EN

Intelect® **RPW 2**
User Manual

Operator and Installation Instructions

INTELECT RADIAL PRESSURE WAVE 2 (RPW 2)
REF 2176 KIT (120 V)

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PRODUCT DESCRIPTION

The Intelect® RPW 2 is a compressed air-operated ballistic shock wave generator. The shock waves in the device are generated with a precision ballistic mechanism in the handpiece. A projectile is accelerated by compressed air. The motion and weight of the projectile produce kinetic energy. When the projectile impacts against an immovable surface, the shock transmitter, this kinetic energy is converted into sound energy. This acoustic pulse is transmitted into the tissue to be treated directly with the help of a gel. These waves are physically classified as radial pressure waves. The applied pressure pulse propagates radially within the tissue and has a therapeutic effect on areas of the tissue near the surface.

The V-ACTOR HF is a "vibration therapy" handpiece and is an optional accessory for RPW therapy. By using this handpiece, it is possible to treat soft tissues using high-frequency where tissues are extremely tense. With the V-ACTOR handpiece and V-transmitters only vibrations are generated. It can be used to help to reduce muscle pain and increase local blood circulation.
Muscle vibrations at low frequency of up to 35Hz lead to relaxation and activation of the neuromuscular system. At lower frequencies (between 20-35Hz) the V-Actor HF is helpful for pre-sports events or to desensitise an area prior to RPW therapies. Muscle vibration at higher frequency of up to 50Hz provides relief from spasticity and tension.

Note: This equipment is to be used only by a licensed medical practitioner.

FOREWORD

This guide is intended for users of Intelect® RPW 2.
It contains general information on operation, precautionary practices, and maintenance.
Before administering any treatment to a patient, the users of this equipment should read, understand, and follow the information contained in this guide for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of Radial Pressure Wave and Vibration therapies.

INTENDED USER PROFILE

The intended user of this device is a licensed medical professional trained to properly use the device:
Physical Therapist, Occupational Therapist, Athletic Trainers, Chiropractors, Osteopaths, Orthotists, Podiatrists, Sport's Medicine Therapists and Medical Doctors.
The device shall not be sold OTC to non professional users

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 cautions and contraindications of the device
- The operator shall operate only one device at a time and treat one patient at a time.
- The device is not intended to be operated by the patient

INTENDED ENVIRONMENT FOR USE

The device is intended to be operated in a clinical environment, it can be moved from room to room.
The device is not intended to be regularly transported from one facility to another. It is not intended for home use.

INTENDED USE

The Intelect RPW 2 device is intended to be used to help reduce muscle pain and aches, temporarily increase blood flow, and activate connective tissue.

Individual results may vary. Neither DJO Global, Inc. nor any of its subsidiaries dispense medical advice. The contents of this document do not constitute medical, legal, or any other type of professional advice.
Information related to various health, medical, and fitness conditions and their treatment is not meant to be a substitute for the advice provided by a physician or other medical professional.

PRECAUTIONARY INSTRUCTIONS

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

CAUTION

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

WARNING

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

DANGER

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

INTENDED USE AND INDICATIONS

The Intelect RPW 2 device is intended to be used to help:

- Reduce muscle pain and aches
- Temporarily increase blood flow
- Activate connective tissue

Below is a list of common painful conditions that can be treated by Radial Pressure Wave (RPW) therapy to help reduce pain, increase blood flow, and activate connective tissue in the affected area. For detailed information please read the contraindications, side effects, precautions and safety instructions within the user manual prior to the treatment.

Myofascial Trigger Points (MTrP)

Localizing and Deactivating Trigger Points

- Triggers are localized at the low energy level (approximately 2 bar) by passing the transmitter over the muscle region being treated (increased sensitivity to pain) and then deactivated using a higher energy level (approximately 3 bar).

Activation of Muscle and Connective Tissue

Increasing Circulation

- Promotes blood flow through the tissue and boosting metabolism.

Pulse vibration Massage

Soothing relief from muscle strain and stress.

Disorder of Tendon Insertions

Plantar Fasciitis, heel Pain, or heel Spur

- Plantar Fasciitis is an inflammatory condition of the foot caused by excessive wear to the plantar facia that supports the arch

Tendinosis Calcarea/Supraspinatus-Tendon

Shoulder calcifications and chronic shoulder pain

Radial and Ulnar Humeral Epicondylitis

Tennis elbow, inflammation of tendon attachments on cubital or radial part of elbow joint (humeral)

Achillodynia

Pain due to inflammation of the Achilles tendon or the bursa associated with it.

Retropatellar Pain Syndrome

Pain in the front of, behind, and around the kneecap.

Tibial Edge Syndrome

Pain located along or just behind the medial edge of the tibia

Proximal Iliotibial band Friction Syndrome/Trochanteric Insertion Tendonitis

Pain or aching on the outer side of the knee or hip

CONTRAINDICATIONS

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

- Brain or spinal column in the treatment area.
- On any body part during pregnancy.
- Direct application over cancerous tumors or lesions due to its potential to increase blood flow to the area of malignancy.
- Polyneuropathy area. A diabetic patient often experiences disturbed or reduced sensory and nervous function in the polyneuropathic area.
- Cortisone therapy: Wait minimum 6 weeks after local cortisone injection before treatment with radial pressure waves.
- Haemophilia, Thrombosis, Deep vein thrombosis, or other coagulation disorders.
- Anticoagulant pharmaceuticals.
- On any Neoplastic tissues or space occupying lesions.
- Reduced thermal sensitivity over the proposed area of treatment, unless the physician in charge of the patient is notified.
- Pulses must not be applied to target areas near large vessels, the spinal column or head (apart from the face).

ADDITIONAL PRECAUTIONS

When administering Radial Pressure Wave treatment, keep in mind the following:

- Radial Pressure Wave treatment should be applied with caution over bone where minimal (bony prominence) or no (Stage IV wounds) soft tissue is present.
- Hearing aids should be removed.
- The function of other patient connected equipment may be adversely affected by the operation of the pulsed radial pressure wave equipment. Maintain maximum distance between devices in order to reduce any tendency to interaction. Refer to the EMC tables at the end of this manual for more information.
- Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic Radial Pressure Wave treatment who have bleeding disorders.
- Frequent monitoring of intensity level and skin response should occur during all treatments.
- Always apply the transmitter on the skin with small circular movements.
- Never use Radial Pressure Wave therapy on the head.
- Do not treat direct in an area with a metal implant.
- Patients with active autoimmune diseases may not respond positively with the treatment

ADVERSE EFFECTS

Side effects could occur after a treatment with Radial Pressure Wave therapy. The majority will appear after 1-2 days. Do not repeat a treatment until the previous side effects have diminished. Common side effects include:

- Erythema, reddening
- Swelling
- Pain
- Hematoma
- Petechiae, red spots
- Skin lesions after previous cortisone therapy

These side effects generally abate after 5 to 10 days

PATIENT APPLIED COMPONENTS

Transmitters for the Falcon handpiece

Transmitters	Material	Applied part Type
A6	Steel 1.4021	Type B
T10	Steel 1.4021	Type B
C15	Ceramic Volcera	Type B
DI 15	Titan grade 5 ELI	Type B
F15	PTFE	Type B
D20-S	Steel 1.4542	Type B
D35-S	Steel 1.4542	Type B
D20-T	Titan grade 5 ELI	Type B
Ro40	Steel 1.4021	Type B
R15	Steel 1.4021	Type B
PERI ACTORS	POM-C LSG (ACETRON)	Type B
SPINE ACTORS	Polyvinylidenfluorid EpoFlon – ECTFE (Halar)	Type B
Atlas	Elastosil m 4641	Type B
Ultrasonic gel	Water de-ionized water Gel (PH7)	Type B

Transmitters for the V-Actor HF

Transmitters	Material	Applied part Type
V10	POM-C LSG (ACETRON)	Type B
V25	POM-C LSG (ACETRON)	Type B
V40	POM-C LSG (ACETRON)	Type B

COMPONENTS

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

Falcon Handpiece

Gel Holder

Cable Holders

Gel Bottle

Gel for diagnostic and therapeutic medical procedures should be water based with deionized water. No formaldehyde, no fat. For external use only.

Pouch

Transmitter Tray

*** Transmitters not included**

IFU DOWNLOAD

1. To download the IFU go to the Chattanooga website www.chattanoogarehab.com
2. Complete the registration to be informed of software and IFU updates and register your device
3. Select your INTELECT RPW 2 model
4. Click download IFU to start the download
5. A pdf viewer will be required to view IFU

SYSTEM START-UP

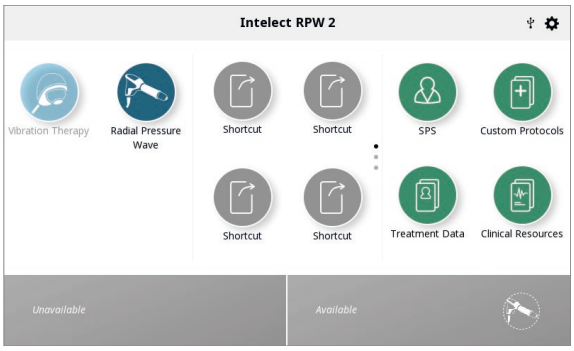
Complete the following steps for start-up of the Intelect® RPW 2:

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 device in an emergency situation.

2. Connect the Falcon handpiece on the right connector.



3. Turn on the power switch located on the back of the device.

TO STOP TREATMENT

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 device.
Trigger the handpiece or press Start/Pause button to pause treatment then press Stop on touch screen. If device is on mains power turn of the switch on the back of the device.

Press and hold for power off

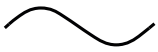
GENERAL TERMINOLOGY

The following are defiitions 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® RPW 2.

SYSTEM SOFTWARE SYMBOLS

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

	Run again
	Exit
	Export
	Import
	Delete
	Delete all
	Stop treatment
	Falcon Radial Pressure Waves handpiece
	Vibration Therapy handpiece V-Actor
	Shortcut
	SPS (Suggested Parameter Setup)
	Custom Protocols
	Treatment Data
	Clinical Resources

	Relative Humidity Range
	Atmospheric Pressure Range
	Testing agency
	Class 1 equipment
	Radio frequency equipment
	WEEE Directive conformity
	Shelf life
	Batch number
	No condensation allowed
	Read the instruction for use
	AC Rated supply voltage
	Medical Device
Rx Only	For provision and use only at a licensed physician's direction and under medical supervision

Markings are conform to ISO7010 and ISO15-223-1"

⚠ CAUTION

- This device should be operated at 10°C to +40°C and 30% to 75% Relative Humidity (no condensation). The device should be transported and stored at -20°C to +60°C and 10% to 90% Relative Humidity (no condensation).
- Atmospheric pressure requirements: 70 kPa to 106 kPa.
- The Falcon handpiece should be operated at 10°C to +40°C and 5% to 95% Relative Humidity (no condensation). The handpiece should be transported and stored at 0°C to +60°C and 5% to 95% Relative Humidity (no condensation).
- The V-Actor HF handpiece should be operated at 10°C to +30°C and 5% to 95% Relative Humidity (no condensation). The handpiece should be transported and stored at 0°C to +60°C and 5% to 55% Relative Humidity (no condensation).
- The time required for Intelect RPW 2 to warm from the minimum storage temperature between uses until Intelect RPW 2 is ready for its intended use when the ambient temperature is 20°C is 5 hours.
- The time required for Intelect RPW 2 to cool from the maximum storage temperature between uses until Intelect RPW 2 is ready for its Intended use when the ambient temperature is 20 °C is 5 hours
- Under single fault condition and extreme usage conditions, the maximum temperature of the hand piece can reach 47°C. There is no particular health risk associated with this temperature besides your comfort.
- Use of parts or materials other than DJO's can degrade minimum safety.
- Connect to this device only items and equipment that have been specified in this IFU as part of the Intelect RPW 2 System or that have been specified as being compatible with the Intelect RPW 2 System.
- DO NOT disassemble, modify, or remodel the device or accessories. This may cause device damage, malfunction, electrical shock, fire, or personal injury.
- Before using the therapy device, the operator must ascertain that it is in correct working order and operating condition. The cables and connectors, in particular, must be checked for signs of damage. The device cannot be used if any part is damaged as there is a risk of electrical shock.
- Before each use always offer the patient hearing protection.
- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area and to the shock transmitter.
- The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.
- DO NOT apply more than 300 shocks to the same spot during treatment.
- The surface of the transmitter can reach 47°C. Extended skin contact can cause minor burns. Interrupt therapy after a maximum of 6000 pulses to allow the transmitter to cool.
- Operating the device at pressures higher than 3 bar without an impact surface can result in damage to the handset.
- To avoid a trip hazard, keep all accessories and their cords separated during treatment by using the hook located on the side of the device.
- Disconnect the instrument from the mains before starting any cleaning or overhaul work.
- Danger of injury due to pulse triggering when handpiece is open.
- Disconnect the handpiece from the control device before starting any cleaning or maintenance work.
- There are no user-serviceable parts inside the device. If a malfunction occurs, discontinue use immediately and contact your local DJO office via www.djoglobal.com for assistance and service information.
- Do not use while sleeping or operating heavy equipment.

⚠ WARNING

- This equipment is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- This device should be used only by a physician or licensed practitioner.
- Contaminated transmitters, and gel can lead to infection. Disinfect the handpiece after each treatment.
- DO NOT use the Intelect RPW 2 in water (Bath, Shower, etc.) that could cause electronic failure
- DO NOT operate the Intelect RPW 2 within the vicinity or environment of any microwave and RF shortwave diathermy system.
- DO NOT operate this device in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- DO NOT apply more than 300 shocks to the same spot during treatment
- Avoid excessive pressure of the shock transmitter to the patient's skin.
- DO NOT trigger pulses unless the pulse transmitter is in contact with the treatment zone.
- Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Intelect RPW 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, handpieces and transmitters 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.
- 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.
- No modification of this equipment is allowed
- The Intelect® RPW 2 may be susceptible to Electro-Static Discharge (ESD) at greater than ±8 kV when first grasping either the Falcon or V actor hand piece. In the event of such a discharge, the Intelect® RPW 2 may experience communication loss. The Intelect® RPW 2 will terminate all active outputs, automatically place the device in a safe state.
- To prevent Electro-Static Discharge (ESD) at greater than ±8 kV:
  - » Grasp and hold the hand piece 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 35% 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 35%.
  - » Communicate these ESD-precautionary procedures to healthcare staff, contractors, visitors, and patients.
- DO NOT block the device's vents.
- Potential electromagnetic or other interference could occur to thsi or other equipment. Try to minimize this interference by not using other equipment in conjunction with it.

⚠ DANGER

- DO NOT connect the device to an electrical supply without first verifying that the power supply is the correct voltage. Incorrect voltage may cause device damage, malfunction, electrical shock, fire, or personal injury. Your device was constructed to operate only on the electrical voltage specified on the Voltage Rating and Serial Number Plate. Contact your DJO dealer if the device 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.
- If the device is not safe for operation, it must be repaired by a certified service technician and the operators must be informed of the dangers posed by the device.

UNPACKING THE DEVICE

The device is generally delivered with the packaging material supplied by the manufacturer. As the device weighs approximately 32 kg (72 lbs), it must be unpacked by at least 2 persons.
Proceed as follows:

- Position the transport packaging so that the arrows are pointing upward.
- Remove the safety bands from the transport packaging.
- Lift off the transport packaging upward.
- Remove the remaining foam material.
- Using at least 2 people, lift the device from the lower packaging element.
- Inspect the device for any damages before proceeding

Immediately upon unpacking the device, perform the following steps:

1. Verify the delivery documents to make sure that the delivery is complete.

2. Check the external components and accessories for possible damage due to transport.

3. Verify that the packaging contains the following

- Intelect® RPW 2 device
- Intelect® RPW 2 Quick Start Guide
- USB Stick
- Pouch
- Gel Holder
- Cables Holder
- Power cord
- Conductor™ Transmission Gel-250 ml (8.5 oz) bottle
- Standard Accessory Kit that Includes the following:
  - » RPW Falcon Handpiece Applicator
  - » Projectile
  - » R0 40 - 15 mm ESWT Transmitter
  - » D20-S D-ACTOR® 20 mm Transmitter
  - » Sealing Set
  - » Guide Tube
  - » Cleaning Brush

4. A pouch is provided with the device. This pouch can be attached onto the side of the device handle and can be useful for accessories storage.

a. Position the pouch on the side of the device, just below the handle rail with the zipper portion facing outward
b. Loop the soft textile flap over the hand rail
c. Attach the soft textile flap to the hook band located on the back of the pouch

5. The Gel Holder cup can be attached on the any side of the device

6. The cable holder is used to hang the handpieces cables

7. Retain the original packaging. It may prove useful for any equipment transport. Please refer to chapter to page 64, the Accessories Section for information on optional accessories.

DEVICE DESCRIPTION

* Device delivered with 2 transmitters. Other transmitters displayed are optional.

* V-actor applicator is optional.

FALCON HANDPIECE SET UP

1. Unscrew the shaft from the handpiece and pull it out of the handpiece handle. Use the supplied open-end spanner for this purpose.

2. Insert the new projectile into the fitted guiding tube

3. Screw the shaft into the handpiece until finger-tight. Using one hand, press the handpiece firmly onto the table and tighten the shaft using the open-end spanner. It must no longer be possible to unscrew the shaft by hand.

4. Screw the transmitter screw cap with the required transmitter firmly back onto the shaft. For two-part transmitter caps: Make sure that the two cap parts are screwed firmly in place and that the transmitter screw cap is screwed firmly to the shaft.

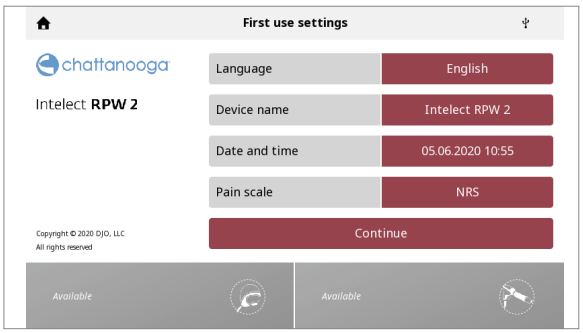
5. Connect the Falcon handpiece to the right connector on the device

POWERING UP THE DEVICE

Insert the power cord into the back of the device, insert the plug into a power outlet.
Switch device on with switch on the back of the device. Make sure the mains connector remain accessible at all times as it can serve as an emergency switch. Turn off the main rocker switch to completely switch off the device. For an all-pole separation from the mains supply, disconnect the mains plug from the socket.

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

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



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 RPW 2 product tab
3. Complete the registration form to be informed about newproduct software version availability and IFU updates.
4. Go to documents tab
5. Click on the latest version of your Intelect RPW 2 device user manual to download

Note: A pdf viewer is required to display IFU

DEVICE LIGHT INDICATORS

Intelect RPW 2 has several light indicators:

ON/OFF BUTTON BLUE INDICATOR:

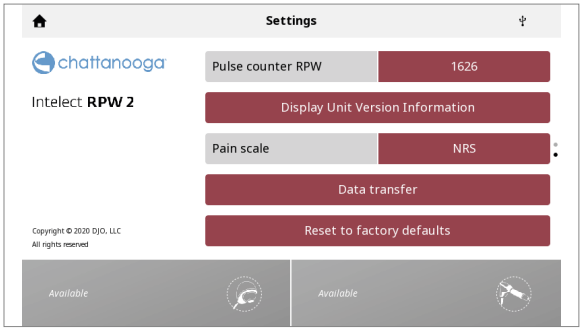
- Steady ON from device connection to the mains
- Flashing while powering ON/OFF

PLAY/PAUSE BUTTON BLUE INDICATOR:

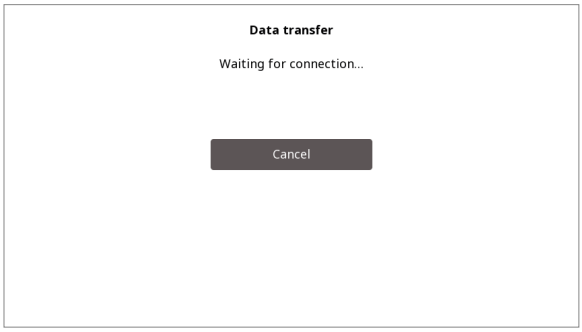
- It flashes when user can start/resume a treatment. Otherwise, steady

COMMUNICATIONS

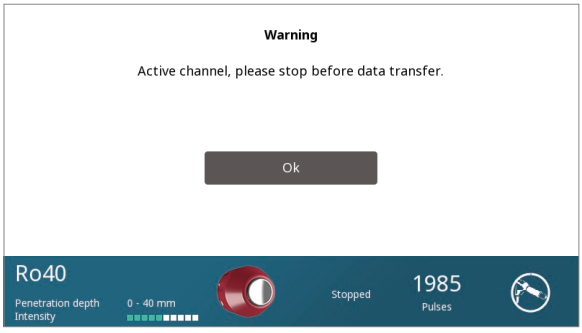
Download and install the Windows 10 Intelect Connect App for free from chattanoogarehab.com
To prepare for communication with the INTELECT RPW2 press the settings button and scroll down the screen and press the Data transfer button to begin the Bluetooth connection.



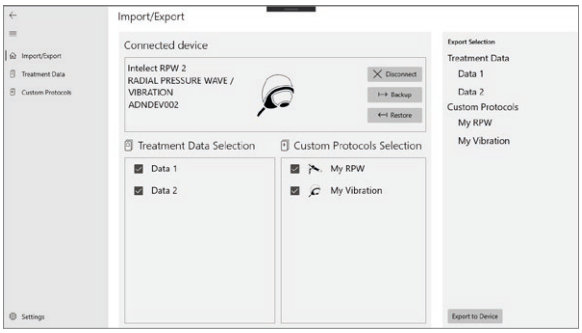
1. You should now see the screen Waiting for connection whilst the device discovers the computer to be paired with



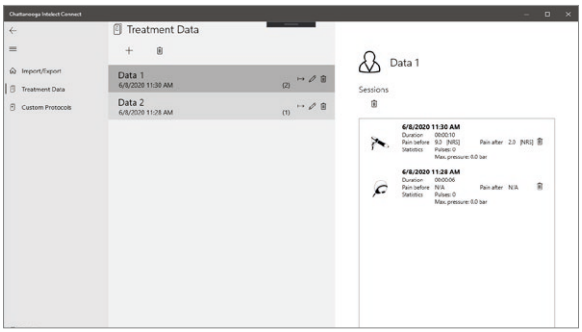
2. If there is one or more active channels on the device delivering treatment an error message will be displayed saying Active channel please stop before data transfer



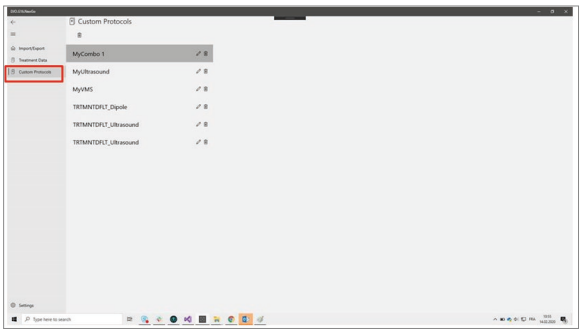
3. The device will give a numerical key ;to complete pairing with computer put the key into the computer to complete connection. The device screen will indicate Connected and data transfer via te Windows 10 App can begin.



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.

OPERATING DATA AND RATINGS

Values displayed on the device are with a tolerance of ±10%
Width.....420 mm
Depth .....410 mm
Height .....1140 mm
Standard Weight (with one handset).....32 Kg (72 lbs)
Ambient temperature.....10 °C - 40 °C
Relative Humidity .....30% to 75%
Air Pressure.....700 hPa to 1060 hPa

Power Consumption
350 VA (Model 2176DEV)

Input
120V AC~ 50 - 60 Hz 350VA (Model 2176DEV)

Output
0.3 - 5 bar 1 - 21 Hz (RPW) 1 - 50 Hz (V-Actor) (Model 2176DEV)

Mode ..... Single or Continuous
Compressed Air Output.....0.3 - 5.0 bar
Power Increment Settings.....0.1 bar
Pulse Amplitude.....approx. 2 mm at 3 bar, idling (without coupling)
Pulse Width .....approx. 6 - 12 ms
Pulse Frequency.....1 - 21 Hz for RPW, 1 - 50 Hz for Vibration
Fuses..... 2 x T6.3A H 250 V 5x20 mm
Electrical Class.....CLASS I
Electrical Type (Degree of Protection).....TYPE B
Regulatory Risk Class.....IIa according to MDD 93/42/EEC
Mass.....29 Kg (64 lbs)
Safe Working Load.....5 Kg (11 lbs)

FALCON HANDPIECE TECHNICAL SPECIFICATIONS

Compressed air input.....1.0 - 5.0 bar
Ambient temperature during operation.....10 - 40 °C
Ambient temperature during storage and transport.....0 - 60 °C
Ambient air pressure during operation.....800 - 1,060 hPa
Ambient air pressure during storage and transport.....500 - 1,060 hPa
Air humidity Storage.....5 - 95%, non-condensing
Air operation.....5 - 95%, non-condensing
Weight.....480 g

SOFTWARE

The software is developed and provided by DJO.
To view the version of the software, press the Settings button. The version number of the Software can be found by pushing the display unit version information.

TRANSPORT AND STORAGE CONDITIONS

Ambient temperature.....-20 °C - 60 °C
Relative Humidity.....10% - 90 % no condensation
Air Pressure.....500 hPa to 1060 hPa

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

PATIENT PREPARATION

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

To prepare the patient's skin for therapy, do the following:
1. Thoroughly wash the skin on which intended treatment is to be administered with mild soap and water or alcohol wipe.
2. Dry the skin thoroughly.
3. Apply the ultrasound gel generously to the target area on the patient

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

TREATMENT TIPS

- Let your patient rest in a relaxing position during a treatment session, providing them a rolled up towel under their limb for comfort if needed during an elevated treatment
- Localise the painful points you plan to treat. It might be a good idea to mark up the points with a felt tip pen.
- Apply a liberal amount of gel on the skin of the treatment area.

Talk to your patient and ensure that they understand the following:

- Treatment should start at minimal Bar level
- Bar level should increase slowly, manually or automatically when using Comfort Mode
- Patient is responsible to let the clinician know at anytime if treatment is becoming painful

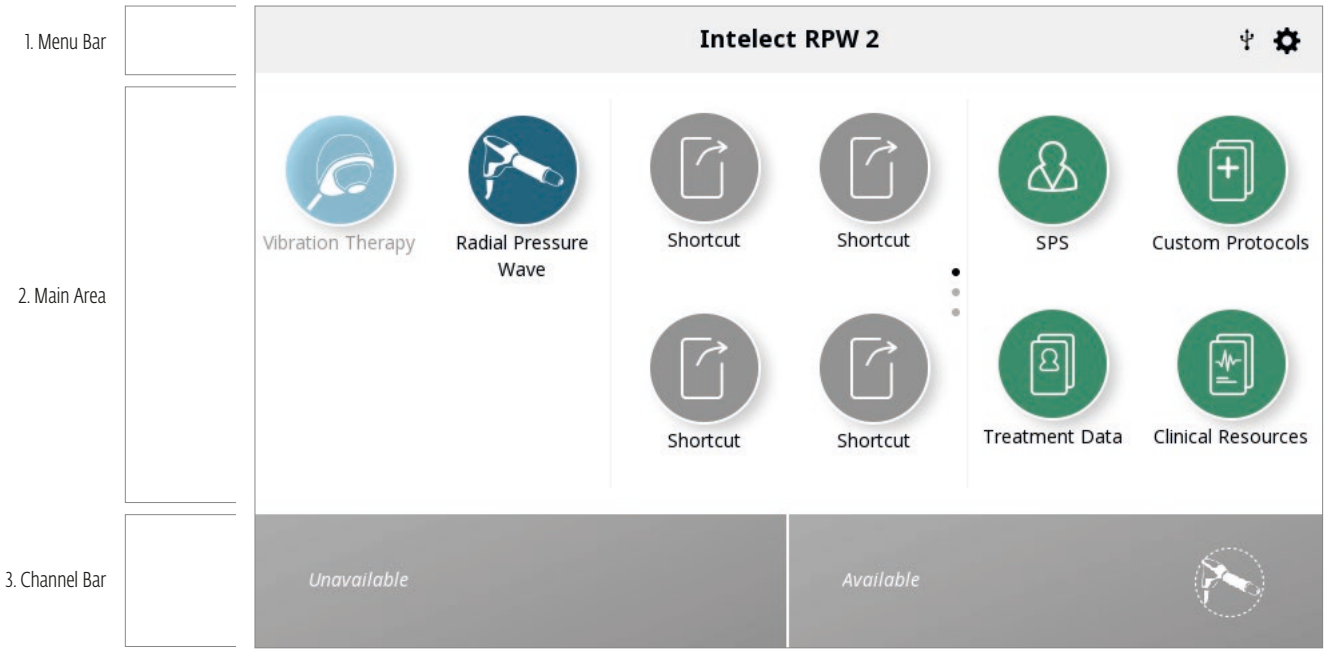
Note: The therapist should pay attention to patient's body's reaction to treatment

DEVICE USER INTERFACE

Intelect® RPW 2 ON/OFF button has several light indicators:
- 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.

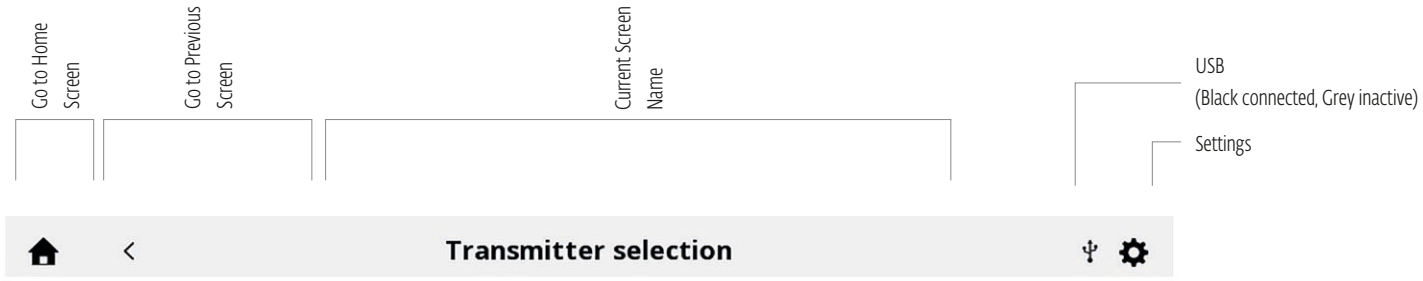
SCREEN DESCRIPTION



Each screen contains the following areas:

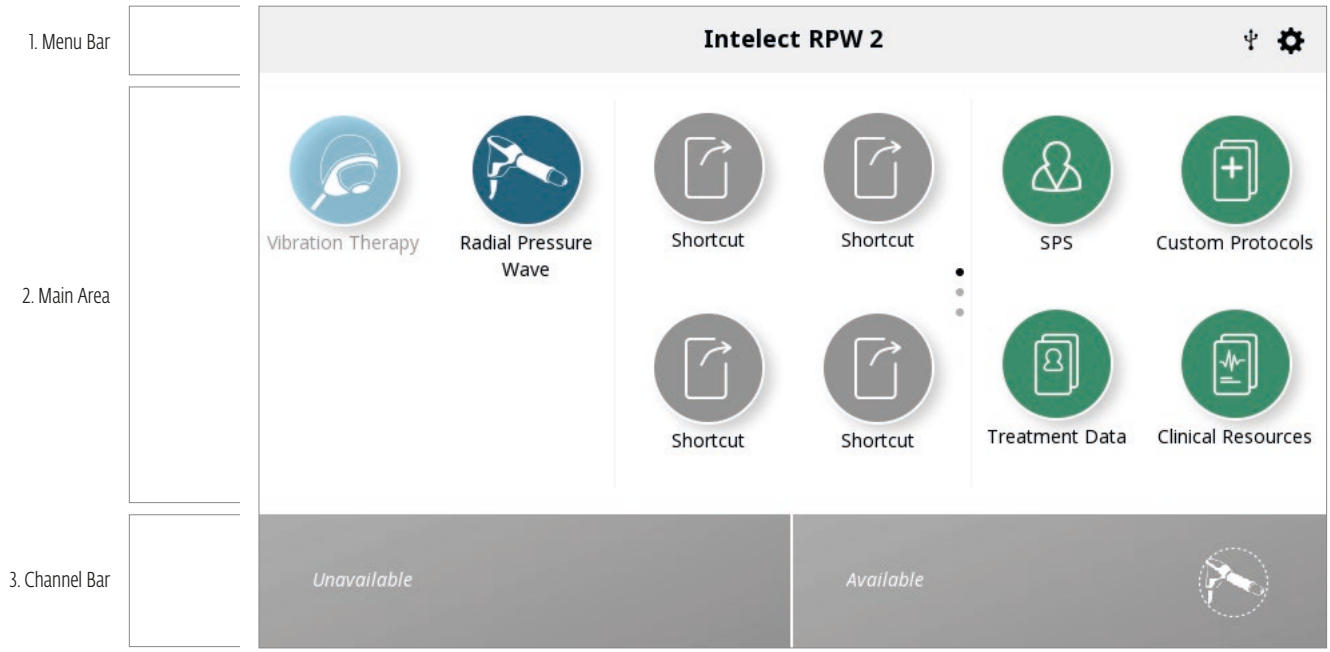
Menu Bar

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



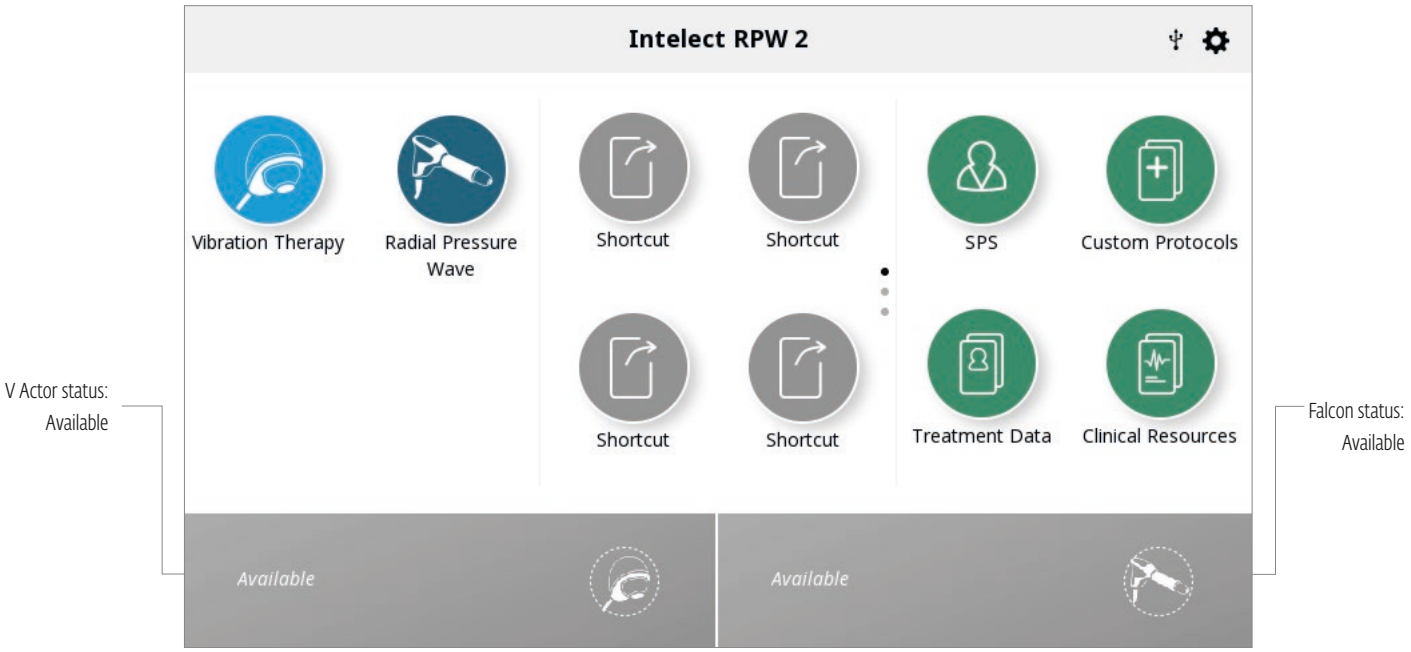
Main area

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



UNDERSTANDING YOUR BOTTOM BANNER

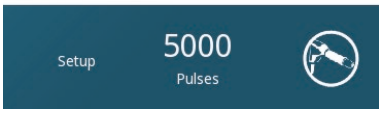
The home screen will tell you if the handpiece(s) is connected (available = connected; unavailable = not connected). If the handpiece is connected but the device detects an error, a message might be displayed, please see page 64 for details.
The left side of the screen will tell you what transmitter you have selected with an image of the transmitter - ensure you have the proper transmitter on the end of the handpiece.
The right side will tell you pulse count, treatment status, handpiece selected (therapy). The treatment status will change as the treatment progresses in generally the following order: Set-up, Arm, Armed, Running, Pause, Completed.



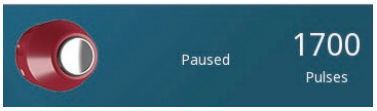
CHANNEL STATUS POSSIBILITIES:

Indicates the handpiece is available for use

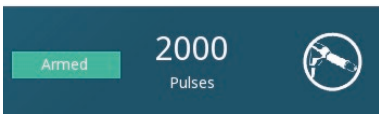
Indicates that handpiece is not available for use



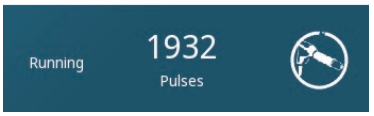
Indicates that transmitter type has not been selected



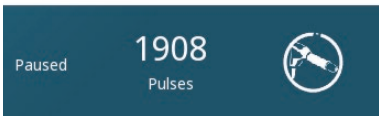
Indicates that transmitter type is selected



Indicates compressor is armed

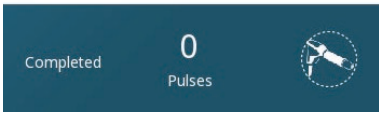


Indicates treatment is running



Indicates treatment is paused

Indicates that the handpiece is not working properly or not compatible with INTELECT® RPW 2



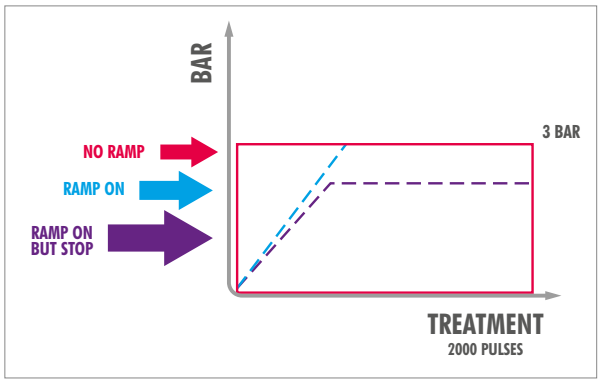
Indicates treatment is completed

BAR EXPLAINED

Bar is the unit of measure for the intensity applied by the handpiece and felt by the patient.
Bar settings can be increased or decreased by using the turning dial on the device.
Bar measurements start at 0.3 and can reach 5.0; Bar will increase in 0.1 increments.
Lower settings, such as <1.0 Bar should be reserved for Spinal and Facial treatments unless the patient has a low pain threshold.
Higher Bar settings above 1.4 should be used for all other treatments.

COMFORT MODE EXPLAINED

In the legacy Intelect® RPW this feature was called Ramp Mode. This same user friendly functionality has been applied to the Intelect RPW 2, but with a name change to better describe the feature itself. This patented unique feature can only be found on the Intelect RPW devices.



The Comfort Mode feature turns the ramping function on and off. This feature slowly increases the Bar and allows the patient to get used to the pressure of the output instead of administering the full output all at once. This feature defaults to 'ON', it allows the device to gradually increase the Bar or intensity to the desired treatment Bar setting. The device will increase to the desired Bar setting starting at 1/10 of the desired Bar, slowly increasing in increments of 1/3 of the set amount of pulses until it reaches full Bar strength.
By touching the screen this feature can be turned 'OFF'.

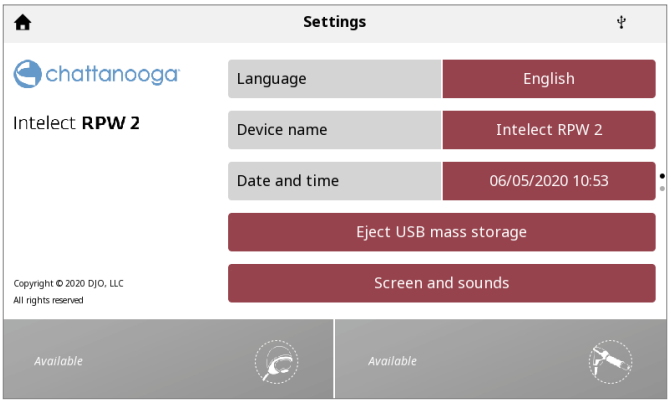
Note: If the Comfort Mode has been turned 'OFF' before the treatment, it cannot be enabled in the middle of a treatment; while a treatment session is in progress.

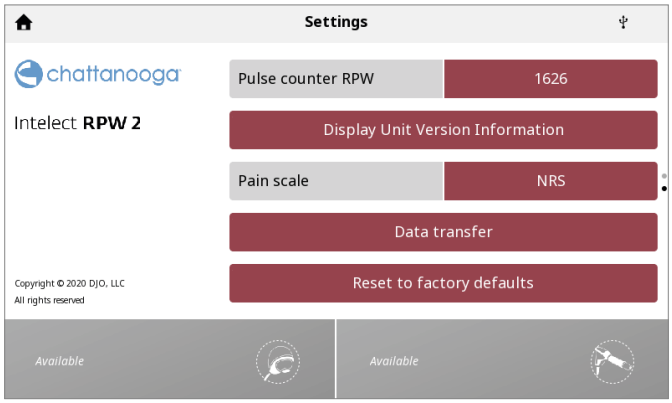
During the treatment, while the device is in the process of ramping up to the treatment Bar level, the device can be paused. When resuming the treatment from being paused the treatment can progress in one of three ways:
1. Continue to ramp to the full treatment Bar
2. The treatment can resume at Bar level when paused during ramp up
3. The treatment can be resumed and the clinician can turn the dial on the device so that the ramp is on a lower setting for the remainder of the treatment.

The Bar adjustment is the most sensitive parameter to be set and is very important to set correctly.
A low level of Bar energy would not be efficient, as 50% of the energy is lost at the skin's surface. While a high level of energy could generate intense pain during the treatment causing the patient to not seek further therapies. The Intelect RPW 2 comfort mode is designed to help the clinician determine what level of Bar energy and discomfort the patient can accept.

SETTINGS

The settings icon on the top right hand corner of the home screen menu bar offrs 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 RPW 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%.

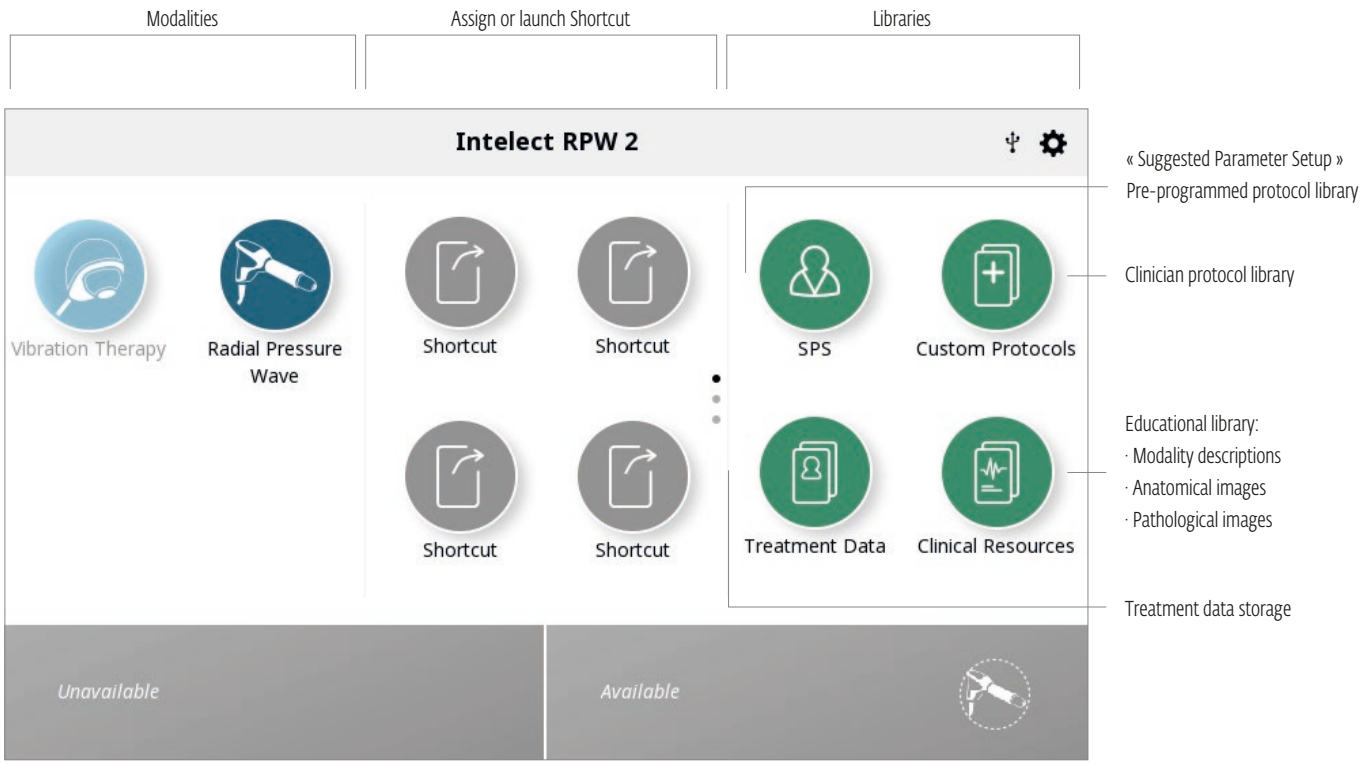
» Pressing the keyboard sounds button selects either on or of for keyboard sounds. Default setting is ON.

» Pressing the Keypad layout button allows the keypad format to be changed to QWERTY, AZERTY or QWERTZ

6. Pulse counter can be reset. Directions on how to reset your counter can be found in the Overhaul section of this IFU.
7. Pressing the Display unit version information will show current software version serial number and several device parameters as shown below.
8. Choose pain scale display as NRS or VAS by pressing pain scale button to set required option.
9. Pressing the Data Transfer button will enable the device to connect via Bluetooth to a Bluetooth enabled Computer.
10. Press Reset to factory defaults to restore the device to the factory settings, pressing this button will result in a restart and the user will be taken to the initial setup screen on restart.
11. When a USB drive is inserted a new button appears to allow safe ejection of the USB drive, simply press the button and follow the on screen prompts.

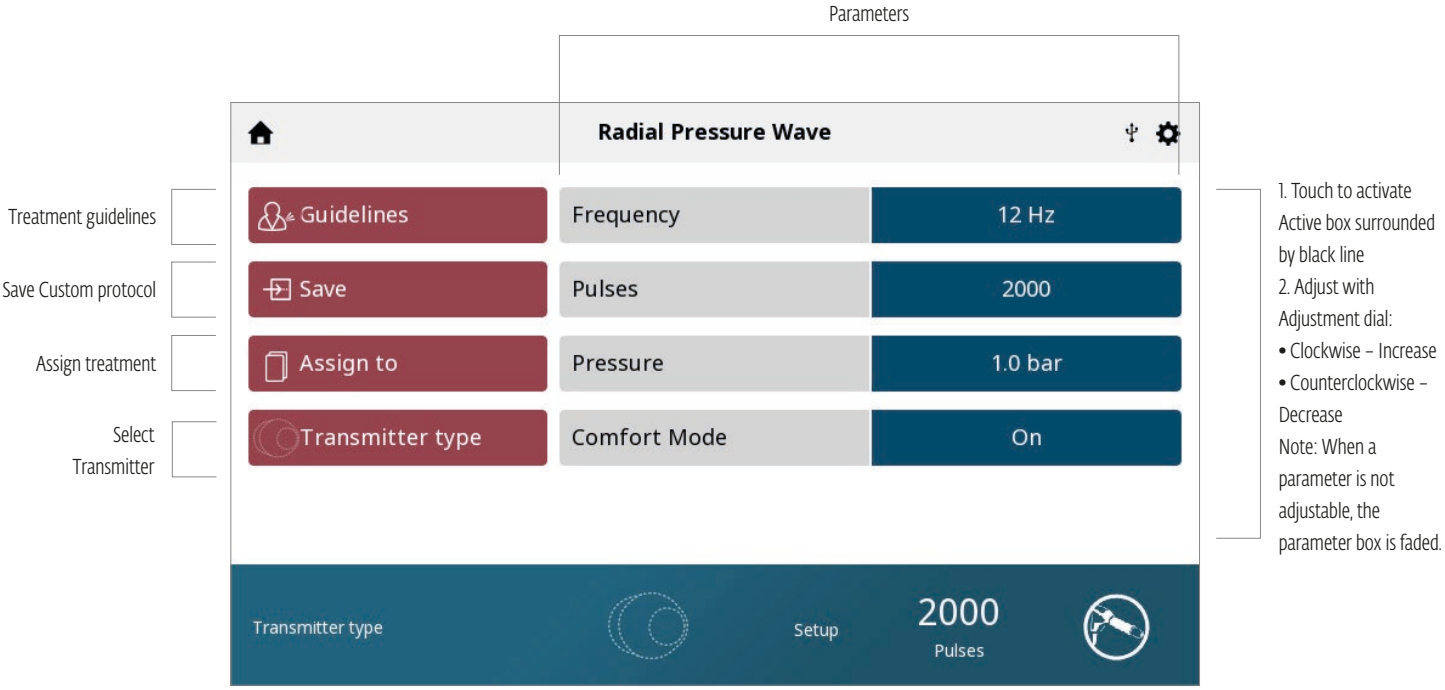
HOME SCREEN

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

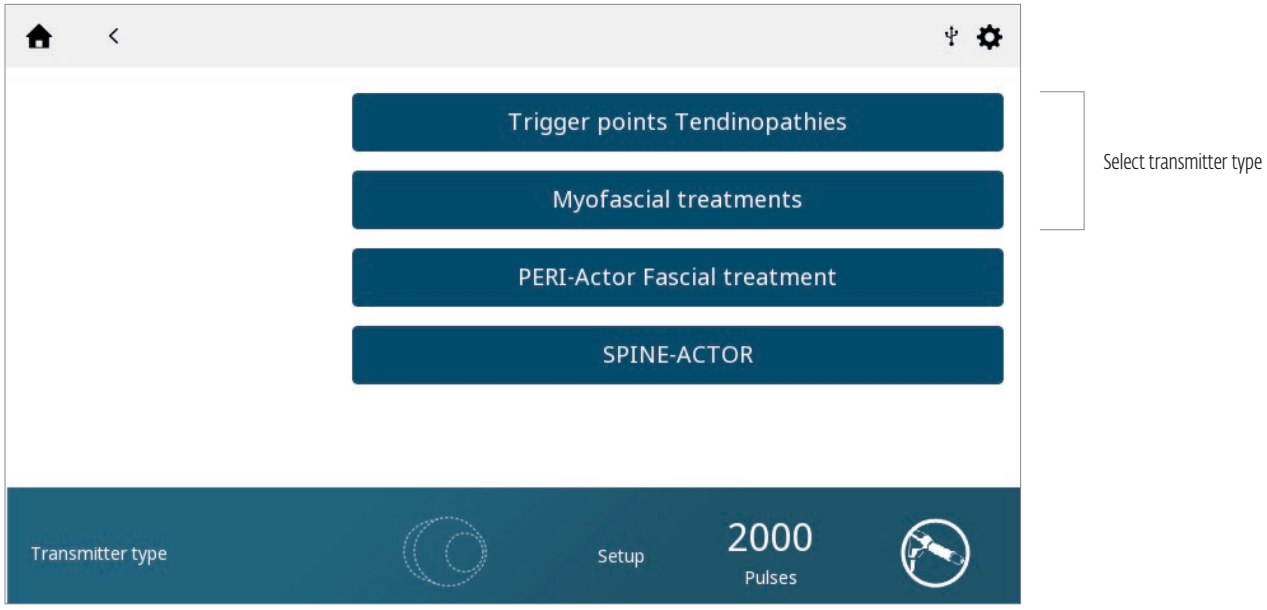


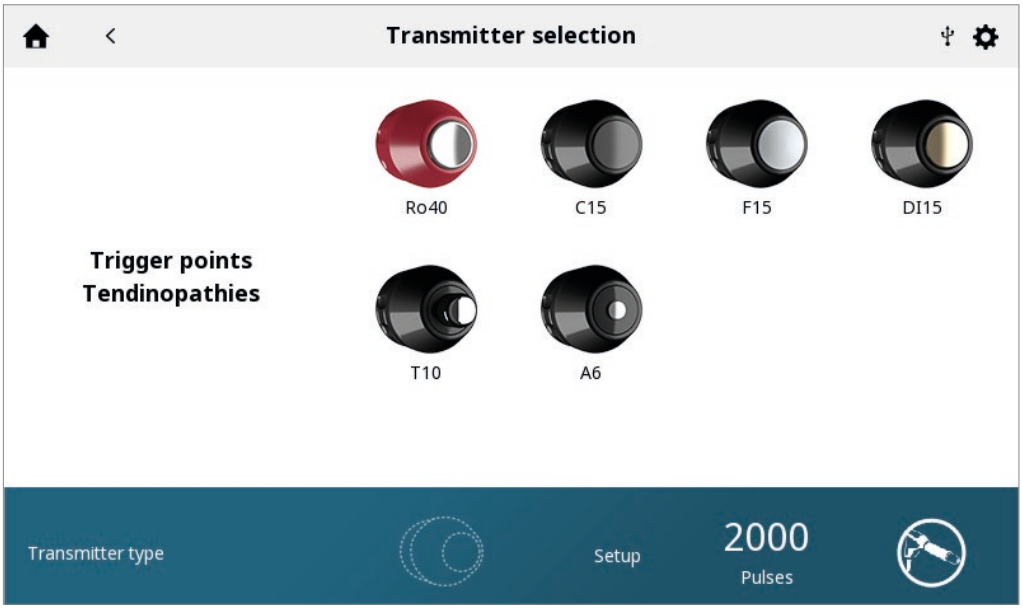
TREATMENT REVIEW SCREEN

By selecting Radial Pressure Wave, Vibration Therapy, or the screen will automatically change to the 'treatment review screen. The Intelect® RPW 2 Treatment Review screens include the following information:



Select transmitter sub menu screen

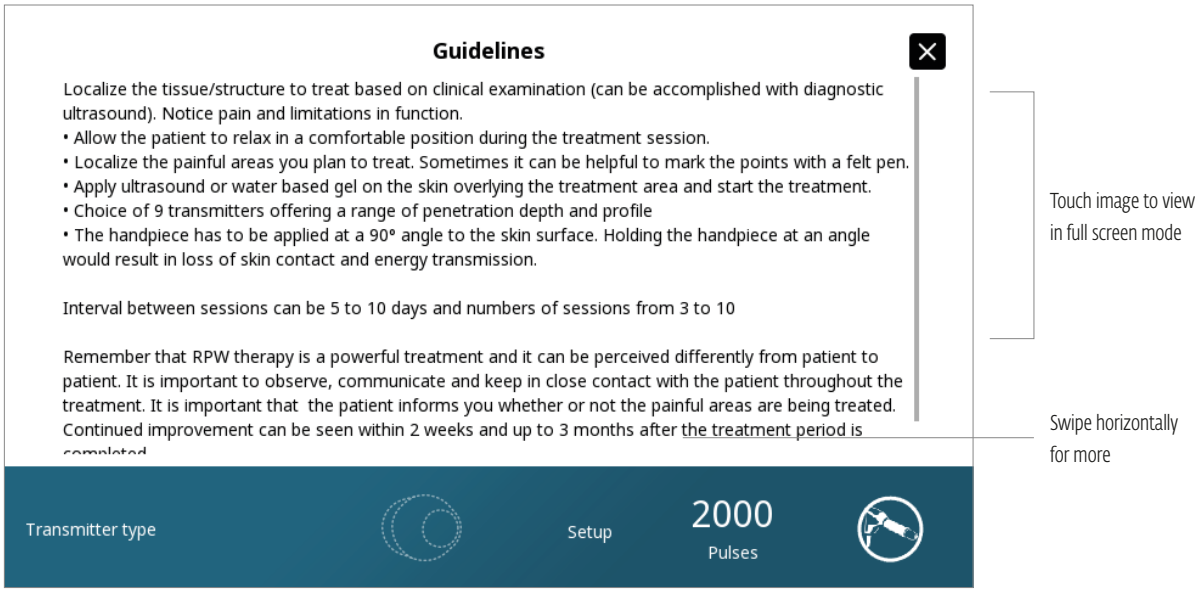




Select transmitter

GUIDELINES SCREEN

The Guidelines provide the following information:
Modality description, terms, indications and contraindications, treatment guidelines

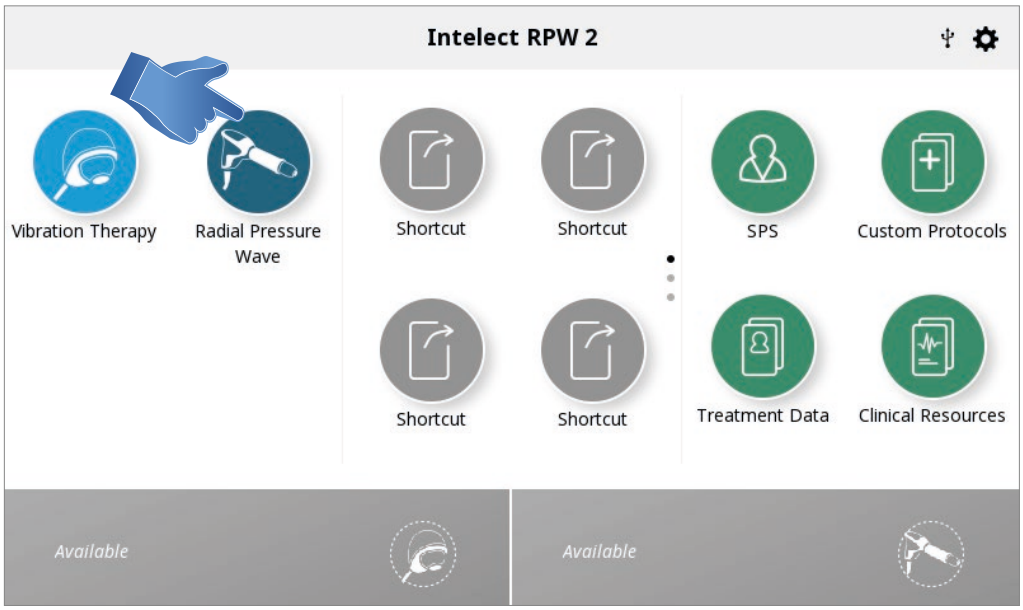


RADIAL PRESSURE WAVE OPERATION

Complete the following steps to begin treatment:

1. Prepare patient for Radial Pressure Wave treatment. Refer to the PATIENT PREPARATION section

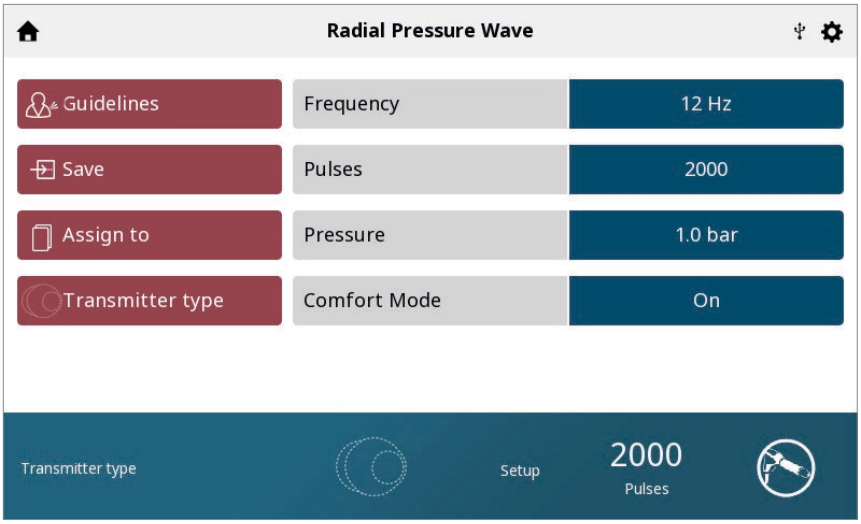
2. Select Falcon handpiece icon from the home screen



3. SET UP TREATMENT

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

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

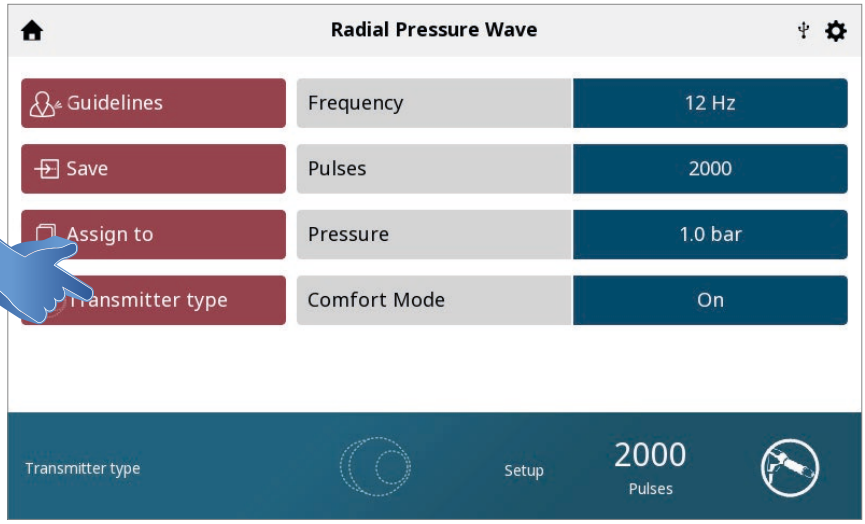


Parameters

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

4. TRANSMITTER SELECTION

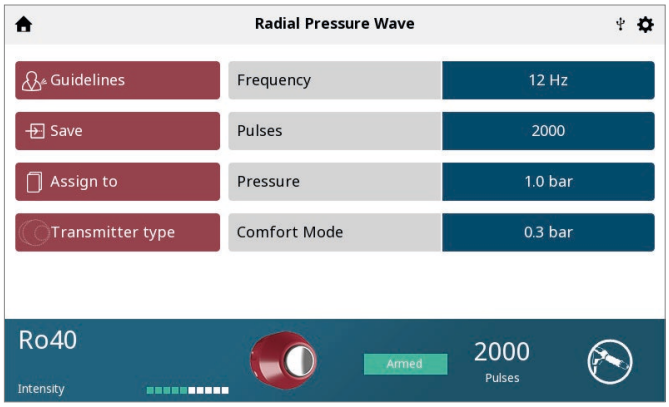
Once selecting the "transmitter type" button (as shown previously), a screen showing four types of transmitter options will be displayed. The second screen will show a listing of the transmitters available for that particular type of transmitter option. Touch the transmitter you wish to use. Once selected, the information will be populated into the treatment screen with the transmitter of choice.



selection indicates the Transmitter type box

5. START TREATMENT WITH COMFORT MODE "ON"

Press the start/pause button



The compressor is arming for a few seconds then when the message "armed" is displayed, the treatment can start by triggering the handpiece.

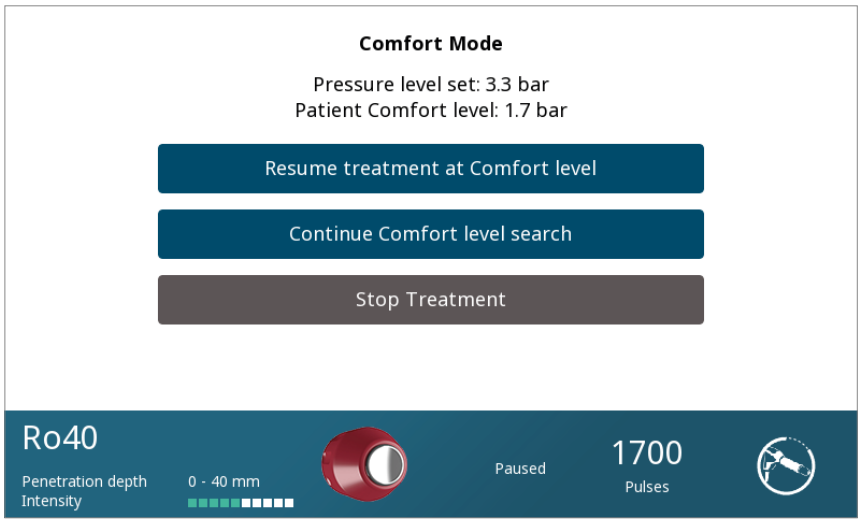
The button on the top of the handpiece is the trigger button, also called the start/stop button.

6. TREATMENT RUNNING

When the treatment starts with Comfort mode "ON" the bar will increase progressively starting at 1/10 of the set value.
The actual value is displayed on the Comfort mode progression bar.
When the patient states that the treatment feels uncomfortable or painful, the therapist pauses the treatment by triggering the handpiece.
The therapist has 2 options :

1. Resume treatment at Comfort mode level.

2. Continue Comfort level search by resuming treatment.



7. PAUSE TREATMENT

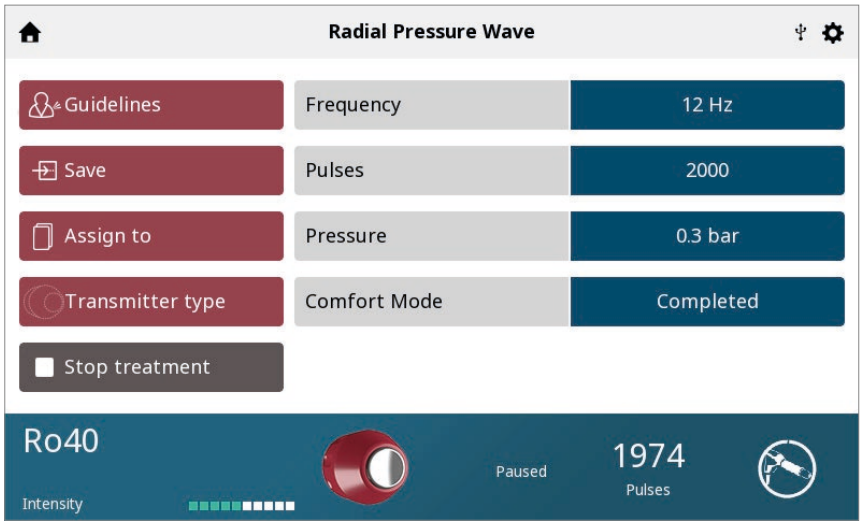
Pausing treatment will automatically display stop treatment on the Treatment Review screen.

The treatment can be paused by pressing the PAUSE buttons located on the device. The treatment can also be paused by pressing the button located on the handpiece.

Please reference the example scenarios:

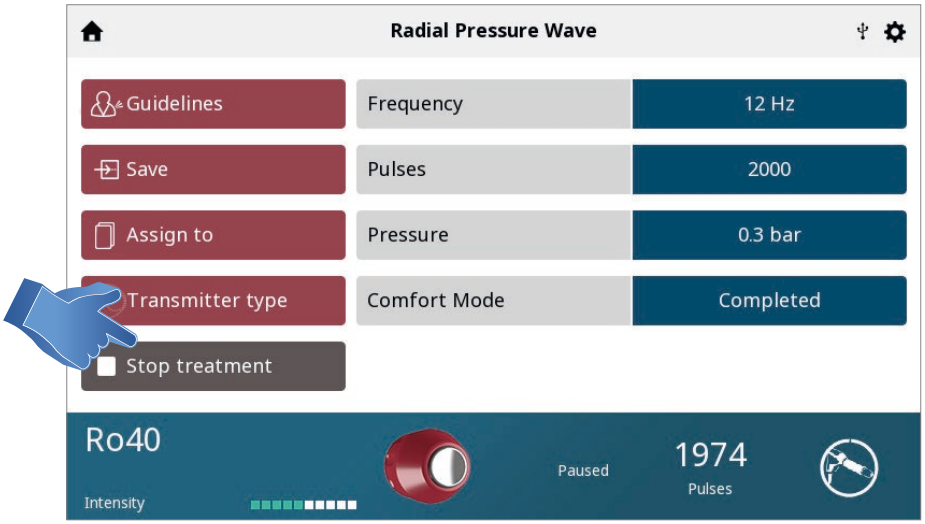
Scenario 1: handpiece is active and projectile is moving. The handpiece button is pressed, projectile stops moving but the handpiece remains active. The button on the handpiece is pressed again, the projectile resumes movement, and treatment can resume.

Scenario 2: handpiece is active and projectile is moving. The device pause button is pressed, projectile stops moving but the handpiece remains active. The handpiece button is pressed, but nothing happens. The device pause button is pressed again and this lets the handpiece know the device is ready to start the treatment. Now if the handpiece button is pressed again the projectile resumes movement and treatment can resume.



8. STOP TREATMENT

If handpiece is active and projectile is moving:
Pause the treatment first, then the handpiece becomes inactive. Then by selecting Stop treatment, the treatment will end and treatment summery displayed.

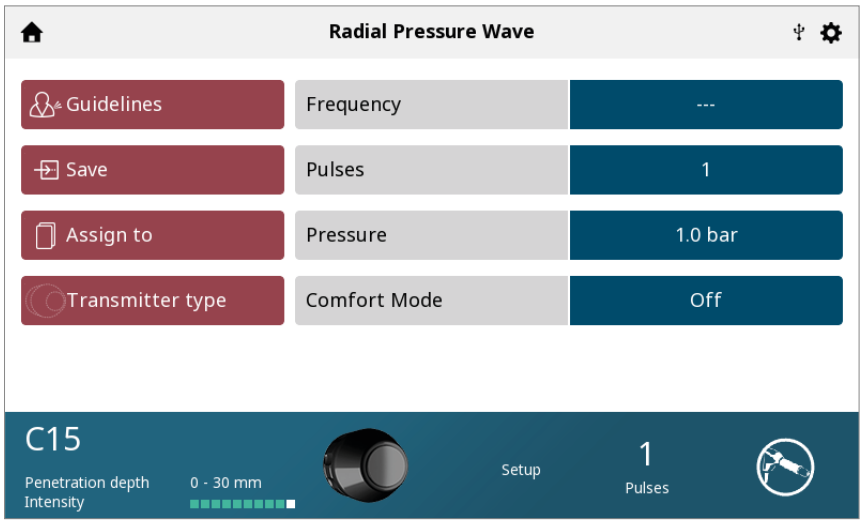


9. SINGLE SHOT MODE

The Falcon D-Actor has the ability to do single shots.

This can be done by selecting Frequency and turning the dial to the left so that the Hz is displayed as "—". Then select Pulses and change the pulse count to '1'.

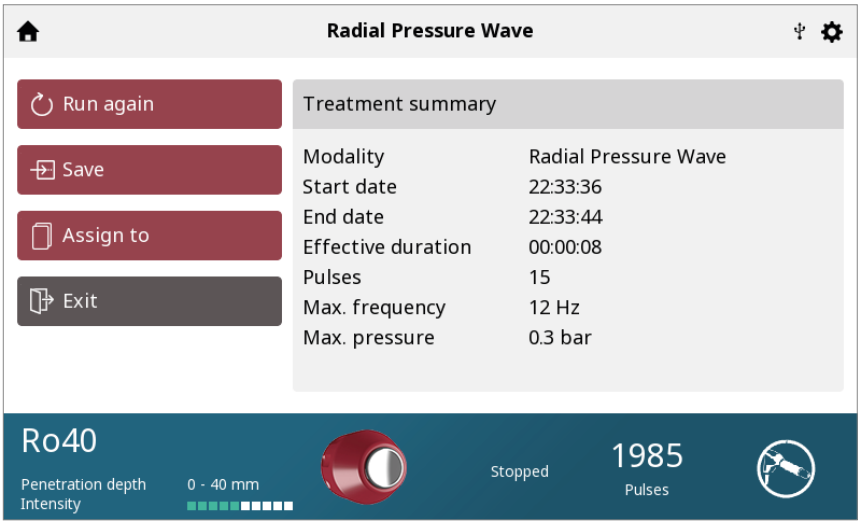
When this single shot treatment is complete the Treatment summery screen will be displayed.



10. TREATMENT SUMMARY

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

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



Settings of completed treatment

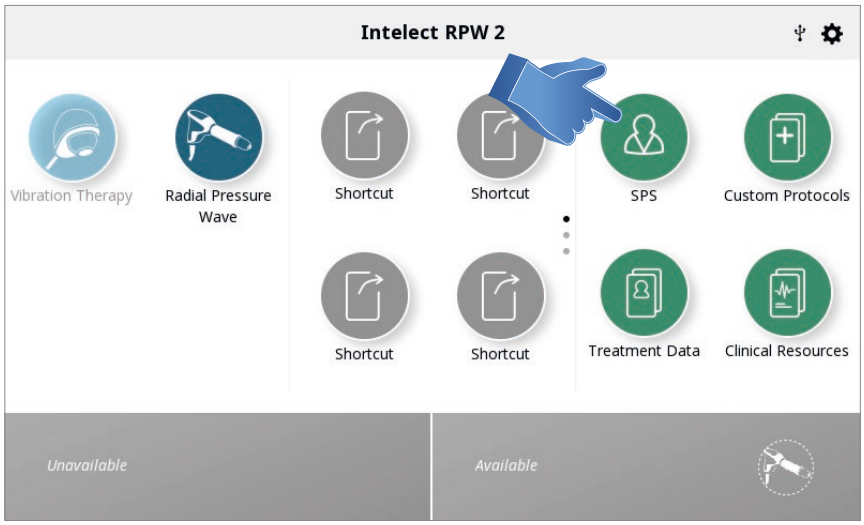
SPS (SUGGESTED PARAMETER SETUP)

The Intelect® RPW 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.

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

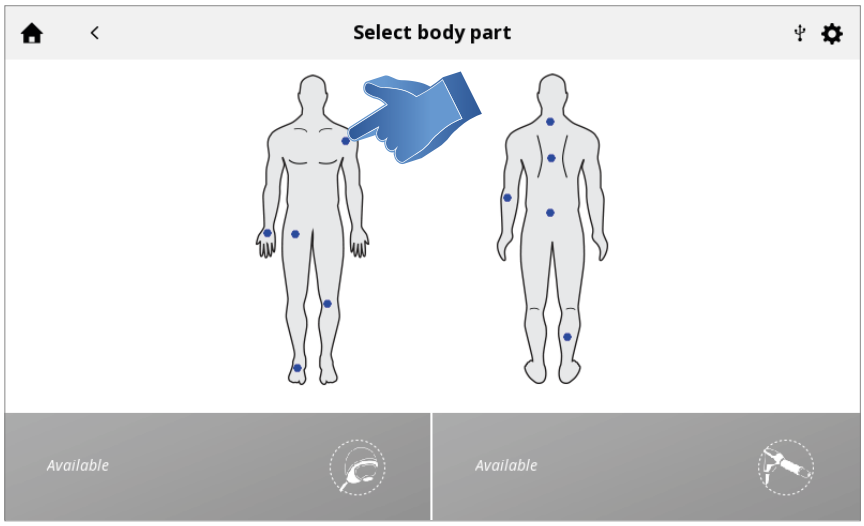
COMPLETE THE FOLLOWING STEPS TO START AN SPS PROTOCOL:

1. Select SPS from the Home Screen

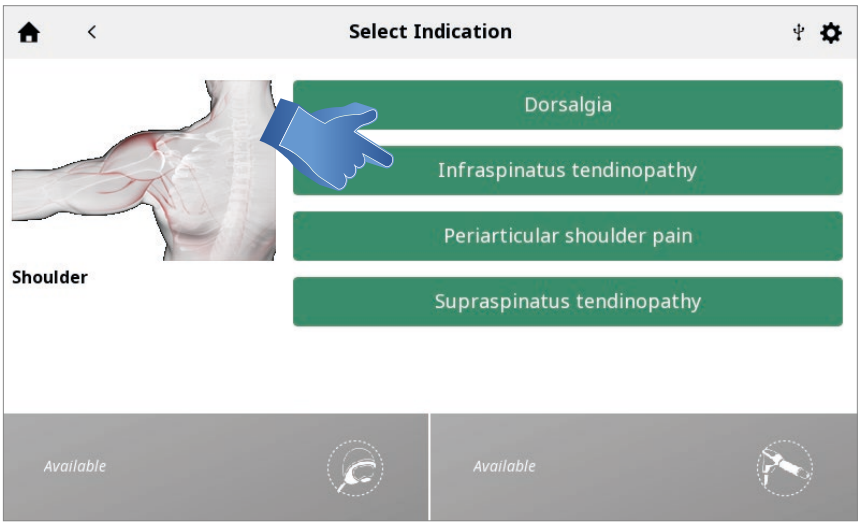


2. Touch the BODY PART you wish to treat

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.

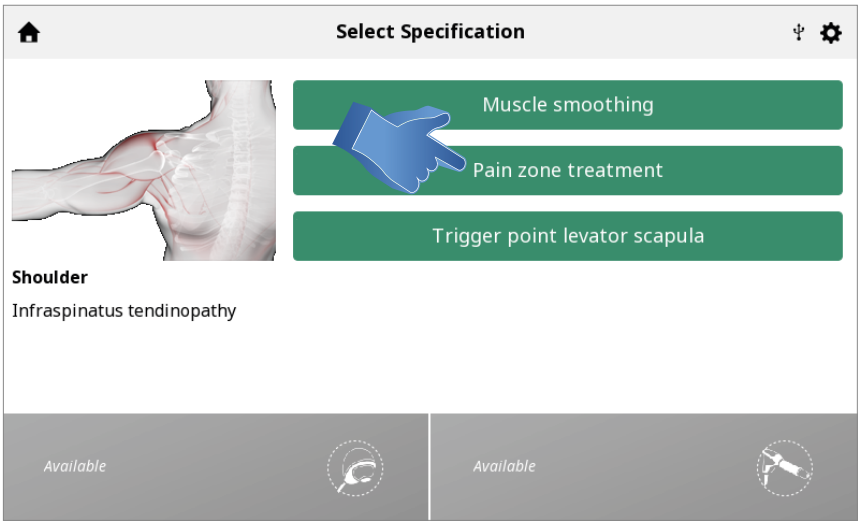


3. Select INDICATION



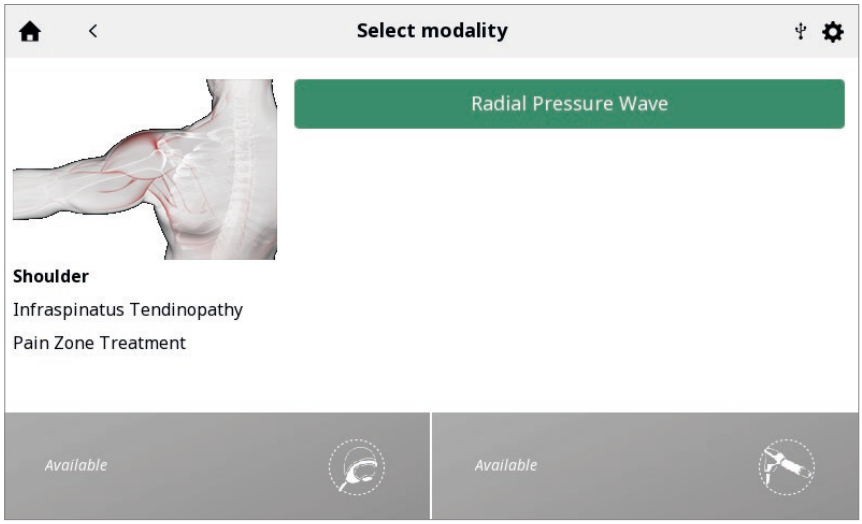
Select Pressure Wave

4. Select SPECIFICATION



Select Pain Zone treatment

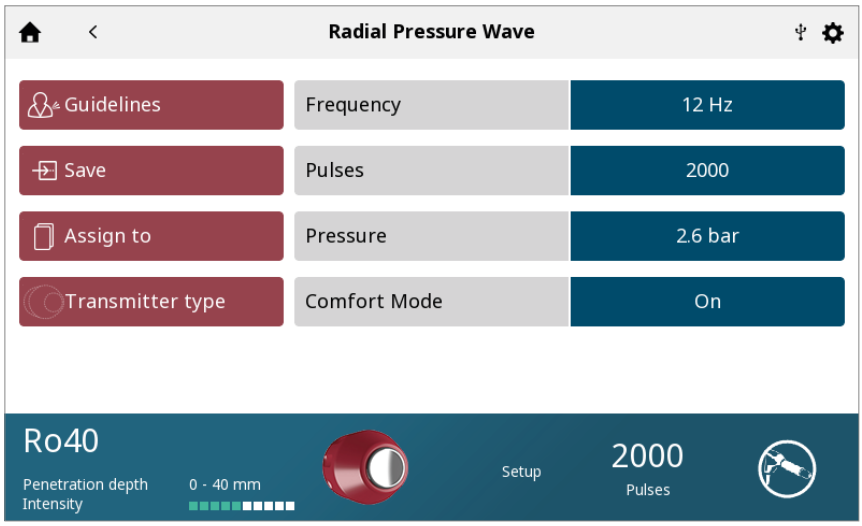
5. SELECT MODALITY



Select Radial Pressure Wave

6. SET UP TREATMENT

On the treatment review screen the suggested treatment settings are displayed and you can adjust parameters to desired level.



Parameters

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

7. START TREATMENT

Press the START button

Treatment Running

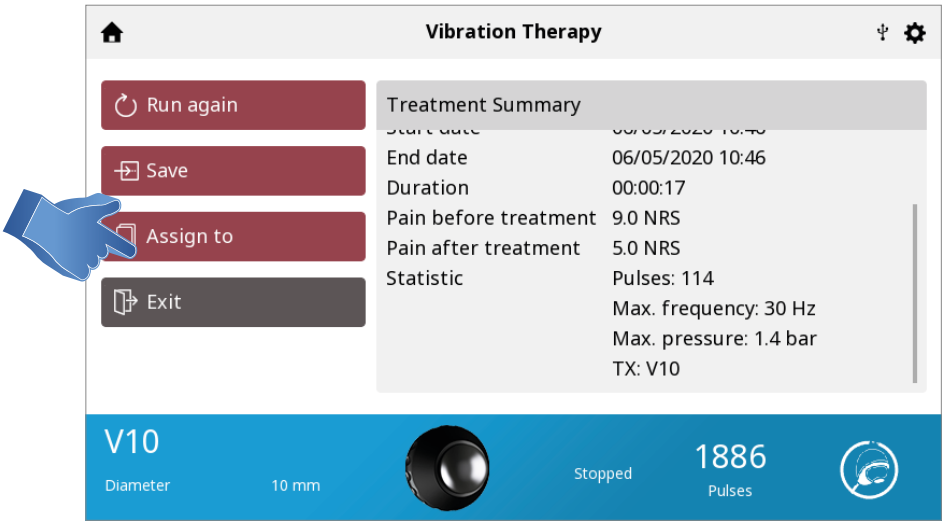
TREATMENT DATA

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

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 fiished and channel is free for next treatment (after pressing EXIT button on Treatment Summary screen)

Open Pain scale to record post-treatment pain

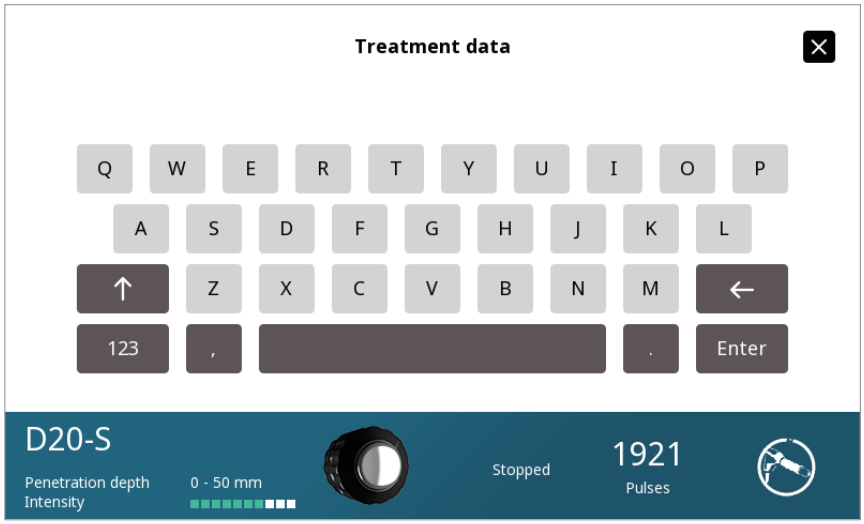


The TREATMENT DATA screen appears

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

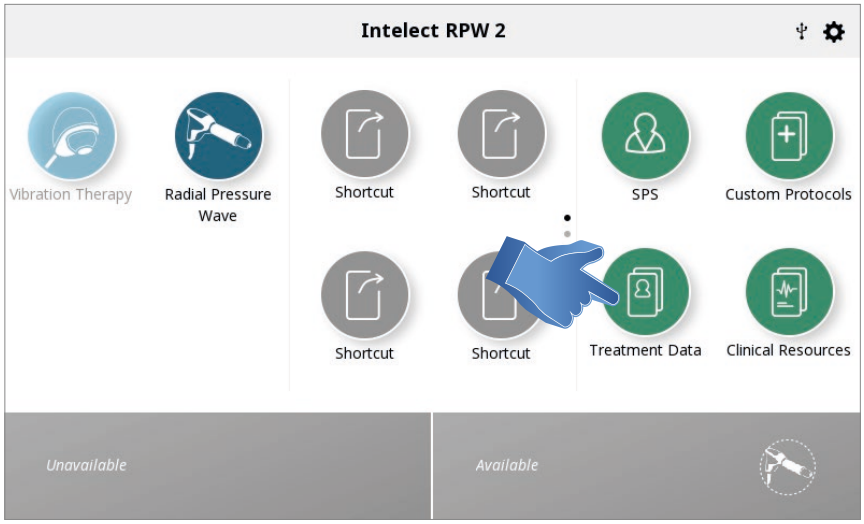
SAVE TREATMENT DATA TO A NEW ID:

Enter ID and Save



VIEW AND MANAGE TREATMENT DATA

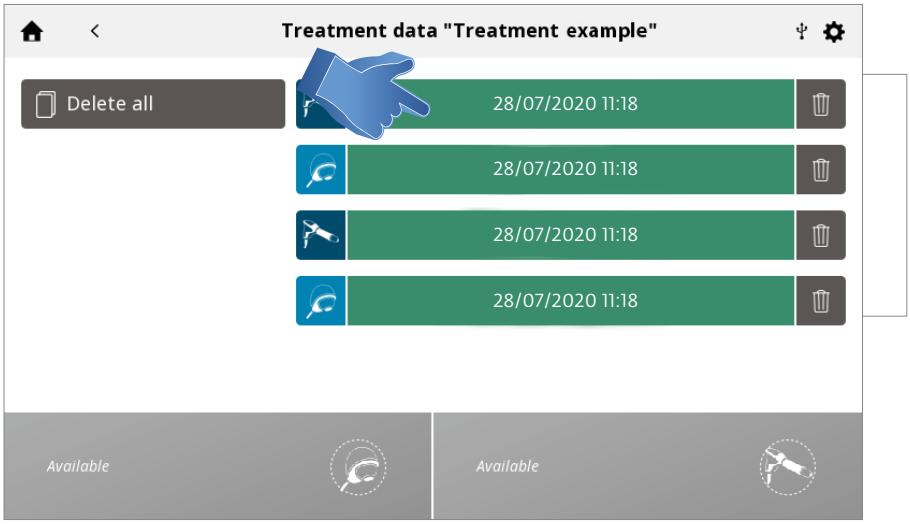
Press the TREATMENT DATA ICON on the home screen



1. VIEW Treatment Data

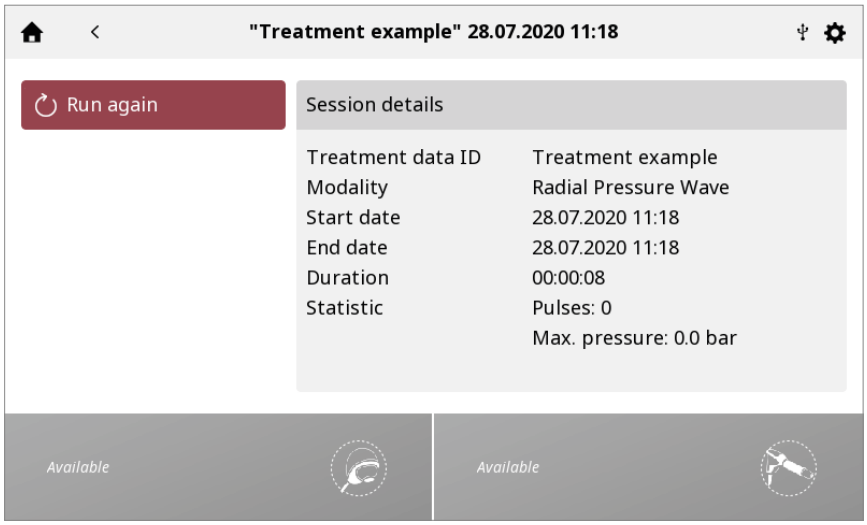
Select Treatment Data

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



Select session to view Treatment Summary for that session.

Session details are displayed

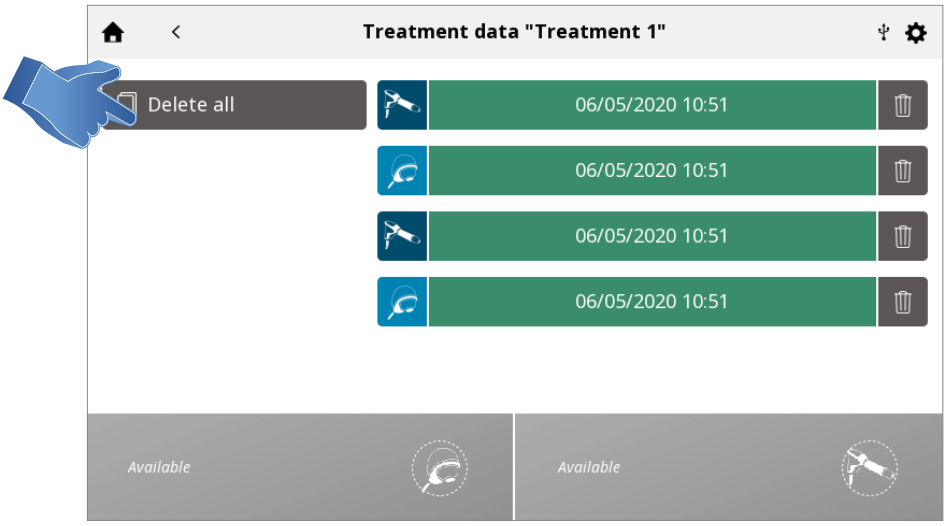


2. DELETE Treatment Data

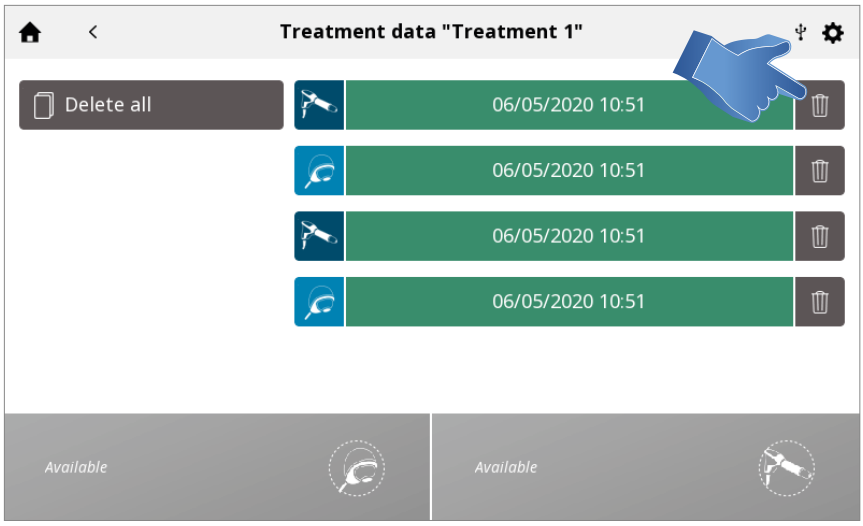
Delete all IDs

Delete one ID

Delete all treatment sessions



Delete one session



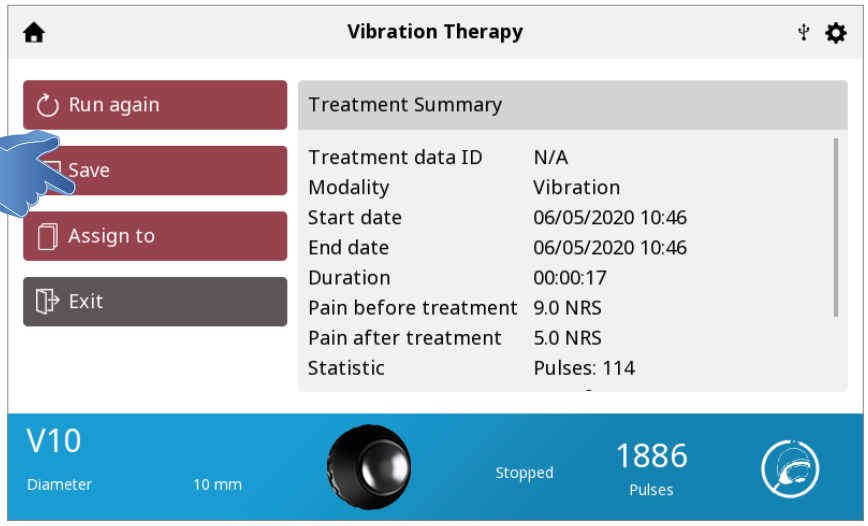
CUSTOM PROTOCOLS

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

SAVE A CUSTOMIZED PROTOCOL

A new custom protocol may be saved at either the Treatment Review or Treatment Summary screen.

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



2. Name custom protocol with keyboard

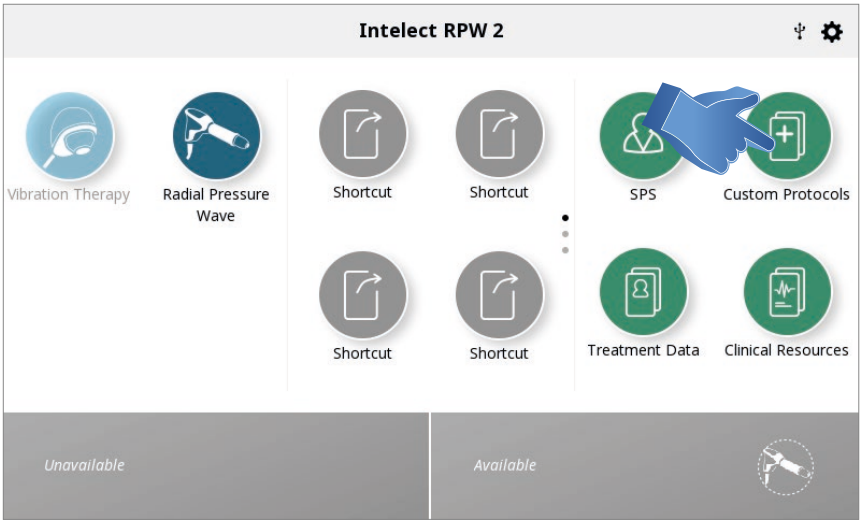
Note: it is also possible the overwrite the default settings of the modality instead of saving to custom protocols.

CREATE NEW CUSTOM PROTOCOL:

Enter Custom Protocol Name and Save

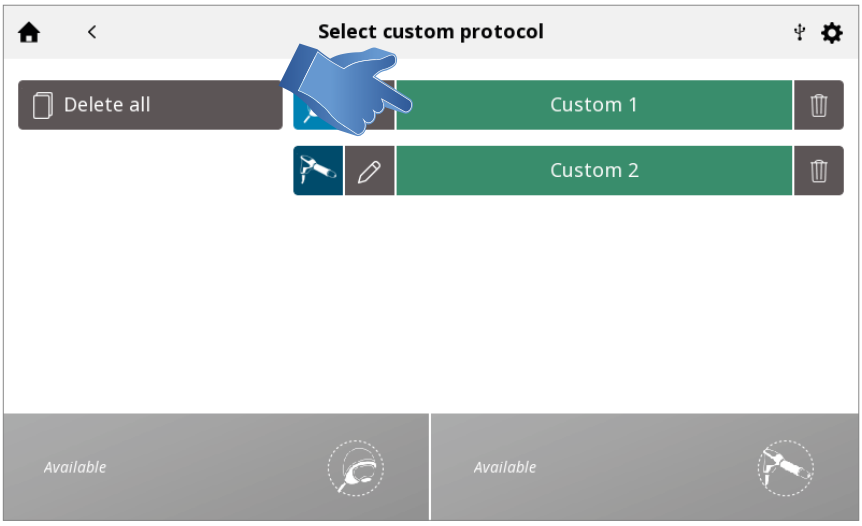
VIEW AND MANAGE CUSTOM PROTOCOLS

Touch the CUSTOM PROTOCOLS icon on the Home Screen

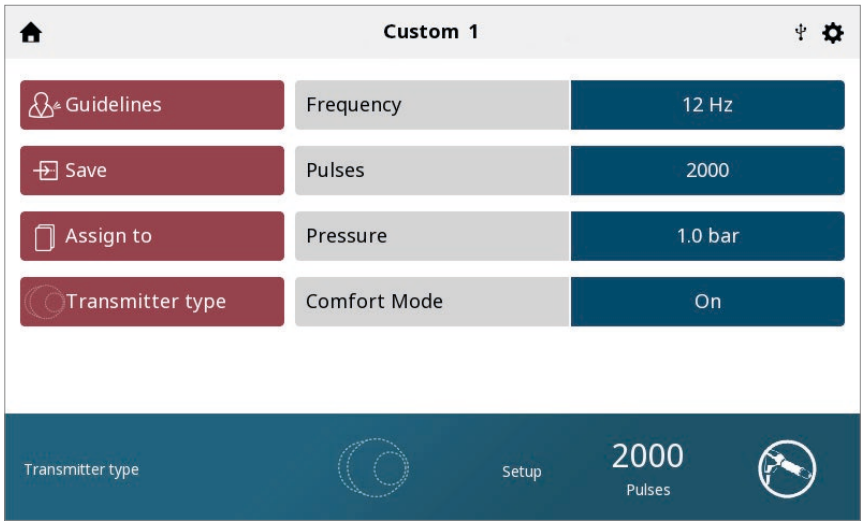


1. VIEW Custom Protocol

Select desired Custom Protocol

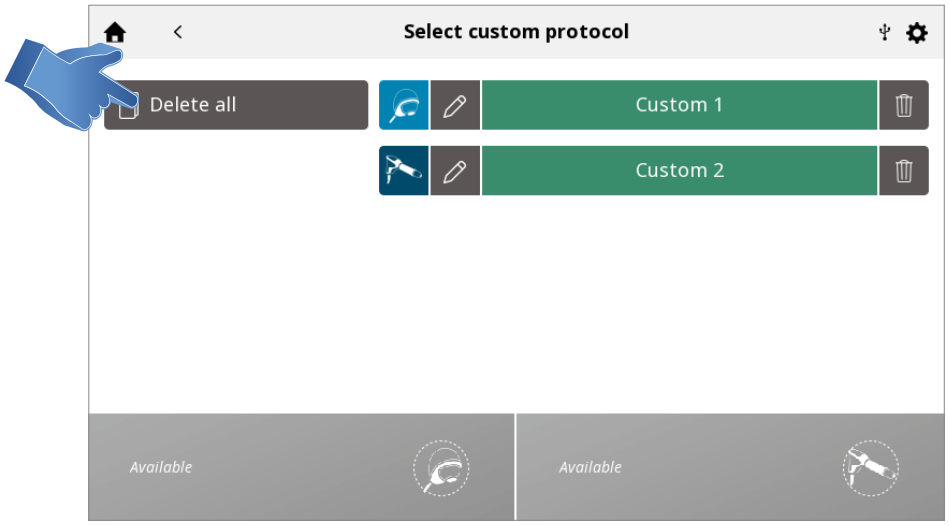


The TREATMENT REVIEW SCREEN is displayed showing the protocol settings.
Start treatment or perform other actions.

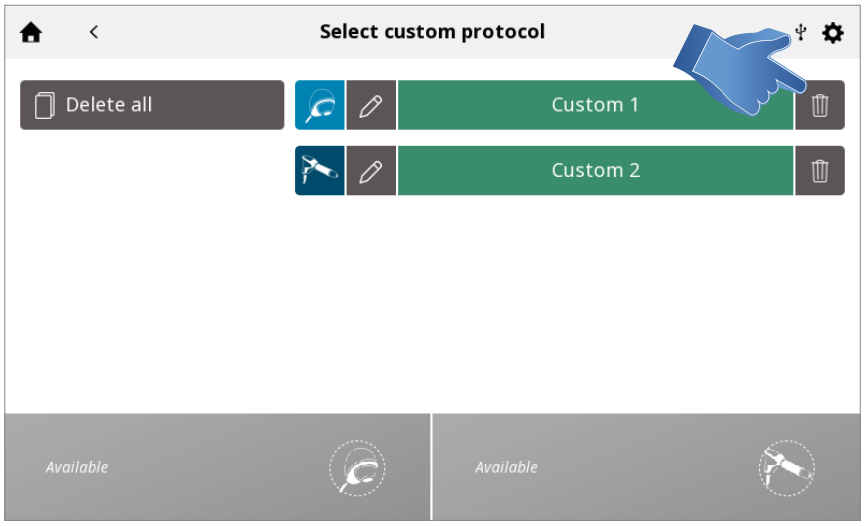


2. DELETE custom protocol

Delete all protocols



Delete individual protocol

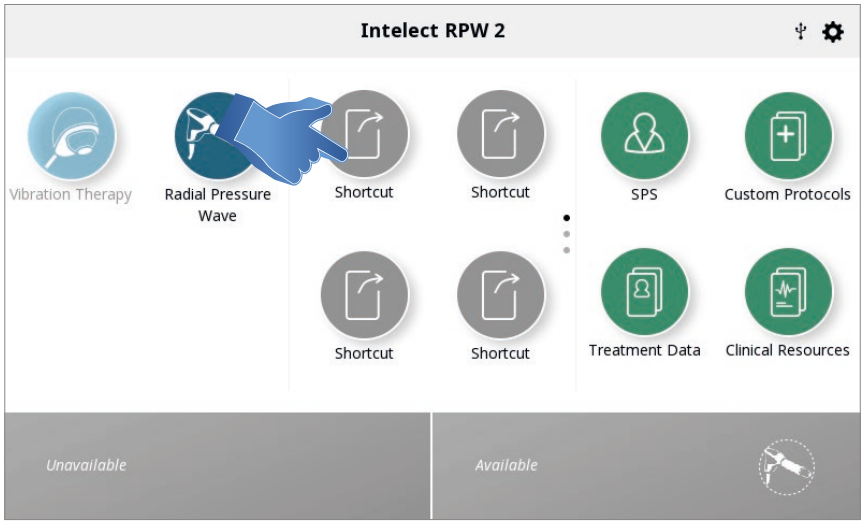


SHORTCUTS

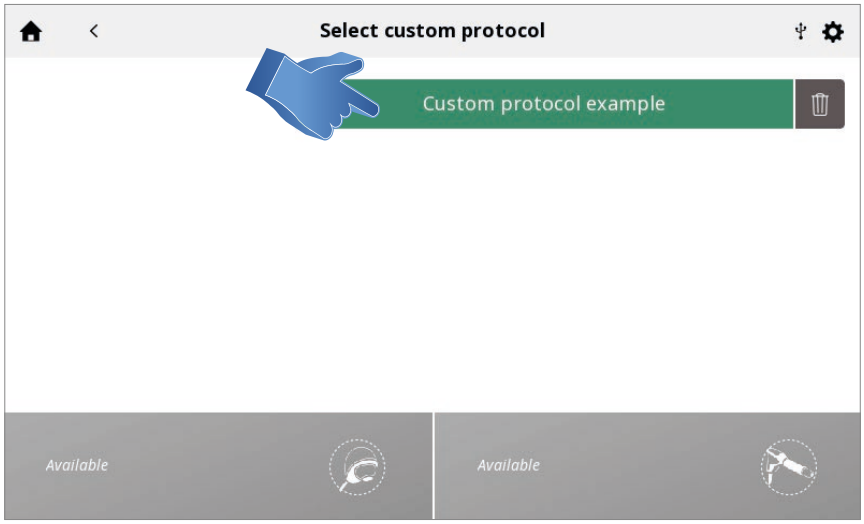
Intelect® RPW 2 allows for 12 custom protocol shortcut assignments on the home screen.

ASSIGN SHORTCUT

Complete the following steps to assign a home screen shortcut unassigned. Short cut icons appear grey in color for a customized protocol: Press one of the unassigned “Shortcut” icons on the home screen .

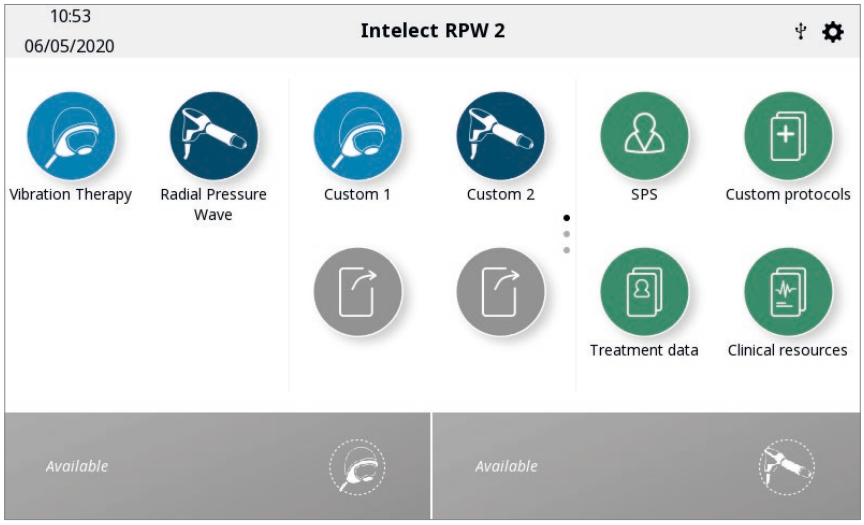


Select the desired protocol in the Custom Protocol library



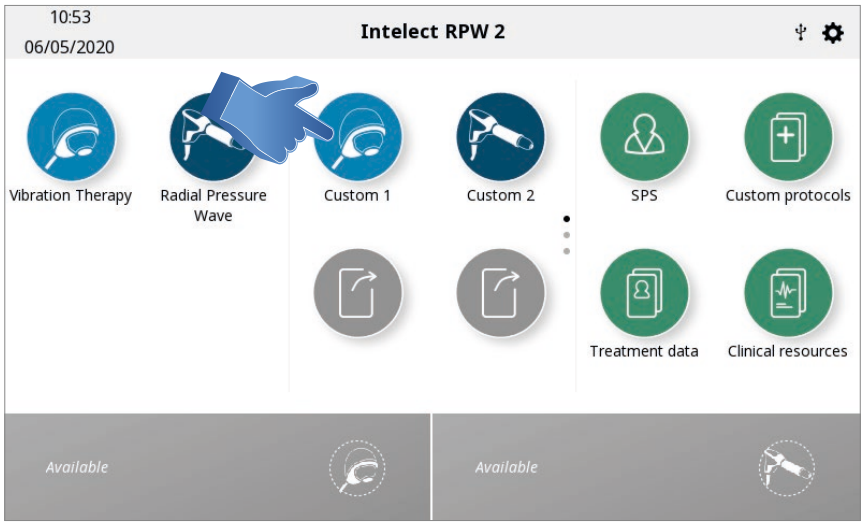
Shortcut assigned on home screen

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

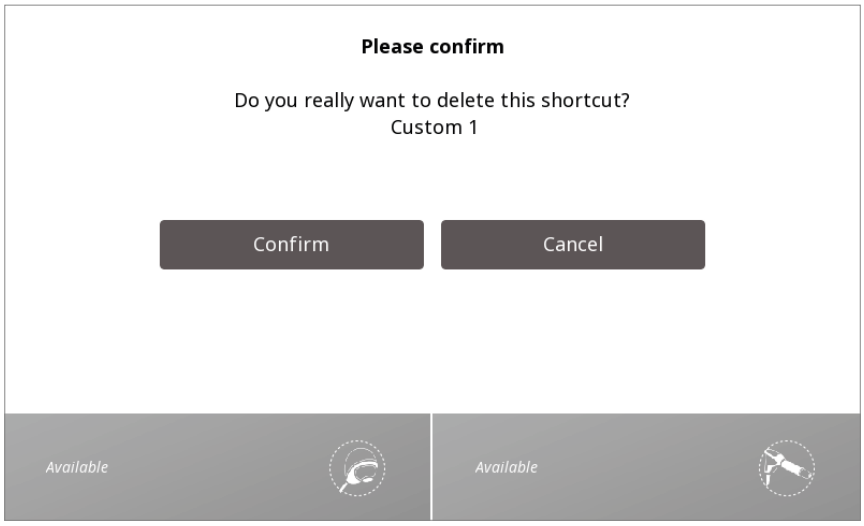


UNASSIGN SHORTCUT

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

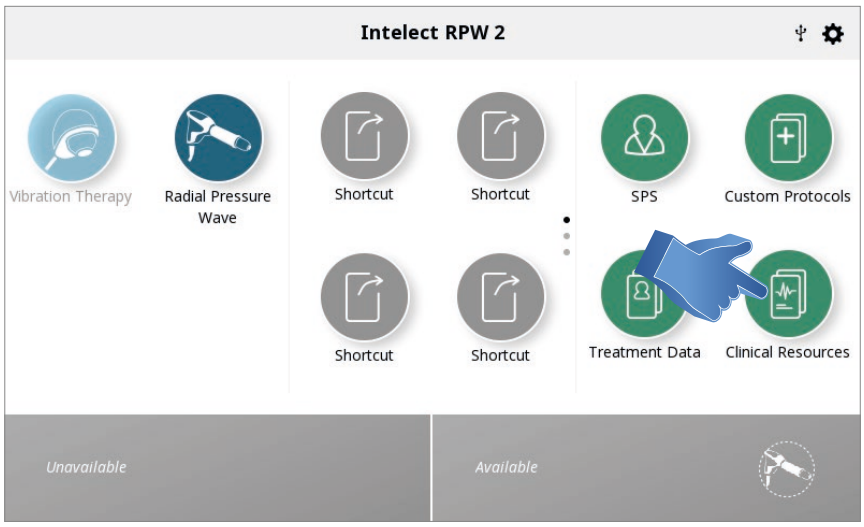


Select Cancel to quit the unassignment process and return to the Home screen or "Confim" to continue with the unassignment process. After selecting "Confim" the previously assigned shortcut will no longer appear on the Home screen.

CLINICAL RESOURCES

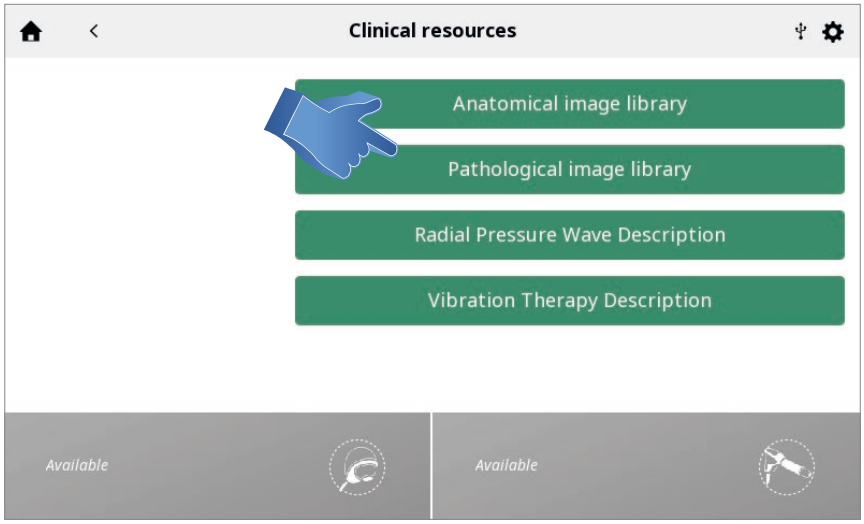
The Intelect® RPW 2 contains a unique Clinical Resources Library.
The anatomical and pathological image library are designed to aid the operator in visually understanding and locating specific muscle groups and commonly found problems associated with pathological conditions, as well as providing an educational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

Press the Clinical Resources Library icon on the Home screen .



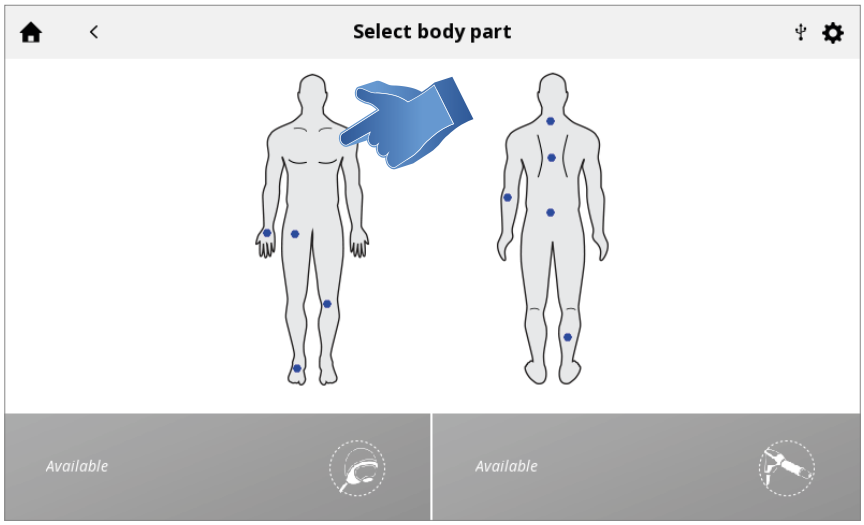
ANATOMICAL/PATHOLOGICAL IMAGE LIBRARY
Complete the following steps to view the Anatomical or Pathological Image Library:

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



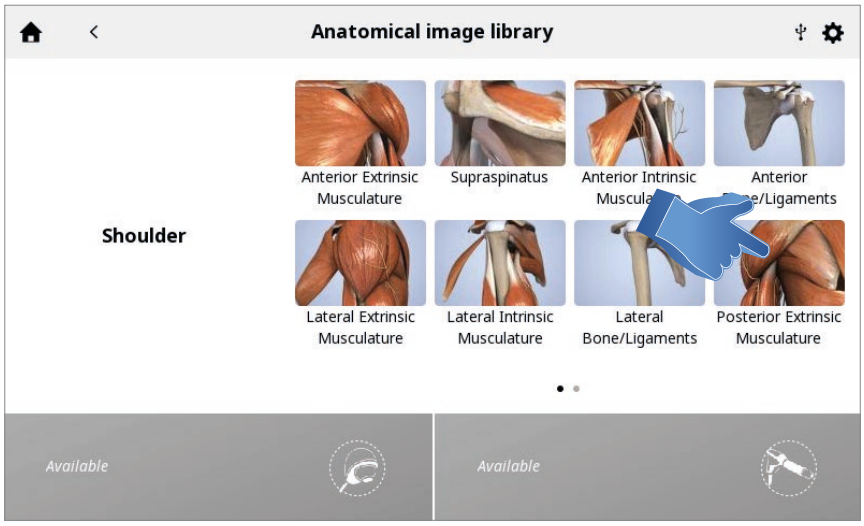
2. Touch the body part for which you wish to view information.

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

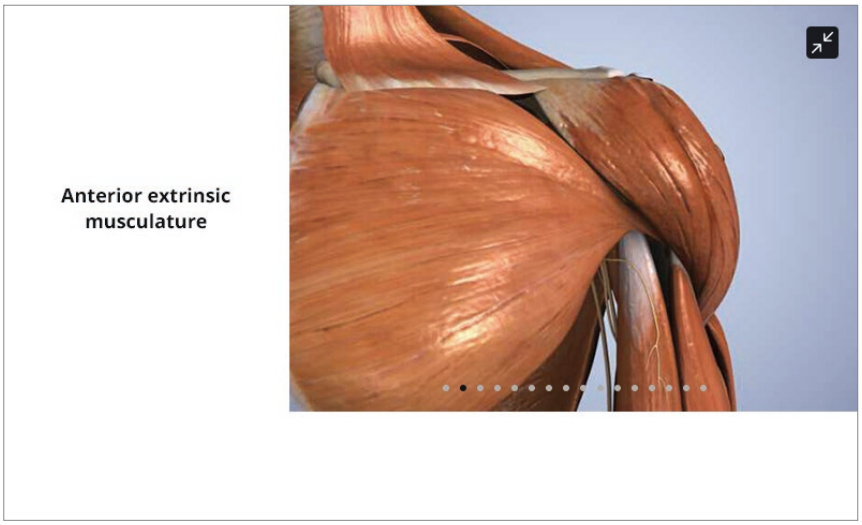


3. The available images for the selected body part are displayed.

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



4. Full screen image

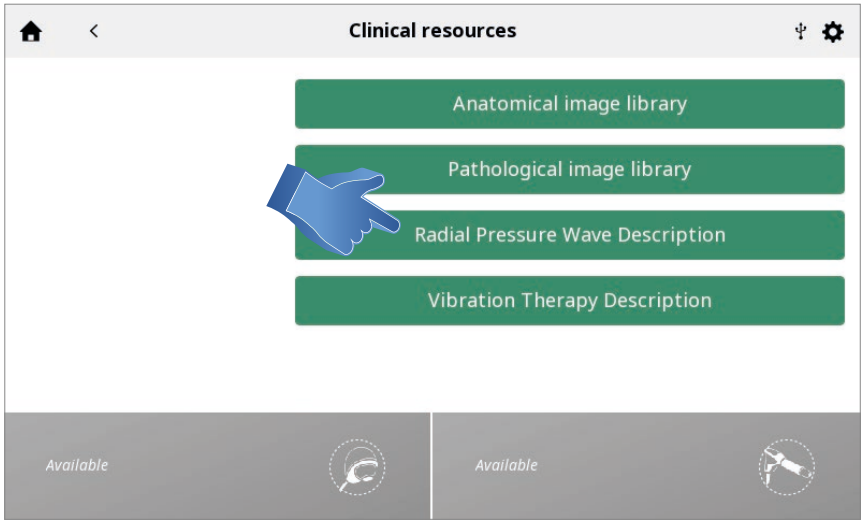


Close full screen mode

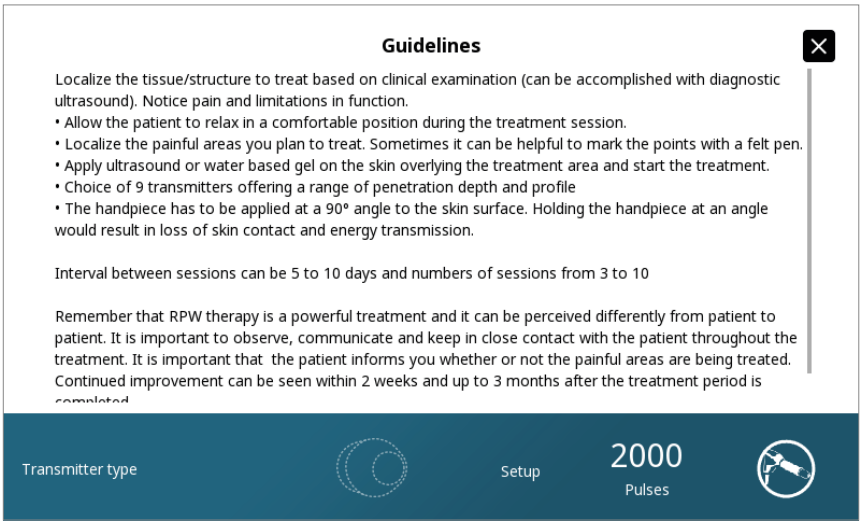
MODALITY DESCRIPTIONS

Complete the following steps to view the Radial Pressure Wave and Vibration therapy descriptions:

1. Select one of the modality description



2. The modality description is displayed



PRINT SCREEN FUNCTION

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

1. Insert USB drive into the USB port on the back of the Intelect® RPW 2 device
2. Press the play pause button and the On/Off button simultaneously 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 Intelect RPW 2 device.
4. The format of the file is a bitmap file and it is date & time coded in the file name.

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

TROUBLESHOOTING CODES

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
3. In case a red triangle is shown, click on the triangle to get an explanation

For US product support please call 1-800-494-3395, or visit www.chattanoogarehab.com

If the device is not powering on, display and lights do not switch on
1. Check that ON/OFF button on the rear of the device is ON
2. Check the power cable is connected to proper alimentation

ACCESSORIES

REPLACEMENT ACCESSORIES

The following tables provide users of the Intelect® RPW 2 the necessary information to order replacement accessories used with the system. This list of replacement accessories is designed for use with the Intelect® RPW 2 . When ordering, provide the respective part number, description, and quantity desired. All part numbers listed below are sold in quantities of 1 unless otherwise specified.

Model Number	Description
18080	Falcon® RPW Handpiece
28178	Ro40 'Beam' Transmitter
29724	D20-S D-Actor® 20mm Transmitter
29104	Revision Kit Short
15-1140	USB Key
22651	Gel cup and holder
82-0274	RPW Pouch
22652	Transmitter tray
13-7611-1	Cable holder
22654	Water reservoir
13-28660-US	Quick Start Guide (Available in English & Spanish with each unit)
14679	Power cord North American

Note: For Falcon handpiece replacement accessories please see page 73

OPTIONAL ACCESSORIES

Model Number	Description
29104	Revision Kit Short
28739	Guiding tube cleaning brush
31800	9 Transmitter Set In Case, Accessory
29801	A6 Point, Transmitter
29802	T10 Finger, Transmitter
29729	C15, 15 mm Cerama-X Transmitter, Black
29728	DI15, 15 mm, Deep Impact Transmitter, Black
29726	F15 Focus-Lens 15 mm Transmitter
29724	D20-S D-Actor® 20mm Transmitter
28736	D20-T Transmitter
29725	D35-S, 35 mm, D-Actor® Transmitter, Black
29539	ATLAS Transmitter
28946	INTELECT RPW 2 SPINE-ACTOR Transmitter set
28945	INTELECT RPW 2 PERI-ACTOR Transmitter set
19365	V-Actor® HF
28740	V-Actor® V25 Transmitter
28741	V-Actor® V40 Transmitter
29742	V-Actor V10 Transmitter without transmitter screw cap
4248	CONDUCTOR US Gel 24x 8.5oz BOTTLES
4238	CONDUCTOR US Gel 5L Cube w/ refillable bottle
4266	Intelect US Gel 5L Cube w/ refillable bottle
82-0274	RPW Pouch
15-1140	USB Key
18638	R15, 15 mm, ESWT transmitter, black

V-ACTOR HF® HANDPIECE OPERATIONS, SET-UP, CLEANING, AND MAINTENANCE

DEVICE DESCRIPTION

The V-ACTOR HF® is a "vibration therapy" handpiece and can be used as an optional accessory with the Intelect® RPW 2.

By using this handpiece, it is possible to treat soft tissues using high-frequency pulses.

The preconditions for using the V-ACTOR HF handpiece correspond to the preconditions for operating the Intelect RPW 2. Please read the Contraindications chapter in this IFU for more details; see page 9.

Depending on the therapy to be performed, the handpiece can be equipped with one of the following three shock transmitter heads:

1: V-ACTOR HF spherical vibration transmitter 10 mm (V10)
2: V-ACTOR HF vibration transmitter 25 mm (V25)
3: V-ACTOR HF vibrationtransmitter 40 mm (V40)

INSTALLATION INSTRUCTIONS

UNPACKING

- Remove the handpiece and accessories from the packaging container.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer immediately if any items are missing or damaged.

SCOPE OF SUPPLY

The standard scope of supply of the V-ACTOR HF handpiece includes the following items:
– Handpiece
– Vibration transmitter V25 with screw cap
– Vibration transmitter V40 with screw cap

Note: The V10 vibration transmitter is an optional accessory for the V-Actor HF and must be ordered separately.

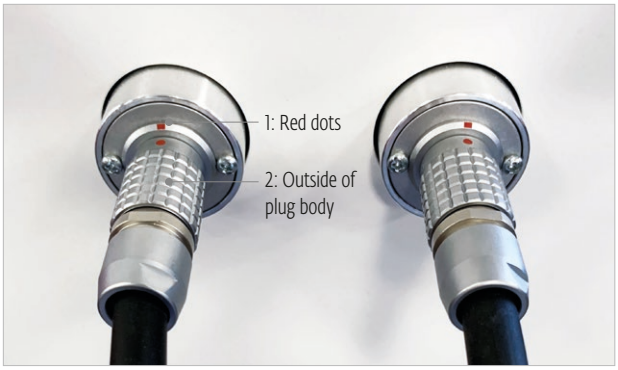
****V-Actor is a registered trade mark of Storz medical AG***

CONNECTING THE HANDPIECE

The Intelect® RPW 2 has a connector for the V-ACTOR HF® handpiece and a designated handpiece holder on the left hand side of the device.

To connect your V-Actor HF, please find the connectors on the front of the device. As the handpiece holder for the V-Actor is on the left hand side of the device it is recommended that the connector plug on the left side is used.

- Insert the plug of the handpiece into the handpiece connector on the Intelect RPW 2.
- Make sure that the red dot on the plug is aligned with the red dot on the handpiece connector.
- Gently pushing the plug into the connector will immediately lock the access and will prevent the connector from disengaging automatically when the cable is pulled.
- Place the handpiece into the handpiece holder.
- To break the connection, pull the outside of the plug body. This first releases the locking function, allowing the plug to be pulled out of the handpiece connector.



V-Actor is a registered trade mark of Storz medical AG

OPERATION

The handpiece is operated via the display on the Intelect® RPW 2. The settings can either be made manually on the display or preprogrammed settings can be applied.

Attention!
Malfunction of the device or its components is possible!
Before starting treatment, it is essential to perform the FUNCTIONAL CHECKS described below.

START-UP

- Connect the V-ACTOR HF® handpiece to the Intelect RPW 2.
- Set the pulse energy in V-ACTOR HF operating mode to an initial value of 2 bar.
- Activate the trigger button.

Note: The trigger button functions as an on/off switch when it is pressed briefly. Pressing it for longer causes it to function as a tip switch, i.e. the pulses will continue until the button is released.

FUNCTIONAL CHECKS

Perform the following functional checks after the device has been installed:

- Set the energy level in V-ACTOR HF mode to 2.4 bar.
- Reset the actual number of pulses on the display of the control panel.
- Release pulses with a pulse frequency of 30 Hz.
- Check that the triggered pulses are correctly counted on the treatment pulse counter of the control device.

STANDARD SETTINGS

- Before each treatment, make sure that the pulse counter is set to zero.
- Start the V-ACTOR HF treatment at an energy level of 2 bar and a frequency of 20 Hz.
- There is a relationship between pressure and frequency; when one increases the other decreases. The V-Actor HF can not be used at full frequency and full pressure at the same time. Please find the chart showing the relationship between pressure and frequency on page 70.

**V-Actor is a registered trade mark of Storz medical AG*

The chart shown here displays the relationship between pressure and frequency when using the V-Actor HF with the Intelect® RPW 2.

Pressure (Bar)	Frequency (Hz)
2.4	50
2.5	46
2.6	42
2.7	41
2.8	39
2.9	38
3.0	36
3.1	35
3.2	34
3.3	33
3.4	31
3.5	30
3.6	28
3.7	27
3.8	26
3.9	25
4.0	24
4.1	23
4.2	22
4.3	21
4.5	20
4.6	19
4.8	18
5.0	17

TREATMENT

SAFETY INFORMATION

Before using the device, the user must make sure it is functioning safely and in proper condition.

Each time the device is transported, subsequently make sure that all functional checks have been performed on the device before you start treatment. For further information, reference page 69, FUNCTIONAL CHECKS.

Note: The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

Caution!

The handpiece may not be operated while idling (without an impact surface).

- Do not trigger pulses unless the vibration transmitter is in contact with the treatment zone!

Caution!

Over extended periods, the noise of the pulses may be perceived as unpleasant!

- Offer ear protection to the patient.
- Recommendation: The user should also wear ear protection.

CARRYING OUT TREATMENT

- Apply a sufficient amount of massage oil to the patient's skin in the treatment area and to the V-ACTOR HF vibration transmitter.
- Perform V-ACTOR HF treatment as recommended in the application brochure/application recommendations.

****V-Actor is a registered trade mark of Storz medical AG***

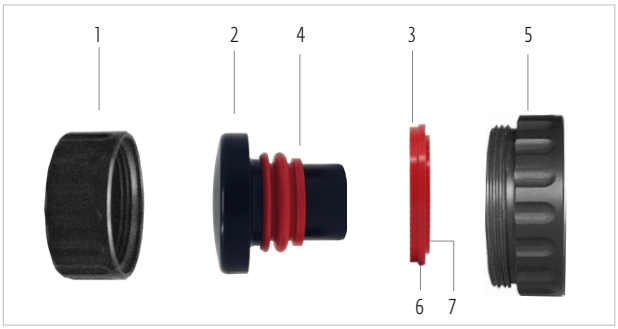
CLEANING, MAINTENANCE, OVERHAUL

CHANGING THE VIBRATION TRANSMITTERS

- To remove the 25 mm vibration transmitter or the 10 mm spherical vibration transmitter, unscrew the vibration transmitter screw cap (1) from the handpiece and pull out the vibration transmitter (2).
- Clean all parts of the vibration transmitter as described on page 73.
- Allow vibration transmitter to air dry
- Reassemble the vibration transmitter in reverse order.
- Screw the new vibration transmitter onto the handpiece until finger-tight.

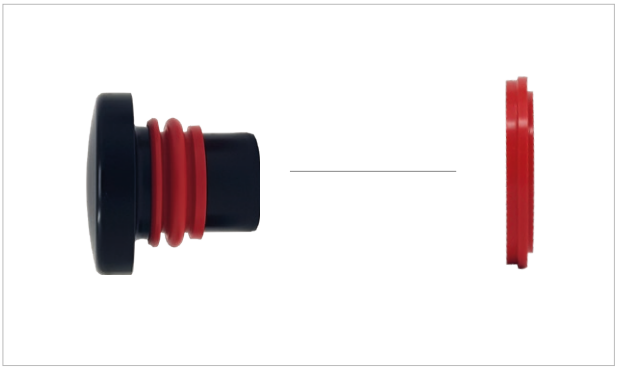
V25 AND V10

V40



1 Front cap
2 Vibration transmitter head
3 Sealing ring
4 Spring element
5 Rear cap
6 Cut
7 Lower lip

- To remove the V40 vibration transmitter, unscrew the vibration transmitter from the handpiece.
- Unscrew the vibration transmitter screw cap (1 and 5) and pull out the shock transmitter.
- Remove the sealing ring (3) by pressing it apart at the cut-through point (6).
- To clean, press the spring element (4) together slightly and remove the residue underneath it. Do not attempt to remove this portion of the transmitter!
- Clean all parts of the vibration transmitter as described on page 73 and allow to air dry. When reassembling the V40, note that the sealing ring has a lower lip (7) that needs to face outward when reassembled.



- Reassemble the vibration transmitter in reverse order.
- Make sure that the smooth side of the sealing ring (3) is in contact with the vibration transmitter head (2).
- Screw the new vibration transmitter onto the handpiece until finger-tight.

**V-Actor is a registered trade mark of Storz medical AG*

HANDPIECE

Caution!

Cleaning agents and disinfectants may generate an explosive atmosphere.
Disconnect the handpiece from the control device before starting any cleaning or maintenance work.

Attention!

It is essential that no fluid be permitted to penetrate either the device or its tubing.

- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning (follow the manufacturer's instructions).
- Clean the vibration transmitters thoroughly after each use.
- The vibration transmitters can be cleaned using the usual cleaning agents and disinfectants after each use.
- As an alternative, you may clean the vibration transmitters each day in an ultrasonic bath.

Attention!

The constituents listed here are non-binding examples. No claims are made regarding the completeness of the list.

REPROCESSING THE HANDPIECE AND VIBRATION TRANSMITTERS

After each use, the parts of the handpiece that come into contact with the patient must be cleaned and disinfected thoroughly before they are used again.

The instructions must be strictly observed in order to prevent damage to the parts and malfunctions.

Make sure that you have the following agents and equipment available to perform the cleaning and disinfection work:

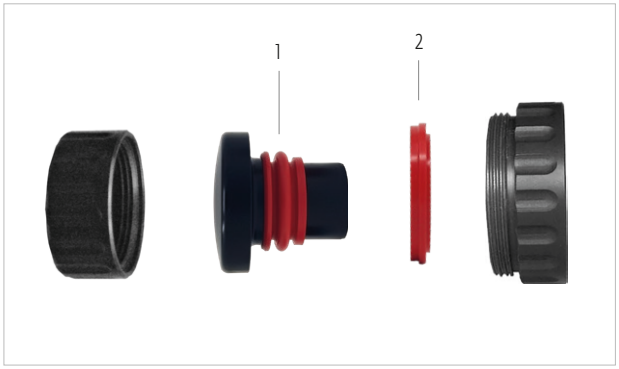
- Clean, soft and lint-free cleaning cloths
- Cleaning agent
- Alcohol-based surface disinfectant
- Ultrasonic bath (if desired)

V25 AND V10

- Unscrew the vibration transmitter from the handpiece.
- Remove the vibration transmitter insert from the front cap.
  - The spring element (1) on the vibration transmitter insert does not need to be removed.
- Clean all of the parts under running water.
- Alternatively, you can clean and disinfect the vibration transmitter insert and the sealing ring in an ultrasonic bath.

V40

- Unscrew the vibration transmitter from the handpiece.
- Disassemble the threaded two-part shock transmitter screw cap.
- Remove the vibration transmitter insert from the front cap.
  - Remove the front sealing ring (2).
  - This is cut open so that it can be removed more readily.
  - The spring element on the vibration transmitter insert (1) does not need to be removed.
- Clean all of the parts under running water.
- Alternatively, you can clean and disinfect the vibration transmitter insert and the sealing ring in an ultrasonic bath.



TROUBLE-SHOOTING

Fault description	Possible cause	Corrective actions
No compressed air supply	Leaks in handpiece cable or cable not properly connected	Check the cable and tube connections and replace them, if necessary
No power output	Handpiece defective	Replace the handpiece

ACCESSORIES AND SPARE PARTS

Accessories	Art. no.:
V-ACTOR HF® handpiece set (contains the V-Actor HF handpiece and the V25, & V40 transmitters)	19365
25 mm vibration transmitter (V25)	28740
40 mm vibration transmitter (V40)	28741
10 mm spherical vibration transmitter without vibration transmitter screw cap (V10)	29742

TECHNICAL SPECIFICATIONS

V-ACTOR handpiece	
V-ACTOR operating frequency	1 – 50 HZ
Energy selection	in steps from 1 – 5 bar
Ambient temperature during operation	10 °C – 30 °C
Ambient temperature during storage and transport	0 °C – 60 °C
Ambient air pressure during operation	800 – 1060 HPA
Ambient air pressure during storage and transport	500 – 1060 HPA
Air humidity during operation	5 – 55%, non-condensing
Air humidity during storage and transport	5 – 95%, non-condensing
Weight incl. cable, filled	approx. 400 G
Protection against ingress of water	IPX0

Subject to technical changes

Note: In the event of the medical product being transferred to third parties, the following must be observed:

– The complete device documentation must be delivered together with the medical product.

– The medical product may only be exported to a foreign country if the medical product and the corresponding indications are allowed there.

This device complies with the applicable standards.
For information about conformity with directives, please refer to the separate operating manual for your control device.

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SYMBOLS AND LABELS

Label	Meaning
	You must read the operating manual!

WARRANTY AND SERVICE

WARRANTY FOR THE V-ACTOR® HF HANDPIECE

The V-ACTOR HF® handpiece is a wear part. We will replace new handpieces that have performed up to 1 million pulses at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship of the handpiece.

Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.
Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the case, with the repair label filled in completely.

Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after we have assessed them.

Vibration transmitters and overhaul kits are not covered by the handpiece's warranty.

Attention!
Modifications to the handpiece and the transmitters are not permitted. Any unauthorised opening, repair or modification of the handpieces by unauthorised 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.

SERVICE

Should you have any further questions or require additional information, please feel free to contact your dealer.
See page 88 in this manual for details.

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DEVICE MAINTENANCE

WATER RESERVOIR

The RPW 2 uses a condenser between the compressor and the handpiece to extract air humidity to avoid water accumulation in the hand piece. The extracted water is collected in the water reservoir located on the back panel just below the power cord port.
The water level should be checked every day before use. The water reservoir should be emptied on a regular basis.

To empty the reservoir follow the instructions.
1. Press the release clip and gently lift-up the water reservoir from the Intelect® RPW 2, sliding it up.
2. Remove the lid of the water reservoir carefully and dispose of the waste water.

To reattach the reservoir
1. Replace the reservoir lid and insert the water tube into the opening on the top
2. Place the reservoir against the Intelect RPW 2 above the connection clip
3. Slide the reservoir down. Press down gently and there will be an audible click. The release clip will still be visible after the water reservoir is installed.

CLEANING THE INTELECT® RPW 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. Do not use solvents. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner. Cleaning should be performed daily. Do not submerse the system in liquids. Should the device accidentally become submersed, contact the dealer or DJO Service Department immediately. Do not attempt to use a system that has been wet inside until inspected and tested by a Trained Technician.

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.

IFU DOWNLOAD

1. Go to the Chattanooga website www.chattanoogarehab.com
2. Go to Intelect RPW 2 product tab
3. Complete the registration form to be informed about new product software version availability and IFU updates if not already done before
4. Go to documents tab
5. Click on the latest version of your Intelect RPW 2 device User manual to download
Nota: a pdf viewer is required to display

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.

DEVICE MAINTENANCE

No internal maintenance or routine calibration is required for the device itself.
For the Falcon®and V-Actor HF® handpieces along with the transmitters, please refer to the correct section in this user manual.
Power cable replacement: Unplug the default cable, then plug the new cable.

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INSTRUCTIONS FOR SOFTWARE UPGRADE

PROCEDURE

Using your computer:

Using the USB drive provided with your device, please follow these step-by-step instructions. Please note that you must use the USB provided with the device for this procedure.

1. Erase the USB drive supplied with the Intelect RPW 2.
2. Go to the Chattanooga website www.chattanoogarehab.com
3. Go to Intelect RPW 2 product page
4. Go to the Software Downloads tab
5. Download firmware upgrade zip file to your computer not the USB drive
6. Extract the file onto the USB drive. Please review the download instruction for Windows® and MAC®
7. Complete the registration form to be informed about new product software version availability and IFU updates (if not already done)

Using your RPW 2:

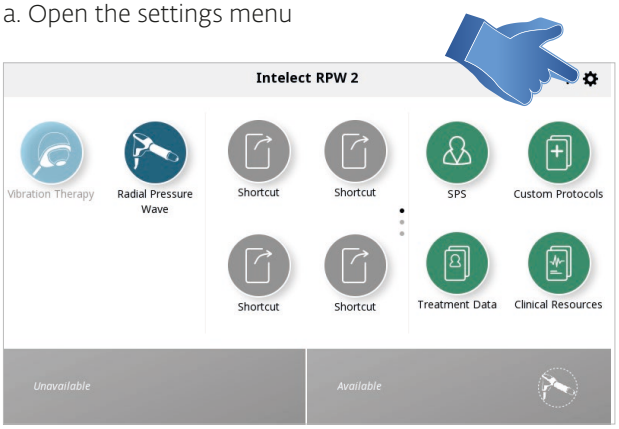
1. Switch OFF the device by power switch on the back of the device.
2. Insert USB key drive into the USB port on the back of the device
3. Switch ON the device

4. Device will automatically detect firmware update availability and commence upgrade. The upgrade will take a few minutes with an animation on the knob LEDs. IMPORTANT: the power must not be switched off during the upgrade.

5. Once firmware update is finished, Home screen will be displayed, and the USB drive can be removed. Device is ready for use.

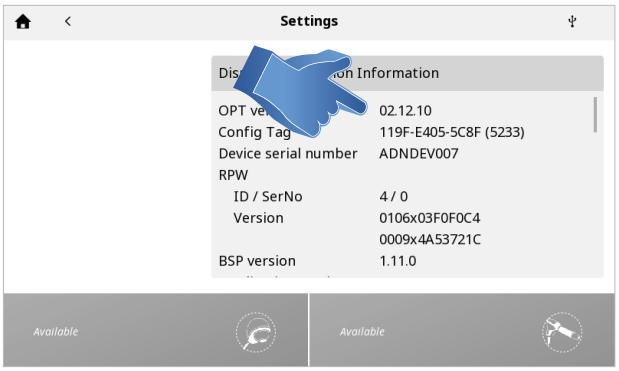
6. Check software version in settings:

a. Open the settings menu



b. Select "Display Unit Version Information"

c. Check the software version is updated



FALCON® HANDPIECE CLEANING, MAINTENANCE; OVERHAUL

CLEANING

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

Caution!

Flammable and volatile cleaning and disinfecting agents may generate an explosive atmosphere.
Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

Attention!

It is essential that no fluid be permitted to penetrate either the device or its tubing.

- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning.

Component	Procedure	Interval
Handpiece shaft and cushion	clean and disinfect	daily or after 20,000 shocks (whichever comes first)
Guide tube	clean from inside with brush	every day
Shock transmitters and O-rings	clean in ultrasonic bath and disinfect	after each treatment or contact with a patient
Guide tube, projectile and O-rings	replace	after 1,000,000 shocks (overhaul the handpiece)

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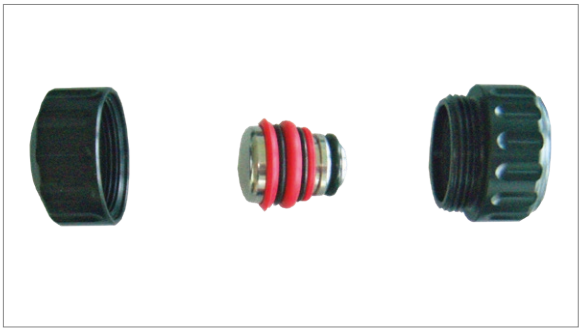
STANDARD SHOCK TRANSMITTERS

1. Disconnect the handpiece from the control device.
2. Unscrew the shock transmitter screw cap from the handpiece.

3. Remove the shock transmitter insert.

4. Insert the shock transmitter insert into the corresponding shock transmitter screw cap.



5. Screw the shock transmitter screw cap onto the handpiece until finger-tight.

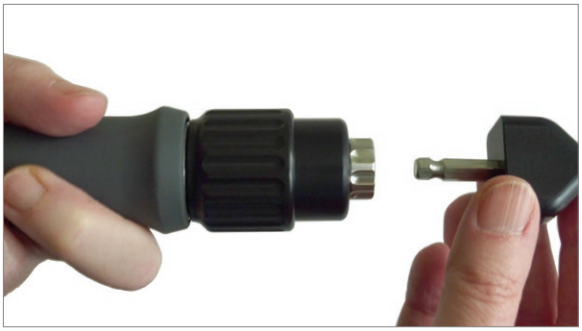
6. After replacing the shock transmitter, make sure that the handpiece cap and the cap parts are screwed firmly in place.

Note: Make sure that the cap parts of the shock transmitters are screwed firmly in place and that the shock transmitter screw cap is screwed firmly to the shaft.
Check the screw connection of the shock transmitter screw cap and cap parts during prolonged treatment phases.

SPINE AND FASCIAE SHOCK TRANSMITTERS

1. Disconnect the handpiece from the control device.
The spine or fasciae transmitter set contents a special clutch for mounting the spine or fasciae transmitters. The shock transmitter can only be mounted if the clutch has already been screwed on the handpiece.
2. Screw the clutch onto the handpiece.

3. Take out the desired shock transmitter from the case.



4. Push the inner part of the clutch in direction to the shaft of the handpiece (1).
    - Push the shock transmitter into the clutch (2).

5. Release the inner part of the clutch.
    - The shock transmitter engages into its place.

Note: Before starting with treatment make sure that the shock transmitter is engaged into its place.

6. To disassemble the shock transmitter proceed as follows:
    - Push the inner part of the clutch in direction to the shaft of the handpiece
    - Pull the shock transmitter out of the clutch.

CLEANING THE HANDPIECE

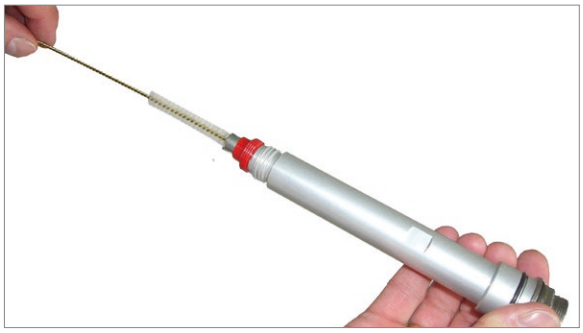
Note: After cleaning, the handpiece must be dry before it can be reassembled. For that reason, schedule sufficient time for the drying of the handpiece and its components.

1. Disconnect the handpiece from the control device.
2. Unscrew the shock transmitter screw cap respectively the clutch for the spine and fasciae shock transmitters from the handpiece.

3. Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
    - Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning

4. Unscrew the shaft from the handpiece and pull it out of the handpiece handle (5).
    - Use the supplied open-end spanner (4) for this purpose.

5. Clean the guide tube with a brush in order to ensure perfect projectile movement.



The assembly of the handpiece is carried out in reverse order.

Note: When mounting the shaft of the handpiece it is necessary to tighten it using the supplied open-end spanner The shaft may no longer be solved manually.

CLEANING THE SHOCK TRANSMITTERS

STANDARD SHOCK TRANSMITTERS

- Unscrew the shock transmitter screw cap and remove the shock transmitter insert from the shock transmitter screw cap.
- Clean all of the parts under running water.

Note: The shock transmitter insert of two-part transmitter caps can only be dismantled and the sealing rings can only be removed using special tools. You should avoid doing this because it could result in damage to the shock transmitter. It is not necessary for cleaning purposes.

- After shockwave application for humans an ultrasonic bath of our shockwave transmitters can have an additional cleaning effect. However, an ultrasonic bath is not a requirement.
- For this purpose, use only instrument disinfectants for heat-sensitive, reusable medical devices.

- Clean and disinfect not only the shock transmitter insert but also the shock transmitter screw cap with the usual alcohol-based cleaning agents and disinfectants.
- Dry the transmitter and shock transmitter screw cap before screwing them together.
- Push the insert into the front cap and screw the two cap parts together until finger-tight.

Note: Make sure that the cap parts of the shock transmitters are screwed firmly in place and that the shock transmitter screw cap is screwed firmly to the shaft.
Check the screw connection of the shock transmitter screw cap and cap parts during prolonged treatment phases.

SPINE AND FASCIAE SHOCK TRANSMITTERS

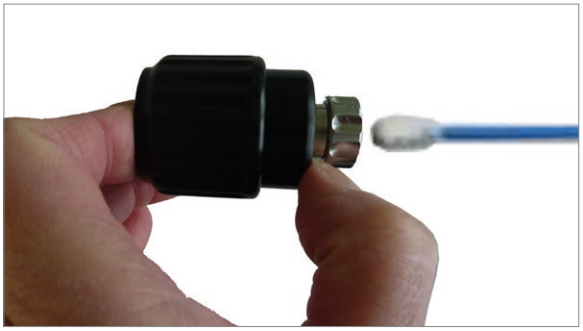
- Remove the applicator from the handpiece and disconnect it from the coupling.
- Remove the residuals of coupling gel immediately after each treatment with a damp cloth.

Note: If coupling gel remains on the applicators or the clutch, corrosion occurs on the metal parts.

- Clean and disinfect the spine and fasciae shock transmitters in ultrasonic bath with a temperature from maximum 40°C.
- Allow shock transmitters to dry before you put them back in the case.

CLUTCH FOR THE SPINE / FASCIAE SHOCK TRANSMITTERS

- Clean the clutch from coupling gel or residual oil using a damp cloth.
- Disinfect the clutch with an alcohol-based disinfectant that is suitable for surface cleaning.
- Spray alcohol-based disinfectant spray in the mountage opening for the transmitter.
- Clean the inside of the clutch using cotton buds.

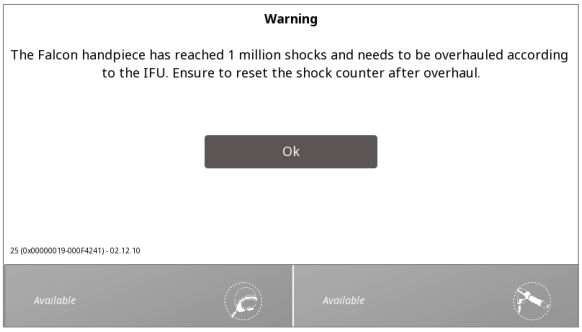


OVERHAUL

Shockwaves are generated mechanically. Due to the effects of friction, the handpiece components are continuously exposed to mechanical stress, which will cause minor wear.

Note: The Falcon* handpiece should be overhauled about every 1,000,000 shocks. This can be done by the user of the device. All that is required is the overhaul kit, which includes all required wear parts.

When your Intelect RPW® 2 device has recorded that 1 millions shocks have been administered by the Falcon handpiece, the below message will be seen upon start-up on the device.



Follow directions on page 87 to remove this pop-up message after the overhaul has been preformed.

Note: The sealing rings, the projectile and the guide tube must always be replaced each time the handpiece is overhauled. Observe the O-ring Guide when selecting the sealing rings to be used. It is contained in the overhaul kit.

OVERHAULING THE HANDPIECE

- Flammable and volatile cleaning and disinfecting agents may generate an explosive atmosphere.
- Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

Attention!

An open end spanner has to be used to release or to assemble handpiece shaft when overhauling the handpiece.

- Place the handpiece on a dry, clean and dust-free surface.

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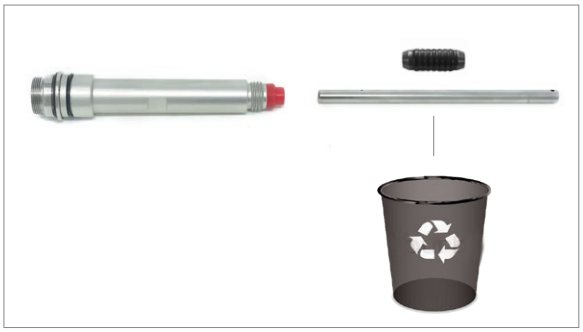
1. Disconnect the handpiece from the control device.
    - Unscrew the shock transmitter screw cap respectively the clutch for the spine and fasciae shock transmitters from the handpiece.

2. Unscrew the shaft from the handpiece and pull it out of the handpiece handle.
    - Use the supplied open-end spanner (3) for this purpose.

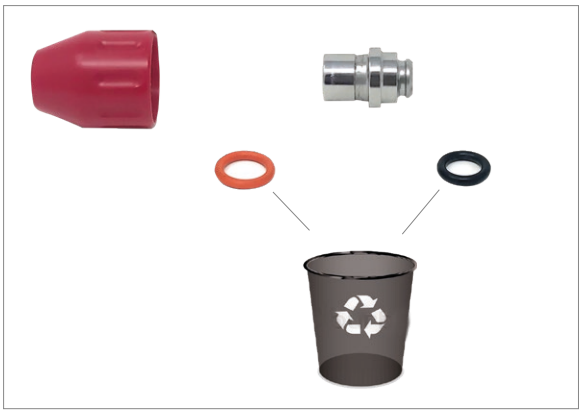
3. Pull the tightly fitting guide tube out of the shaft. If necessary, use a thin metal rod or the supplied hexagonal spanner as a pulling tool by inserting it through the openings in the guide tube.

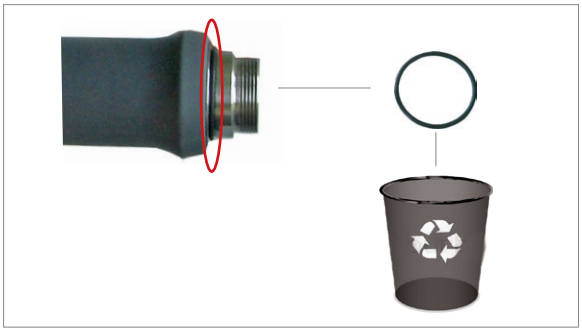
4. A corresponding fixture is provided in the handpiece handle to hold back the projectile. To remove the projectile, hold the handpiece handle with its opening pointing down. Gently knock the handle against the table surface until the projectile falls out. In the event that the projectile breaks apart due to overloading, a fragment of the projectile may be left behind inside the guide tube.

5. Dispose of the used guide tube and the used projectile



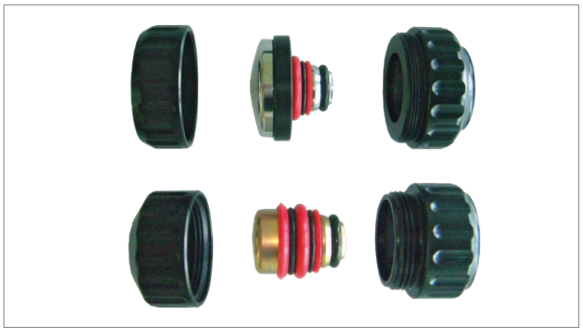
6. Dispose of the detachable sealing rings of the C15, DI15, F15, B15, T10 shock transmitters and the sealing ring on the shaft.





7. Clean the shaft, the shock transmitter (including firmly seated sealing rings) and the shock transmitter screw cap using a disinfectant containing alcohol. These are reused after cleaning.

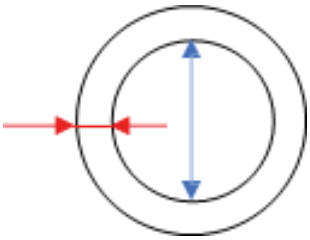
Note: The shock transmitter insert of two-part transmitter caps can only be dismantled and the sealing rings can only be removed using special tools. You should avoid doing this because it could result in damage to the shock transmitter. It is not necessary for cleaning purposes.

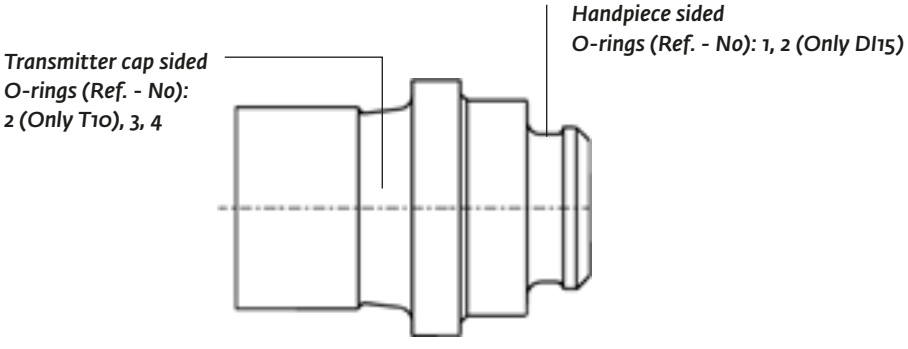


8. Now, from the overhaul kit, take out the new sealing rings and for the shaft and install them. Observe the O-ring Guide for this purpose. It is contained in the overhaul kit.

O - RING GUIDE

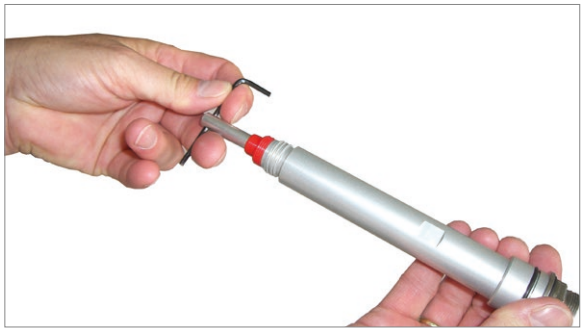
Ref No.	O-Ring (1:1)	Part No.	Measurements	Used For
1		15090	D1 = 11.0 mm D2 = 3.0 mm	R040, T10, F15, C15
2		13411	D1 = 12.0 mm D2 = 2.5 mm	DI15, T10
3		28140	D1 = 14.5 mm D2 = 2.5 mm	C15, DI15
4		28139	D1 = 13.0 mm D2 = 3.0 mm	R040, F15
5		13410	D1 = 24.0 mm D2 = 1.5 mm	Handpiece



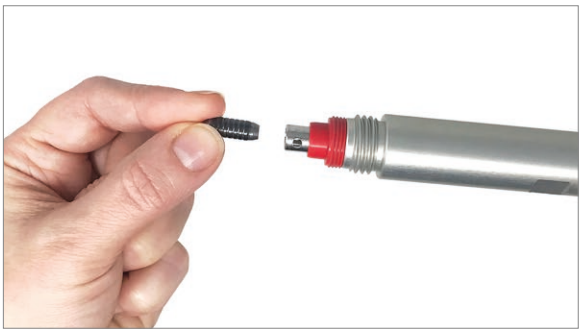


10. Insert the guide tube into the opening in the shaft by pressing in until the stop.

IMPORTANT: Make sure that the end of the guide tube where the two air slots are located is in the direction of the handpiece handle.



11. Insert the new projectile into the fitted guide tube.



12. Screw the shaft into the handpiece until finger-tight.

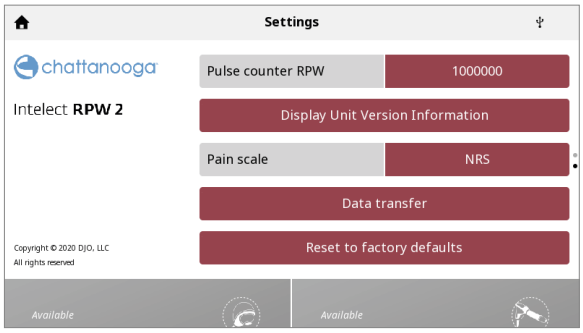
- Using one hand, press the handpiece firmly onto the table and tighten the shaft using the open-end spanner. It must no longer be possible to unscrew the shaft by hand.

13. Screw the transmitter screw cap with the required transmitter firmly back onto the shaft.

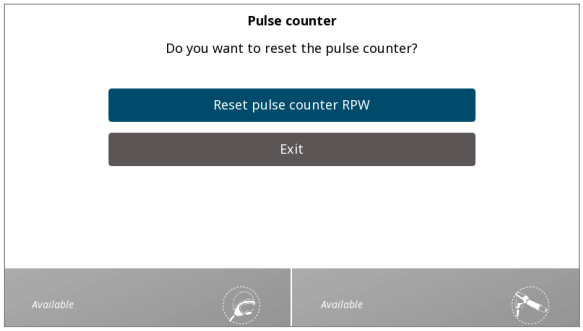
- For two-part transmitter caps: Make sure that the two cap parts are screwed firmly in place and that the transmitter screw cap is screwed firmly to the shaft.
- Carry out a functional check of the handpiece

14. Once the Falcon handpiece has been revised, ensure that the shock/pulse counter is reset in the Settings Menu.

- From the Home Screen, touch the (⚙) icon to get to the Settings Menu
- Scroll down one screen to find the Pulse Counter RPW button



- Touch the Pulse Counter RPW button. The pulse counter pop-up message should appear



- Touch the "Reset Pulse Counter RPW" button and the shocks/pulse counter will reset to 0.

SERVICE & WARRANTY

SERVICE LIFE OF THE FALCON® HANDPIECE

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

- 5 million shocks for the handpiece
- 1 million shocks for the shock transmitters
- 5 million shocks for the clutch.

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

SERVICE LIFE OF THE V-ACTOR HF® HANDPIECE

The average expected service life of the handpiece is approx. 5 million pulses. Exceeding the service life can be expected to result in a failure of the devices.

No warranty claims shall be accepted beyond the information given in the warranty section of this manual.

Falcon and V-Actor are registered trade marks of Storz medical AG

WARRANTY REPAIR/OUT OF WARRANTY REPAIR

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

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

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

Transmitters, guiding tube, projectile, transmitters and o-rings are consumables, they are designed for 1 million shocks expected life.

Ultrasound gel has a shelf life that is lower than the life expectancy of the device, handpieces, and other accessories. Shelf life is indicated on the gel bottle itself.

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

DISPOSAL

Intelect RPW 2
When disposing of this medical product, no special measures have to be observed. Please proceed in accordance with applicable country specific regulations. After expiration of its service life, dispose of the Intelect RPW 2 as waste electronic equipment.

Falcon and V-Actor Handpieces
When disposing of this product, no special measures have to be observed. Please proceed in accordance with applicable country-specifc regulations.
Additionally, after expiration of the service life of the handpiece, please return the device to DJO Global.

WARRANTY

Attention

Modifications to the device or handpiece 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.

DJO FRANCE ("Company") warrants that the Intelect® RPW 2 ("Product") are free of defects in material and workmanship. This warranty shall remain in effect for three years (36 months) from the date of original consumer purchase. During the three-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.

- The warranty for the handpiece is two years or three million shocks, whatever occurs first.
- The warranty for the shock transmitters is one year or one million shocks, whatever occurs fist.
- The consumables are not covered by the handpiece's warranty.
- Valid only in case proper revision of the handpiece is performed every 1 million shocks

This Warranty Does Not Cover:

- Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a certified Company service technician.
- Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a certified 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 necessary maintenance or any use that is inconsistent with the Product User's Manual.
- The Company is not responsible for injury or damage resulting from modifications or service performed by non-authorized Company service personnel.

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 OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

For US product support please call 1-800-494-3395, or visit www.chattanoogarehab.com

ELECTROMAGNETIC COMPATIBILITY (EMC)

The Intelect® RPW 2 has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The guidelines below are intended to help promote electromagnetic compatibility (EMC) in the identified use environment for the Intelect® RPW 2.

- Make use of available resources such as EMC professionals and publications and Internet web pages on the subject of medical device EMC;
- Assess the electromagnetic environment of the facility (e.g., identify radio transmitters in around the facility) and identify areas where critical medical devices are used;
- Manage the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of medical device electromagnetic interference (EMI) and achieve EMC;
- Coordinate the purchase, installation, service, and management of all electrical and electronic equipment used in the facility to achieve EMC;
- Educate healthcare facility staff, contractors, visitors, and patients about EMC and EMI and how they can recognize medical device EMI and help minimize associated risks;
- Establish and implement written policies and procedures that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI and achieving EMC;
- Report EMI problems to the US FDA MedWatch program and communicate EMI/EMC experiences to colleagues in open forums such as medical/technical publications and conferences.

More information is contained within a comprehensive guidance document for EMC in healthcare facilities, developed, with FDA participation, by the Association for the Advancement of Medical Instrumentation (AAMI): Technical Information Report (TIR) 18, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers. AAMI TIR 18-1997. Arlington, Virginia: Association for the Advancement of Medical Instrumentation; 1997.

Caution:
Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or re-orient interfering equipment.
- Increase distance between interfering equipment and your ultrasound system.
- Manage use of frequencies close to ultrasound system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI- related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601- 1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

The product designation Intelect® RPW 2 used in the text below includes all their variants.

The Intelect RPW 2 device is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives set forth in the accompanying documents.

The Intelect RPW 2 device is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives set forth in the accompanying documents.

Portable and mobile RF communication systems may affect the Intelect RPW 2.

The Intelect RPW 2 should not be used adjacent to or stacked with other equipment.

If adjacent or stacked use is necessary, Intelect RPW 2 should be observed to verify normal operation in the configuration in which it will be used.

If you detect damage or malfunctions that may impair the safety of the patient or of the operator, have the device repaired before using it.

If it is necessary to replace assemblies or cables, only the manufacturer's original parts must be used to ensure continued compliance with EMC requirements after repair.

With regards to the electromagnetic compatibility, there is no maintenance operation required during the expected product life time!

WARNING!

Use of accessories 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.

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

12.1 Electromagnetic emissions: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Intelect RPW 2 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Intelect RPW 2 device is used in such an environment.

Emissions Tests	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Intelect® RPW 2 uses RF energy for its internal function. Additionally the Intelect RPW 2 contains a Bluetooth® radio module, which complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF emissions to CISPR 11	Class B	Intelect RPW 2 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	complies with class A requirements	
Voltage fluctuations/flicker emissions to IEC 61000-3-3	complies	

12.2 Electromagnetic immunity : Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Intelect RPW 2 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Intelect RPW 2 device is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ bursts to IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1kV Line to Line ± 2kV Line to Earth	± 1kV Line to Line ± 2kV Line to Earth	Mains power should be that of a typical commercial or hospital environment.
Voltage dips To IEC 61000-4-11	0% UT ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT ; 1 cycle and 70% UT ; 25/30 cycles Single phase at 0°	0% UT ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT ; 1 cycle and 70% UT ; 25/30 cycles Single phase at 0°	Mains power should be that of a typical commercial or hospital environment. If the user of the Intelect RPW 2 device requires continued operation during power mains interruptions, it is recommended that the Intelect RPW 2 device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage prior to application of the test level.

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Intelect® RPW 2 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Intelect RPW 2 device is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF to IEC 61000-4-6	6V 0,15MHz-80 MHz 80% AM at 1kHz	6V 0,15MHz-80 MHz 80% AM at 1kHz	
Radiated RF to IEC 61000-4-3	10 V/m 80MHz-2,7GHz 80% AM at 1kHz	10 V/m 80MHz-2,7GHz 80% AM at 1kHz	
Proximity fields from RF wireless communications equipment to IEC 61000-4-3	27 V/m 380-390MHz PM 18Hz 28 V/m 430-470MHz FM +/- 5kHz 1 kHz sine 9 V/m 704-787 MHz PM 217Hz 28 V/m 800-960 MHz PM 18 Hz 28 V/m 1,7-1,99 GHz PM 217 Hz 28V/m 2,4GHz-2,57GHz at PM 217Hz 9V/m 5,1GHz-5,8GHz at PM 217Hz	27 V/m 380-390MHz PM 18Hz 28 V/m 430-470MHz FM +/- 5kHz 1 kHz sine 9 V/m 704-787 MHz PM 217Hz 28 V/m 800-960 MHz PM 18 Hz 28 V/m 1,7-1,99 GHz PM 217 Hz 28V/m 2,4GHz-2,57GHz at PM 217Hz 9V/m 5,1GHz-5,8GHz at PM 217Hz	

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 RPW 2 exceeds the applicable RF compliance level above, the Intelect RPW 2 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Intelect RPW 2 device.

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES (CONTINUED)

12.3 RF (Radio Frequency) Interference

EMC disturbance can affect the performance of the Intelect® RPW 2. To prevent the user from unacceptable risks the device runs performance checks regularly during operation. This is what happens, if a problem is identified:

– an audio signal sounds
– the device stops immediately
– the message ERROR and an error code appear on the display

In this case you may attempt to restart the device by turning it briefly off and on with the power switch.

WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intelect RPW 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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