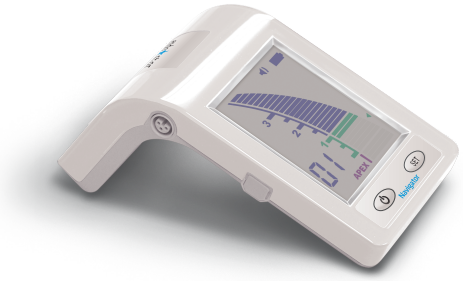
Apex Locator

Navigator

endo★star

INSTRUCTIONS FOR USE



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Thank you for purchasing the Endostar Navigator.
For optimum safety and performance, read this manual thoroughly before using the unit and pay close attention to warnings and notes. Keep this manual in a readily accessible place for quick and easy reference.

Poldent Co. Ltd.

Table of Contents

Accident Prevention

Customers

Make sure to obtain clear instructions concerning the various ways to use the device described in this accompanying manual.

Preventing Accidents

Most operation and maintenance problems result from insufficient attention to basic safety precautions and not being able to foresee potential accidents.
Problems and accidents are best avoided by anticipating potential dangers and operating the device in accordance with the manufacturer's recommendations. First, thoroughly read all precautions and instructions pertaining to safety and accident prevention. Then operate the device with the utmost caution to prevent either damaging the device itself or causing bodily injury.

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the corresponding instructions:

⚠ WARNING

This alerts the user of the possibility of extremely serious injury or complete destruction of the device, as well as other property damage including the possibility of fire.

⚠ CAUTION

This alerts the user of the possibility of minor or moderate injury or damage to the device.

The warning symbols (⚠) and caution symbols (⚠) that appear next to the main text on the right hand side of the page refer to and are explained by the Warnings and Cautions at the bottom of the page.

This alerts the user of important points concerning operation or the risk of equipment damage.

The user (e.g., healthcare facility, clinic, hospital etc.) is responsible for the management, maintenance and use of medical device.

This equipment must only be used by dentists and other legally licensed professionals.
Do not use this equipment for anything other than its specified dental purpose.

Disclaimers

- Poldent Co. Ltd. will not be responsible for accidents, equipment damage, or bodily injury resulting from:
  1. Repairs made by personnel not authorized by Poldent Co. Ltd.
  2. Any changes, modifications, or alterations of its products
  3. The use of products made by other manufacturers, except for those procured by Poldent Co. Ltd.
  4. Maintenance or repairs using parts or components other than those specified by Poldent Co. Ltd. or other than in their original condition
  5. Operating the device in a manner other than described in the operating procedures in this manual or in a manner inconsistent with the safety precautions and warnings in this manual.
  6. Workplace, environmental, or installation conditions that do not conform to those stated in this manual, such as an improper electrical power supply.
  7. Fires, earthquakes, floods, lightning, natural disasters, or forces majeure.
- The useful life of the Endostar Navigator is 6 years from the date of installation provided it is regularly and properly inspected and maintained.

In Case of Accident

If an accident occurs, the Endostar Navigator must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

User Qualifications

Intended Operator Profile

a) Qualification : Legally qualified person such as dentists for endodontic device operation (it may differs among countries).

b) Education and Knowledge: It is assumed that the understands the risks of root canal measuring and treatment. It is also assumed the user is thoroughly familiar with root canal measuring and treatment including the prevention of cross contamination.

c) Language Understanding : English (Intended for professional use as described above)

d) Experience : Experienced person with operating endodontic device.
No special training is required except in cases where this is required by legal regulations of the relevant country or region.

Patient Population

Age	Child to Elderly
Weight	N/A
Nationality	N/A
Sex	N/A
Health	It is not intended for use on patients wearing pacemakers or ICDs.
Condition	Conscious and mentally alert person. (Person who can stay still during treatment.)

⚠CAUTION

- The Endostar Navigator is not recommended for use in children under 12 years of age.

Precautions

* Poldent Co. Ltd. is not responsible for any accidents or other types of trouble that are caused by not following the precautions noted below.

⚠WARNING

- Accurate canal measurement is not always possible depending on the shape and condition of the tooth as well as a decline in the equipment's performance.
- Do not use damaged file holders; an accurate measurement cannot be made with a damaged file holder.
- When a continuous tone is heard while the Power Switch is on and without any operation, some electrical part may be malfunctioning. Do not use the device and send it to Poldent Co. Ltd. for repairing.
- A rubber dam should be used when performing endodontic treatment.
- Some care must be taken concerning electromagnetic compatibility (EMC) when using the device. Refer to the user's manual and other attached documents for EMC information regarding installation and operation.
- Both portable and movable radio frequency transmitters may have some effect on the device.
- Using replacement parts or accessories not supplied by Poldent Co. Ltd. could adversely affect the EMC performance of the device.
- As far as possible, do not use the Endostar Navigator near or simultaneously with other devices. If this cannot be avoided, observe carefully and make sure both the Endostar Navigator and the other device operate normally.
- No modification of the device is allowed.

⚠PROHIBITION : This indicates when not to use the equipment.

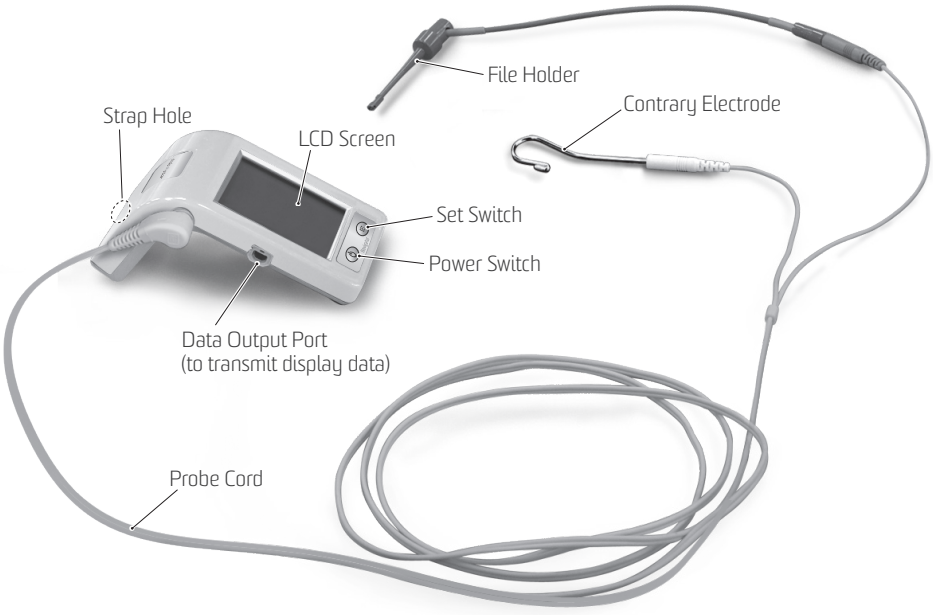
- Do not use the device in conjunction with an electric scalpel or on patients who have a pacemaker.
- Blocked canals cannot be accurately measured.
- Except for ways described in this manual, the device must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system. Poldent Co. Ltd. will not be responsible for accidents, equipment damage, bodily injury or any other trouble which results from ignoring this prohibition.
- Illumination devices such as fluorescent lights and film viewers which use an inverter can cause the Endostar Navigator to operate erratically. Do not use the Endostar Navigator near devices such as these.
- Electromagnetic wave interference could cause the Endostar Navigator to operate in an abnormal, random and possibly dangerous manner. Cellular phone, transceivers, remote controls and all other devices which transmit electromagnetic waves located inside the building should be turned off.
- Do not perform maintenance while using the device for treatment.

Indications for Use

The Endostar Navigator is a dental device, Apex Locator.
It can be used to detect the apex of root canal.

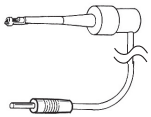
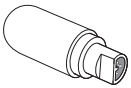
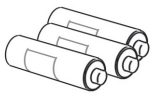
Parts Identification and Accompanying Items

Parts Identification



Accompanying Items (Parts of Device and Consumables)

Standard Parts

Probe Cord (Qty: 1)	File Holder (Qty: 3)	Contrary Electrode (Qty: 5)	Tester (Qty: 1)	Alkaline Dry Cells (Qty: 3)
				(LR03 [AAA size] batteries) 

Optional Parts

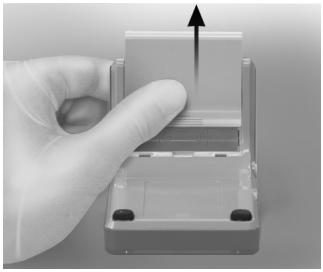
Long File Holder (Qty: 1)


Usage

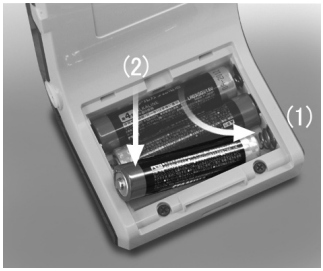
1. Before Using the Endostar Navigator

Before using the device, be sure that all autoclavable components have been sterilized.
☞ p. 22 "Autoclavable Components"

Installing the Batteries

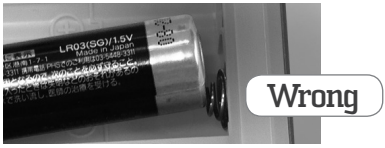


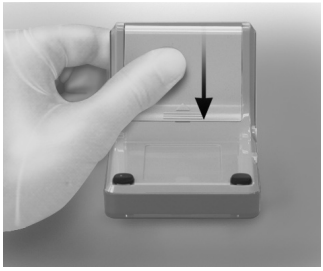
1. Slide the cover in the direction by the arrow in the illustration and remove it from the device.



2. Insert three LR03 (AAA size) batteries included in the package.

   (1) Insert the batteries by first pressing center of the minus end against its spring contact.
   (2) Slide the plus end down into place and make sure the contacts are not bent or damaged.



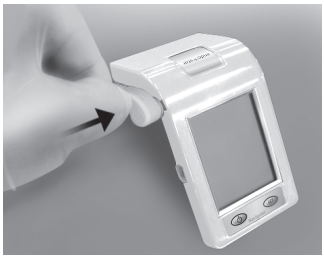


3. Slide the cover all the way down until it is securely closed.

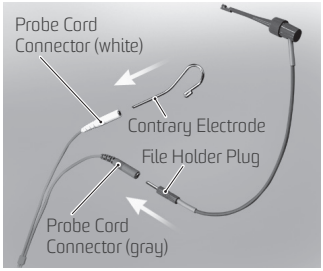
⚠CAUTION

- The device is shipped without the batteries installed. Remove the cover and install three LR03 (AAA size) batteries.
- Do not reverse the plus and minus poles.
- Never allow the spring contact to push against the edge of the battery. This could damage the outer cover causing a short or a leakage of battery liquid.
- After installation, give the cover a light tug to confirm it is securely attached.

Connecting the Probe Cord

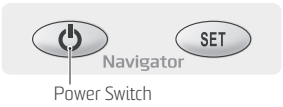


1. Insert the probe cord completely into the jack on the left side of the device.



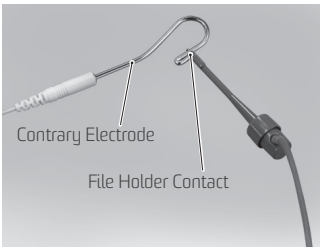
2. Insert the file holder's gray male plug into the gray female connector on the probe cord. Insert the contrary electrode into the white female connector on the probe cord.

Checking the Function



1. Press the Power Switch to turn the device on. The display will appear in the LCD screen.

* The device turns itself off if it is not used for 10 minutes.

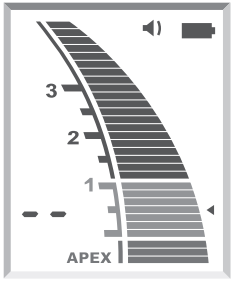


2. Check that the probe cord is properly plugged into the jack.
3. Check that the file holder and contrary electrode are properly connected to the probe cord.
4. Touch the metal part of the file holder with the contrary electrode. Check that all the meter indicator bars on the display light up.

⚠CAUTION

- Handle the device carefully; do not drop, bump or expose the device to other kinds of impacts or shocks. Rough handling could cause damage.
- Make sure the probe cord plug is securely plugged into the jack. A poor connection can prevent measurement.
- Do not drop anything on or bang the probe cord plug after it has been inserted into the jack.
- Make sure to match colors of the file holder and contrary electrode to the probe cord. Measurements cannot be made if these connections are reversed.
- The device may turn off if its side is bumped.

Checking the Function

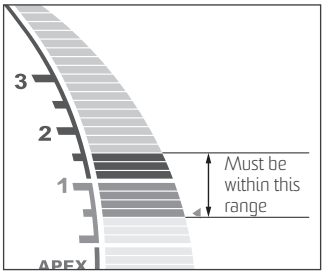


Checking the Function with the Tester

Check device performance with the tester once a week.

1. Press the Power Switch to turn the device on.
2. Insert the tester into the probe cord jack.
   Check that the meter indicates within ±3 bars away from (above or below) 1.

* The meter may jump when the tester is inserted. If it does, wait for about 1 second until the meter stabilizes and then check the reading.
* If the reading is 4 or more bars away from 1, the device will not make an accurate measurement. In this case, contact Poldent Co. Ltd.



WARNING

- Check operation before each patient. If the indicators in the display do not all appear normally, the device may not be able to make an accurate measurement. In this case, stop using the device and have it repaired.

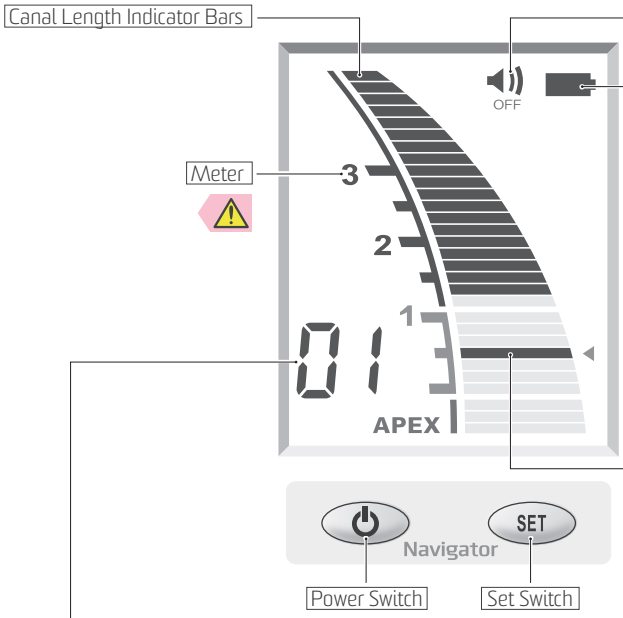
2. Using the Endostar Navigator

Operating Environments

Temperature: +10˚C to +35˚C (+50˚F to +95˚F)
Humidity: 30% to 80% (without condensation)
Atmospheric Pressure: 70 kPa to 106 kPa

* If the device has not been used for some time, make sure it works properly before using it again.

Operation Panel Display and Switches



- Standby (file outside the canal): Memory number for the flash bar.
- During Measurement (file inside the canal): Number of bars left before the flash bar is reached.
- When Flash Bar position is being set: Position of the flash bar.

⚠WARNING

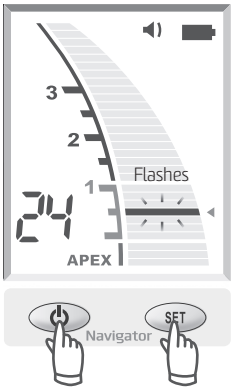
- Never connect the device to any product not approved by Poldent Co. Ltd.
- Never use the device if the battery power indicator is flashing on and off. The device may not function properly if the battery power is low.
- The meter readings 1, 2, and 3 do not correspond to any actual distance and should only be used as estimates.

Settings

1. Select Memorized Flash Bar

Method

Press the Set Switch. Each press of the Set Switch will change the memory selected in the sequence 01 to 02 to 03 and then back to 01 again. The flash bar set for each memory will appear when that memory is selected. The memory selected when the device is turned off is the one that will be selected when is it turned back on again.



2. Set the Flash Bar
   The flash bar can be set anywhere from 2 to the APEX (0). Use it as an estimate of the canal's working length.

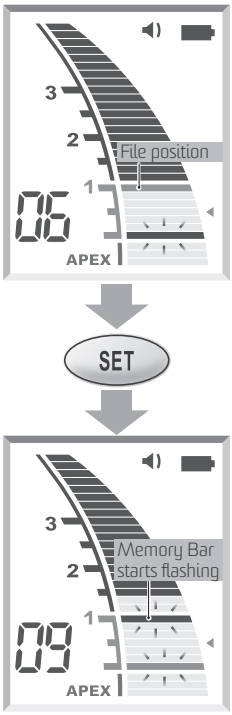
Method

When the file is not inserted, hold down the Power Switch and then press the Set Switch at the same time. Each press of the Set Switch will move the flash bar one bar towards the APEX. The position will be automatically memorized.

⚠CAUTION

- The flash bar cannot be set beyond the APEX.

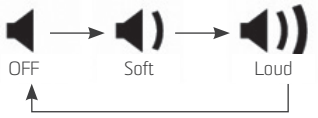
Settings



3. Memory Bar
   The memory bar can be set anywhere up to the APEX.
   The memory bar can be set during treatment to mark a point of interest inside the canal such as the beginning of a curve, a certain distance from the apex, or the point to change file size for enlargement.

Method
Insert the file up to the desired point and then press the Set Switch. This will cause another bar to flash on and off at a slightly slower speed that the main flash bar. This will not change the point where the alarm is activated.

4. Beeper Volume
   The volume of the beep can be set to "Loud" or "Soft", or it can be turned off.



Method
Hold down the Set Switch and turn the device on. This will change the setting of the beep from "Loud" to "OFF". Repeat the procedure to change it from "OFF" to "Soft". The setting will be memorized and stay the same the next time you turn the device on.

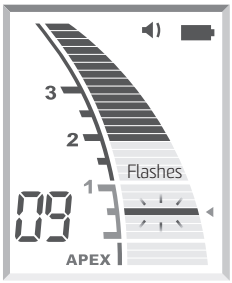
⚠ WARNING

- The memory bar should only be used as an estimate. You may need to change it during enlargement and cleaning. If there seems to be some problem, stop using the device immediately.
- Check the settings displayed after selecting memories.

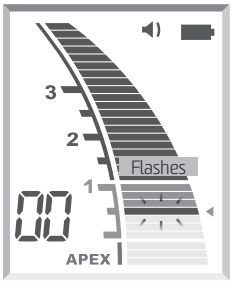
⚠ CAUTION

- The memory bar cannot be set beyond the APEX.
- The memory bar can be set at a different point for each of the 3 memories.
- The memory bar will stay wherever you set it until the device is turned off, but it will not be memorized.
- The volume of the beep that sounds when the device is turned on cannot be adjusted.

Meter Display

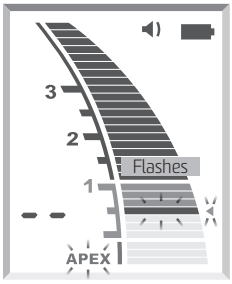


The position of the file tip is shown by the canal length indicator bar on the display. The flash bar flashes on and off once file is inserted into the root canal.



The meter's 0.5 reading indicates that the tip of the file is in or very near the apical constriction.

* The numerals on the meter gauge do not represent millimeters.



If the file tip reaches the apical foramen, a single, sustained beep will sound, and the word "APEX" and the little triangle next to the flash bar will start to flash on and off.

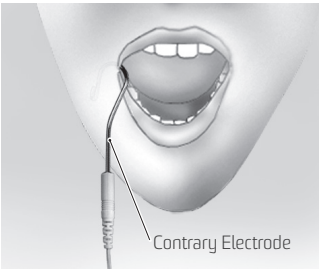
⚠ WARNING

- In some cases such as a blocked canal, a measurement cannot be made. ☞ pp. 16 and 17 "Root Canal Not Suitable for Electronic Measurement"
- Always check the measurement with an X-ray. In some cases, an accurate measurement cannot be made because of the canal shape, unusual cases, or poor performance of the device. ☞ p. 18 "Endostar Navigator Meter Reading and Radiography"
- Stop using the device immediately if you sense something odd or abnormal while taking a measurement.

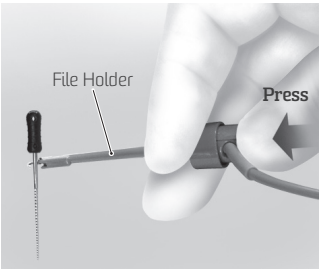
⚠ CAUTION

- Do not let the file touch the gums. This will cause the meter to jump to the APEX.
- If the canal is extremely dry, the meter may not move until it is quite close to the apex. If the meter does not move, try moistening the canal with oxydol or saline.
- Occasionally the canal length indicator bar will make a sudden and large movement as soon as the file is inserted into the root canal, but it will return to normal as the file is advanced down towards the apex.

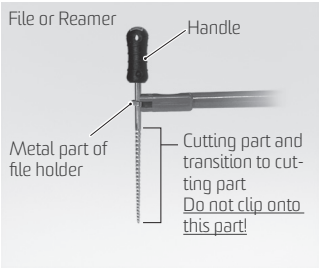
Operating Procedures



1. Turn the device on.
2. Hook the contrary electrode in the corner of the patient's mouth.



3. Clip the file holder to the metal shaft of the file.
   (1) Press in direction of arrow with the thumb.
   (2) Clip the file.
   (3) Release thumb.



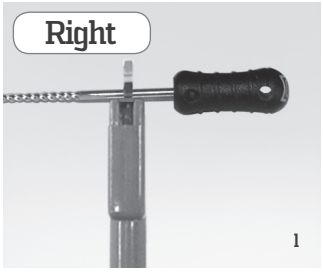
⚠ WARNING

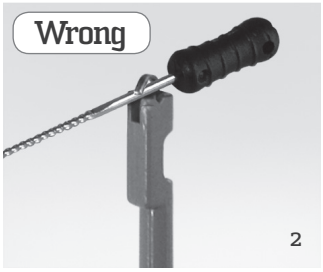
- Do not use an ultrasonic scaler with the contrary electrode attached to the patient. Electrical noise from the scaler could interfere with canal measurements.
- Make sure that the contrary electrode, file holder, etc. do not come into contact with an electric power source such as an electrical socket. This could result in a severe electrical shock.

⚠ CAUTION

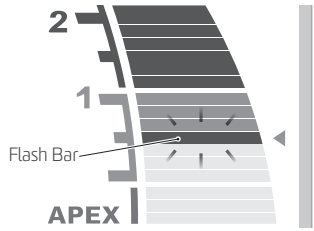
- The contrary electrode could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using the contrary electrode.
- Take care that medicinal solutions such as formalin cresol (FC) or sodium hypochlorite do not get on the contrary electrode or the file holder. These could cause an adverse reaction such as inflammation.
- Always clip the file holder to the upper part of the file shaft, near the handle. The metal and plastic part of the file holder can be damaged if they are attached to the file's cutting part or the transition to the cutting part.

Operating Procedures

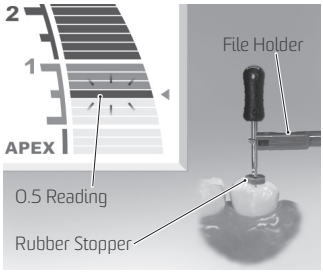




4. Press the Set Switch to select memory 01, 02, or 03.



5. Insert the file up to the flash bar (this point can also be recognized by the change in the beeping). Position the rubber stopper on the tooth surface as a reference point to determine the root canal's working length. Use the 0.5 reading on the meter to estimate the canal's length.



6. Determine the working length.

<u>If the file tip is at the 0.5 meter reading, subtract from 0.5 to 1.0 mm to determine the working length.</u>

* The working length will differ somewhat depending on each individual tooth. This discrepancy must be judged by the dentist as he works on the tooth.

<u>When using the long file holder instead of the file holder</u>

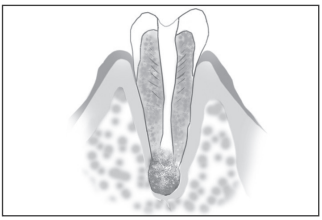
Long File Holder (Option)

⚠CAUTION

- Use files and reamers with plastic handles only. If the file has a metal handle, electrical leakage will occur when the handle is touched by fingers and it will prevent an accurate root canal measurement. Even if the file handle is made of plastic, make sure not to touch the metal part of the file with finger.
- Do not use damaged file holders. An accurate measurement cannot be made using a damaged file holder.
- Clip the file as shown in illustration #1 to the left. If the file is in the position shown in illustration #2, it may not make a correct measurement and the file holder could be damaged.
- Make sure to take an X-ray to check the results.
- Make sure the long file holder does not prick or pierce the patient's oral mucosa .

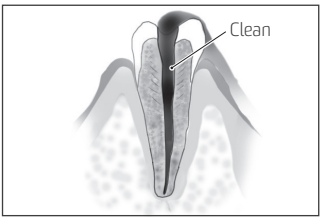
Root Canal Not Suitable for Electronic Measurement

Accurate measurement cannot be obtained with the root canal conditions shown below.
There may be cases other than these where an accurate measurement cannot be made.



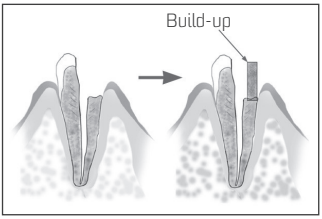
Root canal with a large apical foramen

Root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured; the results will show shorter measurement than the actual length.



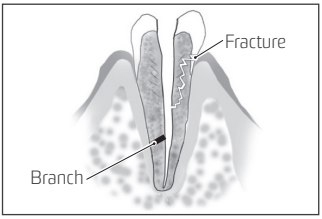
Root canal with blood, saliva or a chemical solution overflowing from the opening

If blood, saliva, or a chemical solution overflows from the opening of the root canal and contacts the gums, this will result in electrical leakage and an accurate measurement cannot be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal thoroughly to get rid of all blood, saliva and chemical solutions and then make a measurement.



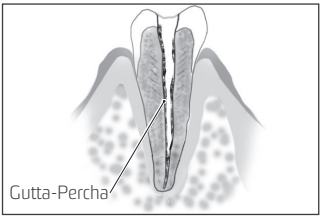
Broken crown

If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.



Fractured tooth
Leakage through a branch canal

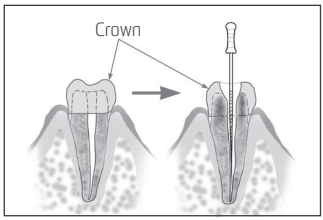
Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.
A branch canal will also cause electrical leakage.



Re-treatment of a root filled with gutta-percha

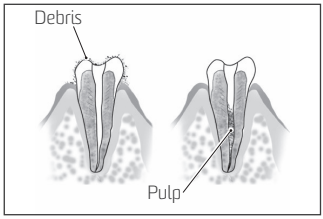
The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.

Root Canal not suitable for Electronic Measurement



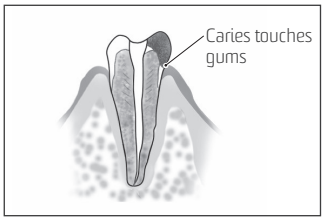
Crown or metal prosthesis touching gingival tissue

Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.



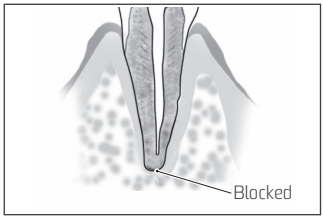
Cutting debris on tooth
Pulp inside canal

Thoroughly remove all cutting debris on the tooth.
Thoroughly remove all the pulp inside the canal; otherwise an accurate measurement cannot be made.



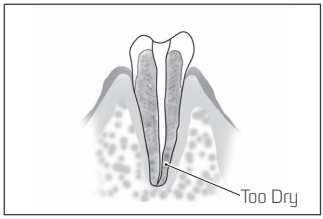
Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums will make it impossible to obtain an accurate measurement.



Blocked canal

The meter will not move if the canal is blocked.
Open the canal all the way to the apical constriction to measure it.



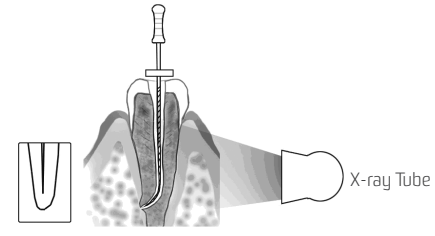
Extremely dry canal

If the canal is extremely dry, the meter may not move until it is quite close to the apex. In this case, try moistening the canal with oxydol or saline.

Endostar Navigator Meter Reading and Radiography

Sometimes the device meter reading and the X-ray image will not correspond. This does not mean that the device is not working properly or that the X-ray exposure is a failure.

* Occasionally, the actual apical foramen does not correspond exactly. The actual apical foramen may be located up towards the crown. In these cases, the X-ray image will seem to indicate that the file has not reached the apex.



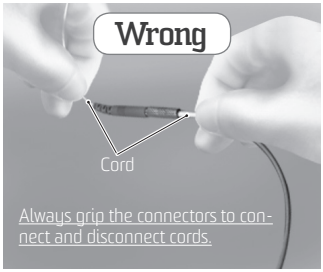
Apical foremen is located up towards the crown.

* Depending on the angle of penetration of the X-ray beam, the apex may not appear correctly, and the position of the apical foramen may appear to be located differently than it actually is.

3. After Using the Endostar Navigator

1. Turn the device off.

* The device will automatically turn off after 10 minutes of non-use.

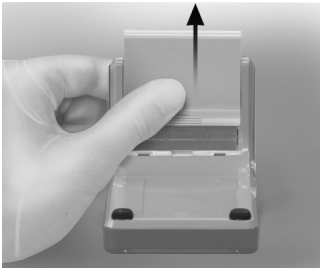


2. Disconnect the probe cord and other cords or cables.

⚠CAUTION

- Do not pull directly on the cords when connecting or disconnecting the probe and file holder. Always grip the connectors to connect and disconnect cords.
- Do not wrap the probe cord around the main unit.

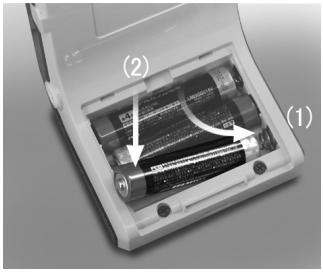
4. Replacing Batteries



Replace the batteries as soon as the battery power indicator starts flashing.

* When battery power falls too much, an alarm will sound and the device will automatically turn itself off.

1. Slide the cover in the direction by the arrow in the illustration and remove it from the device.



2. Insert three LR03 (AAA size) batteries included in the package.

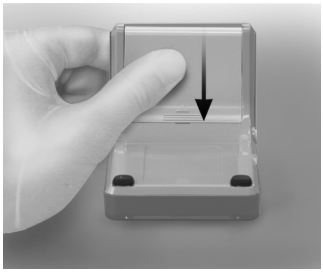
   (1) Insert the batteries by first pressing center of the minus end against its spring contact.
   (2) Slide the plus end down into place and make sure the contacts are not bent or damaged.

⚠WARNING

- Never use the device if the battery power indicator is flashing on and off. The device may not function properly if the battery power is low.

⚠CAUTION

- Do not reverse the plus and minus poles.
- Never allow the spring contact to push against the edge of the battery. This could damage the outer cover causing a short or a leakage of battery liquid.



3. Slide the cover all the way down until it is securely closed.

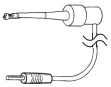
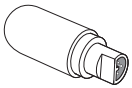
* Overheating or malfunctions could result if the above conditions are not adhered to.
* The three LR03 alkaline dry cells used for the device will last for about 70 hours of use. (This equals 6 to 12 months at the normal rate of usage.)

⚠CAUTION

- After installation, give the cover a light tug to confirm it is securely attached.
- Always use LR03 alkaline, Oxyride™ , or manganese dry cells. (Manganese dry cells will not last as long as Oxyride™ or alkaline dry cells.) Never use rechargeable nickel-hydrogen or nickel-cadmium batteries.
- All the dry cells should be of the same type: i.e., all alkaline, all Oxyride™ , or all manganese.
- Replace all three batteries at the same time.
- Never use batteries that are leaky, deformed, discolored or otherwise abnormal.
- Dispose of old batteries according to local codes and regulations.
- In case of battery leakage, carefully dry the battery terminals and remove all of the leaked liquid. Replace the battery with a new one.

Maintenance

There are two ways to clean and disinfect components depending on the component.
Be sure to follow the procedure below when performing daily maintenance.

Autoclavable Components	Other Components: Wipe with Ethanol (70 vol% to 80 vol%)
 File Holder	 Contrary Electrode
 Long File Holder (option)	 Main Unit
 Probe Cord	 Tester

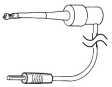
Autoclavable Components

*** Must be autoclaved after use for each patient.**

Maintenance Procedure

Cleaning → Disinfection → Packing → Sterilization

Components maintained this way:

 File Holder

 Contrary Electrode

 Long File Holder (option)

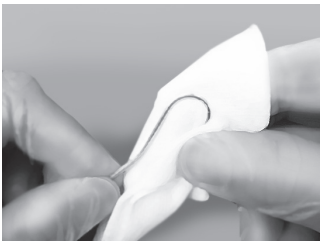
Take out the file before cleaning the file holder or the long file holder.

⚠CAUTION

- Be careful to avoid cross contamination when performing maintenance.

Autoclavable Components

Cleaning



1. Disconnect the file holder, long file holder and contrary electrode from the probe cord.

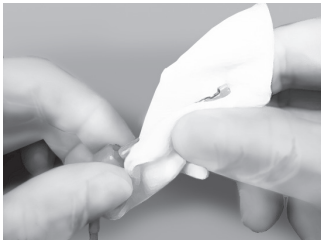
2. Clean them off in running water with a soft brush and then wipe off the water.

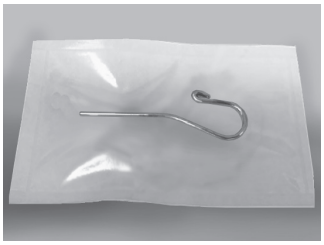
- If a medical agent being used for the treatment has adhered to the components, wash it off in running water.
- Do not clean the components ultrasonically.
- After washing is complete, check to see if the file holder or long file holder, including its inside, is completely dry. If any water remains inside the component, expel it with an air gun or another such tool. Failure to do so could result in the remaining water coming out during use and cause malfunction or poor sterilization.
- If dust or other impurities adhere to the hook of the file holder or long file holder, they may cause malfunction.

- Do not use the high-temperature washer-disinfector.

Autoclavable Components

Disinfection





Wipe the file holder, long file holder and contrary electrode with a piece of gauze dampened with Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%).

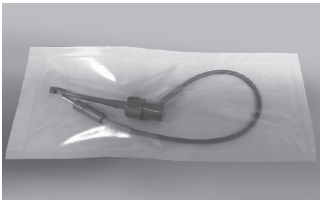
Never wipe the contra angle with any solution other than Ethanol for Disinfection (70 vol% to 80 vol%).

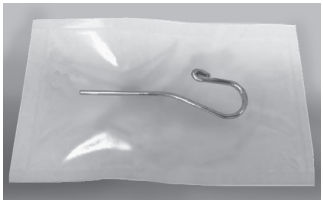
Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, and ozone water), medical agents (glutaral, etc.), medicinal solutions (FC: formalin cresol, sodium hypochloriteor, etc.) or any other special types of water or commercial cleaning liquids. Such liquids may result in plastic degradation, metal corrosion and adhesion of the residual medical agent to the components. If any of these liquids being applied to the components, wash it off in running water.

Packing

Individually place the file holder or long file holder, and contrary electrode in a sterilization pouch.

Do not put stress on the cable when you place the file holder in a sterilization pouch.





⚠CAUTION

- Do not use anything except ethanol (70 vol% to 80 vol%).
- Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agent to the components.
- Never clean the components with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the plastic parts of the components. If any of these liquids being applied to the components, wash it off in running water.
- Use only ethanol (70 vol% to 80 vol%) and OPTI-CIDE-3™ Surface Wipes for cleaning. Any other cleaning chemical or products should not be used including but not limited to the following cleaning products and similar cleaning products listed below because of the potential damage to the plastic components of the Endostar Navigator.
  - CaviWipes™
  - CaviCide™
  - SANI-CLOTH™

Autoclavable Components

Sterilization

Autoclave the file holder, contrary electrode, and long file holder after use for each patient.

Recommended temperature and time:

In a sterilization pouch, minimum 6 minutes at +134°C (+273.2°F) or minimum 60 minutes at +121°C (+249.8°F).

Minimum drying time after sterilization:

10 minutes.

- Never autoclave the main unit.

Not Autoclavable

Main Unit

- Autoclaving and drying temperatures must never exceed +135°C (+275°F). Excess temperature could cause the components to malfunction or could cause discoloration.
- Take the file out of the file holder or the long file holder before autoclaving.
- Clean everything throughly before autoclaving. Any chemicals or foreign debris left on components could cause them to malfunction or could cause discoloration.
- Do not leave the file holder, long file holder, and contrary electrode in the autoclave.
- For sterilizing files, follow the manufacturer's recommendations.

⚠ WARNING

- To prevent the spread of serious, life-threatening infections such as HIV and hepatitis B, the file holder, long file holder, and contrary electrode must be autoclaved after each patient's treatment has been completed.

⚠ CAUTION

- Do not sterilize the autoclavable components by any method other than autoclaving.
- Components are extremely hot right after autoclaving. Wait for them to cool off before touching.
- Do not leave the components in the autoclave.

Other Components: Wiping with Ethanol (70 vol% to 80 vol%)

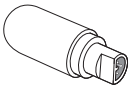
Maintenance Procedure

Disinfection

Components maintained this way:

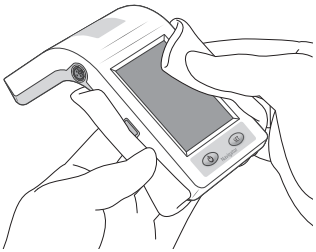
Main Unit

Probe Cord



Tester

Disinfection



Wipe the components with a piece of gauze that has been dampened with ethanol (70 vol% to 80 vol%) and wrung out thoroughly.

⚠CAUTION

- Do not use anything except ethanol (70 vol% to 80 vol%).
- Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agent to the components.
- Never clean the components with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the plastic parts of the components. If any of these liquids being applied to the components, wash it off in running water.
- Use only ethanol (70 vol% to 80 vol%) and OPTI-CIDE-3™ Surface Wipes for cleaning. Any other cleaning chemical or products should not be used including but not limited to the following cleaning products and similar cleaning products listed below because of the potential damage to the plastic components of the Endostar Navigator.
  - CaviWipes™
  - CaviCide™
  - SANI-CLOTH™

Replacement Parts, Transport and Storage

Replacement Parts

* Replace the parts as necessary depending on degree of wear and length of use.
* Order parts from Poldent Co. Ltd.

Transport and Storage Environments

Temperature: -10°C to +45°C (+14°F to +113°F)
Humidity: 10% to 85% (without condensation)
Atmospheric Pressure: 70 kPa to 106 kPa

- Do not expose to X-rays or direct sunlight frequently or for long times.
- If the device has not been used for a long time, make sure it works properly before using.
- Always remove the batteries prior to storing or shipping the device.

Inspection and Warranty

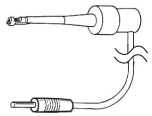
- Maintenance and inspection are generally consider to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, contact Poldent Co. Ltd. for details.
- Replace the parts listed in the Parts Lists as necessary depending on degree of wear and length of use.
- This apparatus should be inspected every 6 months in accordance with the following maintenance and inspection items.

Maintenance and Inspection Items

1. Check that the Power Switch turns the device on and off properly.
2. Insert the tester and check that the indicator is within ±3 lines of 1 on the meter.
3. Check that the Set Switch changes the memory from 01 to 02 to 03.
4. Check that the probe cord can be properly plugged into its jack.
5. Check that the file holder's plug can be connected properly to the probe cord and that the file holder can be clipped onto a file. Check the contrary electrode can be plugged into its probe cord connector.
6. Touch the contrary electrode with the file holder and make sure all the bars on the meter light up.
7. The device should be inspected after a prolonged unused period.

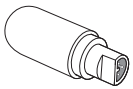
Parts List

File Holder
Code No. 6950-005



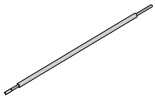
Contrary Electrode
Code No. 6950-004

Function Tester
Code No. 6951-012

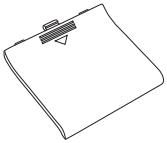


Probe Cord
Code No. 6951-001

Long File Holder
Code No. 6905-009



Battery Cover
Code No. E8449449



Maintenance and Inspection Items

Disposal of Medical Devices

Any medical devices which could possibly be contaminated must be first decontaminated by the responsible doctor or medical institution and then be disposed of in accordance with local laws and regulations.
The battery should be recycled. Metal parts of the equipment are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Material must be disposed according to the relevant national legal regulations. Consult specialized disposal companies for this purpose. Please inquire of the local administration concerning local disposal companies.

Service

The Endostar Navigator should be repaired and serviced by J. MORITA's authorized technicians.
Please contact and call Poldent Co. Ltd's local dealer for more details.

Warranty

2 Year Limited Warranty

1. Poldent Co. Ltd. gives a guarantee for two years beginning from the date of purchase. Within this period any defect that is due to faulty manufacturing or material will be remedied by repair or replacement at the judgment of Poldent Co. Ltd.
2. Warranty repair and service: in the event of a claim under this warranty, please contact with Poldent Co. Ltd's local dealer.
3. In the case of damage caused by wear and tear, careless handling and repairs not carried out by Poldent Co. Ltd., the warranty ceases to be valid. This guarantee may not form the basis for any claims for damages, in particular not for compensation of consequential damages.
   The buyer assumes responsibility for damage due to dropping of the device, improper use and utilization of product and chemicals other than those stated in this instruction manual for cleaning. It is the customer's responsibility to maintain the exact rated voltage indicated at the bottom of the device.
4. This warranty does not include the external accessories, file electrode or batteries.

Troubleshooting

If the equipment does not seem to be working properly, the user should first try to inspect and adjust it himself.

* If the user is unable to inspect the device themself or if the device fails to work properly after being adjusted or after parts are replaced, contact Poldent Co. Ltd.

Problem	Check Points	Response
Does not turn on.	▪ Check battery installation.	▪ Install batteries properly.
	▪ Check battery power.	▪ Replace batteries.
Cannot make a Measurement.	▪ Check cord connections.	▪ Check that all connections are properly secured.
	▪ Check probe cord for broken wire.	▪ Touch the contrary electrode to the file holder to check probe cord conductivity.
No alarm sound.	▪ Check if the sound volume is set to "OFF".	▪ Set it to "Soft" or "Loud".
Cannot switch memories. **Cannot change memory settings.**	▪ Is a measurement being performed?	▪ The memory cannot be changed while the device is making a measurement.
	▪ Does the Set Switch work?	▪ The Set Switch may be broken. Contact Poldent Co. Ltd.
Display does not appear.	▪ Try replacing batteries.	▪ If new batteries do not solve the problem, the LCD may be malfunctioning. Contact Poldent Co. Ltd.
Canal Length Indicator is unstable.	▪ Is contrary electrode making good contact with oral mucosa?	▪ Make sure the contrary electrode makes good contact with the oral mucosa.
	▪ Is the file holder dirty?	▪ Clean the file holder with ethanol (70 vol% to 80 vol%).
Canal Length Indicator overreacts or is too sensitive. (Measurements are too short. Poor accuracy. Erratic results.)	▪ Is blood or saliva overflowing from the opening of the crown?	▪ If blood or other fluids overflow the canal, the current will leak to the gums and the meter will jump to the APEX. Clean the canal, canal opening, and tooth crown thoroughly.
	▪ Is the canal filled with blood, saliva or chemical solutions?	▪ The canal length indicator bar may suddenly swing when it breaks the surface of fluids inside the canal, but it will return to normal as the file is advanced down toward the apex.
	▪ Is the tooth surface covered with cutting debris or chemical solutions?	▪ Clean entire tooth surface.
	▪ Is the file touching the gingival tissue?	▪ This will cause the canal length indicator bar to suddenly jump all the way to the APEX.
	▪ Is there pulp tissue left inside the root canal?	▪ Accurate measurements cannot be obtained if a large amount of pulp tissue is left inside the root canal.
	▪ Is the file touching a metal prosthesis?	▪ Touching a metal prosthesis with the file allows a flow of current to the gingival tissue or periodontal pocket and will cause the meter to jump to the APEX.
	▪ Are proximal surfaces infected with caries?	▪ Current can flow through the caries infected area to the gums and prevent an accurate measurement from being made.

Problem	Check Points	Response
Canal Length Indicator overreacts or is too sensitive. (Measurements are too short, poor accuracy or erratic results.)	▪ Are there lateral canals or is the tooth fractured?	▪ The canal length indicator bar may jump to the APEX when it reaches the opening of a lateral canal or the opening of a fractured tooth that allows the current to flow to the gingival tissue.
	▪ Does a broken crown allow leakage of electric current?	▪ Build up an insulating barrier to stop the leakage.
	▪ Is there a lesion at the apex?	▪ A lesion can destroy the apical foramen through absorption and an accurate measurement cannot be obtained.
	▪ Is the file holder broken or dirty?	▪ Replace or clean the file holder.
Canal Length Indicator does not move at all or only when the file tip is close to the apical foramen.	▪ Is the canal blocked?	▪ Open the passage all the way through the apical constriction first and then take the measurement.
	▪ Is the apical foramen very large and open?	▪ If the apical foramen is large or wide open and not completely formed, the canal length indicator bar will suddenly jump when the file tip gets close to the apex.
	▪ Is the canal extremely dry?	▪ Moisten the canal with oxydol or a saline solution.
Cannot set Memory Bar for file tip at desired point.	▪ Is desired indicator bar lit up?	▪ Advance file to desired point.
	▪ Did you press the Set Switch?	▪ Press the Set Switch firmly.
	▪ Has file tip gone beyond the APEX?	▪ Move file tip up above the APEX.

Technical Specifications

Specifications

*Specifications may be changed without notice due to improvements.

Name	Endostar Navigator
Model	RCM-7
Degree of Protection (IEC 60529)	IPX0
Protection against Electric Shock	Intenal powered ME equipment / Type BF applied part
Intended Use	The Endostar Navigator is intended to detect the apex of the root canal.
Operating Principle	The impedance in the root canal is measured by measuring at two frequencies and the position of the treatment instruments in the root canal is detected.
Essential Performance	None (There is no unacceptable risk.)

Main Unit	
Rated Input Voltage	DC 4.5 V (Three alkaline dry cells [LR03 "AAA size" batteries])
Dimensions	Approx. Height 57 mm × Width 60 mm × Length 103 mm
Weight	Approx. 110 g
Applied Part	File holder, Contrary electrode

Symbols

* Some symbols may not be used.

Manufacturer

Date of manufacture

Serial Number

GS1 DataMatrix

Direct current

Attention, consult accompanying documents.

Type BF applied part (Contrary electrode and File holder)

This way up

Keep away from rain

Temperature limitation

Fragile

Humidity limitation

Atmospheric pressure limitation

Consult Instructions for Use

CE(0197) marking
Conforms with the European Directive, 93/42/EEC.
CE marking
Conforms with the European Directive, 2011/65/EU.

EU Authorized Representative under the European Directive 93/42/EEC

Marking of electrical equipment in accordance with the European Directive 2012/19/EU (WEEE)

Electromagnetic Disturbances (EMD)

Electromagnetic Disturbances (EMD)

The Endostar Navigator (hereafter "this device") conforms to IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances (EMD).
The following is the "Guidance and Manufacturer's Declaration" which is required by IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances.
This is a Group 1, Class B product according to EN 55011 (CISPR 11).
This means that this device does not generate and/or use internationally radio-frequency energy, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material or inspection/analysis purpose and that it is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings use for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
Conducted disturbance CISPR 11	Group 1 Class B	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated disturbance CISPR 11	Group 1 Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current*1 IEC 61000-3-2	Class A	
Voltage fluctuations and flicker*1 IEC 61000-3-3	Clause 5	

*1: The test is not applicable since the EUT does not have AC ports.

⚠ WARNING

- The use environment of this device is the Home healthcare environment.
- This device needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the ACCOMPANYING DOCUMENTS.
- Use of parts other than those accompanied or specified by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Do not use this device as adjacent or stacked as possible with other. When adjoining or stacking is necessary, use it after observing whether this equipment and other equipment work properly.
- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the RCM-7, including cables specified by the manufacturer.

Electromagnetic Disturbances (EMD)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge[*1] IEC 61000-4-5	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output ±2 kV line(s) to earth	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines[*1] IEC 61000-4-11	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s.) 50 Hz or 60 Hz	30 A/m (r.m.s.) 50 Hz or 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level. NOTE 2: r.m.s.: root mean square			

Electromagnetic Disturbances (EMD)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below.
The customer or the user of this device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V ISM[c] / amateur radio frequency band: 6 V 150 kHz to 80 MHz	3 V ISM[c] / amateur radio frequency band: 6 V 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 0.4\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz $d = \frac{6}{E}\sqrt{P}$ Portable wireless RF communication equipment Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the compliance level in V/m and d is the recommended separation distance in meters (m). Field strengths from field RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	10 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	

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 ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating this device.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
(c) The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Essential Performance

None

Cable List

No.	Interface(s):	Max. Cable Length, Shielding	Cable Classification
1.	Probe Cord	1.7 m, Un-shielded	Signal Line (Patient-Coupled Cable)

Memo

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Pub. No.: K333-80002-500 (EN) Printed in Japan