EN

chattanooga®

Intelect® Mobile 2

Ultrasound

User Manual

FOREWORD

This manual is intended for users of Intelect® Mobile 2 . It contains general information on operation, precautionary practices, and maintenance.
In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.
In addition to the above information, this manual contains care and installation instructions for the optional Cart and Vacuum module for the users of the Intelect® Mobile 2.

Before administering any treatment to a patient, the users of this equipment should read, understand, and follow the information contained in this manual for each mode of treatment available, as well as the indications, contraindications, cautions, warnings, and dangers. Consult other resources for additional information regarding the application of electrotherapy and ultrasound.

INTENDED USER PROFILE

The intended user of this device is a licensed medical professional. The user should be able to:

- Read and understand the operator's manual, warnings, cautions and dangers.
- Sense auditory and visual signals.
- Read and understand indications and contraindications of the device

INTENDED ENVIRONMENT FOR USE

The device is intended to be operated in the clinic and remote treatment locations. The intended clinical conditions for use are a typical clinic setting including chiropractic clinics, physical therapist clinics, athletic training rooms or other rehabilitation settings. The patients home will also be a frequent use setting where the clinician treats the patient in his/her own home environment.

INTENDED USE

The Intelect Mobile 2 device will be used to deliver a variety of modalities to the patient, Ultrasound and electrical stimulation delivered either as stand alone therapies or in combination.

PRECAUTIONARY INSTRUCTIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols are as follows:

⚠ CAUTION

Text with a "CAUTION" indicator explains possible safety infractions that have potential to cause minor or moderate injury or damage to the equipment.

⚠ WARNING

Text with a "WARNING" indicator explains possible safety infractions that will potentially cause serious injury and equipment damage.

⚠ DANGER

Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

NOTE: Throughout this manual, "NOTE" indicators provide helpful information regarding the particular area of function being described.

GENERAL TERMINOLOGY

The following are definitions for the terminology used throughout this manual . Study these terms to become familiar with them for ease of system operation and control functionality of the Intelect® Mobile 2 .

SYSTEM SOFTWARE SYMBOLS

	Home
	Back to previous screen
	Settings
	Indicates a USB Flash Drive is Inserted
	Indicates Battery Level
	Indicates more content can be viewed by swiping vertically
	Indicates more content can be viewed by swiping horizontally
	Indicates more content can be viewed by scrolling
	Close window / exit full screen
	Confirm
	Save Data
	Edit
	Guidelines / Assign to
	Pain information

	Run again
	Exit
	Export
	Import
	Delete
	Delete all
	Stop treatment
	Ultrasound
	Shortcut
	SPS (Suggested Parameter Setup)
	Custom Protocols
	Treatment Data
	Clinical Resources

DESCRIPTION OF DEVICE MARKINGS

The markings on the unit are assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility and conform to ISO 7010 and ISO15-223-1 One or more of the following markings may appear on the device:

Refer to Instructional Manual Booklet	
Warning, Caution, or Danger	
Electrical Type BF Equipment	
Ultrasound	
Play	
Pause	
ON/OFF	
Manufacturer	
Date of manufacture	
Catalogue number	
Serial number	
Fragile, handle with care	
This end up	
Keep dry	
Temperature Range	
Relative Humidity Range	

Atmospheric Pressure Range	
Test agency	
CE Mark of Conformity with notified body number	
Alternating current	
Class II equipment	
IP21	
Radio frequency equipment	
WEEE Directive conformity	
Shelf life	
Batch number	
US amplitude modulated	

ULTRASOUND INDICATIONS

INDICATIONS

- Relief of pain from muscle spasm
- Relief of pain from joint contracture
- Relief of pain associated with ligament sprains, tendinitis and muscle sprain

CONTRAINDICATIONS

- Do not use for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- Do not use when cancerous lesions are present in the treatment area.
- Do not use when patient is suspected or known to have infectious disease and/or disease where it is advisable, for general medical purposes, to suppress heat or fevers.
- Do not use over or near bone growth centers until bone growth is complete.
- Do not use over the thoracic area if the patient is using a cardiac pacemaker.
- Do not use over a healing fracture.
- Do not use over or applied to the eye.
- Do not use over a pregnant uterus.
- Tissue necrosis might result if the device is used on ischemic tissues in individuals with vascular disease, where the blood supply would not keep up with the metabolic demand.
- Do not use Intelect® Mobile 2 on patients who have or have had implantable neurostimulating cardiac demand pacemakers, ICD, or other implantable electronic devices.
- Do not use Intelect® Mobile 2 on patients with body worn electro mechanical medical devices, i.e. insulin pump.
- Do not use this system in an MRI or CT environment. The Intelect® Mobile 2, its components, and accessories are not to be present in an MRI or CT environment.

ADDITIONAL PRECAUTIONS

Additional precautions should be used when ultrasound is used on patients with the following conditions:

- Over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed
- Over anesthetic areas
- On patients with hemorrhagic diatheses

PRODUCT DESCRIPTION

The Intelect® Mobile 2 ULTRASOUND is an ultrasound therapy system used with or without an optional Cart, allowing for the inclusion of a Vacuum module. This equipment is to be used only under the prescription and supervision of a licensed medical practitioner.

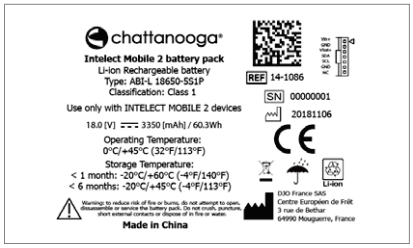
COMPONENTS

Throughout these instructions the terms “left” and“right” referring to the machine sides are from the perspective of a user standing in front of the unit.
The components of the Intelect® Mobile 2 ELECTROTHERAPY are shown below.

HEAD

CART

BATTERY MODULE (optional)



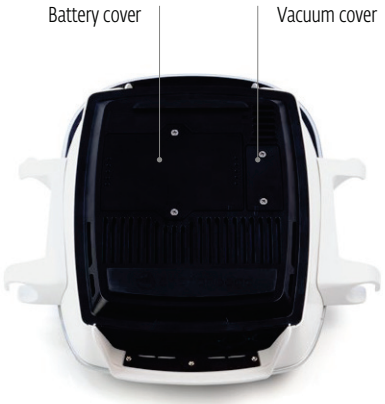
Battery is an 18V 3350mAh LiIon rechargeable battery

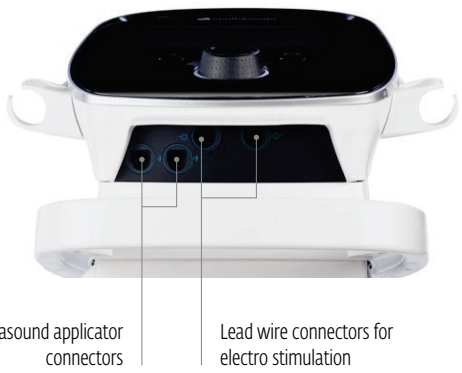
ULTRASOUND APPLICATORS

OPERATOR INTERFACE

The Intelect® Mobile 2 Operator Interface contains all the functions and controls necessary for operator access to all operator utilities, modalities, and parameters for modification and system set up. Color Display and touch screen

1. Adjustment dial
2. Play/pause button
3. "On/Off" button. Press and hold (2 sec) the button to switch OFF the device.
4. ON/OFF switch (only active when connected to the mains)
5. Ultrasound Applicator holder, left and right sides
6. Mains power connector
7. Battery cover
8. USB Flash Drive Port
9. Magnetic fixation to the cart
10. Vacuum cover
11. Device handle





⚠ CAUTION

- This unit should be operated at +5°C to +40°C and 15% to 90% Relative Humidity. The unit should be transported and stored at -20°C to +60°C and 10% to 90% Relative Humidity.
- Use of parts or materials other than DJO's can degrade minimum safety.
- Connect to this unit only items and equipment that have been specified in this IFU as part of the ME SYSTEM or that have been specified as being compatible with the ME SYSTEM.
- DO NOT disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- DO NOT permit foreign materials, liquids or cleaning agents to enter the unit, including, but not limited to, inflammables, water, and metallic objects, to prevent unit damage, malfunction, electrical shock, fire, or personal injury.
- Before each use, inspect Ultrasound Applicator for cracks, which may allow the ingress of conductive fluid.
- Before each use, inspect Applicator cables, STIM cables and associated connectors.
- Handle Ultrasound Applicator with care. Inappropriate handling may adversely affect its characteristics.
- There are no user-serviceable parts inside the unit. If a malfunction occurs, discontinue use immediately and consult dealer for repair service.
- In case of device unused with battery embedded, it is recommended to connect the device at least once every 4 months to allow battery recharge.

⚠ WARNING

- This device should be used only under the continued supervision of a physician or licensed practitioner.
- Contaminated sponges, electrodes, leadwires, and gel can lead to infection.
- DO NOT operate the Intelect® Mobile 2 within the vicinity or environment of an ultrasonic diathermy system.
- DO NOT operate the Intelect® Mobile 2 within the vicinity or environment of any microware and RF shortwave diathermy system.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner.
- Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Intelect Mobile 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.
- Battery replacement by inadequately trained personnel could result in fire or explosion. Please read carefully the battery replacement instructions in the Mobile 2 IFU before attempting to replace the battery.
- Device is designed to comply with electromagnetic safety standards. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions for use, may cause harmful interference to other devices in the vicinity. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
    - » Reorient or relocate the receiving device
    - » Increase the separation between the equipment
    - » Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected
    - » Consult your authorized DJO dealer for help.
- Disconnect the system from the power source before attempting any maintenance, installation, removal, or replacement procedures to prevent electrical shock and possible damage to system.
- The Intelect® Mobile 2 may be susceptible to Electro-Static Discharge (ESD) at greater than ±6 kV when first grasping the Ultrasound applicator. In the event of such a discharge, the Intelect® Mobile 2 may display a permanent error. The Intelect® Mobile 2 will terminate all active outputs (stim, ultrasound,), automatically place the unit in a safe state.
- To prevent Electro-Static Discharge (ESD) at greater than ±6 kV:
    - » Grasp and hold the Ultrasound prior to starting treatment. If the applicator must be put down prior to completion of treatment, stop the current treatment first and then place the applicator in the holder.
    - » Maintain humidity in the use environment to at least 50% relative humidity.
    - » Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, DJO recommends implementing additional controls to maintain relative humidity to at least 50%.
    - » Communicate these ESD-precautionary procedures to healthcare staff, contractors, visitors, and patients.

⚠ DANGER

- DO NOT connect the unit to an electrical supply without first verifying that the power supply is the correct voltage. Incorrect voltage may cause unit damage, malfunction, electrical shock, fire, or personal injury. Your unit was constructed to operate only on the electrical voltage specified on the Voltage Rating and Serial Number Plate. Contact your DJO dealer if the unit is not properly rated.
- Device is not designed to be used in oxygen rich environment, Explosion hazard if the device is used in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

INTELECT MOBILE 2 SET COMPONENTS

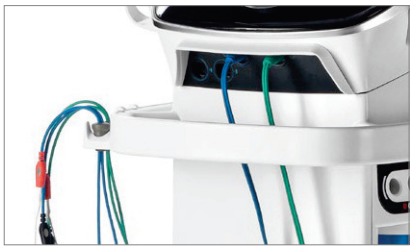
The components of the Intelect® Mobile 2 set are shown below.

15-1200	Intelect Mobile 2 Ultrasound INTL Set EU Plug
15-1201	Intelect Mobile 2 Ultrasound INTL Set All Plug
15-1202	Intelect Mobile 2 Stim INTL Set EU Plug
15-1203	Intelect Mobile 2 Stim INTL Set All Plug
15-1204	Intelect Mobile 2 Combo INTL Set EU Plug
15-1205	Intelect Mobile 2 Combo INTL Set All Plug

HEAD

LEADWIRES

The available leadwires are shown below. If the user orders a Mobile 2 Stim or Mobile 2 Combo, the box will include the blue and green leadwires



POWERCORD

15-0144	Wall Power Cable 2m Black EU
15-0146	Wall Power Cable 2m Black UK
15-0147	Power Cable 2m Black AUS

COMBO SET INCLUDES:

15-0133	INTELECT MOBILE 2 COMBO
79967	Carbon electrodes
70010	STIM lead wires
6522055	Chattanooga straps
42198	Electrodes gel
15-0144/46/47	Power cord
13-1604	Printed Quick Start Guide
15-0142	5 CM^2 Ultrasound Applicator
4248	Ultrasound Gel Bottle
15-1140	USB Drive

STIM SET INCLUDES:

15-0132	INTELECT MOBILE 2 STIM
79967	Carbon electrodes
70010	STIM lead wires
6522055	Chattanooga straps
42198	Electrodes gel
15-0144/46/47	Power cord
13-1604	Printed Quick Start Guide
15-1140	USB Drive

US SET INCLUDES:

15-0131	INTELECT MOBILE 2 ULTRASOUND
15-0144/46/47	Power cord
13-1604	Printed Quick Start Guide
15-0142	5 CM2 Ultrasound Applicator
4248	Ultrasound Gel Bottle
15-1140	USB Drive

ULTRASOUND APPLICATOR

1. Applicator Head

The component of the applicator that makes contact with the patient during Ultrasound or Combination therapy.

2. Applicator

The assembly that connects to the system and incorporates the Applicator head.

3. LED

The component of the applicator that indicates if the Applicator is coupled or uncoupled on the treatment area.

HEAD TO CART FIXATION

The optional Therapy System Cart, is designed for use with the Intelect® Mobile 2 only and allows the user to easily transport the System from patient to patient within the clinic as well as store all necessary accessories, supplies, and applicators used for the various modalities of the System. The fixation of the head to the cart is magnetic.

Remove the Intelect® Mobile 2 device and cart from the shipping carton. Visually inspect for damage. Report any damage to the carrier immediately.
To assemble the Mobile 2 Head to the Cart, follow these steps:

1. Insert device front bottom on the cart lip
2. Release device back gently on the cart. Magnets will help to position the device correctly on the cart top.

CONNECTING CABLES AND INSERTING PLUGS

When inserting the plugs, be sure to align the flat side of the plug with the flat side of the slot and push in gently. This is to avoid bending the pins in the plug.
Insert cable into the appropriate connector prior to starting therapy.

INITIAL RECEIPT

Remove all packaging

IF UNIT SUPPLIED WITH OPTIONAL BATTERY

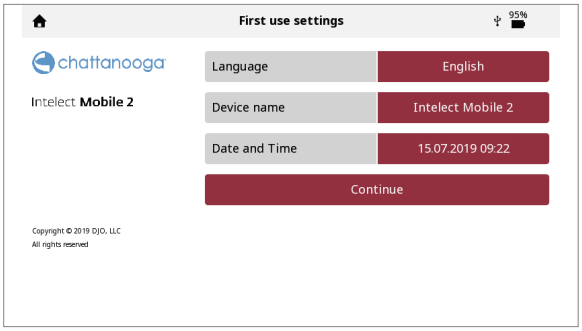
After unpacking Intelect Mobile 2 to fit the battery follow the following steps
1. Unscrew the battery cover from the base of the device by removing the 2 screws see below
2. Remove the battery cover
3. Plug the battery into the battery connector on the device
4. Insert the battery into its location
5. Replace the 2 screws to close the battery cover

POWERING UP THE DEVICE

First time use always use mains power even if battery connected. Insert the power cord into the back of the unit, insert the plug into a power outlet, do not position the Intelect Mobile 2 in such a way that makes it difficult to disconnect from the mains power.
Switch device on with ON/OFF switch switch on the back of the unit

1. The Initialisation screen below will be shown for a few seconds whilst the device starts.

2. The first setup screen will be dispalyed after this allowing the user to set language, device name and time.



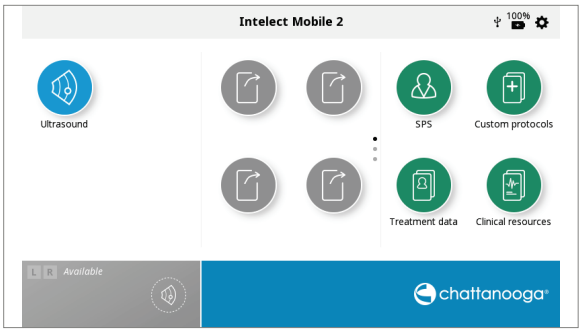
3. Click on "Continue" button to go to home screen

IFU DOWNLOAD

1. Go to the Chattanooga website www.chattanoogarehab.com
2. Go to Intelect Mobile 2 product tab
3. Complete the registration form to be informed about new product software version availability and IFU updates.
4. Go to documents tab
5. Click on the latest version of your Intelect Mobile 2 device (COMBO, US or STIM) User manual to download
Nota: a pdf viewer is required to display IFU

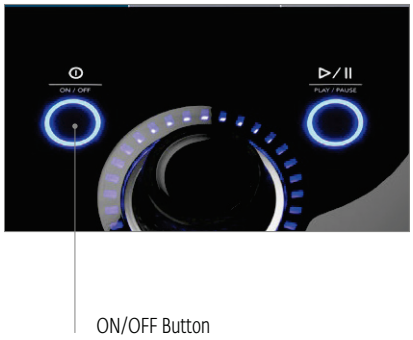
DEVICE CONNECTED TO THE MAINS

1. Plug the Power cord into the back of device. Plug the other end of the cord into an electrical outlet.
NOTE: The Power Cord may be unplugged from the back of the unit in an emergency situation.
2. Turn on the ON/OFF switch located on the back of the device.
3. Select desired function on the Home Screen



DEVICE WORKING ON BATTERY

1. Press the ON/OFF button on the LCD Front panel, as shown below
2. Select desired function on the Home Screen (shown below).



ON/OFF Button

STOP TREATMENT AND TURN OFF THE DEVICE

Press Play/pause button to pause treatment then press stop on touch screen. If device is on mains power press the on/off button on the front panel then turn off the switch on the back of the unit.
If device is working on battery follow the above procedure but to switch off only press the on/off button on the front panel

PLAY/PAUSE button

DEVICE LIGHT INDICATORS

Intelect Mobile 2 ULTRASOUND has several light indicators:

FRONT PANEL INDICATORS:

1. Colors:
    - Light blue around Ultrasound therapy channel Left and Right

2. Behaviour:
    - Steady when modality is selected and output is not active
    - Flashing when output is active
    - Quickly flashing when treatment is interrupted and user action is requested

ON/OFF BUTTON BLUE INDICATOR:

- steady ON from device connection to the mains
- Flashing while powering ON/OFF

PLAY/PAUSE BUTTON BLUE INDICATOR:

- It flashes when user can start/resume a treatment. Otherwise, steady.

SYSTEM SPECIFICATIONS AND DIMENSIONS

	Width	Depth	Height	Weight (no battery)
Intelect Mobile 2 Head Unit				
UltraSound	34cm	35.5cm	15cm	2.8kg
Cart configurations				
Cart (Safe working load 6.5kg)	48cm (MAX)	52cm (MAX)	96cm	10.1kg
Device on cart	-	-	111 cm	-

POWER

Input	100 - 240 V AC, 1.0 to 0.42 A, 50/60 Hz
Electrical Class	CLASS II
Mode of Operation	Continuous

Note: Mains isolation is achieved by use of the double pole switch located on the rear panel.

Electrical Type (Degree of Protection)

Ultrasound	.TYPE BF

ULTRASOUND SPECIFICATIONS

Frequency	1 MHz; 3 MHz
Duty Cycles	10%, 20%, 50%, Continuous
Pulse Repetition Rate	16, 48, or 100 Hz
Pulse duration:	1 -31.25 ms
	Max (ON): 31.25 ms
	Min (OFF): 5ms

OUTPUT POWER

US applicator Frequency	1 cm^2		2cm^2		5cm^2	
	1MHz	3MHz	1MHz	3MHz	1MHz	3MHz
Effective Radiating Area ERA INTL (cm2)	1	0.9	1.5	1	2.5	2.7
Max Output power in Continuous mode	2W	1.8W	3W	2W	5W	5.4W
Max Output power in Pulsed mode	3W	2.7W (*)	4.5W	3W	7.5W	8.1W
Max Amplitude in Continuous mode	2W/ cm^2	2W/ cm^2	2W/ cm^2	2W/ cm^2	2W/ cm^2	2W/ cm^2
Max Amplitude in Pulsed mode	3W/ cm^2	3W/ cm^2	3W/ cm^2	3W/ cm^2	3W/ cm^2	3W/ cm^2

(*) An error of + 0.25 W can be measured with 1cm2 US applicator, pulse mode 100Hz at 10% or 20% Duty Cycle.

Unless otherwise specified, ultrasound controls accuracy is:	± 20 %.
Peak to Average Ratio:	1:1, at 50% Duty Cycle 4:1, at 20% Duty Cycle 9:1, at 10% Duty Cycle
Beam Nonuniformity Ratio	<5:1
Beam Type	Collimating
Treatment Time	1 to 30 min

GENERAL SYSTEM OPERATING AND STORAGE TEMPERATURE

Operating Conditions

The device will meet its requirement under the following conditions:

Temperature:	5°C to 40°C
Relative Humidity:	15% to 90%
Atmospheric Pressure:	70kPa to 106kPa

Transport and Storage Conditions

The device will remain in proper condition under the following conditions:

Temperature:	-20°C to 60°C
Relative Humidity:	10% to 90%
Atmospheric Pressure:	50kPa to 106kPa

Time required for the Intelect Mobile 2 to warm from the minimum storage temperature between uses until the Intelect Mobile 2 is ready for its INTENDED USE when the ambient temperature is 20 °C: 5h

Time required for the Intelect Mobile 2 to cool from the maximum storage temperature between uses until the Intelect Mobile 2 is ready for its INTENDED USE when the ambient temperature is 20 °C: 5h

IPXX Rating for Unit

Rated to IP21
IP2* Protection against fingers or other object not greater than 80mm in length and 12mm in diameter
*1 Protection from vertically dripping water

IPXX Rating for US applicator

Rated to IPX7
IPX7 Protection from immersed in water (up to 1m depth)

RED

RF transmitter/receiver characteristics:

- Frequency Band transmission: 2400–2483.5 MHz
- Modulation type: GFSK
- Data rate: up to 2Mbps 500kHz deviation at 2Mbps
- Effective radiated power: +6dBm

ULTRASOUND PATIENT PREPARATION

1. Examine the skin for any wounds and clean the skin
2. View the Applicator recommendation in the treatment guidelines.
3. Review guidelines for Ultrasound (as a reference point only) on the treatment review screen prior to administering treatment.

NOTE: Applicators are available in the sizes shown below:

1 2 3 4

Applicator Preparation and Use

1. Clean applicator before each therapy session with warm soapy water, check the applicator has no cracks prior to use.
2. Liberally apply transmission gel to the treatment area on the patient.
3. Move the applicator during therapy session in a circular motion. The area treated should be:
   - Twice the diameter of the applicator
   - For 5cm2 US applicator: three times the diameter of the applicator if output power > 4 W, Continuous mode.

The applicator should always be held by the grip and not by the Ultrasound Applicator head.

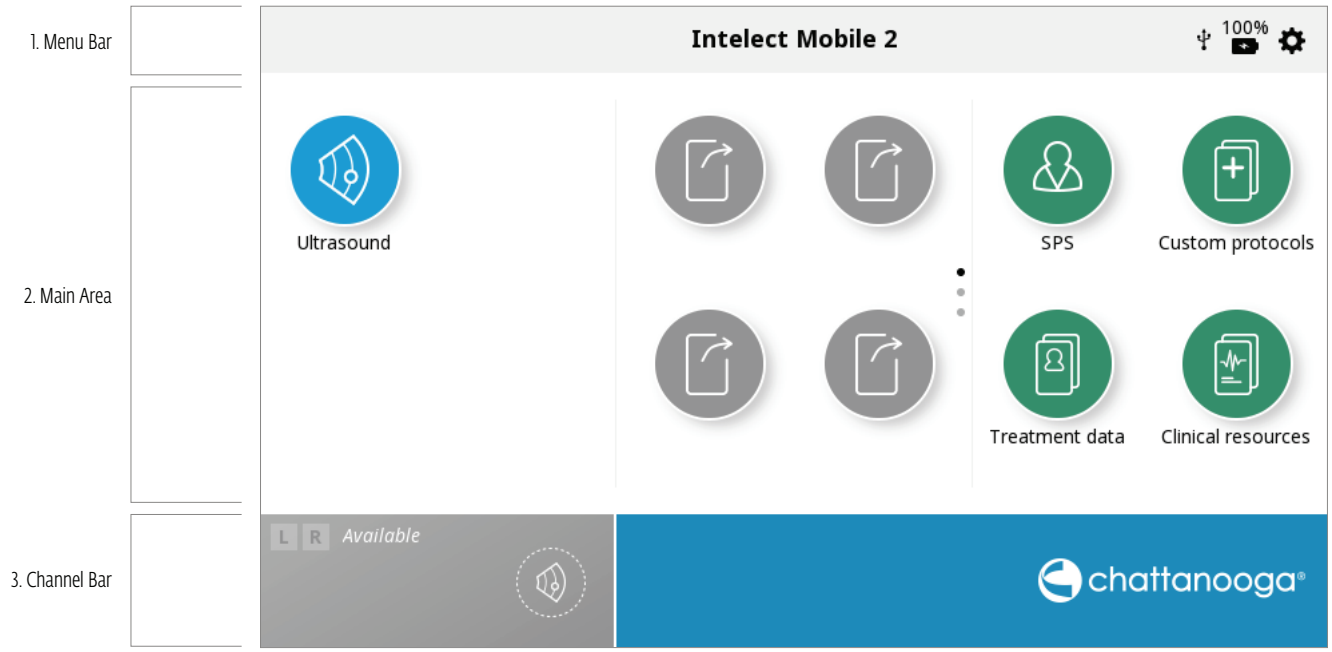
4. If US Coupling is "On", the Applicator is properly coupled to the patient and administering ultrasound when the LED is constantly illuminated. If the applicator head becomes uncoupled the LED on the head will flash. If "US coupling" setting is ON, several beeps will be also heard until the head is coupled again. Treatment time stops during uncoupling.

NOTE: Ultrasound output will continue to be emitted in all US coupling modes even if the applicator is uncoupled. The output power is reduced to a very low level to prevent ultrasound head warming.

For ULTRASOUND OPERATION, refer to page 60

DEVICE USER INTERFACE

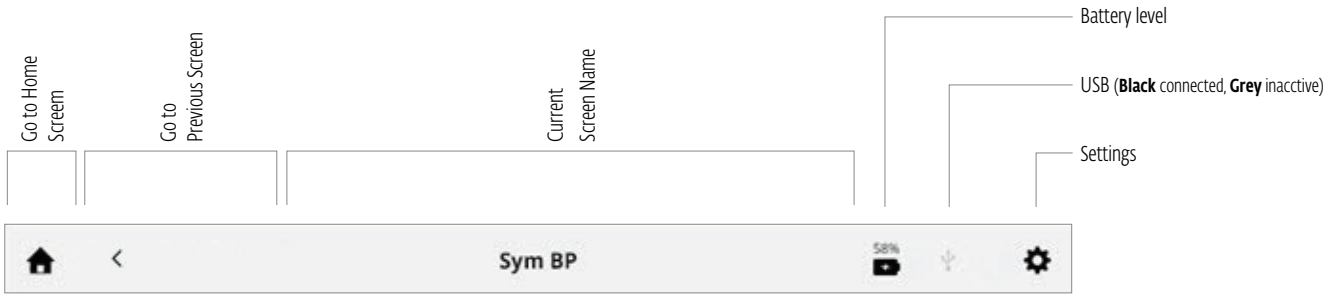
SCREEN DESCRIPTION



Each screen contains the following areas:

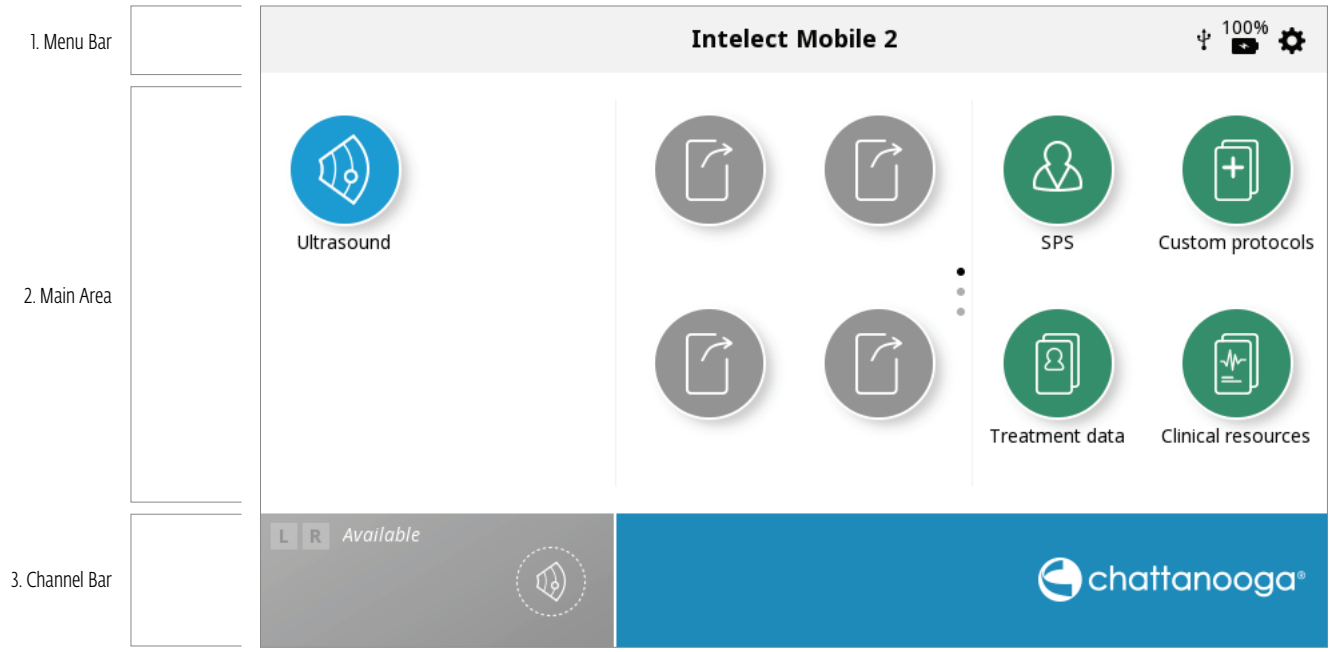
Menu Bar

Located at the top of each screen and lists the current screen name.



Main area

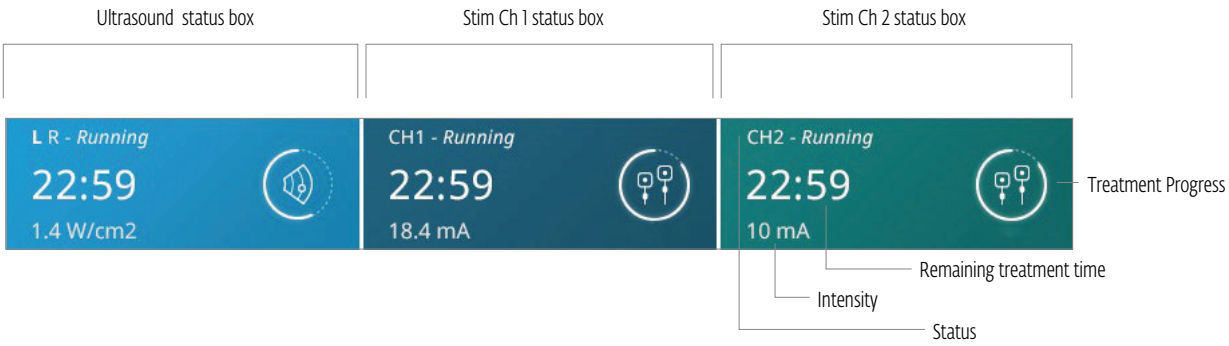
Located under the menu bar, this area displays icons unique to the current screen.



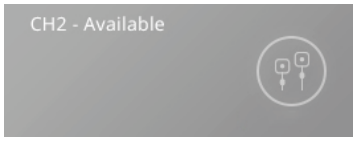
Channel Bar

Located at the bottom of each screen, this area displays the status information about each channel.

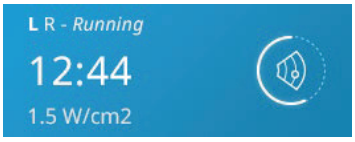
When starting a treatment, channels are automatically assigned to the next available channel. Manual selection is done by touching the desired channel.



Channel status possibilities:

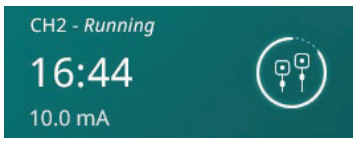


Indicates the channel is available for use



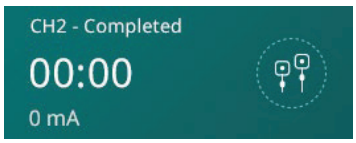
Indicates an ultrasound treatment is running with the left (L) applicator

Indicates a treatment for the channel is currently being setup but treatment has not yet begun



Indicates a treatment for the channel is currently running

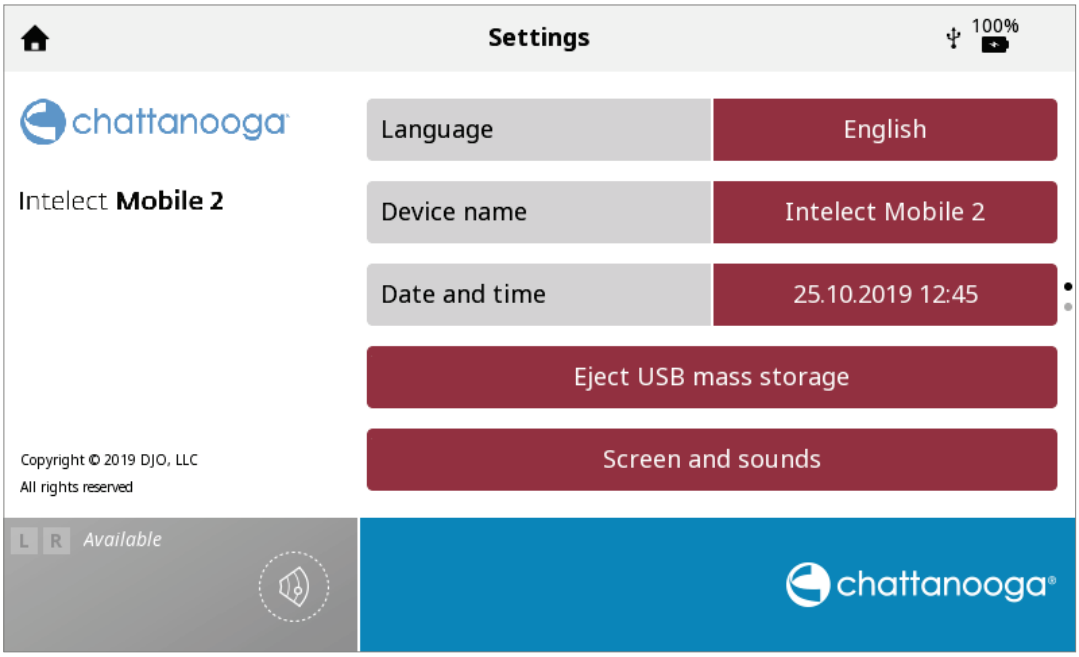
Indicates a treatment for the channel is currently paused



Indicates a treatment for the channel has completed

SETTINGS

The settings icon on the top right hand corner of the home screen menu bar (see page 34) offers users the opportunity to set preferences and can be accessed by pressing the " button.



Swipe vertically to see more settings

1. On the home screen, the "current screen name" displayed in the middle portion of the menu bar is by default 'Intelect Mobile 2'.
2. Language: touch this box if you want to choose another language
3. The device name can be changed to a name of your choice, e.g clinic name to do this press the Device name button and enter the new name with the displayed keyboard press Enter and the new device name will be displayed on the home screen.
4. the date and time can be set by pressing the date and time button, date format and time format can also be set in this screen.
5. Press the screen and sounds button to enter this menu:
   - » To adjust the display brightness, select Brightness button. The brightness range is 0% (dimmest) to 100% (brightest) in increments of 10%. Default setting is 80%.
   - » To adjust the volume of sound, select the volume button. The volume range is 0% (off) to 100% (loudest) in increments of 10%. Default setting is 40%.
   - » Pressing the keyboard sounds button selects either on or off for keyboard sounds. Default setting is ON.
   - » Pressing the US coupling sound button allows the user to switch between US coupling sound on or off. Default setting is ON.
6. Pressing the Display unit version information will show current software version serial number and several device parameters as shown below.
7. Pressing the reset default treatments button will reset al the treatment protocols to their default settings..
8. Press Reset to factory defaults to restore the device to the factory settings, pressing this button will result in a restart and the user will be taken to the initial setup screen on restart.
9. When a USB drive is inserted a new button appears to allow safe ejection of the USB drive, simply press the button and follow the on screen prompts.

PRINT SCREEN FUNCTION

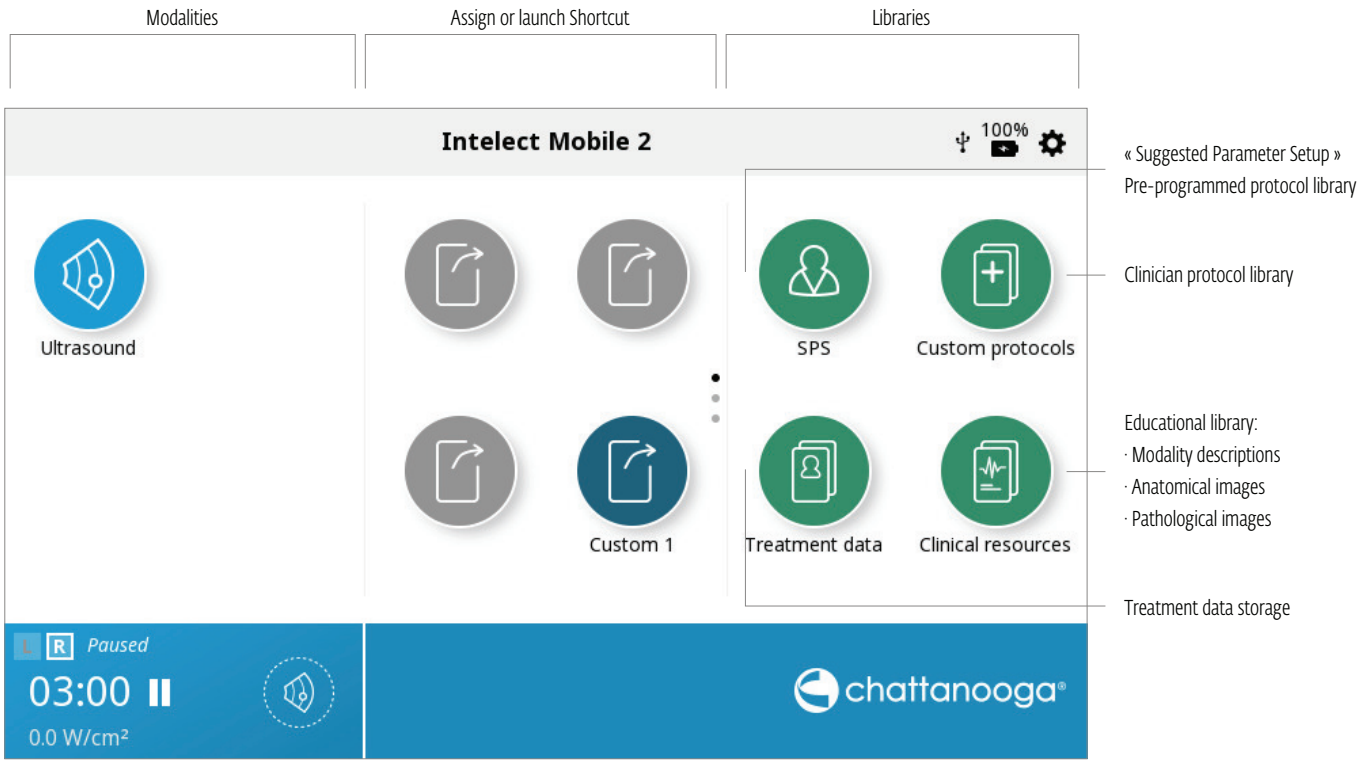
The Intelect Mobile 2 device has a built in function allowing the user to print screen fro example to print a treatment session this performed by:

» 1. insert USB drive into the USB port on the back of the Mobile 2 device
» 2. Press the play pause button and the On/Off button for around 1 second the screen will flash and the image is captured on the USB drive.
» 3. in the setting menu eject the USB drive to enable safe removal from the Mobile 2 device.
» 4.The format of the file is a bitmap file and it is date & Time coded in the filename.

Note : The print screen function should not be used during treatment

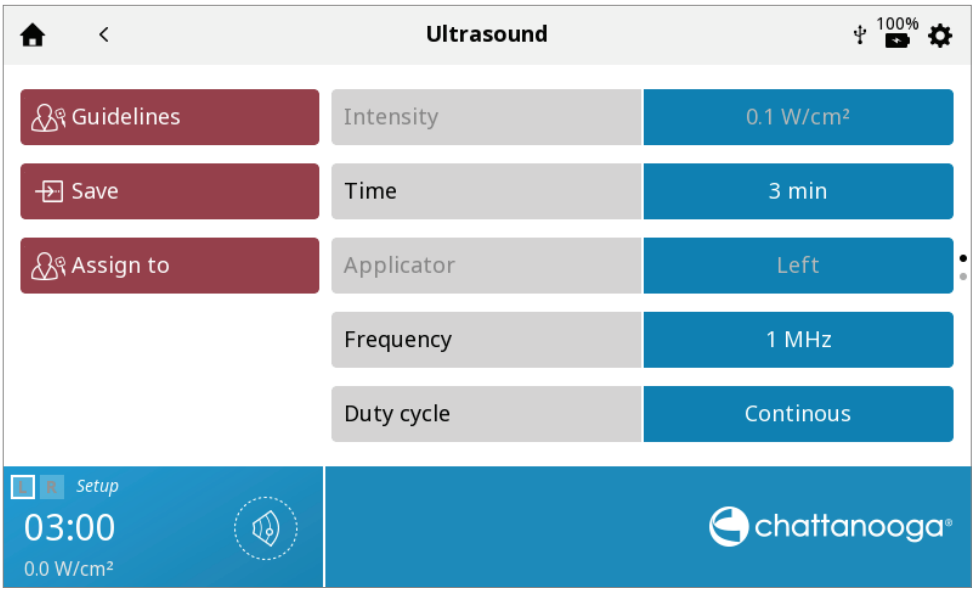
HOME SCREEN

The Intelect® Mobile 2 Home screen provides access to all of the system modalities and functions. The Home screen has the following information:



TREATMENT REVIEW SCREEN

The Intelect® Mobile 2 Treatment Review screens for Ultrasound includes the following information:



Electrode Placement Guidelines

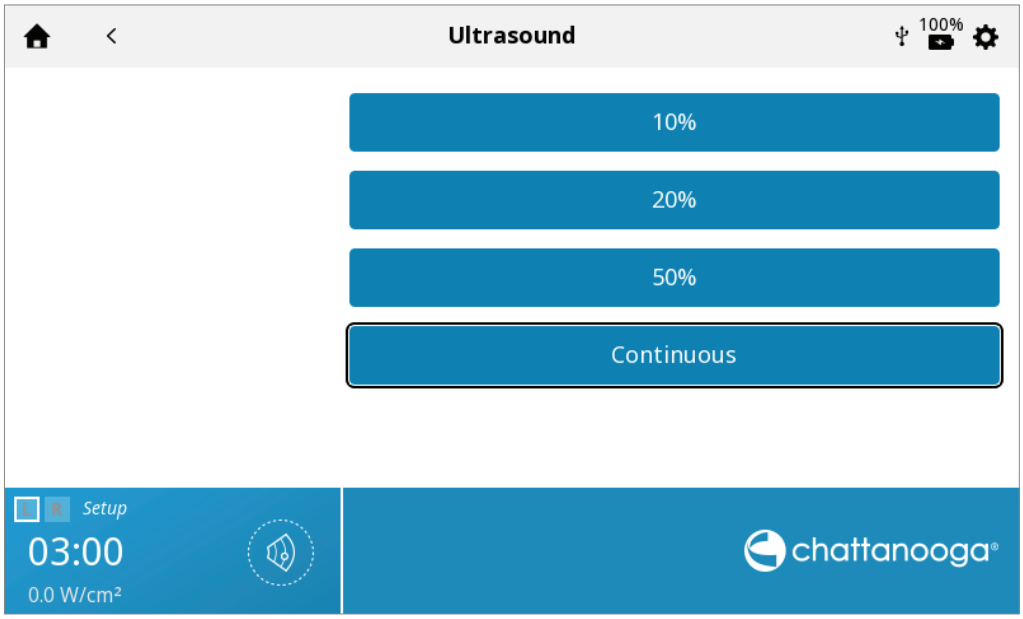
Save/Overwrite default settings or Custom Protocols

Save to Treatment Data

1. Touch to activate
2. Adjust with Adjustment dial:
   - Clockwise – Increase
   - Counterclockwise – Decrease

Note: When a parameter is not adjustable, the parameter box is faded.

Parameter Submenu Screen

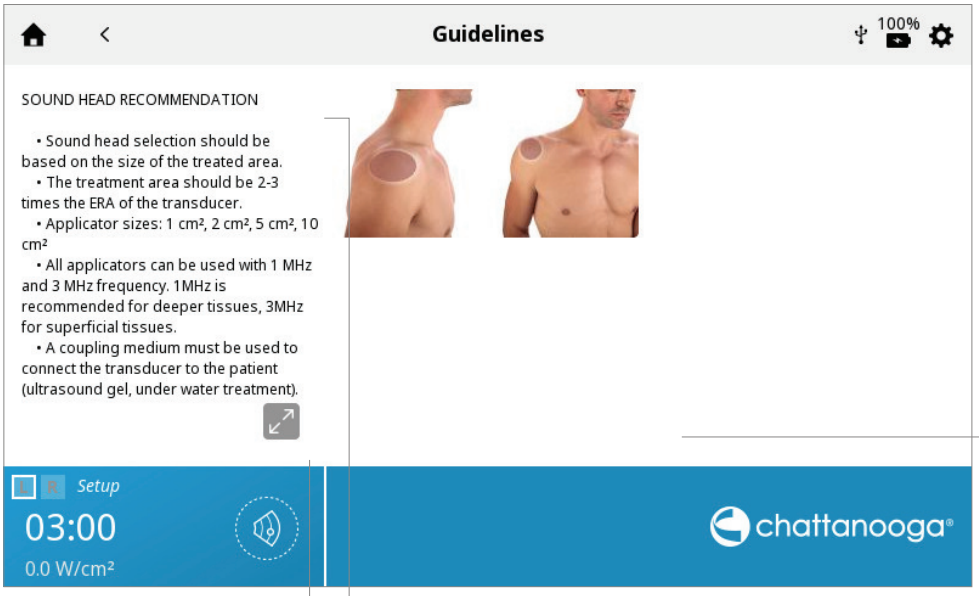


Touch to switch ON or OFF

1. Touch to activate
2. Adjust with Adjustment dial:
   - Clockwise – Increase
   - Counterclockwise – Decrease

GUIDELINES SCREEN

The Guidelines for ultrasound provide the following information:
Instructions for optimal US applicator use at the left side of the screen.
Images illustrating US treatment area and recommended applicator choice at the right side of the screen.



Touch image to view in full screen mode

Swipe horizontally for more

View in full screen mode

Swipe vertically to see more

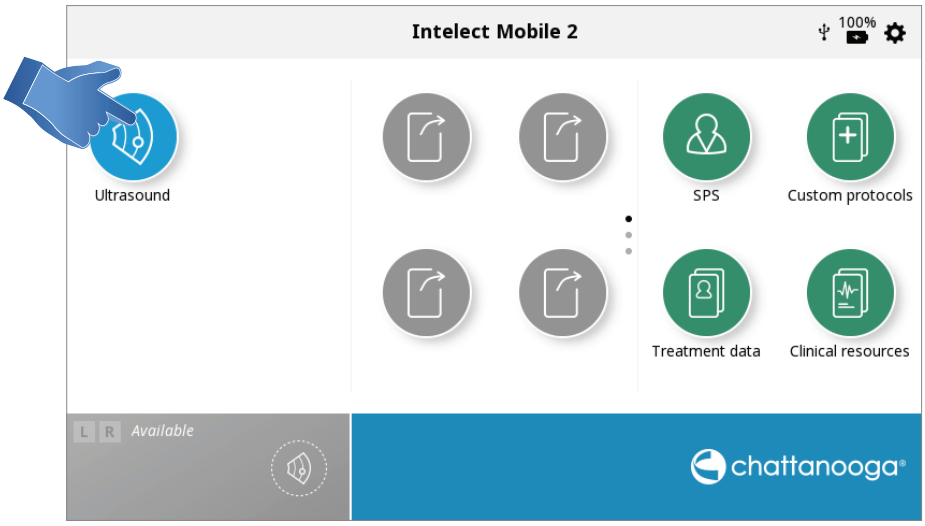
ULTRASOUND OPERATION

Complete the following steps to begin Ultrasound treatment:

1. To prepare the patient's skin for Ultrasound Therapy, prepare patient as described in the ULTRASOUND PATIENT PREPARATION section on page ....

NOTE: Use only Intelect® Mobile 2 Ultrasound Applicators . Previous models of Chattanooga Ultrasound Applicators will not work with the Intelect® Mobile 2.

2. From the home screen, select the Ultrasound icon

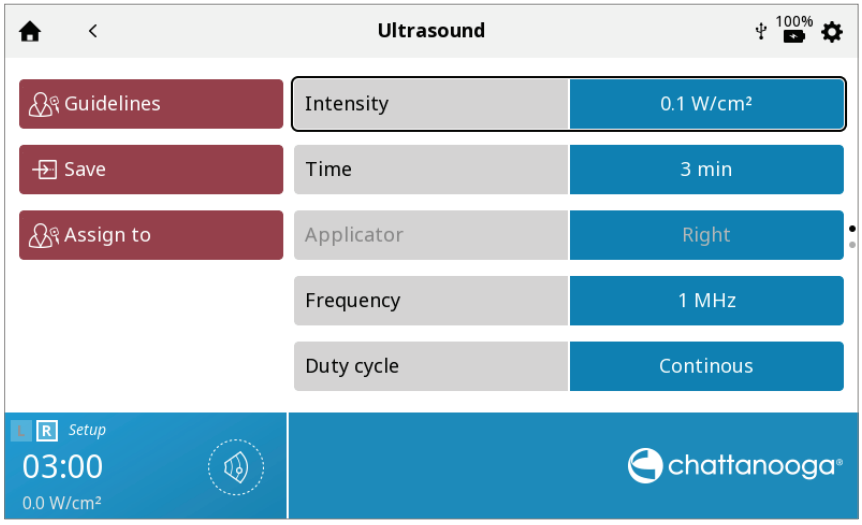


3. SET UP TREATMENT

On the treatment review screen you can adjust treatment parameters to desired level.

Refer to page ... for detailed description of the Treatment Review Screen.

Note: Never start with intensity adjustment – first adjust all other parameters and set Intensity just before starting treatment

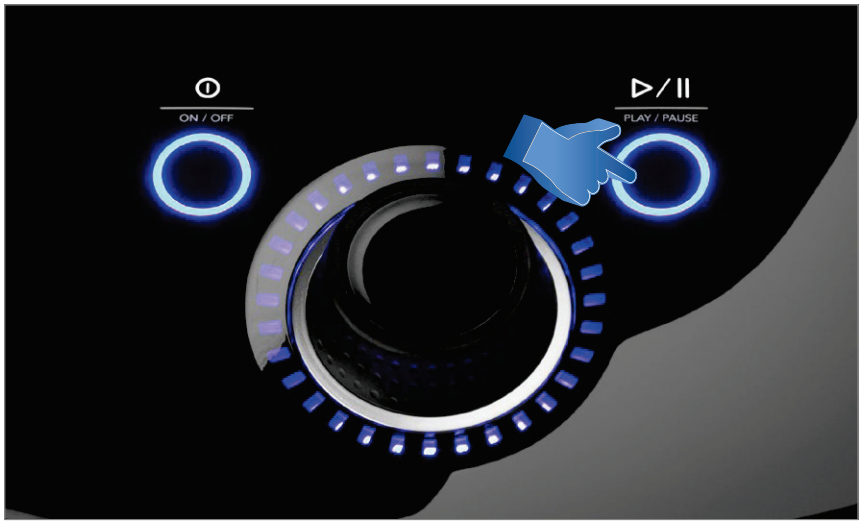


Swipe to see more parameters

Touch to activate
2. Adjust with Adjustment dial:
- Clockwise – Increase
- Counterclockwise – Decrease

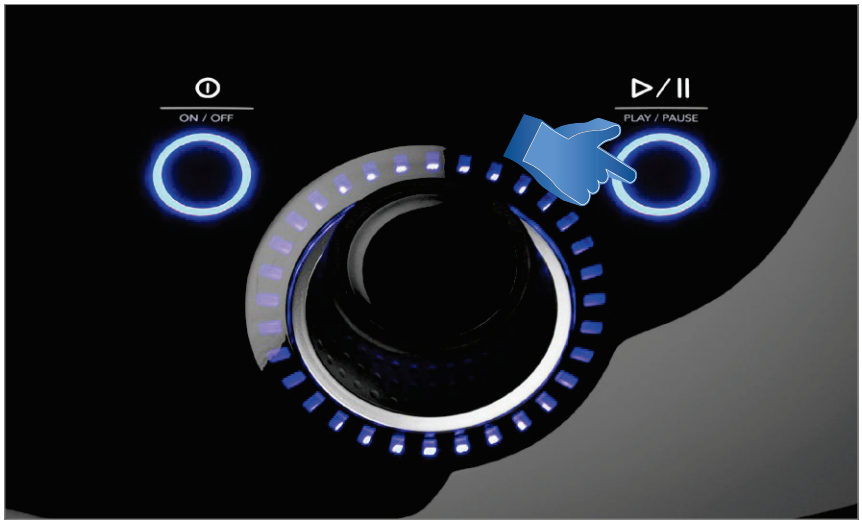
4. START TREATMENT

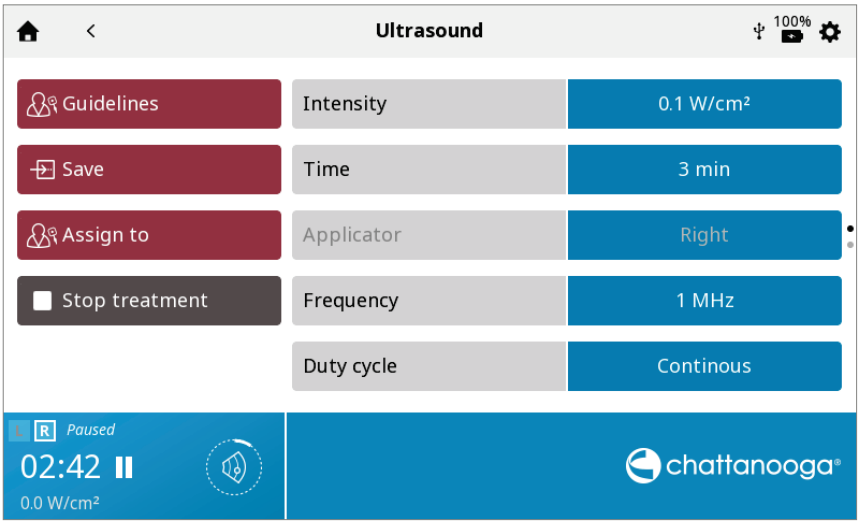
Press the START button to begin the therapy



5. PAUSE TREATMENT

Press the Start/Pause button



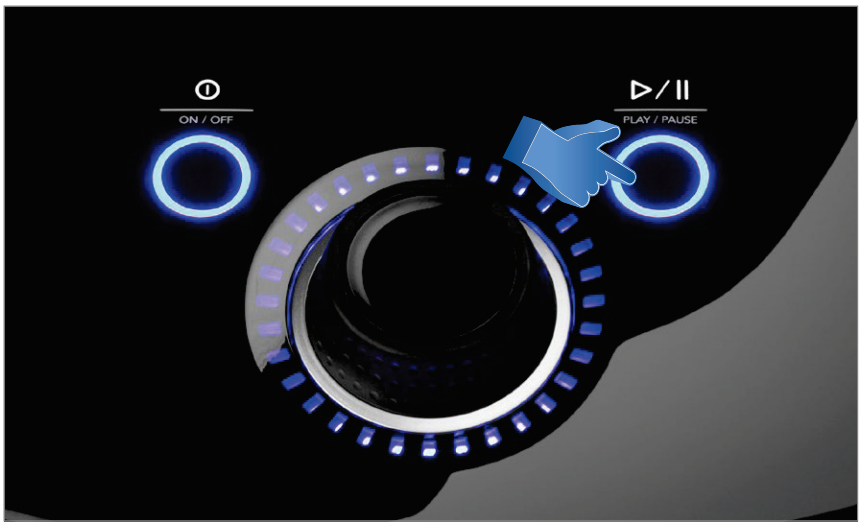


To resume treatment, press the Start /Pause button again

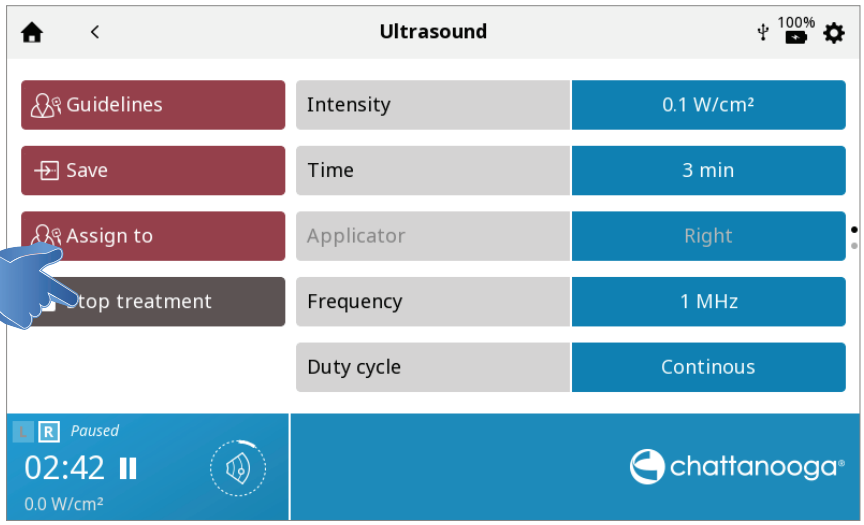
Note: Pause applies to the selected channel only

6. STOP TREATMENT

- First pause treatment by pressing the Start/Pause button



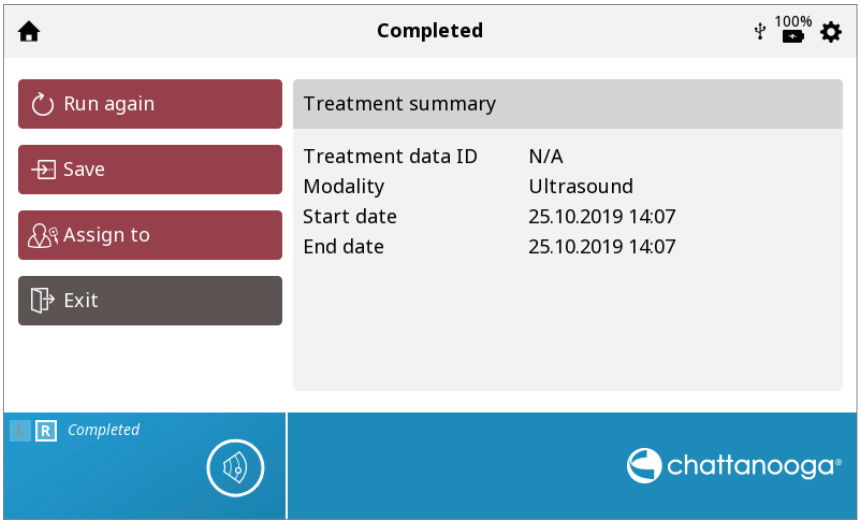
- Then press the 'Stop treatment ' box on the treatment review screen.



Note: A running treatment can only be stopped from the Pause status

When treatment has completed, the Treatment Summary screen will appear with the following options:

- Save
  » the treatment protocol to the Custom Protocols (cfr. Page..)
- Assign to:
  » Assign therapy information to treatment data



Settings of completed treatment

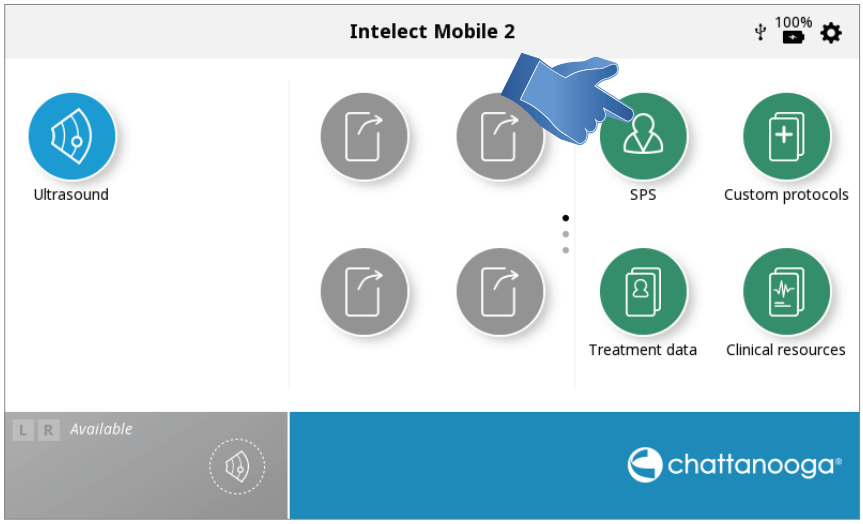
Exit Modality and return to home screen

SPS (SUGGESTED PARAMETER SETUP)

The Intelect® Mobile 2 has a Suggested Parameter Setup (SPS) icon that is a series of protocol presets where the body area, clinical indication, pathological condition and severity are selected by the user, and the suggested algorithm will select the parameter settings. All settings can be edited to suit appropriate patient treatment prescription and patient comfort.

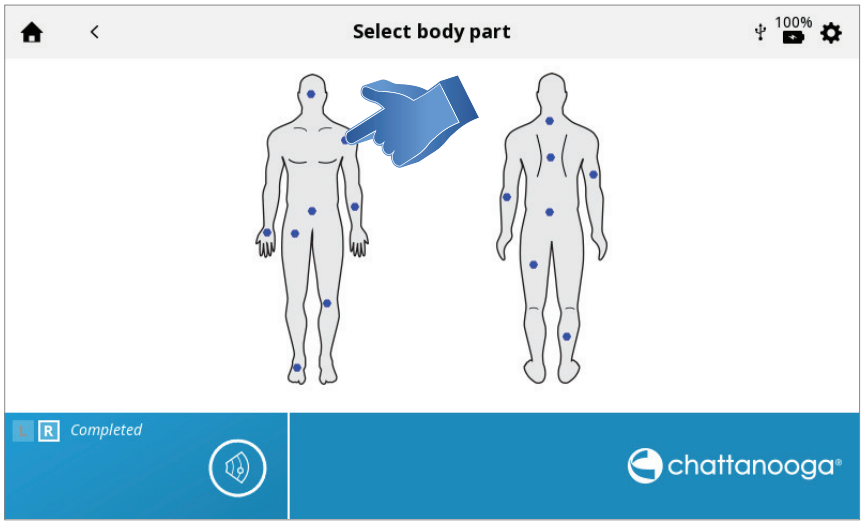
COMPLETE THE FOLLOWING STEPS TO START AN SPS PROTOCOL:

1. Select SPS from the Home Screen

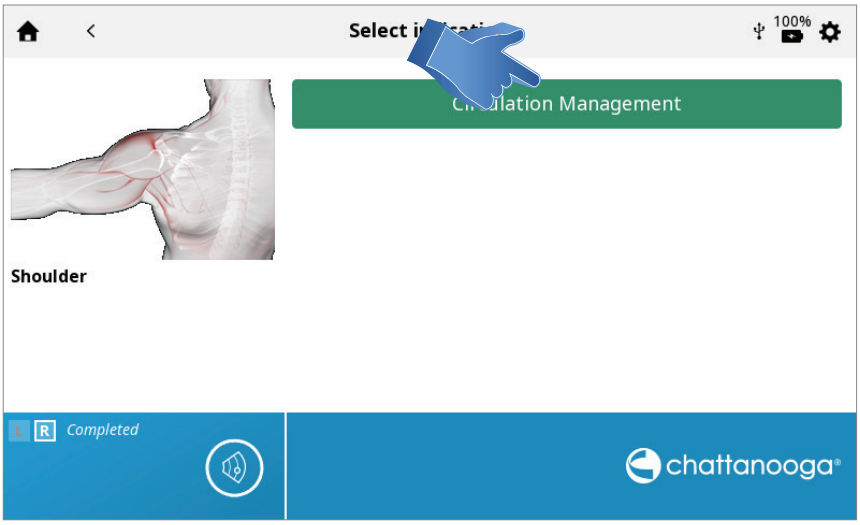


2. Select the BODY PART you wish to treat

Note: the selected body part will be highlighted and moving your finger to another area while holding screen contact will highlight and select another body part.

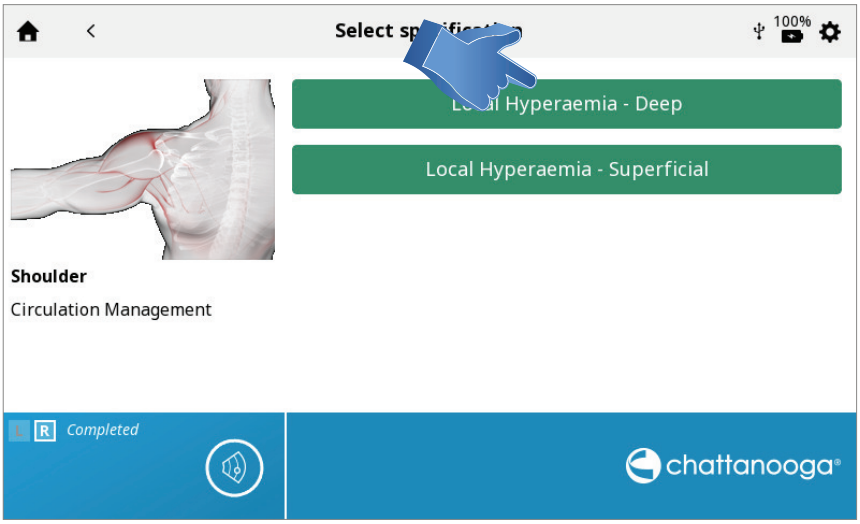


3. Select INDICATION



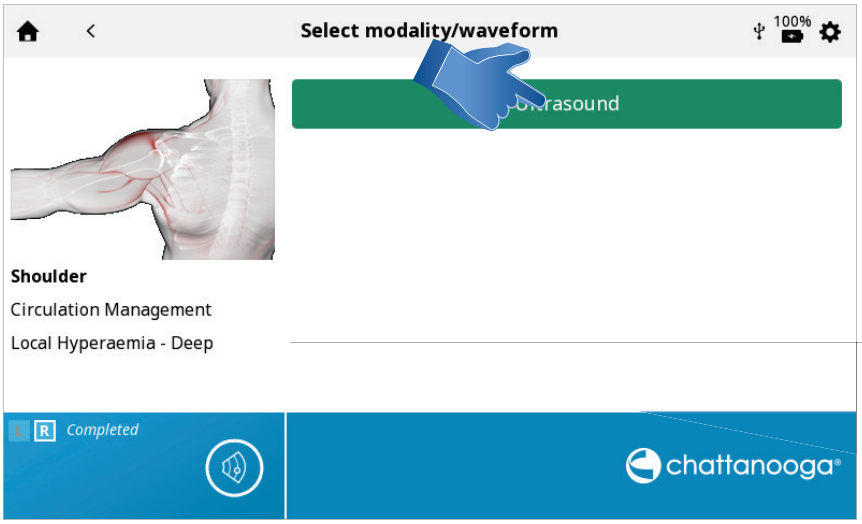
Touch to select
Swipe vertically to see more

4. Select specification



Touch to select

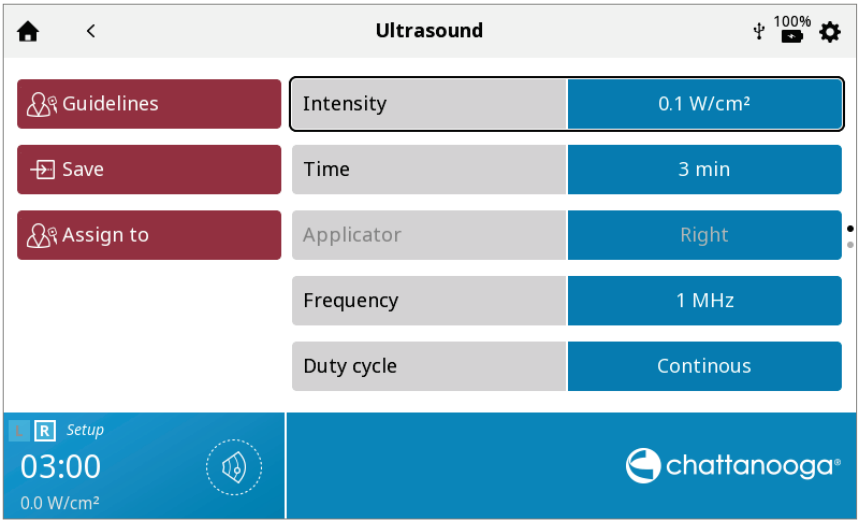
5. Select MODALITY/WAVEFORM



6. SET UP TREATMENT

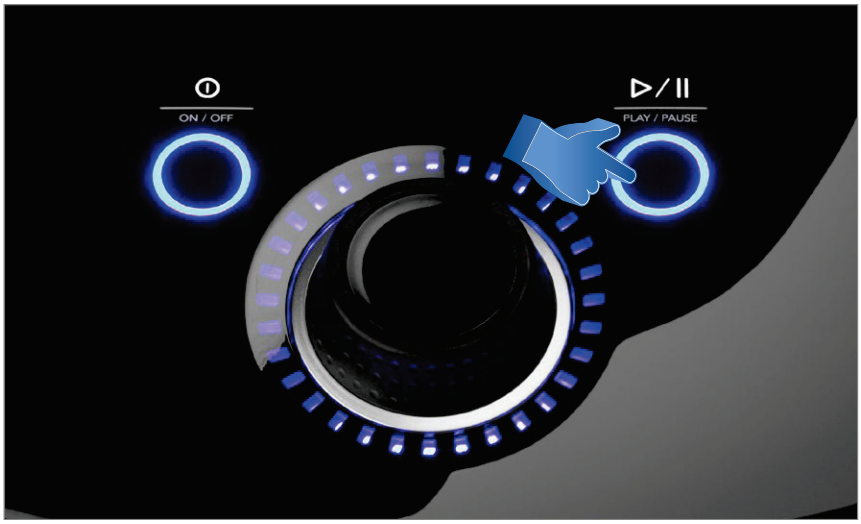
On the treatment review screen the suggested treatment settings are displayed and you can adjust parameters to desired level. Refer to page ... for detailed description of the Treatment Review Screen.

Note: Never start with intensity adjustment – first adjust all other parameters and set Intensity just before starting treatment



7. START TREATMENT

Press the START button

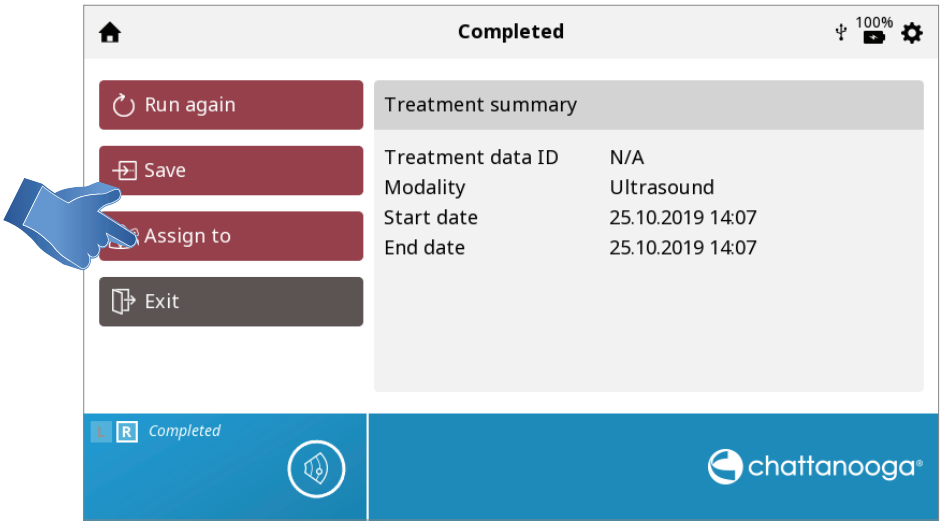


TREATMENT DATA

After a treatment has been completed, Treatment data can be saved on the Intelect Mobile 2 for later use on the unit.

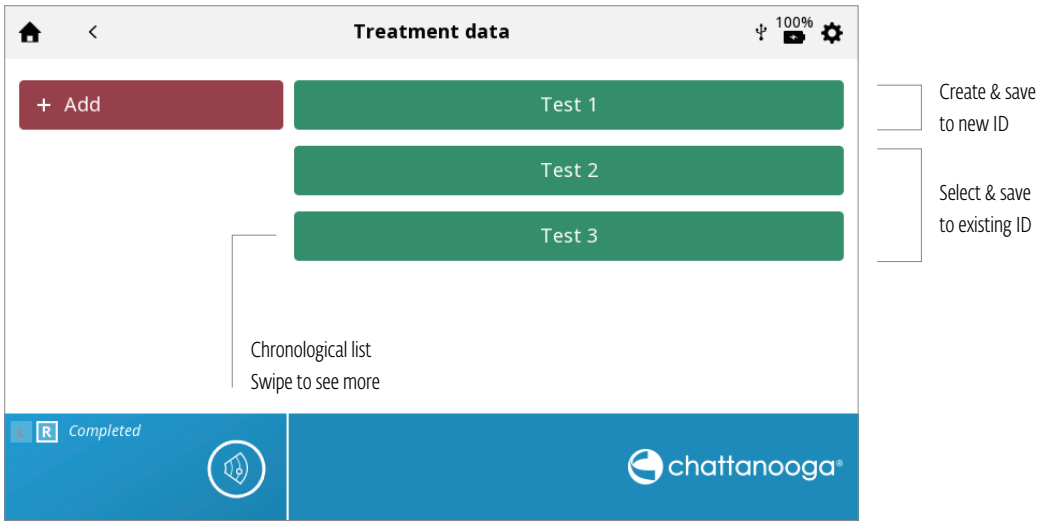
SAVE TREATMENT DATA

Click on Assign To button. Treatment data can be assigned to a folder at any time of the treatment (set up, running or completed) but data will only be saved once the treatment is finished and channel is free for next treatment (after pressing EXIT button on Treatment Summary screen)



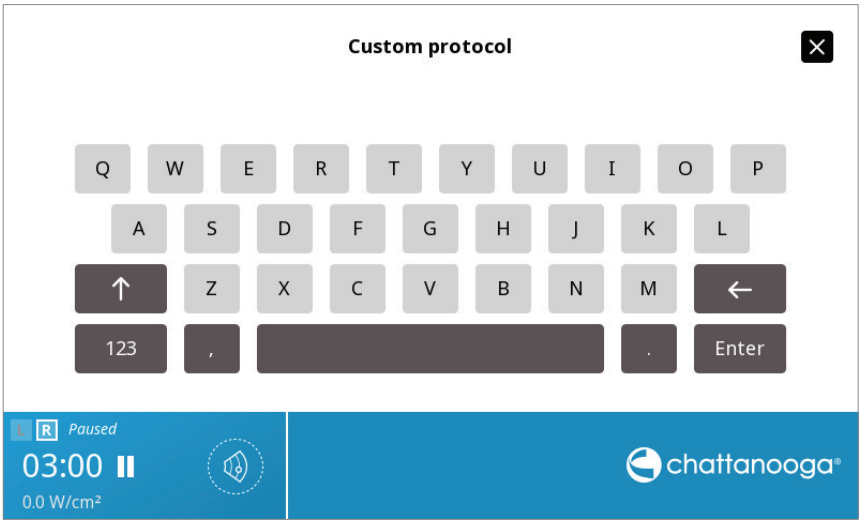
The TREATMENT DATA screen appears

Save treatment data to an existing ID folder or create and save to a new ID folder



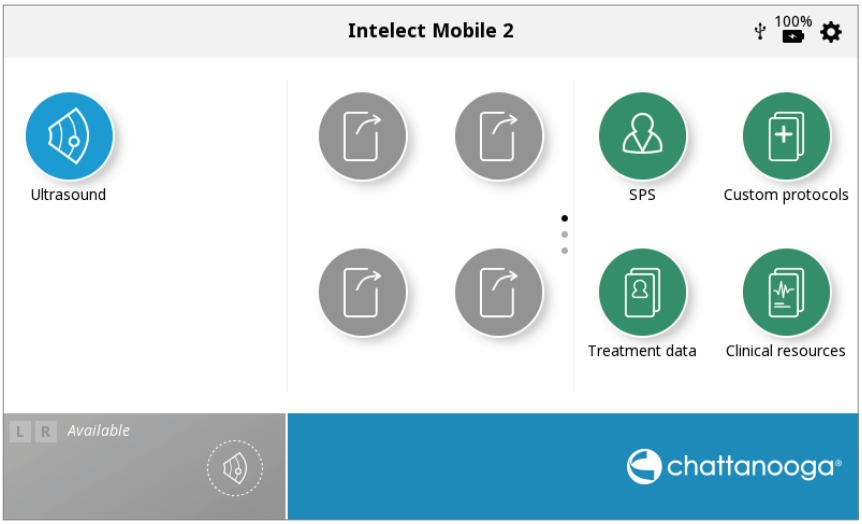
SAVE TREATMENT DATA TO A NEW ID:

Enter ID and Save



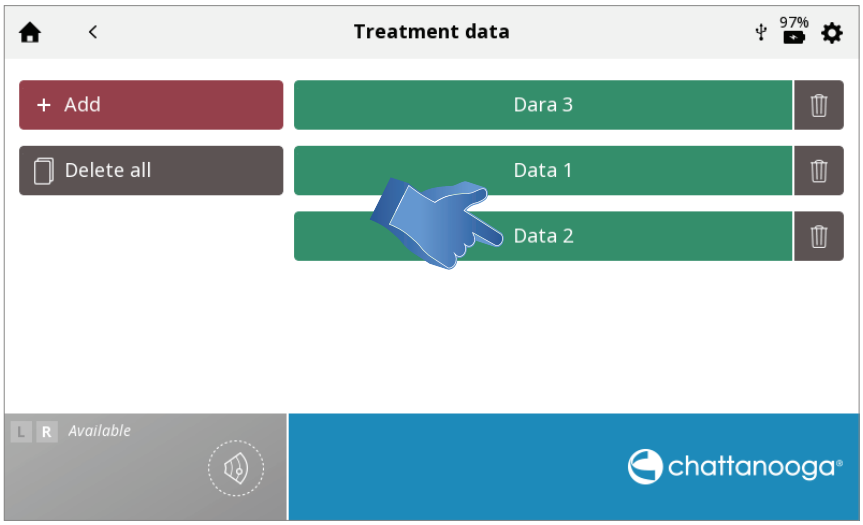
VIEW AND MANAGE TREATMENT DATA

Press the TREATMENT DATA ICON on the home screen

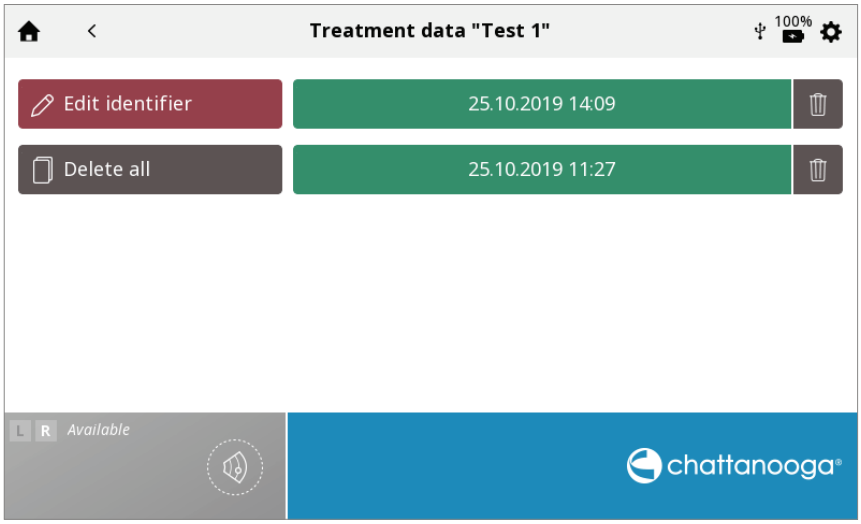


1. VIEW Treatment Data

Select desired ID folder



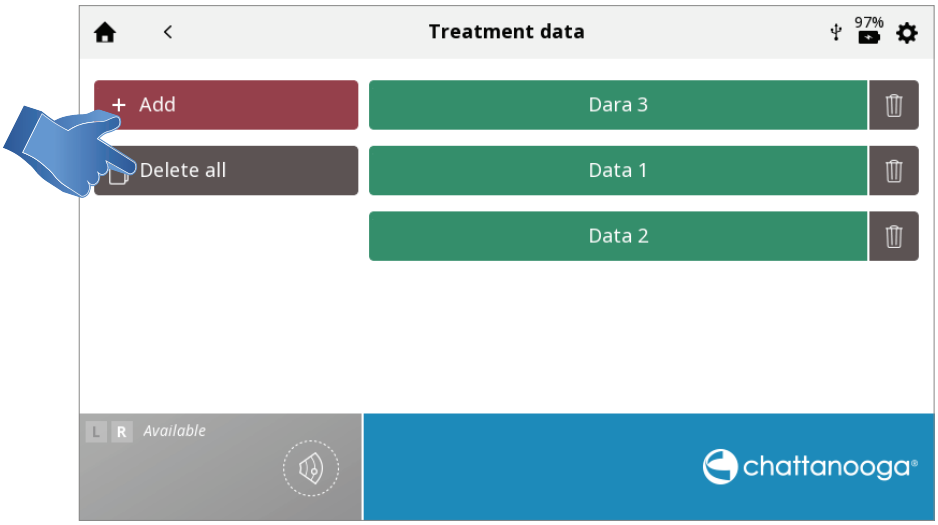
The TREATMENT HISTORY is displayed including all previously saved treatment sessions ranked chronologically



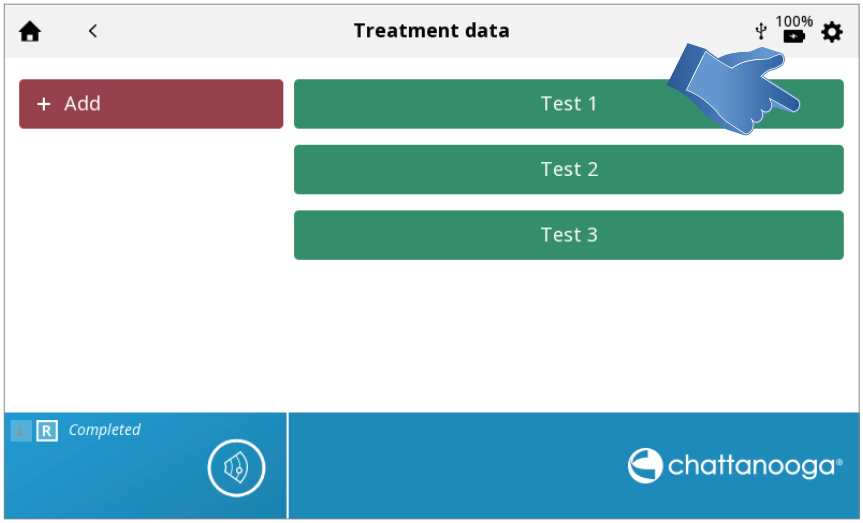
Select session to view Treatment Summary for that session.

2. DELETE Treatment Data

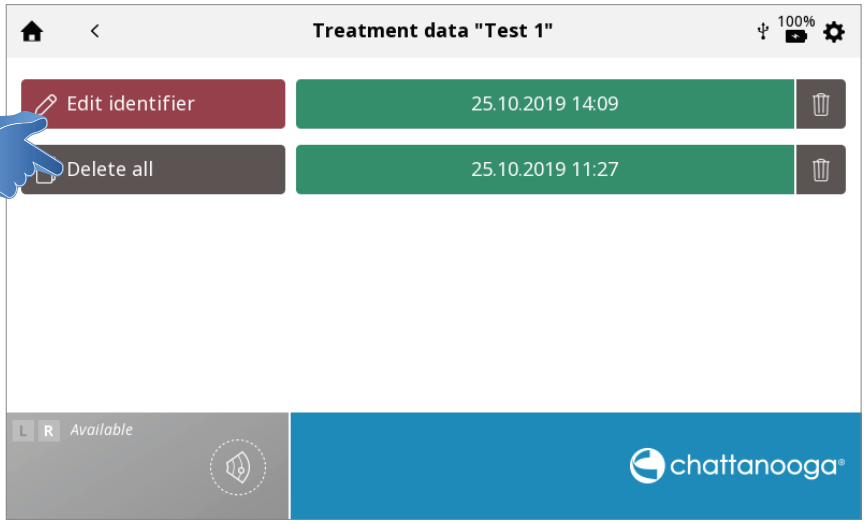
Delete all IDs



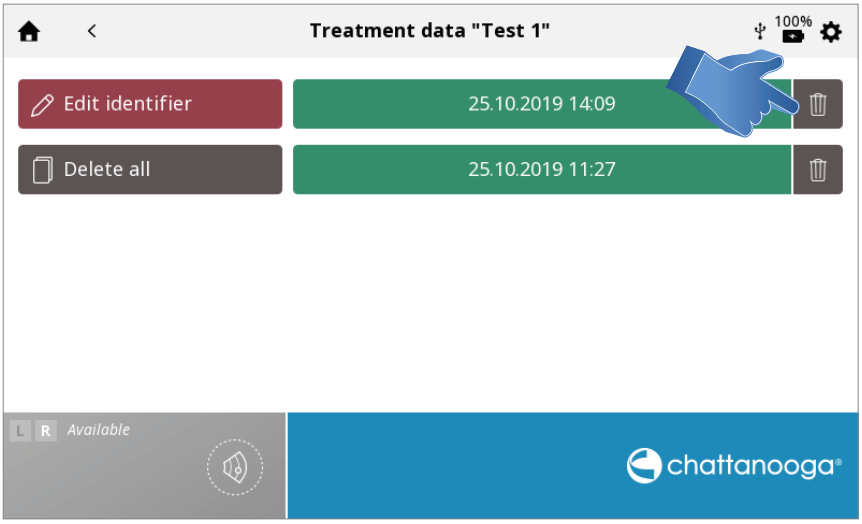
Delete one ID



Delete all treatment sessions



Delete one session

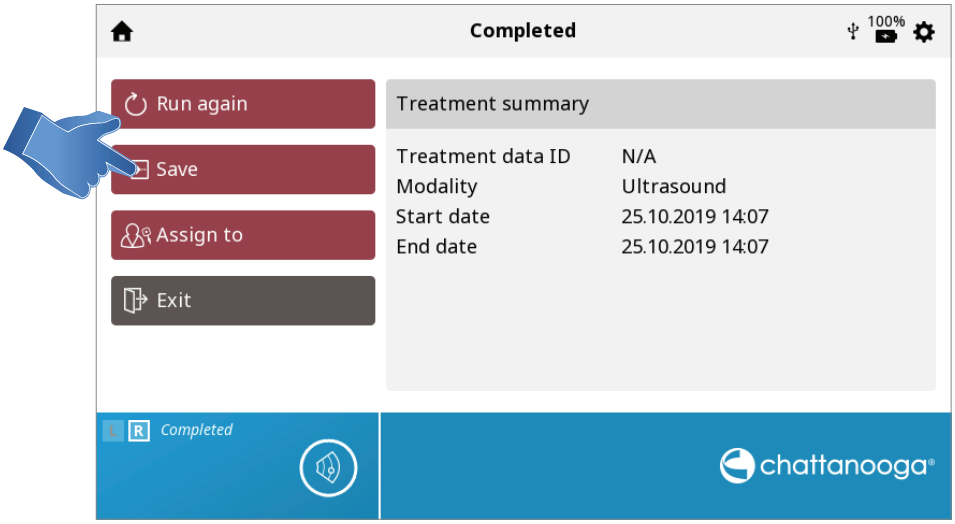


CUSTOM PROTOCOLS

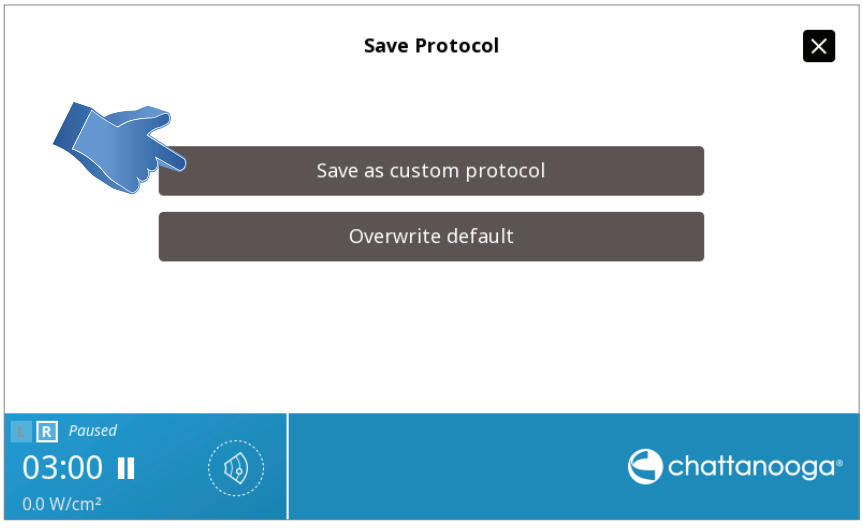
The Intelect® Mobile 2 allows for a maximum of 25 custom protocols to be defined.

SAVE A CUSTOMIZED PROTOCOL
A new custom protocol may be saved at any time using SAVE button

1. Touch SAVE on the TREATMENT REVIEW or TREATMENT SUMMARY screen

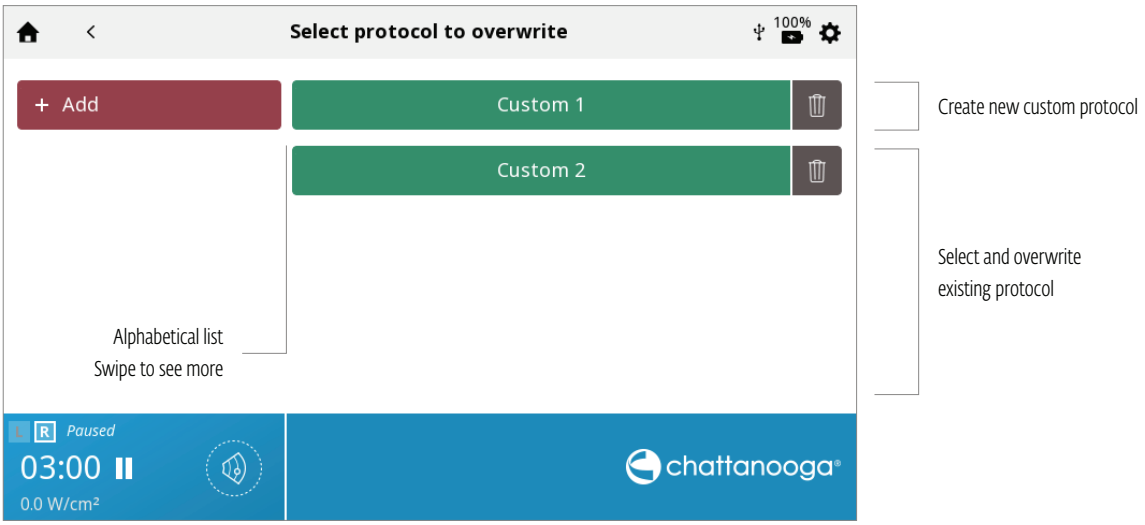


2. Select SAVE TO CUSTOM PROTOCOLS



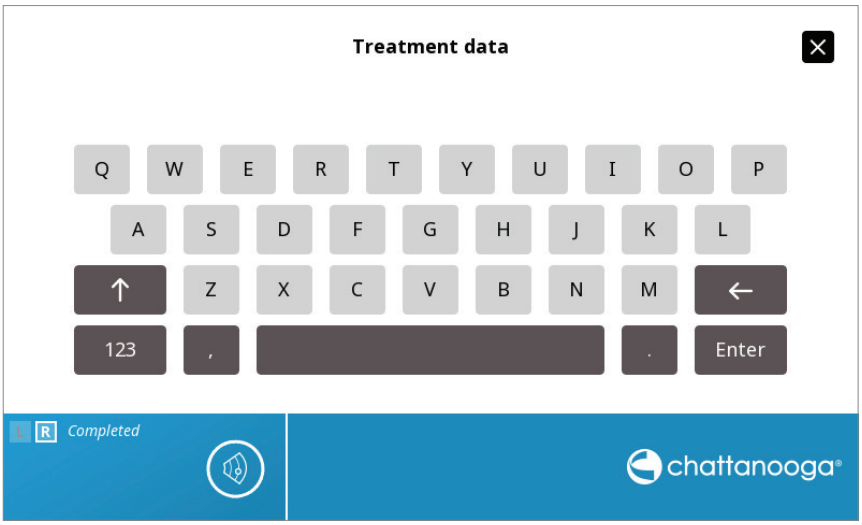
Note: it is also possible the overwrite the default settings of the waveform instead of saving to custom protocols.

3. The Custom Protocol library is displayed where you can save the protocol as NEW custom protocol or OVERWRITE an existing custom protocol



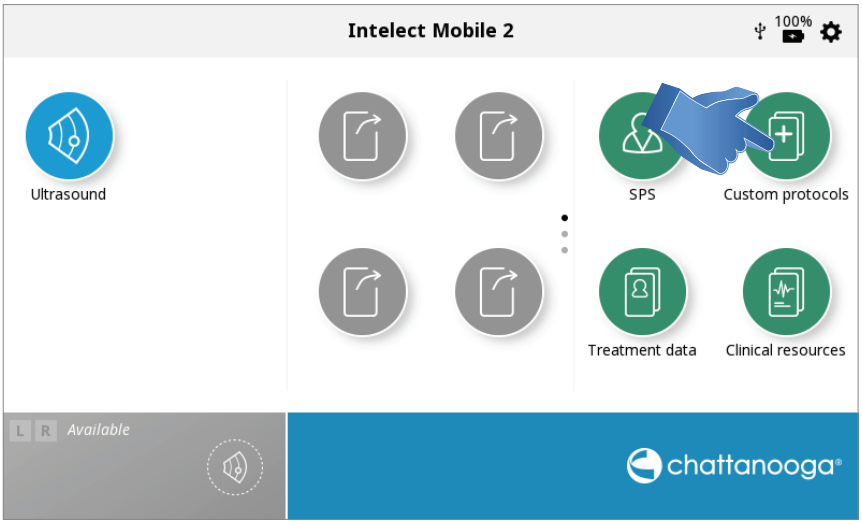
CREATE NEW CUSTOM PROTOCOL:

Enter Custom Protocol Name and Save



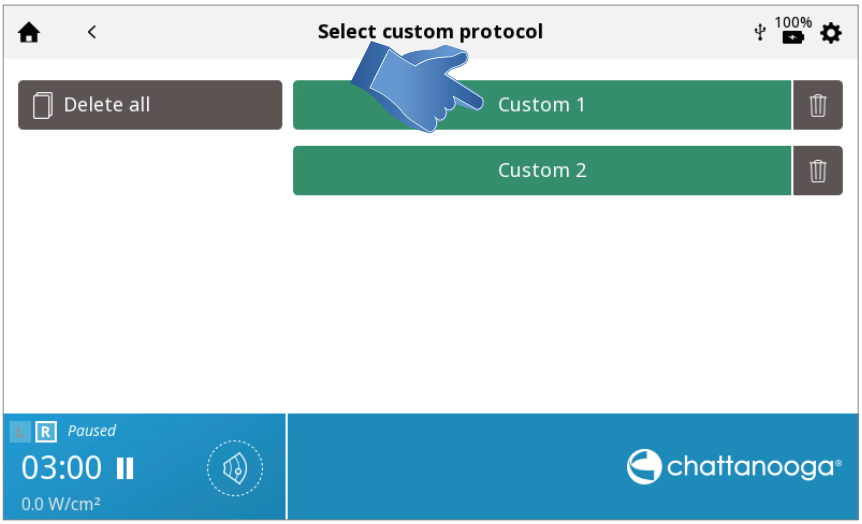
VIEW AND MANAGE CUSTOM PROTOCOLS

Touch the CUSTOM PROTOCOLS icon on the Home Screen

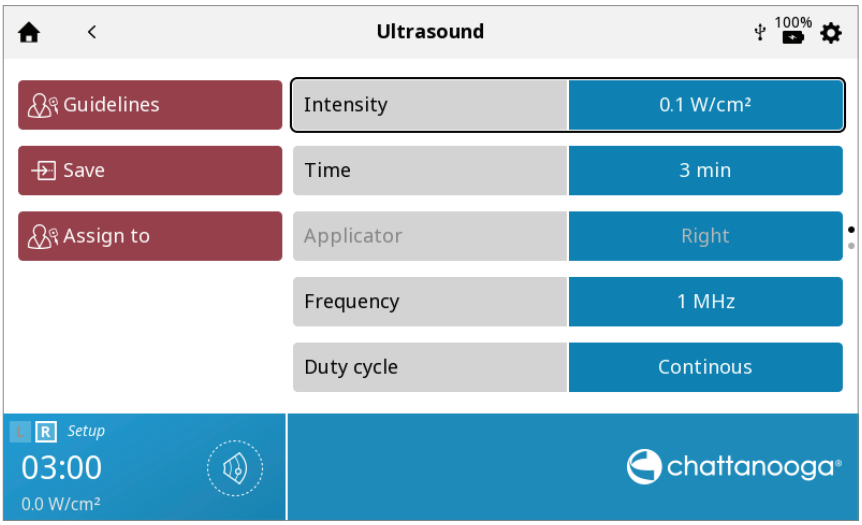


1. VIEW Custom Protocol

Select desired Custom Protocol

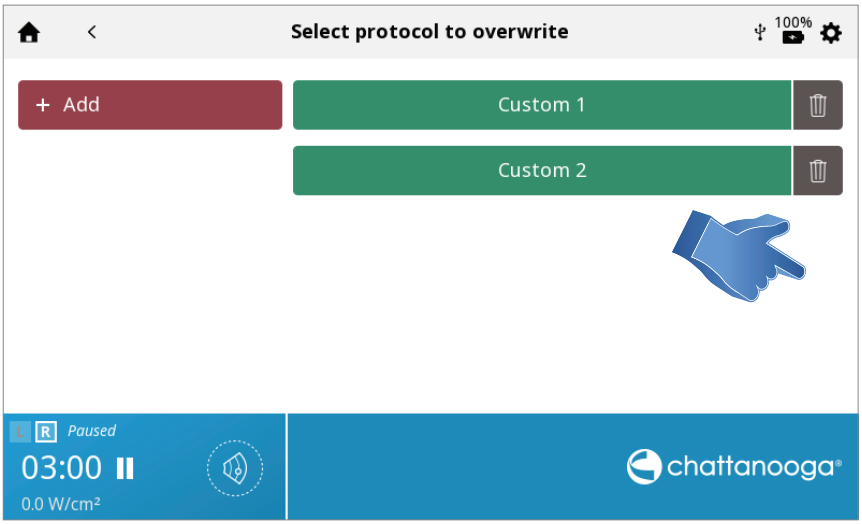


The TREATMENT REVIEW SCREEN is displayed showing the protocol settings.
Start treatment or perform other actions as described in the Ultrasound Operations section



2. DELETE custom protocol

Delete all protocols

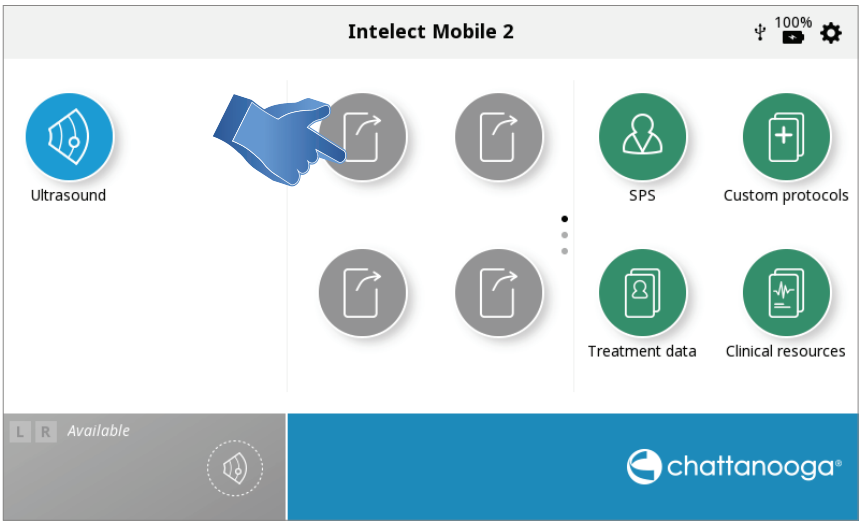


SHORT CUTS

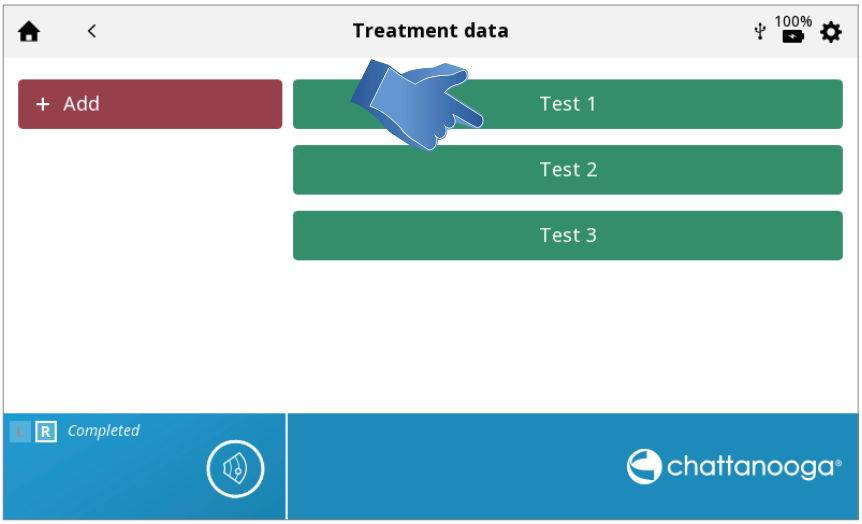
Intelect Mobile 2 allows for 12 custom protocol shortcut assignments on the home screen.

ASSIGN SHORTCUT

Complete the following steps to assign a home screen shortcut. Unassigned Shortcut icons appear grey in colour: Press one of the unassigned "Shortcut" icons on the Home screen .

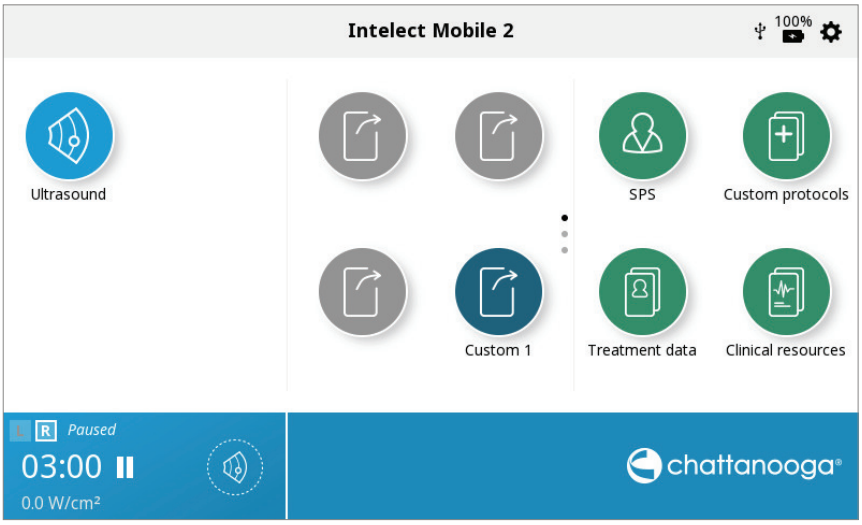


Select the desired protocol in the Custom Protocol library



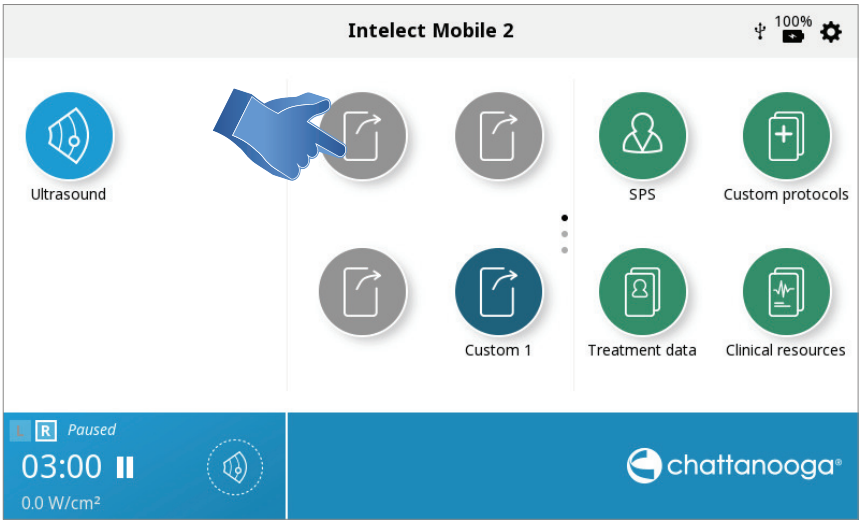
Shortcut assigned on Home screen

Once assigned the shortcut icon becomes the colour associated with the modality it contains

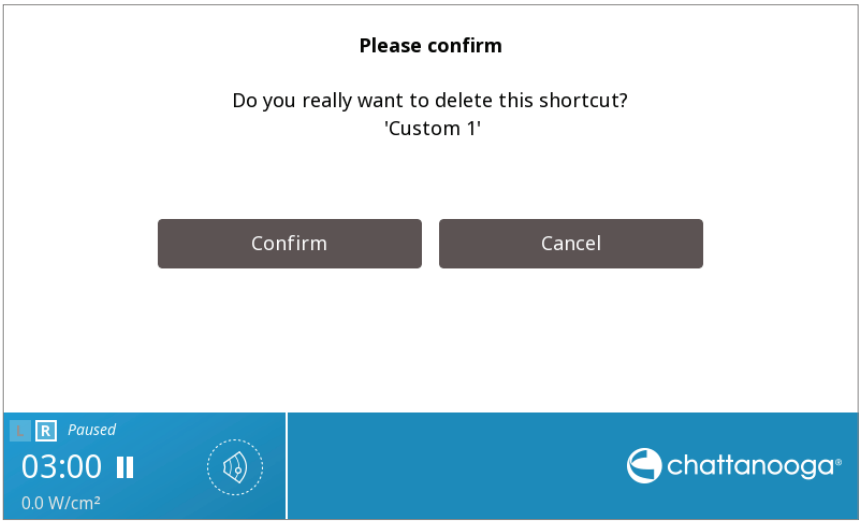


UNASSIGN SHORT CUT

Complete the following steps to unassign a Home screen shortcut for a customized protocol:
From the Home screen, press and hold the shortcut icon you wish to unassign.



The unit will display a text box asking, "Remove "My Custom Protocol 1" shortcut?"

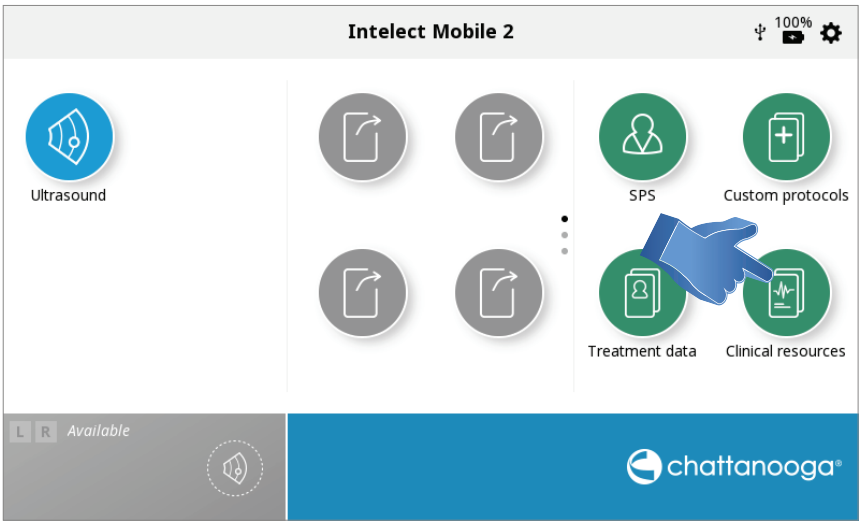


Select "No" to quit the unassignment process and return to the Home screen or "Yes" to continue with the unassignment process.
After selecting "Yes" the previously assigned shortcut will no longer appear on the Home screen.

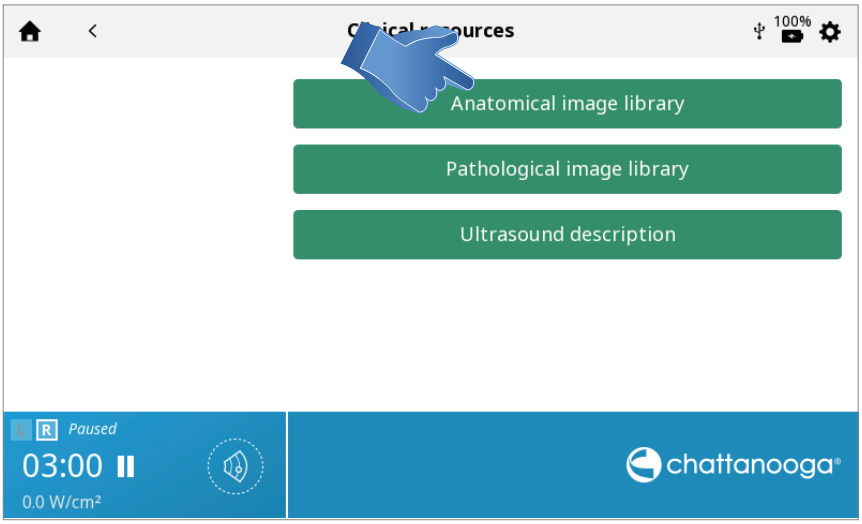
CLINICAL RESOURCES

The Intelect® Mobile 2 contains a unique Clinical Resources Library .
The anatomical and pathological image library are designed to aid the operator in visually understanding and locating specific muscle groups and commonly found problems associated with pathological conditions, as well as providing an educational tool for the clinician to use with the patient.
The modality and waveform descriptions provide information about the physical background and physiological effects of the different electrotherapy waveforms and ultrasound therapy, aiming to assist the user in selecting the appropriate modality/ waveform.
Complete the following steps to view the Clinical Resources Library:

Press the Clinical Resources Library icon on the Home screen .

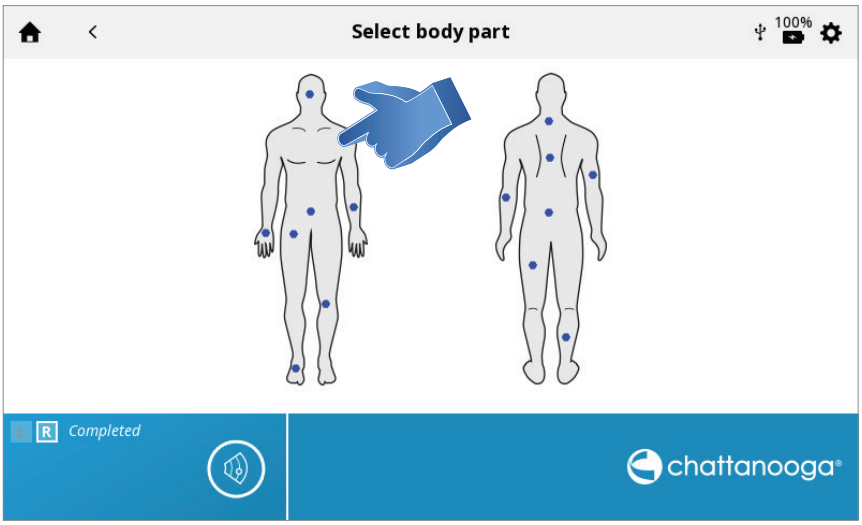


ANATOMICAL /PATHOLOGICAL IMAGE LIBRARY
Complete the following steps to view the Anatomical or Pathological Image Library:
1. Press the Anatomical or Pathological Image Library icon on the Clinical Resources screen



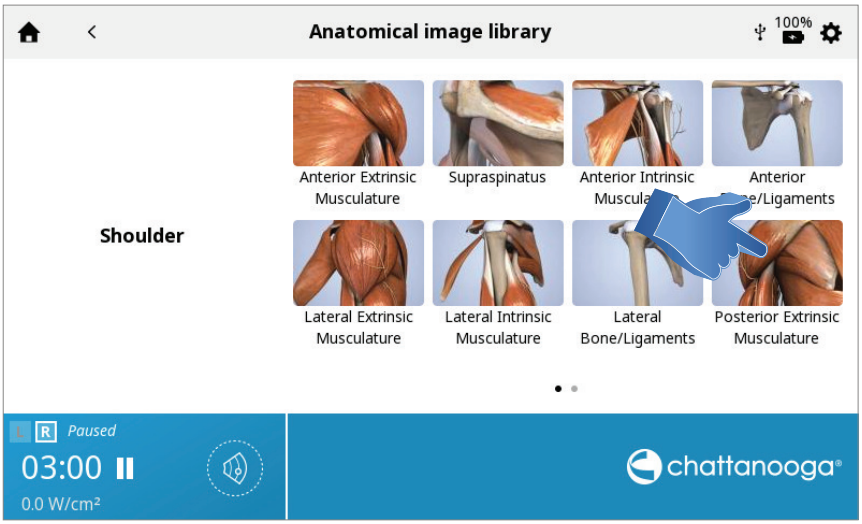
2. Touch the body part for which you wish to view information.

Choose either anterior (on left of screen) or posterior (on right of screen).

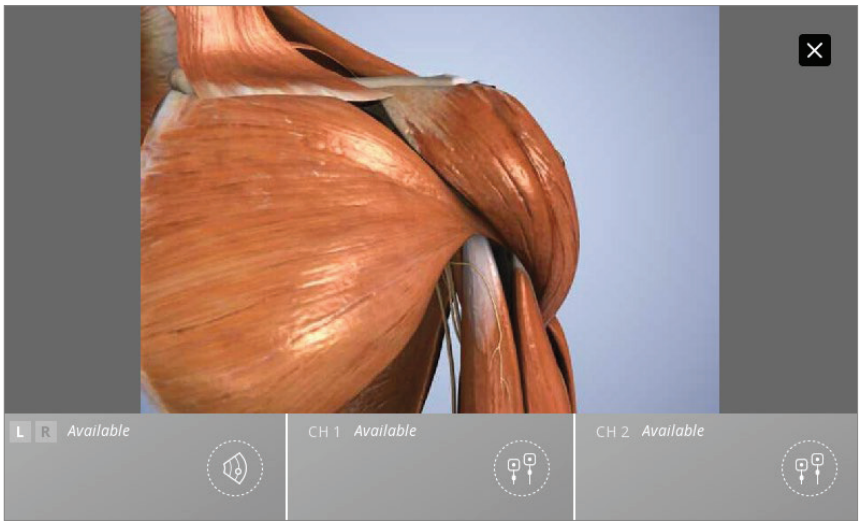


3. The available images for the selected body part are displayed.

Touch the image you want to see in full screen mode.



4. Full screen image

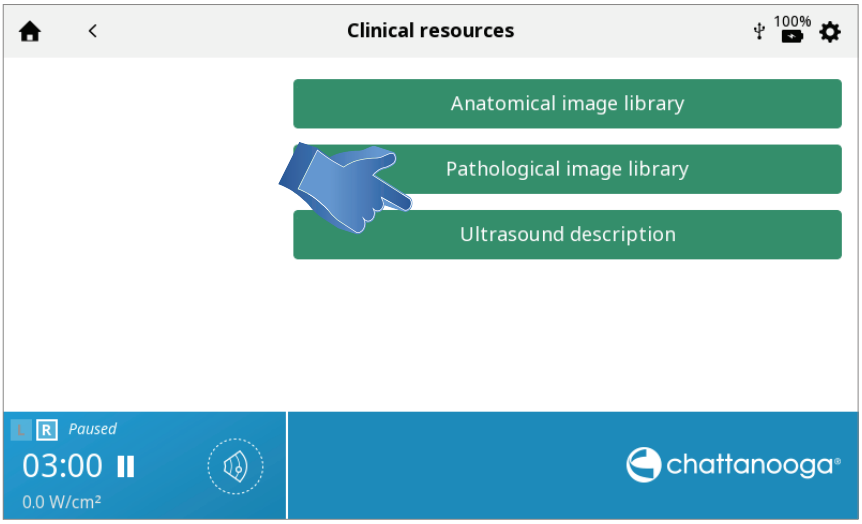


Close full screen mode

MODALITY/WAVEFORM DESCRIPTIONS

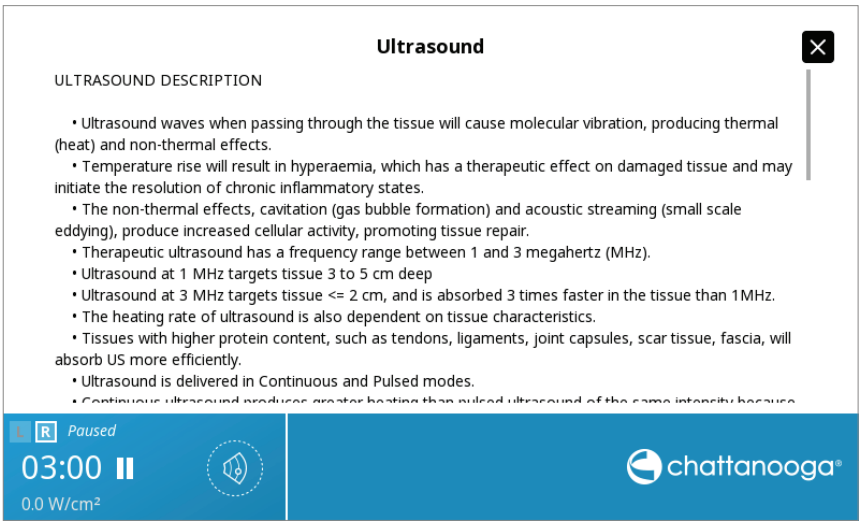
Complete the following steps to view the ultrasound or waveform descriptions:

1. Press the Ultrasound description icon on the Clinical Resources screen



2. Select the desired waveform (in case of Electrotherapy Waveform description)

3. The modality or waveform description is displayed



TROUBLESHOOTING

1. All system messages, warning messages and fault messages that are generated by the device are self-explanatory excepting system error.

2. If System error occurs, note error code and contact DJO selling dealer or DJO Service Department.

GENERAL ACCESSORIES

Model Number	Description
15-1136	Mobile 2 Cart

BATTERY *(Not available at launch)*

Model Number	Description
14-1086	Battery

ULTRASOUND APPLICATORS AND GEL

Model Number	Description
15-0140	G16 Ultrasound Applicator 1 cm^2
15-0141	G16 Ultrasound Applicator 2 cm^2
15-0142	G16 Ultrasound Applicator 5 cm^2
4248	Conductor™ Transmission Gel - 9 oz Bottle

CLEANING THE INTELECT® MOBILE 2

With the system disconnected from the power source, clean the system with a clean, lint-free cloth moistened with water and mild antibacterial soap. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner. Cleaning should be performed daily.
Do not submerge the system in liquids. Should the unit accidentally become submerged, contact the dealer or DJO Service Department immediately.

Cleaning the LCD Screen
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.

Cleaning instruction for the Ultrasound applicator
The sound head may be cleaned with alcohol between each therapy session. The Aluminium surface may be disinfected with alcohol, but avoid the plastic area.

CALIBRATION REQUIREMENTS

The unit was calibrated during the manufacturing process and doesn't need calibration during the product life.

DEVICE DISPOSAL

Council Directive 2012/19/EU concerning Waste Electrical and Electronic Equipment (WEEE) requires not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.

INSTRUCTION FOR SOFTWARE UPGRADE

1. Go to the Chattanooga website www.chattanoogarehab.com
2. Go to Intelect Mobile 2 product tab
3. Complete the registration form to be informed about new product software version availability and IFU updates (if not already done before)
4. Go to documents tab
5. Download firmware upgrade onto USB stick
6. Switch OFF the device
7. Insert USB key
8. Switch ON the device
9. Device will automatically detect firmware update availability
10. Once firmware update is finished, Home screen will be displayed. Device is ready for use.

IFU DOWNLOAD

1. Go to the Chattanooga website www.chattanoogarehab.com
2. Go to Intelect Mobile 2 product tab
3. Complete the registration form to be informed about new product software version availability and IFU updates if not already done before
4. Go to documents tab
5. Click on the latest version of your Intelect Mobile 2 device (COMBO, US or STIM) User manual to download

Nota: a pdf viewer is required to display IFU

A hard copy of the IFU can be requested from DJO either by registration on the website or you local DJO office or dealer, the copy will be delivered to you within 7 days

INSTALLATION OF BATTERY

1. Unscrew the battery door on the bottom of the device (2 screws)
2. Remove the battery door
3. Plug the new battery to the battery connector
4. Insert the battery in its location
5. Replace the battery door with the 2 screws

REPLACEMENT BATTERY

1. Unscrew the battery door on the bottom of the device (2 screws)
2. Remove the battery door
3. Unplug and remove the battery
4. Plug the new battery into the battery connector
5. Insert the battery in its location
6. Replace the battery door with the 2 screws

Note: in case of unused device with the battery installed, it is recommended to connect the device to the mains power and power on the device with the main ON/OFF switch on the back of the device at least once every 4 months to allow the battery to recharge.

WARRANTY REPAIR/OUT OF WARRANTY REPAIR

Service

When the Intelect® Mobile 2 or any accessories require service, contact your selling dealer or your DJO Service Department contact.

Service to these units will be performed only by a service technician certified by the Company.

Expected Life

- Device expected life is five years
- Accessories expected life is one year
- Gel electrodes and ultrasound gel are shelf life accessories and their shelf life is less than device expected service life. Shelf life is indicated in electrodes packaging and gel bottle.

WARRANTY

DJO FRANCE SAS ("Company") warrants that the Intelect® Mobile 2 and Vacuum Module ("Products") are free of defects in material and workmanship. This warranty shall remain in effect for two years (24 months) from the date of original consumer purchase.

During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship.

Attention

Modifications to the device are not permitted. Any unauthorized opening, repair or modification of the device by unauthorized personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.

The warranty period for accessories is 90 days. Accessories consist of Lead Wires and Electrodes.

The warranty period for the Therapy System Cart and Ultrasound Applicators is one year (12 months).

This Warranty Does Not Cover:

- Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a Company service technician
- Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a Company service technician
- Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and required maintenance or any use that is inconsistent with the Product User's Manual

COMPANY SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

This warranty gives you specific legal rights and you may also have other rights which vary from location to location. The Company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product.

Any representative or agreement not contained in the warranty shall be void and of no effect.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacturer's declaration – electromagnetic emissions		
The Intelect® Mobile 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Intelect® Mobile 2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Intelect® Mobile 2 uses RF energy only for its internal function. Additionally the Intelect® Mobile 2 contains a Bluetooth® radio module. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The Intelect® Mobile 2 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.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Intelect® Mobile 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Intelect® Mobile 2 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Risk assessment on the Intelect® Mobile 2 indicates the compliance levels claimed are acceptable when ESD-precautionary measures are taken. The Intelect® Mobile 2 may be susceptible to Electrostatic Discharge (ESD) at greater than ±7 kV when first grasping the Ultrasound applicator. In the event of such a discharge, the Intelect® Mobile 2 may display a permanent error. The Intelect® Mobile 2 will terminate all active outputs (stim, ultrasound), automatically place the unit in a safe state. To prevent Electrostatic Discharge (ESD) at greater than ±7 kV: • Grasp and hold the Ultrasound applicator prior to starting treatment. If the applicator must be put down prior to completion of treatment, stop the current treatment first and then place the applicator in the holder. • Maintain humidity in the use environment to at least 50% relative humidity. • Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, DJO recommends implementing additional controls to maintain relative humidity to at least 50%. • Communicate these ESD-precautionary procedures to healthcare staff, contractors, visitors and patients.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV differential 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 IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intelect® Mobile 2 requires continued operation during power mains interruptions, it is recommended that the Intelect® Mobile 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/M	3 A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Guidance and manufacturer's declaration – electromagnetic immunity

The Intelect® Mobile 2 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Intelect® Mobile 2 should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
		3 Vrms 6 Vrms 10 V/m 9-28V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Intelect® Mobile 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √P d = 2 √P d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM bands[a]		
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz 9-28V/m in wireless bands		

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) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Intelect® Mobile 2 is used exceeds the applicable RF compliance level above, the Intelect® Mobile 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Intelect® Mobile 2.

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Recommended separation distances between portable and mobile RF communications equipment and the Intelect® Mobile 2

The Intelect® Mobile 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Intelect® Mobile 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Intelect® Mobile 2 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 d (m)			
	150 kHz to 80 MHz outside ISM bands D = 1.2 √P	150 kHz to 80 MHz in ISM bands D = 2 √P	80 MHz to 800 MHz D = 1.2 √P	800 MHz to 2,5 GHz D = 2.3 √P
0.01	0.12	0.20	0.12	0.23
0.1	0.38	0.63	0.38	0.73
1	1.2	2.0	1.2	2.3
10	3.8	6.3	3.8	7.3
100	12	20	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CE
2797

DJO France SAS
Centre Européen de Frêt 3 rue de Bethar
64990 Mouguerre • France
T: + 33 (0) 5 59 52 86 90 • F: + 33 (0) 5 59 52 86 91
DJOglobal.com

DJO® | chattanooga®

DJO, LLC | 1430 Decision Street | Vista | CA 92081-8553 | U.S.A.
www.DJOglobal.com