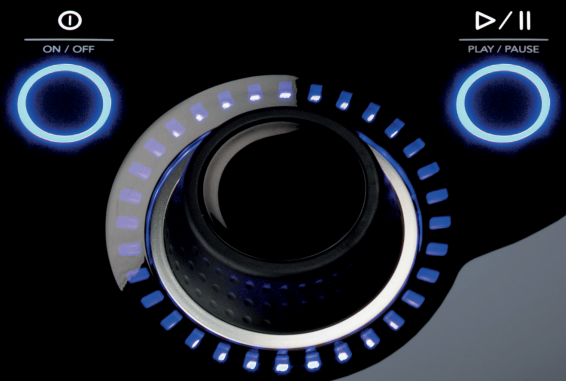
chattanooga®

Intelect® Mobile 2

ULTRASOUND (15-0131), STIM (15-0132), COMBO (15-0133)

User Manual



User Manual · Manual del usuario · Manuel de l'utilisateur · Benutzerhandbuch · Manuale d'uso · Gebruiksaanwijzing · Uživatelská příručka · Manual de utilizare · Podręcznik użytkownika · Εγχειρίδιο χρήσης · Kullanım Kılavuzu · Brugervejledning · Käyttöopas · Brukerhåndbok · Руководство пользователя · Manual do usuário 用户手册 · ユーザーマニュアル · 사용자 설명서

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chattanooga®

Intelect® Mobile 2

ULTRASOUND (15-0131), STIM (15-0132), COMBO (15-0133)

User Manual

FOREWORD

This manual is intended for users of Intelect® Mobile 2 ULTRASOUND (15-0131), Intelect® Mobile 2 STIM (15-0132) and Intelect® Mobile 2 COMBO (15-0133). 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.

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.

INTENDED PURPOSE

The Intelect® Mobile 2 devices comprise of a range of multimodality (TENS; NMES, Ultrasound) therapies intended to be used by healthcare professionals using TENS, NMES and Therapeutic Ultrasound for the treatment of various musculoskeletal and skeletal muscle deficit disorders.

The Intelect® Mobile 2 product range offers the following models:
The Intelect® Mobile 2 Electrotherapy Device delivering TENS and NMES
The Intelect® Mobile 2 Ultrasound device delivering Therapeutic Ultrasound
The Intelect® Mobile 2 Combo Device delivering both Electrotherapy (TENS and NMES) and Therapeutic Ultrasound either simultaneously or independently

INTENDED USER

The intended user of this device is a licensed healthcare 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 both professional and home healthcare environment.

INTENDED PATIENT POPULATION

The Intelect® Mobile 2 Devices are suitable for adult patients requiring symptomatic treatment of musculoskeletal conditions mentioned under "indications" and to whom none of the contraindications apply.

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.

ELECTROTHERAPY INDICATIONS

INDICATIONS

Indication TENS:

- Symptomatic relief of acute and chronic pain associated with musculoskeletal conditions
- Management and alleviation of post operative pain

Indication NMES:

- Skeletal muscle deficit disorders resulting in benefits such as:
  - » - Muscle re-education
  - » - Maintaining/increasing range of motion

CONTRAINDICATIONS

The Intelect® Mobile 2 should NOT be used under the following conditions:

- 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 apply stimulation over swollen, infected, inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).
- 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 place electrode placements to the carotid sinus region (anterior neck) or transcerebrally (through the head).
- Do not use on pregnant women. Safety has not been established

ELECTROTHERAPY INDICATIONS (CONTINUED)

for the use of therapeutic electrical stimulation during pregnancy.

- 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.
- Do not apply stimulation transthoratically or on the chest, the introduction of electrical current into the heart may cause cardiac arrhythmia
- Do not apply stimulation over the anterior neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

ADDITIONAL PRECAUTIONS

- Use caution for patients with suspected or diagnosed heart problems.
- Use caution for patients with suspected or diagnosed epilepsy.
- Use caution in the presence of the following:
- When there is a tendency to hemorrhage following acute trauma or fracture
- Following recent surgical procedures when muscle contraction may disrupt the healing process
- Over a menstruating or pregnant uterus
- Over areas of the skin that lack normal sensation
- Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.
- With TENS waveforms, isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- The effective management of pain by TENS waveforms is highly dependent upon patient selection by a person qualified in pain management.

ADVERSE EFFECTS

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle

stimulators. The irritation can usually be reduced by using an alternative conductive medium or an alternative electrode placement

- Potential adverse effects with TENS are skin irritation and electrode burns

Note: 1. Skin irritation and burns beneath the electrodes can be reduced or avoided by using appropriate electrode size and ensuring optimal contact quality.

2.Some people, with very sensitive skin, may experience redness under the electrodes after a session. Generally, this redness is totally harmless and usually disappears after 10 to 20 minutes. However, do not start another stimulation session on the same area if the redness is still visible

ULTRASOUND INDICATIONS

INDICATIONS

- Musculoskeletal conditions facilitating pain relief to the affected area.

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

ADVERSE EFFECTS

- Stinging sensation and temporary local sensitivity have been reported during or following ultrasound therapy.

GENERAL WARNINGS AND PRECAUTIONS

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.
- Before each use, inspect Vacuum Electrode Cups and Lead Hoses for cracks and damage which may not allow the vacuum to properly secure the electrodes.
- Handle Ultrasound Applicator with care. Inappropriate handling may adversely affect its characteristics.
- Caution should always be exercised with current densities more than 2mA/cm^2.
- 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.
- For waveforms with a DC component:
  - » Do not shave electrodes application area
  - » Warn the patient that tingling sensation under electrodes is normal and it is not linked to burn risk.
  - » Rinse thoroughly treatment area with tap water immediately after the treatment

⚠ 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.
- Use of electrode on multiple patients can lead to infection.
- Do not apply electro stimulation treatment during bath, shower, sauna,..
- 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.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.
- Simultaneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- 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

WARNING

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. 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.

- 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

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.

DEVICE DESCRIPTION

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
	Stim
	Ultrasound
	Combo
	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 ISO 15223-1 One or more of the following markings may appear on the device:

Consult Instruction for Use	
Refer to Instructional Manual Booklet	
Warning, Caution, or Danger	
Electrical Type BF Equipment	
Ultrasound	
Rechargeable	
Stim	
Combo	
Play	
Pause	
ON/OFF	
Manufacturer	
Date of manufacture	
Catalogue number	
Serial number	
Fragile, handle with care	
This end up	
Keep dry	

Storage conditions	
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	
MD	
Unique Device Identification	
This device must be separated from household waste and sent to special collection facilities for recycling and recovery	

PRODUCT DESCRIPTION

The Intelect® Mobile 2 is a two-channel electrotherapy, ultrasound therapy and Combo 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 healthcare professional.

15-1200	Intelect® Mobile 2 Ultrasound INTL Set EU Plug 1cm2
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

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 CM² Ultrasound Applicator Ultrasound
4248	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

HEAD

CART (OPTIONAL)

ULTRASOUND APPLICATORS

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.

VACUUM MODULE (OPTIONAL)

BATTERY MODULE (OPTIONAL)

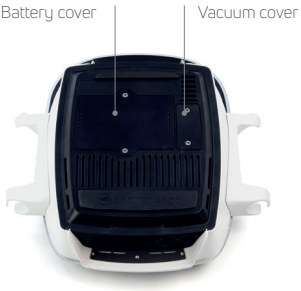
Battery is an 18V 3350mAh LiIon rechargeable battery

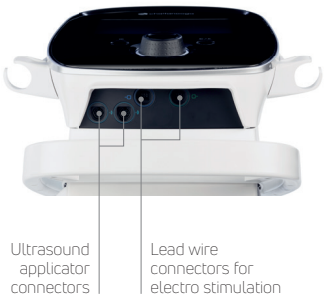
OPERATOR INTERFACE

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.

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


Handle
Colour Touch Screen
"On/Off" button
Play / pause button
Ultrasound applicator support
Adjustment dial


Battery cover
Vacuum cover


Ultrasound applicator connectors
Lead wire connectors for electro stimulation


ON / OFF switch only active on mains power
USB port for software upgrade
Mains power connector

DEVICE LIGHT INDICATORS

Intelect® Mobile 2 has several light indicators:

FRONT PANEL INDICATORS:

1. Colors:
   - Light blue around Ultrasound therapy channel Left and Right
   - Dark blue indicator around Electrostimulation Channel 1
   - Green indicator around Electrostimulation Channel 2

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.

HEAD TO CART FIXATION

The optional Therapy System Cart 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.

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

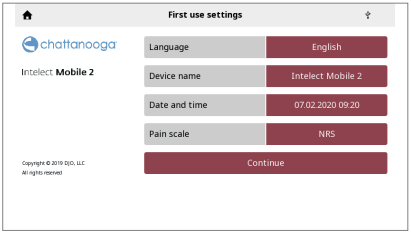
Note: in case of unused device with the battery installed, it is
recommended to connect the device to the mains power and power on the device with the main ON/OFF switch on the back of the device at least once every 4 months to allow the battery to recharge.

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.

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.

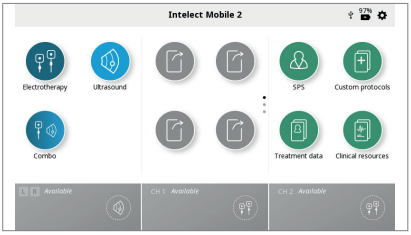
2. The first setup screen will be displayed after this allowing the user to set language, device name, time and choose patient pain scale as either NRS (Numerical Rating Scale) or VAS (Visual Analogue Scale).



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

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. Press ON/OFF button on LCD Front panel
4. 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).

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

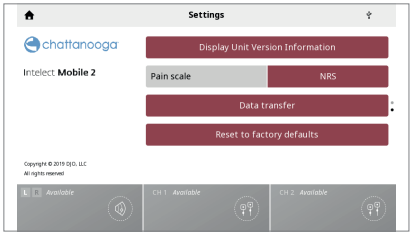
DATA SYNCHRONISATION

Chattannoga Intelect® Connect App is an optional software that can be installed on a computer. It uses Bluetooth® low energy to connect to the device to provide the following features:
1. Import/Export Custom Protocols
2. Import/Export Treatment data
3. Import Sessions of the device on the computer
4. Archive the Treatment Data's session history in a format that can be used for reporting
5. Backup/Restore device configuration

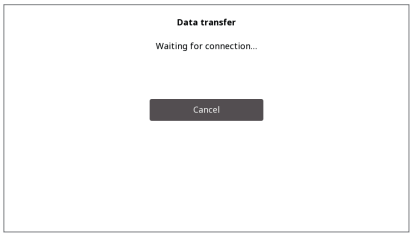
Refer to Chattanooga website to download it, Microsoft Windows 10 or higher with Bluetooth® Low Energy communication capabilities computer is required.

Nota: device can not be used to deliver treatment while data transfer.

To prepare for communication with the App press the settings button, scroll down the screen and press the Data transfer button.



You should now see the screen Waiting for connection whilst the device discovers the computer to be paired with.



Start the Chattanooga Intelect® connect App and follow instructions on computer screen.

SYSTEM

SYSTEM SPECIFICATIONS AND DIMENSIONS

	Width	Depth	Height	Weight (no battery)
Intelect® Mobile 2 Head Unit				
COMBO	34cm	35.5cm	15cm	3.1kg
UltraSound	34cm	35.5cm	15cm	2.8kg
STIM	25.5cm	35.5cm	15cm	2.9kg
Cart configurations				
Cart (Safe working load 6.5kg)	48cm (max)	52cm (max)	96cm	10.1kg
Cart with vacuum	48cm (max)	52cm (max)	96cm	11.5kg
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
Electrotherapy .TYPE BF
Electrotherapy Vacuum .TYPE BF
Ultrasound & Electrotherapy .TYPE BF

ELECTRO STIMULATION SPECIFICATIONS

Output specifications are described for each waveform from pages 24-26.
Unless otherwise specified, electrotherapy controls accuracy is: ± 20 %.
Load impedance: 500-1000 Ohm
CC = constant current, effect of load impedance on voltage
CV = constant voltage, effect of load impedance on current

VACUUM SPECIFICATIONS

Power

Input 20-25 Vdc, maximum peak current 1 A
Electrical Type TYPE BF

General characteristics

Vacuum Range .0 to 600 mbar maximum +/- 5%
Vacuum Modes Continuous or Pulsed Continuous.
10 setting over vacuum range,
60 mbar per setting,
+10 mbar to 10 mbar per setting

Pulsed Mode

Maximum Vacuum settings 2 to 10, +10mbar to -10mbar per setting
Minimum Vacuum settings in 1 to 9, +10mbar to -10mbar per setting
Hold Time in minimum & maximum vacuum settings, 0-20 seconds, in 1 second steps, +/-0.5 seconds

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	1cm2		2cm2		5cm2		10cm2	
	1MHz	3MHz	1MHz	3MHz	1MHz	3MHz	1MHz	3MHz
Effective Radiating Area ERA INTL (cm2)	1	0.9	1.5	1	2.5	2.7	6	6.8
Max Output power in Continuous mode	2W	1.8W	3W	2W	5W	5.4W	12W	6.8W
Max Output power in Pulsed mode	3W	2.7W (*)	4.5W	3W	7.5W	8.1W	18W	13.6W
Max Amplitude in Continuous mode	2W/cm2	2W/cm2	2W/cm2	2W/cm2	2W/cm2	2W/cm2	2W/cm2	1W/cm2
Max Amplitude in Pulsed mode	3W/cm2	3W/cm2	3W/cm2	3W/cm2	3W/cm2	3W/cm2	3W/cm2	2W/cm2

(*) 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

WAVEFORMS

Advice on size and type of electrodes to be used is given in device User Interface treatment guidelines.

CC: Constant Current CV: Constant Voltage

IFC (Interferential) Traditional (4 Pole)

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Interferential Current is a medium frequency waveform. Current is distributed through two channels (four electrodes). The currents cross each other in the body at the area requiring treatment. The two currents interfere with each other at this crossing point, resulting in a modulation of the intensity (the current intensity increases and decreases at a regular frequency).

Output Mode	Electrodes
Available on Channel	1&2,
Treatment Time	1-60 Minutes
Mode Selection	CC
Output Intensity	0-100 mA (CC)
Beat Frequency	1-200 Hz
Carrier Frequency	2000-10,000 Hz
Cycle Time	Continuous or User Defined
Sweep Time	14 sec
Sweep Low Beat Frequency	1-199 Hz
Sweep High Beat Frequency	2-200 Hz
Scan Percentage	Static, 40%, 100%, Manual
IRMS	0-78mA
DC component	No

TENS- Asymmetrical Biphasic

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The Asymmetrical Biphasic waveform has a short pulse duration. It is capable of strong stimulation of the nerve fibers in the skin as well as of muscle tissue. This waveform is often used in TENS devices. Because of its short pulse, the patient typically tolerates the current well, even at relatively high intensities.

Output Mode	Electrodes
Output Intensity (CV)	0-140 mA (CC) 0-140 V
Available on Channel	1,2
Treatment Time (Stim)	1-60 minutes
Treatment Time (Combo)	1-30 minutes
Mode Selection (Stim)	CC or CV
Mode Selection (Combo)	CV
Amplitude Modulation	0% (off) to 100% on 10% steps
Burst Frequency	0-10 bps
Cycle Time	Continuous or User Defined
Frequency	1-200 pps
FrequencySweep	On/Off
Phase Duration	30-400 µsec
Sweep time	14 sec
Sweep Low Frequency	1-199 pps
Sweep High Frequency	2-200 pps
IRMS	0-50mA
DC component	No

WAVEFORMS (CONTINUED)

TENS- Symmetrical Biphasic

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The Symmetrical Biphasic waveform has a short pulse duration and is capable of strong stimulation of nerve fibers in the skin and in muscle. This waveform is often used in portable muscle stimulation units, and some TENS devices.

Output Mode	Electrodes
Available on Channel	1,2
Treatment Time (Stim)	1-60 min
Treatment Time (Combo)	1-30 minutes
Mode Selection (Stim)	CC or CV
Mode Selection (Combo)	CV
Output Intensity (CV)	0-140 mA (CC) 0-140 V
Amplitude Modulation	0% (off) to 100% on 10% steps
Burst Frequency	0-10 bps
Cycle Time	Continuous or User Defined
Frequency	1-200 pps
Frequency Sweep	On/Off
Phase Duration	30-400 µsec
Ramp	0-5 sec
Sweep Time	14sec
Sweep Low Frequency	1-199 pps
Sweep High Frequency	2-200 pps
IRMS	0-50mA
DC component	No

TENS - HAN

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The HAN Waveform provides optimal parameters with a precisely controlled sequence of Dense-and-Disperse (DD) modes of stimulation where a burst of 8 pulses at 80Hz is alternating with continuous stimulation (no burst), each lasting for 3 seconds.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-100 mA (CC)
Burst Frequency	2 bps
Frequency	80 pps
Phase Duration	180 µsec
IRMS	0-19mA
DC component	No

Microcurrent

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Microcurrent is a monophasic waveform of very low intensity.

Output Mode	Electrodes
Available on channels	1, 2
Treatment Time	1-60 Min
Mode Selection	CC
Output Intensity	0-1,000 µA
Duty Cycle	50%
Frequency	0.1-1,000 pps
Polarity	Positive, Negative, or Alternating
IRMS	0- 1mA
DC component	No

WAVEFORMS (CONTINUED)

VMS™

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

VMS is a symmetrical biphasic waveform with a 100 µsec interphase interval. Because the pulse is relatively short, the waveform has a low skin load, making it suitable for applications requiring high intensities, such as in muscle re-education protocols.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time (Stim)	1-60 min
Treatment time (Combo)	1-30 min
Mode Selection	CC or CV
Output Intensity	0- 140 mA (CC) 0-140 V (CV)
Anti-Fatigue	Off or On
Channel Mode	Single, Reciprocal, Co-Contract
Cycle Time	Continuous or User Defined
Frequency	1-200 pps
Phase Duration	30-1,000 µsec
Ramp	0-5 sec
Set Intensity	Individual/both Channel
Intensity Setting in Reciprocal and Co-Contract modes	
IRMS	0-50mA
DC component	No

Diadynamic Waveforms

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The Diadynamic waveforms are rectified alternating currents. The alternating current is modified (rectified) to allow the current to flow in one direction only.

Output Mode	Electrodes
Available on channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0- 60 mA
MF (Monophasé Fixe) - Frequency of 50 Hz: phase duration of 10 ms followed by a pause of 10 ms.	
IRMS [mA]	0-33 mA
DF - Frequency of 100 Hz: phase duration of 10 ms	
CP - 1 second of MF followed abruptly by 1 second of DF.	
LP - Rhythmical fluctuation between 2 MF currents.	
CP-iso - A combination of MF and DF waveforms. CP-id: Same as CP-iso.	
IRMS	0-47mA
DC component	Yes

WAVEFORMS (CONTINUED)

IFC Premodulated (Traditional 2 Pole)

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Premodulated Current is a medium frequency waveform. Current comes out of one channel (two electrodes). The current intensity is modulated: it increases and decreases at a regular frequency (the Amplitude Modulation Frequency).

Output Mode	Electrodes
Available on Channel	1, 2
Treatment Time (STIM)	1-60 Min
Treatment Time (COMBO)	1-30 Min
Mode Selection	CC or CV
Output Intensity	0-100 mA (CC) 0-100 V
(CV)) Carrier	
Beat Fixed (Sweep Off)	1-200 Hz
Cycle Time	Continuous or User Defined
Frequency	2,000-10,000 Hz
Sweep Low Beat Frequency	1- 199 Hz
Sweep High Beat Frequency	2-200 Hz
IRMS	0-55mA
DC component	No

Russian

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Russian Current is a sinusoidal waveform, delivered in bursts or series of pulses.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC or CV
Output Intensity	0-100 mA (CC) 0-100 V
(CV)	
Burst Frequency	1-100 bps
Carrier Frequency	2,500 Hz
Cycle Time	Continuous or User Defined
Duty Cycle	10%, 20%, 30%, 40%,
50%	
Ramp	0-5 sec
IRMS	0-39mA
DC component	

VMS™ Burst

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

VMS Burst is a symmetrical biphasic waveform delivered in a burst format. Because the pulse is relatively short, the waveform has a low skin load, making it suitable for applications requiring high intensities, such as muscle re-education protocols.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC or CV
Output Intensity	0-140 mA (CC) 0-140 V
(CV)	
Anti-	Off or On
Burst Frequency	1-200 bps
Channel Mode	Single, Reciprocal, Co-
Contract Phase	
Cycle Time	Continuous or User Defined
Duration	30-400 µsec
Ramp	0-5 sec
Set Intensity	Individual/both Channel
Intensity	
Setting in Reciprocal and Co-Contract modes	
IRMS	0-50mA
DC component	No

MONOPHASIC: Monophasic Rectangular Pulsed

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The Monophasic Rectangular Pulsed waveform is an interrupted unidirectional current with a rectangular pulse shape.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-60 mA (CC)
Phase Duration	0.1-1,000 ms
Phase Interval	5-5,000 ms
IRMS	0-47mA
DC component	Yes

WAVEFORMS (CONTINUED)

MONOPHASIC: Monophasic Triangular

Pulsed

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The Monophasic Triangular Pulsed waveform is an interrupted unidirectional current with a triangular pulse shape.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-60 mA (CC)
Phase Duration	0.1-1,000 ms
Phase Interval	5-5,000 ms
IRMS	0-27mA
DC component	Yes

GALVANIC: Continuous

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Galvanic Current is a direct current flowing in one direction only. The current can be continuous or interrupted.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-40 mA (CC)
Cycle Time	Continuous, or User Defined
Polarity Reversal	On or Off
With Polarity Reversal On, Polarity will change in the middle of the treatment time.	
IRMS	0-44mA
DC component	Yes

GALVANIC: Interrupted

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

Galvanic Current is a direct current flowing in one direction only. The current can be continuous or interrupted.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-40 mA (CC)
Pulse Duration	136 µsec
Phase Interval	25 usec
Polarity Reversal	On or Off
With Polarity Reversal On, Polarity will change in the middle of the treatment time.	
Polarity Reversal Ramp	1 sec
IRMS	0-41mA
DC component	Yes

Träbert (Ultrareiz)

The Träbert Current is a monophasic waveform with a phase duration of 2 ms and a pause of 5 ms resulting in a frequency of approximately 143Hz.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-80 mA (CC)
Frequency	143 pps
Polarity Reversal	On or Off
With Polarity Reversal On, Polarity will change in the middle of the treatment time.	
Phase Duration	2 ms
IRMS	0-47mA
DC component	Yes

WAVEFORMS (CONTINUED)

SURGED: Monophasic Rectangular
The SURGED: Monophasic Rectangular Current is a series of rectangular, monophasic pulses. The pulses surge to maximum power, hold and then decrease before the pause. This waveform is well suited for muscle re-education.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0- 60 mA (CC)
Frequency	5-60 Hz
Phase Duration	0.2-5.0 ms
Pause	0-57 sec
Surges per minute	1-20
IRMS	0-37mA
DC component	Yes

Low Level Galvanic
Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature
Low Level Galvanic Current is a direct current flowing in one direction only. The intensity is limited to 4.0mA

Output mode	Electrodes
Mode selection	CC
Output Intensity	0-4 mA (CC)
Dosage	40-80 mA-min
Polarity	Fixed at positive
IRMS	0-5mA
DC component	Yes

SURGED:Monophasic Triangular
Surged Monophasic Triangular Pulsed waveform is a one channel waveform. It is a triangular pulse waveform that is ramped up and down in amplitude (surged).

Output mode	Electrodes
Available on channels	1,2
treatment time	1-60min
Mode selection	CC
Output intensity	0-60mA(CC)
Frequency	5-60Hz
Phase duration	0.2-5.0ms
Pause	0-57sec
surges per minute	1-20
IRMS	21mA
DC component	Yes

VMS™ FR
The VMS-FR version of the VMS waveform is a physiologically based channel interaction in which one channel stimulates the agonist and the other the antagonist of the muscle group that is being exercised. The agonistic channel initiates the movement with a brief burst of power, followed by a period of sustained activity to complete the movement. The antagonistic channel has a brief burst of power to slow down the initial acceleration of the agonist, followed by a low output to regulate the movement of the agonist. The movement is completed by a final burst of activity in both channels. VMS is a symmetrical biphasic waveform with a 100 µsec interphase interval. Because the pulse is relatively short, the waveform has a low skin load, making it suitable for applications requiring high intensities, such as in muscle re-education protocols.

Output Mode	Electrodes
Available on	Channels 1&2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	0-140 mA (CC)
Burst Duration	200 - 5,000 ms
Cycle Time	TBD
Frequency	20-80 pps
Phase Duration	30-400 µsec
IRMS	0-39mA
DC component	No

WAVEFORMS (CONTINUED)

High Voltage Pulsed Current (HVPC)

Advice on size and type of electrodes to be used is given in device GUI "treatment guidelines" feature

The High Voltage Pulsed Current (HVPC) has a very brief pulse duration characterized by two distinct peaks delivered at high voltage. The waveform is monophasic (current flows in one direction only). The high voltage causes a decreased skin resistance making the current comfortable and easy to tolerate.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time (Stim)	1-60 Min
Treatment Time (Combo)	1-30 Min
Mode Selection	CV
Output Intensity	0-500 V (CV)
Cycle Time	Continuous or User Defined
Display	Volts
Frequency	1-200 pps
Polarity	Positive or Negative
Ramp	0.5-5 sec
Sweep time	14sec
Sweep High Frequency	2-200 pps
Sweep Low Frequency	1-199 pps
IRMS	0-45mA
DC component	0 - 1.5mA

Isoplanar Vector Interferential Current

Interferential Current is a medium frequency waveform. Current is distributed through two channels (four electrodes). The currents cross each other in the body at the area requiring treatment. The two currents interfere with each other at this crossing point, resulting in a modulation of the intensity (the current intensity increases and decreases at a regular frequency). In Isoplanar Vector IFC Channel B has a fixed phase shift of 45° against Channel A.

Output Mode	Electrodes
Available on Channel	1&2
Treatment Time	1-60 Minutes
Amplitude	0-100 mA (CC)
Beat Frequency	1-200 Hz
Carrier Frequency	2000-10,000 Hz
Cycle Time	Continuous or User Defined
Ramp	0-5 s
Sweep Time	14 sec
Sweep Low Beat Frequency	1-199 Hz
Sweep High Beat Frequency	2-200 Hz
Vector Scan	Fixed at 45°
IRMS	0-55mA
DC component	No

WAVEFORMS (CONTINUED)

Dipole Vector Interferential Current
Interferential Current is a medium frequency waveform. Current is distributed through two channels (four electrodes). The currents cross each other in the body at the area requiring treatment. The two currents interfere with each other at this crossing point, resulting in a modulation of the intensity (the current intensity increases and decreases at a regular frequency). With the dipole vector technique the currents from the two electrode pairs are vectorially summed in the tissue. The effect is that stimulation only occurs into the direction of the resulting vector, which can be adjusted over a range of 360º.
The angle is either manually adjusted and constant, or
automatically generated so that the full revolution (360°) is automatically generated in an adjustable timing (rotation time).

Output Mode	Electrodes
Available on Channel	1&2
Treatment Time	1-60 Minutes
Amplitude	0-100 mA (CC)
Beat Frequency	1-200 Hz
Carrier Frequency	2000-10,000 Hz
Cycle Time	Continuous or User Defined
Ramp	0-5 s
Resolution Vector angle (manual mode)	359°
Rotation Time (automatic mode)	1-10 s
Sweep Time	14 sec
Sweep Low Beat Frequency	1-199 Hz
Sweep High Beat Frequency	2-200 Hz
Vector Scan	Manual / Automatic
IRMS	0-55mA
DC component	No

WAVEFORM GUIDANCE

Top-5 Recomended waveforms for each indication, with a ranking for the grade of recommendation

Ranking	Symptomatic relief of acute pain associated with musculoskeletal conditions	Symptomatic relief of chronic pain associated with musculoskeletal conditions	Management and alleviation of post operative pain	Muscle re-education	Maintaining/ increasing range of motion
1	TENS Asym BP	TENS Asym BP	TENS Asym BP	VMS, VMS burst	VMS, VMS burst
2	TENS Sym BP	TENS Sym BP	TENS Sym BP	VMS FR	VMS FR
3	IFC-4p, IFC-2p, IFC-isoplanar, IFC-dipolar	TENS-Han	IFC-4p, IFC-2p, IFC-isoplanar, IFC-dipolar	Russian current	Russian current
4	VMS, VMS burst	IFC-4p, IFC-2p, IFC-isoplanar, IFC-dipolar	VMS, VMS burst	TENS Sym BP, TENS Asym BP	TENS Sym BP, TENS Asym BP
5	HVPC	VMS, VMS burst	HVPC	Pulsed MP Rect / Triang, Surged MP Rect / Triang	Pulsed MP Rect / Triang, Surged MP Rect / Triang

WAVEFORM GUIDANCE

Recommended parameters for each waveform in each of the indications

Waveform	Default settings	Symptomatic relief of acute pain associated with musculoskeletal conditions			
		Freq	Intensity	Duty cycle	Treatment Time
TENS- Asymmetrical Biphasic	80Hz; cont; 20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
TENS- Symmetrical Biphasic	50Hz; cont; 20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
TENS - HAN	HAN settings (fixed); 30min	-	-	-	-
VMS™	50Hz:2s ramp; 5s/5s:20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
VMS™ Burst	50Hz:2s ramp; 5s/5s:20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
VMS™ FR	50Hz; 500ms burst; 1:3; 20min	-	-	-	-
IFC (Interferential) Traditional (4 Pole)	4000Hz; 80/150Hz; auto 40%; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
IFC Premodulated (Traditional 2 Pole)	4000Hz; 80/150Hz; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Isoplanar Vector Interferential Current	4000Hz; 80/150Hz; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Dipole Vector Interferential Current	4000Hz; 80/150Hz; 45°/6s; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Russian	2500Hz; 50Hz; DC 50%; cont; 20 min	-	-	-	-
High Voltage Pulsed Current (HVPC)	100Hz; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			
MONOPHASIC: Monophasic Rectangular pulsed	1.0ms/500ms; 5min	-	-	-	-
MONOPHASIC: Monophasic Triangular pulsed	1.0ms/500ms; 5min	-	-	-	-
SURGED: Monophasic Rectangular	50Hz; 1ms; 15 min	-	-	-	-
SURGED: Monophasic Triangular	50Hz; 1ms; 15 min	-	-	-	-
Diadynamic Waveforms	Diadyn settings (fixed), 10 min	Use default Diadynamic settings and increase intensity to strong sensory level/ no pain			
Träbert (Ultrareiz)	Träbert settings (fixed), 10min	Use default Träbert settings and increase intensity strong to sensory level/ no pain			
Microcurrent	Neg; 1Hz; 20min	Use default settings and increase intensity to 40-100µA			when in pain/ multiple hours
GALVANIC: Continuous	Pos; 10min	-	-	-	-
Low Level Galvanic	Pos; 1mA; 40min	-	-	-	-
GALVANIC: Interrupted	Pos; 10 min	-	-	-	-

Waveform	Default settings	Symptomatic relief of chronic pain associated with musculoskeletal conditions			
		Freq	Intensity	Duty cycle	Treatment Time
TENS- Asymmetrical Biphasic	80Hz; cont; 20min	2-5 Hz	muscle twitches	continuous	30 min
TENS- Symmetrical Biphasic	50Hz; cont; 20min	2-5 Hz	muscle twitches	continuous	30 min
TENS - HAN	HAN settings (fixed); 30min	Use default HAN settings and increase intensity to strong sensory level / no pain			
VMS™	50Hz:2s ramp; 5s/5s:20min	2-5 Hz	muscle twitches	continuous	30 min
VMS™ Burst	50Hz:2s ramp; 5s/5s:20min	2-5 Hz	muscle twitches	continuous	30 min
VMS™ FR	50Hz; 500ms burst; 1:3; 20min	-	-	-	-
IFC (Interferential) Traditional (4 Pole)	4000Hz; 80/150Hz; auto 40%; cont; 20min	4000Hz; 2-5Hz	muscle twitches	continuous	30 min
IFC Premodulated (Traditional 2 Pole)	4000Hz; 80/150Hz; cont; 20min	4000Hz; 2-5Hz	muscle twitches	continuous	30 min
Isoplanar Vector Interferential Current	4000Hz; 80/150Hz; cont; 20min	4000Hz; 2-5Hz	muscle twitches	continuous	30 min
Dipole Vector Interferential Current	4000Hz; 80/150Hz; 45°/6s; cont; 20min	4000Hz; 2-5Hz	muscle twitches	continuous	30 min
Russian	2500Hz; 50Hz; DC 50%; cont; 20 min	-	-	-	-
High Voltage Pulsed Current (HVPC)	100Hz; cont; 20min	use default settings and increase intensity to strong sensory level/no pain			
MONOPHASIC: Monophasic Rectangular pulsed	1.0ms/500ms; 5min	-	-	-	-
MONOPHASIC: Monophasic Triangular pulsed	1.0ms/500ms; 5min	-	-	-	-
SURGED: Monophasic Rectangular	50Hz; 1ms; 15 min	-	-	-	-
SURGED: Monophasic Triangular	50Hz; 1ms; 15 min	-	-	-	-
Diadynamic Waveforms	Diadyn settings (fixed), 10 min	Use default Diadynamic settings and increase intensity to strong sensory level/ no pain			
Träbert (Ultrareiz)	Träbert settings (fixed), 10min	-	-	-	-
Microcurrent	Neg; 1Hz; 20min	Use default settings and increase intensity to 40-100µA			when in pain/ multiple hours
GALVANIC: Continuous	Pos; 10min	Use default settings, with polarity reversal and increase intensity to mild sensory level/no pain			
Low Level Galvanic	Pos; 1mA; 40min	Use default settings; intensity can be increased up to 4mA - this will decrease the treatment time proportionally			
GALVANIC: Interrupted	Pos; 10 min	Use default settings and increase intensity to mild sensory level/no pain			

WAVEFORM GUIDANCE

Recommended parameters for each waveform in each of the indications

Waveform	Default settings	Management and alleviation of post operative pain			
		Freq	Intensity	Duty cycle	Treatment Time
TENS- Asymmetrical Biphasic	80Hz: cont: 20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
TENS- Symmetrical Biphasic	50Hz: cont: 20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
TENS - HAN	HAN settings (fixed): 30min	-	-	-	-
VMS™	50Hz:2s ramp: 5s/5s:20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
VMS™ Burst	50Hz:2s ramp: 5s/5s:20min	80-150Hz	strong sensation/ no pain	continuous	when in pain
VMS™ FR	50Hz: 500ms burst: 1:3: 20min	-	-	-	-
IFC (Interferential) Traditional (4 Pole)	4000Hz: 80/150Hz: auto 40%: cont: 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
IFC Premodulated (Traditional 2 Pole)	4000Hz: 80/150Hz: cont: 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Isoplanar Vector Interferential Current	4000Hz: 80/150Hz: cont: 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Dipole Vector Interferential Current	4000Hz: 80/150Hz: 45°/6s: cont: 20min	use default settings and increase intensity to strong sensory level/no pain			when in pain
Russian	2500Hz: 50Hz: DC 50%: cont: 20 min	-	-	-	-
High Voltage Pulsed Current (HVPC)	100Hz: cont: 20min	use default settings and increase intensity to strong sensory level/no pain			
MONOPHASIC: Monophasic Rectangular pulsed	1.0ms/500ms: 5min	-	-	-	-
MONOPHASIC: Monophasic Triangular pulsed	1.0ms/500ms: 5min	-	-	-	-
SURGED: Monophasic Rectangular	50Hz: 1ms: 15 min	-	-	-	-
SURGED: Monophasic Triangular	50Hz: 1ms: 15 min	-	-	-	-
Diadynamic Waveforms	Diadyn settings (fixed), 10 min	Use default Diadynamic settings and increase intensity to strong sensory level/ no pain			
Träbert (Ultrareiz)	Träbert settings (fixed), 10min	Use default Träbert settings and increase intensity strong to sensory level/no pain			
Microcurrent	Neg: 1Hz: 20min	Use default settings and increase intensity to 40-100µA			when in pain/ multiple hours
GALVANIC: Continuous	Pos: 10min	-	-	-	-
Low Level Galvanic	Pos: 1mA: 40min	-	-	-	-
GALVANIC: Interrupted	Pos: 10 min	-	-	-	-

Waveform	Default settings	Muscle re-education			
		Freq	Intensity	Duty cycle	Treatment Time
TENS- Asymmetrical Biphasic	80Hz; cont; 20min	35-80Hz	muscle contraction; max tolerable	1:5 to 1:1 with on-time 5s to 20s	10 - 15 min
TENS- Symmetrical Biphasic	50Hz; cont; 20min	35-80Hz	muscle contraction; max tolerable	1:5 to 1:1 with on-time 5s to 20s	10 - 15 min
TENS - HAN	HAN settings (fixed); 30min	-	-	-	-
VMS™	50Hz:2s ramp; 5s/5s:20min	35-80Hz	muscle contraction; max tolerable	1:5 to 1:1 with on-time 5s to 20s	10 - 15 min
VMS™ Burst	50Hz:2s ramp; 5s/5s:20min	35-80Hz	muscle contraction; max tolerable	1:5 to 1:1 with on-time 5s to 20s	10 - 15 min
VMS™ FR	50Hz; 500ms burst; 1:3; 20min	use default settings and increase intensity to max tolerable motor level			10 - 15 min
IFC (Interferential) Traditional (4 Pole)	4000Hz; 80/150Hz; auto 40%; cont; 20min	-	-	-	-
IFC Premodulated (Traditional 2 Pole)	4000Hz; 80/150Hz; cont; 20min	-	-	-	-
Isoplanar Vector Interferential Current	4000Hz; 80/150Hz; cont; 20min	-	-	-	-
Dipole Vector Interferential Current	4000Hz; 80/150Hz; 45°/6s; cont; 20min	-	-	-	-
Russian	2500Hz; 50Hz; DC 50%; cont; 20 min	use default settings and increase intensity to max tolerable motor level			
High Voltage Pulsed Current (HVPC)	100Hz; cont; 20min	-	-	-	-
MONOPHASIC: Monophasic Rectangular pulsed	1.0ms/500ms; 5min	use default settings and increase phase duration (denervated muscles) & intensity to obtain muscle contraction			
MONOPHASIC: Monophasic Triangular pulsed	1.0ms/500ms; 5min	use default settings and increase phase duration (denervated muscles) & intensity to obtain muscle contraction			
SURGED: Monophasic Rectangular	50Hz; 1ms; 15 min	use default settings and increase intensity to max tolerable motor level			
SURGED: Monophasic Triangular	50Hz; 1ms; 15 min	use default settings and increase intensity to max tolerable motor level			
Diadynamic Waveforms	Diadyn settings (fixed), 10 min	-	-	-	-
Träbert (Ultrareiz)	Träbert settings (fixed), 10min	-	-	-	-
Microcurrent	Neg; 1Hz; 20min	-	-	-	-
GALVANIC: Continuous	Pos; 10min	-	-	-	-
Low Level Galvanic	Pos; 1mA; 40min	-	-	-	-
GALVANIC: Interrupted	Pos; 10 min	-	-	-	-

WAVEFORM GUIDANCE

Recommended parameters for each waveform in each of the indications

Waveform	Default settings	Maintaining/increasing range of motion			
		Freq	Intensity	Duty cycle	Treatment Time
TENS- Asymmetrical Biphasic	80Hz; cont; 20min	35-50Hz	muscle contraction producing ROM	5s/5s	20 min
TENS- Symmetrical Biphasic	50Hz; cont; 20min	35-50Hz	muscle contraction producing ROM	5s/5s	20 min
TENS - HAN	HAN settings (fixed); 30min	-	-	-	-
VMS™	50Hz:2s ramp; 5s/5s:20min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
VMS™ Burst	50Hz:2s ramp; 5s/5s:20min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
VMS™ FR	50Hz; 500ms burst; 1:3; 20min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
IFC (Interferential) Traditional (4 Pole)	4000Hz; 80/150Hz; auto 40%; cont; 20min	-	-	-	-
IFC Premodulated (Traditional 2 Pole)	4000Hz; 80/150Hz; cont; 20min	-	-	-	-
Isoplanar Vector Interferential Current	4000Hz; 80/150Hz; cont; 20min	-	-	-	-
Dipole Vector Interferential Current	4000Hz; 80/150Hz; 45°/6s; cont; 20min	-	-	-	-
Russian	2500Hz; 50Hz; DC 50%; cont; 20 min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
High Voltage Pulsed Current (HVPC)	100Hz; cont; 20min	-	-	-	-
MONOPHASIC: Monophasic Rectangular pulsed	1.0ms/500ms; 5min	-	-	-	-
MONOPHASIC: Monophasic Triangular pulsed	1.0ms/500ms; 5min	-	-	-	-
SURGED: Monophasic Rectangular	50Hz; 1ms; 15 min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
SURGED: Monophasic Triangular	50Hz; 1ms; 15 min	use default settings and increase intensity to produce muscle contraction moving the joint through its ROM			
Diadynamic Waveforms	Diadyn settings (fixed), 10 min	-	-	-	-
Träbert (Ultrareiz)	Träbert settings (fixed), 10min	-	-	-	-
Microcurrent	Neg; 1Hz; 20min	-	-	-	-
GALVANIC: Continuous	Pos; 10min	-	-	-	-
Low Level Galvanic	Pos; 1mA; 40min	-	-	-	-
GALVANIC: Interrupted	Pos; 10 min	-	-	-	-

ELECTROTHERAPY PATIENT PREPARATION AND ELECTRODE PLACEMENT

- Examine the skin for any wounds and clean the skin.
- Apply the electrodes to the treatment area.
- Ensure the electrodes are applied securely to the skin.
- Ensure good contact between each electrode and the skin.
- Check the electrode contact regularly during the treatment.
- Examine the skin again after the treatment.
- Choose electrodes that fit the anatomy.
- View the Electrode Placement recommendations in the Treatment Review screen for the particular modality being used for treatment as a reference point only prior to administering treatment.
- Follow electrode manufacturer instructions.
- Please note the smaller the electrode size the higher the current density.

DURA-STICK® Electrodes
DURA-STICK® Electrodes are a self adhesive, disposable product designed specifically for use with Intelect® Mobile 2.
It is recommended that DURA-STICK® Electrodes be used whenever possible to ensure the highest level of contact with the treatment area and most uniform delivery of the prescribed electrotherapy treatment.

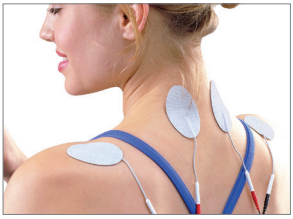
For Electrotherapy operation refer to page 42

DURA-STICK® Electrode Instructions

Connecting Lead Wires
Insert the lead with the Red (+) electrode connector into one DURA-STICK® Electrode.
Insert the lead with the Black (-) electrode connector into the other electrode.
Make certain the lead wires are seated completely into the electrodes.

NOTE: Use of conductive medium or sponges is not required or recommended. DURA-STICK® electrodes are manufactured to ensure the optimum conductivity during therapy when properly applied.

Securing Electrodes
Remove the DURA-STICK® Electrodes from the protective backing.
Apply to the treatment area as prescribed.
Ensure the entire electrode surface is in contact with patient skin by pressing into place.



ULTRASOUND PATIENT PREPARATION

Examine the skin for any wounds and clean the skin
View the Applicator recommendation in the treatment guidelines.
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
Clean applicator before each therapy session with warm soapy water, check the applicator has no cracks prior to use.
Liberally apply transmission gel to the treatment area on the patient.
Move the applicator during therapy session in a circular motion. The area treated should be:

- Twice the diameter of the applicator
- For 5cm^2 and 10 cm^2 US applicator: three times the diameter of the applicator if output power > 4 W, Continuous mode.

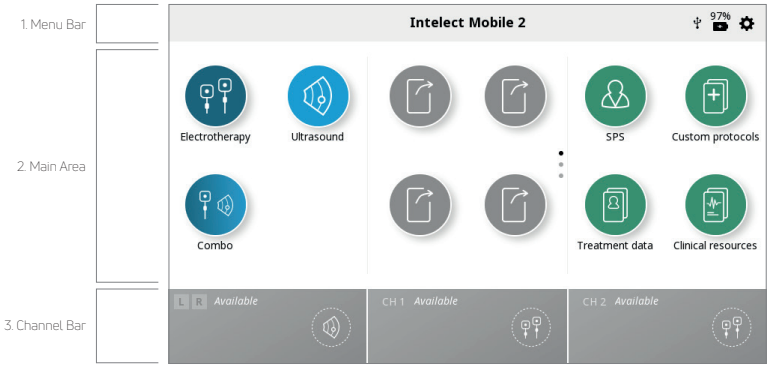
The applicator should always be held by the grip and not by the Ultrasound Applicator head.
If US Coupling is "On", the Applicator is properly coupled to the patient and administering ultrasound when the LED is constantly illuminated. If the applicator head becomes uncoupled the LED on the head will 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 64

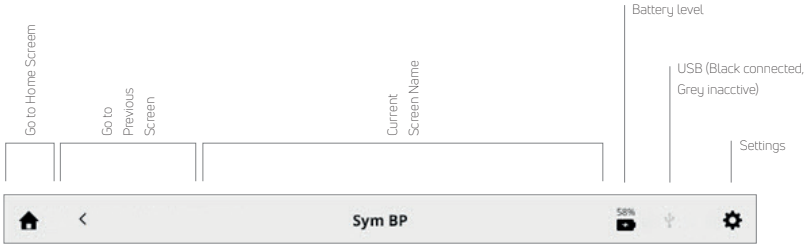
DEVICE USER INTERFACE

SCREEN DESCRIPTION



Each screen contains the following areas:

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



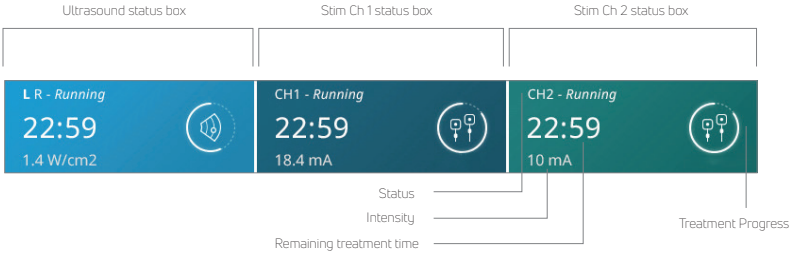
Main area

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

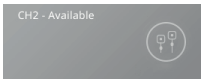
Channel Bar

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:



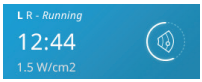
Indicates the channel is available for use

Indicates 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

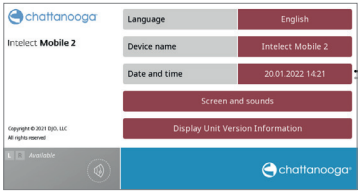
Indicates a treatment for the channel has completed

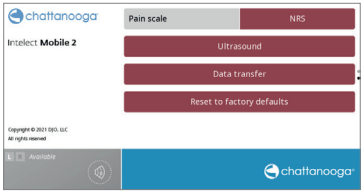


Indicates an ultrasound treatment is running with the left (L) applicator

SETTINGS

The settings icon on the top right hand corner of the home screen menu bar o ers users the opportunity to set preferences and can be accessed by pressing the " button.



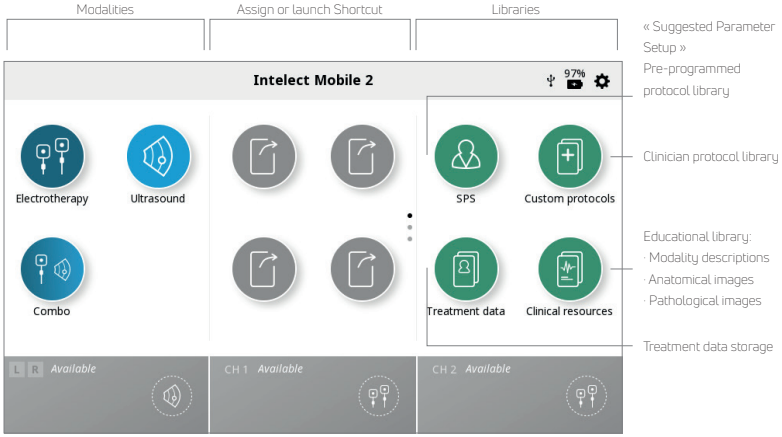


Swipe vertically to see more settings

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 Keypad layout button allows the keypad format to be changed to QWERTY, AZERTY or QWERTZ
   - » Pressing the US coupling sound button allows the user to switch between US coupling sound on or off. Default setting is ON.
6. Press the Ultrasound button to enter this menu:
   - » Pressing the US coupling sound button allows the user to switch between US coupling sound on or off. Default setting is ON
   - » Pressing the coupling time button allows the user to switch between Pause (treatment time stops counting down while applicator is uncoupled) and No pause (treatment time will count down even if ultrasound head is uncoupled). Default setting is Pause.
7. Pressing the Display unit version information will show current software version serial number and several device parameters as shown below.
8. Choose pain scale display as NRS or VAS by pressing pain scale button to set required option.
9. Pressing the Data Transfer button will enable the device to connect via Bluetooth® to a Bluetooth® enabled Computer.
10. 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.
11. 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.

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

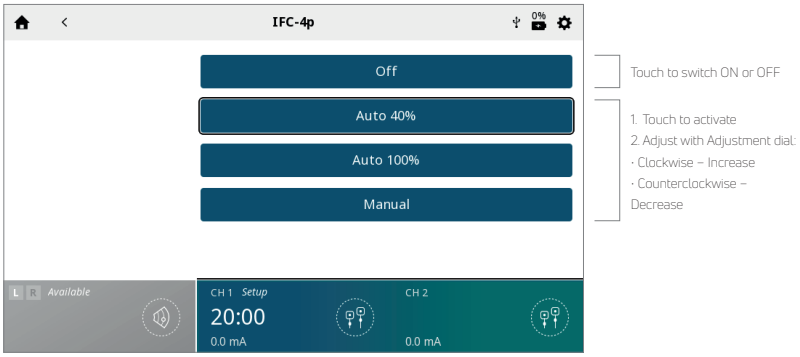
The Intelect® Mobile 2 Treatment Review screens for Electrotherapy, Ultrasound and Combo include the following information:

Treatment Review Screen let the user to confirm and modify treatment parameters.

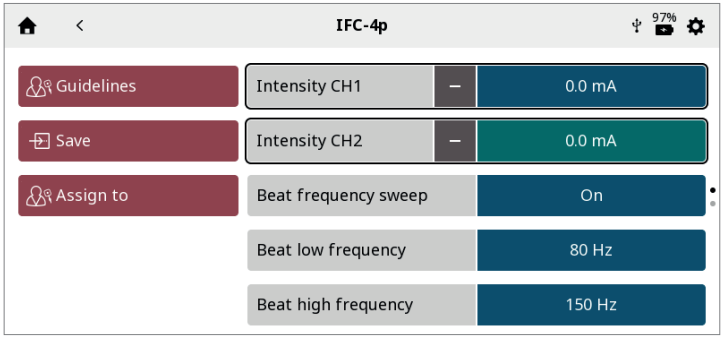
1. Touch to activate
2. Adjust with Adjustment dial:
· Clockwise – Increase
· Counterclockwise – Decrease

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

Parameter Submenu Screen



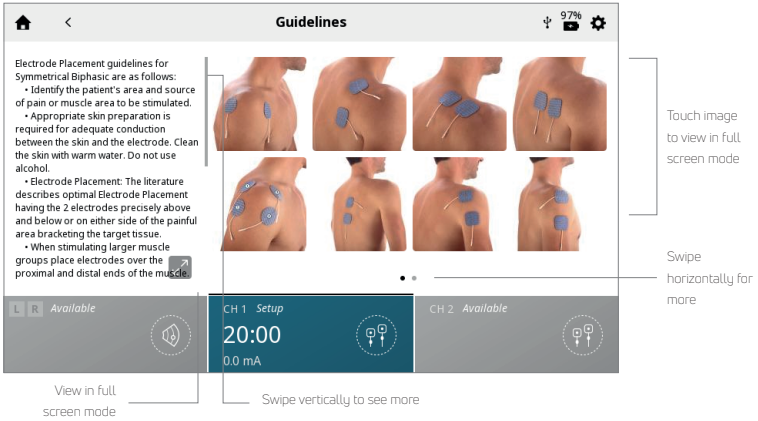
Intensity management in dual channel



- Intensity of each channel can be managed individually by simply touching the box to activate it
- If treatment offers the possibility to manage both channel intensities together, a "+" symbol appears in the channel intensity box
- By touching this symbol, both channel intensities boxes are activated together. Turn the rotary knob to increase/decrease both together
- When intensities are working together, a "-" symbol on each box appears. By touching this symbol the related channel is desactivated so knob will only be aging on the remaining active channel.

GUIDELINES SCREEN

The Guidelines for electrotherapy, ultrasound and combo therapy provide the following information:
Instructions for optimal electrode placement and/or US applicator use at the left side of the screen.
Images illustrating electrode placement and/or US treatment area and recommended applicator choice at the right side of the screen.



PRINT SCREEN FUNCTION

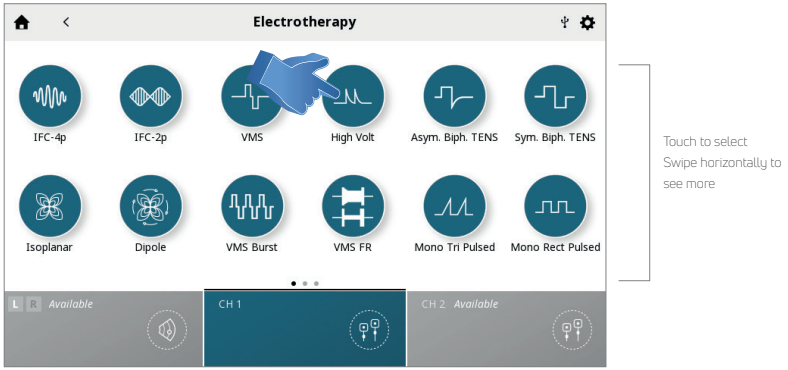
The Intelect® Mobile 2 device has a built in function allowing the user to print screen fro example to print a treatment session this performed by:

- 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

ELECTROTHERAPY OPERATION

Complete the following steps to begin Electrotherapy treatment:
1. Prepare patient and therapy system for Electrotherapy. Refer to the PATIENT PREPARATION section on for electrode selection, preparing the patient, and securing electrodes.
2. Select ELECTROTHERAPY icon from the home screen
3. Select desired waveform



Note: Refer to the System Specifications section of this manual for all waveform specifications for the Intelect® Mobile 2.

4. SET UP TREATMENT
On the treatment review screen - you can adjust treatment parameters to desired level.

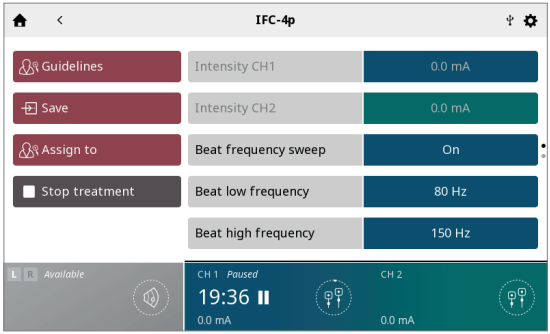
Never start with intensity adjustment – first adjust all other parameters and set Intensity just before starting treatment

Pressing the save button will save the treatment as a custom protocol which can be named by the user
Pressing the Assign to button will give two buttons
-Assign to: this button assigns the treatment data to a specific treatment data file which can be named by the user
-Open pain scale: this button opens up the pain scale so the pre treatment pain can be recorded

5. START TREATMENT
Press the start/pause button

7. PAUSE TREATMENT
Press the Start/Pause button

Pausing treatment will automatically display stop treatment button on the Treatment Review screen



To resume treatment, press the Start /Pause button again

Note: Pause applies to the selected channel only

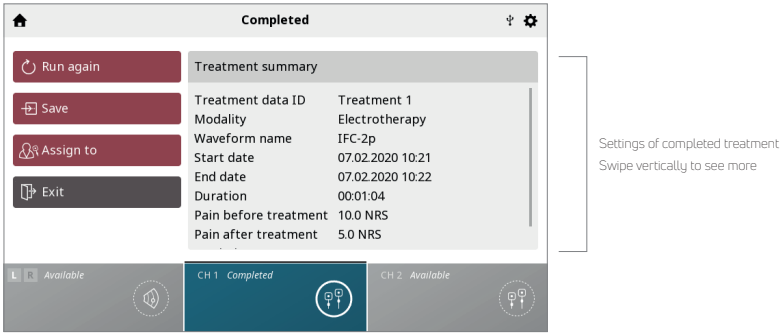
8. STOP TREATMENT

First pause treatment by pressing the Start/Pause button

Then press the 'Stop treatment' button on the Treatment Review screen.

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

- Repeat the treatment by pressing Run again.
- Save button
  - » the treatment protocol as a Custom Protocols
- Assign to button
  - » Assign therapy information to treatment data
  - » Open Pain scale to record post-treatment pain
- Exit Modality and return to home screen



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.

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.

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

Save and Assign to buttons behave the same as in Electrotherapy treatment.

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.

WHEN TREATMENT HAS COMPLETED, THE TREATMENT SUMMARY SCREEN WILL APPEAR WITH THE FOLLOWING OPTIONS:

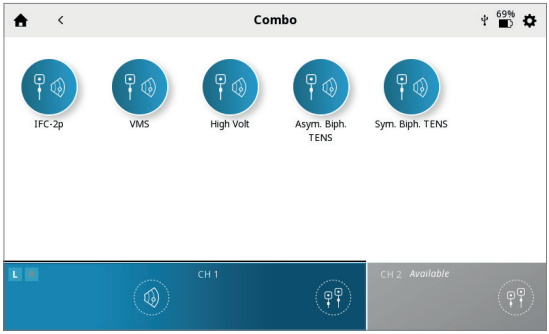
- Repeat the treatment by pressing Run again.
- Save
  - » the treatment protocol to the Custom Protocols (cfr. Page..)
- Assign to:
  - » Assign therapy information to treatment data
  - » Open Pain scale to record post-treatment pain
- Exit Modality and return to home screen

COMBINATION OPERATION

The Combo modality allows the user to select and use ultrasound therapy in combination with electrical muscle stimulation. Combination therapy utilizes the Ultrasound modality in conjunction with High Voltage Pulsed Current (HVPC), IFC Premodulated (2p), Asymmetrical Biphasic, Symmetrical Biphasic, or VMS™ to generate a therapeutic effect .
In this mode of therapy, the Ultrasound Applicator becomes one half of the electrical circuit. An electrode attached to the Red (+) Lead Wire completes the circuit .

Complete the following steps to begin Combo treatment:

1. Prepare Patient and therapy system – Refer to the PATIENT PREPARATION section for electrode selection, preparing the patient, and securing electrodes, page tbc. Ultrasound Patient preparation is found on page tbc.
2. Connect the Red (+) Lead Wire from Channel 1 to the electrode. Make certain the Lead Wire is completely seated in the electrode . The Black (-) Lead Wire is not used. The Ultrasound Applicator completes the circuit for Combination Therapy.
3. From the HOME SCREEN, select the COMBO icon.
4. Select the ultrasound combination therapy desired by touching the corresponding icon.



Note: for safety reasons not all wave forms are available for combo therapy.

5. SET UP TREATMENT
On the treatment review screen you can adjust treatment parameters to desired level.

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

Pressing the save button will save the treatment as a custom protocol which can be named by the user

Pressing the Assign to button will give two buttons as seen below
- Assign to: this button assigns the treatment data to a specific treatment data file which can be named by the user
- Open pain scale: this button opens up the pain scale so the pre-treatment pain can be recorded

6. START TREATMENT

Press the START button to begin the therapy

7. PAUSE TREATMENT

Press the Start/Pause button. To resume treatment, press the Start /Pause button again

Note: Pause applies to the selected channel only

8. STOP TREATMENT

- First pause treatment by pressing the Start/Pause button

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

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

- Repeat the treatment by pressing Run again.
- Save

· the treatment protocol to the Custom Protocols (cfr. Page..)

- Assign to:

· Assign therapy information to treatment data

· Open Pain scale to record post-treatment pain

- 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 clinical benefit and target condition 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.
Please note, the referenced SPS parameters are suggestions/guidelines only, and are based on historical experience obtained for the device within the clinical setting.

COMPLETE THE FOLLOWING STEPS TO START AN SPS PROTOCOL:

1. Select SPS from the Home Screen
2. Select Clinical Benefit
3. Select target
4. Select MODALITY/WAVEFORM
5. SET UP TREATMENT
On the treatment review screen the suggested treatment settings are displayed and you can adjust parameters to desired level.

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

Pressing the save button will save the treatment as a custom protocol which can be named by the user

Pressing the Assign to button will give two buttons as seen below
- Assign to: this button assigns the treatment data to a specific treatment data file which can be named by the user
- Open pain scale: this button opens up the pain scale so the pre-treatment pain can be recorded

6. START TREATMENT
Press the START button

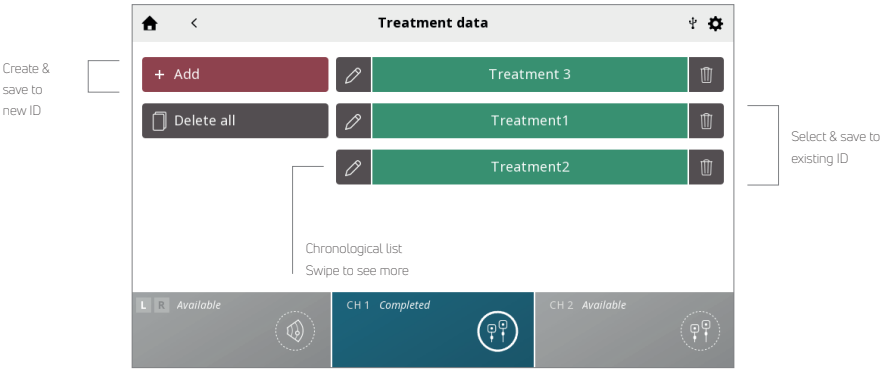
TREATMENT DATA

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)
Open Pain scale to record post-treatment pain

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

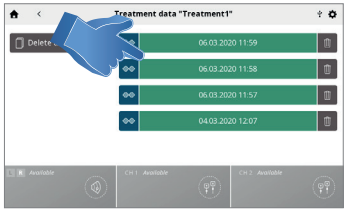
1. VIEW Treatment Data

Select desired ID folder

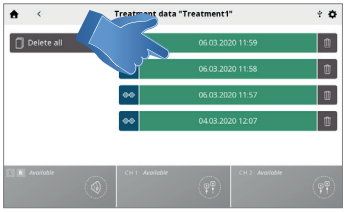
The TREATMENT HISTORY is displayed including all previously saved treatment sessions ranked chronologically

2. DELETE Treatment Data

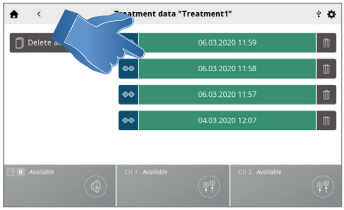
Delete all IDs



Delete one ID



Delete all treatment sessions



Delete one session

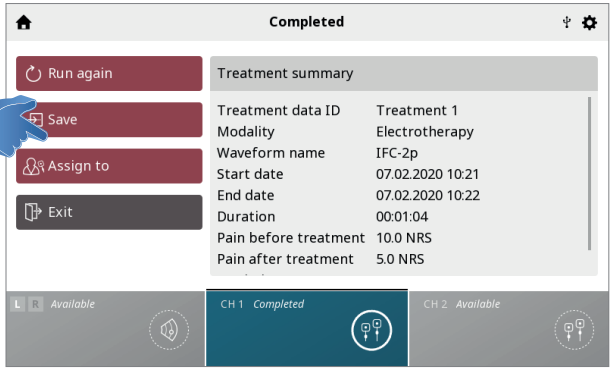
CUSTOM PROTOCOLS

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. Name custom protocol with keyboard

Create new custom protocol: Enter Custom Protocol Name and Save

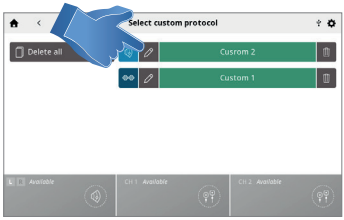
VIEW and MANAGE CUSTOM PROTOCOLS: Touch the CUSTOM PROTOCOLS icon on the Home Screen

1. VIEW Custom Protocol

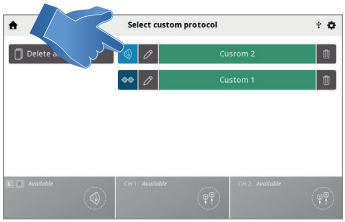
Select desired Custom Protocol. The TREATMENT REVIEW SCREEN is displayed showing the protocol settings. Start treatment or perform other actions as described in the Electrotherapy/Ultrasound/Combo Operations section

2. DELETE custom protocol

Delete all protocols



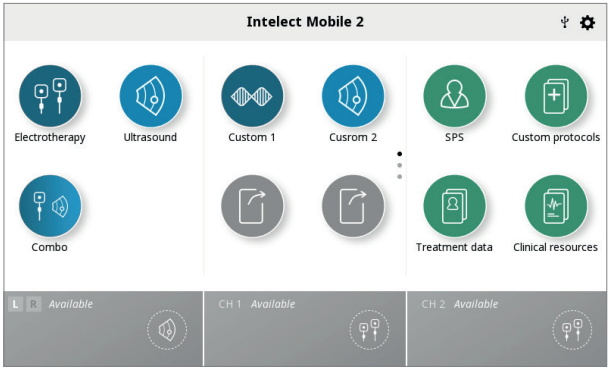
Delete individual protocols



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 and icon associated with the modality it contains



UNASSIGN SHORT CUT

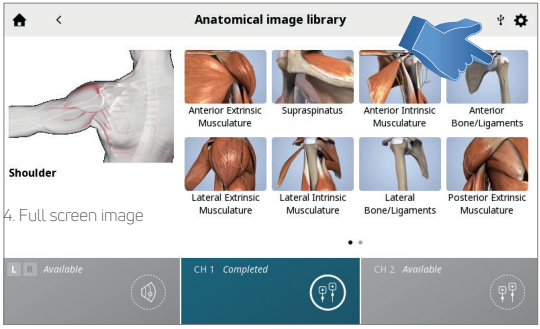
Complete the following steps to unassign a Home screen shortcut for a customized protocol:
From the Home screen, press and hold the shortcut icon you wish to unassign.
The unit will display a text box asking, "Remove "My Custom Protocol 1" shortcut?"

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

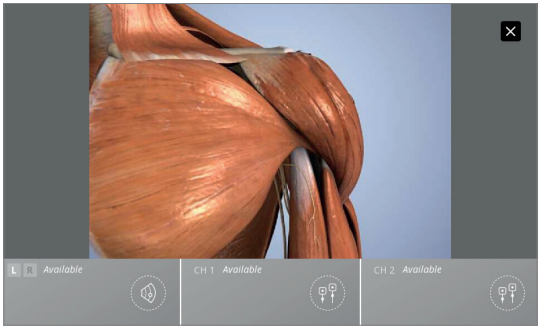
CLINICAL RESOURCES

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 identified issues 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

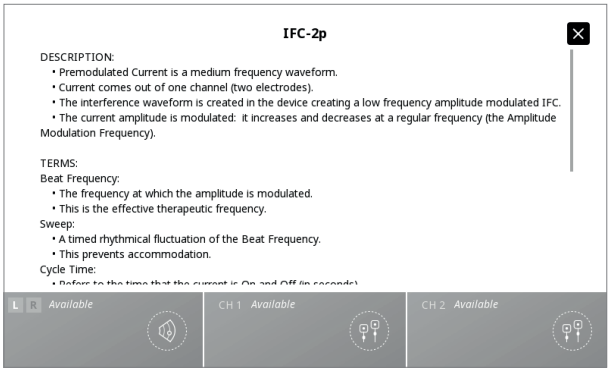


Close full screen mode

MODALITY/WAVEFORM DESCRIPTIONS

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

1. Press the Electrotherapy Waveform/Ultrasound/Combo 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 at internationalproductsupport@djoglobal.com or + 33 (0)5 59 52 68 18

REPLACEMENT ACCESSORIES

The following provides users of the Intelect® Mobile 2 the necessary information to order replacement accessories used with the system. This list of replacement accessories is designed for use with the Intelect® Mobile 2. When ordering, provide the respective part number, description, and quantity desired.

ELECTRODES

Model Number	Description
42209	Durastick Premium 5 cm (2") Square (40/Case = 10 packs of 4)
42210	Durastick Premium 5 x 9 cm (2 x 3.5") Rectangle (40/Case = 10 packs of 4)
42205	Durastick Premium 3.2 cm (1.25") Round (40/Case = 10 packs of 4) (not recommended for sEMG use)
42206	Durastick Premium 5 cm (2") Round (40/Case = 10 packs of 4)
42207	Durastick Premium 4 x 6 cm (1.5 x 2.5") Oval (40/Case = 10 packs of 4)
42208	Durastick Premium 8 x 13 cm (3 x 5") (2 pack)
42211	Durastick Premium 5 cm (2") blue gel Oval (40/Case = 10 packs of 4)
42212	Durastick Premium 4 x 9 cm (1.5 x 3.5") blue gel Rectangle (40/Case = 10 packs of 4)
42198	Durastick Plus 5 cm (2") cloth Square (40/Case = 10 packs of 4)
42193	Durastick Plus 5 cm (2") foam Square (40/Case = 10 packs of 4)
42199	Durastick Plus 5 x 9 cm (2 x 3.5") cloth Rectangle (40/Case = 10 packs of 4)
42194	Durastick Plus 5 x 9 cm (2 x 3.5") foam Rectangle (40/Case = 10 packs of 4)
42200	Durastick Plus 5 x 10 cm (2 x 4") cloth - double wire (2 pack) Rectangle
42218	Durastick Plus 1.5 x 15 cm (0.5 x 6") cloth (6 pack) Rectangle
42219	Durastick Plus 3.2 cm (1.25") cloth Round (40/Case = 10 packs of 4) (not recommended for sEMG use)
42197	Durastick Plus 5 cm (2") cloth Round (40/Case = 10 packs of 4)
42192	Durastick Plus 5 cm (2") foam Round (40/Case = 10 packs of 4)
42195	Durastick Plus 4 x 6 cm (1.5 x 2.5") foam Oval (40/Case = 10 packs of 4)
42196	Durastick Plus 5 x 10 cm (2 x 4") foam Oval (40/Case = 10 packs of 4)
42201	Durastick Plus 5 cm (2") cloth - clip Square (40/Case = 10 packs of 4)
42202	Durastick Plus 5 x 10 cm (2 x 4") cloth - clip Rectangle (40/Case = 10 packs of 4)
42204	Durastick Plus 5 cm (2") cloth Square (40/Case = 10 packs of 4)
42203	Durastick Plus 5 x 10 cm (2 x 4") cloth - double snap (2 pack) Rectangle
42188	Durastick Plus 5 cm (2") (2 pack) Square
42189	Durastick Plus 5 x 9 cm (2 x 3.5") (2 pack) Rectangle
42190	Durastick Plus 5 cm (2") Square (40/Case = 10 packs of 4)
42191	Durastick Plus 5 x 9 cm (2 x 3.5") Rectangle (40/Case = 10 packs of 4)

ELECTROTHERAPY ACCESSORIES

Model Number	Description
6522055	Chattanooga Strap
79967	6 x 8 cm (2.5 x 3") carbon electrodes (4x)

GENERAL ACCESSORIES

Model Number	Description
15-0144	Wall Power Cable 2m Black EU
15-0146	Wall Power Cable 2m Black UK
15-0147	Power Cable 2m Black AUS
15-1136	Mobile 2 Cart
15-1210	Cart with Vacuum
79977	HIGHVOLT PROBE KIT- Includes Probe and Sponge Applicator Tips (15 and 8 mm)
114.121	Finger guard
70010	STIM CH 1/2 LEADWIRE KIT STD
70012	STIM CH 1/2 LEADWIRE KIT XL

BATTERY

Model Number	Description
14-1086	Battery

ULTRASOUND APPLICATORS AND GEL

Model Number	Description
15-0140	G16 Ultrasound Applicator 1 cm2
15-0141	G16 Ultrasound Applicator 2 cm2
15-0142	G16 Ultrasound Applicator 5 cm2
15-0143	G16 Ultrasound Applicator 10 cm2
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.

INSTRUCTION FOR SOFTWARE UPGRADE

1. Go to the Chattanooga website www.chattanoogarehab.com
2. Go to Intelect® Mobile 2 product page
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 the downloads tab
5. Download firmware upgrade zip file and extract the file
6. Erase the USB drive supplied with the Intelect® Mobile 2
7. Copy the extracted files on to the USB drive
8. Switch OFF the device
9. Insert USB key drive into the USB port on the back of the device
10. Switch ON the device
11. Device will automatically detect firmware update availability and commence upgrade, the upgrade will take some minutes and the power must not be switched off during the upgrade
12. Once firmware update is finished, Home screen will be displayed and the USB drive can be removed. Device is ready for use.
13. Check software version in settings

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.

In case of incident occurring in relation to the device, contact local Health Authority and the manufacturer:
DJO France S.A.S. for Chattanooga product range
Centre Européen de Fret
3 rue de Bethar
64990 Mouguerre
France
internationalproductsupport@djoglobal.com

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 Without Vacuum With Vacuum	 Class B Class A 1	
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	
Note 1 use with optional vacuum module: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

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	0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT: 1 cycle and 70% UT: 25/30 cycles Single phase at 0°	0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT: 1 cycle and 70% UT: 25/30 cycles Single phase at 0°	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	30 A/m	30 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.			
Proximity magnetic fields IEC 61000-4-39	CW: 8 A/M 2.1 kHz: 65 A/M 50 kHz: 7.5 A/M	CW: 8 A/M 2.1 kHz: 65 A/M 50 kHz: 7.5 A/M	Test Frequency 30 kHz Test Frequency 134.2 kHz Test Frequency 13.56 MHz

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
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz outside ISM bandsa 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bandsa	3 Vrms 6 Vrms	The device is intended for use in a typical domestic and home healthcare electromagnaetic environment 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 degredation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7GHz 9-28V/m in wireless bands	10 V/m 9-28V/m	

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 kH7 and 80 MH7 are 6,765 MH7 to 6,795 MH7 13,553 MH7 to 13,567 MH7: 26,957 MH7 to 27,283 MHz and 40,66 MH7 to 40,70 MHz. The amateur radio bands between 0,15 MHz and 8,0 MHz are 1,8 MHz to 2,0 MHz 3,5 MHz to 4,0 MHz 5,3 MHz to 5,4 MHz. 7 MHz to 7,3 MHz. 10,1 MHz to 10,15 MHz. 14 MHz to 14,2 MHZ.
18,07MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz 24,89 MHz to 24,99 MHz 28,0 MHz to 29,7 MHz and 50,0 MHzto 54,0 MHz.

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
ENOVIS.FR

CH REP

MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau, Switzerland

enovis™

5919 Sea Otter Place, Suite 200, Carlsbad, CA 92010, USA

enovis-medtech.eu

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