chattanooga™

Moving Rehabilitation Forward

Focus Shockwave Operating Manual

Rx only

DJO® GLOBAL

MOTION IS MEDICINE®

Contents

Introduction

This operating manual contains certain types of text design intended to assist you in comprehending the significance of the text based on its appearance.

Instructions for actions

- This text instructs you in how to operate your device correctly.
  - This text subdivides an action into steps or comments on the action step.

⇨ *This text shows the result of an action.*

Lists

– This text is part of a list.

Menus and buttons

Names of MENUS and BUTTONS are greyed out and highlighted in small caps.

The operating procedure descriptions also contain references to the buttons that you have to press and what you can expect to see in the text.

Cross references to other chapters

Cross references to other chapters are highlighted in bold and in small caps.

Warning notes

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.

DANGER

The source of the danger is stated here.

These are the possible consequences!

► The instructions for avoiding the danger are given here.

WARNING refers to a situation of potential danger which, if not avoided, could lead to serious injury.

WARNING

The source of the danger is stated here.

These are possible consequences!

► The instructions for avoiding the danger are given here.

CAUTION indicates that incorrect operation could lead to minor injuries.

⚠ CAUTION

The source of the danger is stated here.

These are the possible consequences!

► The instructions for avoiding the danger are given here.

NOTICE indicates that incorrect operation could lead to damage to the device.

NOTICE

The source of the danger is stated here.

These are possible consequences!

► The instructions for avoiding the danger are given here.

Other instructions

This text indicates additional information concerning special features, etc. and/or operating instructions.

Safety signs and other symbols used in this manual

Symbol	Notification
	General warning sign
	Type B applied part
	Potential equalisation
	Disconnect mains plug
	Wear hearing protection
	USB connection

Symbol	Notification
	WEEE mark
	Manufacturer
	MR unsafe
	Device serial number
	CSA certification mark
	It is essential to comply with the operating manual
	Fuse
	Electromagnetic interference may occur in the vicinity of instruments marked with this symbol.
	Hot surface
	Explosion
	Electrical warning sign: high voltage

1 General Safety Information

The following chapter contains all safety information that has to be followed when working with the Chattanooga Intelect F-SW USA.

⚠ WARNING

Incorrect handling of the device

Possibility of injuries to the patient and the operating personnel!

- ► Read this chapter carefully before you start using the Chattanooga Intelect F-SW USA.
- ► Read the separate operating manuals for all devices associated with the Chattanooga Intelect F-SW USA.

⚠ CAUTION

Rx only
Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practises to use or order the use of the device.

1.1 Instructions for safe use

1.1.1 Intended Use and Operational Safety

To use this device in accordance with its intended use, the user must possess the necessary technical proficiency, and knowledge of the operating manual.
The device is intended exclusively for use by healthcare professionals who have been trained to use the device (see also **2.2 PRECONDITIONS FOR OPERATION**).
The device is only allowed to be used for the applications described in chapter **2.1.1 INDICATIONS**. Only perform treatments approved by the manufacturer!
Furthermore, the device is only allowed to be operated by trained personnel who comply with the preconditions for operation in the chapter **2.2 PRECONDITIONS FOR OPERATION**.
All status and error messages signaled during treatment must always be attended to without delay.

While applying focused shockwaves at maximum adjustment, do not use more than 6.000 subsequent shocks and stick to a consecutive break of 5 minutes.

Checks and inspections prior to treatment

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

- It is essential to perform the functional checks after switching on the Chattanooga Intelect F-SW USA, before starting treatment. Read about this in Chapter **5.14 FUNCTIONAL CHECKS**.
- Have the maintenance procedures recommended by the manufacturer carried out by personnel suitably authorised. Read about this in Chapter **6.7 MAINTENANCE AND SAFETY CHECKS**.

No treatment is permitted if a display on the control device or a touch screen fails.

Protection against electrical hazards

Sources of voltage can give rise to currents as a result of body resistance, which not only flow through the patient but can also impair or even endanger the personnel administering the treatment.

- Devices that are not medical products in accordance with EN 60601 must be set up outside the patient environment.
- Do not touch electrical connectors while you are touching the patient.
- Disconnect the Chattanooga Intelect F-SW USA from the mains plug before starting any cleaning or maintenance work.
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect it until everything has been completely reassembled.
- Do not try to open the device! Risk of electric shocks!
- Always connect the potential equalisation connector of the Chattanooga Intelect F-SW USA in accordance with national guidelines.

Protection against high voltage

High-voltage components are identified as follows:

DANGER

Contact with high-voltage parts:

Severe or fatal injury!

- ► Only operate the device if the housing is intact and closed
- ► Work in the area of high voltage is only allowed to be performed by personnel suitably authorised by the manufacturer.

Protection against noise

The noise level during administration of shockwaves is within the safe range. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

Protection against explosion

The device is not allowed to be used in potentially explosive atmospheres (according to classification AP and APG of IEC 60601-1) i.e. in the reach of anesthetic gas mixtures with air, oxygen or nitrogen oxide.

DANGER

Risk of explosion due to flammable and explosive materials

Injuries to patients, people administering the treatment and third parties!

- ► During operation, avoid using the substances specified in the following section.
- ► Switch off the device before cleaning and disconnect the mains plug.
- ► Comply with the information on cleaning in Chapter **6 CLEANING, CARE AND MAINTENANCE**

The following agents are NOT to be used during operation:

- Highly inflammable and potentially explosive inhalation anaesthetics and mixtures of the same, such as
  - Ether pro narcosi (diethyl ether)
  - Cyclopropane.
- Inflammable, highly volatile skin cleaning agents and skin disinfectants which can form a potentially explosive atmosphere, such as
  - Washing ether
  - Petrol ether.

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

1.1.2 Safety during treatment of the patient

General note:

- Organs with gas inclusions, in particular parts of the lung, are NOT allowed to be exposed to shock waves.
- As it passes through tissue, the shock wave's energy is slightly reduced; this reduction is significantly weakened by the bone structure.
- Shock waves can give rise to undesirable heart reactions. The patient must be continuously observed during the treatment and attention must be paid to any reactions experienced by the patient.
- The patient must not be under anaesthetic.
- Only perform treatments approved by the manufacturer!
- The user is responsible for correctly positioning the handpieces and correctly selecting the treatment zone.
- Air bubbles reduce the effectiveness of shock waves. Therefore, air bubbles must always be removed from the shock wave path.
- Risk of transmission of microorganisms! Disinfect the handpiece after each use! For information about this, see **6 CLEANING, CARE AND MAINTENANCE**.

While applying focused shockwaves at maximum adjustment, do not use more than 6.000 subsequent shocks and stick to a consecutive break of 5 minutes.

1.1.3 Warning against damage to equipment and the device

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

Electromagnetic compatibility

This device complies with the requirements of the applicable standard on electromagnetic compatibility.

Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones), including antennas, can interfere with medical electrical equipment. They should not be used less than 30 cm from the device - including the cables specified by the manufacturer.

This device is subject to special precautions regarding EMC and needs to be installed according the EMC guidelines in chapter **9.2.2 EMC GUIDELINES AND MANUFACTURER'S DECLARATION**

The use of accessories or cables that are not authorised by the manufacturer can result in increased interference emissions or reduced resistance to interference emissions by the device.

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

The device is not to be used within an MR environment. Within proximity of the device to an Magnetic Resonance source device disturbances may occur. In case of disturbance consider repositioning of the device.

DANGER

Improper connection:

There is a risk of electric shock!

- ► Do not connect the device to a power supply network unless it has a protective conductor.
- ► Never use multi-socket power strips.

Please read Chapter **9.2.2 EMC GUIDELINES AND MANUFACTURER'S DECLARATION**.

If the Chattanooga Intelect F-SW USA is connected to a 240 V mains supply with a mains frequency of 60 Hz, the mains supply must be balanced.

Setup and operation

There are ventilation slits on the device which must not be covered by other objects.

- Check that the installation surfaces have sufficient carrying capacity to avoid equipment damage!
- Check that the device is in perfect working order before each use. Read about this in Chapter **5.14 FUNCTIONAL CHECKS**.
- Never cover the device when in use!
- Make absolutely sure that no liquid can seep into the system housing or handpiece.

Storage and transport

Incorrect storage and transport can result in damage to the device and device failure.

- Completely empty the water circuit and the handpiece before you transport the device or put it into storage.

  Otherwise, there is a risk of the water freezing, which will lead to damage. Please contact your responsible Service centre if this does happen.
- Comply with the ambient conditions specified in Chapter **9 TECHNICAL SPECIFICATIONS**.
- Make sure that no cables are crushed or sheared.
- Make sure that the handpiece cable is not kinked.
- Do not pull on the handpiece or its cable in order to move the device.
- Always disconnect the handpiece from the control device properly.

Disposal

- Comply with national disposal regulations when disposing of the Chattanooga Intelect F-SW USA or individual components.
- Comply with the relevant information in the operating manuals for the additional devices.

1.2 Manufacturer`s Responsibility

⚠ WARNING

No modifications are to be made to this device without the permission of the manufacturer.

The manufacturer of the Chattanooga Intelect F-SW USA is only responsible for the impact of its product on safety, reliability and performance if:

– maintenance of the device is performed at the intervals specified by the manufacturer
– installation, expansions, conversions, new installations, modifications or repairs are performed by people authorised by the manufacturer
– the electrical installation in the rooms in question corresponds to the requirements of DIN/IEC
– the device is used in compliance with the operating manual

The periodic maintenance measures specified by the manufacturer must be performed on schedule by personnel suitably authorised. Original parts from the manufacturer must be used; otherwise, the manufacturer's liability shall be rendered null and void.

1.3 Owner`s Responsibility

The owner is responsible for complying with the relevant national statutory provisions governing setting up and operating technical medical equipment. It is expressly stated that the use of unauthorised accessories and/or unauthorised equipment combinations shall render the product liability null and void.

The device is exclusively allowed to be used with accessories, wearing parts and disposable articles that have been checked by the testing body responsible for testing the device to ensure that they function without risk.

2 Principles

2.1 Physical principles

The Chattanooga Intelect F-SW USA is a universal, compact shock wave generator that generates focused shock waves – hereinafter referred to as F-SW .

The Chattanooga Intelect F-SW USA may be used to perform the following treatments:

- Low-energy focused shock wave therapy with electromagnetically generated shock waves (energy levels below 0.3 mJ/mm^2)
- High-energy focused shock wave therapy with electromagnetically generated shock waves (energy levels above 0.3 mJ/mm^2)

The F-SW have a short pulse length and are concentrated on areas a few millimetres in diameter, allowing shock waves to be applied to a tightly localised area, even in deeper tissue layers.

2.1.1 Indications

The Chattanooga Intelect 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.

2.1.2 Contraindications

- Treatment 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 effects (e.g. foot ulcers, venous stasis, etc.)

⚠ CAUTION

Shock waves must not be applied to target areas located above air-filled tissue nor to any regions near large nerves, vessels, the spinal column or head (except in the facial area).

2.1.3 Side effects

⚠ CAUTION

After treatment with the Chattanooga Intelect F-SW USA

side effects may occur.

- ► Familiarise yourself with the list of side effects.
- ► Inform the patient of possible side effects.

Treatment with the Chattanooga Intelect F-SW USA may cause the following side effects:

- Swelling, reddening, haematomas
- Petechiae
- Pain

These side effects generally abate after 5 to 10 days.

2.1.4 Warnings

Treatment using the Chattanooga Intelect 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 Intelect 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/mm^2 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.

Certain sources of EMI, such as electrosurgery, diathermy or magnetic resonance imaging equipment or similar sources, may exceed the EMC of the Chattanooga Intelect F-SW USA.
Install and operate Chattanooga Intelect F-SW USA no closer than 1 m to EMI sources such as
electrosurgery, diathermy or other medical devices producing excessive radiation during operation.

2.1.5 Precautions

The safety and effectiveness of the Chattanooga Intelect 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

2.2 Preconditions for operation

2.2.1 Operating personnel

DANGER

If treatments and medical procedures are performed by inadequately qualified personnel,

this can result in damage to the health of patients and third parties as well as fire or explosion hazards.

- ► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.
- ► Observe the preconditions for operation that are detailed in this chapter.

The Chattanooga Intelect F-SW USA is intended exclusively for use by healthcare professionals who have been trained to use the device.

It is expected that this professional has practical knowledge of medical procedures and applications as well as of the terminology and should be experienced in treating the indications stated in Chapter **2.1.1 INDICATIONS**.

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

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

2.2.2 Training of the operator

Operators of the Chattanooga Intelect F-SW USA must have been adequately trained in using this device. An introduction to the principles of operation will be provided by your dealer with reference to this operating manual and will be documented in the system logbook.

The operator must be instructed in the following points :

- Operation and intended use of the device with practical exercises
- Mechanism of action and function of the device and the energies delivered by it
- All component settings
- Indications for use of the device
- Contraindications and side effects
- Explanation of the warnings in all operating modes/states
- Training on 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 about training in the operation of this system can be obtained from your dealer. You can also contact the following address directly:

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

T: + 1 800 494 3395
E: ChattProductSupport@djoglobal.com

3 System description

3.1 Control and functional elements

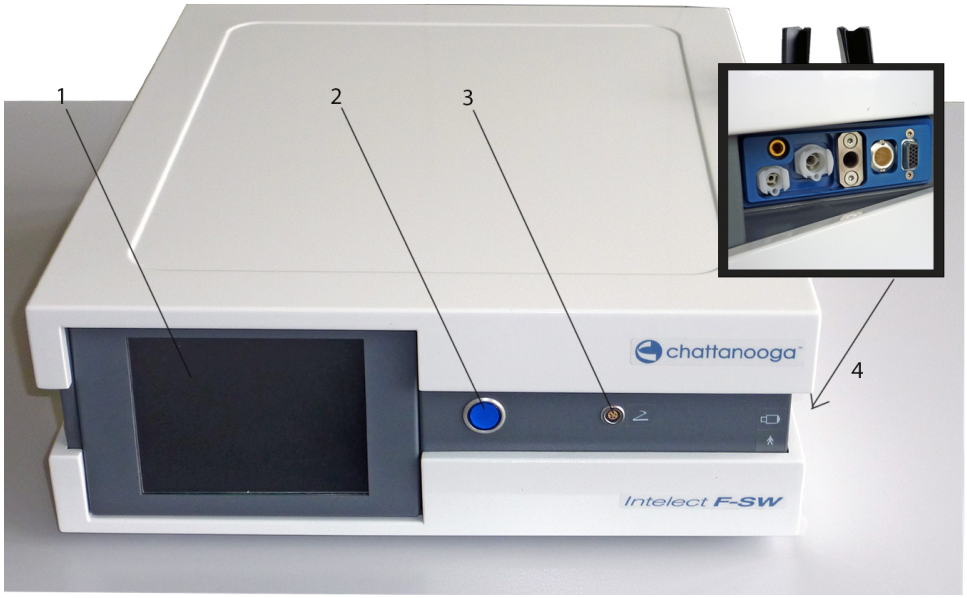


Fig. 3-1 Front view of Chattanooga Intelect F-SW USA

1 Monitor
2 Power indicator
3 Connection for foot switch
4 F-SW handpiece connection

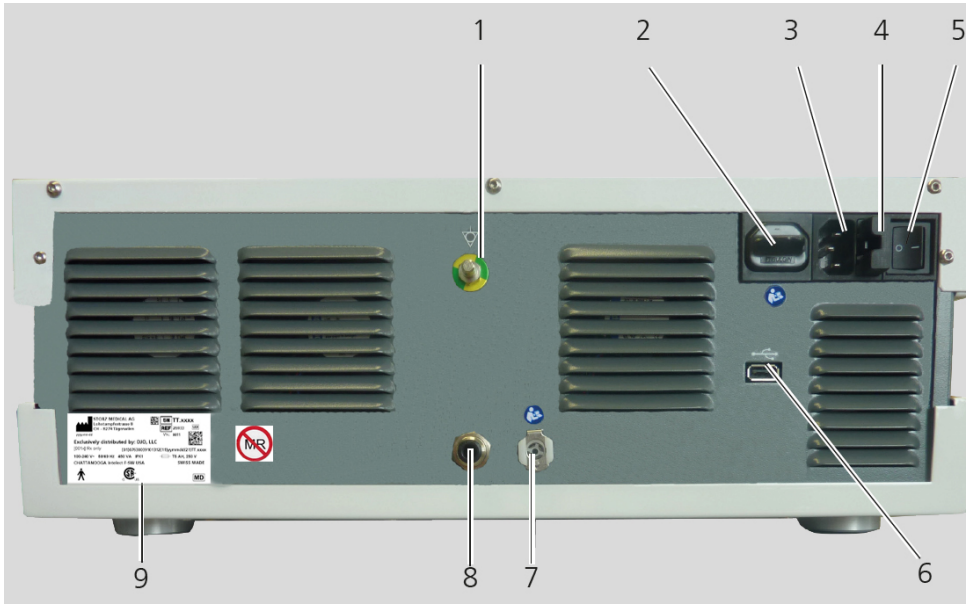


Fig. 3-2 Rear view of Chattanooga Intelect F-SW USA

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
7 Water supply connection
8 not used
9 Type Plate

The following instruments can be connected to the USB connection:
USB memory stick which supports the USB V1.1 protocol
USB mouse
USB keyboard.

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

3.2 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.

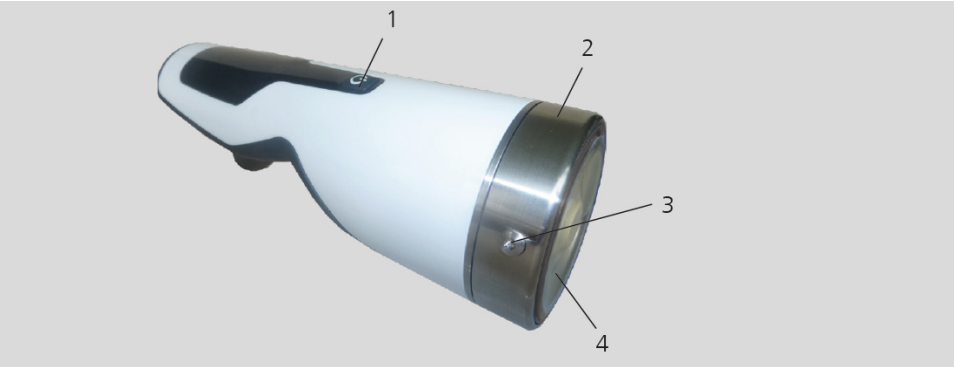


Fig. 3-3 F-SW handpiece

1 Trigger button
2 Clamping ring
3 Fixing screws
4 Coupling diaphragm

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.

3.3 Use of stand-off devices

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

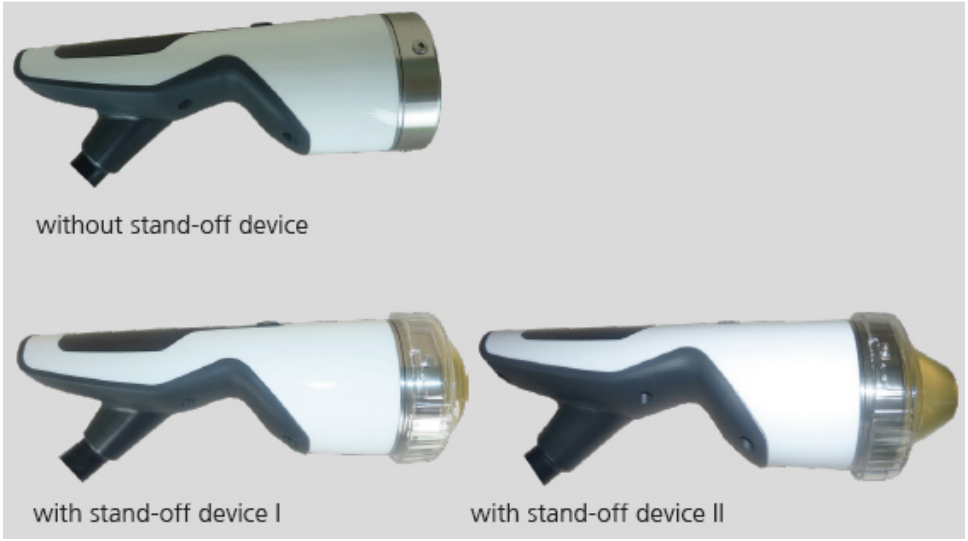


Fig. 3-4 F-SW handpiece

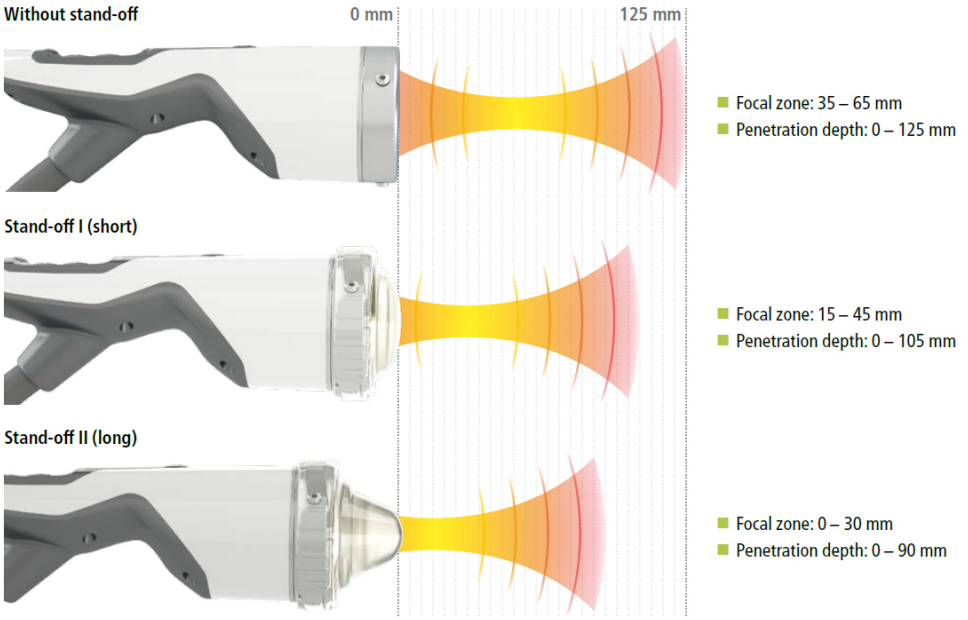


Fig. 3-5 Depth of therapeutical effect of F-SW handpiece

- Perform changing of the stand-off devices as described in chapter **6.2.1 CHANGING THE STAND-OFF DEVICE**.

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.

4 Installation Instructions

4.1 Scope of Supply

The standard scope of supply of the Chattanooga Intelect F-SW USA includes the following items:

- Chattanooga Intelect F-SW USA control device
- F-SW SEPIA LT handpiece
- Handpiece holder
- Mains cables
- Gel bottle
- Silicone oil bottle
- Water bag
- User manual

Please refer to chapter **8 ACCESSORIES** for information on optional accessories.

4.2 Unpacking

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Remove the device and accessories from the packaging container. Proceed with extreme caution.
- 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 delivered items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

4.3 Correct Positioning of the Device

Maintain a minimum distance between the device and the wall so that the mainsplug can be pulled out without restrictions (disconnected from the power supplynetwork) and the ventilation slits on the rear are not blocked.

4.4 Installing the handpiece holder

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 holder onto the right side wall of the Chattanooga Intelect F-SW USA, as shown in the picture below.

Fig. 4-1 Mounted handpiece holder

1 Handpiece holder mounted to right side wall

4.5 Installing the holding arm

To facilitate handling of the F-SW handpiece, you can hook the handpiece onto the optionally available holding arm.

- 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 (see picture below).

Fig. 4-2 Attachment holes for the holding arm

- Place the holding arm into the holder.

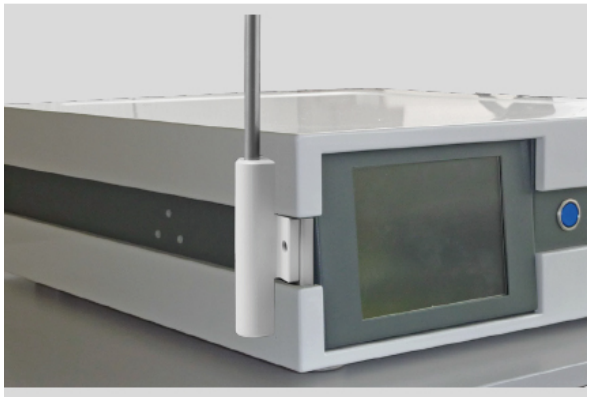


Fig. 4-3 Holding arm attached

4.6 Connecting the electrical power supply

DANGER

Improper connection:

There is a risk of electric shock!

- ► Do not connect the device to a power supply network unless it has a protective conductor.
- ► Never use multi-socket power strips.

- Connect the mains cable to the mains connector on the rear of the device (see **3.1**).
- Insert the mains cable into the electrical socket.

NOTICE

- ► Maintain a minimum distance between the device and the wall so that the mains plug can be pulled out without restrictions (disconnected from the power supply network) and the ventilation slits on the rear are not blocked.

4.7 Connecting Handpiece

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

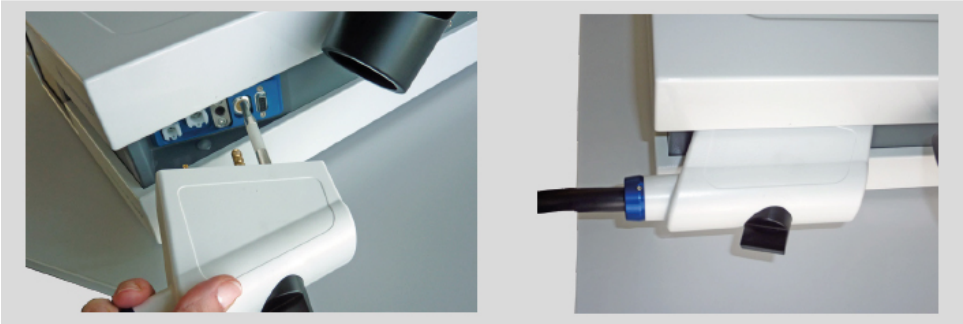


Fig. 4-4 Connecting the F-SW handpiece

Fill the water circuit of the Chattanooga Intelect 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.

4.8 Connecting an optional foot switch

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

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

4.9 Potential equalisation connector

The Chattanooga Intelect F-SW USA features a potential equalisation connection.

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

⚠ CAUTION

Risk of

electrical hazard.

► Always connect the potential equalisation connector in accordance with national guidelines.

4.10 USB connection

The USB connection acts as an interface for data input and output.

- Connect if required

– a USB memory stick which supports the USB V1.1 protocol
– a USB mouse
– a USB keyboard.

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

⚠ CAUTION

Misuse of the USB connector may cause

malfunction of or damage to the device.

► The use of USB connector not authorized by the manufacturer is not permitted.

► Do not connect any wireless technology such as bluetooth and do not connect any devices for battery charging.

4.11 Transport

NOTICE

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).

Make sure that your hands are dry and free of grease.

- Dismount the handpiece holder before transporting the device.
- To transport the instrument, grip the indentations on the side of the housing as shown in the picture below (1) and lift it carefully.

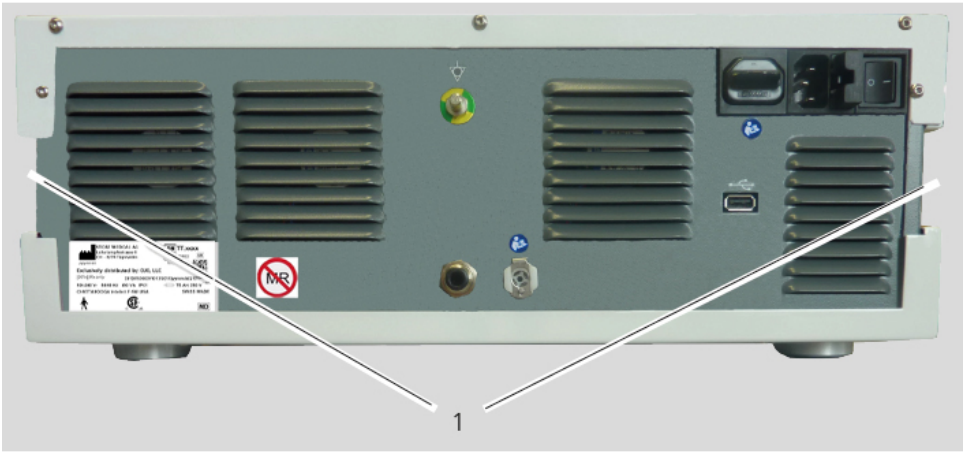


Fig. 4-5 Transporting the device

- Set the device slantly down in order to avoid squeezing the fingers.

4.12 Compatibility

The Chattanooga Intelect F-SW USAis allowed to be operated with the following accessories:

Handpiece F-SW SEPIA LT	Art no. 19000
Foot switch	

5 Operation

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

5.1 Graphical user interface

The user interface of the Chattanooga Intelect F-SW USA is divided into various areas for displaying different information. The individual controls are arranged in function groups (see picture below):

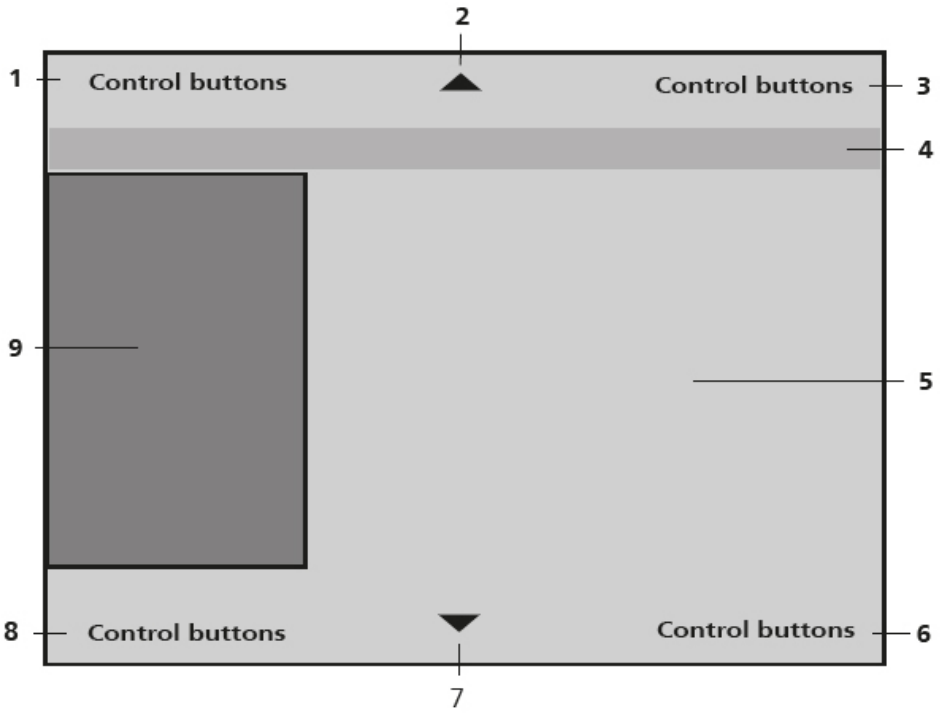


Fig. 5-1 Controls

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

The following functional description refers to control software version 13441.19.x.x or later (this can be seen in the Info menu).

Navigation bars:

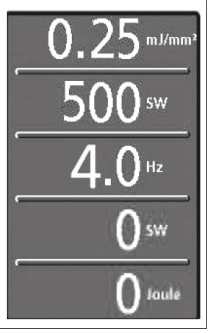
The top and bottom navigation bars (see **FIG. 5-1 CONTROLS**) contain control buttons that you can use for navigating through the menus:

Parameter entry screen

MENU	Open the sub-menu
CONFIGURATION	Jump to the LOAD CONFIGURATION sub-menu (call up saved parameter configurations or patient records)
Main and sub-menu	
BACK	Step back
MENU EXIT	Return to parameter entry screen
DELETE	Delete configurations
SAVE	Save configurations
OK	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.
	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 in the following sequence:

F-SW	
Actual energy level in mJ/mm² or in MPa	
Nominal number of shocks or nominal total energy	
Actual frequency	
Actual number of shocks	
Actual total energy in J	

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 (see picture below) of the parameter entry screen contains the nominal value selection fields “Energy level”, “Number of shocks” and “Frequency”

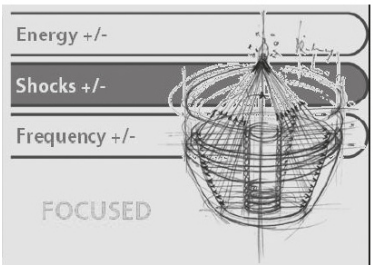


Fig. 5-2 Parameter entry screen

- 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.
- 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. 5-3** /1).
- If there are more than 4 menu items, they can be selected using the arrow keys (**FIG. 5-3** /2). 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

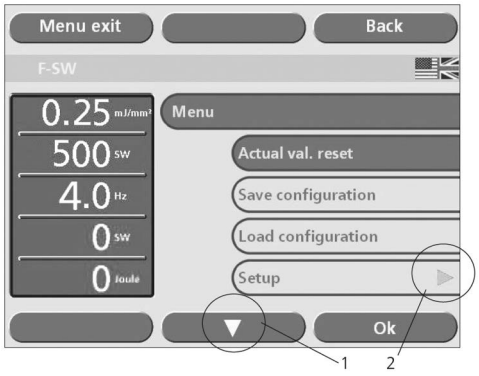


Fig. 5-3 List of the sub-menu items

5.2 Function overview

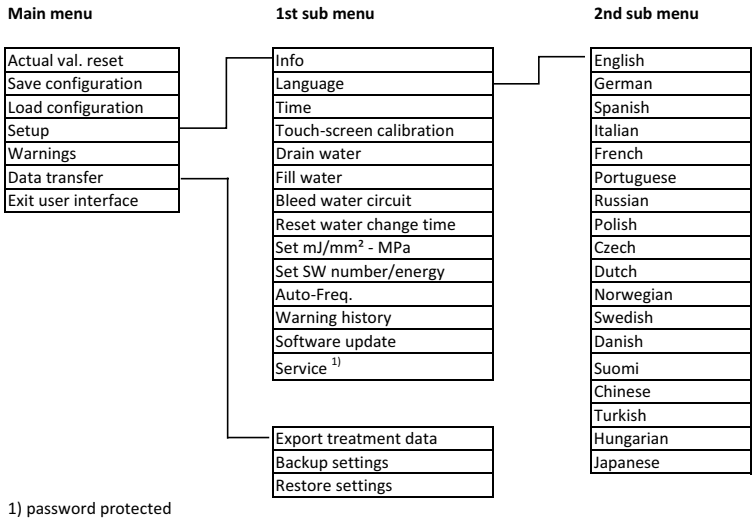


Fig. 5-4 Menu overview

1) password protected

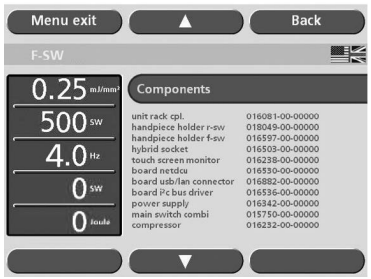
Parameter entry window	–	Determining the treatment parameters

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.
Warnings	–	List of current warnings
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 / Filling the water circuit	–	The corresponding sequences for emptying or filling the water circuit are activated.
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.

5.3 Starting the instrument

- Switch the control device on or off at the mains switch on the rear (see **3.1**).

  The device is operated via the touchscreen display.

⚠ WARNING

If a control panel display or a touchscreen / operating monitor should fail, the safety of the patient can no longer be ensured

Risk of patients being placed under strain due to ineffective treatment or even impairments to their health!

► Abort the treatment.

► Inform your service centre.

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 device is operated via the touchscreen display.

⇨ *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 **6.3.2 FILLING THE WATER CIRCUIT**

Warm-up phase

Once a day, the Chattanooga Intelect F-SW USA starts a warm-up phase lasting about 3 minutes, the progress of which is shown in the progress indicator.
The water circuit is bled.

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

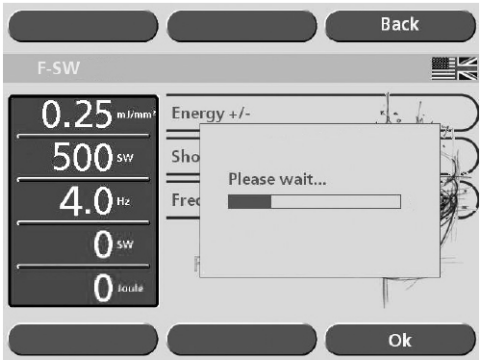


Fig. 5-5 Warm-up phase

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

High voltage test

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

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

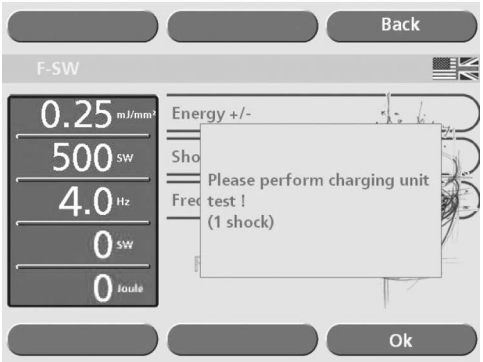


Fig. 5-6 High voltage test

5.4 Setting 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.
  ⇨ *The treatment will be carried out with the displayed values*
  The maximum possible frequency for generating shock waves depends on the selected energy level. When increasing the energy level, the shock wave frequency is reduced if necessary.

The selection of energy levels is based on the medical opinion of the healthcare professional administering treatment. The treatment must never be allowed to cause the patient to experience any excessive amount of pain.

F-SW

Energy flux density in mJ/mm^2	Maximum frequency Handpiece
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
0.12	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

Tab. 5-1 Treatment parameters in F-SW mode

The maximum possible frequency with which shock waves are generated depends on the selected energy level (see tables below and next side). Increasing the energy level may reduce the therapy wave frequency.

5.5 F-SW energy display task

To make sure that the energy level is correctly displayed at all times, the system includes a self monitoring function. Therefore, during shockwave release the system constantly compares the nominal energy value with the actual energy value. If these values do not match the energy level is displayed in grey and turns white as soon as the required set value is reached.

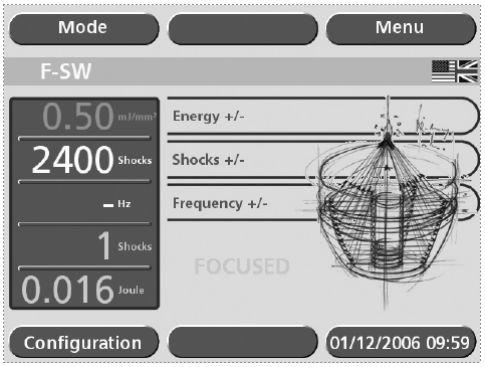


Fig. 5-7 Energy level not yet reached

If the difference persists shock wave release is disabled and an error message is displayed.

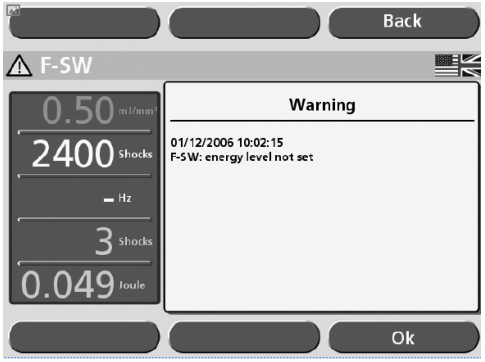


Fig. 5-8 Error: Energy level not set

In case the warning appears, you can acknowledge it by touching OK. Inform your service centre if the fault continues.

5.6 Store treatment notes

- Touch the MENU button.
- Select the SAVE CONFIGURATION function as shown in the picture below to save the current setting of the treatment parameters (**FIG. 5-9 STORING THE TREATMENT PARAMETERS**/1).
- Touch the OK button.

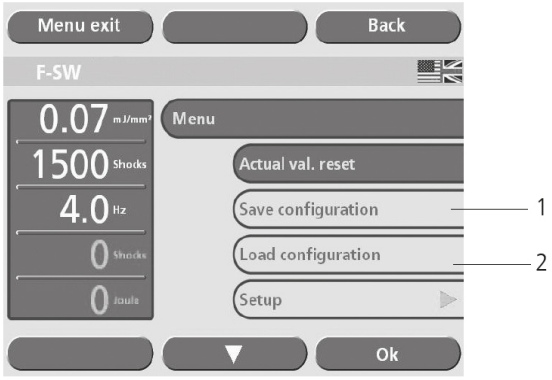


Fig. 5-9 Storing the treatment parameters

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 as shown in the picture below.

- Touch the SAVE key to save the current setting (see picture below **FIG. 5-10 SAVE CONFIGURATION SUB-MENU**/1).

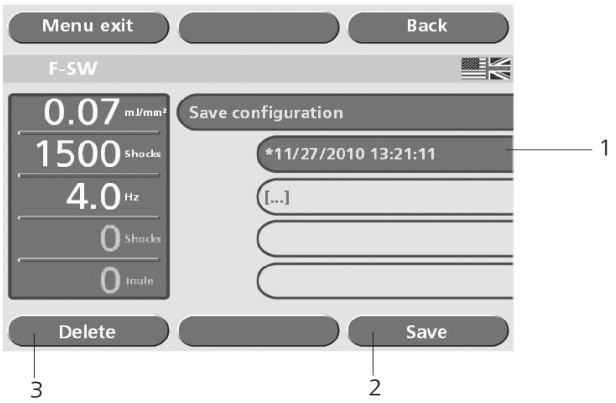


Fig. 5-10 Save configuration sub-menu

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. This activates the keyboard window.

Fig. 5-11 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. 5-10 SAVE CONFIGURATION SUB-MENU**/3).
  ⇨ *Up to 1000 treatments can be stored.*

5.7 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 (see chapter **5.5 F-SW ENERGY DISPLAY TASK**).
- If you are in the main menu, select the LOAD CONFIGURATION function from the list (see chapter **5.6 STORE TREATMENT NOTES**).

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

- In-house applications
- Plantar Fasciitis

5.7.1 Pre-programmed indications from the manufacturer

- Touch the button on which the required application area is displayed (see picture below).
- Touch the OK button.

Fig. 5-12 Loading a configuration I

- Select the required indication

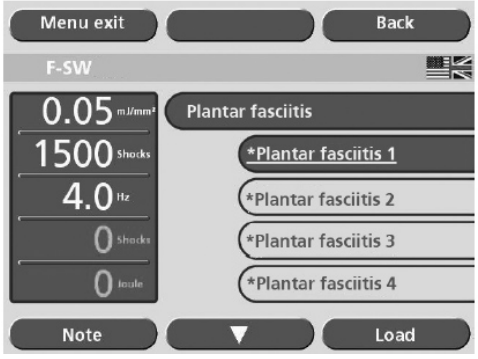


Fig. 5-13 Loading a configuration II

- 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 (see picture below).*

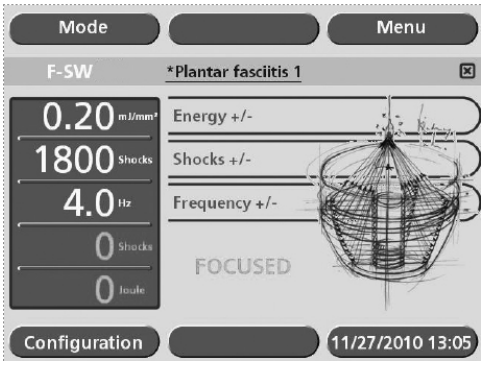


Fig. 5-14 Loaded indication

- 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.

5.7.2 In-house applications

- Touch the IN-HOUSE APPLICATION button (see picture below).
- Touch OK.

Fig. 5-15 In-house applications

- Touch the button for the indication required (see picture below).

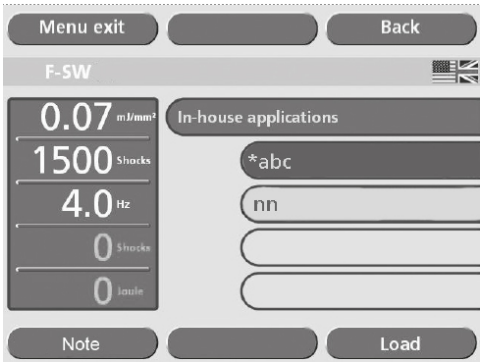


Fig. 5-16 In-house indications

If additional information for the selected indication has been saved, this can be accessed by touching NOTE.

- To add additional information, touch the text box (see picture below) to display the on-screen keyboard.

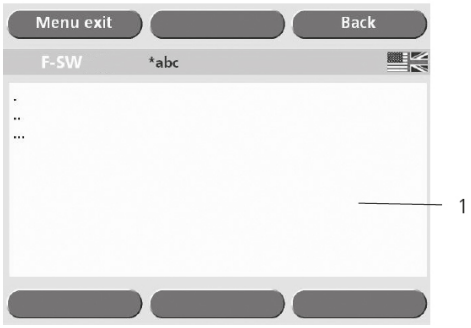


Fig. 5-17 Text box for treatment notes

- 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

5.8 Loading patient data

- Touch the IN-HOUSE APPLICATIONS button (see picture below).
- Touch OK.
- Touch the button on which the required patient name is displayed.

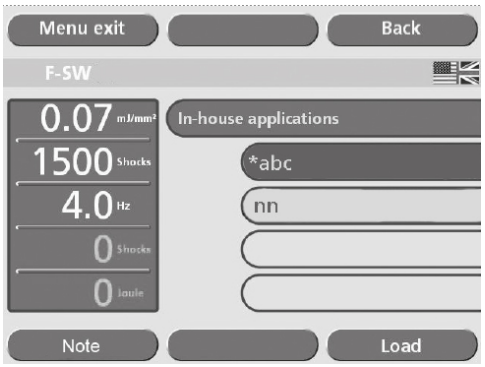


Fig. 5-18 Loading a patient record

- Touch the PROTOCOL button.
  ⇨ *The patient record will be displayed.*

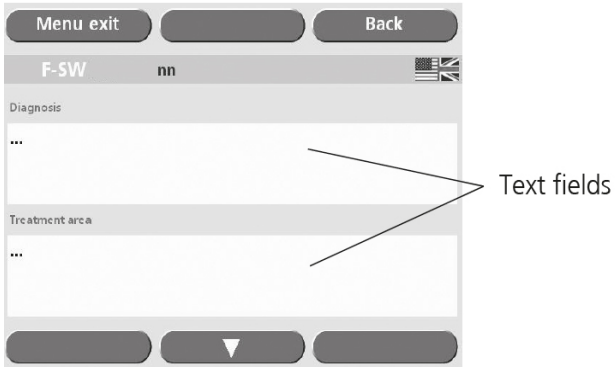


Fig. 5-19 Patient record - treatment details

A patient record consists of treatment details and a table of treatment parameters that is created by the instrument automatically.
Each time a patient is accessed, a new treatment with the current date is saved to his or her patient record.

Fig. 5-20 Treatment parameters

- To add additional treatment details, touch the text field 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.*
- 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.

5.9 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 (see picture below) where the patient has assigned his or her pain intensity.
- Touch OK to fix the arrow.

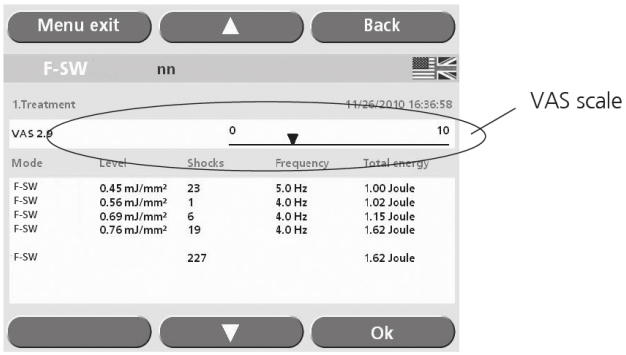


Fig. 5-21 Setting the VAS value

⇨ *The arrow can then no longer be moved and the set value appears at the left-hand edge of the VAS scale.*

Fig. 5-22 Set VAS value

5.10 Data transfer

Exporting treatment data

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
- Load a patient-specific parameter record.
- Select the DATA TRANSFER / EXPORT TREATMENT DATA function in the 1st sub-menu (see picture below).

Fig. 5-23 Data export

- Connect the memory stick to the USB port as soon as you are prompted to do so (see picture below) and confirm by touching OK.

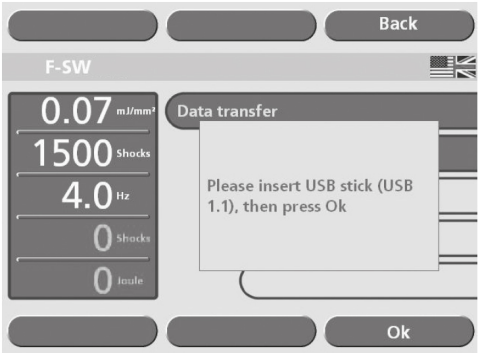


Fig. 5-24 Data export II

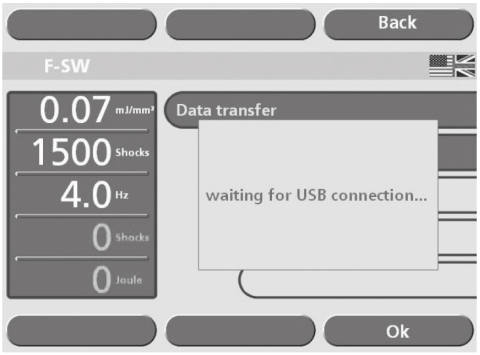


Fig. 5-25 Establishing the USB connection

⇨ *The USB connection is established.*
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 (see picture below), then remove the memory stick.

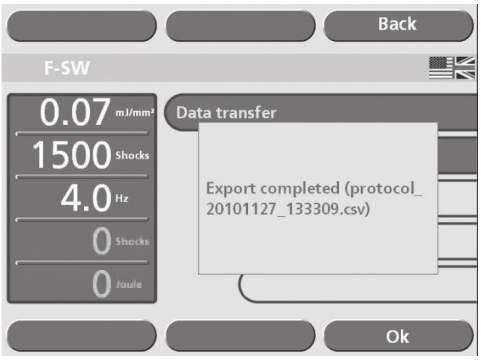


Fig. 5-26 Data export complete

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. 5-23** /2).
- Connect the memory stick to the USB connector as soon as you are prompted to do so 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. 5-23** /3).
- Connect the memory stick with the backup file to the USB port as soon as you are prompted to do so 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.

5.11 Resetting the treatment shock counter

- To reset the applied shock counter to "0", select the ACT. VAL. RESET menu option (see picture below) or touch the counter display.

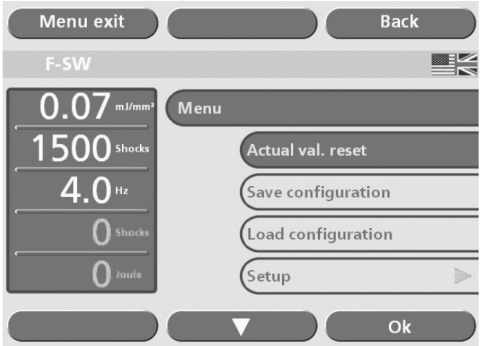


Fig. 5-27 Resetting the treatment shock counter

5.12 "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 **5.4 SETTING TREATMENT PARAMETERS**, **TAB. 5-1 TREATMENT PARAMETERS IN F-SW MODE**).

- Select the F-SW operating mode if this function should be deactivated.
- Press the AUTOFREQ. [ON] item in the SETUP menu (see Fig. **FIG. 5-28** /1) to deactivate the autofrequency function.

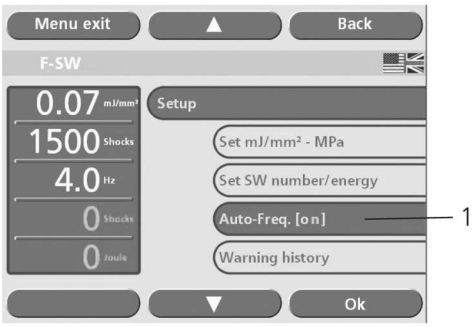


Fig. 5-28 AUTOFREQ. [ON] *item*

⇨ *The instrument automatically changes to* AUTOFREQ. [OFF] *status (see* **FIG. 5-29** */1)*

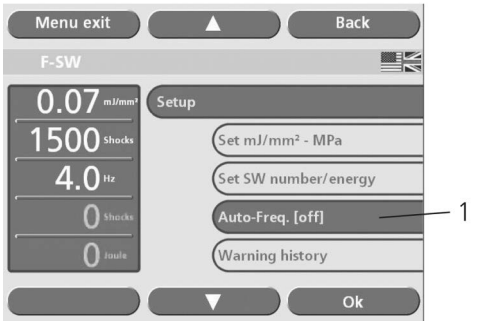


Fig. 5-29 Autofrequency function is deactivated

Now, the selected frequency remains the same even if the energy level is changed.

- Touch the EXIT button to return to the main menu.

This frequency can be reduced manually.

5.13 Start-up

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Switch the instrument on as described in chapter **5.3 STARTING THE INSTRUMENT**.
- Check that there are no bubbles in the handpiece.

  If bubbles are visible under the coupling diaphragm, proceed as follows:
  - Position the handpiece in the handpiece holder.
    ⇨ *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/mm^2. The maximum energy level corresponds to an energy flux density of 0.55 mJ/mm^2.

The highest permitted frequency is always set when an energy level is selected (see chapter **5.4 SETTING TREATMENT PARAMETERS**). This frequency can be reduced manually.

- Press the 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.

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.

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 (see picture below). 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.).

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

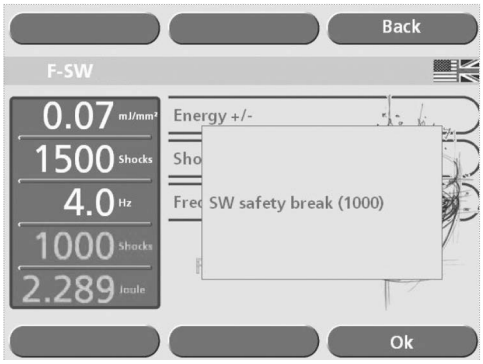


Fig. 5-30 Safety stop

5.14 Functional checks

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

- Check the control unit and handpieces for damage.
- Start the Chattanooga Intelect F-SW USA (see chapter **5.13 START-UP**).
- Set the energy level in F-SW mode to 0.2 mJ/mm^2.
- Reset the actual number of shocks on the parameter display of the control panel. See chaper **5.11 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.

If necessary, the functional capability of the F-SW handpiece can be checked with the aid of special Colour sensitive pressure sensors (see chapter **8 ACCESSORIES**).

5.15 Standard settings

- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero.

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/mm^2 and a frequency of 6 Hz.

5.16 Treatment

Safety information

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

NOTICE

Electromagnetic fields may lead

to uncontrolled reactions.

► To ensure undisturbed operation of the treatment, do not operate the device in the vicinity of RFID devices, safety systems or diathermy devices.

- Each time after the device has been transported, make sure that all functional checks have been performed on the device before you start treatment. Read about this in chapter **5.14 FUNCTIONAL CHECKS**.
- Read chapter **1 GENERAL SAFETY INFORMATION** before beginning treatment.

⚠ CAUTION

If the handpiece is not positioned correctly, there is an

impairment to health due to ineffective treatment!

► Define the treatment zone and make sure that the handpiece position always corresponds to the treatment zone.

► Make sure that the treatment is only administered by users who meet the conditions in Chapter **2.2 PRECONDITIONS FOR OPERATION**.

For safety reasons, using the device for applications other than those specified in chapter **1 GENERAL SAFETY INFORMATION** is not permitted!

- 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 stand off device.

⚠ CAUTION

Cleaning and maintenance work during treatment may lead

to injuries to patients and therapists.

► No cleaning and maintenance work is to be carried out while the device is being used on the patient.

- All status and error messages signaled during treatment must always be attended to without delay!

5.17 Switching Off the Device

- Switch off the Chattanooga Intelect F-SW USA using the main switch.
- If the system is transported or is unused for a longer period of time, always switch it off completely, using the button on the backside.

6 Cleaning, care and maintenance

CAUTION

Injuries to patients and people administering the treatment

► No cleaning and maintenance work is to be carried out while the device is being used on the patient.

6.1 Cleaning the device

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

The frequency of complete exterior cleaning depends on the frequency of use and what the device is used for.

DANGER

Electrical hazard

Disconnect the device from the mains before starting any cleaning, maintenance or overhaul work.

► Disconnect the mains plug.

DANGER

Cleaning agents and disinfectants

can form an explosive atmosphere.

► Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

WARNING

On contact with contaminated surfaces

there is a risk of transmission of infection.

► Clean all parts which come into contact with the patient **before and after** each treatment.

- Wipe down the device parts with a damp cloth.

  For cleaning, use a lukewarm, diluted solution of non-vegetable soapy water.

DANGER

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

Ventilation slots

- Keep the ventilation slits clear.

Monitor and Touch Screen

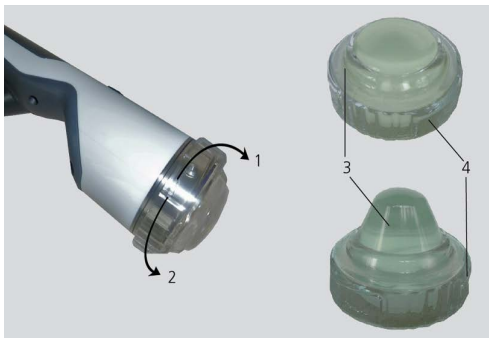
Only a cloth moistened with water, without any cleaning additives, may be used to clean the LC displays.

- Wipe down the screen.
- Rub the screen dry with a cotton cloth.
- Immediately remove contamination (e.g. contrast agent spots).

6.2 Cleaning the handpieces

6.2.1 Changing the stand-off device

- Stand-off devices must be changed for treatment and service reasons. Check before treatment that the stand-off device is tightened firmly.



1 To attach the stand-off device
2 To release the stand-off device
3 Stand-off
4 Closing ring

Fig. 6-1 Attaching the stand-off device

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

Fig. 6-2 Releasing the closing ring

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.

1 stand-off I
2 stand-off II
3 anatomic stand-off (optional)

Fig. 6-3 Stand-offs without ring

- Fit a clean stand-off into the closing ring.
- Apply a drop of silicone oil to the coupling diaphragm as a coupling medium.
- To attach: Screw the closing ring towards the front and tighten it firmly with your hand.

6.2.2 Reprocessing 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 the following means and tools are available for cleaning and disinfection:

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

6.2.2.1 Cleaning

- Screw off the stand-off device from the handpiece as described in chapter **6.2.1 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.

6.2.2.2 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.

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

NOTICE

Cleaning agents and disinfectants

may impair the characteristics of the coupling diaphragm.

► Do not use vegetable-based soap solutions of 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

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

6.2.3 Cleaning the optional foot switch

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

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

6.3 Water renewal

The water in the cooling circuit of the Chattanooga Intelect F-SW USA 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 (see the picture below).

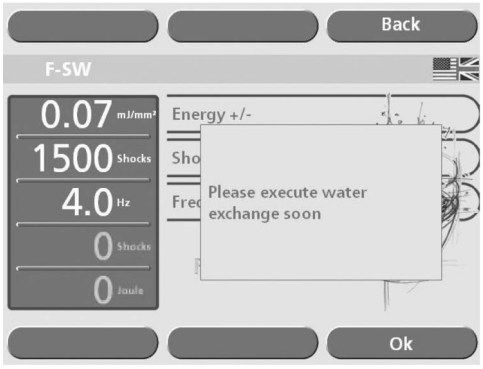


Fig. 6-4 Prompt for water renewal

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

6.3.1 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 DRAIN WATER operating mode in the SETUP menu (see picture below).

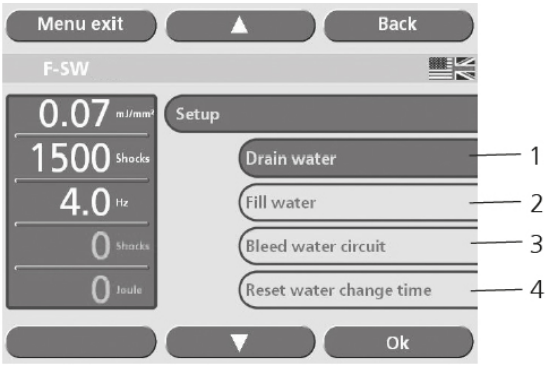


Fig. 6-5 Water renewal

- Connect the water bag to the Chattanooga Intelect F-SW USA and put it on the floor as soon as the message appears.

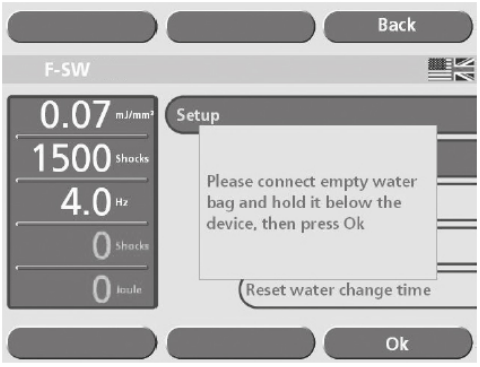


Fig. 6-6 Draining the water circuit I

⇨ *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.

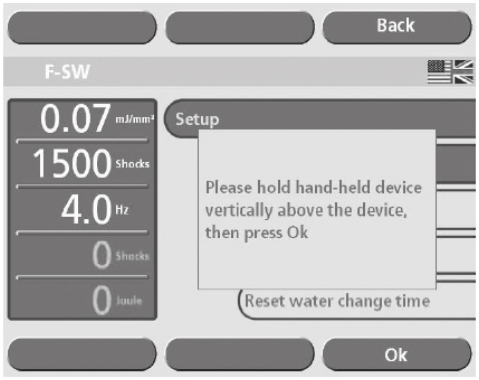


Fig. 6-7 Draining the water circuit II

⇨ *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.

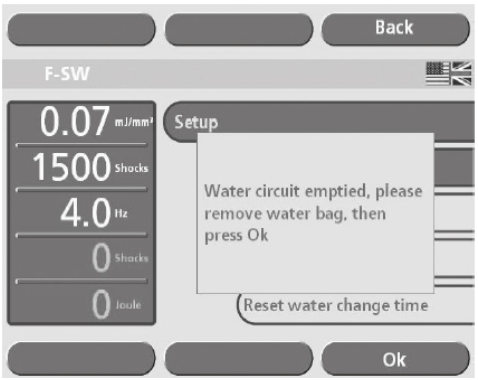


Fig. 6-8 Draining the water circuit III

- 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.

6.3.2 Filling the water circuit

- Make sure that the instrument is standing on a smooth, horizontal surface.
- 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 (minimum 800ml or 27oz.). In order to add the maximum amount of water to the water bag, place the bag on the palm of your hand and squeeze it gently at the sides whilst filling.

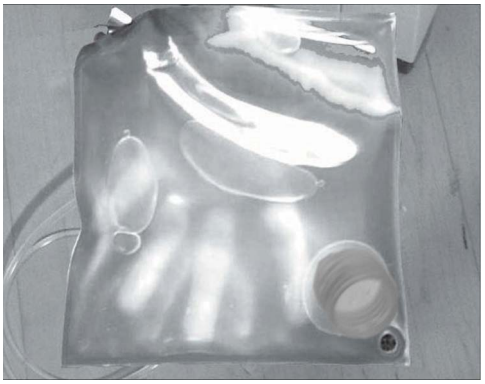


Fig. 6-9 Filling the water bag

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.

- Hold the water bag up with the connection tube hanging vertically downwards to let the air rise automatically into the water bag.
- 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.

Fig. 6-10 Handpiece in holder

- Activate FILL WATER operating mode in the SETUP menu.

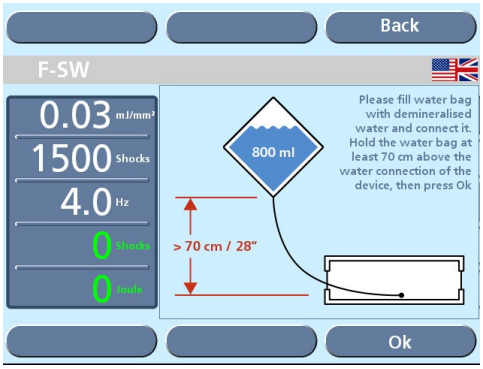


Fig. 6-11 Filling the water circuit I

- Connect the water bag to the water tube connection on the rear of the instrument as soon as the message appears.
- At the same time, hold the water bag at least 70 cm / 28" above the water tube connection, so the water can flow out optimally. Hook the bag onto an infusion stand if necessary.
- Touch OK.

Fig. 6-12 Filling position and progress display

⇨ *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 (see picture below). There may be water left in the bag.

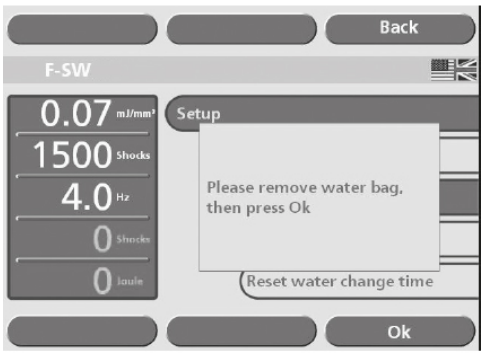


Fig. 6-13 Filling the water circuit II

- 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 (see* **FIG. 6-14** *).*

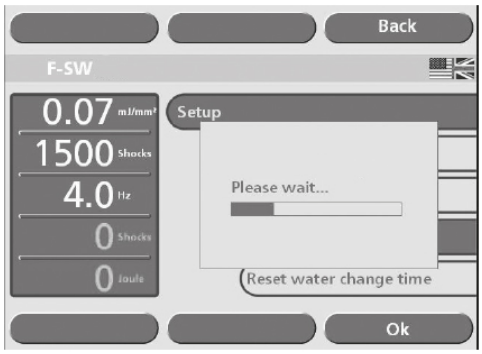


Fig. 6-14 Bleeding the water circuit

- 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.

6.3.3 Bleeding the water circuit

- Select BLEED WATER CIRCUIT from the SETUP menu (see **FIG. 6-6 DRAINING THE WATER CIRCUIT I**, /3).
  ⇨ *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.

6.3.4 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 CHANGE TIME function can be selected to cancel this reminder function or to adapt it to a new date setting.

- Activate RESET WATER CHANGE TIME operating mode in the SETUP menu.
  ⇨ *The time when the water change time 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.

6.4 Mains fuse replacement

The mains fuse holder is located on the rear of the Chattanooga Intelect F-SW USA between the mains connection and the ON/OFF switch.

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

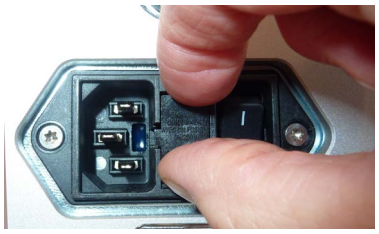


Fig. 6-15 Mains fuse holder

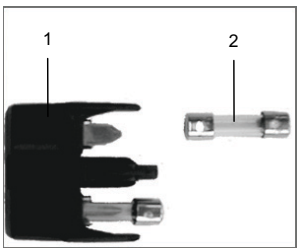


Fig. 6-16 Fuse replacement

1 Fuse holder
2 Fuse

- Pull the old fuses out of the mains fuse holder.
- Replace the fuses (T5AH / 250 VAC).
- Push the mains fuse holder back into the opening until it engages.

6.5 Software updates

For software update, please contact your local dealer.

6.6 Cybersecurity measures

Like all computer-based systems, the system might be exposed to cybersecurity threats.

Safety critical core functions of the device, such as shock wave release are decoupled from software and can be activated by hardware switches only.

In order to minimize the possibility of cyber attacks, it is the user's responsibility to make sure that the following protection measures are followed.

1) The product may only be installed, commissioned, maintained, updated and operated by authorised personnel. These persons are to be employees of the manufacturer or other authorised third parties.
2) Software updates distributed by the manufacturer (functional or safety-relevant) must be installed via the enclosed Technical Product Information (TPI). Subsequent feedback to the manufacturer or its service partner is required.
3) A regular data backup of the system must be carried out. Depending on the number of patients, this should be done daily, but at least weekly.
4) Software that is not distributed by the manufacturer or one of its service partners may not be used with the product.
5) A virus scan of the USB sticks used must be carried out to check whether they are free of viruses, malware or dangerous software.
6) All service and maintenance areas are password protected. Such access can only be granted by the manufacturer to authorized service personnel.

Contact the manufacturer or the authorised customer service in the following cases:

- In case the product shows unknown or not logical behavior, such as a slow reaction of the software or if the password is not accepted, access to the databases is not possible or it switches to a wrong user interface dialogue.
- In case you face issues with the IT security of this product.
- In case you lost your password, login credentials or user access.

6.7 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 device.

Maintenance services can be ordered from our regional representatives in your area.

We recommend that functional and safety checks be performed at least once a year (see Chapter **5.14 FUNCTIONAL CHECKS**), in addition to the national accident prevention regulations and test and inspection intervals prescribed for medical devices that are required to be observed.

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

1. Earth leakage current test from the chassis in accordance with national regulations.
2. Earth impedance test (including housing and with mains cable) in accordance with national regulations.
3. Test of essential performance.

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

6.8 Repair

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

6.9 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 the service life of the device, dispose of the Chattanooga Intelect F-SW USA as waste electronic equipment.

- Please contact the manufacturer or distributing company in relation to this.
- When disposing of wear parts, you must comply with the relevant national disposal regulations.
- Comply with the relevant information in the operating manuals for the additional devices.

6.10 Service life

The average expected service life (MTTF) in accordance with IEC 60601-1:2005 + A1:2012 / EN 60601-1:2006 + A1:2013 is

– 15,000 operating hours for the Chattanooga Intelect F-SW USA
– 5 million shocks for the F-SW SEPIA LT handpiece

The coil is a wear part. After 2 million shocks the coil needs to be exchanged to avoid secondary damages on the handpiece and on the control device.

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

No warranty claims shall be accepted beyond the information given in chapter **10 WARRANTY AND SERVICE**.

7 Status messages, error messages / fault displays

7.1 Status messages

⚠ CAUTION

Malfunction of the device or its components.

Various injuries are possible!

► Immediately comply with all status and error messages which appear during the treatment.

Fault description	Possible cause and remedy
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 **6.3.2 FILLING THE WATER CIRCUIT**)
F-SW : water circuit fault	Pump defect Treatment is not possible. Bleed the water circuit (see chapter **6.3.3 BLEEDING THE WATER CIRCUIT**). 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 overtemperature	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.

Fault description	Possible cause and remedy
Shock wave limit for current handpiece reached	Shock wave limit for current handpiece reached. Contact your service center for coil replacement.
F-SW : charging unit not ready	Acknowledge message. Call your Service centre if the fault continues after a reset.
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.
Water pump malfunction	Restart the instrument. Drain and re-fill water. Call your Service centre if the fault continues. .
Water pressure low	Restart the instrument. Call your Service centre if the fault continues.

7.2 Trouble shooting

DANGER

Electrical hazard

Disconnect the device from the mains before starting any cleaning, maintenance or overhaul work.

► Disconnect the mains plug.

Fault description	Possible cause	Corrective actions
Device 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 black 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.

Tab. 7-1 Trouble shooting

8 Accessories

Product Description	Part Number
Handpiece F-SW Sepia	19000
Water bag	4600
Silicone oil	4700
Gel bottle	22601
Stand-off I 15 mm	19100
Stand-off II 30 mm	19200
Stand-off anatomical	19150
Closing ring	19300
Handpiece holder set	13-27268
User manual	13-00061-US
Mains cable US	0.0032.012-US
Trolley/Cart	4560
Colour sensitive pressure sensor	13-18342

9 Technical specifications

Chattanooga Intelect 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	T5AH / 250 VAC
Power consumption	max. 450 VA
Ambient temperature during operation	10° - 30°C
Ambient temperature during storage and transport	0° C to 60°, frost-free
Ambient air pressure during operation	800 - 1060 hPa
Ambient air pressure during storage and transport	500 - 1060 hPa
Air humidity during operation	5 - 55%, non condensing
Air humidity during storage and transport	5 - 95 %, non condensing
Control device weight	23.6 kg
F-SW handpiece weight	990 g
Housing dimensions (W x H x D)	450 x 165 x 530
Classification according to FDA	Class III device
Protection against ingress of water	IPX1

Subject to technical changes

Shock wave source of the F-SW handpiece			
Generation method	electromagnetic		
Pressure wave expansion	focused		
Focusing method	parabolic reflector		
Energy flux density [mJ/mm^2]	**0.10**	**0.35**	**0.55**
Peak compressional acoustic pressure [MPa]	14	36	62
Peak rarefactional acoustic pressure [MPa]	9	13	15
Axial size of the -6dB focal zone [mm]	57	49	34
Lateral size of the -6dB focal zone [mm]	5.4	3.8	2.8
Focal volume [cm^3]	0.87	0.37	0.14
Energy per pulse (r = 2.5 mm) [mJ]	1.7	5.5	8.5

F-SW handpiece without stand-off device	
Pressure wave generation	electromagnetic
Pressure wave expansion	focused
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	50 mm
Depth of focal zone	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	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	0 - 30 mm
Therapeutically effective penetration depth, 5 MPa	0 - 90 mm

Subject to technical changes

Software Version
The number of the software version of the device can be seen on the touch panel. Pressing INFO / VERSIONS shows the actual software und hardware versions.

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

– The complete device documentation must be delivered together with the medical product.
– The medical product may only be exported to a foreign country if the medical product and the corresponding indications are allowed there.

9.1 Type plate

Fig. 9-1 Type plate Chattanooga Intelect F-SW USA

9.2 Conformity with standards

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

Acc. to EN/IEC 60601-1	
– Type of protection against electric shocks:	Protection class 1
– Applied part of type B	

The following essential performance characteristics apply to the Chattanooga Intelect F-SW USA:

1. The Medical Equipment shall be free from incorrect display of energy levels.
2. The Medical Equipment shall be free from unintended shock wave release.

The essential performance characteristics of the Chattanooga Intelect F-SW USA cannot be disturbed by electromagnetic interference (EMI).

9.2.1 RFID immunity

The device has been tested successfully against AIM (Advancing identification matters) standard 7351731. For further evaluation see chapter **9.2.2 EMC GUIDELINES AND MANUFACTURER'S DECLARATION**.

RFID Specification	**Frequency**
ISO 14223 (Type A)	134.2 kHz
ISO/IEC 14443-3 (Type A)	13.56 MHz
ISO/IEC 14443-4 (Type B)	13.56 MHz
ISO/IEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz
ISO/IEC 18000-7	433 MHz
ISO/IEC 18000-6 Type C	860 - 960 MHz
ISO/IEC 18000-4 Mode 1	2.45 GHz

Tab. 9-1 RFID immunity

9.2.2 EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – Emitted electromagnetic interference		
The Chattanooga Intelect F-SW USA model is intended to be used in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intelect F-SW USA should ensure that it is used in such an environment. The maximum length of the mains cable for the unit is 3 m.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
HF emissions acc. to CISPR 11	Group 1	The Chattanooga Intelect 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. As per EN IEC 60601-2-36:2015 Section 202, this does not apply when triggering and generating the pressure pulse.
HF emissions acc. to CISPR 11	Class B	The Chattanooga Intelect 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 acc. to IEC 61000-3-3	Complies	
Conducted RF emissions	Class B	
Radiated RF emissions	Class B	

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The Chattanooga Intelect F-SW USA model is intended to be used in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intelect F-SW USA should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or concrete, or be covered with ceramic tiles. If floors are covered with synthetic material, the relative air humidity must be at least 30%.
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	±2 kV for mains cables ±1 kV for input/output lines	±2 kV for mains cables ±1kV 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 acc. to IEC 61000-4-11	< 5% U_T[a] (> 95% drop in U_T) for ½ and 1 period 70 % U_T (30% drop in U_T) for 25/30 periods < 5% UT (> 95% drop in U_T) for 250/300 s	< 5% U_T (> 95% drop in U_T) for ½ and 1 period 70 % U_T (30% drop in U_T) for 25/30 periods < 5% UT (> 95% drop in U_T) for 250/300 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Chattanooga Intelect F-SW USA requires continued operation during mains power interruptions, it is recommended that the Chattanooga Intelect F-SW USA be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	30 A/m	The mains frequency magnetic fields should be those of a typical business or hospital environment.

a. NOTE: U_T is the mains alternating voltage prior to application of the test level.

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The Chattanooga Intelect F-SW USA model is intended to be used in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intelect F-SW USA should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
			Portable and mobile RF equipment should be used no closer to any part of the Chattanooga Intelect F-SW USA, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. **Recommended safety distance:**
Conducted RF according to IEC 61000-4-6	$3V_{RMS}/6V_{RMS}$ 150 kHz to 80 MHz	$3V_{RMS}/6V_{RMS}$ 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz
			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). The field intensity of stationary radio transmitters, based on an on-site inspection[a] should be less than the compliance level.[b] Interference may occur in the vicinity of devices marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. 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 at the location in which the Chattanooga Intelect F-SW USA is used exceeds the applicable HF compliance level indicated above, the Chattanooga Intelect 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 Intelect F-SW USA.

b. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended safety distances between portable and mobile HF communications equipment and the Chattanooga Intelect F-SW USA			
The Chattanooga Intelect F-SW USA is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The operator or the user of the Chattanooga Intelect F-SW USA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the Chattanooga Intelect 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 transmission frequency [m]**		
	150 kHz to 80 MHz **d = 1.2 √P**	**80 MHz to 800 MHz** **d = 1.2 √P**	**800 MHz to 2.5 GHz** **d = 2.3 √P**
0.01	0.12	0.12	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 2.7 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area might inadvertently 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.			

9.3 Symbols and labels

The following symbols and labels are affixed to the Chattanooga Intelect F-SW USA:

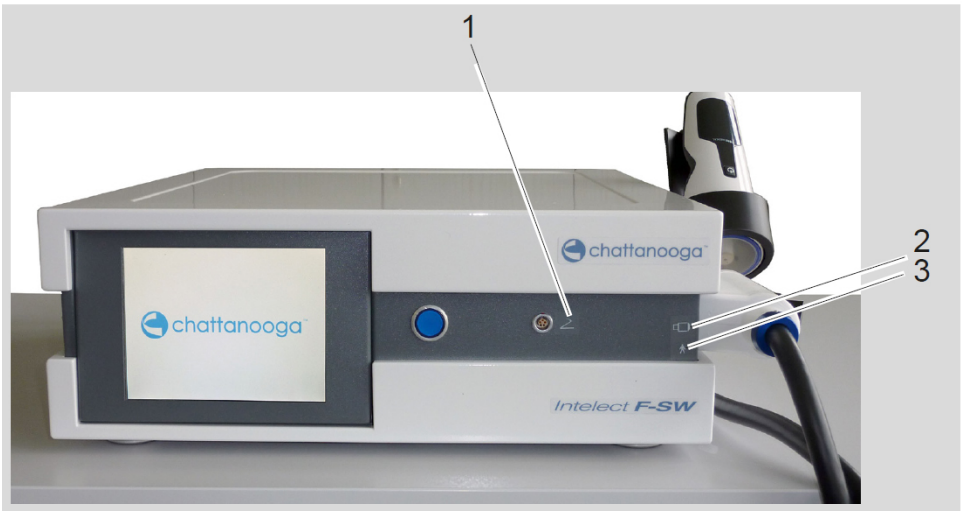


Fig. 9-2 Symbols and labels at the front cover

1 Foot switch connection
2 F-SW handpiece connection
3 Applied part of type B

Label	Notification
1 	foot switch connection
2 	F-SW handpiece connection
3 	Applied part of type B

Tab. 9-2 Symbols attached to the front side

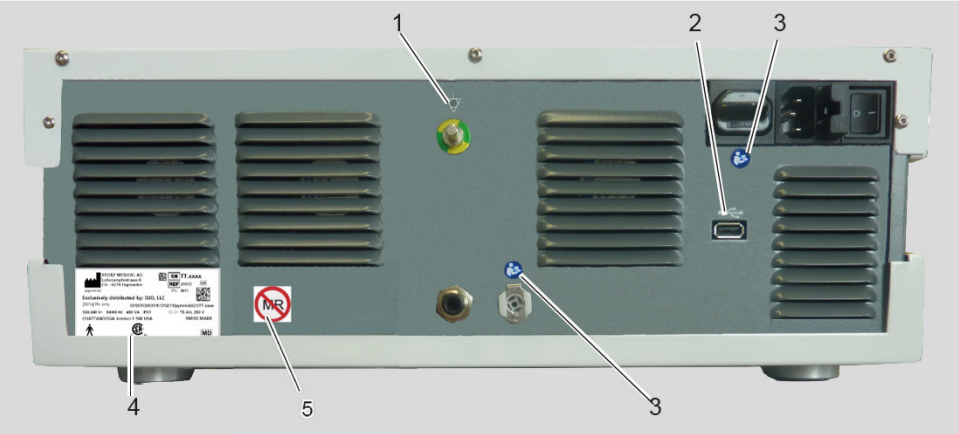


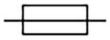
Fig. 9-3 Symbols and labels at the back cover

1 Potential equalisation
2 USB-connection
3 Comply with the OM
4 Type plate
5 MR unsafe label

Label	Notification
1	Potential equalisation
2	USB-connection
3	It is essential to comply with the operating manual
4 	Type plate
5 MR	MR unsafe

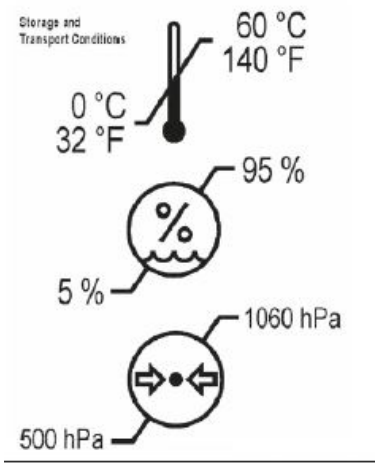
Tab. 9-3 Symbols attached to the rear side

The following symbols and labels are on the type plate of the Chattanooga Intelect F-SW USA

Label	Meaning
	fuse
	Applied part of type B
	CSA certification
	manufacturer
	DataMatrix according to GS1 standards
(01)07630039101312(11)yym-mdd(21)TT.xxxx	Unique Device Identification (UDI): Human Readable Interpretation (HRI)
(01)	Global Trade Item Number (GTIN)
(21)	Application Identifier (AI): Serial Number (SN)
(11)	Application Identifier (AI): Production Date (PRODDATE)

Tab. 9-4 Device labelling

The following symbols and labels are attached to the Chattanooga Intelect F-SW USA packaging:

Label	Meaning
	Ambient temperature during storage and transport
	Air humidity during storage and transport
	Ambient air pressure during storage and transport

Tab. 9-5 Labelling on the packaging

10 Warranty and service

10.1 Warranty for the control device

During the two-year warranty period from the date of invoice, defects will be either replaced or repaired at the discretion of the manufacturer and 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.

NOTICE

Unauthorised opening, repairs and modifications to the device by unauthorised persons

releases the manufacturer from any liability for the safe system operation. This will automatically void the warranty even before the end of the warranty period.

► Do not open the device without authorisation and do not manipulate the device.

10.2 Warranty for the handpiece

The F-SW handpiece is a wear part.
New handpieces that have performed up to 1 million pulses will be either replaced or repaired at the discretion of the manufacturer and at no charge to the customer upon the customer providing adequate proof that the defect is due to defects in material or workmanship.
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.

NOTICE

Modifications to the device are not permitted.

Any opening, repair or modification of the handpiece and the stand-off devices are not permitted. Any opening, repair or modification of the instruments 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.

10.3 Service

If you have any other questions about the Chattanooga Intelect F-SW USA, please contact your certified dealer.

Manufacturer / Publisher

STORZ MEDICAL AG
Lohstampfestrasse 8
CH-8274 Tägerwilen
Switzerland

EXCLUSIVELY DISTRIBUTED BY:

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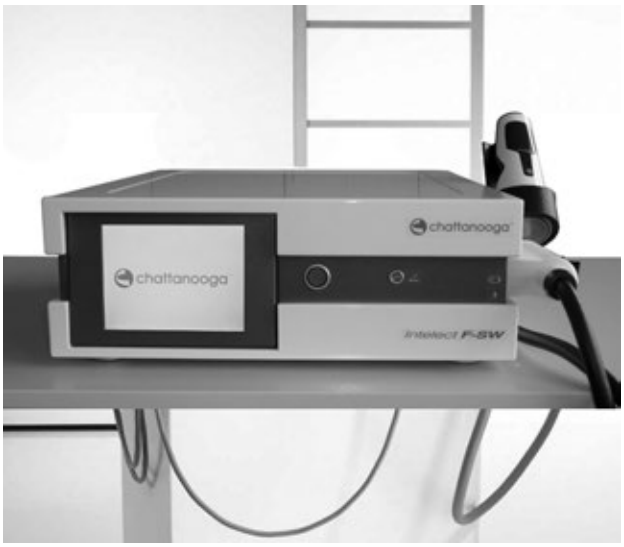
MOTION IS MEDICINE®

Storz Medical AG

Chattanooga Intelect 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 Intelect 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.

Storz Medical AG

Chattanooga Intelect F-SW USA

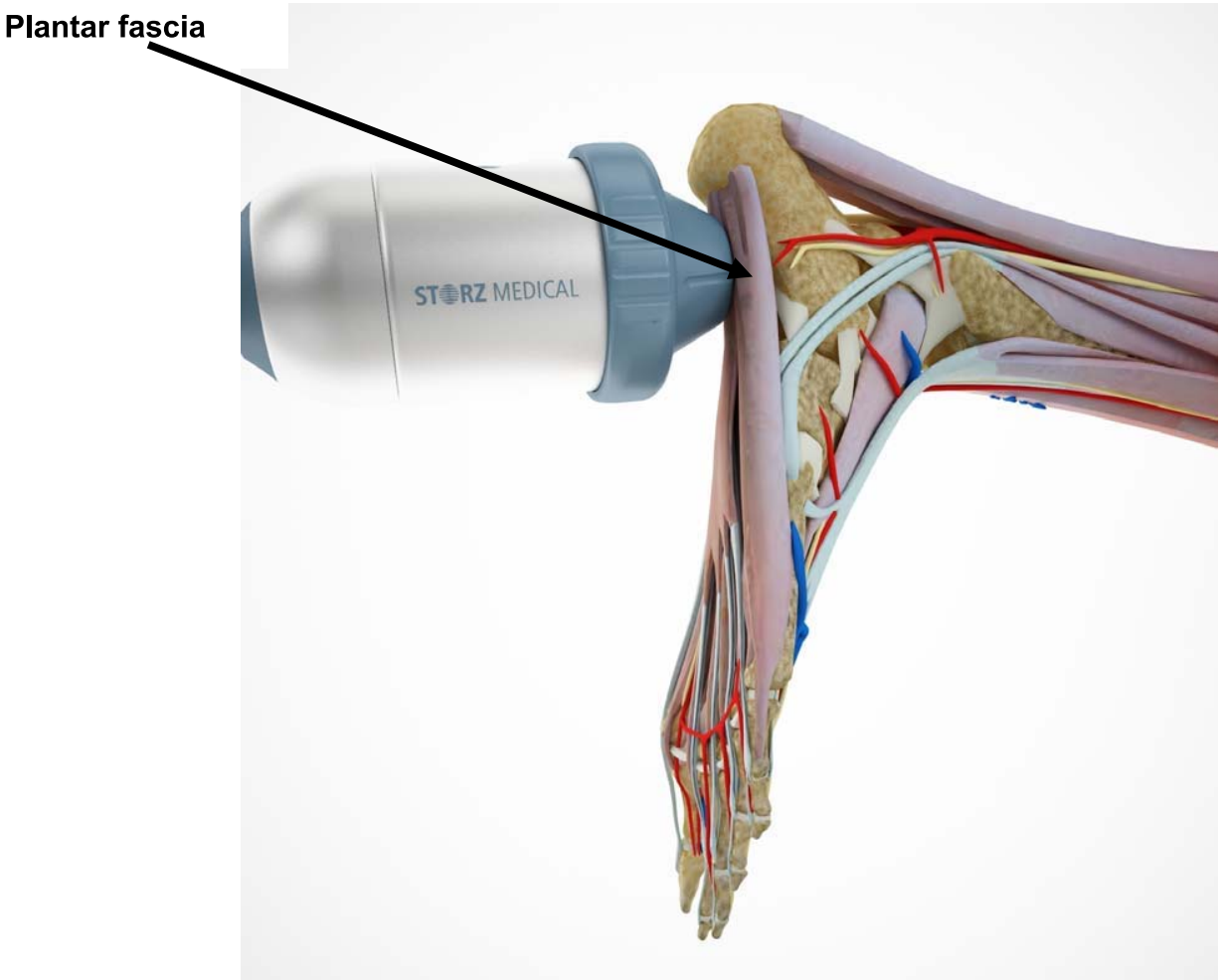
Patient Information Table of Contents

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 photography below) is a tissue band that goes from the base of the toes to the heel.



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 Intelect F-SW USA?

The Chattanooga Intelect F-SW USA is a medical device for the treatment of heel pain using shockwaves. The Chattanooga Intelect 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 Intelect 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 Intelect F-SW USA?

The Chattanooga Intelect 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 Intelect F-SW USA (Contraindications)?

The Chattanooga Intelect 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 Intelect 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 12reports 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 intemal 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® SDl or a device that looked like the Duolith® SDl 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
Lohstampfestrasse 8
8274-Tägerwilen,
Switzerland
T: +41 71 677 4545

US Distributor

DJO, LLC
5919 Sea Otter Place, Suite 200
Carlsbad, CA 92010 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 Intelect 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
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Lohstampfestrasse 8
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E: ChattProductSupport@djoglobal.com

Clinical Application of the Chattanooga Intelect F-SW USA

Indications

The Chattanooga Intelect 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 Intelect 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 Intelect 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/mm^2 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 Intelect 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 Intelect 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 (Vist 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
Duolith Group			
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
Placebo Group			
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 corticosteriod 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, Acetylsalicylicacid 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 (± 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/mm^2 up to a level of 0.25 mJ/mm^2 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/mm^2. 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 (JBJSA (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%)
	Very satisfied	28 (23.53%)	21 (18.42%)
Patient's recommendation of therapy to a friend	Yes	95 (79.83%)	68 (59.65%)
	No	24 (20.17%)	46 (40.35%)
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	Success	68 (54.40%)	45 (37.19%)
	Failure	57 (45.60%)	76 (62.81%)
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))	Success	63 (50.40%)	44 (36.36%)
	Failure	62 (49.60%)	77 (63.64%)
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))	Success	62 (49.60%)	47 (38.84%)
	Failure	63 (50.40%)	74 (61.16%)
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))	Success	67 (53.60%)	51 (42.15%)
	Failure	58 (46.40%)	70 (57.85%)
Frequency count of patients with at least one concomitant analgesic therapy during the study	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. +1 800 965-4846

STORZ MEDICAL AG, Service phone No. +41 71 677 4545

DJO, LLC, T: +1 800 494 3395
E: ChattProductSupport@djoglobal.com