2016.03.07

BRASSELER USA®

Apex Locator

EndoSync™ A.I.

Operation Instructions

Thank you for purchasing the EndoSync A.I.
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.

Brasseler USA

Contents

Prevent Accidents

Attention Customers

Do not fail to receive clear instructions concerning the various ways to use this equipment as described in this accompanying Operator's Manual.
Fill out and sign the warranty and give the dealer from whom you purchased the equipment his copy.

Prevent Accidents

Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents. Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit in accordance with the manufacturer's recommendations. First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the equipment with the utmost caution to prevent either damaging the equipment itself or causing bodily injury.

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

⚠WARNING — This warns the user of the possibility of extremely serious injury or complete destruction of the equipment as well as other property damage including the possibility of fire.

⚠CAUTION — This warns the user of the possibility of mild injury or damage to the equipment.

The warning symbols (⚠) and note 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 Notes at the bottom of the page.

(Usage Note) — This alerts the user of important points concerning operation or the risk of equipment damage.

The user (e.g. the hospital, clinic etc.) is the party responsible for the maintenance and proper operation of a 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.

Rx Only

⚠CAUTION

U.S. Federal law and Health Canada Medical Device Regulations restrict this device to sale by or on the order of a physician or properly licensed practitioner.

Disclaimer

- Brasseler USA will not be responsible for accidents, equipment damage, or bodily injury resulting from:
  1. repairs made by personnel not authorized by Brasseler USA.
  2. any changes, modifications, or alterations of its products
  3. the use of products or equipment made by other manufacturers, except for those procured by Brasseler USA.
  4. maintenance or repairs using parts or components other than those specified by Brasseler USA and other than in their original condition
  5. operating the equipment in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed
  6. workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply
  7. fires, earthquakes, floods, lightning, natural disasters, or acts of God.
- Brasseler USA will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.

Warnings and Prohibition

⚠WARNING

- Except for ways described in this manual, this unit 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. Brasseler USA will not be responsible for accidents, equipment damage, bodily injury or any other trouble which results from ignoring this prohibition.
- 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 main power switch is ON and without any operation, some electrical part may be malfunctioning. Do not use the unit and send the unit to Brasseler USA for repairing.
- A rubber dam should be used when performing endodontic treatment.
- Some care must be taken concerning electromagnetic compatibility (EMC) when using the EndoSync A.I. 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 EndoSync A.I.
- Using replacement parts or accessories not supplied by the original manufacturer or vender could adversely affect the EMC performance of the EndoSync A.I.
- As far as possible, do not use the EndoSync A.I. near or simultaneously with other devices. If this cannot be avoided, observe carefully and make sure both the EndoSync A.I. and the other device operate normally.

⚠IMPORTANT PRECAUTIONS

: These caution remarks are especially critical for safe operation and use.

- Do not use this unit in conjunction with an electric scalpel or on patients who have a pacemaker.
- Blocked canals cannot be accurately measured.
- Illumination devices such as fluorescent lights and the Film viewer which use an inverter can cause the EndoSync A.I. to operate erratically. Do not use the EndoSync A.I. near devices such as these.
- Electromagnetic wave interference could cause this device 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.

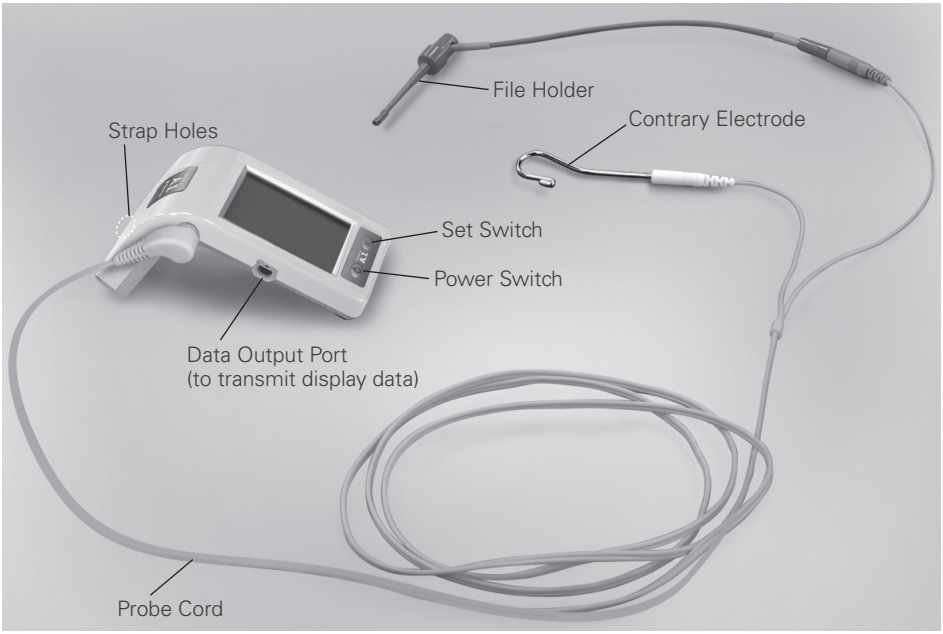
* Brasseler USA is not responsible for any accidents or other types of trouble that are caused by not following the warnings and important kprecautions noted above.

Indications for Use

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

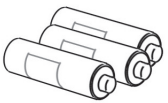
Parts Identification and Accessories

Parts Identification

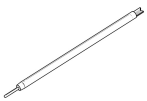


Accessories

Standard Accessories

Probe Cord (1)	File Holder (3)	Contrary Electrode (5)	Tester (1)	Alkaline Dry Cells (3)
				(LE03 (AAA size) batteries) 

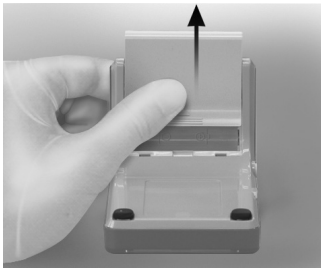
Optional Accessories

Long File Holder (1)


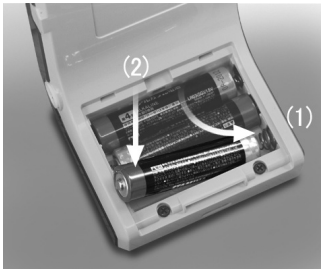
Usage

1. Before Using the Unit

Installing the Batteries

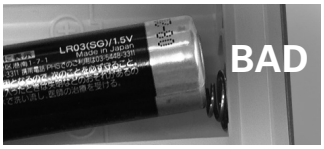


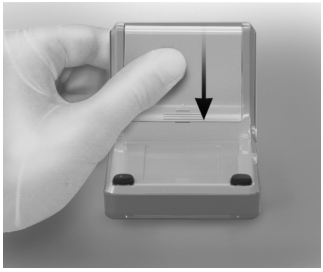
1. Slide the cover in the direction by the arrow in the illustration and remove it from the EndoSync A.I.



2. Insert the 3 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.



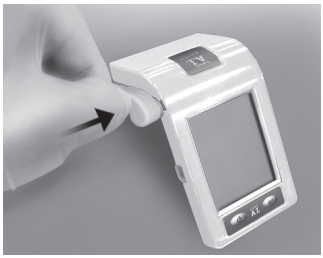


3. Slide the cover all the way down until it is securely closed.

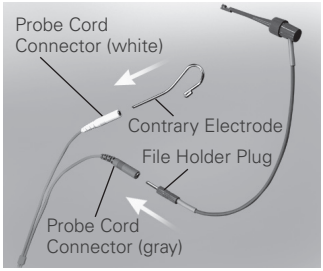
⚠CAUTION

- The EndoSync A.I. is shipped without the batteries installed. Remove the cover and install the 3 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 EndoSync A.I.



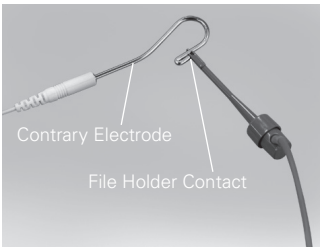
2. Insert the file holder's gray male plug into the gray female connector on the probe cord. Insert the contrary electrode into the white female connector on the probe cord.

Checking the Function

Power Switch

1. Press the Power switch to turn the unit ON. The display will appear in the LCD screen.

* The instrument turns itself OFF if it is not used for 10 minutes.

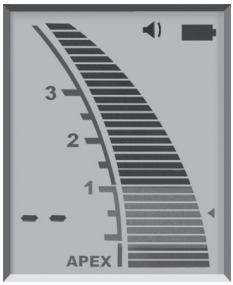


2. Check that the probe cord is properly plugged into the jack.
3. Check that the file holder and contrary electrode are properly connected to the probe cord.
4. Touch the metal part of the file holder with the contrary electrode. Check that all the meter indicator bars on the display light up.

⚠CAUTION

- Handle the EndoSync A.I. carefully; do not drop, bump or expose the unit 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 unit may turn OFF if its side is bumped.

Checking the Function

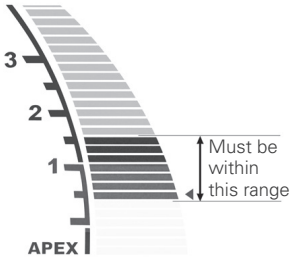


Checking the Function with the Tester

Check the EndoSync A.I.'s performance with the tester once a week.

1. Press the Power switch to turn the unit 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 one second until the meter stabilizes and then check the reading.
* If the reading is 4 or more bars away from 1, the unit will not make an accurate measurement. In this case, contact Brasseler USA.



⚠WARNING

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

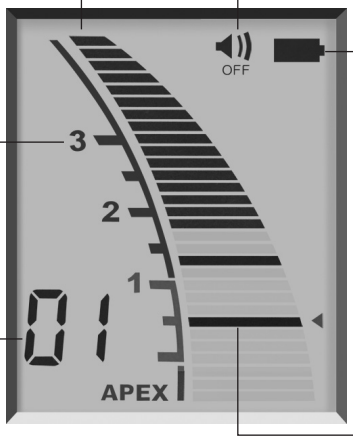
2. Operating the Unit

Operation Conditions for the main unit

Temperature: 10 to 40°C (50 to 104°F), Relative Humidity: 30 to 80% (without condensation), Atmospheric Pressure : 800 to 1,060 hPa

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

Operation Panel Display and Switches



Canal Length Indicator Bars

Meter

Sound Volume

OFF, Low, High

Battery Power Indicator

This bar graph indicates remaining battery power. Replace the batteries when this indicator begins flashing.

* When battery power falls too much, alarm will sound and the unit will automatically turn itself OFF.
* The unit will automatically turn OFF after 10 minutes of non-use.

Flash Bar

Use this line as an estimate for root canal measurement.

Memory Bar

Use this as an estimate of some intermediate point inside the canal.

Power Switch

Set Switch

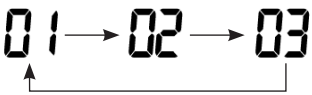
Information Display

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

⚠WARNING

- Never connect the EndoSync A.I. to any device not approved by Brasseler USA.
- Never use the unit if the battery power indicator is flashing ON and OFF. The unit 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 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 unit 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 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.

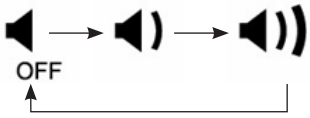
Settings

3. Memory Bar
   The Memory Bar can be set anywhere up to 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 for Loud or Soft, or it can be turned OFF.



Method

Hold down the Set Switch and turn the EndoSync A.I. 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 unit ON.

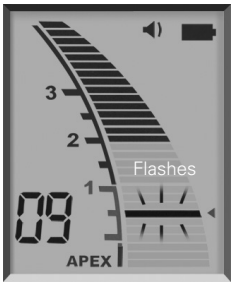
⚠WARNING

- 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 instrument immediately.
- Check the settings displayed after selecting memories.

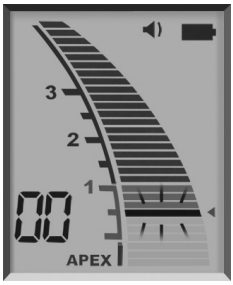
⚠CAUTION

- 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 EndoSync A.I. is turned OFF, but it will not be memorized.
- The volume of the beep that sounds when the unit is turned on cannot be adjusted.

Meter Display

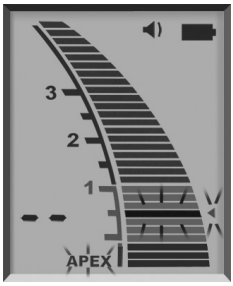


The position of the file tip is shown by the canal length indicator bar on the display. The Flash Bar flashes ON and OFF once file is inserted into the root canal.



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.

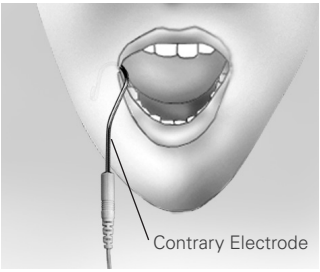
⚠WARNING

- In some cases such as a blocked canal, a measurement cannot be made. (For details "Root Canals 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 instrument.
- Stop using the instrument immediately if you sense something odd or abnormal while taking a measurement.

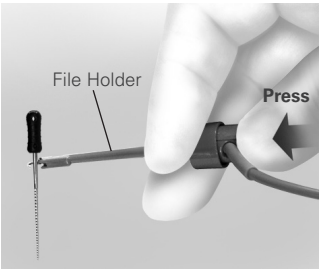
⚠CAUTION

- Do not let the file touch the gums. This will cause the meter to jump to 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.

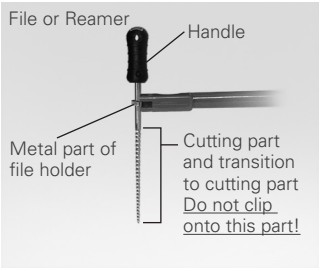
Operating the Unit



1. Turn the unit 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 file.
   (3) Release thumb.



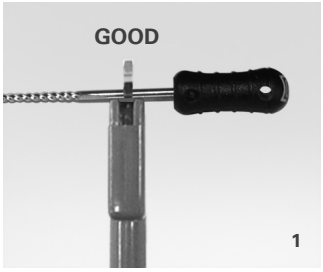
⚠WARNING

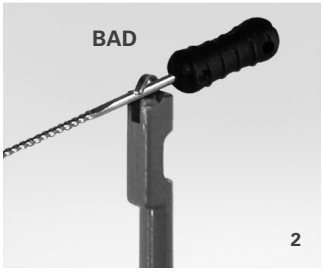
- Do not use an ultrasonic scaler with the contrary electrode attached to the patient. Electrical noise from the scaler could interfere with canal measurements.
- Make sure that the contrary electrode, file holder etc. do not come into contact with an electric power source such as an electrical socket.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

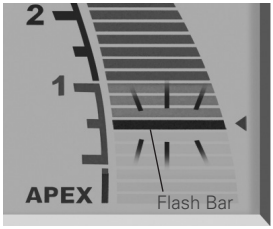
Operating the Unit



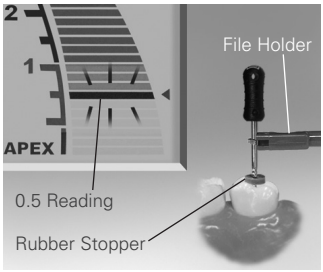


Set Switch

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>

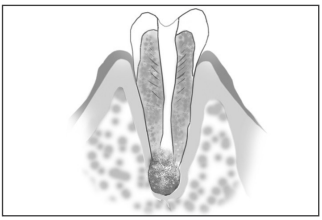
Long File Holder (Option)

⚠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 .

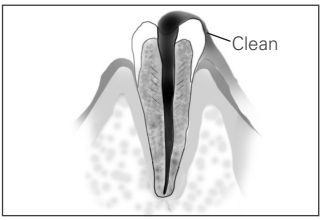
Root Canal not suitable for Electronic Measurement

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.



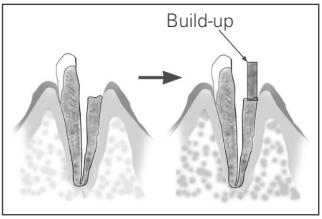
Root Canal with a large apical foramen

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.



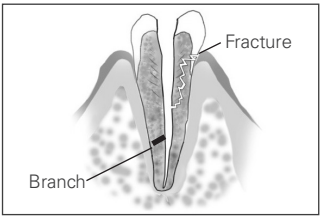
Root Canal with blood, saliva or a chemical solution overflowing from the opening

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.



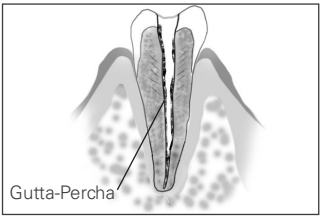
Broken crown

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

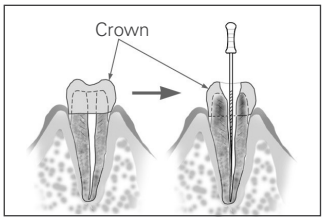
Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.
A branch canal will also cause electrical leakage.



Re-treatment of a root filled with gutta-percha

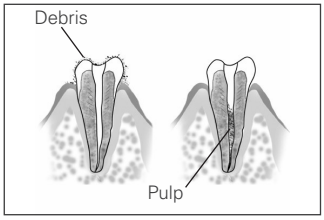
The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.

Root Canal not suitable for Electronic Measurement



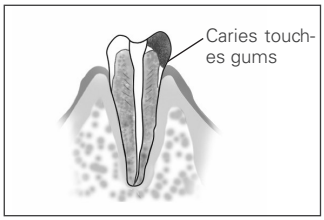
Crown or metal prosthesis touching gingival tissue

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.



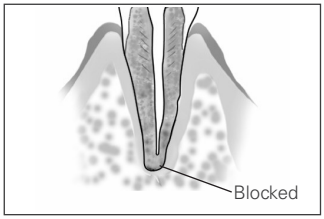
Cutting debris on tooth
Pulp inside canal

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



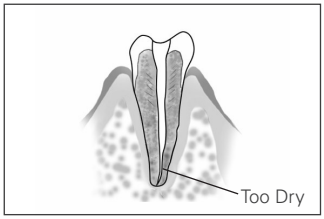
Caries touching the gums

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.



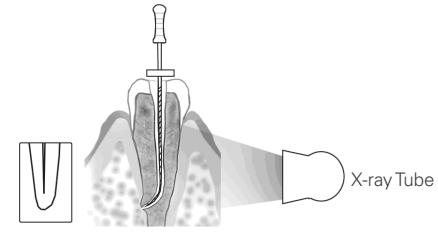
Extremely dry canal

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.

EndoSync A.I. Meter Reading and Radiography

Sometimes the EndoSync A.I. meter reading and the x-ray image will not correspond. This does not mean that the EndoSync A.I. 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.



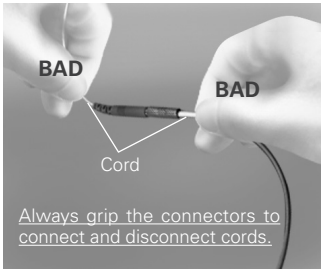
Apical foremen is located up towards the crown.

* 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 Unit

1. Turn the unit OFF.

* The unit will automatically turn OFF after 10 minutes of non-use.

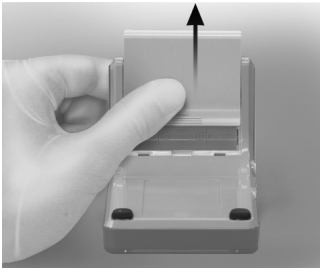


2. Disconnect the probe cord and other cords or cables.

⚠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 body of the main unit.

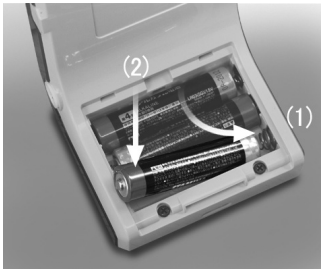
4. Replacing Batteries



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

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

1. Slide the cover in the direction by the arrow in the illustration and remove it from the EndoSync A.I.



2. Insert the 3 LR03 (AAA size) batteries included in the package.

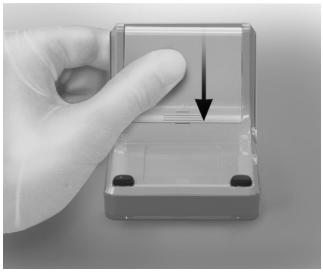
   (1) Insert the batteries by first pressing center of the minus end against its spring contact.
   (2) Slide the plus end down into place and make sure the contacts are not bent or damaged.

⚠WARNING

- Never use the unit if the battery power indicator is flashing on and OFF. The unit 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 this unit 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.

Sterilization, Replacement Parts and Storage

Sterilization

a. Autoclavable Components [File Holder, Long File Holder(Option) and Contrary Electrode]

Recommended temperature and time: 135°C (275°F), 4 minutes minimum with a sterilization pouch.
Minimum drying time after sterilization: 10 minutes.
or Recommended temperature and time: 121°C (249.8°F), 35 minutes minimum with a sterilization pouch. Minimum drying time after sterilization: 30 minutes.

- Autoclaving and drying temperatures must never exceed 135°C/ 275°F.
- The file holder, long file holder and contrary electrode must be thoroughly washed and cleaned before autoclaving.
- Any chemicals or foreign debris left on instruments could cause them to malfunction or could cause discoloration.

b. Sterilize Surface of Main Unit and Probe Cord with Ethanol

* Wipe with a piece of gauze dampened with Ethanol for Disinfection (Ethanol 70 to 80 vol%). Wring the gauze out to make sure it is not too wet.

- Never wipe components with a piece of gauze that is excessively wet with Ethanol for Disinfection (Ethanol 70 to 80 vol%). Do not apply or spray with any fluid. Also, do not immerse in any fluid or wash with water. It could seep inside the instrument and damage it. Be especially careful around the connection jacks for the transmission cable.
- Use only Ethanol for Disinfection (Ethanol 70 to 80 vol%) for disinfection. Any other type of solution could cause cracking, cloudiness, discoloration or some similar kind of damage.
- Use only Ethanol for Disinfection (Ethanol 70 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 EndoSync.
  - CaviWipes™
  - CaviCide™
  - SANI-CLOTH™

* The "™" mark indicates that each trade name is a trademark or registered trademark owned by the manufacturer in US or other territories.

⚠WARNING

- Autoclave file holder, long file holder and contrary electrode after each patient.

⚠CAUTION

- Do not sterilize in any way other than autoclave.
- It is highly recommended that instruments be autoclaved in a sterilization pouch (wrapped) or similar device.
- Do not autoclave probe cord.
- Follow the manufacturer's recommendations to disinfect files.
- On rare occasions, static electricity produced by wiping the liquid crystal display with a dry cloth may have some influence on the appearance of the display.
- Avoid spilling chemical solutions used for treatment on the EndoSync A.I. These chemicals could cause damage, deform or discolor the EndoSync A.I. Be especially careful to avoid spilling formalin cresol (FC) and sodium hypochlorite as they are quite strong. Wipe up any chemical spills immediately. (Some chemicals may leave discoloration and spots even if they are immediately wiped up.)

Replacement Parts

* Replace the parts as necessary depending on degree of wear and length of use.
* Order parts from Brasseler USA.

Storage

Transport and Storage Conditions:
Temperature: -10 to 70°C (14 to 158°F), Relative Humidity: 8 to 80% (without condensation), Atmospheric Pressure : 700 to 1,060 hPa

- Do not expose to x-rays or direct sunlight frequently or for long times.
- If the unit 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 unit.
- Brasseler USA will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.

Maintenance, 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, he may rely on a qualified medical device serviceman. Contact Brasseler USA 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 unit 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. This unit should be inspected after prolonged unusual period.

Parts Lists

Probe Cord

Code No. 8449716

File Holder

Code No. 7503670

Contrary Electrode

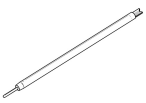
Code No. 7503680

Tester

Code No. 8449430

Long File Holder

Code No. 8447047



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 EndoSync A.I. may be repaired and serviced by Brasseler USA and Brasseler Canada technicians.

- For customers in the U.S., call 1-800-841-4522.
- For Customers in Canada, call 1-800-363-3838.

Warranty

1 Year Limited Warranty

1. Brasseler USA gives a guarantee for one year 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 the manufacturer or its distributor.
2. Warranty repair and service: In the event of a claim under this guarantee, the device is to be sent to Brasseler USA. For customers in the U.S., call 1-800-841-4522. For customers in Canada, call 1-800-363-3838.
3. In the case of damage caused by wear and tear, careless handling and repairs not carried out by Brasseler USA, 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 unit, 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 unit, and the office maintains electrical outlets for proper performance of the unit.
4. <u>This warranty does not include the external accessories, file electrode or batteries.</u>

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 equipment himself or if the equipment fails to work properly after being adjusted or after parts are replaced, contact Brasseler USA.

Problem	Check Points	Response
No power	Check battery installation. Check battery power.	Install batteries properly. Replace batteries.
Cannot make a Measurement.	Check cord connections. Check probe cord for broken wire.	Check that all connections are properly secured. Touch the contrary electrode to the file holder to check probe cord conductivity.
No alarm sound.	Check if sound is turned OFF.	Turn the sound ON.
Cannot switch memories. Cannot change memory settings.	Is a measurement being performed? Does the switch work?	The memory cannot be changed while the unit is making a measurement. Switch may be broken.
Display does not appear.	Try replacing the dry cells.	If new dry cells do not solve the problem, the LCD may be malfunctioning.
Canal Length Indicator is unstable.	Is contrary electrode making good contact with oral mucosa? Is the file holder dirty?	Make sure the contrary electrode makes good contact with the oral mucosa. Clean the file holder with Ethanol for Disinfection (Ethanol 70 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? Is the canal filled with blood, saliva or chemical solutions? Is the tooth surface covered with cutting debris or chemical solutions? Is the file touching the gingival tissue? Is there pulp tissue left inside the root canal? Is the file touching a metal prosthesis? Are proximal surfaces infected with caries?	If blood or other fluids overflow the canal, the current will leak to the gums and the meter will jump to Apex. Clean the canal, canal opening and tooth crown thoroughly. 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. Clean entire tooth surface. This will cause the canal length indicator bar to suddenly jump all the way to the "APEX". Accurate measurements cannot be obtained if a large amount of pulp tissue is left inside the root canal. 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". 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 "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 Set switch firmly.
	Has file tip gone beyond Apex Bar?	Move file tip up above the Apex Bar.

Technical Description

Specifications

Main Unit and Accessories

Model RCM-7 Type BSL

Classification

Safety according to IEC 60601-1, IEC 60601-1-2, UL60601-1, CAN/CSA C22.2 NO.601.1-M90
European Directive 93/42/EEC IIa
Canada Medical devices Class II

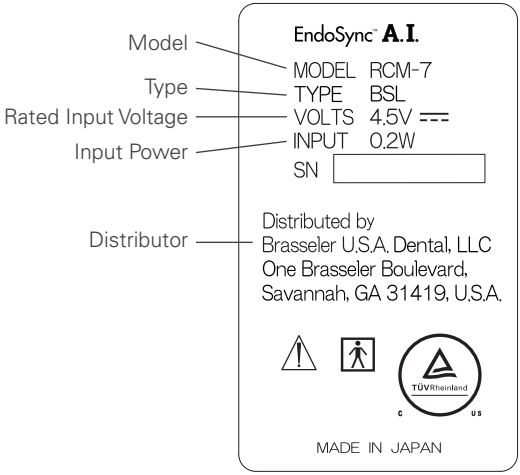
Type of Protection against Electric Shock	Battery operated
Degree of Protection against Electric Shock	Type BF applied part
Degree of Protection (IEC 60529)	IPX O
Mode of Operation	Continuous

Main Unit

Power Supply	DC 4.5 V (three alkaline dry cells (LR03 (AAA size) batteries))
Power Rating	0.2 W
Measurement Voltage	AC 80 mV, maximum
Measurement Current	10 μA, maximum
Display	Reflective Color LCD Piezoelectric Beeper
Dimensions	Approx. 60 (mm) × 103 (mm) × 57 (mm)
Weight	Approx. 110 (g)

Symbols

Rating Label



SN

Serial Number

Example)

SN B A 00001

① ② ③

① Year of Manufacture
A : 2012, B : 2013, C : 2014...

② Month of Manufacture
A: Jan., B: Feb., C: March...

③ Lot No.
00001, 00002, 00003...

Attention, consult accompanying documents.

Type BF applied part (Contrary Electrode and File Holder)

cTUVus certification mark for the U.S. and Canadian

Symbols

Operation Instructions

Rx Only

Caution:
U.S. Federal law and Health Canada Medical Device Regulations restrict this device to sale by or on the order of a physician or properly licensed practitioner.

Package

TEMPERATURE LIMITATION

Attention, consult accompanying documents.

THIS WAY UP

FRAGILE

KEEP DRY

Rx Only

Caution:
U.S. Federal law and Health Canada Medical Device Regulations restrict this device to sale by or on the order of a physician or properly licensed practitioner.

Appendix- Electromagnetic declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The EndoSync A.I. (hereafter the RCM-7-BSL) is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7-BSL should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RCM-7-BSL 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.
RF emissions CISPR 11	Class B	The RCM-7-BSL is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The RCM-7-BSL is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7-BSL 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	±6 kV contact ±8 kV air	±2, 4, 6 kV contact ±2, 4, 8 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	Not applicable Not applicable	The test is applicable since the EUT does not have AC/DC power ports and signal / interconnecting cable longer than 3 m.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	The test is not applicable since the EUT does not have AC power port.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable Not applicable Not applicable Not applicable	The test is not applicable since the EUT does not have AC power port.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3.15 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The RCM-7-BSL is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7-BSL 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3.15 V 3.5 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RCM-7-BSL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.11\sqrt{P}$ $d = 1.00\sqrt{P}$ 80 MHz to 800 MHz $d = 2.00\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed 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: 

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 be 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 the RCM-7-BSL is used exceeds the applicable RF compliance level above, the RCM-7-BSL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the RCM-7-BSL

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the RCM-7-BSL.

The RCM-7-BSL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RCM-7-BSL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RCM-7-BSL as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.11\sqrt{P}$	80 MHz to 800 MHz $d = \sqrt{P}$	800 MHz to 2.5 GHz $d = 2\sqrt{P}$
0.01	0.11	0.10	0.20
0.1	0.35	0.32	0.63
1	1.11	1.00	2.00
10	3.51	3.16	6.32
100	11.10	10.00	20.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

Essential Performance:

Noise does not substantially change measurement.

Probe Cord:

Length: 1.7 meters

⚠WARNING

- Use of the parts other than those accompanied or specified by Brasseler USA may result in increased EMC emissions or decreased EMC immunity of the EndoSync A.I.

2016.03.07

BRASSELER
USA®

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