.



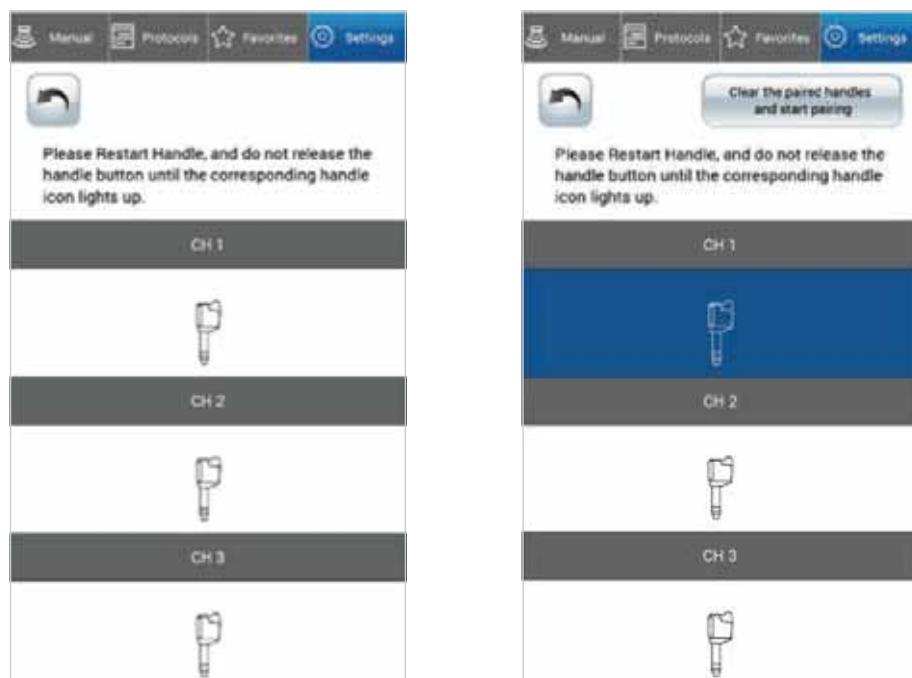
First, delete the existing pairing information by clicking the button Clear the paired handles and start pairing.

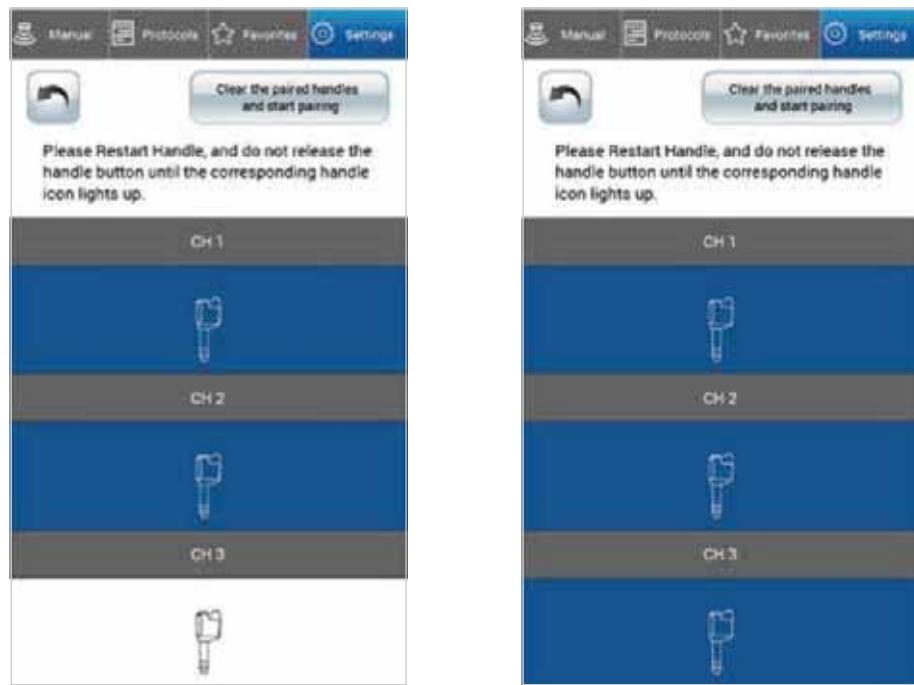


Second , Press and hold the "POWER Button" of wireless handpiece until the corresponding wireless handpiece icon in this screen lights up.

A total of 3 wireless handpiece can be paired. Please pair the wireless handpiece one by one until the pairing is complete .

NOTE: In this screen, SW3200 2 in 1 only has one wireless handpiece icon.





The main device prompt tone is played when the pair is successful.

## **⚠️ CAUTION**

- Release the "POWER Button" of wireless handpiece until the wireless handpiece icon turns blue. Otherwise, pairing will fail. If pairing fails, please turn off the wireless handpiece, exit pairing mode on the device and repeat the pairing process.
- If you want to pair more than one wireless handpiece, complete all the necessary pairing processes in the same pairing session.

## Maintenance:

The software can be upgraded via USB flash drive.

Before upgrade the software, please contact your dealer or manufacturer.



## 5.3 Manual Therapy

### Enter to Manual Therapy

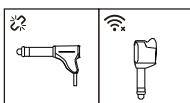
Press manual button to enter Manual therapy treatment interface.



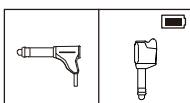
Before setting the parameters, please make sure the handpiece is connected.

#### Handpiece state icons:

Disconnected: Handpiece not connected

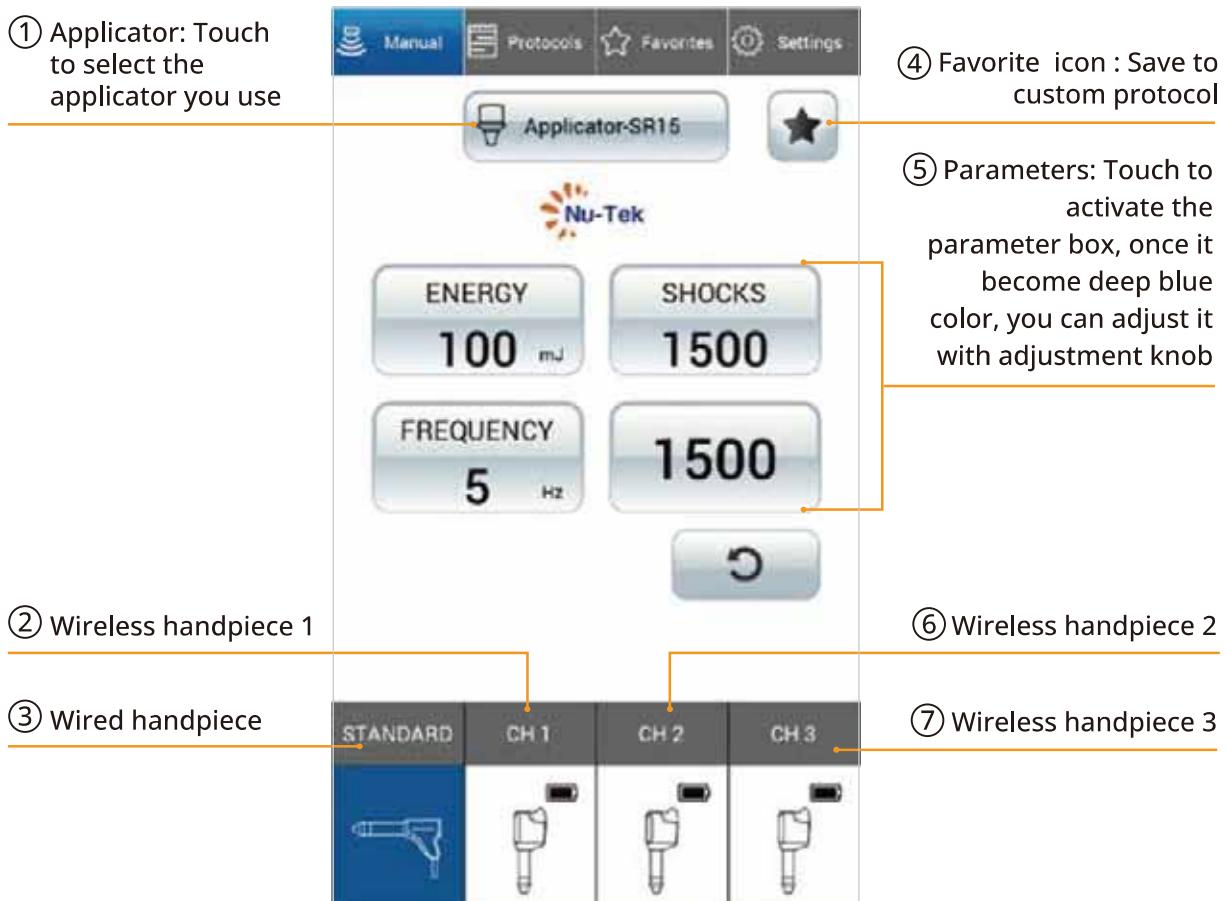


Ready/Working: Handpiece connected or handpiece is working



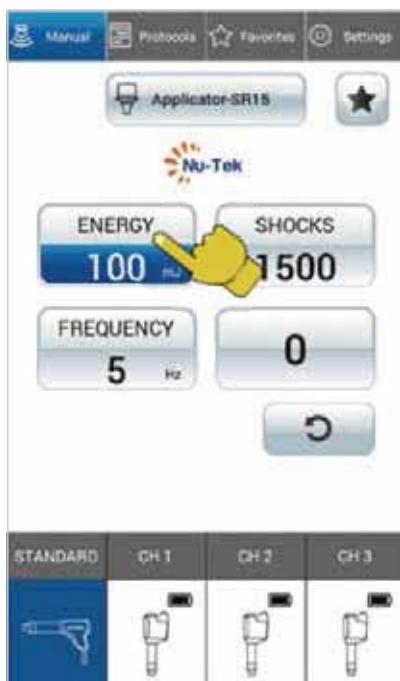
#### Treatment Screen:

This interface allows the user to set the working parameters of the wired handpiece, displays the handpiece's status and number of operations, allows the selection of the applicator size, and enables saving the current treatment parameters.



## Energy:

Press on "Energy" to be selected and the button will light up (blue). Rotate controller knob to adjust energy parameters, the adjusting range of 1~ 5 bar/60 ~ 225 mJ, step 5 mJ.



## Energy Unit Correspondence:

mJ	60	65	70	75	80	85	90	95	100	105
Bar	1.0	1.1	1.2	1.4	1.5	1.6	1.7	1.8	2.0	2.1

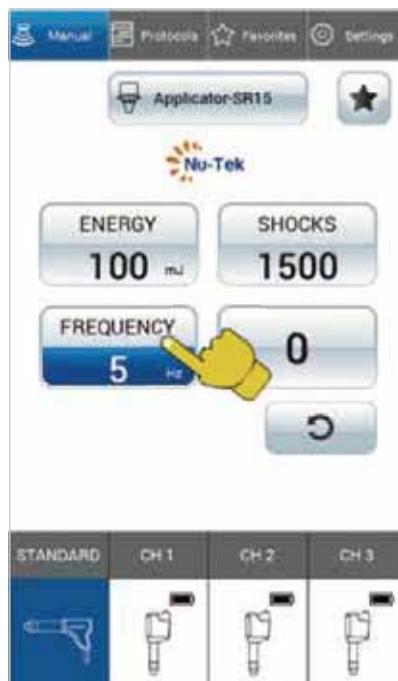
mJ	110	115	120	125	130	135	140	145	150	155
Bar	2.2	2.3	2.4	2.6	2.7	2.8	2.9	3.0	3.2	3.3

mJ	160	165	170	175	180	185	190	195	200	205
Bar	3.4	3.5	3.6	3.8	3.9	4.0	4.1	4.2	4.4	4.5

mJ	210	215	220	225						
Bar	4.6	4.7	4.8	5.0						

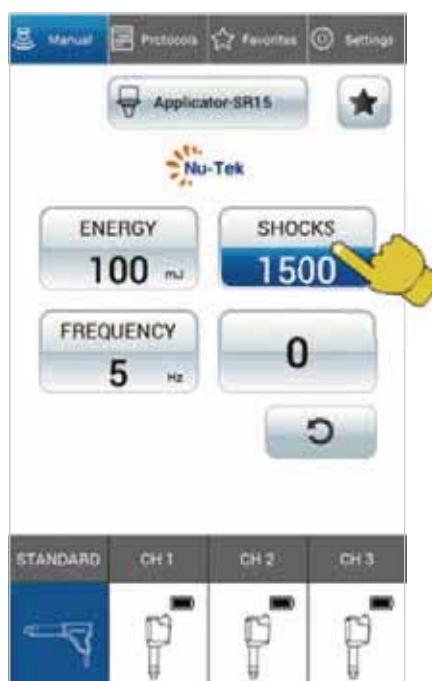
## Frequency:

Press on Frequency button, you can adjust it to desired level with adjustment knob. The adjustment range is 1~22 Hz, with 1 Hz increments.



## Shocks:

Press on shocks button, you can adjust it to desired level with adjustment knob. The adjustment range is 100~10,000 shocks, with 100 shocks increments.



NOTE:

The adjustment range relationship between frequency and energy would be defined here according to the specific device's technical parameters.

Frequency (Hz)	1	2	3	4	5	6	7	8	9
Maximum energy (mJ)	225	225	225	225	225	225	225	225	220
Frequency (Hz)	10	11	12	13	14	15	16	17	18
Maximum energy (mJ)	200	180	170	160	150	140	130	120	110
Frequency (Hz)	19	20	21	22					
Maximum energy (mJ)	100	90	90	90					

Once you finished the set up of parameters, you can follow the Chapter 5.6 to start treatment.

## Save Custom Protocols:

SW3200 allows for a maximum of 30 custom protocols to be defined.

Press the Pentagram button to save your custom program.



Name the custom protocol with keyboard.

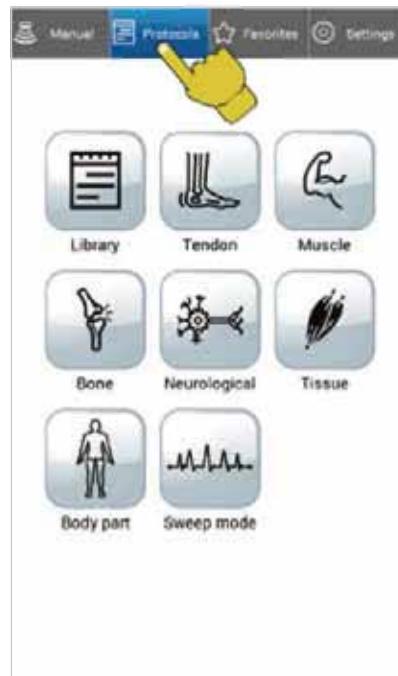


Enter the name and click save .

You can view and manage the custom protocols in FAVORITES on home screen, please refer to Chapter 5.6.

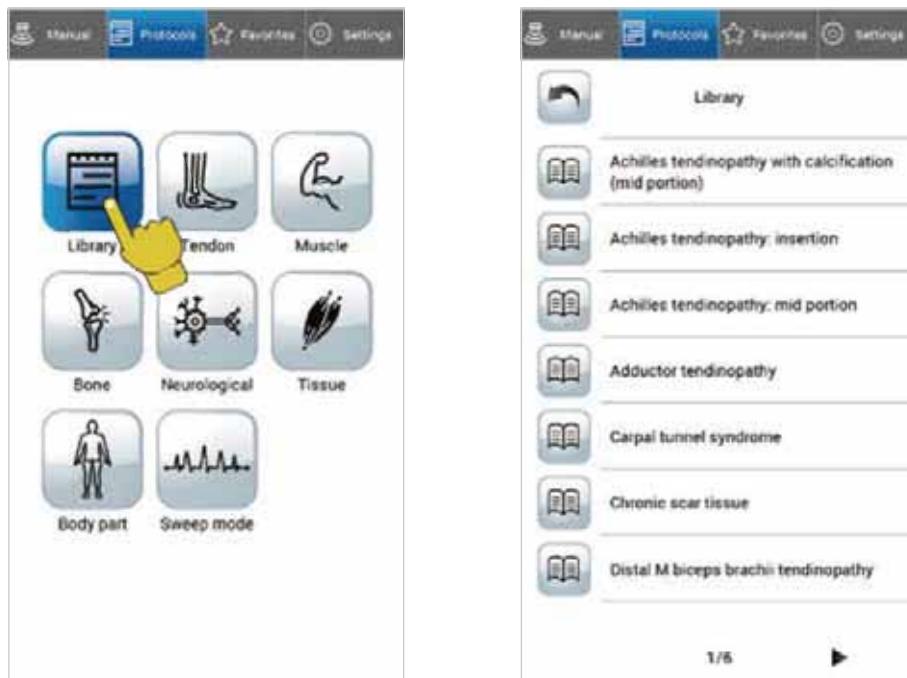
## 5.4 Protocols

Press the protocols button to enter the pre-programmed protocol list.

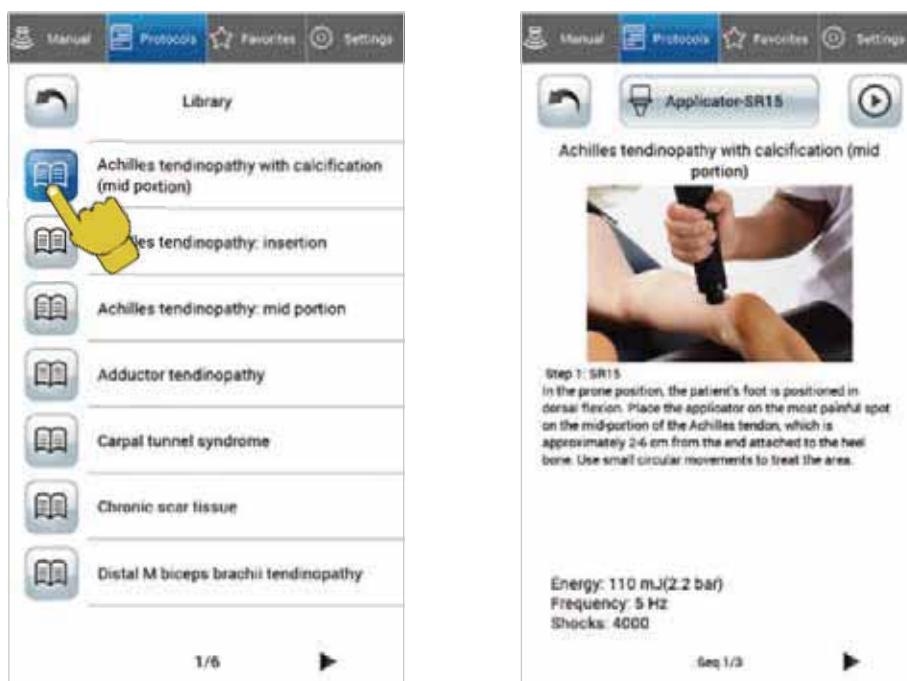


## Library program list:

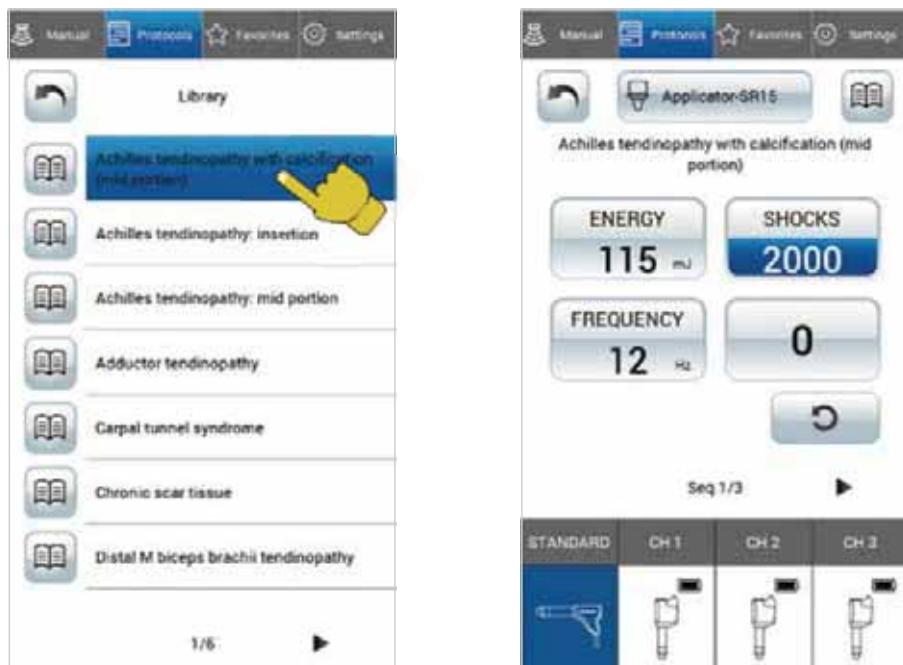
Press the library button, you will see the total pre-programmed protocols list.



Press the  icon to enter the details of the pre-programmed protocol.



Press on the program name to enter the corresponding program treatment interface.



On the treatment screen, you will see the suggested treatment settings. You can also adjust parameters to desired level. Refer to Chapter 5.6 to carrying out treatment.

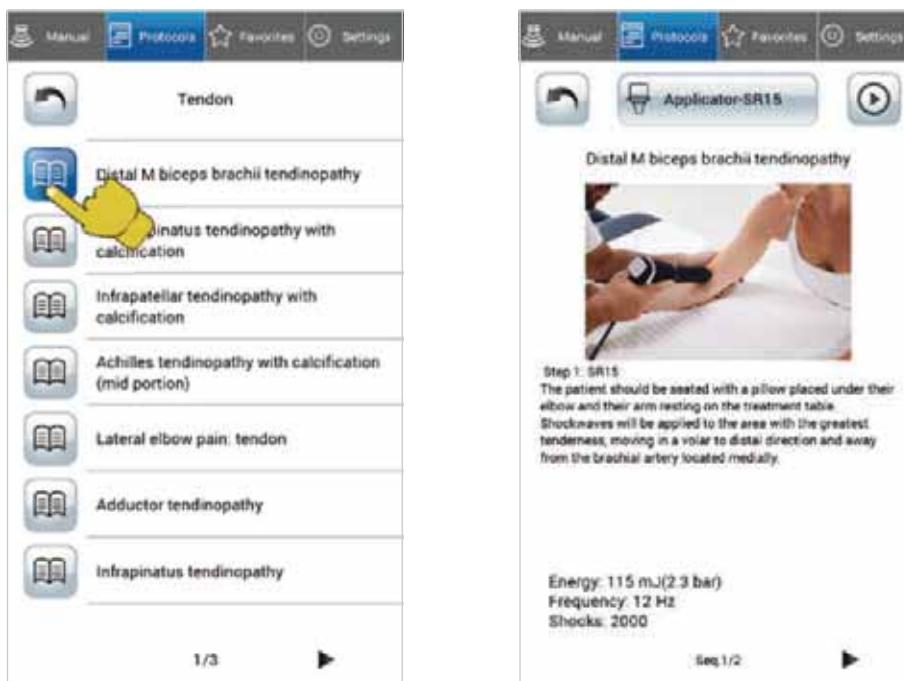
## Musculoskeletal and nervous system

You can choose the program base on the type of disorders . It offers the pre-programmed protocols for tendon, muscle, bone, neurological and tissue disorders.

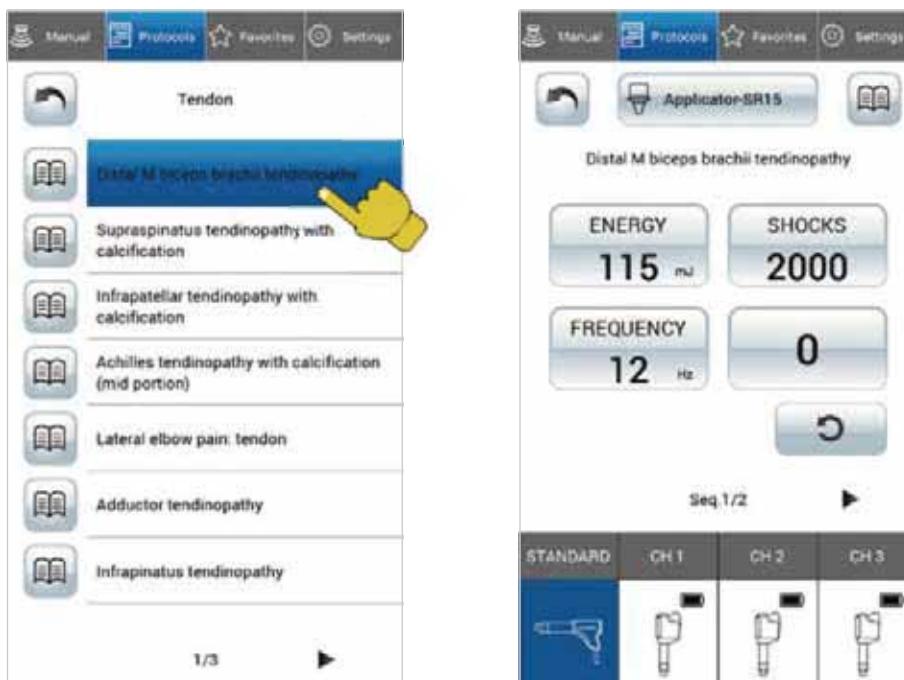
Press the disorder icon to see the program list. For example press the tendon icon, you can see all the programs for tendon disorder.



Press the  enter the details of the pre-programmed protocol.



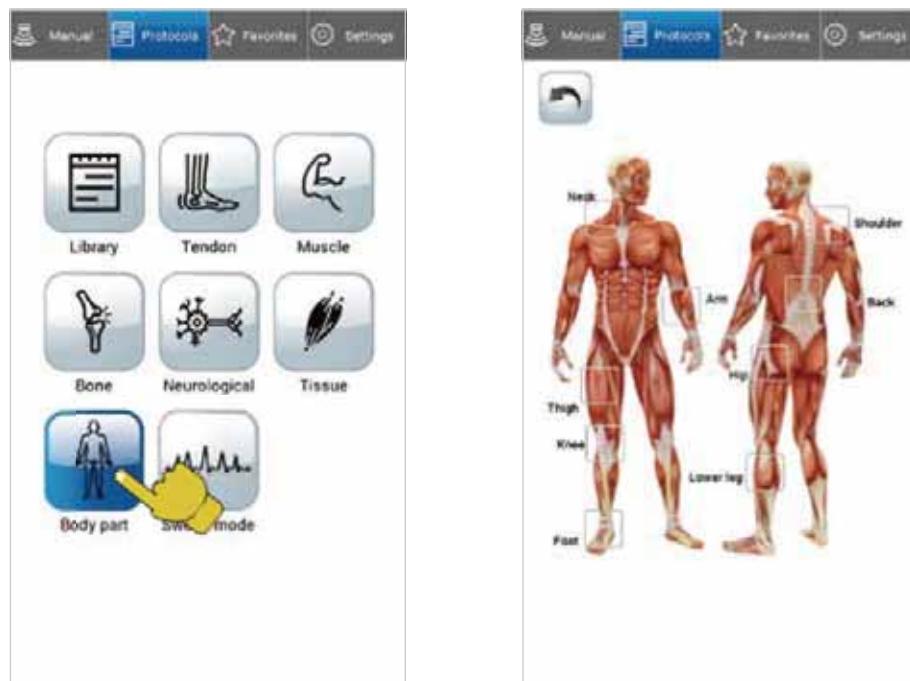
Press on the program name to enter the corresponding program treatment interface.



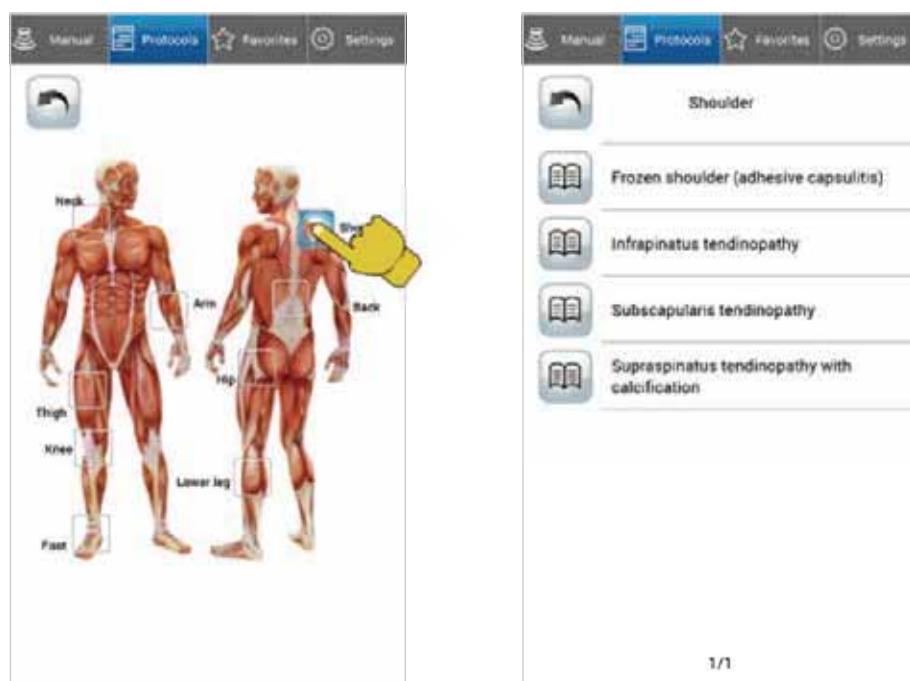
On the treatment screen, you will see the suggested treatment settings. You can also adjust parameters to desired level. Refer to Chapter 5.6 to carrying out treatment.

## Body Part

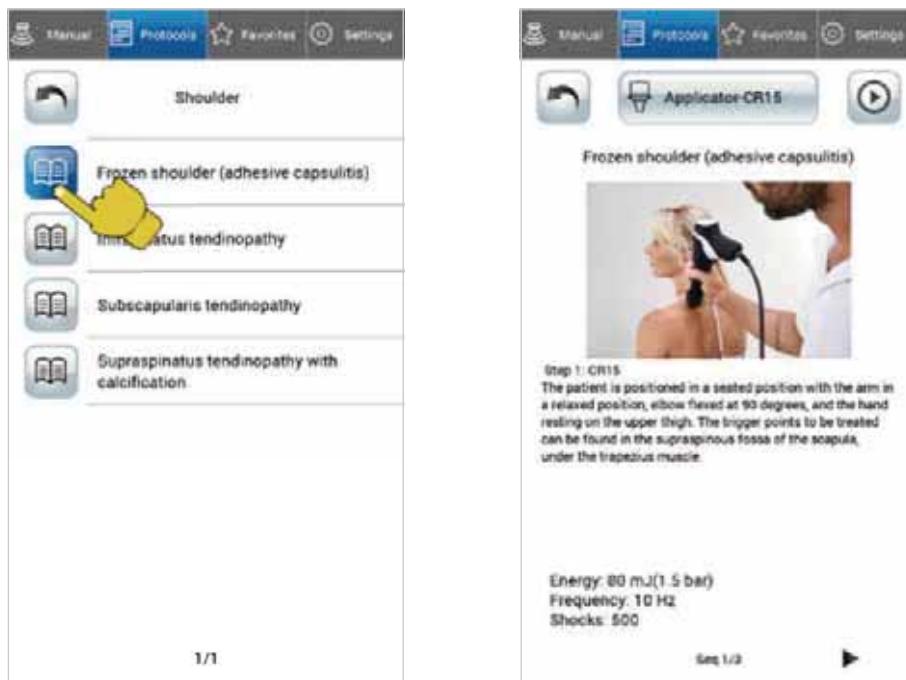
Press body part icon, it divided into 9 categories: Neck, Shoulder, Arm, Back, Hip, Thigh, Knee, Lower Leg, Foot.



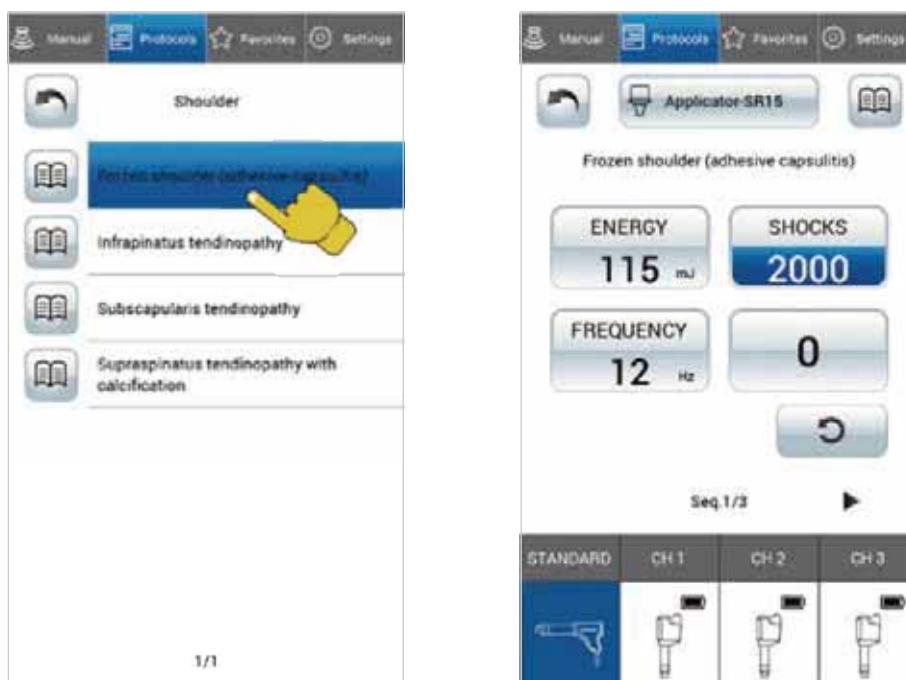
Press one of the body parts to enter protocol list.



Press on  enter the details of the protocol.



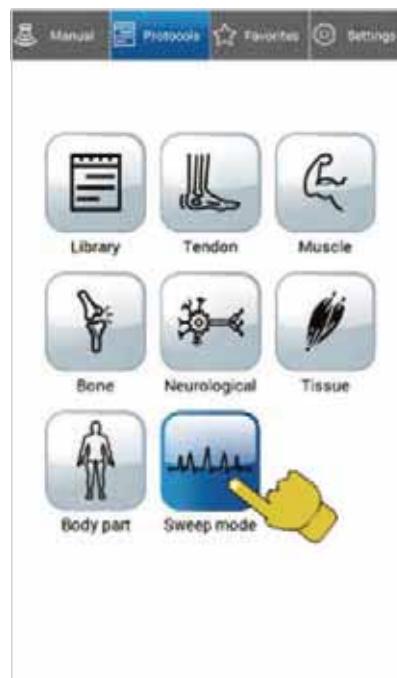
Press on the program name to enter the corresponding program treatment interface.



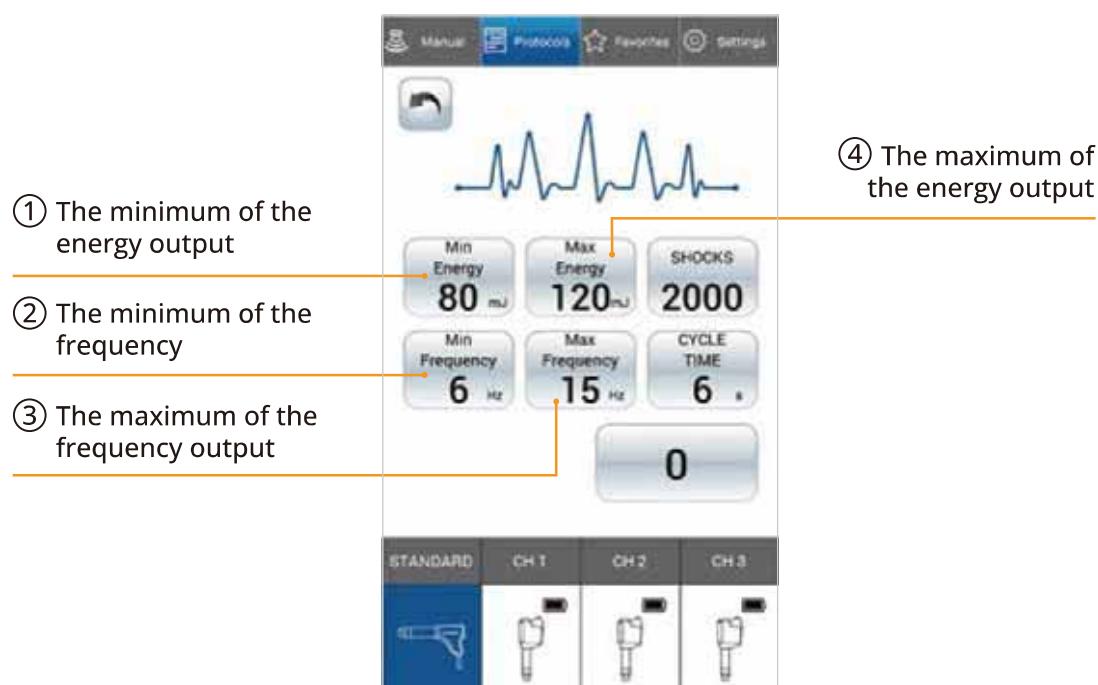
On the treatment screen, you will see the suggested treatment settings. You can also adjust parameters to desired level. Refer to Chapter 5.6 to carrying out treatment.

## Sweep Mode

Press sweep mode button to enter the treatment screen of sweep mode.



## Sweep mode treatment screen



In this mode, you can set the modulation output for frequency and energy. The output of frequency and energy will conduct from minimum to maximum to minimum as cycles. You can press on the icons to adjust them to get desired level.

Once you adjust parameters to desired level. Refer to Chapter 5.6 to carrying out treatment.

## **WARNING**

The pre-programmed parameter-settings are based on the experiences of medical experts or physiotherapists. They are indicative and can be used as an example, but can also be adjusted to one's own expertise.

**Attention:** this is at the risk of the operator!

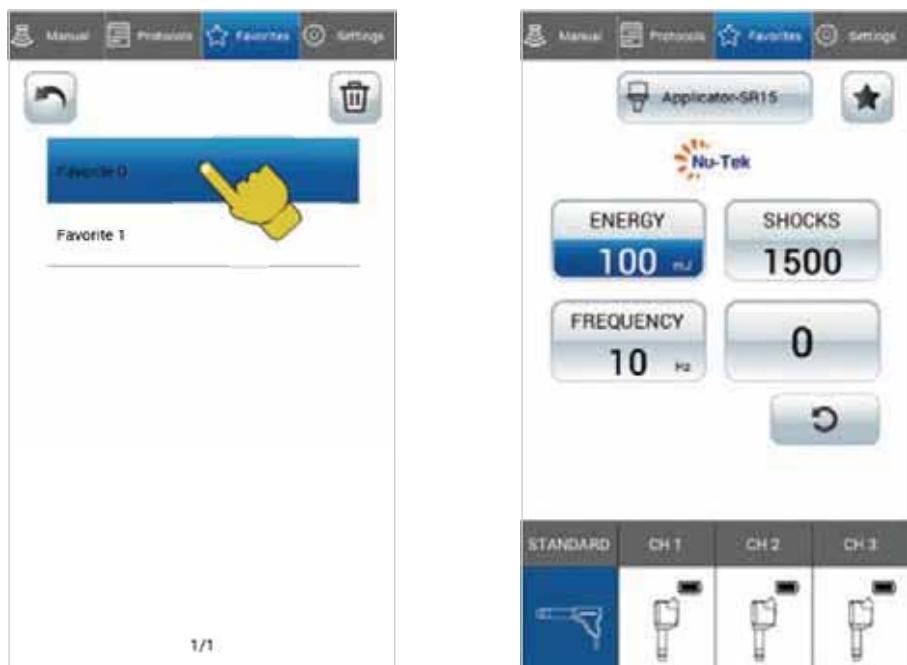
## **5.5 Favorites**

Press the "Favorites" button to access the custom protocol list. Here, you can save all the programs used for each disorder or patient based on their previous treatments.



## Custom Protocol List

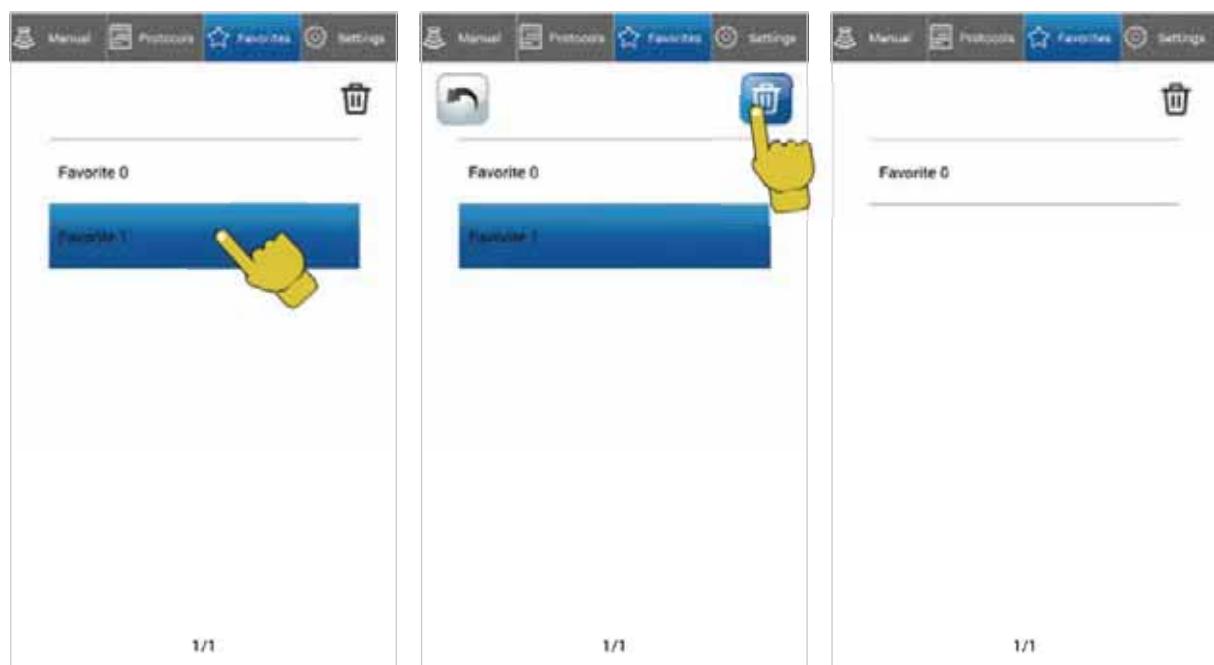
Short press the program name to enter the treatment interface.



On the treatment screen, you can also adjust parameters to desired level. Once you finished the set up of parameters, you can follow the Chapter 5.7 to start treatment.

## Delete the Favorites Program

Long press the program you want to delete to select it, and then click the delete button  to delete that program.



## 5.6 Carrying Out Treatment

### Functional Check

- Perform the following functional checks after the system has been installed:
- Check the control unit and handpiece for damage.
- Switch on the device.
- Set the energy level to 60mJ and frequency 5 Hz.
- Reset the actual number of shocks on the operating panel's parameter display.
- Press the handpiece button and release shocks in continuous shock mode.
- Check that the triggered shocks are correctly counted on the treatment shock counter.

### Patient preparation

Before applying Radial Pressure Wave therapy to the patient, first prepare the patient's skin. By properly preparing the patient's skin for therapy, it allows more energy to reach the targeted areas and reduces the risk of skin irritation.

#### To prepare the patient's skin for therapy, do the following:

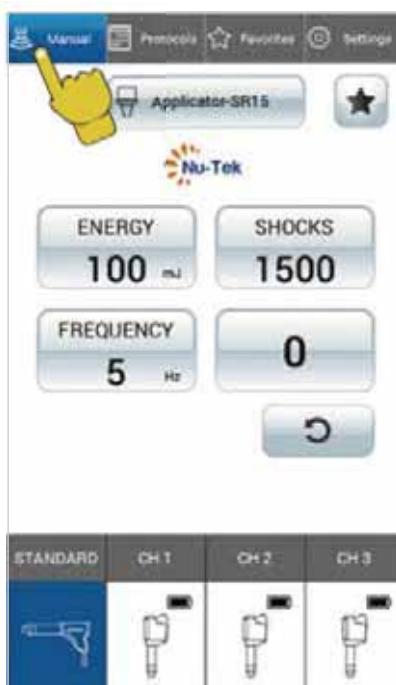
1. Thoroughly wash the skin on which intended treatment is to be administered with mild soap and water or alcohol wipe.
2. Dry the skin thoroughly.
3. Apply the coupling gel generously to the target area on the patient.

Radial Shockwave treatment, given in the right dose and for the correct indications, is an excellent treatment for many chronic conditions that other treatment methods can't improve or heal. RPW therapy is very well perceived among therapists thanks to its positive outcomes and its relatively short treatment period.

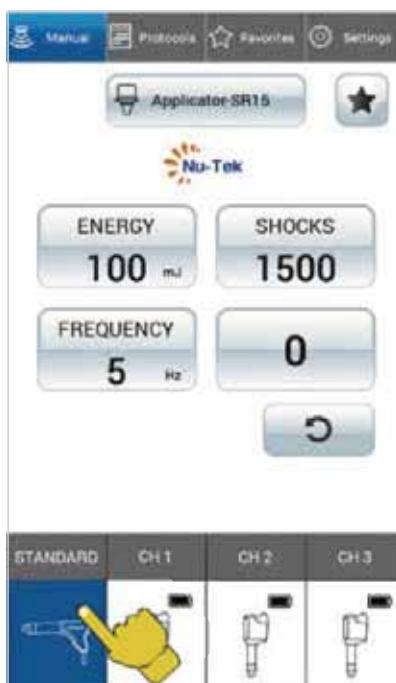
## Set-up Treatment

1. Select Manual, Protocols, or Favorites on home screen. Press to the treatment screen of selected program.
2. On the treatment screen, you can adjust treatment parameters to desired level.

Take Manual mode as example.



3. Select the handpiece you will use.



If you chose the wireless handpiece, please press the download  to transfer the treatment parameters into the wireless handpiece.



#### 4. Select applied applicator.

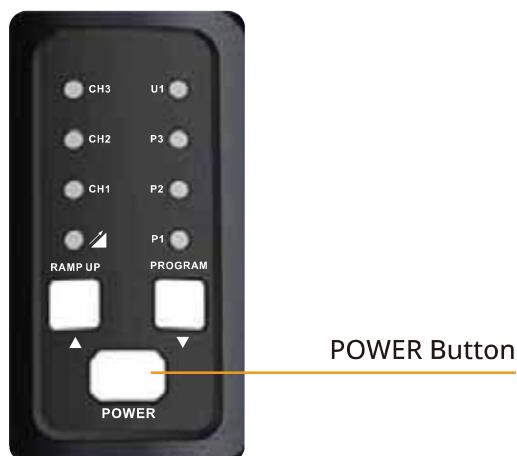


## 5. Start treatment

For wired handpiece, press the trigger button to start treatment.



For wireless handpiece, press the power button to start treatment.



## 6. Pause treatment

For wired handpiece , press the trigger button again to pause the treatment.



For wireless handpiece, press the power button again to pause the treatment.

## 7. Finish of treatment

The handpiece will keep working until the actual shocks reach the preset shocks. Then it comes to the end of treatment. You can restart treatment by select reset button.

## Monitoring the Handpiece Temperature

The generation of mechanical shockwave energy leads to a significant build-up of heat in the handpiece. To ensure the longevity of the handpiece and prevent overheating, we have integrated a temperature switch. This switch acts as an internal safeguard and triggers an automatic switch-off if the temperature becomes too high, requiring the handpiece to cool down.

Once the handpiece reaches the correct operating temperature, the pop-up warning will disappear, indicating that the device is ready for use again. However, in the event of the temperature switch being activated, a message will be displayed on the screen, and the emission of shocks will be temporarily disabled for safety reasons. It is crucial to wait until the handpiece cools down and the warning clears before resuming treatment. This feature is designed to protect the handpiece and ensure optimal performance during each session.



## Treatment Tips

- Let your patient rest in a relaxing position during a treatment session, providing them a rod up towel under their limb for comfort if needed during an elevated treatment.
- Localize the painful points you plan to treat. It might be a good idea to mark up the points with a felt tip pen.

- Apply a liberal amount of coupling gel on the skin of the treatment area. Talk to your patient and ensure that they understand the following:
  - Treatment should start at minimal Bar/mJ level.
  - Bar/mJ level should increase slowly, manually.
  - Patient is responsible to let the clinician know at anytime if treatment is becoming painful.
- The device operates through mechanical energy transmission, where the patient receives treatment using a handheld applicator. To initiate treatment, the applicator is placed vertically on the target area or point with the handpiece held firmly in one hand. The shockwave can be activated to work steadily on a single spot or dynamically over a broader area.
- For optimal performance and patient comfort, it is recommended to use the coupling gel to reduce friction on the skin during treatment.
- Due to the ergonomic design of the handpiece, applying additional pressure on the treatment area is generally unnecessary. Simply position the handpiece on the target area with a loose grip. However, if needed, gentle pressure may be applied in the direction of the tissue, and the working angle can be adjusted accordingly.

## **CAUTION**

- This device is not equipped with coupling gel, please use the coupling gel with the CE medical device mark. The coupling gel must be stored used and disposed of according to the information supplied by the manufacturer of the product.
- Patients with sensitivity to the coupling gel should use caution when using the device.
- There may be a red and swollen or skin itch if patient is allergic with coupling gel.
- There will be red and swollen on the treatment area after treatment for a short time.
- It is recommended to wear suitable ear protection during treatment to for both user and patient.

### NOTE:

- Although measures have been designed inside the handpiece to eliminate vibration, the inevitable vibration will still cause pressure on the user's hand.
- Recommended protective measure: Limit the duration of exposure.
- The patient should be carefully monitored throughout the treatment.
- If the device malfunctions during normal use, immediately stop treatment and disconnect the power, then consult the instruction manual. If the problem cannot be resolved, please contact a professional or return the device to the manufacturer for repair.

## 6 Troubleshooting

### Error Message and Tips

Please unplug the power cable from the instrument before you carry out any maintenance work!

Fault description	Possible cause	Corrective action
Device does not work	<ul style="list-style-type: none"><li>• Power failure</li><li>• Defective power cable</li></ul>	<ul style="list-style-type: none"><li>• Check the power supply</li><li>• Replace the power cable</li></ul>
The handpiece is too hot	<ul style="list-style-type: none"><li>• Working too long time</li><li>• The fan of the handpiece is broken</li></ul>	<ul style="list-style-type: none"><li>• Have a break after long time working</li><li>• Call authorized agency</li></ul>
No shock wave power output	<ul style="list-style-type: none"><li>• The handpiece is not connected to the main device</li><li>• Blocked or worn projectile</li><li>• Malfunction in control device</li><li>• Handpiece defective</li></ul>	<ul style="list-style-type: none"><li>• Check the connector the handpiece</li><li>• Clean the guide tube and projectile</li><li>• Overhaul the handpiece</li><li>• Call authorized agency</li><li>• Replace the handpiece</li></ul>
The output energy of the handpiece is irregular or the output energy is significantly smaller	<p>Wear of applicator heads. Applicator heads is difficult to move due to wear. They are wear parts and should be replaced after a specific number of shocks.</p>	<ul style="list-style-type: none"><li>• Removal of parts subject to abrasion</li><li>• Remove the applicator heads from the handpiece and clean the rear dome thoroughly</li><li>• Then hold the handpiece, without the applicator heads, with the opening downward and, at 2 or 5 Hz frequency, release a few shocks (maximum 10) at the lowest energy level. Then reinsert the handpiece</li><li>• If the error still occurs, the handpiece has to be changed</li></ul>
	The bullet got caught in the dust	<ul style="list-style-type: none"><li>• Remove the treatment head, bullet and tube to clean the dust</li></ul>

The output energy of the handpiece is irregular or the output energy is significantly smaller	O-ring aging, wear and tear	<ul style="list-style-type: none"> <li>• After 1,000,000 shocks shall be replace</li> <li>• Replace the new O-ring</li> </ul>
	Wear of shockwave generator	<ul style="list-style-type: none"> <li>• The shockwave generator is an expendable part and should be replaced after 5,000,000 shocks. Check the total number of shocks of the device in the configuration menu</li> <li>• If the total number of 5,000,000 shocks has been reached or exceeded, the tube and projectile should be replaced</li> <li>• Call authorized agency to replace the tube and projectile</li> <li>• Replace the handpiece</li> </ul>
	The connection cable of the wired handpiece is damaged	<ul style="list-style-type: none"> <li>• Call authorized agency to replace the cable</li> <li>• Replace the wired handpiece</li> </ul>
Wireless Handpiece Charging Issues	Wireless Handpiece cannot charge properly	Turn off the main device, remove the wireless handpiece from the charging base, and wait 10 minutes. Check if the charging base and host are properly connected. Once powered on and the host is in standby, check if the charging indicator is steadily green. If not, inspect or replace the charging cable or base
Wireless Handpiece Communication Issues	The host does not display a specific handpiece.	First, verify if all handpieces are unable to communicate with the host. If other handles still display correctly, it indicates that the host's communication function is working properly. Repair all handpieces according to the instructions in the manual

# 7 Cleaning, Maintenance, Repair, Disposal

## 7.1 Cleaning

### Cleaning the Device and Handpiece

With the device disconnected from the power source, clean the device with a clean, lint-free cloth moistened with water and mild antibacterial soap. Do not use solvents. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

- Cleaning should be performed daily. Do not submerge the device in liquids.
- Clean the LCD with a clean, dry cloth, in the same way as cleaning the computer monitor screen. Do not use abrasive materials or chemicals or liquids.
- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning.

#### CAUTION

- Before starting any maintenance and cleaning measures the device must always be switched off at the main switch and the mains cable unplugged.
- Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.
- If liquid penetrates the device during cleaning or disinfecting, please put the unit out of service, protect it from being used again and contact your service representative.
- Do not use cleaning agents that contain strong alkalis, lye, acid, detergents with fluoride or detergents with ammonia.
- Check the mains cable, cable of the handpiece for damage, such as cracks, splitting or holes. If damage is evident, stop using and contact your local distributor.
- Except the applicator, we recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Always perform cleaning prior to disinfection. For applicator, ensure the applicator is cleaned and disinfected prior to treating a patient.

### Cleaning the Applicator

Regular cleaning ensures perfect hygiene and operation of the handpiece. The handpiece, in particular the applicator, must be thoroughly cleaned and disinfected after each therapy session.

## **WARNING**

Disconnect the handpiece from the main device before starting any cleaning or maintenance work.

Component	Procedure	Interval
Handpiece shaft and cushion	Clean and disinfect	Daily or after 20,000 shocks (whichever comes first)
Shock applicator and O-rings	Clean and disinfect	After each treatment or contact with a patient

- Before cleaning and disinfection of the applicator, the applicator should be disassembled from the handpiece.
- For the 15mm applicator, the removed applicator screw cap, 2 O-rings, and the applicator itself should be cleaned. For the 20/35mm applicator, the removed applicator screw cap, applicator inner cap, 2 O-rings, and the applicator itself should be cleaned. For detailed disassembly procedures, see summaries 4.5.
- When the above parts are cleaned, please dry them and install them according to the steps in summaries 4.5.

## **Cleaning**

### **Tools:**

- Disposable wipes (cellulose, paper).
- Alcohol-based plastic cleaner (e.g. cleaner for medical devices)

In case of visible contaminations the housing, the handpiece, the applicator and the applicator removal tool can be cleaned with commercially available alcohol-based plastic cleaners.

Wipe the surface until the contamination is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

## **Disinfection**

### **Tools:**

- Disposable wipes (cellulose, paper).
- Commercially available alcohol-based disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties or wipes. Observe the application instructions of the manufacturer.

The housing, the handpiece, the applicator and the applicator removal tool can be disinfected by wiping. Use a commercially available alcohol-based disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloth pre-impregnated with disinfectant (wipes).

Then visually observe whether there is dirt on the surface. If there is, wipe it several times until the dirt is no longer visible to the naked eye. Finally, dry the device housing, the handpiece, the applicator and the applicator removal tool with a dry soft cloth.

## **7.2 Maintenance**

### **Device Maintenance**

The main device is designed for a minimum service life of 5 years of normal usage and proper maintenance. Separate servicing is not required for this product. Before starting any maintenance or cleaning, the device must always be switched off at the main switch and the plug pulled out.

No internal maintenance or routine calibration is required for the device itself.

### **Software upgrade**

The software can be upgraded via USB flash drive.

Before upgrade the software, please contact your dealer or manufacturer.

## **7.3 Repair**

Repair work on defective device and handpieces must only be carried out by personnel suitably authorized by manufacturer. Only original manufacturer parts may be used for this purpose. The suitably authorized personnel can be from manufacturer or be representatives of manufacturer and dealers.

## **7.4 Overhaul**

Due to friction, the handpiece components will experience continuous mechanical stress, resulting in minor wear over time. The handpiece should be overhauled approximately every 1,000,000 shocks. This overhauled can be performed by the device user using the repair kit, which contains all necessary replacement parts.

## **7.5 Service**

Should you have any further questions or require additional information, please feel free to contact your dealer.

## 7.6 Disposal

The device contains materials that can be recycled and/or are noxious to the environment. Specialized companies can dismantle the device and sort out these materials.

When you dispose of the device, find out about local regulations concerning waste management.



## 8 Technical Specifications

Name	Technical Parameters
Model	SW3200
<b>REF</b>	SW3200.2-IN-1 SW3200.4-IN-1
Power Supply	100-240V~, 50Hz/60Hz, 300VA
Input power (Wireless handpiece)	DC 16.8V, 1000mAh
Lithium-ion Battery (Wireless handpiece)	DC 14.8V, 1000mAh
Battery charge time (Wireless handpiece)	≤3h
Input power (Wireless handpiece charging holder)	DC 26.5V, 2500mAh
Output power (Wireless handpiece charging holder)	DC 16.8V, 1000mAh
Operation Times of Fully Charged Battery	Fully charged battery can work for about 8000 shocks when used for 120mJ/10Hz
Conformity	Protection class I / Application class BF
Applied part	The applicator
Frequency Range	1-22 Hz

Shock Energy Levels	60–225mJ (for wired handpiece) 60–185mJ (for wireless handpiece)
Accuracy	± 20%
Mode of Operation	Suggested Intermittent use max. 6000 shocks/15mins break
Dimension of Wired Handpiece	About 259.2*113.7mm (L*W)
Dimension of Wireless Handpiece	About 262.5*117mm (L*W)
Service Life of Handpiece	5,000,000 shocks (minimum) Applicators exchangeable
Dimension of Applicator	15 / 20 / 35 mm diameter, ±0.1mm
Weight of Main Device	About 4 kg
Dimension of Main Device	285mm*197mm*280mm (L*W*H), ±2.0mm
Weight of CartRehab	About 14 kg
Dimension of CartRehab	555mm*450mm*930mm (L*W*H), ±2.0mm
Operational Environment	Ambient temperature: 5°C to 30°C Relative humidity: 20% to 80% Ambient pressure: 700 hPa to 1060 hPa
Storage/Transport Environment	Ambient temperature: -10°C to +50°C Relative humidity: 10% to 93% Ambient pressure: 700 hPa to 1060 hPa

## 9 Service & Warranty

### 9.1 Service Life

#### Service Life of the Handpiece

The handpiece should be overhauled after around every 1 million shocks. Provided this interval is observed, the average expected service life is approx.

- 5 million shocks for the handpiece
- 1 million shocks for the applicator

Exceeding the service life can be expected to result in a failure of the devices. No warranty claims shall be accepted beyond the information given.

When the device or any accessories require service, contact the selling dealer or your Service Department contact.

Service to these devices should be performed only by a service technician certified by manufacturer.

#### Expected Life of device

The product as well as the parts and accessories supplied with it are designed for a minimum service life of 5 years of normal usage and proper maintenance.

Applicator, guiding tube, projectile and o-rings are consumables; applicator and o-rings are designed for 1 million shocks expected life, guiding tube and projectile are designed for 5 million shocks expected life.

Repair work on defective device and handpieces must only be carried out by personnel suitably authorised by manufacturer. Only original manufacturer parts may be used for this purpose. The suitably authorised personnel can be from manufacturer or be representatives of manufacturer and dealers.

NOTE:

- The handpiece of the device has a usage lifespan of 5,000,000 shockwaves.
- Under certain conditions, the treatment handpiece may remain effective beyond its specified usage lifespan, depending on performance and frequency.
- Each applicator is designed to deliver a minimum of 1,000,000 shockwaves during its usage lifespan.
- Same as the handpiece, the applicator may continue to be effective beyond its specified usage lifespan, depending on performance and frequency.

## 9.2 Warranty

This Shenzhen Dongdixin Technology Co., Ltd. (hereinafter called the company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The company will at its option, repair or replace components which prove to be defective during the warranty period, provide that the repairs or replacement are carried out by the company or its approved agents. All repairs to the product must be performed by a service center certified by the company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

The warranty for the handpiece is one year or one million shocks, whatever occurs first.

The warranty for the shock applicator is one year or one million shocks, whatever occurs first.

The consumables (rechargeable battery, guiding tube, projectile and o-rings) are not covered by the handpiece's warranty.

For services under this warranty, the products must be returned by the buyer within the applicable warranty period to company. Shipping charges to company under this warranty must be paid by the buyer. The buyer must also include a copy of the sales receipt or other proof of the date of purchase. If the product is returned without proof of the date of purchase, it will be serviced as out-of-warranty product at company's prevailing service rates.

This warranty does not cover:

- Alteration, misuse, or neglect of this product voids this warranty.
- Any malfunction or failure in the product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the product user's manual.
- All damage which is due to repairs or tampering by customers or unauthorized third parties or individuals.
- Damage which has arisen during the transport from the company to the buyer or to the service center.
- Accessories which are subject to normal wear and tear.



### WARNING

Some states do not allow limitations on how long an implied warranty last or the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to the buyer. This warranty gives the buyer specific legal rights, and buyer may have other rights that vary from state to state.

## 10 Manufacturer and Contact



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# 11 Appendices

## 11.1 Electromagnetic Compatibility EMC

- The device is suitable for professional healthcare facility environment.
- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Medical electrical devices such as the device are subject to special precautions with regard to electromagnetic compatibility (EMC) and must be installed and commissioned in accordance with the EMC advice given in the instructions for use and accompanying documents.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The device should only be operated with the original cable specified in the package contents.
- Portable RF communications equipment (including peripherals such as antenna cables, mobile phones and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- The presence of applicators near the device could affect its performances. The distances mentioned in the tables prepared by manufacturer could help to prevent any disturbances of the equipment in normal operation.
- The loss or degradation of the following essential performance due to electromagnetic disturbances could result in affecting patient's treatment:
  - a) No interruption of shockwave output;
  - b) No changes of mode;
  - c) No changes in set-values.
- When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the device may be affected as follows:
  - The device stops output;
  - The device turns off;
  - The device restarts.

The above phenomenon does not affect the basic safety and essential performance of the device, and the user can use it according to the instruction. If you want to avoid the above phenomenon, please use it according to the environment specified in the manual.

- The maximum length of the power cable for the device is about 3m.

- Instructions for maintaining BASIC Safety and Essential performance for the expected Service life.

Do not change the once installed final application due to EM DISTURBANCE. If the environment doesn't correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the device.

**Table 1**

Guidance and Manufacturer's Declaration - Electromagnetic Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. Line(s)-to-ground(s): ± 0.5 kV, ± 1 kV, ± 2 kV	line(s) to line(s): ±1 kV. Line(s)-to-ground(s): ± 0.5 kV, ± 1 kV, ± 2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC 61000-4-6	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE: UT is the a.c.mians voltage prior to application of the test level.		

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity								
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601 -1-2 Test level (V/m)	Compliance level (V/m)
Radiated RF IEC 61000-4-3 (Test specifications for ENCL-OSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430 – 470	GMRS 460, FRS 460	FM $\pm 5$ kHz deviation 1 kHz sine	2	0.3	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							

	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
	5500							
	5785							

Table 4

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation <sup>a</sup> 2,1 kHz	65 <sup>b</sup>
13,56 MHz	Pulse modulation <sup>a</sup> 50 kHz	7,5 <sup>b</sup>

a) The carrier shall be modulated using a 50% duty cycle square wave signal.  
b) r.m.s., before modulation is applied.