

Intelect® Mobile 2 Electrotherapy User Manual



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FOREWORD

This manual is intended for users of Intelect® Mobile 2 . It contains general information on operation, precautionary practices, and maintenance.

In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

In addition to the above information, this manual contains care and installation instructions for the optional Cart and Vacuum module for the users of the Intelect® Mobile 2.

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

INTENDED USER PROFILE

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

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

INTENDED ENVIRONMENT FOR USE

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

INTENDED USE

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

PRECAUTIONARY INSTRUCTIONS

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

A 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.

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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

A	Home		0	Run again
<	Back to previous screen			Exit
*	Settings		\bigcirc	Export
Ψ	Indicates a USB Flash Drive is Inserted		4	Import
58%	Indicates Battery Level			Delete
•	Indicates more content can be viewed by swiping vertically			Delete all
• • •	Indicates more content can be viewed by swiping horizontally			Stop treatment
	Indicates more content can be viewed by scrolling		0 0	Stim
×	Close window / exit full screen			Shortcut
~	Confirm		&)	SPS (Suggested Parameter Setup)
	Save Data		(Custom Protocols
0	Edit			Treatment Data
25%	Guidelines / Assign to			Clinical Resources
&≥e	Pain information	_		

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DESCRIPTION OF DEVICE MARKINGS

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

Refer to Instructional Manual Booklet		Atmospheric Pressure Range	9
Warning, Caution, or Danger	\wedge	Test agency	SGS
Electrical Type BF Equipment	☀	CE Mark of Conformity with notified body number	(€ 2797
Stim	~	Alternating current	\sim
Play	\triangleright	Class II equipment	
Pause		IP21	IP21
ON/OFF	\bigcirc	Radio frequency equipment	((lacksquare))
Manufacturer		WEEE Directive conformity	X
Date of manufacture	<u></u>	Shelf life	\subseteq
Catalogue number	REF	Batch number	LOT
Serial number	SN	MD	MD
Fragile, handle with care	Ţ		
This end up	<u>††</u>	VACUUM MODULE MARKI	NGS
Keep dry	*	Channel 1 device connection to vacuum	P
Temperature Range	1	Channel 2 device connection to vacuum	Q
Relative Humidity Range		+/- Channel 1 polarity	⊕
		+/- Channel 2 Polarity	Θ

INDICATIONS FOR USE EN

ELECTROTHERAPY INDICATIONS

INDICATIONS

TENS

- Symptomatic relief of chronic pain
- Management of post-operative pain

NMES

- Muscle re-education
- · Increasing local blood supply
- Relaxation of muscle spasms
- 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 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 transthoraticorally 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.

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EN

ELECTROTHERAPY INDICATIONS (CONTINUED)

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. If any question arises as to the proper electrode size, consult a licensed practitioner prior to therapy session.

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

DEVICE DESCRIPTION EN

PRODUCT DESCRIPTION

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

COMPONENTS

Throughout these instructions the terms "left" and "right" referring to the machine sides are from the perspective of a user standing in front of the unit.

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

HEAD



CART



BATTERY MODULE (optional)



Battery is an 18V 3350mAh Lilon rechargeable battery

VACUUM MODULE (OPTIONAL)



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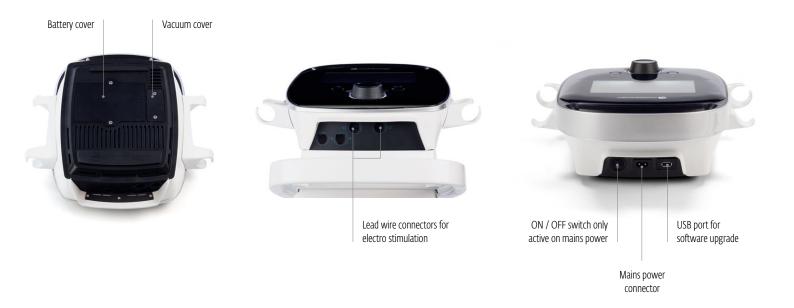
OPERATOR INTERFACE

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

- 1. Adjustment dial
- 2. Play/pause button
- 3. "On/Off" button. Press and hold (2 sec) the button to switch OFF the device.

- 4. ON/OFF switch (only active when connected to the mains)
- 5. Mains power connector
- 6. Battery cover
- 7. USB Flash Drive Port
- 8. Magnetic fixation to the cart
- 9. Vacuum cover
- 10. Device handle

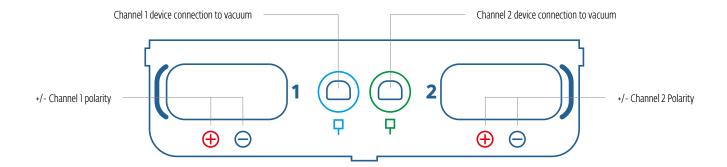




11 DEVICE DESCRIPTION EN

VACUUM MODULE OPERATOR INTERFACE





⚠ 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 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.
- Caution should always be exercised with current densities more than 2mA/cm².
- 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

MARNING

- 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.

DANGER

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

INTELECT MOBILE 2 SET COMPONENTS

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

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

HEAD



LEADWIRES

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



POWERCORD

15-0144 Wall Power Cable 2m Black EU15-0146 Wall Power Cable 2m Black UK15-0147 Power Cable 2m Black AUS

SET INCLUDES:

15-0133 INTELECT MOBILE 2
 79967 Carbon electrodes
 70010 STIM lead wires
 6522055 Chattanooga straps
 42198 Electrodes gel
 15-0144/46/47 Power cord

13-1604 Printed Quick Start Guide15-0142 5 CM² Ultrasound Applicator

4248 Ultrasound Gel Bottle

15-1140 USB Drive

STIM SET INCLUDES:

15-0132 INTELECT MOBILE 2 STIM
79967 Carbon electrodes
70010 STIM lead wires
6522055 Chattanooga straps
42198 Electrodes gel
15-0144/46/47 Power cord

13-1604 Printed Quick Start Guide

15-1140 USB Drive

US SET INCLUDES:

15-0131 INTELECT MOBILE 2 ULTRASOUND

15-0144/46/47 Power cord

13-1604 Printed Quick Start Guide15-0142 5 CM2 Ultrasound Applicator

4248 Ultrasound Gel Bottle

15-1140 USB Drive

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HEAD TO CART FIXATION

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

Remove the Intelect* Mobile 2 device and cart from the shipping carton. Visually inspect for damage. Report any damage to the carrier immediately.

To assemble the Mobile 2 Head to the Cart, follow these steps:

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

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CONNECTING CABLES AND INSERTING PLUGS

When inserting the plugs, be sure to align the flat side of the plug with the flat side of the slot and push in gently. This is to avoid bending the pins in the plug.

Insert cable into the appropriate connector prior to starting therapy.

INITIAL RECEIPT

Remove all packaging

IF UNIT SUPPLIED WITH OPTIONAL BATTERY

After unpacking Intelect Mobile 2 to fit the battery follow the following steps

- 1. Unscrew the battery cover from the base of the device by removing the 2 screws see below
- 2. Remove the battery cover
- 3. Plug the battery into the battery connector on the device
- 4. Insert the battery into its location
- 5. Replace the 2 screws to close the battery cover



POWERING UP THE DEVICE

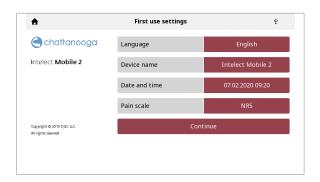
First time use always use mains power even if battery connected. Insert the power cord into the back of the unit, insert the plug into a power outlet, do not position the Intelect Mobile 2 in such a way that makes it difficult to disconnect from the mains power.

Switch device on with ON/OFF switch switch on the back of the unit

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



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



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

IFU DOWNLOAD

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

Nota: a pdf viewer is required to display IFU

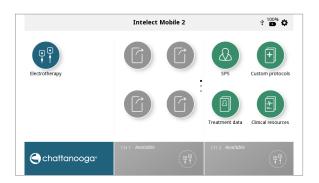
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DEVICE CONNECTED TO THE MAINS

1. Plug the Power cord into the back of device. Plug the other end of the cord into an electrical outlet.

NOTE: The Power Cord may be unplugged from the back of the unit in an emergency situation.

- 2. Turn on the ON/OFF switch located on the back of the device.
- 3. Select desired function on the Home Screen



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



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).



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DEVICE LIGHT INDICATORS

Intelect Mobile 2 ELECTROTHERAPY has several light indicators:

FRONT PANEL INDICATORS:

1. Colors:

- 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

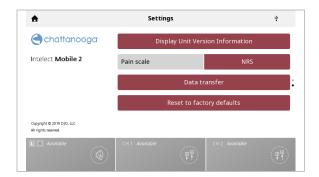
PLAY/PAUSE BUTTON BLUE INDICATOR:

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

20 | SETUP INSTRUCTIONS

COMMUNICATIONS

To prepare for communication with the INTELECT mobile2 press the settings button and scroll down the screen and press the Data transfer button to begin the Bluetooth connection.



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



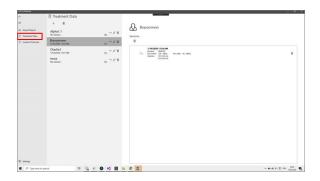
2. If there is one or more active channels on the device delivering treatment an error message will be displayed saying Active channel please stop before data transfer



3. The device will give a numerical key; to complete pairing with computer put the key into the computer to complete connection. The device screen will indicate Connected and data transfer via te Windows 10 App can begin.



4. When connected in the App we will see the device name and type and the treatment data/ protocols available for export to the computer



5. Treatment data will be displayed by identifier, selecting an item displays the treatmnet data associated with thaty iD



6. Custom protocols will be listed by name and can be exported to the computer and imported from the computer to the device. Please note treatment data can only be exported and not imported.

SYSTEM SPECIFICATIONS AND DIMENSIONS

	Width	Depth	Height	Weight (no battery)
Intelect Mobile 2 Head Unit				
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)

Electrotherapy .TYPE BF Electrotherapy Vacuum .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 4A 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

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 GUI 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 quidelines" 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).

Electrodes
1&2,
1-60 Minutes
CC
0-100 mA (CC)
1-200 Hz
2000-10,000 Hz
Continuous or User Defined
14 sec
1-199 Hz
2-200 Hz
Static, 40%, 100%, Manual
0-78mA
No



TENS- Asymmetrical Biphasic

Advice on size and type of electrodes to be used is given in device GUI "treatment quidelines" 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	0-140 mA (CC) 0-140 V (CV)
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

Electrodes
1,2
1-60 min
1-30 minutes
CC or CV
CV
0-140 mA (CC) 0-140 V (CV)
0% (off) to 100% on 10% steps
0-10 bps
Continuous or User Defined
1-200 pps
On/Off
30-400 μsec
0-5 sec
14sec
1-199 pps
2-200 pps
0-50mA
No



TENS - HAN

Advice on size and type of electrodes to be used is given in device GUI "treatment quidelines" 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. This produces a synergistic analgesic effect.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC
Output Intensity	o-100 mA (CC)
Burst Frequency	2 bps
Frequency	8o pps
Phase Duration	18o µsec
IRMS	0-19mA
DC component	No

No

WAVEFORMS (CONTINUED)



DC component

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

such as in mascic re-c	aucución prococoisi
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



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.

The literature reports beneficial effects of this waveform in the treatment of wounds. The physiological working mechanism of this effect is as yet not clearly understood. It is thought to stimulate tissue healing by stimulating the 'current of injury', a current which naturally occurs in healing tissue.

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

0-47mA

Yes

WAVEFORMS (CONTINUED)



IRMS

DC component

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	o- 60 mA
MF (Monophasé Fixe) - Frequency of 50 Hz:	
phase duration of 10 ms followed by a pause of 10 ms.	
IRMS [mA]	o-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.	



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

27 ΕN **SYSTEM**

WAVEFORMS (CONTINUED)



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. This method was claimed by its author (Kotz) to produce maximal muscle re-education effects without significant discomfort to the patient.

Output Mode	Electrodes
Available on Channels	1, 2
Treatment Time	1-60 min
Mode Selection	CC or CV
Output Intensity	o-100 mA (CC) o-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	O-5 SEC
IRMS	o-39mA
DC component	No



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	Flactrodes
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	o-5 sec
Set Intensity	Individual/both Channel Intensity
	Setting in Reciprocal and Co-Contract modes
IRMS	o-5omA
DC component	No

WAVEFORMS (CONTINUED)



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	o-60 mA (CC)
Phase Duration	0.1-1,000 MS
Phase Interval	5-5,000 ms
IRMS	0-47mA
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	o-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	o-44mA
DC component	Yes



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	o-60 mA (CC)
Phase Duration	0.1-1,000 MS
Phase Interval	5-5,000 ms
IRMS	0-27mA
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	o-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
IDMC	O 41mA

IRMS o-41mA
DC component Yes

WAVEFORMS (CONTINUED)



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	o-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	o-47mA
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	o-4 mA (CC)
Dosage	40-80 mA-min
Polarity	Fixed at positive
IRMS	o-5mA
DC component	Yes



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	o- 60 mA (CC)
Frequency	5-60 Hz
Phase Duration	0.2-5.0 ms
Pause	O-57 Sec
Surges per minute	1-20
IRMS	o-37mA
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	1-6omin
Mode selection	CC
Output intensity	o-6omA(CC)
Frequency	5-60Hz
Phase duration	0.2-5.OMS
Pause	o-57sec
surges per minute	1-20
IRMS	21mA
DC component	Yes

WAVEFORMS (CONTINUED)



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.

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	o-140 mA (CC)
Burst Duration	200 - 5,000 ms
Cycle Time	TBD
Frequency	20-80 pps
Phase Duration	30-400 µsec
IRMS	o-39mA
DC component	No



High Voltage Pulsed Current (HVPC)

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

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WAVEFORMS (CONTINUED)

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	o-100 mA (CC)
Beat Frequency	1-200 Hz
Carrier Frequency	2000-10,000 Hz
Cycle Time	Continuous or User Defined
Ramp	O-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	o-55mA
DC component	No

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 360°.

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	o-100 mA (CC)
Beat Frequency	1-200 Hz
Carrier Frequency	2000-10,000 Hz
Cycle Time	Continuous or User Defined
Ramp	0-5 \$
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	o-55mA
DC component	No

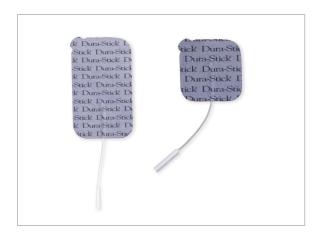
32 | PATIENT PREPARATION EN

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.
- 2. Insert the lead with the Black (-) electrode connector into the other electrode.
- 3. 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

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



33 | PATIENT PREPARATION EN

VACUUM ELECTRODE PREPARATION (OPTIONAL)

Connecting the Mobile 2 to the Vacuum cart

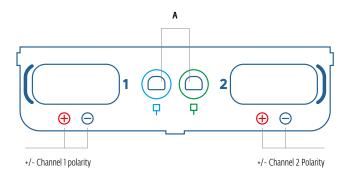
With the device power switched off remove the 2 screws attaching the vacuum door on the bottom of the device.



It is important that the power is off at this stage or the vacuum module will not perform correctly if attached whilst power is on.

Take the ribbon cable from the vacuum cat and plug it into the socket exposed on the bottom of the cart (the cable only fits one way)

Place the device on the cart, connect the blue and green vacuum leadwires to the device and the vacuum module (A) on diagram below and switch the power on, the vacuum system is now ready to use.



Note: The vacuum system cannot be used when device is powered by battery

Electrodes

DJO Vacuum Electrodes are designed specifically for optimal use with the Intelect* Mobile 2 Vacuum Module. These electrodes are multi-use when properly maintained and cleaned. The associated sponges are recommended for single patient use only, should be cleaned with a mild antibacterial solution containing no chlorine, before and after each therapy session.

Vacuum Electrodes

Refer to the image below for available sizes of vacuum electrodes. For waveform setup and parameter changes, refer to the VACUUM OPERATION section on page 56. View the Electrode Placement recommendations in the Treatment Review Screen for the particular modality being used for prior to administering treatment.



Connecting Lead Hoses

- Insert the red lead hose WITH THE NARROW
 DIAMETER HOUSING to the positive (+) lead hose connection port for the channel desired on the Vacuum Module.
- Connect the other lead hose, again with the NARROW DIAMETER HOUSING to the negative (-) lead hose connection port on the Vacuum Module.
- Place the Vacuum plugs on all vacuum channels not being used to prevent vacuum leakage during a therapy session.

4. Select the prescribed Vacuum Electrode size and install one to the opposite end of each Vacuum lead hose.
The CORRECT connection, showing a SNUG fit of the leads, WITH THE LARGER DIAMETER HOUSING, against the electrode is shown here:



Compare the INCORRECT connection shown here:



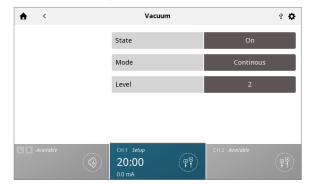
5. Using cleaned sponges, liberally wet the respective sponges, with distilled water, for the electrode size being used. Squeeze out the excess water.

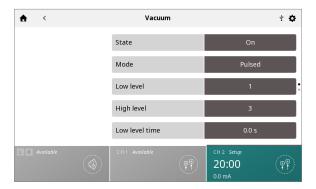
- 6. Place one sponge inside each Vacuum electrode cup.
- Select "Vacuum" on the treatment review screen. Select "ON" on the vacuum settings screen as indicated in the images below





8. Select Vacuum Mode: In continuous mode, the vacuum unit will maintain the desired vacuum pressure. In the pulsed mode, the vacuum pressure will fluctuate between a high and low pressure level. The high and low pressure value can be adjusted, as well as the time for both levels of pressure.





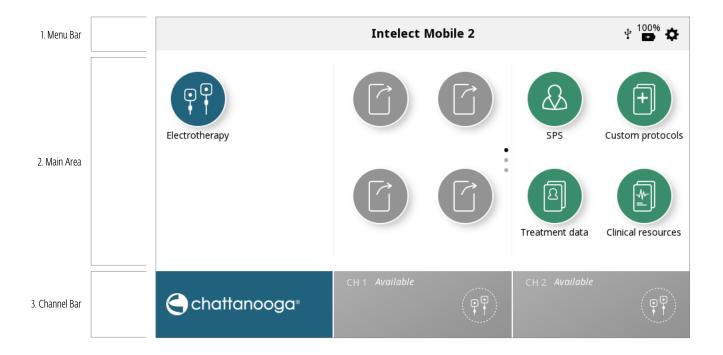
9. With the Vacuum Electrodes placed face down on a clean, firm surface, increase the intensity of the Vacuum with the adjustment dial until the electrodes are secure on the surface. Individually remove each electrode from the surface and place on the treatment area of the patient, as prescribed.

NOTE: Adjust Vacuum intensity until Vacuum Electrodes are secure to patient.

36 | USER INTERFACE EN

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



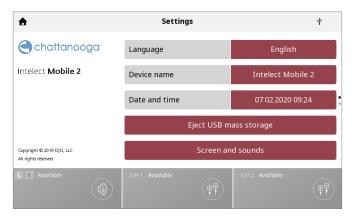
Indicates a treatment for the channel is currently paused

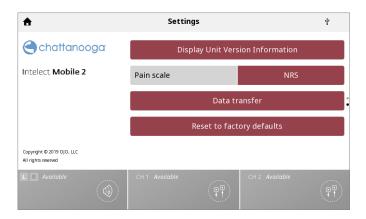


Indicates a treatment for the channel has completed

SETTINGS

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





Swipe vertically to see more settings

- 1. On the home screen, the "current screen name" displayed in the middle portion of the menu bar is by default 'Intelect Mobile 2'.
- 2. Language: touch this box if you want to choose another language
- 3. The device name can be changed to a name of your choice, e.g clinic name to do this press the Device name button and enter the new name with the displayed keyboard press Enter and the new device name will be displayed on the home screen
- 4. the date and time can be set by pressing the date and time button, date format and time format can also be set in this screen.
- 5. Press the screen and sounds button to enter this menu:
 - » To adjust the display brightness, select Brightness button. The brightness range is 0% (dimmest) to 100% (brightest) in increments of 10%. Default setting is 80%.
 - » To adjust the volume of sound, select the volume button. The volume range is 0% (off) to 100% (loudest) in increments of 10%. Default setting is 40%.
 - » Pressing the keyboard sounds button selects either on or off for keyboard sounds. Default setting is ON.
 - » Pressing the 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. Pressing the Display unit version information will show current software version serial number and several device parameters as shown below.
- 7. Choose pain scale display as NRS or VAS by pressing pain scale button to set required option.
- 8. Pressing the Data Transfer button will enable the device to connect via Bluetooth to a Bluetooth enabled Computer.
- 9. 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.
- 10. When a USB drive is inserted a new button appears to allow safe ejection of the USB drive, simply press the button and follow the on screen prompts.

PRINT SCREEN FUNCTION

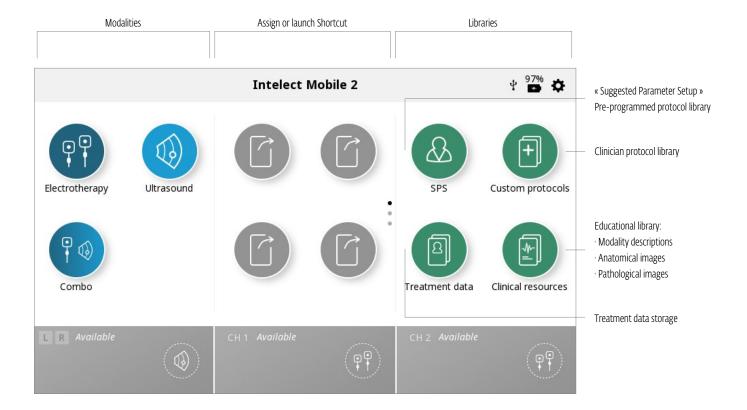
The Intelect Mobile 2 device has a built in function allowing the user to print screen fro example to print a treatment session this performed by:

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

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

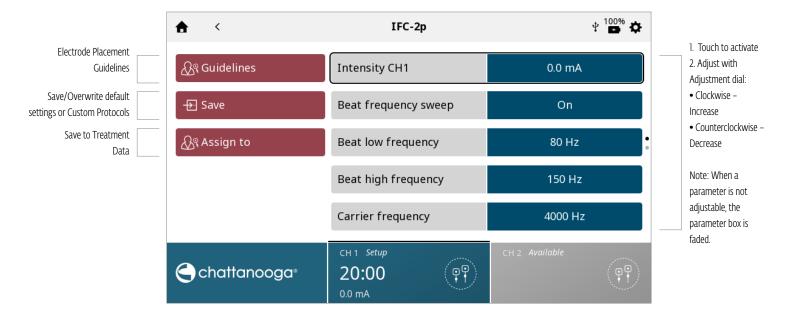
HOME SCREEN

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

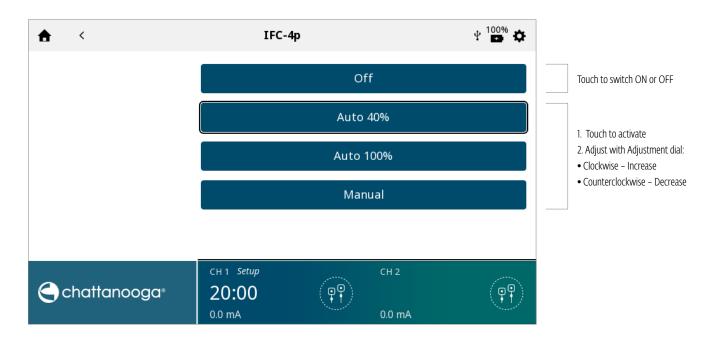


TREATMENT REVIEW SCREEN

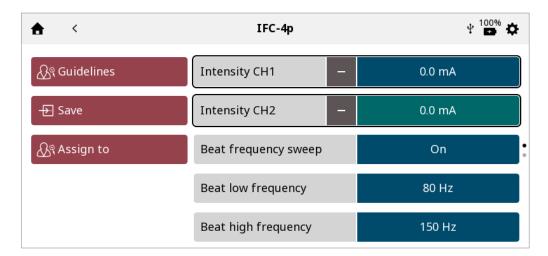
The Intelect® Mobile 2 Treatment Review screens for Electrotherapy include the following information:



Parameter Submenu Screen



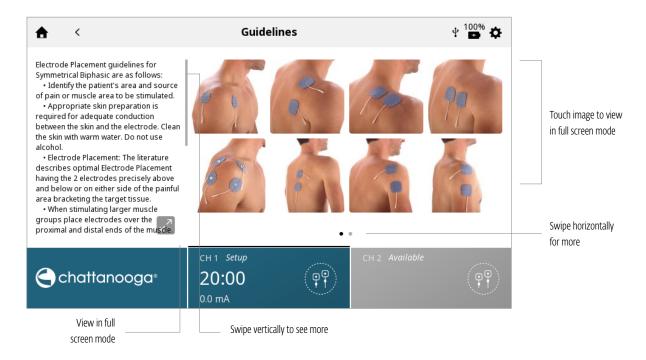
Intensity management in dual channel

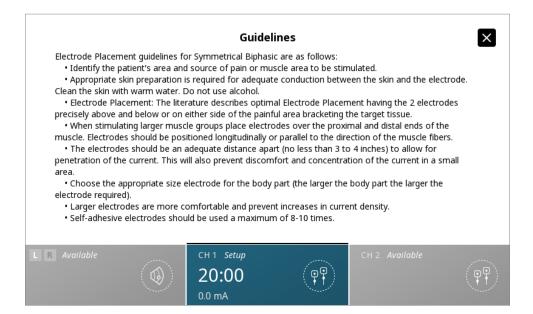


- Intensity of each channel can be managed individually by simply touching the box to activate it
- If treatment offers the possibility to manage both channel intensities together, a "+" symbol appears in the channel intensity box
- By touching this symbol, both channel intensities boxes are activated 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 provides the following information: Instructions for optimal electrode placement at the left side of the screen. Images illustrating electrode placement area.



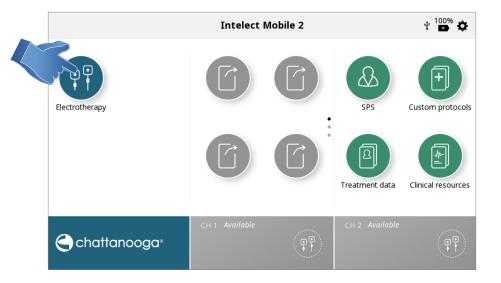


ELECTROTHERAPY OPERATION

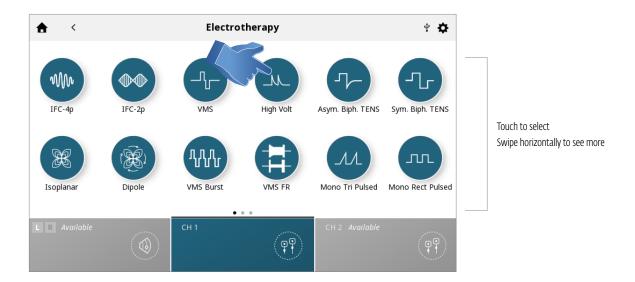
Complete the following steps to begin Electrotherapy treatment:

1. Prepare patient and therapy system for Electrotherapy. Refer to the PATIENT PREPARATION section on page... for electrode selection, preparing the patient, and securing electrodes.

2. Select ELECTROTHERAPY icon from the home screen



3. Select desired waveform

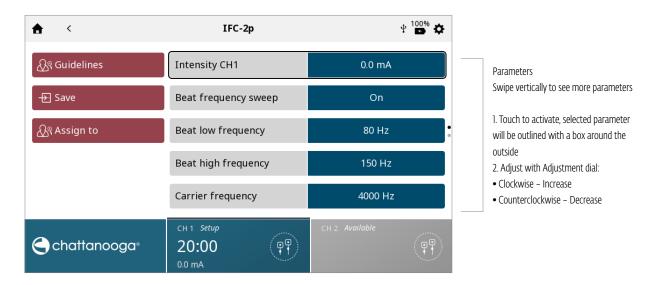


Note: Refer to the System Specifications section of this manual for all waveform specifications for the Intelect* Mobile 2.

4. SET UP TREATMENT

On the treatment review screen - you can adjust treatment parameters to desired level. Refer to page ... for detailed description of the Treatment Review Screen.

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



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

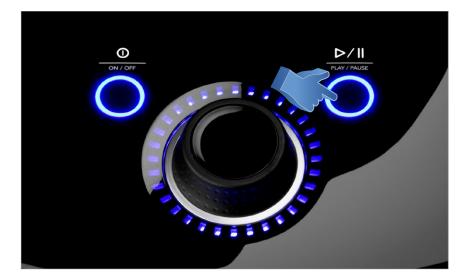
5. START TREATMENT

Press the start/pause button

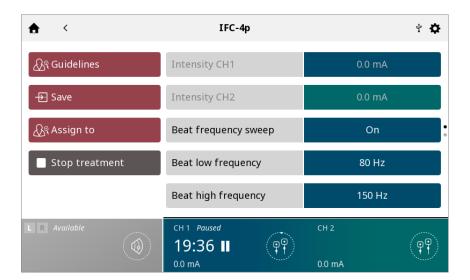


7. PAUSE TREATMENT

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

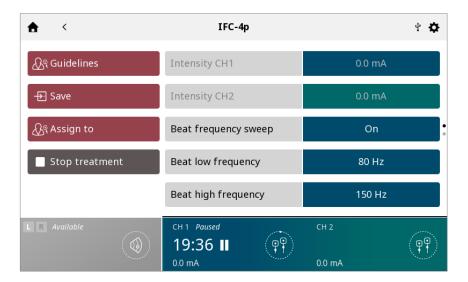
Note: Pause applies to the selected channel only

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:
 - » Assign therapy information to treatment data
 - » Open Pain scale to record post-treatment pain
- Exit Modality and return to home screen

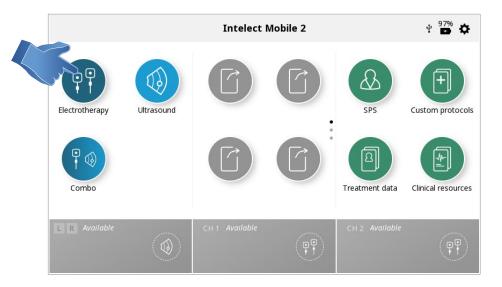


VACUUM OPERATION

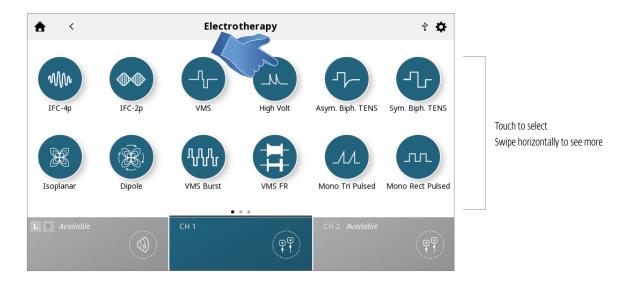
Complete the following steps to begin Electrotherapy with Vacuum treatment:

1. Prepare patient and therapy system for Vacuum Electrotherapy. Refer to the PATIENT PREPARATION section on page... for electrode selection, preparing the patient, and securing electrodes.

2. From the home screen select the ELECTROTHERAPY icon



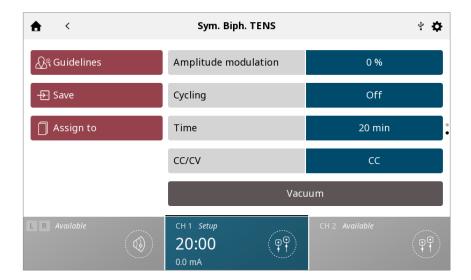
3. Select desired waveform



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

4. The Treatment Review Screen appears.

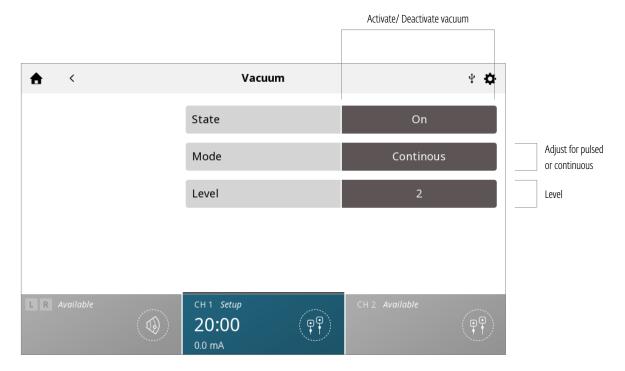
Scroll down the screen until the vacuum button is displayed



Press the button to turn on the vacuum



5. Review the settings on the Vacuum Submenu and adjust accordingly.

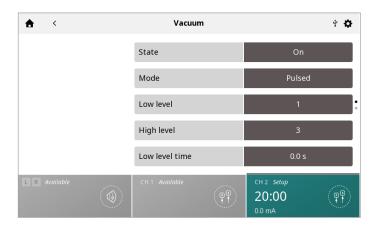


Vacuum Mode:

Continuous: Vacuum unit maintains the desired vacuum pressure. The vacuum pressure level can be adjusted from 1 (minimum) to 5 (maximum).

Pulsed: Vacuum unit will maintain the low pressure for the desired set time, then ramp up the pressure to the desired high vacuum pressure and maintain it. The cycle begins again and repeats according to time of treatment.

- The high and low vacuum pressure level can be adjusted from 1 (minimum) to 10 (maximum).
- The duration of high and low level pressure in the cycle can be adjusted from 0 seconds (minimum) to 20 seconds (maximum)



Repeat steps explained in the section ELECTROTHERAPY OPERATION on page - to adjust other treatment parameters and to start/pause/resume/stop treatment.

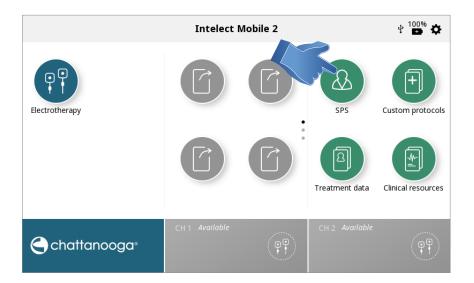
NOTE: Combination therapy cannot be administered using the Vacuum Electrode Module.

SPS (SUGGESTED PARAMETER SETUP)

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

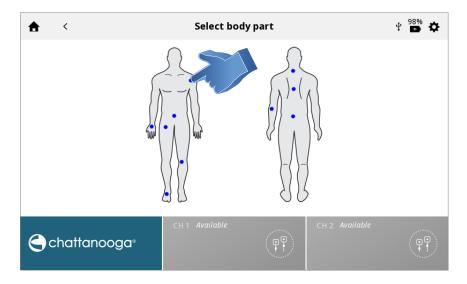
COMPLETE THE FOLLOWING STEPS TO START AN SPS PROTOCOL:

1. Select SPS from the Home Screen

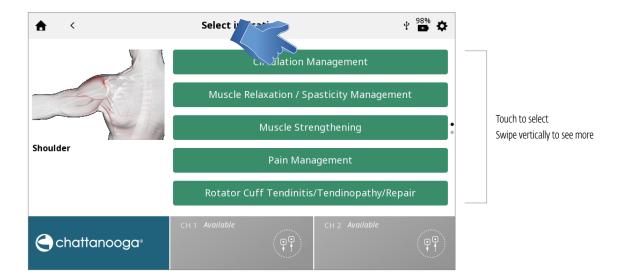


2. Select the BODY PART you wish to treat

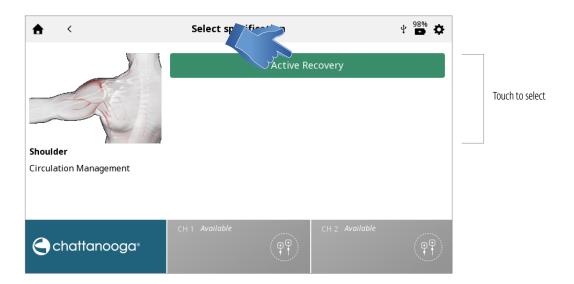
Note: the selected body part will be highlighted and moving your finger to another area while holding screen contact will highlight and select another body part.



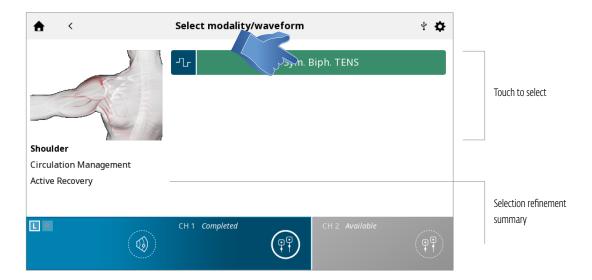
3. Select INDICATION



4. Select specification



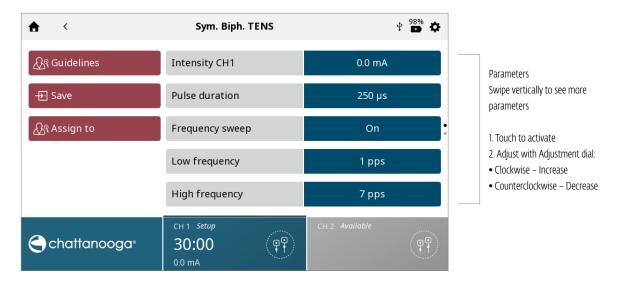
5. Select MODALITY/WAVEFORM



6. SET UP TREATMENT

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

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



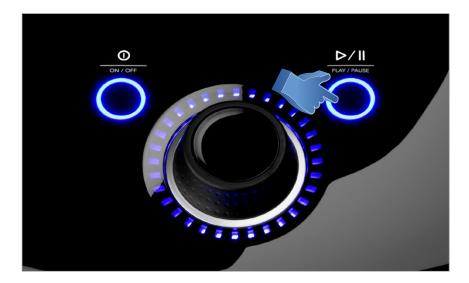
Pressing the save button will save the treatment as a custom protocol which can be named by the user

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

7. START TREATMENT

Press the START button



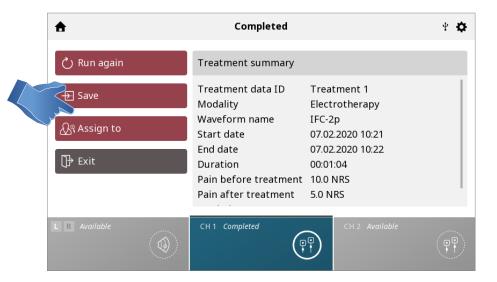
TREATMENT DATA

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

SAVE TREATMENT DATA

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

Open Pain scale to record post-treatment pain



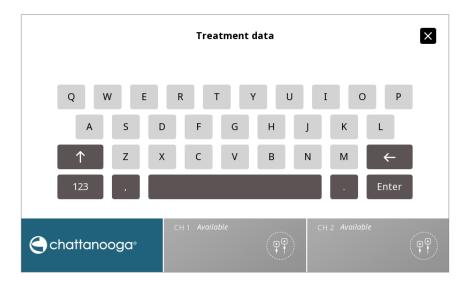
The TREATMENT DATA screen appears

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

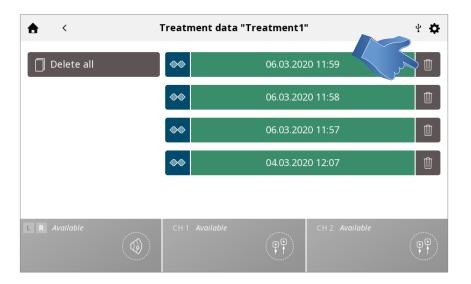


2. DELETE Treatment Data

Delete all IDs



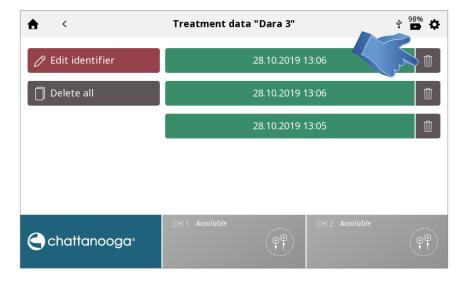
Delete one ID



Delete all treatment sessions



Delete one session



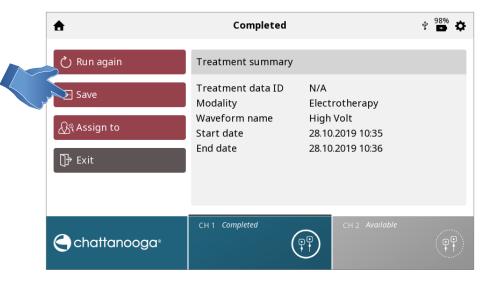
CUSTOM PROTOCOLS

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

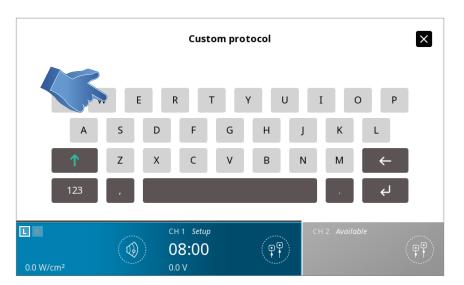
SAVE A CUSTOMIZED PROTOCOL

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

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

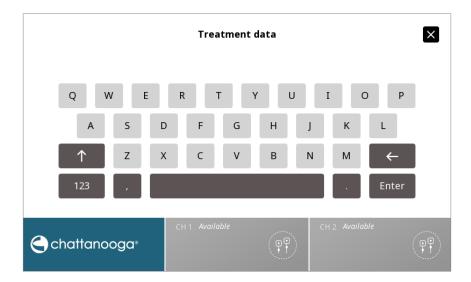


2. NAME CUSTOM PROTOCOL WITH KEYBOARD



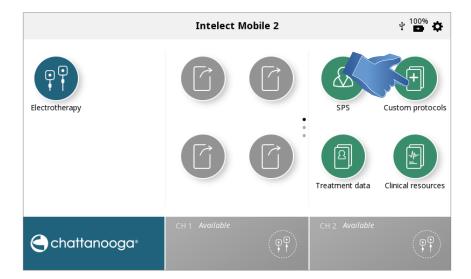
CREATE NEW CUSTOM PROTOCOL:

Enter Custom Protocol Name and Save



VIEW AND MANAGE CUSTOM PROTOCOLS

Touch the CUSTOM PROTOCOLS icon on the Home Screen



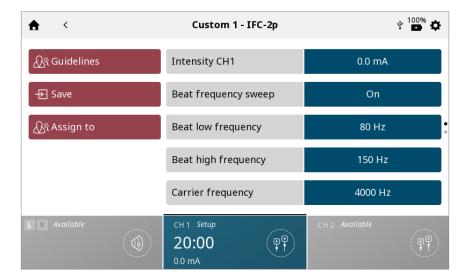
1. VIEW Custom Protocol

Select desired Custom Protocol



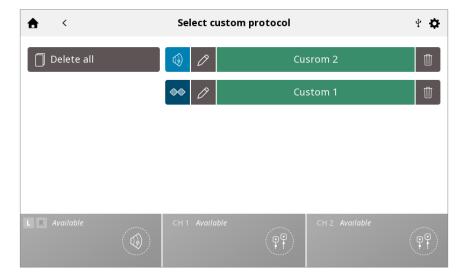
The TREATMENT REVIEW SCREEN is displayed showing the protocol settings.

Start treatment or perform other actions as described in the Electrotherapy/Ultrasound/Combo Operations sectio

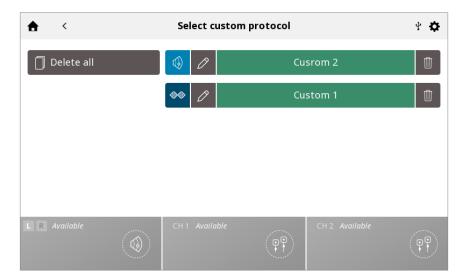


2. DELETE custom protocol

Delete all protocols



Delete individual protocols

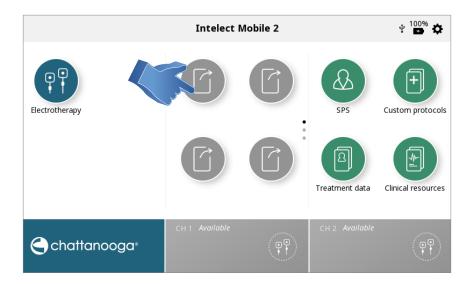


SHORT CUTS

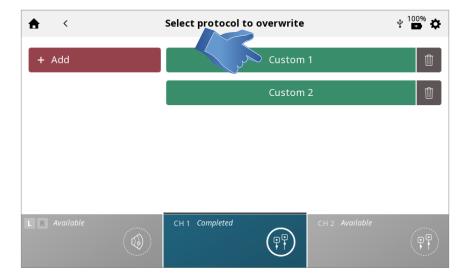
Intelect Mobile 2 allows for 12 custom protocol shortcut assignments on the home screen.

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 .

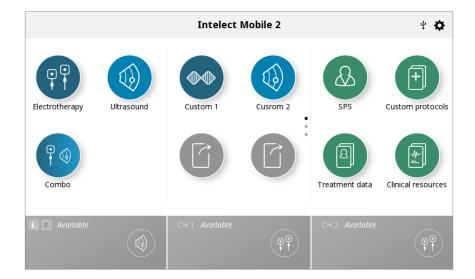


Select the desired protocol in the Custom Protocol library



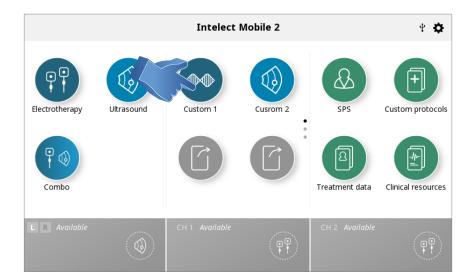
Shortcut assigned on Home screen

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

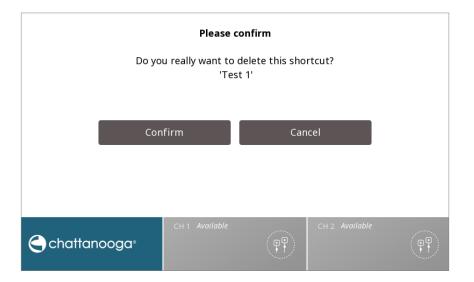


UNASSIGN SHORT CUT

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

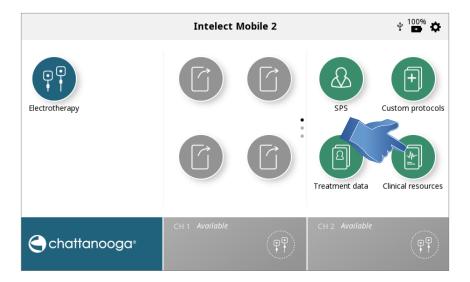
The Intelect® Mobile 2 contains a unique Clinical Resources Library .

The anatomical and pathological image library are designed to aid the operator in visually understanding and locating specific muscle groups and commonly found problems associated with pathological conditions, as well as providing an educational tool for the clinician to use with the patient.

The modality and waveform descriptions provide information about the physical background and physiological effects of the different electrotherapy waveforms and ultrasound therapy, aiming to assist the user in selecting the appropriate modality/ waveform.

Complete the following steps to view the Clinical Resources Library:

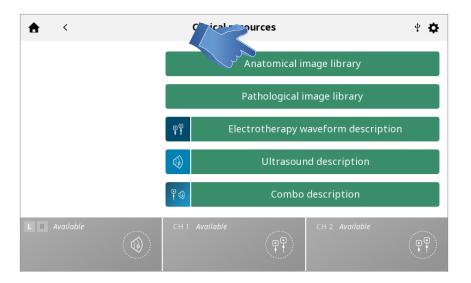
Press the Clinical Resources Library icon on the Home screen.



ANATOMICAL /PATHOLOGICAL IMAGE LIBRARY

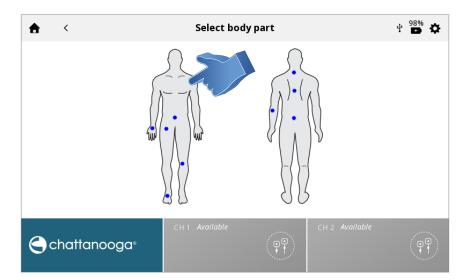
Complete the following steps to view the Anatomical or Pathological Image Library:

1. Press the Anatomical or Pathological Image Library icon on the Clinical Resources screen



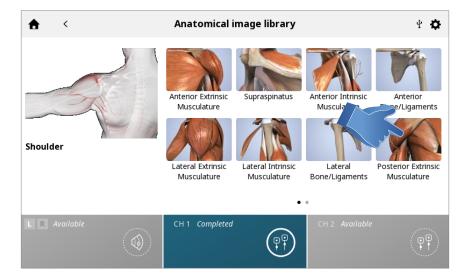
2. Touch the body part for which you wish to view information.

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

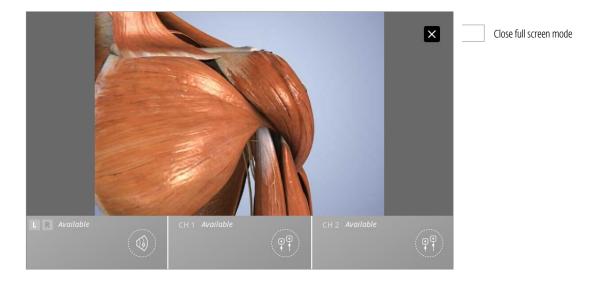


3. The available images for the selected body part are displayed.

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



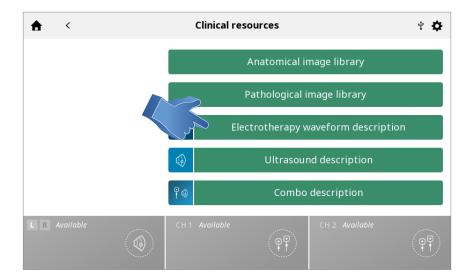
4. Full screen image



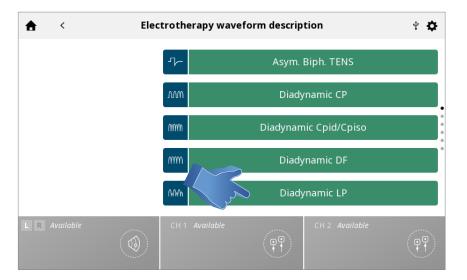
MODALITY/WAVEFORM DESCRIPTIONS

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

1. Press the Electrotherapy Waveform description icon on the Clinical Resources screen

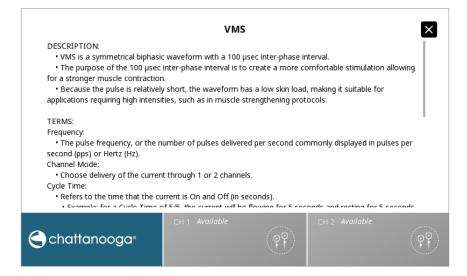


2. Select the desired waveform (in case of Electrotherapy Waveform description)



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3. The modality or waveform description is displayed



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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.

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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)

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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
15-1136	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 (Not available at launch)

Model Number	Description
14-1086	Battery

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VACUUM ACCESSORIES (Not available at launch)

Model Number	Description
70030	LEADHOSEVACUUM CH 1/2 KIT
70032	LEADHOSEVACUUM CH 1/2 KIT XL
70034	90mm VACUUM ELECTRODE KIT
70035	60mm VACUUM ELECTRODE KIT
70036	30mm VACUUM ELECTRODE KIT
70037	90mm VACUUM SPONGE KIT
70038	60mm VACUUM SPONGE KIT
70039	30mm VACUUM SPONGE KIT
70040	VACUUM MODULE ELECTRODE/LEADHOSE KIT
70041	VACUUM PLUG KIT

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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.

VACUUM MODULE CLEANING

Reservoir Draining

 When draining the reservoir, wear surgical type gloves. To drain the reservoir cup, rotate clockwise direction, shown below. Dispose of contents in accordance with your national, state or local disposal guidelines.

Flushing Lead Hoses and Reservoir

- Connect all two lead hoses to the Vacuum Module.
 Submerse the other end of the lead hoses into a container filled with at least 250 ml (8 fl oz) of hot water and one drop of dishwashing detergent added.
- 2. Turn Vacuum Module ON and set Vacuum Intensity to maximum.
- 3. Repeat this procedure until no particles are visible when the reservoir is drained.
- 4. Dispose of reservoir contents according to national, state and local rules and regulations.
- 5. The Vacuum system should be flushed weekly.

Note: The vacuun system should be flushed and drained prior to vacuum module storage or transport if temperature could potentially be below 0°C

Cleaning the Vacuum Module

- With the system disconnected from the power source, clean the vacuum module 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.
- Do not submerse the vacuum module in liquids.
 Should the vacuum module accidentally become submersed, contact the dealer or DJO Technical
 Service Department immediately.

Cleaning Instructions for the Electrodes and Suction Cups

 A mild antibacterial solution containing no chlorine can be administered with a cloth and wiped or air dried. This is recommended between patient treatments. These electrodes are multiuse when properly maintained and cleaned.

Cleaning Instructions for the Sponges

 The associated sponges are recommended for single patient use only and should be cleaned with a 70% alcohol solution before and after each therapy session.

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.

CALIBRATION REQUIREMENTS

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

Annual factory calibration is required for all Ultrasound Applicators. Only the Applicators should be sent to the factory or a Trained Technician for this procedure

DEVICE DISPOSAL



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

INSTRUCTION FOR SOFTWARE UPGRADE

- Go to the Chattanooga website www.chattanoogarehab.com
- 2. Go to Intelect Mobile 2 product page
- 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
- 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 t be switched off during the upgrade
- 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

IFU DOWNLOAD

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

Nota: a pdf viewer is required to display IFU

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

INSTALLATION OF BATTERY

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

REPLACEMENT BATTERY

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

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



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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®	
RF emissions CISPR 11	Class B	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.	
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	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	buildings used for domestic purposes.	

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Guidance and manufacturer's declaration - electromagnetic immunity

The Intelect® Mobile 2 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Intelect® Mobile 2 should assure that it is used in such an environment.

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

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Guidance and manufacturer's declaration - electromagnetic immunity

The Intelect® Mobile 2 is intended for use in the electromagnetic environment specified below.

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

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

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

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

- a) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
- b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
- c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Intelect® Mobile 2 is used exceeds the applicable RF compliance level above, the Intelect® Mobile 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Intelect® Mobile 2.
- d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m $\,$

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

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

The Intelect® Mobile 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Intelect® Mobile 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Intelect® Mobile 2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter d (m)				
power of transmitter W	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz	
	D = 1.2 √P	D = 2 √P	D = 1.2 √P	D = 2.3 √P	
0.01	0.12	0.20	0.12	0.23	
0.1	0.38	0.63	0.38	0.73	
1	1.2	2.0	1.2	2.3	
10	3.8	6.3	3.8	7.3	
100	12	20	12	23	

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

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

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

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

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





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