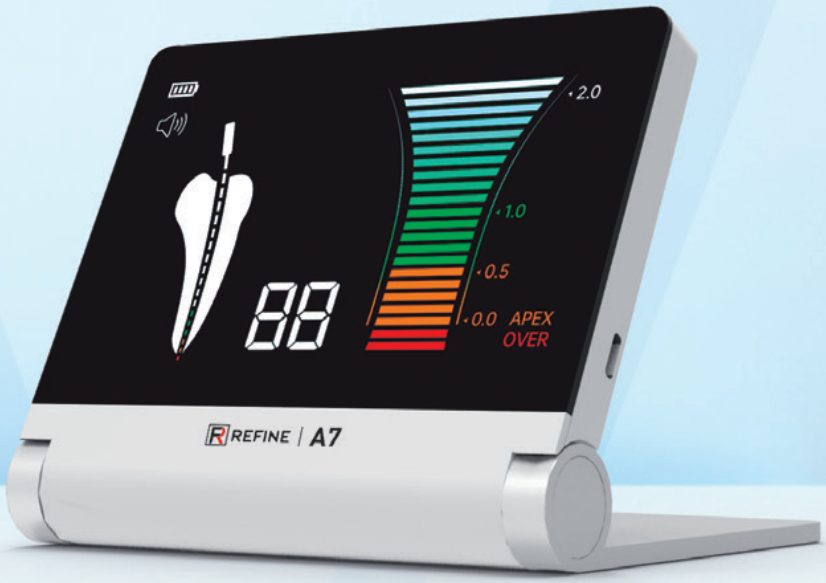
REFINE

CE 0123

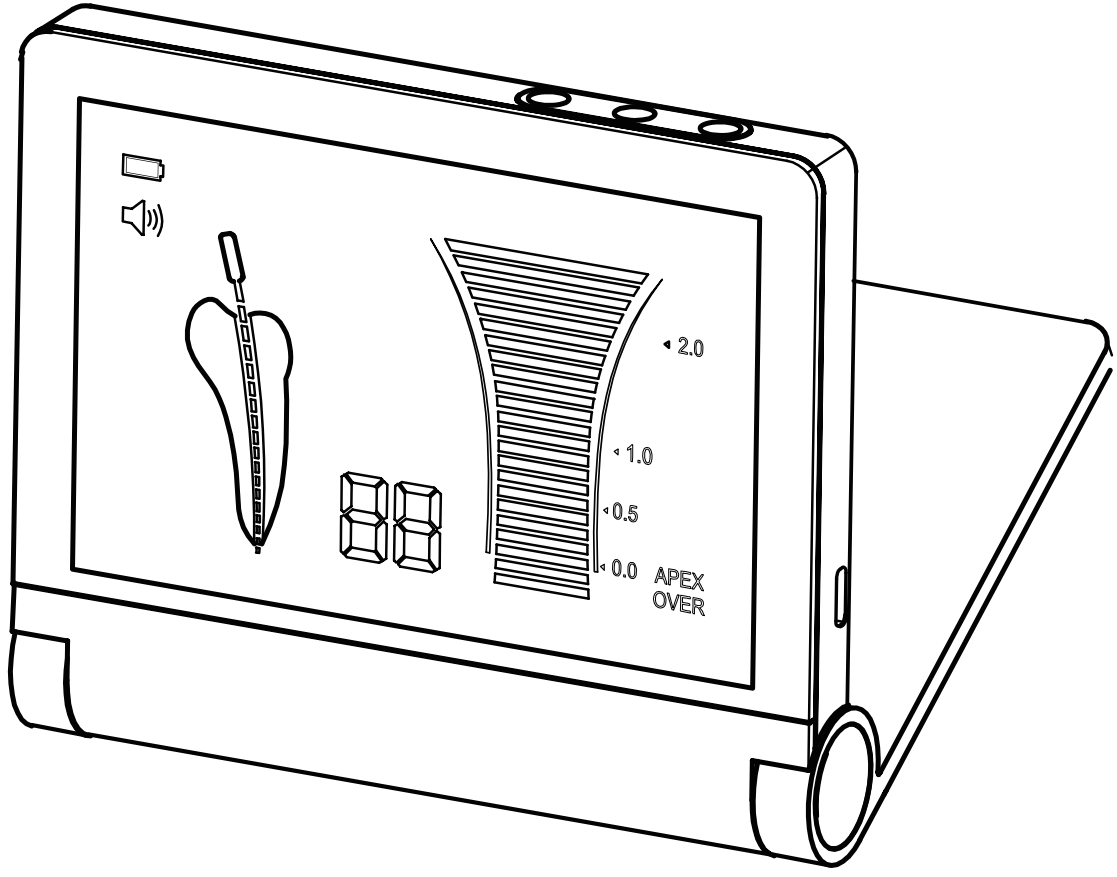
# Apex Locator

## Instruction Manual

Model: A7




RF-APL-M001 Version: 1.8 20241014




For your safety and the safety of your patients please read this user manual carefully before use and file for future reference.
This manual is published by Manufacturer.
We do not guarantee its contents and reserves the right to amend at anytime without prior notice, amendments will be published in new editions of this manual.

# Contents

# 1. Intended use

Apex Locator is used for determination of the apical foramen position and measurement of the root canal length.

The product is only to be used in dental surgeries by qualified dental personnel.

# 2. Precautions

• All precautions should be read and understood before use.

• Equipment is only to be used for its specified intended use.

• Safety instructions are provided in order to prevent the risk of personal injury or damage to the device and are classified as below in accordance with the level of potential risk.

⚠ **WARNING:** Indicates a hazard that may result in serious injury/device damage if instructions are not correctly followed.

⚠ **CAUTION:** Indicates a hazard that may result in mild to moderate injury/device damage if instructions are not correctly followed.

⚠ **WARNING:**

• Use this product in accordance with its intended use and proper method of use.

• This product is not waterproof. Avoid water or chemical solutions on the control unit as it may cause electric shock due to a short circuit.

• The scale indication on the screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file's progression towards the apex.

• Do not expose to or dispose of the battery in a fire.

• Be sure to prevent the lip hook, file clip, file probe and their connector parts from having contact with household power supply sources (such as electrical outlets) as it may cause an electric shock.

• The components in the product package are delivered in a non-sterile condition, be sure to sterilize the file clip, file probe and lip hook by autoclave sterilization prior to use and after each patient.

• Do not operate close to patients with cardiac pacemakers as there is a danger that it may affect the pacemaker.

• Keep away from explosive substances and flammable materials.

**⚠ CAUTION:**

• Do not keep using the product when the battery indicator "  " is flashing. Normal operation or indication may not be performed. Please recharge the battery.

• Should the product function abnormally during operation, cease operation immediately.

• Do not use the product by connecting or integrating into other medical devices.

• Do not drop or allow impact on the product. This may result in personal injury or damage to the unit.

• Avoid using chemical solutions on the lip hook, file probe or file clip during procedures. Use of solutions may cause inflammation.

• When gripping the metallic part of a file or reamer with the file clip, grip the upper part (near the handle). If the lower part (blade transition part and blade part) is gripped, the root canal length cannot be correctly measured and the tip of the file clip may be broken.

• Do not use or leave the product in a high-temperature environment such as under strong direct sunlight, or next to equipment that produces heat as it may cause overheating or fire due to a failure of the internal circuit.

• Do not attempt to disassemble the product nor tamper with the mechanism except as recommend by manufacturer in this User manual.

• This device is for indoor use only.

• Keep the control unit on a level surface.

• If the product is not used for a long period check it is functioning correctly before using on a patient.

• Portable and mobile RF communications equipment can affect Medical Electrical equipment. Do not use RF equipment near the product.

• During operation the Apex Locator may interfere with computers, LAN cables or may cause noise in radio receivers nearby.

• Installation and use of this product requires special precautions regarding EMC according to the EMC information.

• Use only original accessories with this device.

• The apical position is indicated on the screen with "00". In order to avoid over instrumentation, it is suggested to subtract 0.5mm from the reading when determining the working length for shaping.

• Always dry the cavity entrance with a cotton pellet in order to obtain an accurate measurement.

• Users are responsible for the operational control, maintenance and continual inspection of this product.

• The battery can be replaced, please contact our distributor if a replacement battery is required.

• The device must not be used in MRI environment for the device is easily affected by the electromagnetic emission

and would not work or work normally.

• When you meet circumstances where the main unit expires, the misuses lead to the short circuit of the circuit board or accidentally dropping the device results in the damage of components, the device should no longer be reused.

# 3. Contraindication

The Apex Locator is not recommended for use:

a. In patients who have a pacemaker or other implanted electrical devices or have been cautioned by their physicians against the use of small electric appliances such as shavers, hair dryers etc.

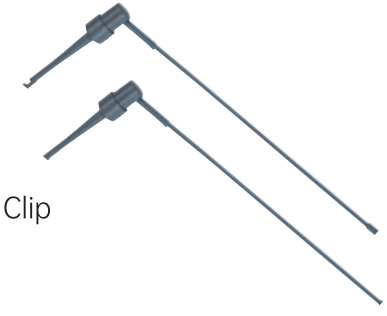
b. In patients allergic to metals.

c. Children with immature teeth.

# 4. Package contents

Apex Locator is composed of a control unit, AC adapter, plug adaptor, measuring wire, lip hook, file clip, file probe .

## Accessories



a). File Clip

b). Measuring wire


c). Battery

d). Lip Hook

e). File Probe

f). AC adapter

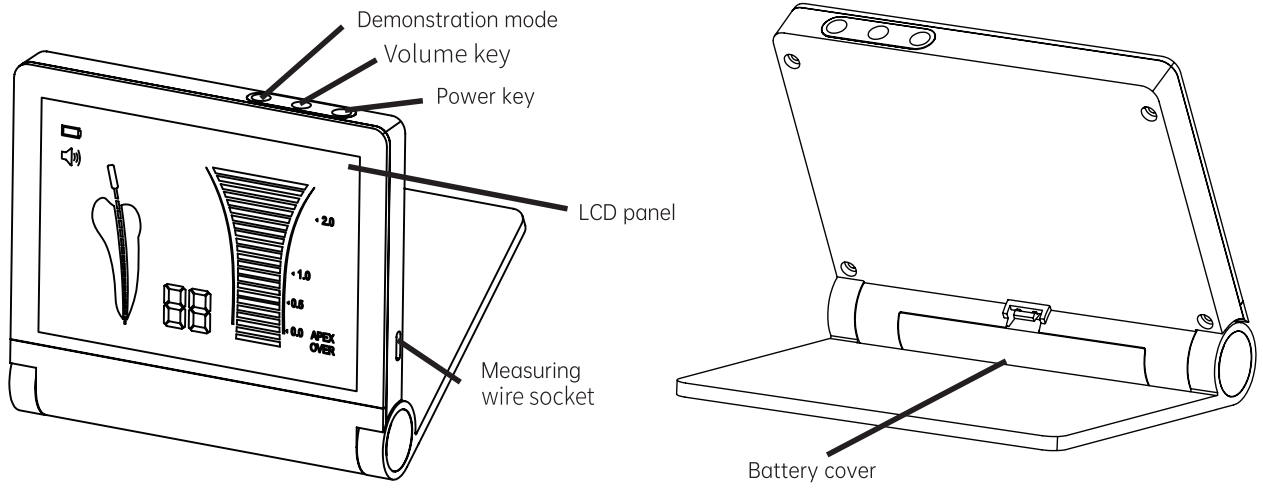
g). Tester

## Accessories list

| No. | Name | Quantity | Consumable? | Can be sterilized? |
|---|---|---|---|---|
| a | File clip | 4 PCS | YES | YES |
| b | Measuring wire | 1 PCS | YES | NO |
| c | Battery | 1 PCS | NO | NO |
| d | Lip hook | 4 PCS | YES | YES |
| e | File probe | 4 PCS | YES | YES |
| f | AC adapter | 1 PCS | NO | NO |
| g | Tester | 1 PCS | NO | NO |

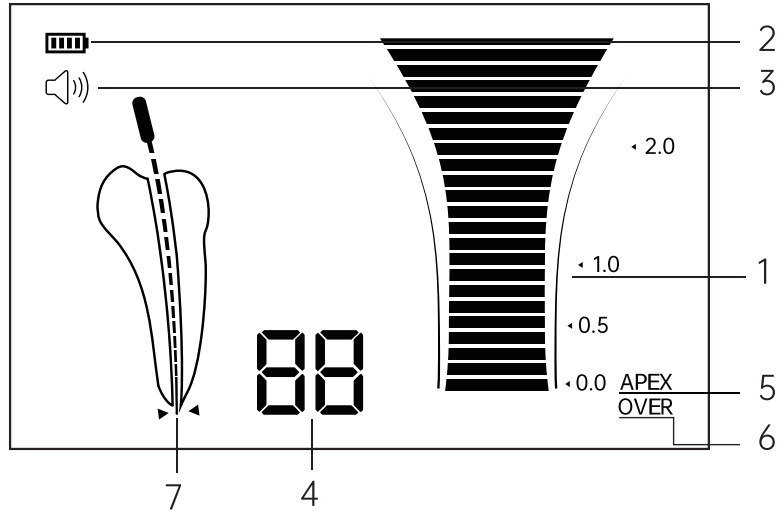
# 5. Component

## 5.1 Control unit



| | |
|---|---|
| **LCD Panel** | Displays the position of the file tip, remaining battery level and sound volume |
| **Power key** | When the Power key is pressed, the power turns on sounding a prompt, then the LCD panel lights up, press the Power key again, the power and the LCD panel turns off |
| **Volume key** | When the Volume key is pressed, the audio volume can be adjusted (rotation of OFF->Low->Medium->High) |
| **Measuring wire socket** | Socket to which the measuring wire is inserted |
| **Battery cover** | Secures battery in place |
| **Demonstration mode** | Press the button to demonstrate the measurement process |
| **Charging socket** | Socket to which the AC adapter is inserted |

## 5.2 LCD panel



| | | |
|---|---|---|
| 1 | **Bar graph** | Displays the approximate position of the end of the file |
| 2 | **Battery indicator** | Displays the remaining battery level. When the Battery indicator flashes, immediately recharge the device with AC adapter |
| 3 | **Volume indicator** | Displays the audio volume<br>(rotation of OFF ->Low ->Medium ->High ) |
| 4 | **Number display** | Displays the present position from the end of the root canal in numerical value. When the value displays “1.0” to “0.6”, a prompt corresponding to each value sounds. When the value reaches "0.5" to "0.1", the prompt sounds is more urgent. When the value reaches "0.0", the prompt sounds with "APEX" displayed on the LCD panel |
| 5 | **Apex indicator** | Indicates the file position has reached the range of anatomical apical foramen. |
| 6 | **OVER Display** | Turns on when the value representing the present position of the file end reaches “oU” |
| 7 | **Measurement indicator** | Indicates the files position in the root canal |

* 4 is not a value to show the actual distance from the end of the root canal in the unit of mm. It is to be used as indication for measurement.

# 6. Testing and installation

## 6.1 Tester test

The tester is used to test whether the Apex Locator works normally, please follow the following steps to test before the first time you use this product (or if necessary):

A) Press the Power key to turn on the Apex Locator (accompanied by a "beep" prompt and the LCD display

lights up).

B) Insert the tester into the measuring wire socket (Figure 1). The LCD display should show a value within the range of "0.5-0.0" and the root canal indicator is in the yellow area, then it means normal.

If the value is not in the "0.5-0.0" range, then the device may be damaged and should not be used.

## 6.2 Installation

1) Connect the measuring wire: securely insert the plug of the measuring wire into the Measuring wire socket on the unit. (Fig.1)

2) Connect the file clip: connect the plug of the file clip to either plug of the measuring wire. Connect the lip hook: connect the lip hook to the other plug of the measuring wire. (Fig.2)

Fig.1

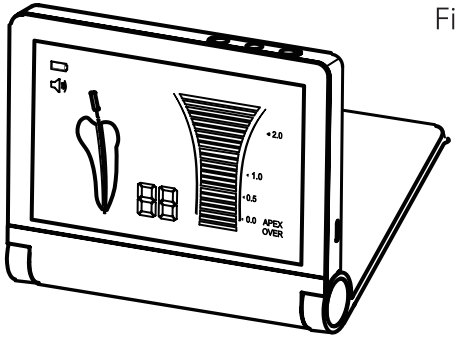



Fig.2

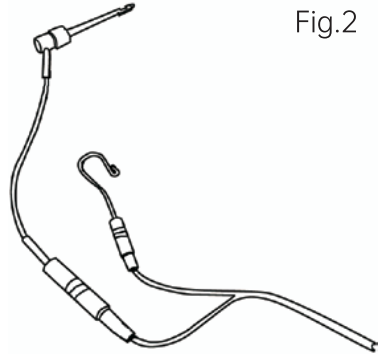
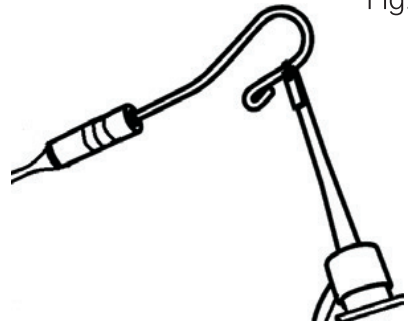


Fig.3

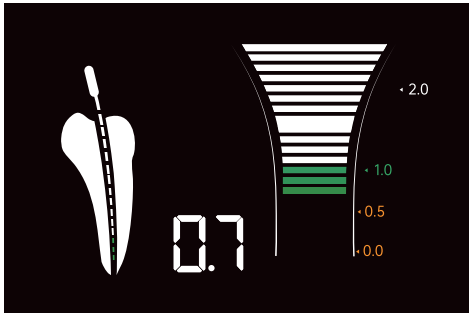


3) Make the lip hook touch the bent section of the file clip (Fig.3), the screen will display"OVER"(as show in Fig.4 c), otherwise, it means the file clip or the measuring wire is damaged, and should be replaced.

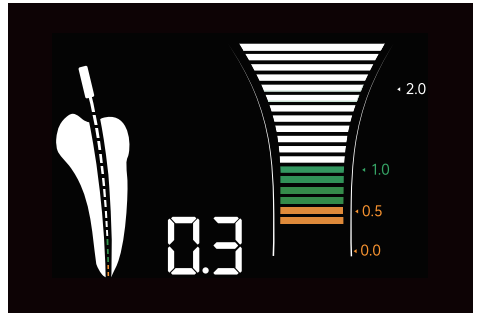
4) Display explanation

- "1.0 to 0.6", Green bar graph and/or low frequency sound: File has reached the front region of the Apex;
- "0.5 to 0.0", Yellow bar graph and/or middle frequency sound: File is very close to the Apex;
- "oU", Red bar graph and/or high frequency sound: File has exceeded the Apex.

Display Screen explanation




a. The file has reached the front region of the apex




b. The file is very close to the apex


c) The file has already exceeded the Apex

Fig.4

5) Demonstration mode

Demonstration mode tracks the movement of the file

a. Pull out the measuring wire and adapter.

b. Turn on Apex Locator

c. Press " ▷|| "button to enter demonstration mode

Demonstration mode will be exited by finishing demonstration or pressing demonstration mode button.

# 7. Operation

## 7.1 Preparation

7.1.1 The use of apex locators alone, without a preoperative and postoperative radio graph, is not a recommended practice as apex locators may not work properlyin all conditions. It is recommended to take an X-ray prior to the use of the Apex Locator, to compare the information given by both devices.

7.1.2 The dentist should have a good understanding of the tooth and root canal in question

7.1.3 The root cavity should be sufficiently exposed and the root should be unblocked.

7.1.4 The largest file that can correctly reach the apex should be selected.

7.1.5 Avoid contact between the file, file clip and the gingiva or any metal crown and bridge appliances. If the crown of the tooth is broken and there is a possibility of the gingiva contacting either the file, file clip or a probe, an incorrect reading may occur. An isolating barrier around the rim of the broken tooth must be

created before proceeding with the Apex location.
7.1.6 Dry canals should be treated with an irrigation solution such as saline or hydrogen peroxide. Access to the cavity should then be air dried or wiped dry with a cotton pellet.
7.1.7 If there is bleeding from the root canal or apical foramen, it must be stopped before a correct measurement can be taken.
7.1.8 Canals must be cleaned of all remnants after root canal treatment before measurement can be taken.
7.1.9 Accessories such as file clips, lip hooks and file probes should be clean and free from any chemical disinfectant or medical solution residue.
7.1.10 Mark the treated tooth and record the information on the patients medical records. Be careful to make sure the tooth is marked in a practical and most resilient part of the tooth.
7.1.11 The root canal must be cleared of any pulp or necrotic tissue and there must be no inflammation or infected material surrounding the apex.
7.1.12 The following cases are not for use with the apex locator.
a) The measurement length of the canal may be shorter than its real length due to root hypoplasia and thus a true reading is not possible
b) A crack in the root may allow electric leakage thus affecting accuracy of the reading
7.1.13 An X-ray shot at a difficult or unusual angle may sometimes cause the illusion that the file tip has not reached the apex. Results of the Apex Locator and X-ray may possibly not correlate falsely indicate that the file tip has not reached the root canal tip.

## 7.2 Operating procedure

7.2.1 Grip the file inserted in the root canal with the file clip. Grip the upper part (near the handle) of the file's metallic part. (Fig.6)
7.2.2 Hang the lip hook on a corner of the patient's mouth. (Fig.7)
7.2.3 Insert the file into the canal and push it slowly towards the Apex. A continuous Prompt sound will sound when the file is less than 2mm from the apex. Gloves must be worn to avoid contact of the operators skin and metal shank of the file.
7.2.4 The "APEX" will be indicated when the screen displays "0.0" but as previously stated 0.5mm to 1mm

should be subtracted from the reading so as to not over instrumentate.

7.2.5 When the file reaches this point, adjust the endo stop and remove the file. By measuring the distance between the endo stop and the tip of the file, the working length of the canal can be determined. (Fig.8)

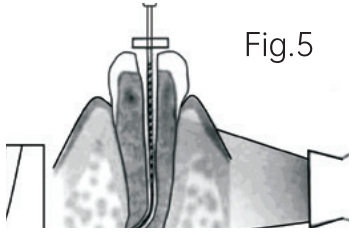


Fig.5

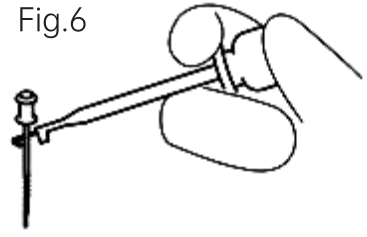


Fig.6

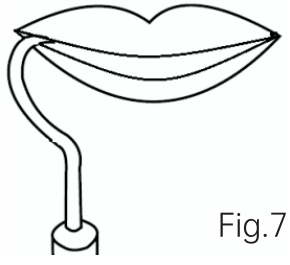


Fig.7

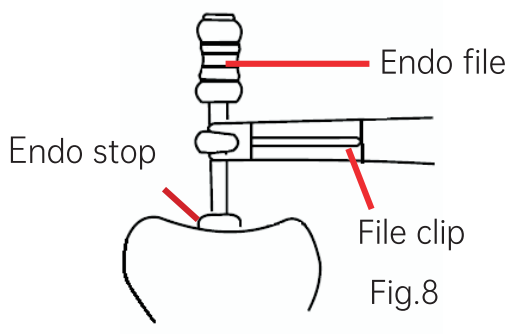



Fig.8

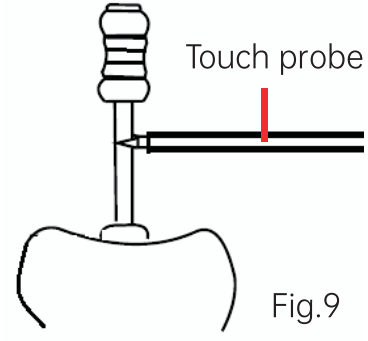



Fig.9

7.2.6 The file probe may also be used instead of the file clip to touch the file when working on posterior to determine the working length of the canal. (Fig.9)

7.2.7 After use, press the Power key for approximately one second to turn off the power (the prompt sounds and the LCD panel turns off). The device will shut down automatically after 5 minutes if unit is not in operation.

7.2.8 Remove the file from the file clip.

7.2.9 Remove the lip hook and file clip from the measuring wire.

7.2.10 Remove the measuring wire from the control unit.

⚠ **CAUTION:** Never hold the measuring wire when removing the lip hook and file clip from the measuring wire. Always hold the connector section.

# 8. Audio volume control

Audio volume can be adjusted to "OFF ", "Low ", Medium ", and "High ".

1) Press the Volume key.

2) The Volume Indicator on the LCD panel and the sound volume will change.

3) Each time the key is pressed the sound volume changes.

NOTICE

The last setting is stored when the control unit is switched off.

# 9. Maintenance

## 9.1 Cleaning

Preparation prior to cleaning

1. Remove the file clip and lip hook from the measuring wire.
2. Remove the measuring wire from the control unit.
3. Check for damage on each cord or deformation on each connector.

Cleaning

1. Rinse accessories thoroughly with clean suitable water, then wipe clean with alcohol-immersed cotton or cloth.
2. Repeat until accessories are visibly clean.

Note:

a. Clean and sterilize the accessories before each use to prevent any contamination. This includes the first use as well as any subsequent use.

b. Accessories that should be cleaned include: measuring wire, file clip, lip hook, file probe.

c. Do not use highly acidic water to immerse or clean .

⚠ **CAUTION:**

Non observance of the following precautions could lead to the deterioration or failure of the accessories. Be sure to follow these precautions when cleaning the accessories.

•For cleaning and disinfection, use disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts). Use of other disinfectants may cause discoloration or cracking.

* For details, contact the manufacturer of the disinfectant.
* In this operation manual, disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts) is called by "disinfectant alcohol".
• When cleaning the product never use solvent such as benzine or thinner.
• Do not use a chlorinated cleaner.
• Do not clean the product with an ultrasonic cleaning apparatus.
• For your own safety, please wear personal protective equipment (gloves, glasses, mask)
• After cleaning the measuring wire, make sure to dry the connector part of the measurement wire.

## 9.2 Sterilization

**Note:** File clip, file probe and lip hook can be sterilized, other parts of Apex Locator can not be sterilized. Please conform to the recommendations of the manual in attachment 1 Reprocessing Instructions of Cleaning Disinfecting and Sterilizing.

**Autoclave Procedure:**

1) Insert into an autoclave pouch.
2) Seal the pouch.
3) Sterilize at 134℃ (0.22MPa - 0.23Mpa) for 3 minutes.
4) The product should remain in a sealed pouch until required for use.

⚠ **CAUTION:**

• The product must be cleaned before sterilization.
• Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.
• Do not use Autoclaves exceeding 138°C during sterilization.
• We recommends sterilization according to EN13060, class B. Always follow autoclave manufacturer's instructions for use.
• Do not touch the product immediately after autoclaving as it will be very hot and must remain in a sterile condition.
• Reprocessed products should be stored, protected from dust with minimum exposure to germs in a dry, dark and cool place.

• Autoclave sterilization is the only agreed method to correctly sterilize this product. The validity of other sterilization methods is not confirmed or guaranteed.
• Resistance to sterilization of File clip ,file probe and lip hook: 300 times.

## 10. Charging battery

Do not use the Apex Locator whilst the indicator is flashing. Charge battery as below:
1) Connect the AC adapter to the Charging Socket of the device, then insert AC adapter plug into supply power socket.
2) The Apex Locator will take approximately 2-3 hours to fully charge.

**Attention:**

a. Battery symbol flashes when charging, and stop flashes when fully charged.
b. The device does not work when it is charging.
c. We provide a plug adapter for certain target markets, if the AC adapter can not match the supply power socket, you can insert the plug of AC adapter into the Plug adapter, then insert the plug adapter into the supply power socket.

⚠ **CAUTION:**

• If not use for a long time, please charge and work on the machine once every 3 months.
• Avoid shorting the battery.
• Do not disassemble or tamper with the battery.
• Use the AC adapter provided by manufacturer (complies with IEC 60601-1) to charge the device, never use a modified or damaged charger.
• Battery will discharge over time if Apex Locator is not used. Always recharge if the unit has not been used for extended periods.
• Only the ICR 14500 DC 3.7V/800mAh Rechargeable Li-ion Battery Cells which have passed the IEC 62133 certification can be used.
3) If you need to replace battery please contact us or your dealer.
How to install the battery:
a. Open the battery housing
b. Insert battery connector into the square notch

c. Make sure it is firmly installed by gently pulling the battery
d. Reinstall the battery housing

Note: the square notch is an anti-mistake design, if the polarity is reversed, the battery can not be installed.

## 11. Regular maintenance checks

Regular maintenance should be performed every 3 months as per the below chart.
If any abnormalities are found, immediately contact our authorized dealer or us.

| Points to check | Process |
|---|---|
| ON/OFF operation | Check that the power turns ON and OFF correctly |
| Remaining battery level | Check that the Battery indicator does not flash. If the display flashes, recharge the battery following the instruction in "10.Charging battery" |
| Sound volume | Press the Volume key and check that the audio volume changes.(rotation of OFF->Low->Medium->High) |
| Connector part | Check for debris or corrosion on the lip hook or connector terminals of the cable |
| Product operation | Check with the tester, that the cable and the control unit operate properly, following the instruction in "6. Testing and installation" |

* See trouble shooting chart if problems are discovered

## 12. Trouble shooting

When a problem is detected, check the following again before requesting a repair.

| Malfunction | Cause | Solution |
|---|---|---|
| The power does not turn on | Battery is not inserted | Insert battery |
| | Battery is not correctly inserted | Correctly insert the battery |
| | The battery level is low | Recharge the battery |

| | | |
|---|---|---|
| Root canal length measurement cannot be performed | The measuring wire or other connectors are not properly connected. | Securely insert the connector Connect the lip hook and file clip and make the lip hook touches the bent section of file clip to check whether the device has been connected correctly.(refer to"6. Testing and installation". ) |
| Sound volume is low | The sound volume is adjusted to"OFF." | Check the sound volume. |
| The LCD panel does not display | The battery level is low | If the LCD panel does not display after the battery is charged, failure of the LCD panel is suspected |
| Bar graph is not stable | The lip hook is not firmly in contact with the membrane of the patient's oral cavity | Adjust the lip hook position so that it correctly contacts the membrane in the oral cavity |
| | Perforation of the canal or an adjacent surface has caries | Remove the file , close the perforation and repair the caries, then repeat the apex detection procedure, carefully inserting the file in canal |
| | Large lateral canal | Try continuing the procedure by gently advancing the file |
| | The file is in contact with the gingiva | When the file contacts the gingiva the entire bar graph will light be lit up. Check if the file is in contact with gingiva |
| | The file is in contact with a metal prosthesis. | When the file contacts a metal prosthesis, the measured current flows to the gingiva or periodontal tissues and the bar graph moves.Check if the file has contacted a metal prosthesis |
| | Current leakage to the gingiva is occurring due to a major collapse of the crown | Form a matrix around the tooth to prevent current leakage to the gingiva |
| Bar graph is not stable | The file clip is not clean or is damaged | Replace or clean the file clip |

| | | |
|---|---|---|
| Bar graph does not move | The root canal is closed | Bar graph operates correctly when the file reaches the apical constriction. In this case, always check in combination with X-ray photography |
| | The inside of the root canal is extremely dry. | Moisten the root canal with a saline solution |
| | Bad electrical contact | Perform the cable connection test as described in "6. Testing and installation" |
| Bar graph does not move | The connection hook of file clip is not properly connected to the file | Place the connection hook on the metal part of the file below the plastic handle |
| | In the case of retreatment: residue from old filling material may be blocking the root canal | Remove old root filling material residues prior to measuring |
| Bar graph does not move | Root canal may be blocked by remnants of medical products (e.g. calcium hydroxide) | Rinse the root canal with NaCl solution. Dry the access cavity with a cotton pellet/air-blower |
| | The selected file is too small for a large root canal | Use the largest file possible for the canal to produce the most accurate result |
| | Electronic malfunction | Contact your distributor or us |
| Display indications are incorrect, i.e. unit displays that "APEX" is reached before it has | Short circuit due to excess liquid(irrigation solution, saliva or blood) in the pulp chamber | Dry the access cavity with a cotton pellet/air blower. In case of excess bleeding, wait until it has stopped |
| | A direct contact of the file with the gingiva proliferations or metal restorations (crown, amalgam filling) | For isolation:<br>A)Do adequate preparation filling.<br>B)Use a rubber dam or isolate the file by placing 2-3 silicone stoppers on it |

If none of these are applicable or if the trouble is not fixed after the appropriate action has been taken, a failure in this product is suspected. Contact our Authorized Dealer.

# 13. Specifications

| | | | |
|---|---|---|---|
| Model | | A7 | |
| Input (charge the battery) | | DC 5V 1A | |
| AC Adapter: UES06WZ-XXXYYYSPA | | 100-240V AC 50Hz/60Hz | |
| Battery: ICR 14500 | | DC 3.7V/800 mAh | |
| Working Voltage | | DC 3.7V | |
| Working Current | | DC: 0.13-0.14A | |
| Rated Power | | ≤0.5W | |
| Measurement Voltage | | AC 200mV | |
| Measurement Current AC | | AC 100μA | |
| Screen | | 5.1" LCD ( 110 mm x 70 mm ) | |
| Display | | Reflective colour LCD display | |
| Prompt Sound | | The beeper will sound when the file is less than 2 mm from the apex | |
| Software Version | | 1.0.0 | |
| Control Unit | Dimensions | L130 mm × W112 mm × H23.5 mm | |
| | Weight | 370 g ( including battery ) | |
| Use Environment | Temperature :5°C - +40°C | Humidity: 30%-75%RH | Atmospheric pressure: 70kPa-106kPa |

## 14. Classification of equipment

• Type of protection against electric shock: Class II internally powered equipment
• Degree of protection against electric shock: Type BF applied part
• Method of sterilization recommended by the manufacturer:
– See "9-2 Sterilization "
• Degree of protection against ingress of water as detailed in the current edition of IEC 60529:
– Control unit: IPX0
• Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:
– Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
• Mode of operation: Continuous operation

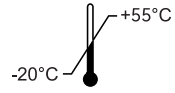
## 15. Operation principle

The lip hook, file clip and file probe are used as electrodes and are attached to the patient's mouth and the operating instrument such as a file. The motion of the instrument in the root canal causes an impedance variation between the pair of electrodes. The position of the apical foramen is detected by measuring the impedance variation using two different frequencies.

## 16. Transportation and storage environment

Keep away from environmental conditions including but not limited to harmful chemicals like acids and alkali.
Temperature: -20°C - +55°C, Humidity: 10% - 93%
Atmospheric Pressure: 70kPa - 106kPa

# 17. Symbols

| | | | |
|---|---|---|---|
|  | Waste of Electric and Electronic Equipment (WEEE) |  | Follow operating instructions |
|  | Type BF applied part |  | Temperature limit: -20℃ - +55℃ |
|  | Manufacturer |  | Power key |
|  | Authorized representative in the European community |  | Voice key |
|  | Serial number |  | Demonstration mode |
|  | Keep dry |  | Direct current |
|  | Class II equipment |  | Handle with care |
|  | Date of manufacture |  | Medical device |
| CE 0123 | CE marking with identification number of the Notified Body |  | Unique device identifier |

# 18. Warranty

Our products are warranted against manufacturing errors and defects in materials. We reserve the right to analyze and determine the cause of any problem. Warranty is voided should the product be not used correctly or for the intended purpose or has been tampered with by unqualified personnel or has had non parts installed.

# 19. EMC Information(Electromagnetic Compatibility Information)

## 19.1 Instructions for use

The ME EQUIPMENT or ME SYSTEM is used in hospitals or dental clinics.

⚠ Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

⚠ Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

⚠ Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

## List of all cables

| No | Name | Length | Shielded or not | Detachable or not | Note |
|---|---|---|---|---|---|
| 1 | Power adapter output line | 1.2m | No | No | / |
| 2 | Measuring wire | 1.6m | No | No | / |
| 3 | File clip line | 0.2m | No | No | / |

## Replaceable accessories

| No | Name | Model | Manufacturer | Connection method | Note |
|---|---|---|---|---|---|
| 1 | Power adapter | DJ-0500100-A5 | / | plug | / |
| 2 | Measuring line | 1600±20mm | / | plug | / |
| 3 | File clip | A7 | / | / | / |
| 4 | File probe | A7 | / | / | / |
| 5 | Lip hook | A7 | / | / | / |
| 6 | Battery | ICR14500 3.7V 800mAh | / | plug | / |
| 7 | Tester (optional) | A7 | / | plug | / |

## Performance of the me equipment

The main unit sends out the waves of different frequencies to excite the oral mucosa and pulp tissue, and collects the impedance between the apex position and the oral mucosa in time, and calculates the position of apex according to the measuring algorithm of the unit. During the measuring process, the LCD screen of the main unit has four colors to indicate the distance between the endo file and the apex position. When the me equipment essential performance is lost or degraded due to em disturbances, the doctor should immediately stop using it to ensure that there is no treatment error. And then remove the source of disturbances or adjust the direction or position of me equipment to ensure me equipment can be used in normal performance condition.

## 19.2 Technical description

**1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life:**

(1)Portable and mobile RF communications equipment may affect the performance of equipment, use of equipment should be avoided strong electromagnetic interference, and do not closer to mobile phone, microwave oven, etc.

(2)Use of equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

(3)Except for the cables sold by manufacturers of as spare parts of internal components, the use of accessories and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

(4)Use of accessories, transducers and cables other than those specified or provided by the manufacturer together with equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity**

**Table 1**

| Guidance and manufacturer's declaration - electromagnetic emissions | |
|---|---|
| **Emissions test** | **Compliance** |
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class A |
| Harmonic emissions IEC 61000-3-2 | Not applicable |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable |

Table 2

| Guidance and manufacturer's declaration - electromagnetic Immunity | | |
|---|---|---|
| **Immunity Test** | **IEC 60601-1-2 Test level** | **Compliance level** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Electrical fast transient/ burst<br>IEC 61000-4-4 | ±2 kV power supply lines<br>±1 kV signal input/output<br>100 kHz repetition frequency | ±2 kV power supply lines<br>Not applicable<br>100 kHz repetition frequency |
| Surge<br>IEC 61000-4-5 | ±0.5 kV, ±1 kV differential mode<br>±0.5 kV, ±1 kV, ±2 kV common mode | ±0.5 kV, ±1 kV differential mode<br>Not applicable |
| Voltage dips, short interruptions and voltage variations on power supply | 0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.<br>0 % UT; 1 cycle and 70 % UT; | 0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.<br>0 % UT; 1 cycle and 70 % UT; 25/30 |
| input lines<br>IEC 61000-4-11 | 25/30 cycles; Single phase: at 0°.<br>0 % UT; 250/300 cycle | cycles; Single phase: at 0°.<br>0 % UT; 250/300 cycle |

| | | |
|---|---|---|
| Power frequency magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |
| Conducted RF<br>IEC61000-4-6 | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between<br>0,15 MHz and 80 MHz<br>80 % AM at 1 kHz | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between<br>0,15 MHz and 80 MHz<br>80 % AM at 1 kHz |
| Radiated RF<br>IEC61000-4-3 | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz |
| NOTE UT is the a.c. mians voltage prior to application of the test level. | | |

## Table 3

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | |
|---|---|---|---|---|---|---|
| | **Test Frequency (MHz)** | **Band (MHz)** | **Service** | **Modulation** | **IEC 60601-1-2 Test Level (V/m)** | **Compliance level (V/m)** |
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | 385 | 380 –390 | TETRA 400 | Pulse modulation 18 Hz | 27 | 27 |
| | 450 | 430 –470 | GMRS 460, FRS 460 | FM± 5 kHz deviation 1 kHz sine | 28 | 28 |
| | 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 9 | 9 |
| | 745 | | | | | |
| | 780 | | | | | |
| | 810 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 28 | 28 |
| | 870 | | | | | |
| | 930 | | | | | |
| | 1720 | 1700 –1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 28 | 28 |
| | 1845 | | | | | |
| | 1970 | | | | | |
| | 2450 | 2400 –2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2 450, LTE Band 7 | Pulse modulation 217 Hz | 28 | 28 |
| | 5240 | 5100 –5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 9 | 9 |
| | 5500 | | | | | |
| | 5785 | | | | | |

Table 4

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | |
|---|---|---|---|---|
| **Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)** | **Test Frequency** | **Modulation** | **EC 60601-1-2 Test Level (A/m)** | **ICompliance level (A/m)** |
| | 30 kHz | CW | 8 | 8 |
| | 134,2 kHz | Pulse modulation 2.1 kHz | 65 | 65 |
| | 13,56 MHz | Pulse modulation 50 kHz | 7,5 | 7,5 |

# 20 Disposal and Scrapping

After the device is out of its service life, you must not discard it in domestic household waste. Please comply with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country.

Disposal of battery at appropriate collection sites should follow your national or local regulations.

Lip hook, file clip, file probe, those which could easily contact to the biological sources and cause biological hazards, shall be detached from the main unit and reprocessed according to the reprocessing treatment in Attachment 1 before the disposal and scrapping.

## Attachment 1. Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing

# 1. Beginning work

1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.
1.2 To prevent injury to people and damage to property, please heed the corresponding directives.
1.3 The instructions in this manual are only applicable to the product which it was delivered with.

# 2. Introduction

2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.
2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental instruments are based on the potential risk of infection associated with their use.
2.3 It is recommended to use steam sterilization.
2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.
2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.
2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

# 3. Reprocessing - instructions for reusable products

3.1 The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

⚠ **Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.**

3.2 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures

have only limited implications to this device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

⚠ **In case of damage the product should be reprocessed before sending back to the manufacturer for repair.**

## 4. Preparation - basic principles

4.1 It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

4.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

## 5. Preparation at the point of use

Disconnect product. Remove gross soiling of the products with cold water (<40° C) immediately after use. Don't use a fixating detergent or hot water (>40° C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

Store the products in a humid surrounding.

## 6. Transportation

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

## 7. Preparation for decontamination

The products must be reprocessed in a disassembled state, as far as possible.

## 8. Pre-cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

## 9. Cleaning

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.
Automated Cleaning:
Use a washer-disinfector (WD) meeting the requirements of the ISO 15883 series.
Put the products into the machine on a tray. Connect the products with the WD by using suitable adapter and start the program:
4 min pre-washing with cold water (<40° C)
Emptying
5 min washing with a mild alkaline cleaner at 55° C
Emptying
3 min neutralising with warm water (>40° C);
Emptying
5 min intermediate rinsing with warm water (>40° C)
Emptying
The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

## 10. Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).
A disinfection cycle of 5 min disinfection at 93° C has been validated for the product to achieve an A0 value of 3000.

## 11. Drying

Automated Drying:
Drying of outside of products at 40°C , 5 min through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

## 12. Functional testing, maintenance

Visual inspection for cleanliness of the products and reassembling if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until products is visibly clean.
Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

## 13. Packaging

Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

## 14. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.
Minimum requirements: 3 min at 134 ° C (in EU: 5 min at 134 ° C)
Maximum sterilization temperature: 138° C
Drying time:
For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.

After sterilization:
a. Remove the product from the autoclave.
b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
Check that the sterilization wraps or pouches are not damaged.
⚠ **Flash sterilization is not allowed on lumen products.**

⚠ **The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).** In such cases, please observe the respective valid standards (EN ISO 14937/ANSI AAMI ISO 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

## 15. Storage

Storage of sterilized products in a dry, clean and dust free environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of-20 ° C to +55 ° C; refer to label and instructions for use.
After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

## 16. Service life

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in aging of the devices. If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions.
⚠ The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.
⚠ The devices may not be exposed to temperatures above 138 ° C.
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

Note: We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

Shelf life: 5 years, the date of  manufacture see product label.

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