97055462
Rev. 01
2023-07

APEX LOCATOR

OPERATOR'S MANUAL

CEFLA S.C. VIA SELICE PROVINCIALE 23/A - 40026 IMOLA (BO) ITALY
PLANT: VIA BICOCCA 14/C - 40026 IMOLA (BO) - ITALY
VIA GAMBELLARA 43/C - 40026 IMOLA (BO) - ITALY

EN

Contents

1. DESCRIPTION

1.1. DESCRIPTION OF THE DEVICE

Code	Name	Description	Supplied as
76000201	APEX LOCATOR	2023	Non-Sterile and Re-usable

The instrument is used to locate the apex of the root canal during endodontic treatments.

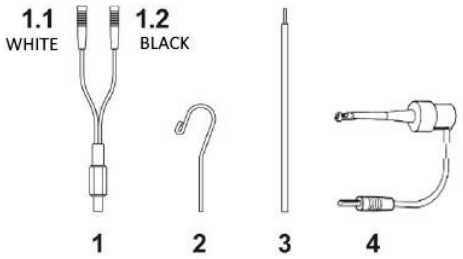
The apex localisation is useful to obtain the work length together with the visible reference rubber stopper, which is manually positioned on the probe inserted in the canal.
With micromotor in ENDODONTIC or RECIPROCATING mode and with suitable contra angles, the locator uses the same file inserted in the canal as the active detection probe.
The instrument does not replace X-ray diagnostics, which must be implemented in any case.

1.2. INDICATIONS FOR USE

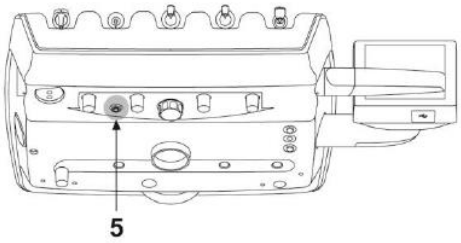
APEX LOCATOR is a device intended for locating the apex of the root canal during endodontic treatments.

Read carefully the user manual before using Apex Locator.
The use of the device must respect the instructions provided.

1.3. COMPONENT DESCRIPTION



1 External wiring.
1.1 External wiring WHITE Connector - neutral pole.
1.2 External wiring BLACK Connector - active pole.
2 Lip Hook.
3 Touch Probe.
4 File clip.
5 Dental unit Apex Locator port.



1.4. IMPORTANT WARNINGS

For the correct interpretation of the indications in this manual the Italian text is binding.

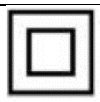
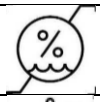
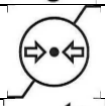
- The device is not suitable for use with blends of inflammable anaesthetics and oxygen or nitrous oxide.
- The instrument is provided in a non-sterile state. Before use, proceed with the applicable reprocessing procedure as detailed in this manual.
- Use of electrically-powered devices may interfere with the operation of active implantable devices such as pacemakers or other active devices. In case of doubt regarding the treatment of patients with such devices, consult a cardiology expert or another competent medical institute.
- Protect the patient, when possible, using a dental dam.
- Instruct the patient to breathe through the nose in cases where the dam is not applicable.
- Medical personnel must put on suitable personal protection equipment.
- Suitably cool the surgical field during use.
- Before each use, verify the proper locking of the wiring kit to the dental chair
- In case of visible damage to the wiring kit do not use the device and call authorised technical service assistance.

The manufacturer will not be held responsible regarding safety, reliability or performance of the device if:

- The essential requirements for the location, detailed in the Dental Unit User Manual are not respected;
- The assembly, the additions, the adjustments, the calibrations and/or the repairs are not performed by authorised technical service personnel;
- If modifications, tampering, incorrect maintenance have been performed, or incompatible and/or non-original spare parts have been used on the device;
- The device is not used in compliance with the use instructions and its intended use.

CONTRAINDICATIONS
We do not advise the use of Apex Locator kit on patients fitted with pacemakers (or other electrical equipment) or on those patients who are advised not to use the electric equipment (like an electric shaver, electric blower) for safety reasons

1.5. SYMBOLS

	WARNING! Failure to observe may result in equipment damage or injury to the user and/or patient.
	Symbol to call the attention to other information found in the equipment User Manual.
	NOTE: Identifies information that is especially important for the user and/or the assistant.
	Symbol corresponding to “TYPE B PART APPLIED” according to IEC 60601-1. Indicates a protection grade against direct and indirect contacts.
	Part that may be sterilised in an autoclave.
	Disposal symbol in accordance with Directive 2012/19/EU.
	Device serial number.
	Manufacturer.
	Manufacturing date (YYYY-MM-DD).
	Prescription Only. Caution: Federal law restricts this device to sale by or on the order of a dentist
	Class II equipment
	Unique device identifier.
	Humidity limitation
	Temperature limitation
	Atmospheric pressure for storage
	Keep dry
	Handle with care

2. TECHNICAL DATA

For the correct operation of the device it must be connected to the specific power supply and electronic control circuits, designed by the manufacturer.
The manufacturer promises to provide, upon request, wiring diagrams, component parts lists, calibration instructions or any other information that may be needed by authorized technical service assistance personnel.
The manufacturer reserves the right to bring about modifications at any moment without notice.

2.1. MODE OF USE

Continous mode.

2.2. ENVIRONMENTAL CONDITIONS FOR USE

- Ambient Temperature 10 ÷ 40 °C
- Relative Humidity 30 ÷ 75 %
- Atmospheric Pressure 700 ÷ 1060 hPa (700 ÷ 1060 mBar)

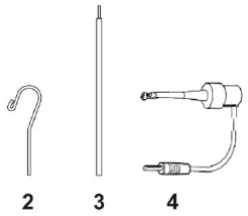
2.3. ENVIRONMENTAL CONDITIONS PERMITTED FOR TRANSPORT AND WAREHOUSING

- Ambient Temperature between -20 ÷ +70 °C
- Relative Humidity 10 ÷ 100 %
- Atmospheric Pressure 500 ÷ 1060 hPa (500 ÷ 1060 mBar)

2.4. APPLIED PARTS

The parts that, during standard use, necessarily come into contact with the patient are the folllowing:

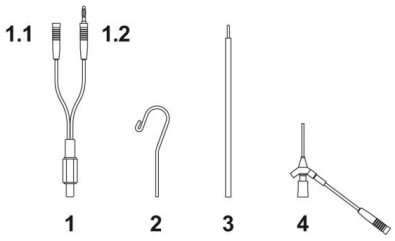
- **Lip Hook (2).**
- **Touch Probe (3).**
- **File clip (4).**

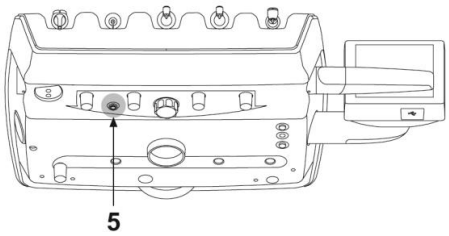


3. OPERATION OF THE DEVICE

3.1. INSTALLATION

- Insert the external wiring (**1**) into the Dental unit apex locator port (**5**) positioned under dentist's board, on dental unit. The apex locator is automatically activated. The position of the dental unit port and the user interface are described inside the dental unit operator's manual. A generic representation is provided below.





- Connect the Lip Hook (**2**) to the WHITE Connector (neutral pole, **1.1**) and position it on the patient's lip.

- Connect the BLACK Connector (active pole, **1.2**) to the Touch Probe (**3**) or to the File clip (**4**).

For the complete installation and operation of the APEX LOCATOR in conjunction with the dental unit, refer to the specific User Manual provided with the dental unit.

3.2 INSTALLATION WITH MICROMOTOR

This locator can also be used in combination with the electric micromotor when set to ENDO mode or to RECIPROCATING mode.
When the locator is enabled, if electric micromotor is extracted in ENDO mode both the information relating to the micromotor and those relating to locator (bargraph and APEX values) are shown at the same time on the DISPLAY.

When APEX LOCATOR is used with the micromotor do not use the Touch Probe (**3**) or the File clip (**4**).
In this case, the micromotor acts as the active and requires Sirona Endo 6:1 [1] contra angles to correctly close the circuit, as the 6:1 Sirona makes electrical contact between the motor housing and the file.

[1] Sirona Endo 6:1 contra angles (manufactured by DENTSPLY SIRONA INC., York, Pennsylvania, USA) are not the property of Cefla or of any company associated with it.

3.3 USAGE REQUIREMENTS

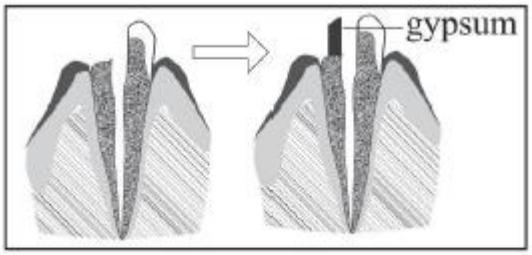
The following criteria are necessary to ensure proper operation:
- The device should be operated according to the manual's instructions.
- The dentist should know teeth position and average length and have the skill to operate the equipment.
- There should be a fully exposed access cavity to show the pulpal cabin.
- An X-ray photo to show the whole range and root canal of the teeth.
- The endo file should not be too big nor too small to avoid cutting through the apical foramen.

- Mark an anatomized symbol on the diseased tooth and note it on the case history. This symbol should be marked on the health bridge or on the tooth filled integrated. The position of the mark should be on the incisal edge of the anterior tooth or on the spire of the molars. For bridges that are broken, this symbol should be on the tooth surface supported by the dentin instead of on the suspended enamel.
- The acute inflammation surrounding the apex is gone, and the infected material has been cleaned. It is also necessary to get rid of the pulp and necrosis tissue.
- The following cases are not suited for a standard measurement:

a) The size of the root is similar to the size of apical foramen.In this case, the measurement result of the length of the root canal will be shorter than the actual length because of the hypoplasia of the root [**Picture 1**].
b) Bleeding or the blood overflow from the apical foramen. In this case, the blood will overflow from the root canal and reach the gingival that the blood and the gingival will conduct which will cause an inaccurate result while measuring. The measurement can continue when the bleeding is stopped [**Picture 2**].
c) The tooth crown is broken. The tissue of the gingival may reach the cavity of the endo hole at the broken point which will cause inaccuracy because of the electronic conduction. The measurement can continue when the crown is fixed by gypsum or other insulators [**Picture 3**].


Picture 1

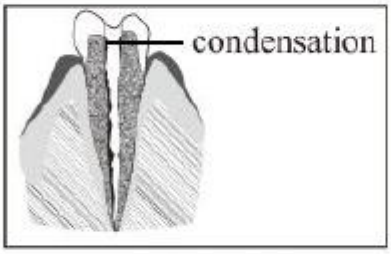

Picture 2



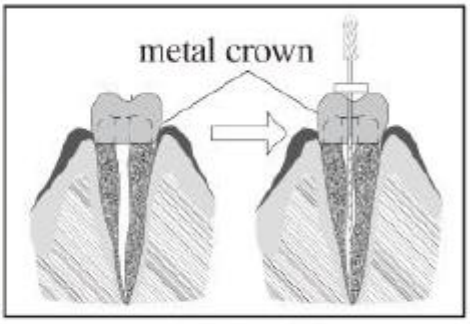
Picture 3

d) There is a crack on the tooth root. In this case, the crack may cause electric leakage which will affect the accuracy of measurement [**Picture 4**].
e) Re-treatment of a root canal which was filled with gutta-percha. Clean the remaining material in the root canal and fill it with a little normal saline before a measurement [**Picture 5**].
f) There is a metal crown which has connected to the gingival. This will cause inaccuracy when the endo file touches metal crown [**Picture 6**].Sometimes, the results of the Apex Locator and X-rays do not match, which is neither because the machine is not normal, nor the photo is incorrect taken. The actual position of the apical foramen is different from the anatomical one, and it is very common that the apical foramen is slightly to the side of the root canal crowns. In this case, according to the pictures below show, it will cause the illusion that the front tip of the root canal hasn't reached the canal tip. [**Picture 7**] (Because of the angles of X-rays, sometimes it can't take a photo of the apical foramen properly, so it can't show the accurate position of the apical foramen.)

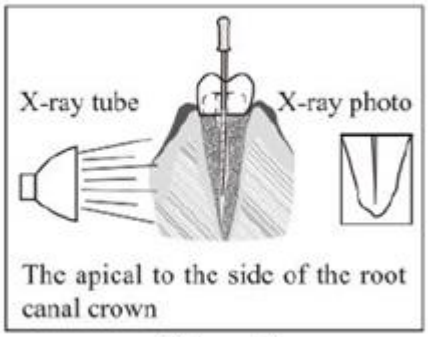

Picture 4



Picture 5



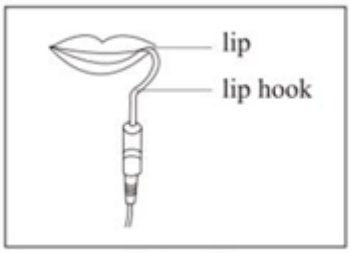
Picture 6



Picture 7

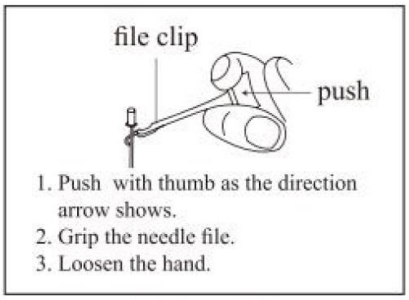
3.4 INSTRUCTION

- Hang the lip hook on the lip, make sure it contacts the oral mucosa as a reference electrode [**Picture 8**].



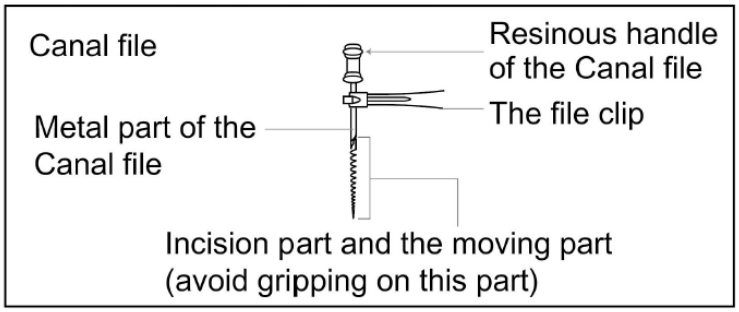
Picture 8

- Clip the file with the file clip, when you approach to the apex there will be continuous alarm when the distance is less than 2mm [**Picture 9**].

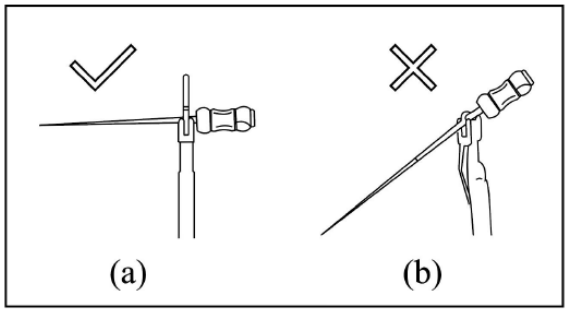


Picture 9

a) When gripping the root canal with a canal file, please grip the upper portion of the canal file metal part (near the root canal at the needle handle). If you grasp the lower part (blade or moving part), it will cause excessive wear the file clip surface. [Picture 10]
b) When measuring the length of the root canal, use the canal file with a resinous handle. If you operate the device without a dentistry glove, it will cause leakage, and the result of the measurement will be inaccurate. Therefore, please use a resin canal file and remember don't touch the metal part with your bare finger.
c) DO NOT use a worn file clip or it will result in an inaccurate measurement.
d) Reference [Picture 11 (a)] to grip the canal file. If it is not possible to use as shown in [Picture 11 (b)], the root canal length measurements will not be accurate due to the improper force, and the front of the root canal pin is worn easily.

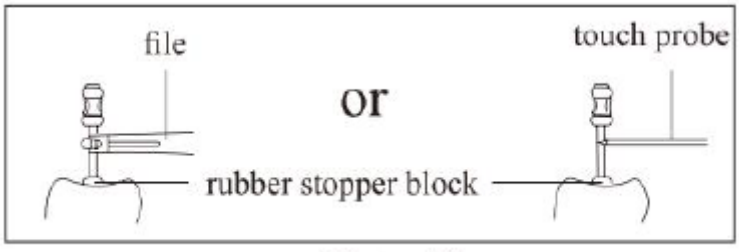


Picture 10



Picture 11

- When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incisal edge or fossa edge). Pull out the endo file, measure the length between the top of the file and the rubber piece. This is the working length of the tooth. It also can be used with the touch probe instead of file clip, when it is inconvenient to measure the back teeth [**Picture 12**].



Picture 12

- The components that touch the patient must be autoclaved under high temperature and high pressure. The shell and measuring wire should be cleaned with 75% alcohol.

4. MAINTENANCE, CLEANING, DISINFECTION AND STERILIZATION

4.1 GENERAL

CEFLA Apex Locator is maintenance free and does not contain user serviceable parts.
NOTE:
Service and repair should be provided by factory trained service personnel only.
Measuring wire should be cleaned using a tissue or soft cloth soaked with aldehyde free disinfecting and detergent solution (e.g. bactericidal and fungicidal).

Wipe the surface of the device and the measuring wire with a clean cloth, lightly moistened with a non-aggressive disinfectant.
Do not apply any liquid or spray directly on the device, especially on the display.
Do not use high-proof alcohol for disinfection.

Remove the lip hook, file clip or touch probe from the measuring wire before reprocessing. The accessories lip hook, file clip, and touch probe must be cleaned, disinfected and sterilized before each use. This also applies to the first use of accessories. Thorough cleaning and disinfection are essential prerequisites for effective sterilization. The specific instructions for cleaning/ sterilization must be implemented according to the guidelines in chapter "Cleaning, Disinfection and Sterilization" 4.2 Also, the operating instructions of the devices used in your practice must be followed.

As part of your responsibility for accessories sterility, always ensure that only validated methods for cleaning/disinfection and sterilization are used, and that devices (disinfector, sterilizer) are regularly serviced and inspected and the validated parameters are maintained with each cycle.

Always observe the validated legal regulations and regulations on hygiene relating to your practice or the hospital. This applies in particular to the guidelines regarding effective prion inactivation.
For your safety, always wear protective gloves, glasses, mask when handling contaminated accessories.

The measuring wire cannot be autoclaved.
Use of agents other than specified above may cause damage to the equipment and its accessories.
Do not use heat, radiation, formaldehyde or ethylene oxide or plasma sterilization methods.

4.2 CLEANING, DISINFECTION, AND STERILIZATION (ACCORDING TO ISO 17664)

The procedure for cleaning, disinfection, and sterilization applies only to the accessories lip hook, file clip, and touch probe.
For cleaning and disinfection procedure of external wiring please refer to section 4.2.8.

4.2.1 PRE-TREATMENT

Pulp and dentin residues must be removed immediately from the accessories (within maximum 2 hrs.).
Do not let them dry!

After the accessories have been used on patients, place the accessories for cleaning, pre-disinfection, and interim storage directly into a bowl filled with an appropriate cleaning and disinfecting solution (for max. 2hrs.). Then clean the accessories under running water or clean in a disinfecting solution to remove all visible contamination. The disinfectant should be aldehyde-free (aldehyde fixes blood stains), tested for effectiveness (e.g., VAH/DGHM or FDA approval, HC approval, or CE mark), suitable for accessories disinfection and compatible with the accessories (see chapter "Material Resistance").
Only use clean, soft brushes to manually remove contamination or a clean, soft cloth which you only use for this purpose. Do not use metal brushes or steel wool. For better cleaning of the inner parts, the file clip must be pressed and released five times during the cleaning process. Please note that disinfectants used for pre-treatment are only for personal protection and do not replace disinfection when cleaning is completed. The pre-treatment process should be performed in every case.

Do not use an automated procedure or ultrasonic bath to clean or disinfect the accessories.

4.2.2 MANUAL CLEANING AND DISINFECTION

When selecting the cleaning and disinfecting agents, you should ensure that:
• They are suitable for cleaning or disinfecting instruments
• A disinfectant with tested effectiveness is used (e.g., VAH/DGHM or FDA approval, HC approval, or CE mark) and that it is compatible with the cleaning agent
• The chemicals used are consistent with the accessories (See chapter "Material Resistance"). Combined cleaning/disinfectant agents should only be used when the instruments are only slightly soiled (no visible contamination).

Adherence to the concentration and contact time for application as well as the intensity of post-rinsing indicated by the Manufacturers of the cleaning agents and disinfectants must be followed.
Only use freshly prepared solutions, sterile or low-germ (< 10 cfu/ml) and low-endotoxin water (<0.25 EU/ml, e.g., purified water (PW/HPW)), and filtered and oil-free air for drying.

STEP-BY-STEP-PROCESS

A. CLEANING

• Place the pre-cleaned accessories into the cleaning bath for the prescribed contact time, and the accessories must be sufficiently covered (if necessary, careful brushing with a soft brush). For better cleaning of the inner parts, the file clip must be pressed and released five times during the cleaning process.
• Then remove the instruments from the cleaning bath and rinse them thoroughly with water for at least three times for 1 min. and press and release the file clip five times.

B. DISINFECTION

• Place the cleaned and inspected accessories into the disinfection bath for the prescribed contact time; the accessories must be sufficiently covered. For better disinfection of the inner parts, the file clip must be pressed and released five times during the disinfection process.
• Then remove the accessories from the disinfection bath and rinse them thoroughly with water for at least five times for 1 min. and press and release the file clip five times.
• Inspect, dry and pack the accessories as quickly as possible after removal (see chapter INSPECTION and PACKING). Please make sure that the accessories do not have direct contact.

4.2.3 INSPECTION/MAINTENANCE

Check all accessories after cleaning or cleaning/disinfection. Defective accessories should be immediately discarded. These defects include:
• plastic deformation
• corrosion
Accessories which are still contaminated must be cleaned and disinfected again. Maintenance is not required. Instrument oil must not be used.

4.2.4 PACKING

Please pack the accessories to be steam sterilized into disposable sterilization pouch/wraps /containers, close and mark it.

4.2.5 STERILIZATION

The validated procedures require the use legally marketed and approved (e.g. FDAcleared, HC licensed, CE mark) sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2010 Rapid sterilization method or the sterilization method of unpacked accessories is not permitted.
Do not use any other sterilization method including radiation sterilization, formaldehyde or ethylene oxide sterilization, and plasma sterilization, etc.

Place the accessories into the applicable steam sterilizer and set the parameter as defined below.

Dynamic-Air-Removal Steam Sterilization method:
132ºC (270ºF) for 4 minutes, drying time Min. 20 minutes;
OR
135ºC (275ºF) for 3 minutes, drying time Min. 16 minutes

4.2.6 STORAGE

After sterilization, the instruments must be stored in the sterilization package and kept dry and dust-free.

4.2.7 MATERIAL RESISTANCE

When selecting the cleaning and disinfecting agents, please ensure that they do not contain phenol, strong acids or strong aldehyde disinfectants or anticorrosion solutions.
The material is resistant up to 137 ºC/279 ºF (maximum exposure temperature).

4.2.8 CLEANING AND DISINFECTION OF THE EXTERNAL WIRING

- Before each use: wipe the surface of the machine and the measuring wire with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.
- After each use: wipe the surface of the device and the measuring wire with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

5 TROUBLESHOOTING

FAULTS	PROBABLE CAUSES	INTERVENTION SUGGESTED
Display not steady while measuring: the measurement result is somewhat longer or	The connection between the lip hook and the oral mucosa is ok?	Make sure the lip hook has contacted the oral mucosa at a good position.

shorter; numerical display irregular.	Is there blood/saliva overflowing, glued to the crown?	Blood, liquid overflow from the root canal, glued to the crown or the tooth neck, will cause short-circuit then cause the in-normal phenomena. Clean the blood and the liquid.
	The root canal is filled with blood, liquid?	Once the endo needle contacts the surface of the root canal which is filled with blood, liquid the measure will not be accurate. In this case, push the needle to the apical root canal, then the display will be normal, you can measure the length of the root canal correctly.
	Liquid, scrap on the tooth surface?	Clean the tooth surface.
Display not steady while measuring: the measurement result is slightly longer or shorter; numerical display irregular.	Still pulp in the root canal?	If there is much pulp left in the root canal, the root canal length can't be measured correctly.
	Did needle touch the metal repaired material?	If there are metal repaired material, the length of the root canal can't be measured accurately.
	The adjacent surface has caries?	Current measurement flow from caries of the adjacent surface to gums, then the root canal length can't be measured correctly.
	Collateral or the tooth root is broken?	If tooth root is broken, the length of the root canal can't be measured accurately.
	The adjacent surface has caries?	Current measurement flow from caries of the adjacent surface to gums, then the root canal length can't be measured correctly.
	Is it because in addition to the top pulp hamber, low tooth crown? Or there are residues left?	Use rubber dam to prevent the current flow to gums.
Display not steady while measuring: the measurement result is somewhat longer or shorter; numerical display irregular.	Are there cysts apical?	If there are cysts, the length of the root canal can't be measured accurately.
	Is the file clip not clean or broken?	Clean the file clip by alcohol, or replace it.
	Measuring wire is broken or poor contact?	Change the wiring kit.
The length measurement indicator only full display near the narrow part of the apical.	The root canal is occlusive?	The display will be normal after penetrating the narrow part of apical
	The root canal is too dry?	Wet the endo with Hydrogen peroxide or NaCl.
	Is Endo file too small for a large root canal?	Replace the current endo file with a larger one.

6. SCRAPPING

Scrapping the device must be carried out with respect for the laws in force for electrical and electronic equipment, according to the individual national laws.
The materials used for the manufacture are not harmful for human beings or animals that come into contact with or are exposed to them.

7. GUARANTEE CONDITIONS

The manufacturer provides the end user with a 12-month warranty, starting from the date of installation, covering all operational faults, defects of materials or manufacture.
In case of justified complaints the manufacturer or the Authorised Repair Centre will proceed with the repair or substitution of the product free of charge.
To be able to make use of the free repair or substitution, it is an indispensable condition that, shipped together with the device, there is a proof of user's purchase document for the same device, which must include clearly legible references to the product, its serial number and date of purchase.
The guarantee expires when any damages and/or their consequences may be attributed to unsuitable procedures or modifications of the product performed by third parties not authorised by the manufacturer: that is, if non-original spare parts or components are used.
The recognition of any other claims from any origin whatsoever, in particular any requests for indemnification for damages or interest are excluded.

The manufacturer may not be held responsible for damages, or injuries and their respective consequences derived:

- From excessive wear.

- From connection of the instrument not compliant with the CE regulations.
- From improper tampering or maintenance performed by unauthorised personnel.
- From use of non-original accessories or spare parts.
- From the lack of observance of the instructions for use, for assembly or maintenance, or from improper use of the product.
- From unusual chemical, electrical or electronic influxes.
- From faulty connections (air water, electricity).

The guarantee does not cover the conductors such as the flexible “fibre optics”, nor any other elements made of synthetic materials.

8. DISPOSAL

Dispose of the device and accessories in compliance with local regulations.
Abide by national recycling laws and the hospital's current recycling procedures in order to ensure proper disposal of the Micromotor device.
For more information on recycling, contact the Minister of the Environment or local authorities.

Do not dispose of this product as household waste. The directive does not apply to contaminated products.

9. MANUFACTURER

Manufactured by
CEFLA s.c.

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