



Focus Shockwave Operating Manual

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General Information

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1.1 Introduction

This manual contains warnings, safety instructions and specific operating instructions in accordance with liability regulations.



DANGER

Refers to a situation of acute danger which, if not avoided, could lead to serious or fatal injury..



WARNING

Refers to a situation of potential danger which, if not avoided, could lead to serious or fatal injury.



CAUTION

Refers to a situation of potential danger which, if not avoided, could lead to minor injury.

ATTENTION

Warns against possibly harmful situations that could lead to damage to either the product or to the surrounding area.

NOTE

Additional information concerning specific features or operating instructions is preceded by the term "NOTE".



CAUTION!

Before you start using the Chattanooga Intellect F-SW USA for the first time, please make sure that you have read in full and understood all the information provided in this operating manual.

Familiarity with the information and instructions contained in this manual is essential for ensuring efficient and optimal use of the instrument, for avoiding hazards to personnel and equipment and for obtaining good treatment results.

Thorough knowledge of the information included in this manual will also enable you to react promptly and effectively in the event of malfunctions and errors.

When using optional accessories, please also refer to the separate operating manuals for each of these accessories. It is imperative that users be familiar with the content of this manual before operating any part of this system.

The Chattanooga Intellect F-SW USA is a universal, compact shock wave unit that can be used for treatment involving medium- to high-energy electromagnetically generated shock waves.

1.1.1 Indications

The Chattanooga Intellect F-SW USA is indicated for extracorporeal shock wave treatment of heel pain due to chronic proximal plantar fasciitis for patients of age greater than 18 years with a history of failed alternative conservative therapies for at least six months. Chronic proximal plantar fasciitis is defined as traction degeneration of the plantar fascial band at the origin on the medial calcaneal tuberosity that has persisted for six months or more.

1.1.2 Contraindications

- Over or near bone growth center until bone growth is complete
- When a malignant disease is known to be present in or near the treatment area
- Infection in the area to be treated
- Patient has a coagulation disorder or taking anti-coagulant medications
- Patient has a prosthetic device in the area to be treated
- Over ischemic tissue in individuals with vascular disease

1.1.3 Warnings

Treatment using the Chattanooga Intellect F-SW USA should be performed by a physician or licensed medical professional under the direct supervision of a physician who is trained and experienced in the care of patients with foot and ankle and/or lower extremity disorders and who has completed a training course on the use of the Chattanooga Intellect F-SW USA for treatment of heel pain due to chronic proximal plantar fasciitis.

Patients may experience pain/discomfort during and after treatment. To minimize the potential for pain, the working pressure should be slowly increased to a level of 0.25 mJ/mm² during the first 500 impulses. Treatment with analgesics may be appropriate.

Careful positioning of the patient is required to avoid damage to vascular and nerve structures in the treatment area if inadvertently treated with shockwaves.

The Chattanooga Intellect F-SW USA may be sensitive to excessive electromagnetic emissions which could result in device malfunction. Do not perform procedures in close proximity to electrosurgery, diathermy or magnetic resonance imaging equipment.












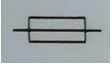

1.1.4 Precautions

The safety and effectiveness of the Chattanooga Intellect F-SW USA has not been demonstrated in patients with the following conditions/observations:

- 1 Children less than 18 years of age
- 2 Inflammation of the lower and upper ankle
- 3 History of rheumatic diseases, and/or collagenosis and/or metabolic disorders
- 4 History of hyperthyroidism
- 5 Paget disease or calcaneal fat pad atrophy
- 6 Osteomyelitis (acute, sub acute, chronic)
- 7 Fracture of the Calcaneus
- 8 Immunosuppressive therapy
- 9 Long-term (≥ 6 months duration) treatment with any corticosteroid
- 10 Insulin-dependent diabetes mellitus, severe cardiac or respiratory disease
- 11 Coagulation disturbance and/or therapy with anticoagulants or antiplatelet agents that may prolong bleeding time
- 12 Bilateral painful heel, if both feet need medical treatment
- 13 Previous surgery of the painful heel syndrome
- 14 Previous unsuccessful treatment of the painful heel with a similar shockwave device
- 15 History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
- 16 Significant abnormalities in hepatic function
- 17 Poor physical condition
- 18 Pregnant female
- 19 History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
- 20 History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.
- 21 Implanted pacemakers, insulin pumps, defibrillators and/or neurostimulators
- 22 Open wounds or skin rashes
- 23 Tendon rupture, neurological or vascular insufficiencies of the painful heel, as assessed using the Semmes-Weinstein Monofilament test and the Ankle Brachial Index

1-6

1.2 Symbols

	Operating manual must be observed!
	Application unit of type B
	Potential equalisation
	F-SW handpiece connection
	Foot switch
	USB connection
	Ethernet connection
	WEEE label
	Wear hearing protection!
	manufacturer
	CSA certification
	Fuse
	Electromagnetic interference may occur in the vicinity of instruments marked with this symbol.

1.3 Requirements for operating the Chattanooga Intellect F-SW USA

1.3.1 Operator

The Chattanooga Intellect F-SW USA is intended exclusively for use by healthcare professionals and may only be used by suitably qualified and trained medical personnel.

Such a healthcare professional is expected to have practical knowledge of medical procedures and applications as well as of the terminology, and should be experienced in treating the indications stated in **CHAPTER 1.1.1 INDICATIONS**.

The healthcare professional must have the basic physical and cognitive prerequisites such as vision, hearing and reading. Furthermore, the basic functions of the upper extremities must be guaranteed.

The instrument is designed for a demographic target group between 18 and 65 years.

1.3.2 Training of the operator

Operators of the Chattanooga Intellect F-SW USA must have been adequately trained in using this system safely and efficiently before they operate the instrument described in this handbook. An introduction to the principles of operation will be provided by your dealer with reference to this operating manual.

The operator must be instructed in the following points:

- Instruction in the operation and designated use of the instrument with practical exercises
- Mechanism of action and function of the instrument and the energies delivered by it
- All component settings
- Indications for use of the instrument
- Contraindications and side effects of the therapy waves
- Explanation of the warning notes in all operating statuses
- Instruction in how to perform the functional checks

Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Further information on training in the operation of this system is available from your dealer. However, you can also contact the following address directly:

DJO, LLC
1430 Decision Street
Vista, CA 92081
USA
T: +1 800 494 3395
E: ChattProductSupport@djoglobal.com

1.4 Description of controls and functional elements

1.4.1 Chattanooga Intellect F-SW USA



- 1 Monitor
- 2 Power indicator
- 3 Foot switch connection
- 4 F-SW handpiece connection

Fig. 1-1 Front view of Chattanooga Intellect F-SW USA



- 1 Potential equalisation connection
- 2 not used
- 3 Mains connection
- 4 Mains fuse holder
- 5 Mains switch
- 6 USB connection for USB stick, USB mouse, USB keyboard and medical printer
- 7 LAN/Ethernet connection for service personnel only
- 8 Water supply connection
- 9 not used
- 10 Type plate

Fig. 1-2 Rear view of Chattanooga Intellect F-SW USA

NOTE

The following instruments can be connected to the USB connection:

- USB memory stick which supports the USB V1.1 protocol
- PCL3-capable printer
- USB mouse
- USB keyboard

The connected instruments must be approved as medical products in accordance with EN IEC 60601.

1.4.2 F-SW handpiece

Focused shock waves with a short wavelength that are concentrated on a focal zone outside the handpiece are administered over the F-SW handpiece into the body at the treatment zone that has been established by diagnosis.

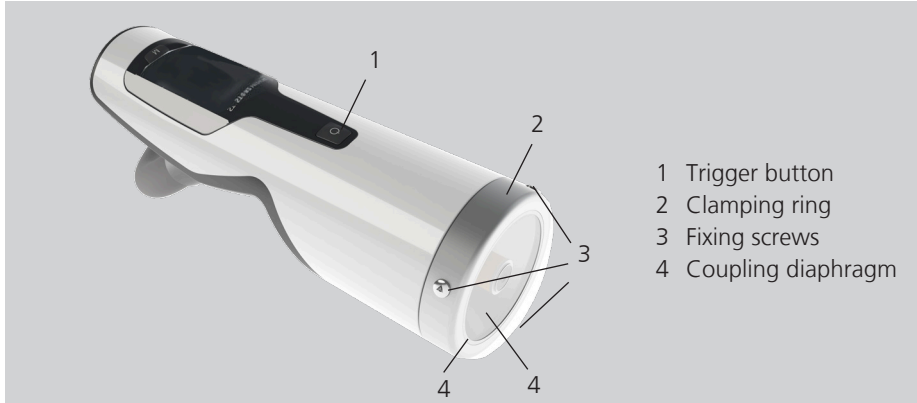


Fig. 1-3 F-SW handpiece

The coupling diaphragm is fixed by a clamping ring and 3 fixing screws. It can only be opened from authorised personnel with special tools.

The penetration depth of the shock wave can be varied by stand-off devices (see **CHAPTER 4.1.2.1 CHANGING THE STAND-OFF DEVICE**).

1.5 Use of stand-off devices

The penetration depth of the shock wave can be adjusted by using different stand-off devices

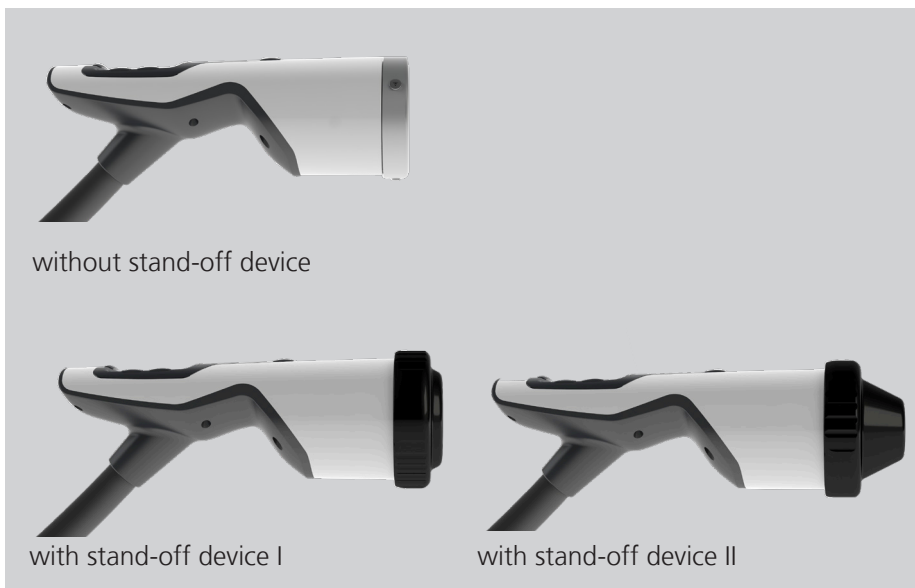


Fig. 1-4 F-SW handpiece

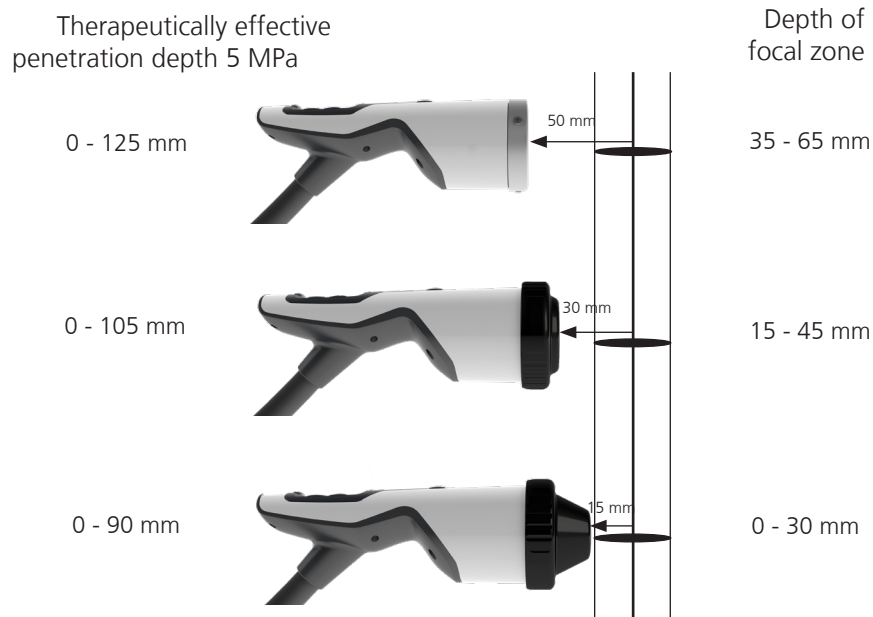


Fig. 1-5 Depth of therapeutical effect

Perform changing of the stand-off devices as described in **CHAPTER 4.1.2.1 CHANGING THE STAND-OFF DEVICE**.

NOTE

The stand-off has a limited service life. It should be replaced if there are visible changes in the material (discolouration, tarnishing, streaks, gas bubbles), deformation of the surface in the coupling area or leaks.

The stand-off should be replaced at least every 12 months.

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Installation Instruction

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2.1 Unpacking

- Carefully remove the equipment 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/dealer immediately if any items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

2.2 Scope of supply

The standard scope of supply of the Chattanooga Intellect F-SW USA:

- Chattanooga Intellect F-SW USA
- F-SW Sepia handpiece set
- handpiece holder
- Mains cables
- Gel bottle
- Silicone oil bottle
- Water bag
- User manual

Please refer to **CHAPTER 6 ACCESSORIES** for information on optional accessories.

2.3 Installation

2.3.1 Handpiece holder installation

The handpiece holder can be mounted on the right as well as on the left side.

- Use a 2.5 mm Allen key for installation.
- Screw the handpiece holders onto the right side wall of the Chattanooga Intellect F-SW USA, as shown in Fig.2-1/1.



Fig.2-1 Mounted handpiece holder

2.3.2 Installing the F-SW holding arm (optionally)

To facilitate handling of the F-SW handpiece, you can hook the F-SW handpiece onto the optionally available holding arm (Fig.2-3).

- Use a 2.5 mm Allen key for installation.
- Screw the holder for the arm firmly onto the holes provided for it on the left of the instrument (Fig.2-2).

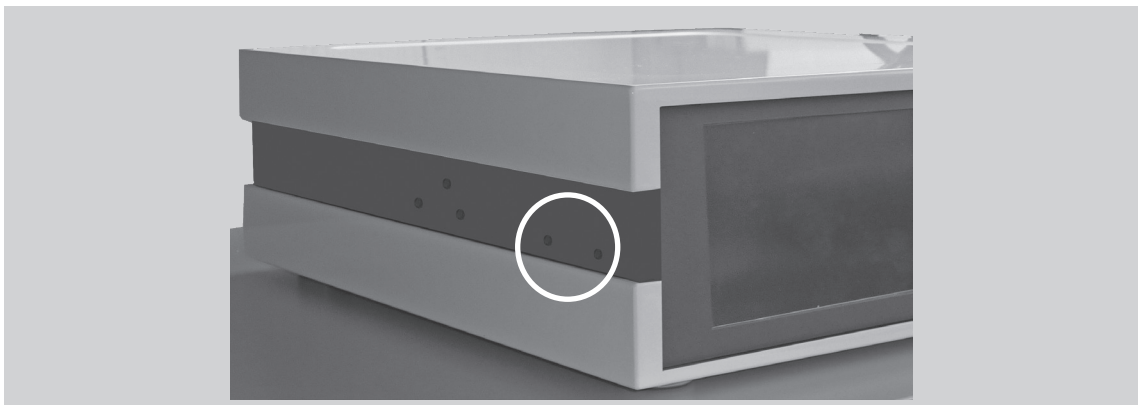


Fig.2-2 Attachment holes for the holding arm

- Place the holding arm into the holder.

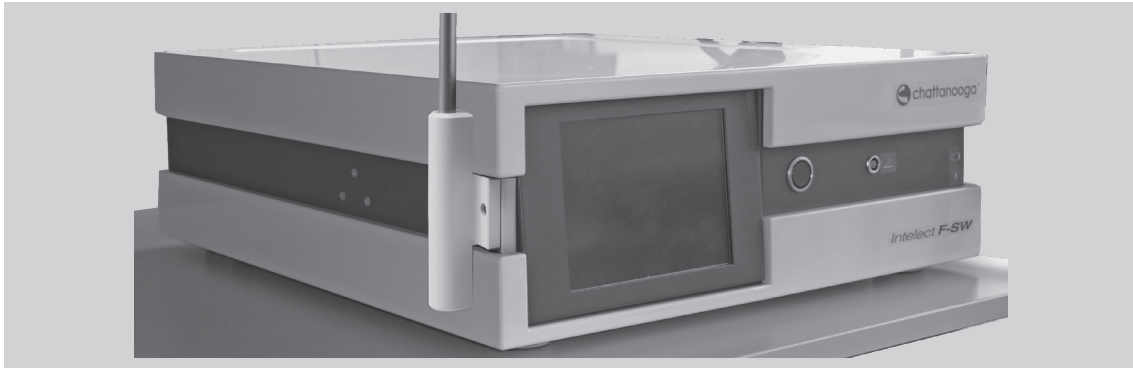


Fig.2-3 Holding arm attached

2.3.3 Connecting power supply cables

- Connect the Chattanooga Intellect F-SW USA via the mains cable to the mains connector (Fig. 1-2/3).

2.3.4 Handpiece connection

- Connect the connector of the F-SW handpiece (Fig.2-4) to the handpiece connection provided on the Chattanooga Intellect F-SW USA and secure it using the black locking screw. The locking screw must be tightened up to the stop until finger-tight.

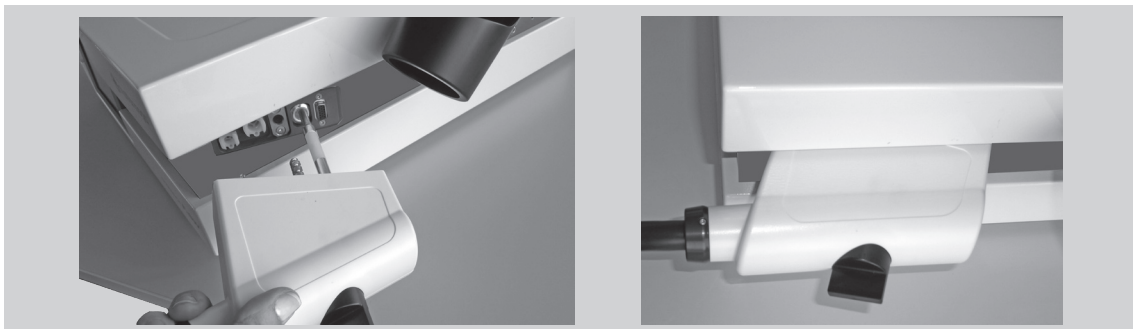



Fig.2-4 Connecting the F-SW handpiece

NOTE

Fill the water circuit of the Chattanooga Intellect F-SW USA first when the F-SW handpiece is first connected after delivery. The instrument will signal "water level too low" when it is switched on.

2.3.5 Connecting the optional foot switch

- Connect the connection cable of the foot switch to the appropriate connection  on the front side of the instrument.

NOTE

The foot switch is protected against ingress of water according to classification IPX8 as per IEC 60529.

2.3.6 Potential equalisation (optional)

The Chattanooga Intellect F-SW USA ifeatures a potential equalisation connection: 

- Connect one end of the potential equalisation cable to the PE connection on the Chattanooga Intellect F-SW USA and the other end to your PE connection.



CAUTION

The potential equalisation connection on the Chattanooga Intellect F-SW USA must be connected in accordance with the relevant national regulations.

2.3.7 USB connection

The USB connection (Fig. 1-2/6) acts as an interface for data input and output.

- Connect if required
 - a USB memory stick which supports the USB V1.1 protocol
 - a PCL3-capable printer
 - a USB mouse
 - a USB keyboard

The connected instruments must be approved as medical products in accordance with EN IEC 60601.

2.3.8 Transporting the instrument

ATTENTION

The side walls of the device can be bent if it is not transported correctly.

Defect of the touchscreen or other components!

- DO NOT carry the device by means of mounted accessory parts (e.g. F-SW plug)

To transport the instrument, grip the indentations on the side of the housing (Fig.2-5/1).



Fig.2-5 Indentations

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Operation

3-2

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3.1 General warnings and safety information



CAUTION !

The Chattanooga Intellect F-SW USA is intended exclusively for use by medical specialists and may only be used by such suitably qualified and trained medical personnel (see also CHAPTER 1.3 REQUIREMENTS FOR OPERATING THE CHATTANOOGA INTELECT F-SW USA).

The user is responsible for correctly positioning the handpiece of the Chattanooga Intellect F-SW USA.

Correct determination of the location of the treatment zone is the responsibility of the user.

Only perform treatments approved by the manufacturer!

To avoid safety hazards, use of the instrument for applications other than those specified in CHAPTER 1.1.1 INDICATIONS is not allowed!

Do not use the Chattanooga Intellect F-SW USA in potentially explosive environments, i.e. in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

If instruments are connected that are not medical products as defined by EN IEC 60601, they must be set up outside the vicinity of the patient.

The optional KARL STORZ foot switch must not be used in potentially explosive atmospheres according to classification AP as per IEC 60601.

The Chattanooga Intellect F-SW USA has a potential equalisation connection. This must be connected in accordance with the relevant national regulations.

Disconnect the Chattanooga Intellect F-SW USA from the mains before starting any cleaning or maintenance work!

Do not try to open the instrument! Risk of electric shocks!

Risk of transmission of microorganisms! Disinfect the handpiece after each use! Refer to CHAPTER 4 CLEANING, MAINTENANCE, OVERHAUL for details.



CAUTION !

High voltage is generated when the Chattanooga Intellect F-SW USA is operated. For safety reasons, wait 2 minutes after switching off the power supply before starting work in the high-voltage area.

Only personnel authorised by the manufacturer are allowed to perform such work.

ATTENTION

Check that the installation surfaces have sufficient carrying capacity to avoid equipment damage!

Electric medical devices are subject to special regulations regarding electromagnetic compatibility (EMC). Hence, medical electric devices must be installed and commissioned in accordance with the EMC guidelines detailed in the accompanying documents.

Portable and mobile HF communications equipment (such as cell phones) may cause interference with electric medical devices.

The use of accessories or cabling not authorised by the manufacturer may cause increased emissions or may lead to reduced interference resistance of the device.

The Chattanooga Intellect F-SW USA may not be positioned immediately next to or stacked with other devices. If the operation near or jointly with other devices is required, the Chattanooga Intellect F-SW USA must be tested in that particular environment to ensure operation according to technical specification.

The Chattanooga Intellect F-SW USA may be positioned and operated near the listed accessories.

The instrument must only be connected to properly earthed and correctly installed shockproof sockets!

Check that the instrument is in perfect working order before each use (see CHAPTER 3.4 FUNCTIONAL CHECKS).

Never cover the instruments when in use!

Make absolutely sure that no liquid can seep into the system housing or handpiece.

Any damage to the instrument resulting from incorrect operation is not covered by the manufacturer's warranty.

ATTENTION

Disposal of the instrument and its components must be carried out in accordance with national waste disposal regulations.

The Chattanooga Intellect F-SW USA must only be used with accessories that have been approved by the system manufacturer. To prevent safety hazards, unauthorized system modifications are not allowed. This will void the warranty.

NOTE

The Chattanooga Intellect F-SW USA meets the requirements of the applicable electromagnetic compatibility (EMC) standards EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The instrument described here generates and uses high-frequency energy and can emit the same. If not installed and used in accordance with these instructions, the instrument may cause harmful interference with other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference with other devices, which can be determined by turning the instrument off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the distance between the devices.
- Connect the devices to an outlet on a circuit different from that to which the other device is connected.
- Consult the manufacturer or field service technician for help.

3.2 Operation

The Chattanooga Intellect F-SW USA is operated using a colour TFT LCD monitor with touch screen function and a graphical user interface.

3.2.1 User interface

The user interface of the Chattanooga Intellect F-SW USA is divided into various areas for displaying different information. The individual controls are arranged in function groups (Fig.3-1):

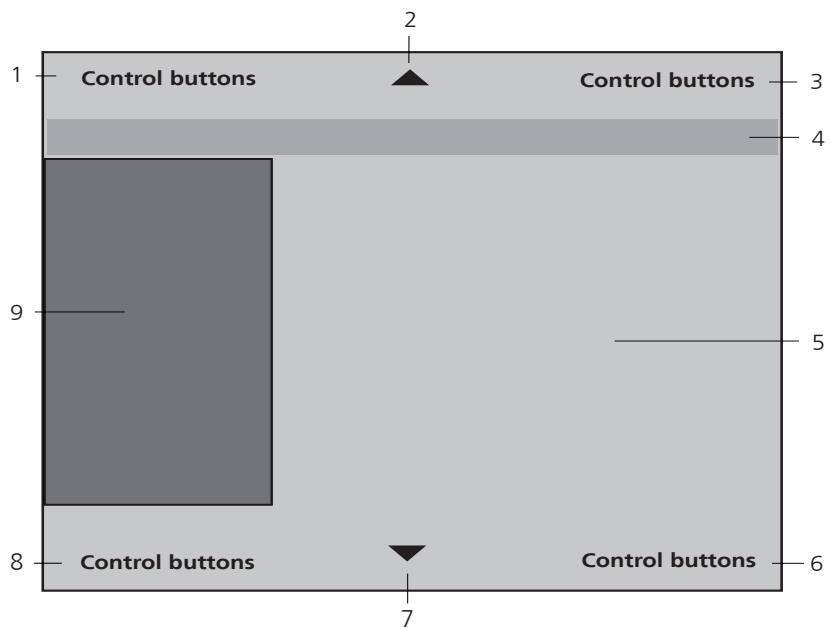


Fig.3-1 Controls

- 1 - 3 Top navigation bar
- 4 Status bar
- 5 Selection area
- 6 - 8 Bottom navigation bar
- 9 Parameter display (nominal and actual values)



NOTE

The following functional description refers to control software version 13441.9.x.x or later (this can be seen in the Info menu).









Navigation bars:

The top and bottom navigation bars (Fig.3-1/1 to Fig.3-1/3 and 3, Fig.3-1/6 to Fig.3-1/8) contain control buttons that you can use for navigating through the menus:

Parameter entry screen:

-  Open the sub-menu
-  Jump to the "Load configuration" sub-menu (call up saved parameter configurations or patient records)

Main and sub-menu:

-  Step back
-  Return to parameter entry screen
-  Delete configurations
-  Save configurations
-  Confirm entries, acknowledge messages
-  The arrow keys can be used for changing (increasing or decreasing) the parameter values.
-  If you are in a sub-menu that contains more menu items than can be displayed in the top part of the display, you can use the arrow keys to scroll to the bottom of the list (page up/down).
-  Press the date key on the parameter input page to open the "Info" window.

Status bar:



The flag on the right of the status bar displays the menu language. Touching the flag icon takes you directly to the "Languages" sub-menu where you can select a different menu language.



A warning symbol appears at the far left of the status bar if there is an error. Touching this symbol takes you directly to the "Warnings" sub-menu that displays all warning messages that are currently active.

name

The name of the loaded configuration/patient record (* indication/patient name) is displayed.

Parameter display:

The treatment parameters are displayed in the parameter display field (Fig.3-1/9) in the following sequence:

F-SW	
Actual energy level in mJ/mm ² or in MPa	0.25 mJ/mm ²
Nominal number of shocks or nominal total energy	500 SW
Actual frequency	4.0 Hz
Actual number of shocks	0 SW
Actual total energy in J	0 Joule

After the first start-up of the unit as well as after operating mode change, configuration loading and parameter change, the display flashes and must be confirmed by touching the display field or a parameter.

Selection area:

- The selection area (Fig.3-2) of the parameter entry screen contains the nominal value selection fields "Energy level", "Number of shocks" and "Frequency"

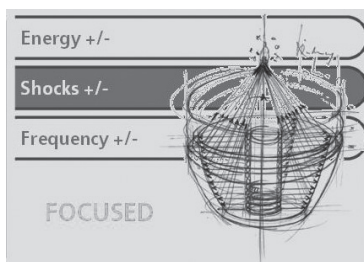


Fig.3-2 Parameter entry screen

- When you open a menu, the name of the opened menu appears in the top line against a dark blue background. The sub-menu items are indented (Fig.3-3).
- A sub-menu item is selected by touching the corresponding display area.
- The selected sub-menu item appears against a dark blue background.
- Sub-menu items that themselves have an additional sub-menu are identified by a green arrow to the right (Fig.3-3/2).
- If there are more than 4 menu items, they can be selected using the arrow keys (Fig.3-3/1). If one of the arrow keys disappears, this means no more selections can be made in this direction.
- Once a sub-menu has been selected, it is opened using the "OK" button.

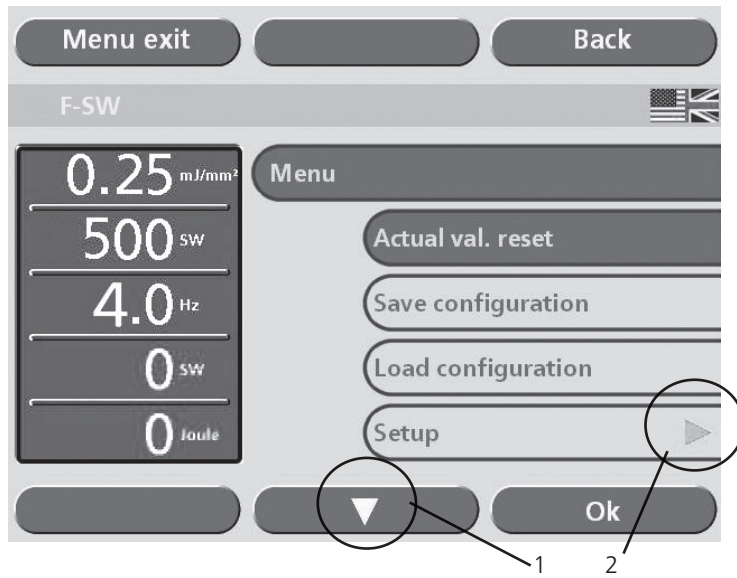


Fig.3-3 List of sub-menu items

3.2.2 Overview of menu functions

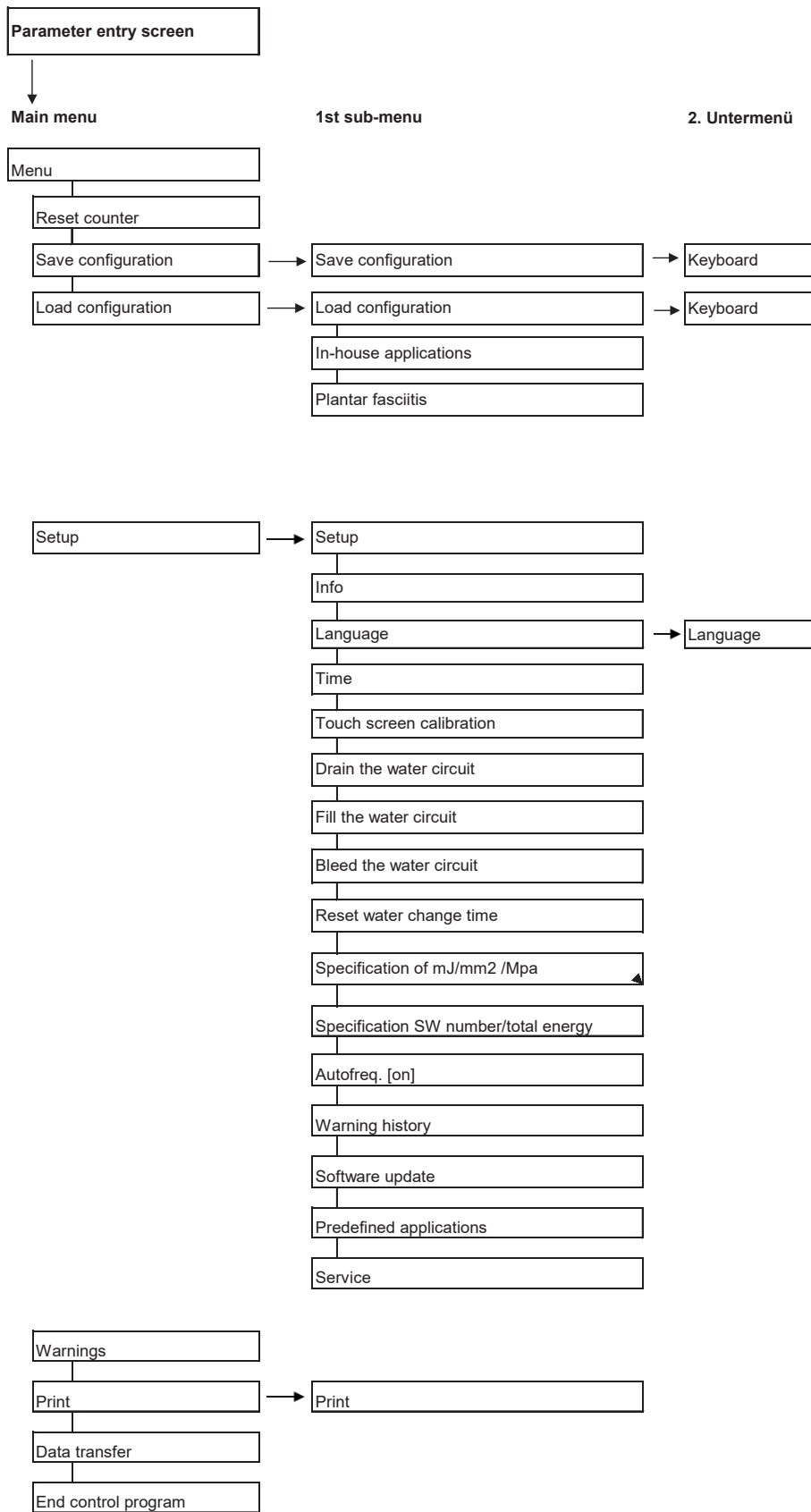


Fig.3-4 Menu overview

3-10

Parameter entry window

- Determining the treatment parameters

Main menu

Reset counter

- Resetting the actual values in the selected operating mode (treatment shock counter, total energy, close patient record)

Save configuration

- Saving indication-specific (preceded by *) or patient-specific treatment parameters

Load configuration

- Loading already stored treatment parameters, opening the patient record.
- The keyboard window in the 2nd sub-menu enables you to make your own text entries. However, you can also do this by connecting a separate USB keyboard (USB connection).

Warnings

- List of current warnings

Print

- The following reports can be printed using a PCL3-capable, medically approved printer with USB port connection:
 - 1 Configuration report
 - 2 Fault report
 - 3 Treatment report

Data transfer

- Export treatment data (using this sub-menu, it is possible to transfer the treatment data as files onto a USB memory stick and open them in Excel)
- Backup settings (backup)
- Restore settings (backup)

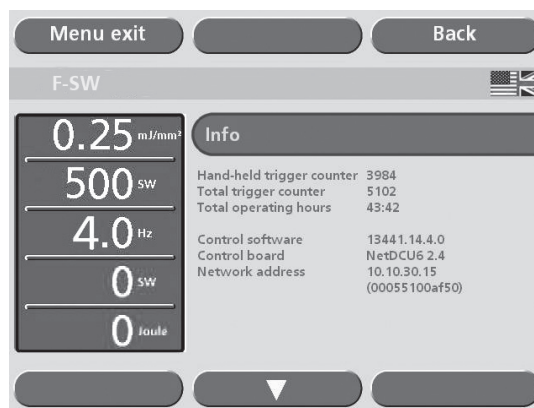
1st sub-menu

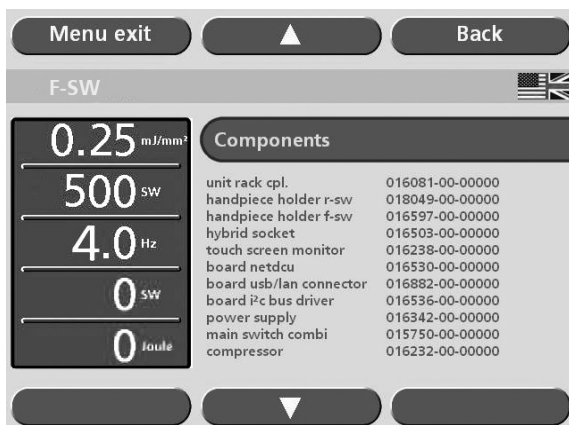
Setup

See 1st sub-menu

Info

- Total shock count and instrument operating hours (depending on operating mode selected)
- Total number of shocks of the respective handpiece, data on monitoring software, operating system, hardware serial numbers and modification status
- Information about modules: To view serial numbers and indexes of the modules, scroll to the second page of the Info window by using the arrow key.





- Warning history – List of the last 100 warning and error messages
- Language – Setting the language
- Time – Setting the date and time
- Touch screen calibration – This function makes it possible to recalibrate the touch screen, i.e. for correct recognition of the touch coordinates

- Draining the water circuit – The corresponding sequences for emptying or filling the water circuit are activated.
- Filling the water circuit
- Bleeding the water circuit – The corresponding sequences for bleeding the water circuit are activated.

- Resetting water renewal time – Reset the reminder function for the water renewal
- Software update – Transferring a software update from the USB memory stick

- Specification of shock wave number/total energy – Changeover between shock number and total energy nominal value specification
- Autofreq. on / off – Selecting an energy level causes the instrument to switch to the maximum permitted frequency automatically. If this function is not activated, the selected frequency is not exceeded when the energy level is changed. However, it is adapted according to the energy level.

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3.2.3 Starting the instrument

- Switch on the Chattanooga Intellect F-SW USA using the main switch.

Filling the water circuit

The first time the instrument is switched on and each time the F-SW handpiece is replaced, the instrument will display the message “Fill water circuit”.

Touch “OK” to confirm the message.

The instructions on the display will guide you through the steps required.

- Connect the full water bag
- Filling the water circuit
- Remove the water bag

A detailed description can be found in **CHAPTER 4.2.2 FILLING THE WATER CIRCUIT**.

Warm-up phase

- Once a day, the Chattanooga Intellect F-SW USA starts a warm-up phase lasting about 3 minutes, the progress of which is shown in the progress indicator (Fig.3-5).

The water circuit is bled.

Check that the F-SW handpiece is correctly positioned in the holder and that no stand-off is fitted.



Fig.3-5 Warm-up phase

NOTE

No F-SW shock triggering is possible during the warm-up phase. All other functions of the instrument can be used, however.

Load test

A load test is performed once a day when the Chattanooga Intellect F-SW USA, is switched on for the first time. This test takes place after the warm-up phase.

- When prompted to do so (Fig.3-6), briefly touch the trigger button on the F-SW handpiece or the foot switch.

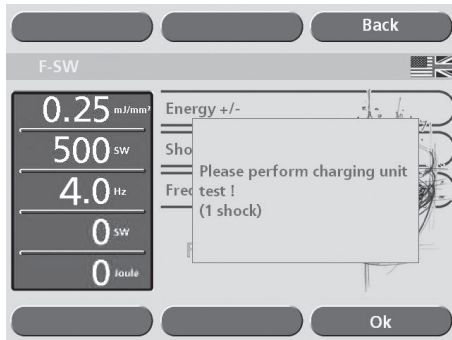


Fig.3-6 High-voltage test

3.2.4 Setting the treatment parameters

Once the unit has been started, the display automatically shows the last setting.

- Touch the flashing parameter display or one of the parameter selection fields to confirm the operating mode.
- Select the line of the parameter that you would like to change.
- Set the value using the arrow keys.
- Release shocks.

NOTE

The maximum possible frequency with which shock waves are generated depends on the selected energy level (see Table 3-1). Increasing the energy level may reduce the shock wave frequency.

Energy flux density in mJ/mm ²	Maximum frequency
0.55	3 Hz
0.50	3 Hz
0.45	3 Hz
0.40	3 Hz
0.35	4 Hz
0.30	4 Hz
0.25	4 Hz
0.20	5 Hz
0.15	6 Hz
0.10	6 Hz
0.07	6 Hz
0.05	7 Hz
0.03	8 Hz
0.02	8 Hz
0.01	8 Hz

Table 3-1 Setting the treatment parameters in F-SW mode

3.2.5 Storing the treatment parameters

- Touch the “Menu” button.
- Select the “Save configuration” function to save the current setting of the treatment parameters.
- Touch the “OK” button.

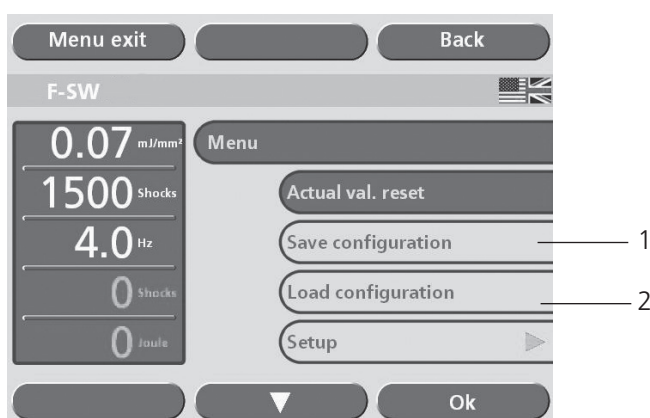


Fig.3-7 Storing the treatment parameters

A list with a total of 100 memory locations appears on the touch screen display in the “Save configuration” sub-menu. The system automatically stores the new parameter configurations at the end of the list with the corresponding creation date and time (Fig.3-8/1).

- Touch the “Save” key to save the current setting (Fig.3-8/2).

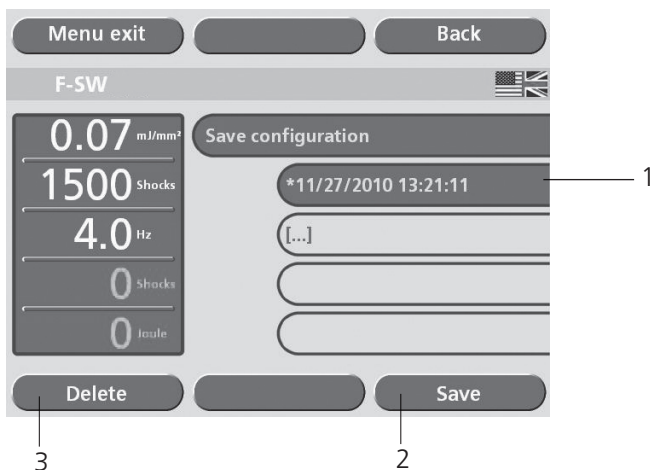


Fig.3-8 "Save configuration" sub-menu

NOTE

If you select a field that is already occupied, you are asked if you want to overwrite the content. Confirm by touching "OK" or revoke your selection by touching the "Back" key.

- To rename the configuration, touch the button again that has already been selected (Fig.3-8/1). This activates the keyboard window (Fig.3-9).*

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* Text can also be entered using an external USB keyboard. Connect the keyboard to the USB connection of the Chattanooga Intellect F-SW USA.



Fig.3-9 Keyboard-window

You can save your parameter setting either as an indication or under a patient's name.

- To save the parameters as an indication, place an "*" before the name of the indication or leave it in place ("*Indication name").

The saved and selected or loaded indication appears in the status bar. This display disappears if a parameter is subsequently changed.

- To save the parameters for a particular patient (patient record), store the setting directly under the name of the patient ("last name, first name").

The configuration stored for a patient name is also displayed in the status bar. The display of patients' names does not disappear when the parameters are changed. All parameter changes are logged in a table. The patient record is closed when:

- a new patient record is called up (loaded),
 - an indication is loaded,
 - a parameter reset is performed (actual value),
 - the unit is switched off.
- Confirm each of your entries by touching the "OK" button.
 - Delete a stored configuration that is no longer required using the "Delete" button (Fig.3-8/3).

Up to 1000 treatments can be stored.

3.2.6 Loading treatment parameters

The alphabetical list of treatment parameters that have already been stored or of the patient record can be opened either directly from the parameter entry screen or from the main menu screen.

- If you are in the parameter entry screen, touch the "Configuration" button.
- If you are in the main menu, select the "Load configuration" function from the list.

The "Load configuration" menu contains the following indication groups:

- In-house applications
- Plantar fasciitis

3-17

3.2.6.1 Pre-programmed indications from the manufacturer

- Touch the button on which the required application area is displayed (Fig.3-10).
- Touch the "OK" button.



Fig.3-10 Loading a configuration I

- Select the required indication.



Fig.3-11 Loading a configuration II

Prior to loading an indication, you can view further information on the selected indication.

- To accomplish this, touch "Note."

The treatment notes will be displayed.

To load the indication, touch "Back" to return to the previous screen.

- Touch "Load".

The indication has been loaded successfully when the loaded indication is displayed on the grey status bar (Fig.3-12).

3-18

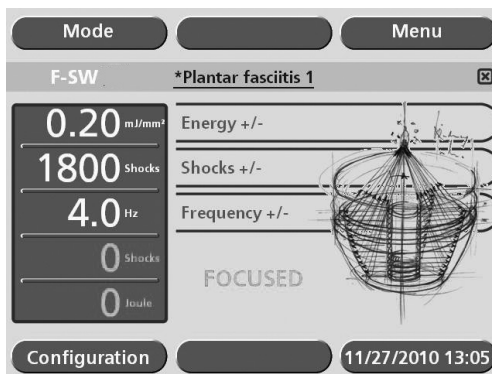


Fig.3-12 Loaded indication

- To review the treatment notes, touch the name of the indication on the grey status bar.

The loaded indication is exited by

- Opening a new indication
- Changing a treatment parameter range
- Switching off the instrument

3.2.6.2 In-house applications

- Touch the “In-house application” button (Fig.3-13).
- Touch “OK”.

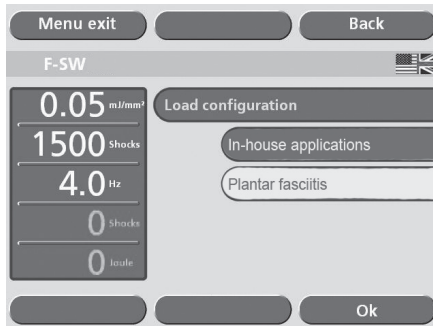


Fig.3-13 In-house applications

- Touch the button for the indication required (Fig.3-14).



Fig.3-14 In-house indications

If additional information for the selected indication has been saved, this can be accessed by touching “Note” (Fig.3-14).

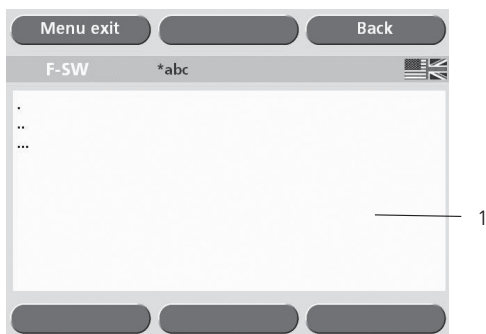


Fig.3-15 Text box for treatment notes

- To add additional information, touch the text box (Fig.3-15/1) to display the on-screen keyboard.
- Save the text by touching “OK”.
- Touch the “Back” button to view the list of in-house applications.
- Touch the “Load” button.

The highlighted indication will be loaded. The indication has been loaded successfully when the loaded indication is displayed on the grey status bar.

- To review the treatment notes, touch the grey status bar.

The loaded indication is exited by

- Opening a new indication
- Changing a treatment parameter range
- Switching off the instrument

3.2.6.3 Patient record

- Touch the “In-house applications” button (Fig.3-16).
- Touch “OK”.
- Touch the button on which the required patient name is displayed.

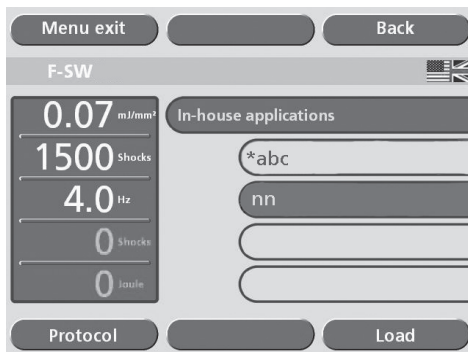


Fig.3-16 Loading a patient record

- Touch the “Protocol” button.

The patient record will be displayed.

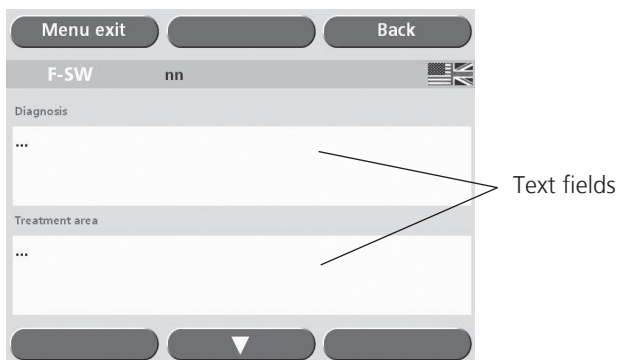


Fig.3-17 Patient record – treatment details

A patient record consists of treatment details (Fig.3-17) and a table of treatment parameters that is created by the instrument automatically (Fig.3-18).

Each time a patient is accessed, a new treatment with the current date is saved to his or her patient record.



Fig.3-18 Treatment parameters

- To add additional treatment details, touch the text field (Fig.3-17) to display the on-screen keyboard.
- Save the text by touching “OK”.
- Touch the “Back” button to view the list of in-house applications.
- Touch the “Load” button.

The treatment parameters for the highlighted patient will be loaded.

The treatment parameters have been loaded successfully when the patient’s name is displayed on the grey status bar on the protocol screen (Fig.3-17).

- To review the patient record, touch the grey status bar.

The patient record is closed by

- Opening a new patient record or indication
- Resetting the shock counter
- Switching off the instrument

3.2.6.3.1 Visual analogue scale (VAS)

The visual analogue scale in the patient record can be used for assessing the progress of the therapy.

The VAS measures the patient's subjective pain sensation on a scale from 0 to 10, within which the patient can classify his or her pain intensity. The starting point (0) stands for "no pain" while the ultimate point (10) stands for the "worst imaginable pain".

In each therapy session, the patient is asked once again to assign a value to the pain he/she has felt since the last treatment.

The reduction in VAS values over the course of the therapy gives an indication of the success of the treatment.

- Touch and drag the arrow to move it to the point on the scale (Fig.3-19) where the patient has assigned his or her pain intensity.
- Touch "OK" to fix the arrow.

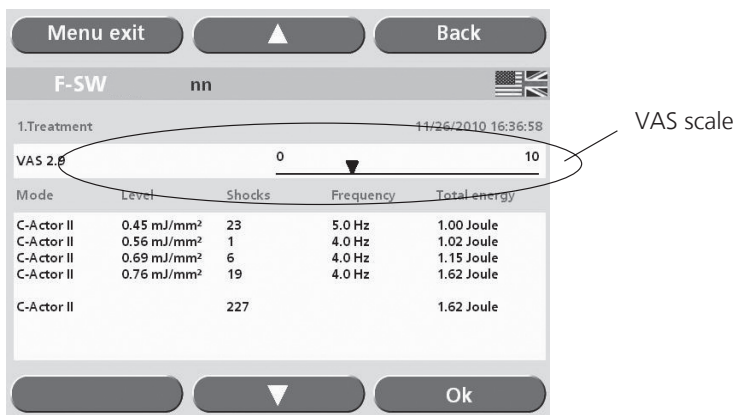



Fig.3-19 Setting the VAS value

The arrow can then no longer be moved and the set value appears at the left-hand edge of the VAS scale (Fig.3-20).



Fig.3-20 Set VAS value

3.2.6.4 Printing data*

- Connect a printer with USB interface connection to the USB port  on the rear of the Chattanooga Intellect F-SW USA.

Printing treatment data

- Load an indication.
- Select the “Print” / “Configuration report” function in the 1st sub-menu.

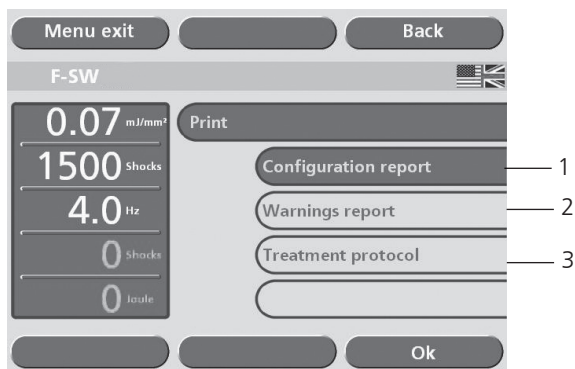


Fig.3-21 Printing data

The indication or the treatment parameters are printed.
If no indication is opened then all treatment parameters are printed.

Printing a patient record

- Load a patient data record.
- Select the “Print” / “Treatment protocol” function in the 1st sub-menu (Fig.3-21/3).

The patient record is printed.

If no patient-specific parameter record is opened then all patient-specific data is printed.

Printing a warnings report

- Select the “Print” / “Warnings report” function to print the list of errors that have occurred (Fig.3-21/2).

The warnings report is printed.

*The “Print data” function can only be used with a PCL3-capable, medically approved printer.

3.2.6.5 Data transfer

Using this function, treatment data can be exported onto a USB memory stick in a format that can be opened in Excel. Also, operating data can be saved (backup) or restored following a repair or if the instrument is replaced.



- Ensure that your USB memory stick supports the USB V1.1 protocol. You can order a validated USB stick from your dealer.

Exporting treatment data

- Load a patient-specific parameter record.
- Select the "Data transfer" / "Export treatment data" function in the 1st sub-menu (Fig.3-22/1).



Fig.3-22 Data export

- Connect the memory stick to the USB port as soon as you are prompted to do so (Fig.3-23) and confirm by touching "OK".

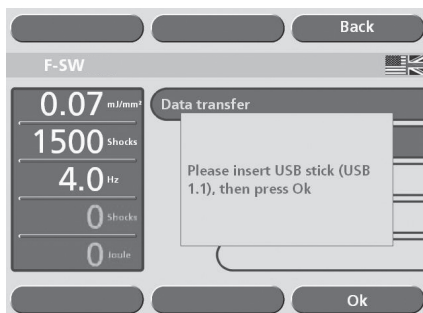


Fig.3-23 Data export

The USB connection is established (Fig.3-24).

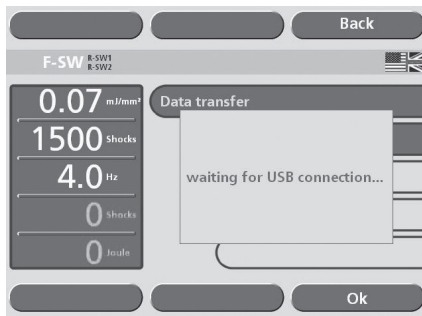


Fig.3-24 Establishing the USB connection

The data is transferred once the USB connection has been established. The export file name of the patient record is protocol_name.csv. All data is exported if no patient record or no indication has been opened. The export file name of the record data is protocol_DateTime.csv.

- Wait until the “Export completed” message appears on the display (Fig.3-25), then remove the memory stick.

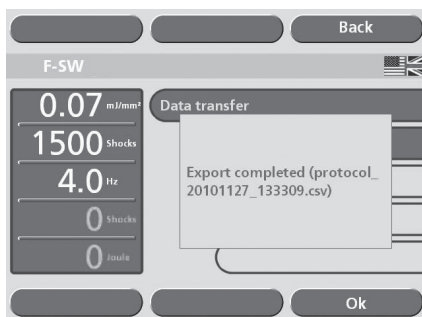


Fig.3-25 Data export complete

3-25

Backing up the settings

Using the “Backup settings” function, you can save configuration settings, patient and indication data onto a USB memory stick as a backup (in a file format that can only be read by the instrument).

- Select the “Data transfer” / “Backup settings” function in the 1st sub-menu (Fig.3-22/2).
- Connect the memory stick to the USB connector as soon as you are prompted to do so (Fig.3-23) and confirm by touching “OK”.

After the USB connection has been established, the data backup is performed and the text window shows the name of the backup file.

- Remove the USB memory stick.

Restoring the settings

The system is restored to the data status of the last backup using the “Restore settings” function.

- Select the “Data transfer” / “Restore settings” function in the 1st sub-menu (Fig.3-22/3).
- Connect the memory stick with the backup file to the USB port as soon as you are prompted to do so (Fig.3-23) and confirm by touching “OK”.

The backup file is loaded onto the system once the USB connection has been established. You are prompted to restart the system when the loading procedure has finished.

- Remove the USB stick and restart the instrument.

3.2.7 Software updates

3.2.7.1 Loading the software onto the USB stick

3.2.7.1.1 Extracting the software using Windows XP

- Save the ZIP file onto your computer's hard disk.
- Right-click on the ZIP folder icon.
- In the shortcut menu that appears, select the "Explorer" item (Fig.3-26).

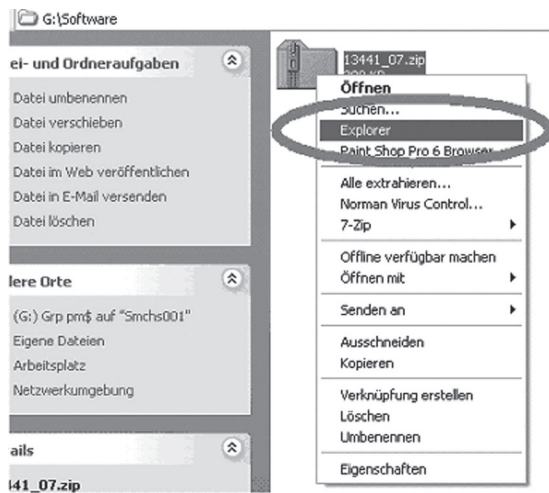


Fig.3-26 "Explorer" auswählen

The folder with the update files appears on the left of the window.

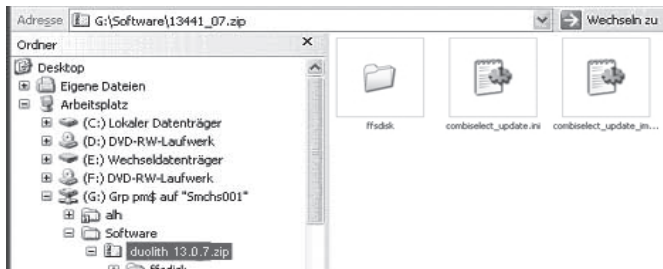


Fig.3-27 Folder with update files

- In this folder, select the "combiselect_update.ini" and "combiselect_update_img.ini" files and the "ffsdisk" folder (Fig.3-27) and copy them onto your USB stick.
- Start the software update as described in **CHAPTER 3.2.7.2 UPDATING THE SOFTWARE ON THE INSTRUMENT.**

3.2.7.1.2 Extracting the software with WinZip

- Connect the USB stick to your computer.
- Save the ZIP file onto the USB stick.



Fig.3-28 Zip file saved on USB stick

- Right-click on the ZIP file icon.
- In the shortcut menu, select the WinZip icon.
- Select "Extract to here" (Fig.3-29).

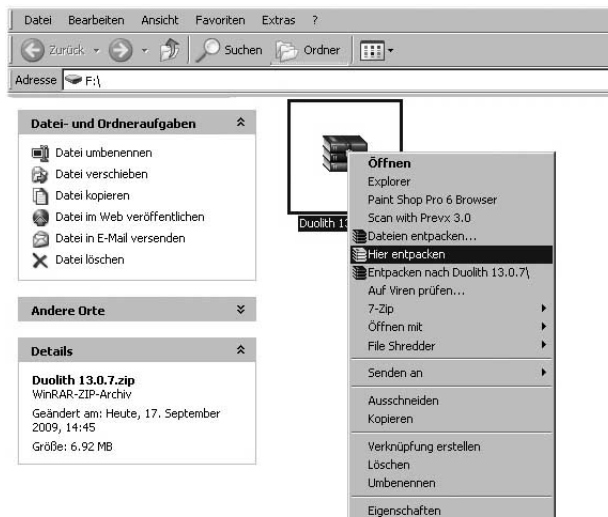


Fig.3-29 Extracting files

- Following extraction, the following files are displayed on the USB stick: "combiselect_update.ini", "combiselect_update_img.ini" and "ffsdisk" folder (Fig.3-30).



Fig.3-30 Files have been extracted

- Remove the USB stick and start the software update as described in **CHAPTER 3.2.7.2 UPDATING THE SOFTWARE ON THE INSTRUMENT.**

3.2.7.2 Updating the software on the instrument

- Select the “Update software” function in the “Setup” menu.
- Connect the USB stick to the USB port of the Chattanooga Intellect F-SW USA, as soon as you are prompted to do so and confirm by touching “OK” (Fig.3-31).

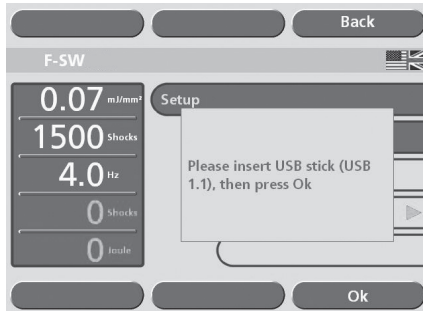


Fig.3-31 Software update

The update is performed once the USB connection has been established.

- Wait until the update has finished.

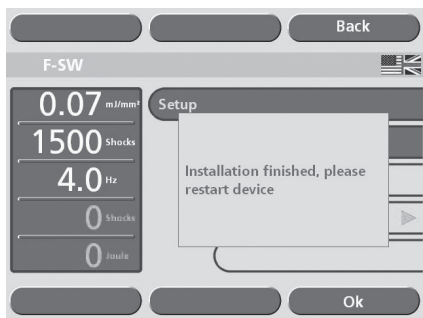


Fig.3-32 Installation completed

- Touch “OK”.
- Remove the USB stick.

The instrument is ready for use.

3.2.8 Resetting the treatment shock counter

- To reset the applied shock counter to “0”, select the “Reset treatment counter” menu option (Fig.3-33) or touch the counter display.



Fig.3-33 Resetting the treatment shock counter

NOTE

The internal instrument counter is not reset.

3.2.9 “Autofrequency” function

If the “Autofrequency” function is activated, the frequency is automatically increased to the maximum possible setting when the energy level is reduced in F-SW mode (see **CHAPTER 3.2.4 SETTING THE TREATMENT PARAMETERS** in F-SW mode, Table 3-1).

- Select the F-SW operating mode if this function should be deactivated.
- Activate the “Autofreq. on” item in the “Setup” menu (Fig.3-34/1).



Fig.3-34 Autofreq. on

The instrument automatically changes to “Autofreq. [off]” status (Fig.3-35/1).



Fig.3-35 Autofreq. off

The selected frequency will now not be exceeded even when the energy level is changed.

- Touch the “Exit” button to return to the main menu.

3.3 Start-up

Switch the instrument on as described in **CHAPTER 3.2.3 STARTING THE INSTRUMENT.**

- Check that there are no bubbles in the F-SW handpiece.
- If bubbles are visible under the coupling diaphragm, proceed as follows: Position the handpiece in the handpiece holder. No stand-off should be attached. Ensure that the blue dot is facing upwards (Fig. 3 - 36).



Fig.3-36 Optimum handpiece position

This ensures that air bubbles will always be sucked out of the handpiece.

- Secure the handpiece in this position for approx. 3 minutes until the suction procedure has finished.
- To work in F-SW mode, set the shock energy to an initial value of 0.1 mJ/mm².

The maximum energy level corresponds to an energy flux density of 0.55 mJ/mm².

NOTE

The highest permitted frequency is always set when an energy level is selected (see **CHAPTER 3.2.4 SETTING THE TREATMENT PARAMETERS**, Table 3-1). This frequency can be reduced manually. (See also **CHAPTER 3.2.9 "AUTOFREQUENCY" FUNCTION**.)

- Press the F-SW trigger button.

The trigger button functions as an on/off switch when it is pressed briefly (< 1.5 s). Pressing it for longer (> 1.5 s) causes it to function as a tip switch, i.e. the shocks will continue until the button is released.

NOTE

If a nominal shock wave value of less than 1000 shock waves is selected (e.g. 400 shock waves), a window with the following text appears after the nominal value has been reached: "Number/energy set value reached".

The message can be acknowledged by touching the "OK" button or the corresponding trigger button. Further treatment is possible.

If the nominal shock value is 0 (displayed as "-"), the stop only occurs at 19,999 shocks.

This message is activated again as soon as a multiple of the set nominal value is reached (e.g. 800 shock waves, 1200 shock waves, etc.).

If a nominal value above 1000 shock waves is selected (e.g. 1700 shock waves), the instrument automatically triggers a safety stop at 1000 shock waves (Fig.3-37). The next stop occurs when the set nominal value is reached. Following this, the counter continues to stop at intervals of 1000 (e.g. 2700, 3700, etc.).

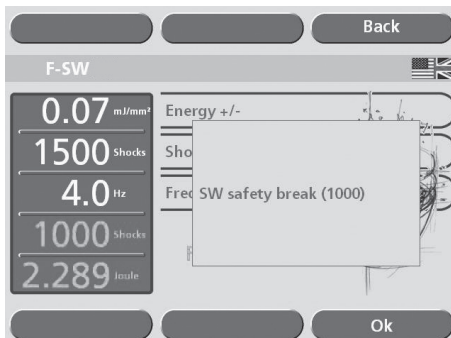


Fig.3-37 Safety stop

3.4 Functional checks

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

- Check the control unit and handpieces for damage.
- Start the Chattanooga Intellect F-SW USA (see **CHAPTER 3.3 START-UP**).
- Set the energy level in F-SW mode to 0.2 mJ/mm².
- Reset the actual number of shocks on the parameter display of the control panel (see **CHAPTER 3.2.8 RESETTING THE TREATMENT SHOCK COUNTER**).
- Release shocks with a shock frequency of 4 Hz.
- Release shocks by means of the foot switch, if used.
- Check that the triggered shocks are correctly counted on the treatment shock counter.

NOTE

If necessary, the functional capability of the F-SW handpiece can be checked with the aid of special Colour sensitive pressure sensors sensors.

3.5 Standard settings


- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero (see **CHAPTER 3.2.8 RESETTING THE TREATMENT SHOCK COUNTER**).



NOTE

Set the nominal value counter to the required value. The "-" symbol appears if zero is selected. The instrument then operates without a nominal value specification.

- Start the F-SW treatment at an energy level of 0.1 mJ/mm² and a frequency of 6 Hz.
- A total of about 2,000 shocks must generally be applied per therapy session.

3.6 Treatment

	CAUTION !
	<p>Read CHAPTER 3.1 GENERAL WARNINGS AND SAFETY INFORMATION before beginning treatment.</p> <p>Each time after the instrument has been transported, make sure that all functional checks have been performed on the instrument before you start treatment.</p> <p>Only perform treatments approved by the manufacturer.</p> <p>To avoid safety hazards, use of the instrument for applications other than those specified in CHAPTER 1.1.1 INDICATIONS is not allowed!</p> <p>All status and error messages signaled during treatment must always be attended to without delay!</p> <p>The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.</p>

 	CAUTION !
	<p>We recommend that the user and the patient wear suitable hearing protection.</p> <ul style="list-style-type: none">• 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 F-SW coupling diaphragm or the coupling cushion.

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Cleaning, Maintenance, Overhaul

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4.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the Chattanooga Intellect F-SW USA.



CAUTION

Disconnect the instrument from the mains before starting any cleaning or overhaul work!

4.1.1 Cleaning the instrument

- Wipe the exterior of the housing with a damp cloth. Use soapy water or a mild cleaning agent.

ATTENTION

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

4.1.2 Cleaning the F-SW handpiece

4.1.2.1 Changing the stand-off device

NOTE

To change the stand-off device, apply a drop of silicone oil to the coupling diaphragm as a coupling medium.

- Screw the stand-off device firmly onto the handpiece using the clamping ring.

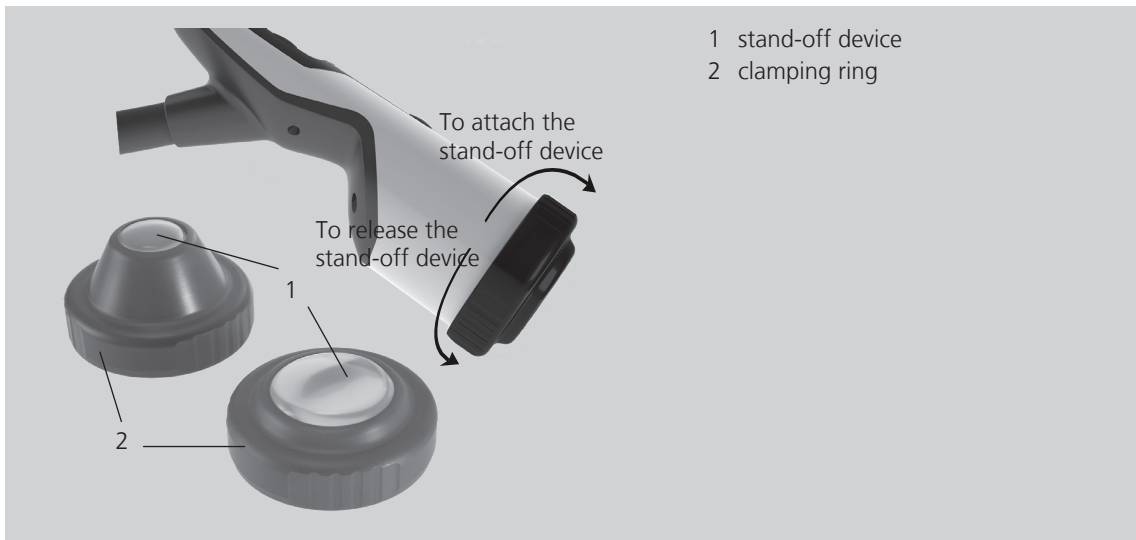


Fig. 4-1 Mounting the stand-off devices

- To release: Press the clamping ring towards the rear and then unscrew it.

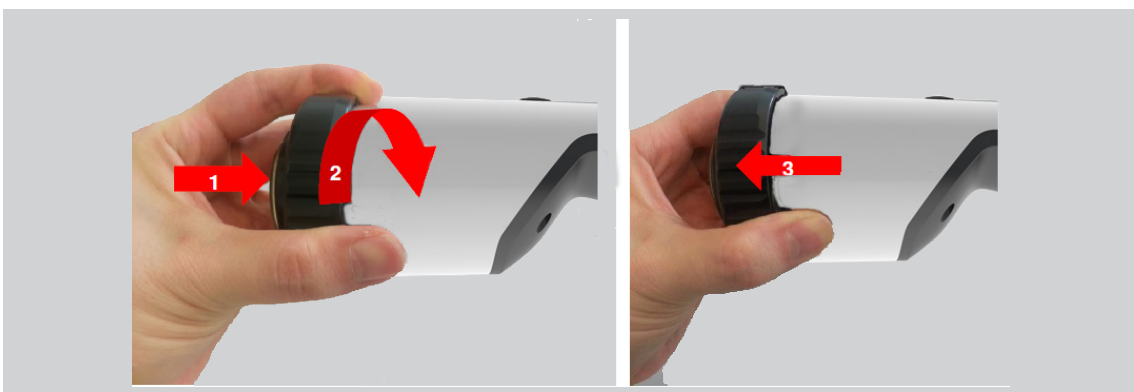


Fig. 4-2 To release the stand-off device

NOTE

The stand-off has a limited service life. It should be replaced if there are visible changes in the material (discolouration, tarnishing, streaks, gas bubbles), deformation of the surface in the coupling area or leaks.

The stand-off device should be replaced at least every 12 months.

4.1.2.2 Reprocessing of the handpiece and the stand-off devices

After each therapy session all parts of the handpiece which have been in contact with the patient must be thoroughly cleaned and disinfected for further treatments.

Therefore the instruction must be strictly followed in order to avoid damage to the parts and prevent malfunctions.

Make sure that following means and tools are available for cleaning and disinfection:

- clean, soft and lint-free cleaning tissues
- cleaning agent
- alcohol-based surface disinfectant

4.1.2.3 Cleaning

- Screw off the stand-off device from the handpiece as described in **CHAPTER 4.1.2.1 CHANGING THE STAND-OFF DEVICE**.
- Clean the handpiece and the stand-off devices of coupling gel, residual oil and other water-soluble contaminants using a damp tissue.

4.1.2.4 Disinfection

- Disinfect the handpiece and the stand-off devices with a alcohol-based surface disinfectant.
- Spray the handpiece and the stand-off devices with a disinfectant spray.
- Wipe the handpiece and the stand-off devices with a damp soft tissue.
- Dry the handpiece and the stand-off devices with a dry, absorbent soft and lint-free tissue.

NOTE

Coupling cushion and stand-off devices must be protected against mechanical damage. Do not use metallic or sharp objects for cleaning.

ATTENTION !

Cleaning agents and disinfectants may impair the characteristics of the coupling diaphragm.

- Do not use vegetable-based soap solutions or vegetable oils.
- Do not use agents containing any of the following:
 - Aniline
 - Dimethylformamide
 - Ethyl acetate
 - Methylene chloride
 - N-methylpyrrolidone
 - Nitric acid, 20 percent
 - Hydrochloric acid, 20 percent
 - Sulphuric acid, 20 percent
 - Trichlorethylene
 - Tetrahydrofurane
 - Toluene

NOTE

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

4.1.3 Cleaning the optional KARL STORZ foot switch

- Clean the KARL STORZ foot switch with soapy water or a mild cleaning agent.

NOTE

The foot switch is protected against ingress of water according to classification IPX8 as per IEC 529.

4.2 Water renewal

The water in the cooling circuit of the F-SW handpiece should be renewed every 6 months or so. The instrument automatically displays a message to this effect when it is switched on if the water renewal is due (Fig. 4-3).

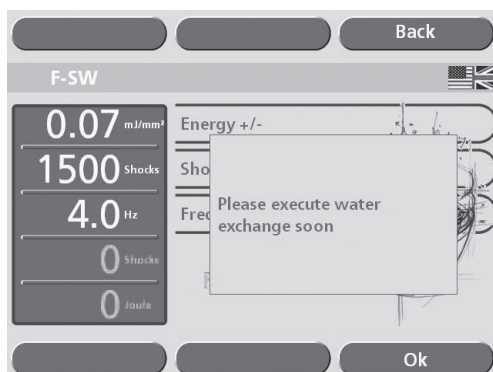


Fig. 4-3 Prompt for water renewal

Touch the "OK" button to acknowledge this message. The message no longer appears once the water has been renewed.

4.2.1 Draining the water circuit

The water circuit must be drained if the instrument will not be used for several weeks.

- Make sure that the instrument is standing on a smooth surface.
- Activate "Empty water circuit" operating mode in the "Setup" menu (Fig. 4-4/1).



Fig. 4-4 Water renewal

- Connect the water bag to the Chattanooga Intellect F-SW USA as soon as the message appears (Fig. 4-5).

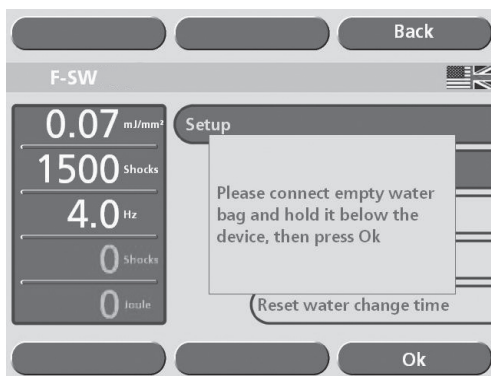


Fig. 4-5 Draining the water circuit I

The "Please wait" message and a progress indicator appear on the display.

- Allow the remainder of the water to drain out of the handpiece by holding the F-SW handpiece vertically above the instrument as soon as you are prompted to do so. Make sure that the coupling diaphragm of the handpiece is pointing upwards.

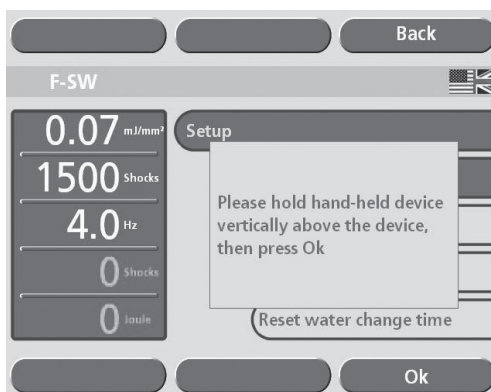


Fig. 4-6 Draining the water circuit II

The "Please wait" message and a progress indicator appear on the display.

- Wait until the instrument is ready. The display shows when the water circuit is empty.

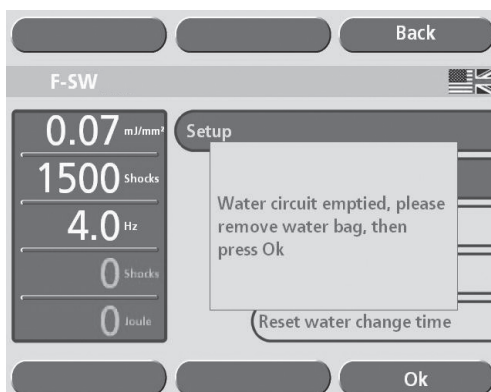


Fig. 4-7 Draining the water circuit III

- Open the lock on the tube connection and pull the tube out of the tube connector.
- Remove the full water bag and dispose of the contents.

4.2.2 Filling the water circuit

- Make sure that the instrument is standing on a smooth, horizontal surface.
- Rinse out the water bag.
- Use only deionised water (in compliance with VDE 0510, e.g. water for batteries or clothing irons) to rinse or fill the water bag.
- Fill the water bag to the brim.

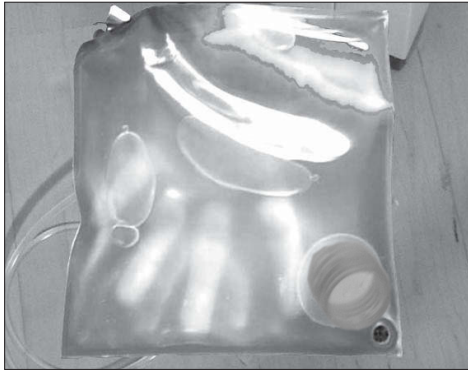


Fig. 4-8 Filling the water bag

ATTENTION

Do not use water that has been distilled more than once!

- After the water bag has been filled, there should be as few bubbles as possible in the connection tube. Press the closing valve inwards to let the air escape (Fig. 4-9) until the hose is fully filled with water.

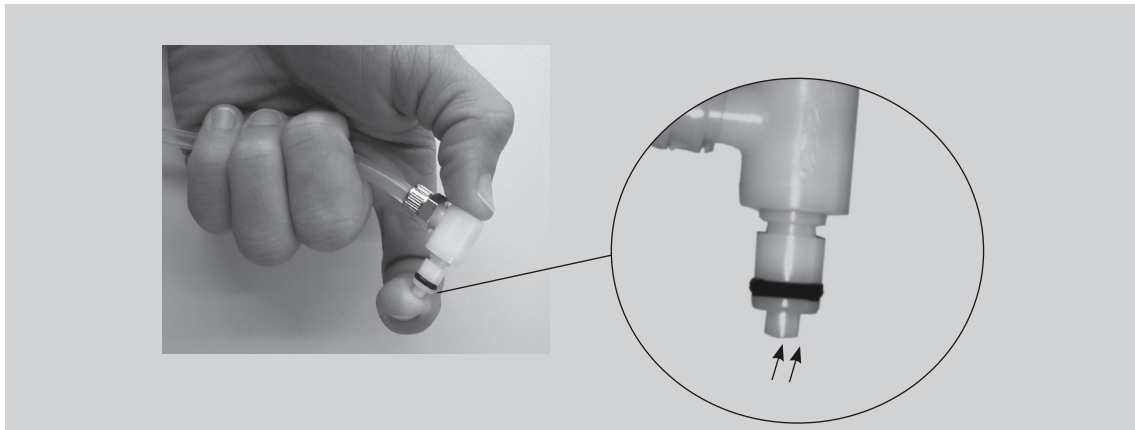


Fig. 4-9 Venting the connection tube

- Place the F-SW handpiece into the F-SW handpiece holder so that any air bubbles that form will be immediately sucked up by the bubble trap. Note the handpiece positions defined in **CHAPTER 3.5 STANDARD SETTINGS**
- Activate "Fill water circuit" operating mode in the "Setup" menu.
- Connect the water bag to the water tube connection on the rear of the instrument as soon as the message appears.

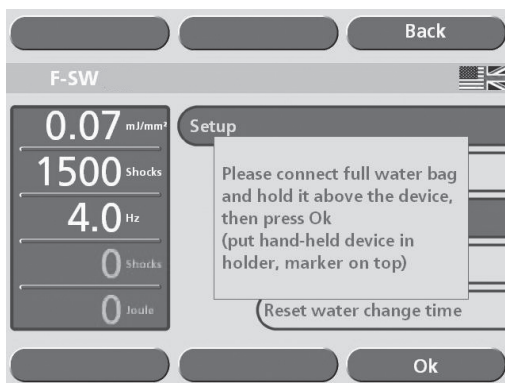


Fig. 4-10 Filling the water circuit I

- At the same time, hold the water bag above the instrument so the water can flow out optimally. Hook the bag onto an infusion stand if necessary.
- Touch "OK".

A progress display with the message "Please wait" appears on the display.

- As soon as the water circuit has been filled, the instrument prompts you to remove the water bag. (Fig. 4-11) There may be water left in the bag.

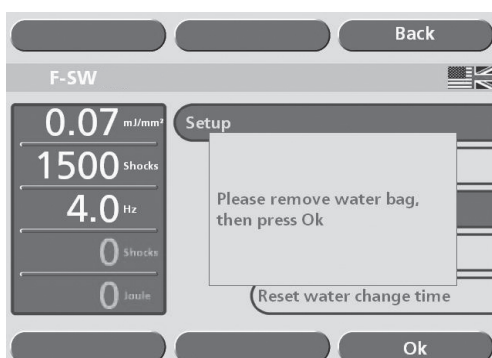


Fig. 4-11 Filling the water circuit II

- Push the lock on the tube connector and pull the tube out of the connection.
- confirm by touching "OK".

There might be air bubbles in the system after the water has been changed. The instrument needs about 15 minutes to remove these air bubbles. A progress bar will be displayed (Fig. 4-12).

4-10

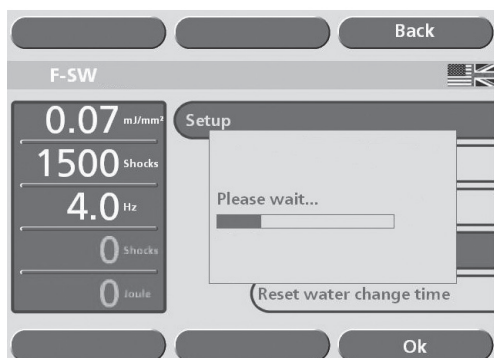


Fig. 4-12 Venting the water circuit

- Wait for the message to disappear, then return to the parameter entry screen by touching the "Menu exit" button.
- Check that there are no bubbles under the coupling diaphragm of the F-SW handpiece. If bubbles are present, briefly hold the handpiece pointing downwards in a vertical position. The air bubbles will then be automatically sucked in by the bubble trap.

4.2.3 Bleeding the water circuit

- Select "Bleed water circuit" from the "Setup" menu.

A progress bar will be displayed.

- Wait for the message to disappear, then return to the parameter entry screen by touching the "Menu exit" button.
- Check that there are no bubbles under the coupling diaphragm of the F-SW handpiece. If bubbles are present, briefly hold the handpiece pointing downwards in a vertical position. The air bubbles will then be automatically sucked in by the bubble trap.

4.2.4 Resetting the water renewal time

Every six months, the instrument prompts you to renew the water; the prompt does not disappear permanently until the water has been renewed.

The "Reset water renewal time" function can be selected to cancel this reminder function or to adapt it to a new date setting.

- Activate "Reset water renewal time" operating mode in the "Setup" menu.

The time when the water renewal reminder is triggered is automatically moved forwards by six months. A window showing the new date of water renewal appears briefly on the display.

- Press the "Exit" button to open the parameter entry screen.

Failure to renew the water regularly may shorten the service life of the instrument.

4.3 Fuse replacement

The mains fuse holder is located on the rear panel of the Chattanooga Intellect F-SW USA (see Fig. 4-13/1).

- Push the clip of the mains fuse holder to the right and take the holder off the housing.

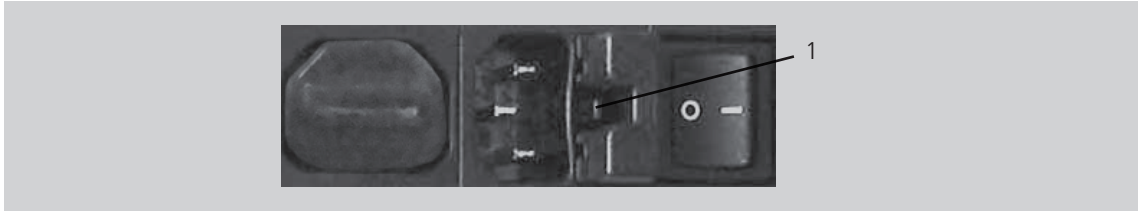


Fig. 4-13 Mains fuse holder

- Pull the old fuses out of the mains fuse holder.

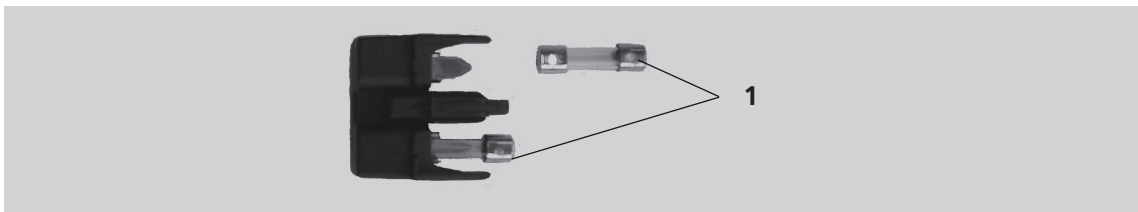


Fig. 4-14 Fuse replacement

- Replace the fuses (T5 AL/250 VAC).
- Push the mains fuse holder back into the opening until it engages.

4.4 Maintenance and safety checks

Preventive maintenance is not necessarily required. However, regular maintenance may help to identify possible defects at an early stage and thus increase the safety and service life of the instrument.

Maintenance services can be ordered from our regional representatives in your area or directly the manufacturer.

We recommend that functional and safety checks be performed at least once a year. National accident prevention regulations and test and inspection intervals prescribed for medical devices must, of course, be observed.

The following checks should be performed to ensure that the Chattanooga Intellect F-SW USA operates safely.

- 1 Earth leakage current test according to national regulations.
- 2 Earth impedance test (with mains cable, incl. applicator housing) according to national regulations.

NOTE

For further details on content and performance of the safety checks please contact your local dealer.

4.5 Disposal

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 Chattanooga Intellect F-SW USA as waste electronic equipment.



4.6 Repair

Repair work on defective instruments must only be carried out by personnel suitably authorised by the manufacturer. Only original spare parts may be used for this purpose. The personnel suitably authorised can be from representatives agencies and dealers.

4.7 Service life

The average expected service life (MTTF) is according to EN 60601-1:2005 +A1:2012 for the electrical medical device Chattanooga Intellect F-SW USA approx

- 15 000 operating hours.

4.7.1 Service life of the handpiece

The coil is a wear part. After 1 million shocks the coil needs to be exchanged to avoid secondary damages on the handpiece and on the control device.

The average expected service life (MTTF) is according to EN 60601-1:2005 +A1:2012 for the F-SW handpiece

- 5 million shocks.

If service is required, contact your local distributor.

Exceeding the service life can be expected to result in a failure of the instrument and accessories. This also applies to handpieces.

No warranty claims shall be accepted beyond the information given in **CHAPTER 8 WARRANTY AND SERVICE**.

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Status Messages and Troubleshooting

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5.1 Status messages

Specified number of shock waves reached	Acknowledge message, further treatment is possible.
Shock wave safety stop	Acknowledge message, further treatment is possible.
F-SW: load test unsuccessful	Restart the instrument and repeat the test. Do not continue to use the instrument if the fault continues. Notify your Service centre
F-SW: charging timeout	Acknowledge message. Inform your Service centre if the fault continues.
F-SW: water temperature too high	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: water temperature too low	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: water level too low	Fill the water circuit (see CHAPTER 4.2.2 FILLING THE WATER CIRCUIT)
F-SW: water circuit fault	Pump defect Treatment is not possible. Bleed the water circuit (see CHAPTER 4.2.3 BLEEDING THE WATER CIRCUIT). Inform your Service centre if the fault continues.
F-SW: water pump current too low	Acknowledge message. Inform your Service centre if the fault continues.
F-SW: pump temperature too high	Acknowledge message, further treatment is possible once the pump temperature has returned to permitted values.
F-SW: therapy head over-temperature	Acknowledge message, further treatment is possible once the therapy head temperature has returned to permitted values.
F-SW: water temperature sensor failure	Restart the instrument. Inform your Service centre if the fault continues.
Shock wave limit for current handpiece reached	Shock wave limit for current handpiece reached. Replace the handpiece.
F-SW: charging unit not ready	Acknowledge message. Call your Service centre if the fault continues after a reset.
Printer not ready	Connect and switch on the printer.
USB stick was not recognised	Remove the USB stick, then switch off and restart the instrument. Reinsert the USB stick. Check that there is software on the USB stick. If the fault persists, check that the USB stick supports the USB V1.1 protocol. If it does not, replace the USB stick.
Water amount insufficient, please check supply	Fill the water bag and check whether water is flowing into the water circuit. If the fault persists, inform your Service centre.

5.2 Trouble-shooting



CAUTION

Unplug the mains cable from the instrument before you carry out any maintenance work!

Fault description	Possible cause	Corrective action
Instrument does not work	Power failure	Check the power supply.
	Defective mains fuse	Replace the fuses.
	Defective mains plug	Replace the mains cable.
No F-SW power output	F-SW handpiece defective	Replace the handpiece.
	Malfunction in control device	Call your Service centre.
No F-SW power output	Handpiece has not been recognised	Check that the blue screw is screwed to the correct tightness.
Shock triggering noise changes after several shocks	Air in handpiece	Hold handpiece vertically with coupling diaphragm downwards so that air is sucked out.

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Accessories

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6.1 Accessories

Product Description	Part Number
Intelect F-SW USA Set incl.	21090-US
– Intelect F-SW USA unit	21095-US
– F-SW Handpiece	19000
– Water bag	4600
– Silicone oil	4700
– Gel bottle	22601
– Stand-off I 30 mm	19100
– Stand-off II 15 mm	19200
– Closing ring	19300
– Operating manual	13-00061-US

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Technical Specifications

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7.1 Chattanooga Intellect F-SW USA

F-SW operating mode	F-SW: Single shock, continuous shock 1–8 Hz
F-SW energy selection	in steps from 0.01 to 0.55 mJ/mm ²
Mains input voltage	100 – 240 VAC
Mains frequency	50 / 60 Hz
Mains fuse	T5AL/250 VAC
Power consumption	max. 450 VA
Ambient temperature during operation	10 – 30 °C
Ambient temperature during storage and transport	0 – 50 °C frost free
Ambient pressure during storage and transport	500 – 1060 hPa
Ambient air pressure during operating	800 – 1060 hPa
Air humidity	5 – 90%, non-condensing
Control device weight	22.1 kg
F-SW handpiece weight	590 g
Housing dimensions (W x H x D)	450 x 165 x 530 mm
Classification according to FDA	class III (FDA)
Protection against the ingress of water	IPX1

F-SW handpiece without stand-off device	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	50 mm
Depth of focal zone	min. 35 - 65 mm
Therapeutically effective penetration depth, 5 MPa	0 - 125 mm

F-SW handpiece with stand-off device I (short)	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	30 mm
Depth of focal zone	min. 15 - 45 mm
Therapeutically effective penetration depth, 5 MPa	0 - 105 mm

F-SW handpiece with stand-off device II (long)	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	15 mm
Depth of focal zone	min. 0 - 30 mm
Therapeutically effective penetration depth, 5 MPa	0 - 90 mm

Subject to technical modifications

<p>NOTE</p> <p>When the medical product is distributed to third parties, the following must be observed:</p> <ul style="list-style-type: none"> - The complete device documentation must be delivered together with the medical product. - The medical product may only be exported to a foreign country when the medical product and the corresponding indications are allowed there.
--

7.2 Type plate



yyyy-mm-dd

T5AL, 250 V

100-240 V~ / 50/60 Hz / 450 VA / IPX1



SN TT.xxxx



(01)GTIN(21)SN(11)PRODDATE
SWISS MADE

Exclusively distributed by:
DJO, LLC

CHATTANOOGA
Intelect F-SW USA

7.3 Conformity with standards

This device complies with the applicable standards EN 60601-1, CAN / CSA-C22.2 No.601.1, UL Std. No 60601-1.

According to EN 60601-1	
- Type of protection against electric shocks:	Protection class 1
- Application unit of Type B	

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EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – emitted electromagnetic interference		
The Chattanooga Intellect F-SW USA model is intended for operation in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intellect F-SW USA should ensure that it is used in such an environment.		
Emitted interference measurements	Compliance	Electromagnetic environment – guidelines
HF emissions according to CISPR 11	Group 1	The Chattanooga Intellect F-SW USA uses HF energy only for its internal functioning. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment. In the sense of EN IEC 60601-2-36:1997 section 36, this information does not apply to the period when pressure pulses are generated and released.
HF emissions according to CISPR 11	Class B	The Chattanooga Intellect F-SW USA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

**Guidelines and manufacturer's declaration –
Resistance to emitted electromagnetic interference**


The Chattanooga Intellect F-SW USA model is intended for operation in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intellect F-SW USA should ensure that it is used in such an environment.

Emissions resistance tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	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 disturbances / bursts according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Chattanooga Intellect F-SW USA requires continued operation during power mains interruptions, it is recommended that the Chattanooga Intellect F-SW USA be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	The mains frequency magnetic fields should be those of a typical business or hospital environment.
NOTE U_T is the mains alternating voltage prior to application of the test level.			

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**Guidelines and manufacturer's declaration –
Resistance to emitted electromagnetic interference**

The Chattanooga Intellect F-SW USA model is intended for operation in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intellect F-SW USA should ensure that it is used in such an environment.

Emissions resistance tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
			<p>Portable and mobile RF equipment should be used no closer to any part of the Chattanooga Intellect F-SW USA, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended safety distance:</p>
Conducted HF interference according to IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms} 150 kHz to 80 MHz	d = 1.2√P
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	<p>d = 1.2√P for 80 MHz to 800 MHz</p> <p>d = 2.3√P for 800 MHz to 2.5 GHz</p>
			<p>Where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m).</p> <p>The field intensity of stationary radio transmitters, based on an on-site inspection ^a, should be less than the compliance level ^b.</p> <p>Interference may occur in the vicinity of instruments marked with the following symbol.</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Chattanooga Intellect F-SW USA is used exceeds the applicable HF compliance level above, the Chattanooga Intellect F-SW USA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Chattanooga Intellect F-SW USA.</p>			
<p>^b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended safety distances between portable and mobile HF communications equipment and the Chattanooga Intellect F-SW USA

The Chattanooga Intellect F-SW USA is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the Chattanooga Intellect F-SW USA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the Chattanooga Intellect F-SW USA as recommended below, according to the maximum output power of the communications equipment.

Rated power of transmitter [W]	Safety distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended safety distance can be estimated using the equation applicable to the frequency of the transmitter, where P is the rated power of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1

An additional factor of 10/3 was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.5 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area inadvertently might lead to a malfunction.

NOTE 2

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

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Warranty and Service

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8.1 Warranty for the Chattanooga Intellect F-SW USA

During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts.

Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.

ATTENTION
Modifications to the system are not permitted.
Any unauthorised opening, repair or modification of the system 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.

8.2 Warranty for the F-SW handpiece

The F-SW handpiece is a wear part. Up to a total of 1 million shocks from the date of delivery of the product to the end customer, we will provide remuneration for demonstrably defective material or defects in workmanship of the F-SW 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.

The coil is a wear part. It is not covered by the handpiece's warranty.

ATTENTION
Modifications to the handpiece are not permitted.
Any unauthorised opening, repair or modification of the handpiece 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.

DJO GLOBAL

UNITED STATES:

T: +1 800 494 3395

E: ChattProductSupport@DJOglobal.com



MOTION IS MEDICINE⁺

Storz Medical AG

Chattanooga Intellect F-SW USA

Patient Information

Extracorporeal Shockwave Treatment for Heel Pain Due to Chronic Proximal Plantar Fasciitis



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

For more information about your treatments, contact:

Dr. Name: _____ **Telephone:** _____

The Chattanooga Intellect F-SW USA is an alternative tradename for the same device, the Storz DUOLITH SD1. The clinical data presented in PMA approval P080028 applies to both tradenames.

Release Date: To be determined.

Storz Medical AG

Chattanooga Intellect F-SW USA

Patient Information Table of Contents

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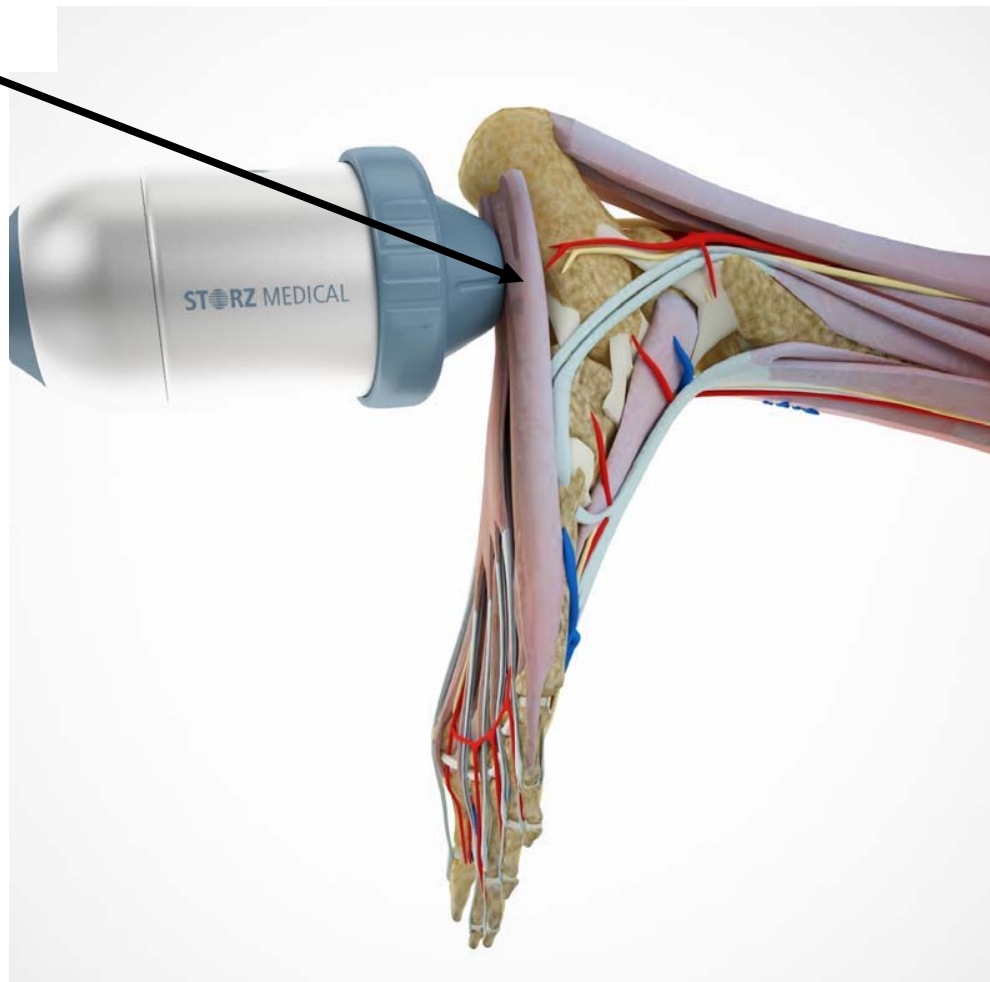
What is extracorporeal shockwave therapy?

“Extracorporeal” means outside the body. Extracorporeal shockwave therapy is the use of shockwaves (usually sound waves) outside the body. This kind of treatment has been used to break up kidney stones from the outside of the body for many years. It is also used to treat heel pain with shockwaves applied to the heel of the foot, but using much lower energy.

What is chronic heel pain syndrome?

“Chronic heel pain syndrome” is the common name of a foot condition with the medical name “chronic plantar fasciitis”. The plantar fascia (shown in the photograph below) is a tissue band that goes from the base of the toes to the heel.

Plantar fascia



Plantar fasciitis is a condition that can come and go. When it happens, the band is inflamed and causes pain on the inner side of the heel and sometimes in the arch of the

foot. You can find out more about chronic plantar fasciitis at most reliable medical websites like www.mayoclinic.com, www.heelspurs.com, or www.aaos.org.

What is the Chattanooga Intellect F-SW USA?

The Chattanooga Intellect F-SW USA is a medical device for the treatment of heel pain using shockwaves. The Chattanooga Intellect F-SW USA has a control unit and a handpiece with a soft cushion at the front end that is used to apply the treatment.

How is the Chattanooga Intellect F-SW USA treatment performed?

The control unit creates an electrical pulse that is sent down to the handpiece where the shockwave is produced and focused by a reflector. Your doctor will apply the cushioned end of the handpiece to the place on your foot where the pain is the greatest.

Because the amount of pain that patients feel can vary quite a bit, your doctor will start the treatment with low energy and slowly increase the energy for a few shockwaves. Once your doctor and you agree that you can tolerate the shockwaves at the right energy, the actual treatment of 2,000 impulses will be applied. If the shockwaves are too uncomfortable, your doctor can inject your heel with local anesthetic to numb the area. Only one (1) patient in the Duolith Group (0.8% of patients) received an anesthetic and only at the first treatment visit (Visit 2).

The full treatment program is three (3) treatment sessions about one (1) or two (2) weeks apart.

Are there any other treatments?

Treatment of heel pain usually starts with conservative non-surgical and non-invasive treatments that have been reported to improve some patients' symptoms over time. These treatments usually start with pain medications like non-steroidal anti-inflammatory drugs (NSAIDs), rest, and heat. Some other treatments that are available include night splints, orthotics, and physical therapy.

Night splints go from your calf and over the bottom of your foot that you wear while you're sleeping. This splint keeps the foot in the right position, keeping the fascia and tendons in the foot slightly stretched.

Off-the-shelf (over the counter) or individually fitted arch supports can cushion and distribute pressure.

Exercises can be used to stretch the plantar fascia and Achilles tendon. These exercises strengthen lower leg muscles. A therapist can also explain and teach you to use taping to support the bottom of the foot.

If these treatments don't work, steroid injections and surgery are also possible treatments.

Steroid injections: Steroid medication is injected into the area where the plantar fascia attaches to the heel bone. These injections sometimes give temporary relief but having repeated injections can weaken the plantar fascia.

Surgery: Surgery is usually the last treatment option and is typically only performed with the pain cannot be relieved with any other treatments. Like any other treatment, surgery is not always successful and can weaken the arch of the foot.

Who could have treatment with the Chattanooga Intellect F-SW USA?

The Chattanooga Intellect F-SW USA is a non surgical alternative indicated for the treatment of heel pain due to chronic plantar fasciitis in patients:

- Who are 18 years of age or older
- Who have had symptoms of proximal plantar fasciitis for 6 months or more
- For whom conservative treatments have not relieved heel pain

Chronic proximal plantar fasciitis is defined as traction degeneration of the plantar fascial band at the origin on the medial calcaneal tuberosity that has persisted for six months or more.

Who should not have treatment with the Chattanooga Intellect F-SW USA (Contraindications)?

The Chattanooga Intellect F-SW USA and other devices like it should not be used in any of the following situations:

- Over or near bone growth center until bone growth is complete
- When a malignant disease is known to be present in or near the treatment area
- Infection in the area to be treated
- Coagulation disorder or taking anti-coagulant medications
- Prosthetic device in the area to be treated
- Over ischemic tissue in individuals with vascular disease

What are the side effects (adverse effects) of treatment with the Chattanooga Intellect F-SW USA?

Side effects (adverse events) were reported by patients in both the Duolith Group and the Placebo Group. In the Duolith Group, a total of 77 events were reported for 43/126 patients (76.2% of 101 adverse events; 34.1% of 126 patients). In the Placebo Group, a total of 24 events were reported for 17/124 patients (23.8% of 101 adverse events; 13.7% of 124 patients). Pain and/or discomfort during or after treatment were reported 60 times in the Duolith Group (60 of 77 events; 77.9%) and 11 times in the Placebo Group (11 of 24 events; 45.8%). Swelling was reported five (5) times in the Duolith Group (5 of 77 events; 6.5%). These differences are logical since patients in the Duolith Group received active shockwave therapy. A variety of other side effects were reported 25 times with 12 reports in the Duolith Group and 13 reports in the Placebo Group. Of these 25 reports, none in the Duolith Group were rated as related to the treatment. In the Placebo Group, however, two (2) events were rated as possibly related (painful heel) and for two (2) events (tendon disorder) the relationship was rated as doubtful.

There were six (6) reports for four (4) patients during the long term follow up period of 12 months. No event was serious but one (1) patient left the study participation during long term follow up (12 months) due to ankle pain.

Other side effects (potential adverse events) reported for other similar devices used for treatment of chronic plantar fasciitis include bruising, collection of blood beneath the skin's surface resulting from internal bleeding (hematoma), temporary or permanent damage to the blood vessels, broken blood vessels visible as red or purple spots on the skin's surface (petechiae), temporary or permanent nerve damage causing decreased sensitivity (hyposthesia) or abnormal skin sensations such as tingling (paresthesia), and rupture of the plantar fascia (tear in the tissue along the bottom of the foot) - a very *rare side effect*.

What results can I expect?

A clinical study of patients with chronic heel pain syndrome who had not gotten relief with conservative treatment was performed. The treatment program was three (3) weekly treatments with the Duolith[®] SD1 or a device that looked like the Duolith[®] SD1 but did not transmit the shockwave (Placebo). Patients and their doctors didn't know which device was being used. On average, patients in the Duolith group had more pain relief (pain scores between their first visit and the 3 month follow up visit decreased about 55%) than patients in the Placebo Group (pain scores between their first visit and the 3 month follow up visit decreased about 40%). Also on average, patients in the Duolith group had better functioning (function scores between their first visit and the 3 month

follow up visit decreased about 1.1 points) than patients in the Placebo Group (function scores between their first visit and the 3 month follow up visit decreased about 0.8 points). Even though some patients treated with the Duolith[®] SDI had good pain relief, some had only a little, and others didn't have any pain relief.

Some patients in both the Duolith Group and the Placebo Group continued to improve after treatments were finished (Duolith Group: 92% (67 of 73 patients); Placebo Group: 84% of patients (43 of 51 patients). At the end of the 3 month follow up, 80% of patients in the Duolith Group said that they would recommend the Duolith[®] SDI therapy to friends while only 60% of patients in the Placebo Group said they would. At the end of the 12 month follow up, 97% of patients in the Duolith Group said that they would recommend the Duolith[®] SDI therapy to friends while only 90% of patients in the Placebo Group said they would.

Where can I get more information?

To get more information about treatment with the Chattanooga Intelect F-SW USA, talk to the doctor whose name and phone number are on the cover of this information.

User Assistance Information

Manufacturer

STORZ MEDICAL AG
Lohstampfstrasse 8
Tägerwilen, Switzerland CH-8274
1(800) 965-4846

US Distributor

DJO, LLC
1430 Decision Street
Vista, CA 92081
USA
T: +1 800 494 3395
E: ChattProductSupport@DJOglobal.com

Physician Labeling

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The Chattanooga Intellect F-SW USA is an alternative tradename for the same device, the Storz DUOLITH SD1. The clinical data presented in PMA approval P080028 applies to both tradenames.

Manufacturer

STORZ MEDICAL AG
Lohstampfstrasse 8
Tägerwilen, Switzerland CH-8274

US Distributor

DJO, LLC
1430 Decision Street
Vista, CA 92081
USA

Release Date: To be determined.

Clinical Application of the Chattanooga Intellect F-SW USA

Indications

The Chattanooga Intellect F-SW USA is indicated for extracorporeal shock wave treatment of heel pain due to chronic proximal plantar fasciitis for patients of age greater than 18 years with a history of failed alternative conservative therapies for at least six months. Chronic proximal plantar fasciitis is defined as traction degeneration of the plantar fascial band at the origin on the medial calcaneal tuberosity that has persisted for six months or more.

Contraindication

- Over or near bone growth center until bone growth is complete
- When a malignant disease is known to be present in or near the treatment area
- Infection in the area to be treated
- Patient has a coagulation disorder or taking anti-coagulant medications
- Patient has a prosthetic device in the area to be treated
- Over ischemic tissue in individuals with vascular disease

Warnings

Treatment using the Chattanooga Intellect F-SW USA should be performed by a physician or licensed medical professional under the direct supervision of a physician who is trained and experienced in the care of patients with foot and ankle and/or lower extremity disorders and who has completed a training course on the use of the Chattanooga Intellect F-SW USA for treatment of heel pain due to chronic proximal plantar fasciitis.

Patients may experience pain/discomfort during and after treatment. To minimize the potential for pain, the working pressure should be slowly increased to a level of 0.25 mJ/mm² during the first 500 impulses. Treatment with analgesics may be appropriate.

Careful positioning of the patient is required to avoid damage to vascular and nerve structures in the treatment area if inadvertently treated with shockwaves.

The Chattanooga Intellect F-SW USA may be sensitive to excessive electromagnetic emissions which could result in device malfunction. Do not perform procedures in close proximity to electrosurgery, diathermy or magnetic resonance imaging equipment.

Precautions

The safety and effectiveness of the Chattanooga Intellect F-SW USA has not been demonstrated in patients with the following conditions/observations:

1. Children less than 18 years of age
2. Inflammation of the lower and upper ankle
3. History of rheumatic diseases, and/or collagenosis and/or metabolic disorders
4. History of hyperthyroidism
5. Paget disease or calcaneal fat pad atrophy
6. Osteomyelitis (acute, sub acute, chronic)
7. Fracture of the Calcaneus
8. Immunosuppressive therapy
9. Long-term (≥ 6 months duration) treatment with any corticosteroid
10. Insulin-dependent diabetes mellitus, severe cardiac or respiratory disease
11. Coagulation disturbance and/or therapy with anticoagulants or antiplatelet agents that may prolong bleeding time
12. Bilateral painful heel, if both feet need medical treatment
13. Previous surgery of the painful heel syndrome
14. Previous unsuccessful treatment of the painful heel with a similar shockwave device
15. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
16. Significant abnormalities in hepatic function
17. Poor physical condition
18. Pregnant female
19. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
20. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.
21. Implanted pacemakers, insulin pumps, defibrillators and/or neurostimulators
22. Open wounds or skin rashes
23. Tendon rupture, neurological or vascular insufficiencies of the painful heel, as assessed using the Semmes-Weinstein Monofilament test and the Ankle Brachial Index

Study Design

The study was a multicenter, randomized, placebo-controlled, prospective, double-blind clinical study enrolling 250 patients (in 1:1 allocation to active treatment with the Duolith[®] SD1 or sham treatment with a device identical to the active device but in which the transmission of the shockwaves to the patient was blocked). The study was conducted to assess the safety and effectiveness of the Storz Duolith[®] SD1 when used to treat unsuccessful conservatively treated patients suffering from painful heel syndrome. For the purpose of this study, painful heel syndrome was defined as chronic proximal plantar fasciitis that had persisted for at least 6 months before study enrollment. The patient and the clinician performing the efficacy assessments were blinded; the clinician administering the treatment (active and placebo) was not. All study procedures for both groups were identical except that of the stand-off used. Active or sham procedures were administered at three (3) treatment visits approximately 1 week apart, with subsequent follow-up visits at 6 weeks, 3 months (Visit 6), 6 months, and 12 months (Visit 8) after the last treatment session. The primary endpoint of comparison between the Duolith Group and Placebo Group is 3 months after the last treatment session (approximately 14 weeks after randomization). Patients considered to be “responders” at the three (3) month follow up, continued to be followed at 6 and 12 months after the last treatment session. A responder is a patient whose heel pain percentage decrease is larger than 60% from baseline at Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurements.

The study was conducted at six (6) clinical sites, all in the United States, with two (2) of the six (6) geographic sites for a single investigator. Therefore, results are based on a five (5) clinical sites.

Adverse Events

A total of 101 adverse events in 250 patients were reported during the main IDE approved clinical study (enrollment through 3-Month follow up (Visit 6)). Adverse events reported for the Duolith[®] SD1 consist primarily of pain or discomfort during and after treatment. Events are summarized by treatment group and event category in the table below.

Summary of Number and Percent (%) of Adverse Events by Category and Treatment Group – Safety Population

Category		Duolith Group (n=126)		Placebo Group (n=124)		Total (n=250)	
		Number of Events	%	Number of Events	%	Number of Events	%
1	Pain and/or Discomfort During Treatment	39	50.7	3	12.5	42	41.6
6	Swelling	5	6.5	0	0.0	5	5.0
7	Pain After Treatment	21	27.3	8	33.3	29	28.7
8	Other	12	15.6	13	54.2	25	24.8
Total		77		24		101	

In the Duolith Group, a total of 77 events were reported for 43/126 patients (76.2% of 101 adverse events; 34.1% of 126 patients). In the Placebo Group, a total of 24 events were reported for 17/124 patients (23.8% of 101 adverse events; 13.7% of 124 patients). Pain and/or discomfort occurring during or after treatment represent 60 events in the Duolith Group (60 of 77 events; 77.9%) and 11 events in the Placebo Group (11 of 24 events; 45.8%). Swelling was observed only in the Duolith Group (5 of 77 events; 6.5%). These differences are logical since patients in the Duolith Group received active shockwave therapy.

As shown in the table above, a total of 25 events were categorized as “other” (Duolith Group: 12 events; Placebo Group: 13 events). These events, their rated intensity, relationship, and seriousness are listed by treatment group in the table below. Of these 25 events, none in the Duolith Group were rated as related to treatment. In the Placebo Group, however, two (2) events were rated as possibly related and for two (2) events the relationship was rated as doubtful.

Listing of Adverse Events by Treatment Group

EVENT DESCRIPTION	INTENSITY	RELATION	SERIOUS
<i>Duolith Group</i>			
BONE FRACTURE SPONTANEOUS	Severe	Not Related	No
FALSE SENSATION	Moderate	Not Related	No
INFLICTED INJURY	Mild	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Severe	Not Related	No
INFLUENZA-LIKE SYMPTOMS	Mild	Not Related	No
NEUROPATHY PERIPHERAL	Mild	Not Related	No
PNEUMONIA	Severe	Not Related	Yes
PYELONEPHRITIS	Severe	Not Related	Yes
SINUSITIS	Mild	Not Related	No
SINUSITIS	Mild	Not Related	No

EVENT DESCRIPTION	INTENSITY	RELATION	SERIOUS
<i>Placebo Group</i>			
BONE FRACTURE SPONTANEOUS	Moderate	Not Related	No
BRONCHITIS	Mild	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Severe	Not Related	No
JOINT PAIN	Severe	Not Related	No
PAINFUL HEEL	Moderate	Possible	No
PAINFUL HEEL	Severe	Not Related	No
TENDON DISORDER	Moderate	Possible	No
TENDON DISORDER	Moderate	Doubtful	No
TENDON DISORDER	Moderate	Doubtful	No
TENDON DISORDER	Moderate	Not Related	No
TOOTH ACHE	Moderate	Not Related	No
UPPER RESP TRACT INFECTION	Moderate	Not Related	No

For adverse events there were 12 events in the Duolith Group (12 of 77; 15.6%) and 13 events in the Placebo Group (13 of 24 events; 54.2%).

Six (6) adverse events were reported for four (4) patients during the long term follow up period of 12 months. No event was serious but one patient discontinued during study participation during long term follow up (12 months) due to ankle pain*. These events are summarized in the Table below.

Adverse Events During Long Term Follow Up (by Treatment Group)

GROUP	REPORTED TERM	INTENSITY	RELATION	SERIOUS
Duolith	Sinus infection, took antibiotics	Moderate	Not Related	No
	Reaction to antibiotics – allergy	Moderate	Not Related	No
	Respiration system infect with Asthma	Moderate	Not Related	No
Placebo	Fracture of 5 metatarsals while vacation	Moderate	Not Related	No
	Patient believes he developed ankle pain*	Mild	Doubtful	No
	Feels ankle hurts from repositioning**	Moderate	Probable	No

*Either non-related, or due to repositioning of ankle during sham treatment

**Repositioning of ankle during sham treatment

Clinical Study

The clinical study used to support approval of the Duolith[®] SD1 for marketing in the United States was a multicenter, randomized, placebo-controlled, prospective, double-blind clinical study enrolling 250 patients (in 1:1 allocation to active treatment with the Duolith[®] SD1 or sham treatment). The study was conducted to assess the safety and effectiveness of the Storz Duolith[®] SD1 when used to treat unsuccessful conservatively treated patients suffering from painful heel syndrome. For the purpose of this study,

painful heel syndrome was defined as chronic proximal plantar fasciitis, or chronic heel spur pain that had persisted for at least 6 months before study enrollment. The patient and the clinician performing the efficacy assessments were blinded; the clinician administering the treatment (active and placebo) was not. All study procedures for both groups were identical except that of the stand-off used. Active or sham procedures were administered at three (3) treatment visits approximately 1 week apart, with subsequent follow up visits at 6 weeks, 3 months (Visit 6), 6 months, and 12 months (Visit 8) after the last treatment session. The primary endpoint of comparison between the Duolith Group and Placebo Group is 3 months after the last treatment session (approximately 14 weeks after randomization). Patients considered to be “responders” at the three (3) month follow up are being followed at 6 and 12 months after the last treatment session (A responder is a patient whose heel pain percentage decrease of heel pain larger is than 60% from baseline at Visit 6 for at least two (2) of the three (3) heel pain (VAS) measurements).

After a screening visit to determine eligibility, the study started at the second visit with the first treatment (after randomization). However, study procedures assigned to the first two (2) visits could be performed at a single visit. Patients were required to meet the following inclusion criteria in order to be enrolled into the study:

1. Age greater than 18 years
2. Ability of patient or legal respondent to give written informed consent after being told of the potential benefits and risks of participating in the study
3. Signed informed consent
4. Diagnosis of painful heel syndrome (i.e., chronic proximal plantar fasciitis) proven by clinical examination. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity
5. 6 months of unsuccessful conservative treatment (i.e., must have undergone at least 2 unsuccessful non-pharmacological treatments and at least 2 unsuccessful pharmacological treatments within the past year). The following conservative treatments could have been completed as single, combined or consecutive treatments:

Non-pharmacological treatments

- Physical therapy (e.g., ice, heat or ultrasound)
- Physiotherapy (e.g., massage and stretching)
- OTC-devices like orthosis, taping and heel pads
- Prescribed orthosis
- Shoe modification like higher heels
- Cast/immobilization
- Night splints

Pharmacological treatments

- External (topical) application of analgesic and/or anti-inflammatory gels
 - Therapy with prescription analgesics and/or NSAIDs
 - Local anesthetic injections
 - Local corticosteroid injections
6. Time gap of at least:
 - 6 weeks since the last corticosteroid injection
 - 4 weeks since the last anesthetic injection; iontophoresis, ultrasound and electromyostimulation
 - 1 week since the last NSAIDs
 - 2 days since the last prescription or non-prescription analgesics, heat, ice, massage, stretching, night splinting and orthosis
 7. Scores of ≥ 5 on the three (3) VAS pain scales
 8. Score of 3 (fair) or 4 (poor) on the Roles and Maudsley Scale
 9. Willingness to refrain from the following painful heel related, concomitant therapy: iontophoresis; electromyostimulation; ultrasound; NSAIDs; steroid injections or surgery until Visit 6 (3 months) of this study (shoe modifications and rescue pain medication are allowed during the entire study)
 10. Willingness to keep a Subject Heel Pain Medication and Other Heel Pain Therapy Diary until 12 months after the last treatment
 11. Females of childbearing potential may be entered if they provide a negative urine pregnancy test immediately before the first ESWT treatment
 12. Willingness of females of childbearing potential to use contraceptive measures for 2 months after enrollment into the study

Patients were excluded from study participation for any of the following conditions/observations:

1. Inflammation of the lower and upper ankle
2. History of rheumatic diseases, and/or collagenosis and/or metabolic disorders
3. Patients with a history of hyperthyroidism
4. Active malignant disease with or without metastases
5. Patients suffering from Paget disease or calcaneal fat pad atrophy
6. Patients suffering from Osteomyelitis (acute, sub acute, chronic)
7. Patients suffering from fracture of the Calcaneus
8. Patients with an immunosuppressive therapy
9. Patients with a long-term (≥ 6 months duration) treatment with any corticosteroid
10. Patients suffering from insulin-dependent diabetes mellitus, severe cardiac or respiratory disease
11. Patients suffering from coagulation disturbance and/or therapy with Phenprocoumon, Acetylsalicylic acid or Warfarin

12. Bilateral painful heel, if both feet need medical treatment
13. Patients who, at entry, are known to have treatment planned within the next 8 weeks, which may abruptly alter the degree or nature of pain experienced such that the extracorporeal shockwave therapy will no longer be necessary (e.g., surgery)
14. Time gap of less than:
 - 6 weeks since the last corticosteroid injection
 - 4 weeks since the last anesthetic injection; iontophoresis, ultrasound and electromyostimulation
 - 1 week since the last NSAIDs
 - 2 days since the last prescription or non-prescription analgesics, heat, ice, massage, stretching, night splinting and orthosis
15. Previous surgery of the painful heel syndrome
16. Previous unsuccessful treatment of the painful heel with a similar shockwave device
17. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
18. Patients with significant abnormalities in hepatic function
19. Patients in a poor physical condition
20. Pregnant female
21. Active infection or history of chronic infection in the treatment area
22. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
23. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.
24. History or documented evidence of worker's compensation or litigation
25. Participation in an investigational device study within 30 days prior to selection, or current inclusion in any other clinical study or research project
26. Patients who, in the opinion of the investigator, will be inappropriate for inclusion into this clinical study or will not comply with the requirements of the study
27. Patients with implanted pacemakers, insulin pumps, defibrillators and/or neurostimulators
28. Patients with prosthetic devices implanted in the area of treatment
29. Patients with open wounds or skin rashes
30. Patients suffering from tendon rupture, neurological or vascular insufficiencies of the painful heel, as assessed using the Semmes-Weinstein Monofilament test and the Ankle Brachial Index

Patients who consented to enrollment were randomized but were blinded to treatment assignment. The treatment was repeated three (3) times approximately one week (\pm 4 days) apart. The study procedures, except for the treatment devices, were the same for all patients. Safety and effectiveness data were analyzed through Visit 6 (3 month follow

up). In general, therapy was performed without local anesthesia. Due to a possible pain sensation caused by the shockwave treatment, the applied energy was increased smoothly from lowest energy level 0.01 mJ/mm² up to a level of 0.25 mJ/mm² within the first 500 impulses. After these 500 introductory impulses, 2000 treatment impulses were performed with the regular working application level of 0.25 mJ/mm². Only one (1) patient in the Duolith Group required local anesthesia at Visit 2 (first treatment visit).

The determination of effectiveness was based on two (2) criteria: a composite score for pain (using a 10 cm visual analog scale) and Roles and Maudsley scores when measured at the 3-month follow up visit (Visit 6). The composite score is the sum of three (3) pain (VAS) measurements for the following:

- Heel pain when taking the first steps of the day
- Heel pain while doing daily activities
- Heel pain after application of a standardized pressure device (F-meter)

Heel pain after application of a standardized pressure device (F-Meter) was based on the patient-specific force level at Visit 2 (first treatment visit). Using this same pressure at subsequent visits, the pain level was assessed using the same anchored VAS pain scales.

The second primary criterion for effectiveness was the four-point Roles and Maudsley-Score (JBJS (Br) 1972; Aug 54 3; 499-508) as follows:

- 1 Excellent (No pain, full movement, full activity)
- 2 Good (Occasional discomfort, full movement and full activity)
- 3 Fair (Some discomfort after prolonged activity)
- 4 Poor (Pain limiting activities)

There were eight (8) secondary criteria for effectiveness criteria as follows: Physician's Global Judgment of Effectiveness, Patient Satisfaction with the Outcome of the Treatment, Patient willingness to recommend treatment as judged by patient, Patient's analgesic medication consumption for painful heel, Heel pain overall success defined as percentage decrease of heel pain larger than 60% from baseline at Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurement, Heel pain single success when taking the first steps of the day, Heel pain single success while doing daily activities, and Heel pain single success after application of a standardized pressure device. The study results for effectiveness were based on the intent-to-treat population consisting of all patients who received at least one treatment and who had at least one

evaluation visit. Missing values were handled using the Last Observation Carried Forward (LOCF) technique.

Safety endpoints were adverse events (type, intensity, severity, relationship to treatment, etc.) and the clinician’s rating of treatment tolerability. The safety population consisted of all patients receiving at least one treatment.

Patients who were defined as having sufficient response to treatment were followed for an additional six (6) months. Criteria for participation in long term follow up were as follows:

- Percentage decrease of heel pain greater than 60% from baseline to Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurements or
- Fulfill three (3) conditions at Visit 6 (3 month follow up): (1) Able to return to work, (2) satisfied with the treatment outcome, and (3) required no concomitant therapy to control heel pain

In addition, all patients with at least one visit at six (6) and 12 months were included in the long term follow up analysis. There were no exclusion criteria.

Summary of Clinical Study Results

Patients were randomized immediately before treatment, with 126 patients assigned to the Duolith Group and 124 patients assigned to the Placebo Group. A total of 17 patients discontinued the study prematurely before Visit 6 (3 month follow up) (Duolith Group: 7 patients, Placebo Group: 10 patients). Reasons for premature discontinuation are summarized by treatment group below.

Reasons for Premature Discontinuation of Patients in the Safety Population (by Treatment Group)

Reason for Premature Discontinuation	Duolith Group (N=126)	Placebo Group (N=124)	Total (N=250)
Worsening of condition	2 (1.6%)	4 (3.2%)	6 (2.4%)
Adverse Event	2 (1.6%)	1 (0.8%)	3 (1.2%)
Worsening of condition and Adverse Event	1 (0.8%)	2 (1.6%)	3 (1.2%)
Administrative Reason	0	2 (1.6%)	2 (0.8%)
Lost to follow-up	2 (1.6%)	1 (0.8%)	3 (1.2%)
Total	7 (5.6%)	10 (8.1%)	17 (6.8%)

Results for the primary effectiveness criteria are statistically significant ($P < 0.025$ one-sided). All sensitivity analyses agreed with confirmatory results and showed statistical significant results. The same trend was demonstrated across study centers. A tabular summary of changes in the median VAS composite score of heel pain and changes in the Roles and Maudsley Score is provided below.

The intent-to-treat (ITT) population consisted of all subjects who received at least one treatment and who had at least one evaluation visit. Missing values were handled using the Last Observation Carried Forward (LOCF) technique.

Summary Comparison of Baseline and Visit 6 (3 Month Follow Up) Composite VAS for Pain with Score Correction* by Treatment Group – ITT Population (LOCF)

COMPOSITE VAS	DUOLITH GROUP (N=125)			PLACEBO GROUP (N=121)		
	Baseline	Visit 6	Change (%)	Baseline	Visit 6	Change (%)
Mean	8.38	3.80	-54.53	8.38	5.01	-40.31
Median	8.30	2.70	-69.20	8.30	5.30	-34.50
SD	0.996	3.247	38.495	1.016	3.400	39.968
Min	5.30	0.00	-100.00	5.30	0.00	-100.00
Max	10.00	10.00	43.80	10.00	10.00	37.50

**Score correction for interfering analgesic therapy as defined in the statistical analysis plan*

Using the Wilcoxon-Mann-Whitney, one-sided test for superiority, the results of the Duolith Group were determined to be superior to the Placebo Group ($P = 0.0027$ one-sided, $MW = 0.6026$, $LB-CI = 0.5306$).

The mean Roles and Maudsley score was reduced from 3.6 to 2.5 in the Duolith Group and from 3.7 to 2.9 in the Placebo Group, with a final group difference for Roles and Maudsley scores of 0.4 in favor of the Duolith Group.

Comparison of Baseline and Visit 6 (3 Month Follow Up) Roles and Maudsley Scores with Score Correction* by Treatment Group – ITT Population (LOCF)

COMPOSITE VAS	DUOLITH GROUP (N=125)			PLACEBO GROUP (N=121)		
	Baseline	Visit 6	Change	Baseline	Visit 6	Change
Mean	3.6	2.5	-1.1	3.7	2.9	-0.8
Median	4.0	2.0	-1.0	4.0	3.0	-1.0
SD	0.49	0.94	1.02	0.48	0.97	0.92
Min	3.0	1.0	-3.0	3.0	1.0	-3.0
Max	4.0	4.0	1.0	4.0	4.0	1.0

**Score correction for interfering analgesic therapy as defined in the statistical analysis plan*

Using the Wilcoxon-Mann-Whitney, one-sided test for superiority, the results for the Duolith Group were determined to be superior to the Placebo Group (P = 0.0006 one-sided, MW = 0.6135, LB-CI = 0.5466).

A tabular summary of the results for secondary effectiveness criteria are summarized below.

Summary of Secondary Effectiveness Results by Treatment Group

SECONDARY EFFECTIVENESS CRITERION	RATING/RESULT	DUOLITH GROUP NUMBER OF PATIENTS (% OF PATIENTS)	PLACEBO GROUP NUMBER OF PATIENTS (% OF PATIENTS)
Investigator's Global Judgment of Effectiveness at Visit 6	Very good	46 (38.66%)	41 (35.96%)
	Good	42 (35.29%)	21 (18.42%)
	Moderate	11 (9.24%)	11 (9.65%)
	Unsatisfactory	11 (9.24%)	16 (14.04%)
	Poor	9 (7.56%)	25 (21.93%)
Patient's global judgment of therapy satisfaction	Very unsatisfied	9 (7.56%)	18 (15.79%)
	Moderately unsatisfied	13 (10.92%)	20 (17.54%)
	Less satisfied	6 (5.04%)	9 (7.89%)
	Neutral	15 (12.61%)	18 (15.79%)
	In general satisfied	19 (15.97%)	11 (9.65%)
	Satisfied	29 (24.37%)	17 (14.91%)
Patient's recommendation of therapy to a friend	Very satisfied	28 (23.53%)	21 (18.42%)
	Yes	95 (79.83%)	68 (59.65%)
Heel Pain Overall Success (larger than 60% from baseline at Visit 6 (3 month) for at least two (2) of the three (3) heel pain (VAS) measurements)	No	24 (20.17%)	46 (40.35%)
	Success	68 (54.40%)	45 (37.19%)
Heel pain single success when taking first steps of the day (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	57 (45.60%)	76 (62.81%)
	Success	63 (50.40%)	44 (36.36%)
Heel pain single success while doing daily activities (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	62 (49.60%)	77 (63.64%)
	Success	62 (49.60%)	47 (38.84%)
Heel pain single success after application of a standardized pressure device (F-meter) (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	63 (50.40%)	74 (61.16%)
	Success	67 (53.60%)	51 (42.15%)
Frequency count of patients with <u>at least one</u> concomitant analgesic therapy during the study	Failure	58 (46.40%)	70 (57.85%)
	No	32 (25.60%)	35 (28.93%)
	Yes	93 (74.40%)	86 (71.07%)

The clinician's judgment of treatment tolerability (a safety endpoint) was rated as "very good" or "good" in 89.1% (106/119) of the patients in the Duolith Group and in 91.2% (104/114) patients in the Placebo Group at Visit 6. However, 74.4 % (n=93 patients) of the Duolith Group and 71.1% (n=86patients) in the Placebo Group required one or more concomitant analgesic medications during the study. The difference between the two (2) treatment groups for tolerability was only 2.1 percentage points in favor of the Placebo Group. (P = 0.1434, two-sided Wilcoxon-Mann-Whitney test, MW = 0.4522, LB-CI = 0.3888).

The results of the multi-center, randomized, placebo-controlled, double-blind clinical study demonstrate that treatment of heel pain due to chronic proximal plantar fasciitis with the Storz Duolith[®] SD1 provides relief for up to 12 weeks duration in a significant proportion of the patient population who have previously failed conservative treatment for a period of at least 6 months. The most likely side effect is pain during/after treatment which was reported by 50.7% of patients in the Duolith Group and 41.6% of patients in the Placebo Group. On average, patients in the Duolith group had more pain relief (pain scores decreased about 55%) compared to patients in the placebo group (pain scores decreased about 40%) between the first visit and the 3 month follow up visit. For this study 74.4% of the Duolith Group and 71.1% of the Placebo Group required one (1) or more concomitant analgesic therapy during the study.

Product Complaints

Product complaints should be reported to Storz Medical at one of the following telephone numbers:

Karl Storz Lithotripsy-America, Inc., Service phone No. (800) 965-4846

DJO, LLC

T: +1 800 336 6569