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Preface

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 the 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.

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

⚠️ **ATTENTION!**
---
The source of the danger is stated here.
**These are the possible consequences!**
- The instructions for avoiding the danger are given here.

Other instructions

**NOTE**
Additional information concerning specific features or operating instructions is preceded by the term 'NOTE'.
Safety signs and other symbols used in this manual

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>General warning sign</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Electrical warning sign</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Wear hearing protection!</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>WEEE (waste electrical and electronic equipment)</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Device serial number</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>CE mark</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Electromagnetic interference may occur in the vicinity of instruments marked with this symbol.</td>
</tr>
</tbody>
</table>

Table 1-1
1 General Safety Information

1.1 Instructions for safe use

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

⚠️ 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.
• Read the separate operating manuals for all devices associated with the Chattanooga Intelect F-SW.

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 Chattanooga Intelect F-SW is intended exclusively for use by healthcare professionals who have been trained to use the device (see also Chapter 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 Chapter 2.2.

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 before starting treatment. Read about this in Chapter 5.15 Functional checks.

• Have the maintenance procedures recommended by the manufacturer carried out by authorised personnel (see also Chapter 6.6 Maintenance and safety checks).

No treatment ist permitted if a display on the control device or a touch screen fails.
Protection against electrical hazard
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 physician and the nursing staff.

- Therefore, always connect the potential equalisation connector of the Chattanooga Intelect F-SW in accordance with national guidelines.
- Devices which are not medical products in accordance with EN 60601 must be set up outside the vicinity of the patient.
- Do not touch electrical connectors while you are touching the patient.
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect them until they have been completely reassembled!
- Do not try to open the instrument! Risk of electric shocks!

Protection against high voltage
Very high voltages are generated when operating the device. High-voltage components are identified as follows:

![DANGER!](image)

**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 shock waves is within the safe area. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

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

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.

- 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.
- 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.

1.2 **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) can interfere with medical electrical equipment.

This device is subjected to special precautions regarding EMC and needs to be installed according to the EMC guidelines in chapter 9.4 Conformity with standards.

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

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

The system must only be connected to properly earthed and correctly installed shockproof sockets!
Set-up and operation

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

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

- Check that the system is in perfect working order before each use. Read about this in **Chapter 5.15 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.

- Make sure that no cables are crushed or sheared.

Disposal

- Comply with national disposal regulations when disposing of the Chattanooga Intelect F-SW or individual components.

- Comply with the relevant information in the operating manuals for the additional devices.
1.3 Manufacturer’s responsibility

**WARNING!**

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

STORZ MEDICAL AG as the manufacturer of the Chattanooga Intelect F-SW is only responsible for effects on the safety, reliability and performance of its product 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 authorised personnel.

The manufacturer’s liability shall be rendered null and void if non-genuine parts are used.

1.4 Owner’s responsibility

The owner is responsible for complying with the relevant national statutory provisions governing setting up and operating technical medical equipment. (For Germany, the Medical Products Act.)

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 is a universal, compact shock wave unit that can be used for treatment involving medium- to high-energy electromagnetically generated shock waves - focused shock waves – referred to below as F-SW. F-SW waves have a short pulse length and are concentrated on areas a few millimetres in diameter, allowing pulse waves to be applied to a tightly localised area, even in deeper tissue layers.

2.1.1 Indications

The Chattanooga Intelect F-SW is designed in order to treat the indications specified below:

Orthopaedics / Pain Therapy
- Plantar fasciitis / heel spur / heel pain / calcaneal spur
- Trigger Point Therapy
  - Treatment of deep muscle trigger points
  - Treatment of superficial muscle trigger points
  - Myofascial pain syndrome / Myofascial trigger points* / Acupuncture points
  - e.g. chronic back pain (cervical and lumbar parts of vertebral column), trapezius, pelvic floor muscle trigger points
- Tendinopathy / Tendinitis / Tendonitis / Tendinosis / Tendon Pain
  - Insertion tendonitis in general
  - Superficial insertion tendonitis (paratendinary area)
  - Shoulder pain with or without calcifications / tendinopathy of the shoulder, the supraspinatus, or / and the rotator cuff (with or without calcifications)
  - (Radial/ulnar humeral) epicondylitis / tennis elbow / golfer's elbow / elbow tendinopathy
  - Greater trochanteric pain syndrome (GTPS) / Trochanteric tendonitis / Trochanteric bursitis
  - Hamstring tendinopathy
  - Patellar tip syndrome/ proximal iliotibial band (friction) syndrome / Patellar tendonitis / Jumper's knee
  - Tibial edge syndrome / tibial stress syndrome / tibial tendonitis
  - Achillodynia / Achilles tendinitis
- Pseudarthrosis / non-unions / delayed unions
Dermatology

- Wound healing
  - Ulceration
    - Arterial ulcers
    - Venous ulcers
    - Diabetic foot ulcers
    - Pressure sore / Decubital ulcer
  - Burns
  - Acute and chronic lesions
  - Traumatic and post-traumatic skin lesions
  - Wounds with disturbed healing
  - Postsurgical wounds
  - Cellulitis / lipo- / lymphedema

Urology

- CPPS / prostatitis
- IPP / Peyronie’s disease
- Vascular / vasculogenic / organic erectile dysfunction

Neurology

- Spastic muscle paralyses (caused by infantile cerebral palsy or stroke for example)

* A sound knowledge of trigger point therapy and trigger point shock wave therapy (TrST) is required for therapeutic application of the Chattanooga Intelect F-SW in the field of trigger point shock wave therapy.
2.1.2 Contraindications

**CAUTION!**

The contraindications listed here are examples. No claims are made regarding the completeness or unlimited validity of this list of contraindications.

No patient treatment is allowed under the following circumstances:

- Air-filled tissue (in particular lung tissue) in the treatment area
- Brain or spine in the treatment area
- Untreated coagulopathies (hemophilia)
- Malignant tumor in the treatment area
- Epiphyseal plate areas in children
- Pregnancy
- Use of anticoagulants, especially Marcumar
- Thrombosis in the treatment area
- Cortisone therapy up to 6 weeks before first treatment

**CAUTION!**

Shock waves must not be applied to target areas located above air filled tissue (lungs), nor to any regions near large nerves, vessels, the spinal column or head (apart from the face).

2.1.3 Side effects

- Swelling, reddening, hematoma
- Petechiae
- Pain

These side effects normally disappear after 5-10 days.
2.2 Preconditions for operation

2.2.1 Operating personnel

The Chattanooga Intelect F-SW is intended exclusively for use by healthcare professionals who have been trained to use the device. Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the terminology, and should be experienced in treating the indications stated in Chapter 2.1.1 Indications.

Users must have basic physical and cognitive abilities such as vision, hearing and literacy, and have basic functional use of their upper extremities.

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 must have been adequately trained in using this system safely and efficiently before they operate the device described in this handbook. 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:

- Instruction in the 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 of the therapy waves
- Explanation of the warnings in all operating modes
- Instruction in how to perform the functional checks

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

DJO France
3 Rue de Bethar
Centre Européen de Frêt
64990 Mouguerre
France

T: +33 (0)5 57 52 86 90
F: +33 (0)5 57 52 86 91
E: sce.cial@DJOglobal.com
3 System Description

3.1 Control and functional elements

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

Fig. 3-2 Rear view of Chattanooga Intelect F-SW
3.2 **F-SW handpiece and optional C-ACTOR 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 or the C-ACTOR handpiece into the body at the treatment zone that has been established by diagnosis.

**NOTE**

Optical difference between F-SW handpiece and C-ACTOR handpiece: The F-SW handpiece has a blue ring around the coupling diaphragm and the C-ACTOR handpiece has a red ring around the coupling diaphragm.

![Fig. 3-3 F-SW handpiece or C-ACTOR handpiece](image)

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 or C-ACTOR handpiece](image)

![Fig. 3-5 Depth of therapeutic effect of F-SW handpiece](image)
Perform changing of the stand-off devices as described in **CHAPTER 6.2.1 CHANGING THE STAND-OFF DEVICE.**

**NOTE**
The stand-off has a limited service life. It should be replaced if there are visible changes in the material (discolouration, tarnishing, streaks, gas bubbles), deformation of the surface in the coupling area or leaks. The stand-off should be replaced at least every 12 months.
4 Installation Instruction

4.1 Scope of supply

The standard scope of supply of the Chattanooga Intelect F-SW:

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

4.2 Unpacking

- Carefully remove the instrument and accessories from the packaging container.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer immediately if any items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

4.3 Correct positioning of the device

Make sure that the device is positioned at a distance from the wall so that the mains plug can be pulled without restriction.
4.4 **Handpiece holder installation**

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

- Use a 2.5 mm Allen key for installation.

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

![Mounted handpiece holder](image)

**Fig. 4-7** Mounted handpiece holder

4.4.1 **Installing the F-SW holding arm (optionally)**

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

- 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).

![Attachment holes for the holding arm](image)

**Fig. 4-8** Attachment holes for the holding arm

- Place the holding arm into the holder.
4.4.2 Connecting power supply cables

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

4.4.3 Handpiece connection

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

NOTE
Fill the water circuit of the Chattanooga Intelect F-SW first when the F-SW handpiece is first connected after delivery. The instrument will signal “water level too low” when it is switched on.
4.4.4 Connecting the optional foot switch

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

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

4.4.5 Potential equalisation (optional)

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

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

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

4.4.6 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.
4.5 Transport

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

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

Defect of the touchscreen or other components!
- DO NOT carry the device by means of mounted accessory parts (e.g. F-SW plug).
- 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. 4-11 Transporting the device

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

4.6 Compatibility

The Chattanooga Intelect F-SW is allowed to be operated with the following accessories:
- Handpiece F-SW SEPIA LT Art. no. 19000
- Handpiece C-ACTOR SEPIA LT Art. no. 29204.0001
- Foot switch
5 **Operation**

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

5.1 **User interface**

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

![Diagram of user interface](image)

**Fig. 5-12  Controls**

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

**NOTE**

The following functional description refers to control software version 13441.19.x.x or later (this can be seen in the Info menu).
Navigation bars:
The top and bottom navigation bars (Fig. 5-12/1 to Fig. 5-12/3 and 3, Fig. 5-12/6 to Fig. 5-12/8) contain control buttons that you can use for navigating through the menus:

Parameter entry screen:
Open the sub-menu
Jump to the “Load configuration” sub-menu (call up saved parameter configurations or patient records)

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

Status bar:
The flag on the right of the status bar displays the menu language. Touching the flag icon takes you directly to the “Languages” sub-menu where you can select a different menu language.
A warning symbol appears at the far left of the status bar if there is an error. Touching this symbol takes you directly to the “Warnings” sub-menu that displays all warning messages that are currently active.
The name of the loaded configuration/patient record (* indication/patient name) is displayed.
Parameter display:
The treatment parameters are displayed in the parameter display field (Fig. 5-12/9) in the following sequence:

<table>
<thead>
<tr>
<th>F-SW</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual energy level in mJ/mm² or in MPa</td>
<td>0.25 mJ/mm²</td>
</tr>
<tr>
<td>Nominal number of shocks or nominal total energy</td>
<td>500 SW</td>
</tr>
<tr>
<td>Actual frequency</td>
<td>4.0 Hz</td>
</tr>
<tr>
<td>Actual number of shocks</td>
<td>0 SW</td>
</tr>
<tr>
<td>Actual total energy in J</td>
<td>0 J</td>
</tr>
</tbody>
</table>

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. 5-13  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. 5-14/2).
- If there are more than 4 menu items, they can be selected using the arrow keys (Fig. 5-14/1). If one of the arrow keys disappears, this means no more selections can be made in this direction.
- Once a sub-menu has been selected, it is opened using the “OK” button.
Fig. 5-14  List of sub-menu items
## 5.2 Overview of menu functions

<table>
<thead>
<tr>
<th>Parameter entry screen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main menu</strong></td>
</tr>
<tr>
<td><strong>1st sub-menu</strong></td>
</tr>
<tr>
<td><strong>2nd sub-menu</strong></td>
</tr>
<tr>
<td><strong>Menu</strong></td>
</tr>
<tr>
<td>Reset counter</td>
</tr>
<tr>
<td>Save configuration</td>
</tr>
<tr>
<td>Load configuration</td>
</tr>
<tr>
<td><strong>Setup</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Info</strong></td>
</tr>
<tr>
<td><strong>Language</strong></td>
</tr>
<tr>
<td><strong>Time</strong></td>
</tr>
<tr>
<td>Touch screen calibration</td>
</tr>
<tr>
<td>Drain the water circuit</td>
</tr>
<tr>
<td>Fill the water circuit</td>
</tr>
<tr>
<td>Bleed the water circuit</td>
</tr>
<tr>
<td>Reset water change time</td>
</tr>
<tr>
<td>Specification of mJ/mm²/Mpa</td>
</tr>
<tr>
<td>Specification SW number/total energy</td>
</tr>
<tr>
<td>Autofreq. [on]</td>
</tr>
<tr>
<td>Warning history</td>
</tr>
<tr>
<td>Software update</td>
</tr>
<tr>
<td>Predefined applications</td>
</tr>
<tr>
<td>Service</td>
</tr>
<tr>
<td><strong>Warnings</strong></td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
</tr>
<tr>
<td><strong>End control program</strong></td>
</tr>
</tbody>
</table>

Fig. 5-15   Menu overview
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.

![Image of the keyboard window with Info section]

Menu exit  Back

F-SW

Info

Hand-held trigger counter  3184
Total trigger counter  3102
Total operating hours  4943

Control software  1544.1.14.4.0
Network address  10.10.30.13
(000155100a510)
Warning history - List of the last 100 warning and error messages
Language - Setting the language
Time - Setting the date and time
Touch screen calibration - This function makes it possible to recalibrate the touch screen, i.e. for correct recognition of the touch coordinates

Draining the water circuit - The corresponding sequences for emptying or filling the water circuit are activated.
Filling the water circuit - The corresponding sequences for bleeding the water circuit are activated.
Bleeding the water circuit - Reset the reminder function for the water renewal
Resetting water renewal time - Transferring a software update from the USB memory stick
Software update - Changeover between shock number and total energy nominal value specification

Specification of shock wave number/total energy - Only in F-SW mode: 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.

Autofreq. on / off
5.3 Starting the instrument

- Switch on the Chattanooga Intelect F-SW using the main switch.

**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 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 6.4.2 Filling the water circuit.

Warm-up phase

Once a day, the Chattanooga Intelect F-SW 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. 5-16  Warm-up phase

**NOTE**

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

A load test is performed once a day when the Chattanooga Intelect F-SW 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. 5-17  High-voltage test
5.4 Setting the treatment parameters

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

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

NOTE

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

<table>
<thead>
<tr>
<th>Energy flux density in mJ/mm²</th>
<th>Maximum frequency Handpiece</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.55</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.50</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.45</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.40</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.35</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.30</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.25</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.20</td>
<td>5 Hz</td>
</tr>
<tr>
<td>0.15</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.12</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.10</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.07</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.05</td>
<td>7 Hz</td>
</tr>
<tr>
<td>0.03</td>
<td>8 Hz</td>
</tr>
<tr>
<td>0.02</td>
<td>8 Hz</td>
</tr>
<tr>
<td>0.01</td>
<td>8 Hz</td>
</tr>
</tbody>
</table>

Table 5-1 Setting the treatment parameters in F-SW mode
### C-ACTOR

<table>
<thead>
<tr>
<th>Energy flux density in mJ/mm²</th>
<th>Maximum frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.24</td>
<td>3 Hz</td>
</tr>
<tr>
<td>1.14</td>
<td>3 Hz</td>
</tr>
<tr>
<td>1.02</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.88</td>
<td>3 Hz</td>
</tr>
<tr>
<td>0.76</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.69</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.56</td>
<td>4 Hz</td>
</tr>
<tr>
<td>0.45</td>
<td>5 Hz</td>
</tr>
<tr>
<td>0.33</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.25</td>
<td>6 Hz</td>
</tr>
<tr>
<td>0.13</td>
<td>7 Hz</td>
</tr>
<tr>
<td>0.08</td>
<td>8 Hz</td>
</tr>
<tr>
<td>0.05</td>
<td>8 Hz</td>
</tr>
<tr>
<td>0.03</td>
<td>8 Hz</td>
</tr>
</tbody>
</table>

Table 5-2 Setting the treatment parameters in C-ACTOR mode
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.

![Energy level is not yet reached](image1)

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

![Error: Energy level not set](image2)

In case the warning appears, you can acknowledge it by touching “OK”. Inform your service centre if the fault continues.
5.6 Storing the treatment parameters

- Touch the “Menu” button.
- Select the “Save configuration” function as shown in the picture below (1) to save the current setting of the treatment parameters.
- Touch the “OK” button.

![Fig. 5-20 Storing the treatment parameters](image)

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 (1).

- Touch the “Save” key to save the current setting (see picture below).

![Fig. 5-21 “Save configuration” sub-menu](image)

**NOTE**

If you select a field that is already occupied, you are asked if you want to overwrite the content. Confirm by touching “OK” or revoke your selection by touching the “Back” key.
• To rename the configuration, touch the button again that has already been selected. This activates the keyboard window.

Fig. 5-22 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. 5-21/3).

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 (Fig. 5-18).
- If you are in the main menu, select the "Load configuration" function from the list (Fig. 5-20/2).

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

- In-house applications
- Orthopaedic indications
- Urological indications

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.

- Select the required indication.

Fig. 5-23  Loading a configuration I

Fig. 5-24  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. 5-25  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. 5-26 In-house applications](image)

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

![Fig. 5-27 In-house indications](image)

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. 5-28 Text box for treatment notes](image)
• 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 Patient record

• Touch the “In-house applications” button (see picture below).
• Touch “OK”.
• Touch the button on which the required patient name is displayed

![Fig. 5-29 Loading a patient record](image)

• Touch the “Protocol” button.

The patient record will be displayed.

![Fig. 5-30 Patient record – treatment details](image)
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.

- 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.

![VAS scale](Fig. 5-32 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.

![VAS scale](Fig. 5-33 Set VAS value)
5.10 Data transfer

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

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

Exporting treatment data

- Load a patient-specific parameter record.
- Select the “Data transfer” / “Export treatment data” function in the 1st sub-menu (see picture below).

![Fig. 5-34  Data export](image)

- 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. 5-35  Data export](image)

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. 5-36 Establishing the USB connection](image)

**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. 5-34/2).
- 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. 5-34/3).

- 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 Software updates

5.11.1 Loading the software onto the USB stick

5.11.1.1 Extracting the software using Windows

- Save the ZIP file onto your computer’s hard disk.
- Right-click on the ZIP folder icon.
- In the shortcut menu that appears, select the “Explorer” item.

![Fig. 5-38 Selecting “Explorer”](image)

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

![Fig. 5-39 Folder with update files](image)

- In this folder, select the “combiselect_update.ini” and “combiselect_update_img.ini” files and the “ffsdisk” folder and copy them onto your USB stick.
- Start the software update as described.
5.11.2 Extracting the software with WinZip

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

![Zip file saved on USB stick](Fig. 5-40)

- Right-click on the ZIP file icon.
- In the shortcut menu, select the WinZip icon.
- Select “Extract to here” (see picture below).

![Extracting files](Fig. 5-41)

- Following extraction, the following files are displayed on the USB stick: “combiselect_update.ini”, “combiselect_update_img.ini” and “ffsdisk” folder.

![Files have been extracted](Fig. 5-42)

- Remove the USB stick and start the software update as described in the following chapter.
5.11.3 Updating the software on the instrument

- Select the “Update software” function in the “Setup” menu.
- Connect the USB stick to the USB port of the Chattanooga Intelect F-SW as soon as you are prompted to do so and confirm by touching “OK”.

Fig. 5-43  Software update

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

- Wait until the update has finished.

Fig. 5-44  Installation completed

- Touch “OK”.
- Remove the USB stick.

The instrument is ready for use.

5.12 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. 5-45  Resetting the treatment shock counter
5.13 “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 the Treatment Parameters, Table 5-1).

- Select the F-SW operating mode if this function should be deactivated.
- Activate the “Autofreq. on” item in the “Setup” menu (see picture below).

**Fig. 5-46  Autofreq. on**

The instrument automatically changes to “Autofreq. [off]” status (see picture below).

**Fig. 5-47  Autofreq. off**

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

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

**NOTE**

This frequency can be reduced manually.
5.14 Start-up

Switch the instrument on as described in chapter 5.3 Starting the Instrument.

- Check that there are no bubbles in the F-SW handpiece.
- If bubbles are visible under the coupling diaphragm, proceed as follows: Position the handpiece in the handpiece holder. No stand-off should be attached.

![Fig. 5-48 Optimum handpiece position](image)

Fig. 5-48 Optimum handpiece position

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

- Secure the handpiece in this position for approx. 3 minutes until the suction procedure has finished.
- To work in F-SW mode, set the shock energy to an initial value of 0.1 mJ/mm². The maximum energy level corresponds to an energy flux density of 0.55 mJ/mm².

- Optional: To work in C-ACTOR mode, set the pulse energy to an initial value of 0.03 mJ/mm². The maximum energy level corresponds to an energy flux density of 1.24 mJ/mm².

**NOTE**

The highest permitted frequency is always set when an energy level is selected (see chapter 5.4 Setting the Treatment Parameters, Table 5-1 and Table 5-2) This frequency can be reduced manually. (See also chapter 5.13 “Autofrequency” function.)

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

NOTE

If a nominal shock wave value of less than 1000 shock waves is selected (e.g. 400 shock waves), a window with the following text appears after the nominal value has been reached: “Number/energy set value reached”. The message can be acknowledged by touching the “OK” button or the corresponding trigger button. Further treatment is possible.

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

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

If a nominal value above 1000 shock waves is selected (e.g. 1700 shock waves), the instrument automatically triggers a safety stop at 1000 shock waves (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.).

Fig. 5-49  Safety stop
5.15 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 (see CHAPTER 5.14 Start-up).
- Set the energy level in F-SW mode to 0.2 mJ/mm².
- Optional: Set the energy level in C-ACTOR mode to 0.69 mJ/mm².
- Reset the actual number of shocks on the parameter display of the control panel (see CHAPTER 5.12 Resetting the treatment shock counter).
- Release shocks with a shock frequency of 4 Hz.
- Release shocks by means of the foot switch, if used.
- Check that the triggered shocks are correctly counted on the treatment shock counter.

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

5.16 Standard settings

- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero (see CHAPTER 5.12 Resetting the treatment shock counter).

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

- Start the F-SW treatment at an energy level of 0.1 mJ/mm² and a frequency of 6 Hz.
- Start the C-ACTOR treatment at an energy level of 0.03 mJ/mm² and a frequency of 6 Hz.
5.17 Treatment

Safety information

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

- 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 5.15 Functional checks.

- Read Chapter 1 General Safety Information before beginning treatment.

CAUTION!

Handpiece not positioned correctly.
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 2.1.1 Indications is not permitted!

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

CAUTION!

Injuries to patients and therapists
- No cleaning and maintenance work is to be carried out while the device is being used on the patient.

- Apply a sufficient amount of coupling gel to the patient’s skin in the treatment area and to the F-SW coupling diaphragm or the coupling cushion.

5.18 Switching off the device

- Switch off the Chattanooga Intelect F-SW using the main switch.
6 Cleaning, Maintenance and Overhaul

6.1 Cleaning the device

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

**CAUTION!**

Injuries to patients and therapists

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

**CAUTION!**

Electrical hazard!

- Disconnect the device and the accessories from the mains before starting any cleaning and overhauling work!
- Unplug the mains plug!

Overall external cleaning depends on the frequency of use and application of the device.

All parts which come into contact with the patient must be cleaned after each treatment.

- Wipe down the device parts with a damp cloth.
- For cleaning, use a lukewarm, dilute solution of non-vegetable soapy water.

**ATTENTION**

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

**Ventilation slits**

- Keep the ventilation slits clear.

**Monitor and Touchscreen**

To clean the LC display only a tissue dampened with water but without any cleaning additives may be used.

- Wipe the display.
- Dry the screen with a cotton tissue.
- Remove contamination (eg. contrast media spots) immediately.
6.2 Cleaning the handpiece

6.2.1 Changing the stand-off device

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

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

Fig. 6-50 Mounting the stand-off devices

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

Fig. 6-51 To release the stand-off device
NOTE
The stand-off has a limited service life. It should be replaced if there are visible changes in the material (discolouration, tarnishing, streaks, gas bubbles), deformation of the surface in the coupling area or leaks.
The stand-off device should be replaced at least every 12 months.

6.2.2 Reprocessing of the handpiece and the stand-off devices

After each therapy session all parts of the handpiece which have been in contact with the patient must be thoroughly cleaned and disinfected for further treatments.
Therefore the instruction must be strictly followed in order to avoid damage to the parts and prevent malfunctions.
Make sure that 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 desinfectant spray.
• Wipe the handpiece and the stand-off devices with a damp soft tissue.
• Dry the handpiece and the stand-off devices with a dry, absorbent soft and lint-free tissue.

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

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

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

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

6.3 Cleaning the optional foot switch

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

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

The water in the cooling circuit of the F-SW handpiece should be renewed every 6 months or so.

The instrument automatically displays a message to this effect when it is switched on if the water renewal is due (see the picture below).

![Prompt for water renewal](image)

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

6.4.1 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.
- Select F-SW mode.
- Activate “Bleed water circuit” operating mode in the “Setup” menu (see picture below).

![Water renewal](image)

- Connect the water bag to the Chattanooga Intelect F-SW as soon as the message appears (see picture next side).
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.

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

- 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.
6.4.2  Filling the water circuit

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

Fig. 6-57  Filling the water bag

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

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

Fig. 6-58  Venting the connection tube

- Place the F-SW handpiece into the F-SW handpiece holder so that any air bubbles that form will be immediately sucked up by the bubble trap.
- Activate “Fill water circuit” operating mode in the “Setup” menu
- Connect the water bag to the water tube connection on the rear of the instrument as soon as the message appears.
Cleaning, Maintenance and Overhaul

Fig. 6-59  Filling the water circuit I

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

A progress display with the message “Please wait” appears on the display.
- As soon as the water circuit has been filled, the instrument prompts you to remove the water bag (see picture below). There may be water left in the bag.

Fig. 6-60  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 picture next side).
6.4.3 **Bleeding the water circuit**

- Select “Bleed water circuit” from the “Setup” menu (Fig. 6-53/3).
  A progress bar will be displayed (Fig. 6-61).
- 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.

6.4.4 **Resetting the water renewal time**

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

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

- Activate “Reset water renewal time” operating mode in the “Setup” menu

The time when the water renewal reminder is triggered is automatically moved forwards by six months. A window showing the new date of water renewal appears briefly on the display.
- Press the “Exit” button to open the parameter entry screen.

Failure to renew the water regularly may shorten the service life of the instrument.
6.5 **Fuse replacement**

The mains fuse holder is located on the rear panel of the Chattanooga Intelect F-SW.

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

![Mains fuse holder](image)

**Fig. 6-62** Mains fuse holder

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

![Fuse replacement](image)

**Fig. 6-63** Fuse replacement

- Replace the fuses (5A/250 VAC).
- Push the mains fuse holder back into the opening until it engages.

6.6 **Maintenance and safety checks**

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

Maintenance services can be ordered from our regional representatives in your area. We recommend that functional and safety checks be performed at least once a year. National accident prevention regulations and test and inspection intervals prescribed for medical devices must, of course, be observed.

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

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

**NOTE**

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

When disposing of this medical product, please proceed in accordance with applicable country-specific regulations. After expiration of its service life, dispose of the Chattanooga Intelect F-SW as waste electronic equipment. Never dispose of the device together with municipal household waste.

- 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.

6.8 Repair

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

6.9 Service life


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

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.
# Status messages and trouble-shooting

## 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.

<table>
<thead>
<tr>
<th>Specified number of shock waves reached</th>
<th>Acknowledge message, further treatment is possible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock wave safety stop</td>
<td>Acknowledge message, further treatment is possible.</td>
</tr>
<tr>
<td>F-SW: load test unsuccessful</td>
<td>Restart the instrument and repeat the test. Do not continue to use the instrument if the fault continues. Notify your Service centre.</td>
</tr>
<tr>
<td>F-SW: charging timeout</td>
<td>Acknowledge message. Inform your Service centre if the fault continues.</td>
</tr>
<tr>
<td>F-SW: water temperature too high</td>
<td>Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.</td>
</tr>
<tr>
<td>F-SW: water temperature too low</td>
<td>Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.</td>
</tr>
<tr>
<td>F-SW: water level too low</td>
<td>Fill the water circuit (see <strong>CHAPTER 6.4.2 FILLING THE WATER CIRCUIT</strong>)</td>
</tr>
<tr>
<td>F-SW: water circuit fault</td>
<td>Pump defect. Treatment is not possible. Bleed the water circuit (see <strong>CHAPTER 6.4.3 BLEEDING THE WATER CIRCUIT</strong>). Inform your Service centre if the fault continues.</td>
</tr>
<tr>
<td>F-SW: water pump current too low</td>
<td>Acknowledge message. Inform your Service centre if the fault continues.</td>
</tr>
<tr>
<td>F-SW: pump temperature too high</td>
<td>Acknowledge message, further treatment is possible once the pump temperature has returned to permitted values.</td>
</tr>
<tr>
<td>Status message</td>
<td>Action</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>F-SW: therapy head overtemperature</td>
<td>Acknowledge message, further treatment is possible once the therapy head temperature has returned to permitted values.</td>
</tr>
<tr>
<td>F-SW: water temperature sensor failure</td>
<td>Restart the instrument. Inform your Service centre if the fault continues.</td>
</tr>
<tr>
<td>Shock wave limit for current handpiece reached</td>
<td>Shock wave limit for current handpiece reached. Replace the handpiece.</td>
</tr>
<tr>
<td>F-SW: charging unit not ready</td>
<td>Acknowledge message. Call your Service centre if the fault continues after a reset.</td>
</tr>
<tr>
<td>USB stick was not recognised</td>
<td>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.</td>
</tr>
<tr>
<td>Water amount insufficient, please check supply</td>
<td>Fill the water bag and check whether water is flowing into the water circuit. If the fault persists, inform your Service centre.</td>
</tr>
</tbody>
</table>
7.2 **Trouble-shooting**

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

<table>
<thead>
<tr>
<th>Produkt Description</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece F-SW SEPIA LT</td>
<td>19000</td>
</tr>
<tr>
<td>Handpiece C-ACTOR SEPIA LT</td>
<td>29204.0001</td>
</tr>
<tr>
<td>Water bag</td>
<td>4600</td>
</tr>
<tr>
<td>Silicone oil</td>
<td>4700</td>
</tr>
<tr>
<td>Gel bottle</td>
<td>22601</td>
</tr>
<tr>
<td>Stand-off I 30 mm</td>
<td>19000</td>
</tr>
<tr>
<td>Stand-off II 15 mm</td>
<td>19200</td>
</tr>
<tr>
<td>Closing ring</td>
<td>19300</td>
</tr>
<tr>
<td>Handpiece holder set</td>
<td>13-27268</td>
</tr>
<tr>
<td>User manual</td>
<td>13-00061</td>
</tr>
<tr>
<td>Power cord EU</td>
<td>0.0032.012</td>
</tr>
<tr>
<td>Trolley/Cart</td>
<td>4560</td>
</tr>
</tbody>
</table>
# Technical Specifications

## 9.1 Technical Specifications

<table>
<thead>
<tr>
<th>Chattanooga Intelect F-SW</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>F-SW operating mode</td>
<td>F-SW: Single shock, continuous shock 1–8 Hz</td>
</tr>
<tr>
<td>C-ACTOR operating mode</td>
<td>F-SW: Single shock, continuous shock 1–8 Hz</td>
</tr>
<tr>
<td>F-SW energy selection</td>
<td>in steps from 0.01 to 0.55 ( \text{mJ/mm}^2 )</td>
</tr>
<tr>
<td>C-ACTOR energy selection</td>
<td>0.03 – 1.24 ( \text{mJ/mm}^2 )</td>
</tr>
<tr>
<td>Mains input voltage</td>
<td>100 – 240 VAC</td>
</tr>
<tr>
<td>Mains frequency</td>
<td>50 / 60 Hz</td>
</tr>
<tr>
<td>Mains fuse</td>
<td>T5AH/250 VAC</td>
</tr>
<tr>
<td>Power consumption</td>
<td>max. 450 VA</td>
</tr>
<tr>
<td>Ambient temperature during operation</td>
<td>10 – 30 °C</td>
</tr>
<tr>
<td>Ambient temperature during storage and transport</td>
<td>0 – 60 °C, frost free</td>
</tr>
<tr>
<td>Ambient pressure during storage and transport</td>
<td>500 – 1060 hPa</td>
</tr>
<tr>
<td>Ambient air pressure during operating</td>
<td>800 – 1060 hPa</td>
</tr>
<tr>
<td>Air humidity during operation</td>
<td>5 – 55%, non-condensing</td>
</tr>
<tr>
<td>Air humidity during storage and transport</td>
<td>5 – 95%, non-condensing</td>
</tr>
<tr>
<td>Control device weight</td>
<td>23.6 kg</td>
</tr>
<tr>
<td>F-SW handpiece weight with cable, filled</td>
<td>990 g</td>
</tr>
<tr>
<td>C-ACTOR handpiece weight with cable, filled</td>
<td>990 g</td>
</tr>
<tr>
<td>Housing dimensions (W x H x D)</td>
<td>450 x 165 x 530 mm</td>
</tr>
<tr>
<td>Classification according to MDD</td>
<td>Class IIb device</td>
</tr>
<tr>
<td>Protection against the ingress of water</td>
<td>IPX1</td>
</tr>
</tbody>
</table>

Subject to technical changes
### Shock wave source of the F-SW handpiece

<table>
<thead>
<tr>
<th></th>
<th>minimum</th>
<th>typical</th>
<th>maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generation method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focusing method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Energy settings</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy flux density (mJ/mm²)</td>
<td>0.10</td>
<td>0.35</td>
<td>0.55</td>
</tr>
<tr>
<td>Peak positive acoustic pressure [MPa]</td>
<td>14</td>
<td>36</td>
<td>62</td>
</tr>
<tr>
<td>Peak negative acoustic pressure [MPa]</td>
<td>9</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>Axial focus size (-6dB focal zone) [mm]</td>
<td>57</td>
<td>49</td>
<td>34</td>
</tr>
<tr>
<td>Lateral focus size (-6dB focal zone) [mm]</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Focus volume [cm³]</td>
<td>0.87</td>
<td>0.37</td>
<td>0.14</td>
</tr>
<tr>
<td>Derived acoustic pulse energy (r=2.5mm) [mJ]</td>
<td>1.7</td>
<td>5.5</td>
<td>8.5</td>
</tr>
</tbody>
</table>

### F-SW handpiece without stand-off device

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure wave generation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure wave expansion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focus size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focal zone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutically effective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pressure wave generation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pressure wave expansion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Focus size</strong></td>
<td>5 mm x 5 mm x 30 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focus</strong></td>
<td>50 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focal zone</strong></td>
<td>min. 35 - 65 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Therapeutically effective</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td>0 - 125 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### F-SW handpiece with stand-off device I (short)

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focal zone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutically effective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Focus size</strong></td>
<td>5 mm x 5 mm x 30 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focus</strong></td>
<td>30 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focal zone</strong></td>
<td>min. 15 - 45 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Therapeutically effective</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td>0 - 105 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### F-SW handpiece with stand-off device II (long)

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of focal zone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutically effective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Focus size</strong></td>
<td>5 mm x 5 mm x 30 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focus</strong></td>
<td>15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Depth of focal zone</strong></td>
<td>min. 0 - 30 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Therapeutically effective</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>penetration depth, 5 MPa</td>
<td>0 - 90 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subject to technical changes
Technical Specifications

Shock wave source of C-ACTOR handpiece

<table>
<thead>
<tr>
<th>Erzeugungsart</th>
<th>electromagnetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focusing method</td>
<td>parabolic reflector</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Energy settings</th>
<th>minimum</th>
<th>typical</th>
<th>maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy flux density (mJ/mm²)</td>
<td>0.25</td>
<td>0.76</td>
<td>1.24</td>
</tr>
<tr>
<td>Peak positive acoustic pressure [MPa]</td>
<td>18</td>
<td>44</td>
<td>78</td>
</tr>
<tr>
<td>Peak negative acoustic pressure [MPa]</td>
<td>12</td>
<td>20</td>
<td>23</td>
</tr>
<tr>
<td>Axial focus size (-6dB focus zone) [mm]</td>
<td>24</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>Lateral focus size (-6dB focus zone) [mm]</td>
<td>3.9</td>
<td>2.8</td>
<td>2.1</td>
</tr>
<tr>
<td>Focus volume [cm³]</td>
<td>0.2</td>
<td>0.1</td>
<td>0.04</td>
</tr>
<tr>
<td>Derived acoustic pulse energy (r=2.5mm) [mJ]</td>
<td>3.3</td>
<td>9.5</td>
<td>15</td>
</tr>
</tbody>
</table>

C-ACTOR handpiece with stand-off device I (short)

<table>
<thead>
<tr>
<th>Focus size</th>
<th>3 mm x 3 mm x 20 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of focus</td>
<td>15 mm</td>
</tr>
<tr>
<td>Depth of focal zone</td>
<td>min. 5 – 25 mm</td>
</tr>
<tr>
<td>Therapeutically effective penetration depth, 5 MPa</td>
<td>0 – 50 mm</td>
</tr>
</tbody>
</table>

C-ACTOR handpiece with stand-off device II (long)

<table>
<thead>
<tr>
<th>Focus size</th>
<th>3 mm x 3 mm x 20 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of focus</td>
<td>0 mm</td>
</tr>
<tr>
<td>Depth of focal zone</td>
<td>min. 0 – 10 mm</td>
</tr>
<tr>
<td>Therapeutically effective penetration depth, 5 MPa</td>
<td>0 – 35 mm</td>
</tr>
</tbody>
</table>

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.

Subject to technical changes
Essential performance:

Equipment safety ("essential performance") according to IEC/EN 60601-1, 3rd edition:

- The ME Equipment shall be free from incorrect display of energy levels.
- The ME Equipment shall be free from unintended shock wave release.

NOTE
When the medical product is distributed 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 when the medical product and the corresponding indications are allowed there.
9.2 Type plate Chattanooga Intelect F-SW

![Type plate Chattanooga Intelect F-SW](image)

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

9.3 Conformity with directives

This medical product bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.

9.4 Conformity with standards

This device complies with the applicable standards

CAN/CSA-C22.2 NO. 60601-1-6:11 + AMD1
ANSI/AAMI ES 60601-1:2005(R)2012,
AND C1:2009 AND A2:2010(R)2012 (CONSOLIDATED TEXT)
IEC 60601-1:2012.

<table>
<thead>
<tr>
<th>Acc. to IEC/EN 60601-1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Type of protection against electric shocks:</td>
<td>Protection class 1</td>
</tr>
<tr>
<td>- Applied part of type B</td>
<td></td>
</tr>
</tbody>
</table>

* The applied part contains of the coupling foil of the handpiece.
EMC guidelines and manufacturer’s declaration

<table>
<thead>
<tr>
<th>Interference emission measurements</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF emissions acc. to CISPR 11</td>
<td>Group 1</td>
<td>The Chattanooga Intelect F-SW 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. According to EN IEC 60601-2-36:1997 Section 36 this does not apply during the generation and release of the pressure pulse.</td>
</tr>
<tr>
<td>HF emissions acc. to CISPR 11</td>
<td>Class B</td>
<td>The Chattanooga Intelect F-SW 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.</td>
</tr>
<tr>
<td>Harmonic emissions according to IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations /flicker emissions according to IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
## Technical Specifications

### Guidelines and manufacturer’s declaration – Resistance to emitted electromagnetic interference

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

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) acc. to IEC 61000-4-2</td>
<td>±6 kV contact discharge</td>
<td>±6 kV contact discharge</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±8 kV air discharge</td>
<td>±8 kV air discharge</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient disturbances / bursts according to IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surges according to IEC 61000-4-5</td>
<td>±1 kV line(s) to line(s)</td>
<td>±1 kV line(s) to line(s)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2 kV line(s) to earth</td>
<td>±2 kV line(s) to earth</td>
<td></td>
</tr>
<tr>
<td>Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11</td>
<td>&lt; 5% U&lt;sub&gt;T&lt;/sub&gt; (&lt; &gt; 95% drop in U&lt;sub&gt;T&lt;/sub&gt;) for ½ period</td>
<td>&lt; 5% U&lt;sub&gt;T&lt;/sub&gt; (&lt; &gt; 95% drop in U&lt;sub&gt;T&lt;/sub&gt;) for ½ period</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>40% U&lt;sub&gt;T&lt;/sub&gt; (60% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 5 periods</td>
<td>40% U&lt;sub&gt;T&lt;/sub&gt; (60% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 5 periods</td>
<td>If the user of the Chattanooga Intelect F-SW requires continued operation during power mains interruptions, it is recommended that the Chattanooga Intelect F-SW be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>70% U&lt;sub&gt;T&lt;/sub&gt; (30% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 25 periods</td>
<td>70% U&lt;sub&gt;T&lt;/sub&gt; (30% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 25 periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% U&lt;sub&gt;T&lt;/sub&gt; (&lt; &gt; 95% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 5 s</td>
<td>&lt; 5% U&lt;sub&gt;T&lt;/sub&gt; (&lt; &gt; 95% drop in U&lt;sub&gt;T&lt;/sub&gt;) for 5 s</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>The mains frequency magnetic fields should be those of a typical business or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: U<sub>T</sub> is the mains alternating voltage prior to application of the test level.
The Chattanooga Intelect F-SW model is intended for operation in the electromagnetic environment specified below. The customer or the user of the Chattanooga Intelect F-SW should ensure that it is used in such an environment.

### Immunity tests

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 V&lt;sub&gt; rms &lt;/sub&gt; 150 kHz to 80 MHz</td>
<td>3 V&lt;sub&gt; rms &lt;/sub&gt; 150 kHz to 80 MHz</td>
</tr>
<tr>
<td>Radiated HF interference according to IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

**Electromagnetic environment – guidelines**

- Portable and mobile RF equipment should be used no closer to any part of the Chattanooga Intelect F-SW, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter.

**Recommended safety distance:**

- Conducted RF: 
  \[ d = 1.2 \sqrt{P} \]
- Radiated HF: 
  \[ d = 1.2 \sqrt{P} \text{ for 80 MHz to 800 MHz} \]
  \[ d = 2.3 \sqrt{P} \text{ for 800 MHz to 2.5 GHz} \]

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

\(^b\) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The Chattanooga Intelect F-SW is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the Chattanooga Intelect F-SW can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the Chattanooga Intelect F-SW as recommended below, according to the maximum output power of the communications equipment.

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

<table>
<thead>
<tr>
<th>Rated power of transmitter [W]</th>
<th>Safety distance according to frequency of transmitter [m]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1.2\sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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

NOTE 1
An additional factor of $10/3$ was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.5 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area 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.
9.5 Certificates

**Fig. 9-2 Declaration of conformity**

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nombre y dirección del fabricante: / Nome e indirizzo del fabbricante:

STORZ MEDICAL AG
Lohstapfstr. 6
8374 Tägerwilen
SWITZERLAND

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Declaramos bajo nuestra única responsabilidad que / Dichiamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / el dispositivo sanitario: / il dispositivo medico:

Chattanooga Intelect F-SW - 21095 / Produktcode: TT
Product code: TT / Código del producto: TT / Codice prodotto: TT

der Klasse: / der Klasse: / de la clase: / di classe:

IIb nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / conforme al anexo IX de la directiva 93/42/CEE / secondo l’allegato IX della direttiva 93/42/CEE


meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device.

cumple las disposiciones pertinentes de la Directiva de productos sanitarios 93/42/CEE y sus transposiciones a la legislación nacional. La presente declaración se aplicará junto con el protocolo de aceptación final que corresponda al producto.

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il rapporto di ispezione finale del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procedimiento para la evaluación de la conformidad: / Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Directive 93/42/EEC Annex II, excluding Section 4
Directiva 93/42/CEE, anexo II, sin el apartado 4
Direttiva 93/42/CEE senza Allegato II, sezione 4

Gültigkeitsdatum: / Validity date: / fecha de validez: / data di validità:

01.01.2020

Benannte Stelle: / Notified Body: / Organismo notificato: / Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
GERMANY
CE 0197

Tägerwilen, 11-09-2018

Ort, Datum / Place, date / Lugar, fecha / Luogo, data

COO_GF_041_01_00  Version 5

Fig. 9-2 Declaration of conformity
9.6 Symbols and labels

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

<table>
<thead>
<tr>
<th>Label</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>foot switch connection</td>
</tr>
<tr>
<td>2</td>
<td>F-SW handpiece connection</td>
</tr>
<tr>
<td>3</td>
<td>Applied part of type B</td>
</tr>
</tbody>
</table>

Table 9 -3 Symbols attached to the front side
Table 9 - Labels and symbols attached to the rear side

<table>
<thead>
<tr>
<th>Label</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Potential equalisation</td>
</tr>
<tr>
<td>2</td>
<td>USB-connection</td>
</tr>
<tr>
<td>3</td>
<td>It is essential to comply with the operating manual!</td>
</tr>
<tr>
<td>4</td>
<td>Type plate</td>
</tr>
</tbody>
</table>

Technical Specifications
Technical Specifications

Table 9-5 Labels and symbols of the type plate

<table>
<thead>
<tr>
<th>Label</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Ambient temperature" /></td>
<td>Ambient temperature during storage and transport</td>
</tr>
<tr>
<td><img src="image" alt="Ambient air pressure" /></td>
<td>Ambient air pressure during storage and transport</td>
</tr>
<tr>
<td><img src="image" alt="Air humidity" /></td>
<td>Air humidity during storage and transport</td>
</tr>
</tbody>
</table>

Table 9-6 Labelling packaging
10  Warranty and Service

10.1  Warranty for the control device

During the two-year warranty period from the date of delivery of the product to
the end customer, defects will be remedied at no charge to the customer upon the
customer furnishing adequate proof that the defect is due to defects in material or
workmanship. The warranty does not extend to wear parts.
Transport costs and the risk of loss during the shipping of returned products shall be
borne by the customer.

ATTENTION

Modifications to the device are not permitted.
Any unauthorised opening, repair or modification of the device 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.
10.2 Warranty for the F-SW handpiece and the C-ACTOR Handpiece

The F-SW handpiece and the C-ACTOR handpiece are wear parts. We will replace new handpieces that have performed up to 1 million pulses at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship.

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

Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the case, with the repair label filled in completely.

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

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

**ATTENTION !**

Modifications to the handpiece and the stand-off devices are not permitted. Any unauthorised 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

Should you have any further questions or require additional information, please feel free to contact your dealer.