

Apex Locator

S-Apex

Operation Instructions



CE
0197

Thank you for purchasing the S-Apex.

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.

Table of Contents

Prevent Accidents	3
Warnings and Prohibitions	5
Indications for Use	5
Parts Identification and Accessories	6
Usage	7
1. Before Using the Unit.....	7
Installing the Batteries.....	7
Connecting the Probe Cord.....	8
Checking the Function.....	8
2. Operating the Unit.....	10
Operation Panel Display and Switches.....	10
Settings.....	11
Meter Display.....	13
Root Canal not suitable for Electronic Measurement.....	16
S-Apex Meter Reading and Radiography.....	18
3. After Using the Unit.....	19
4. Replacing Batteries.....	20
Maintenance	22
Cleaning.....	22
Disinfection.....	23
Disinfection (other components): Wipe with Ethanol.....	23
Packing.....	24
Sterilization.....	24

Replacement Parts, Transport and Storage Conditions.....25
 Replacement Parts.....25
 Transport and Storage Conditions..... 25
Inspection and Warranty.....26
 Maintenance and Inspection Items..... 26
 Warranty.....27
Troubleshooting.....28
Technical Specifications.....30
 Specifications.....30
 Symbols.....31
Appendix – Electromagnetic Declaration.....32

NOTICE TO PROTECT INTELLECTUAL PROPERTY

US PAT. 8920166
US DESIGN 601262

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.

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 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.

(Mandatory Action)

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.

Disclaimer

- FKG will not be responsible for accidents, equipment damage, or bodily injury resulting from:
 1. Repairs made by personnel not authorized by FKG.
 2. Any changes, modifications, or alterations of its products
 3. The use of products or equipment made by other manufacturers, except for those by FKG.
 4. Maintenance or repairs using parts or components other than those specified by FKG 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.

In Case of Accident

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

Intended Operator Profile

The S-Apex must only be used by dentists and other legally licenced professionals.

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 S-Apex is not recommended for use in children under 12 years of age.

Warnings and Prohibitions

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 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 FKG for repairing.
- A rubber dam should be used when performing endodontic treatment.
- Some care must be taken concerning electromagnetic compatibility (EMC) when using the S-Apex. 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 S-Apex.
- Using replacement parts or accessories not supplied by FKG could adversely affect the EMC performance of the S-Apex.
- As far as possible, do not use the S-Apex near or simultaneously with other devices. If this cannot be avoided, observe carefully and make sure both the S-Apex and the other device operate normally.

PROHIBITION: This indicates when not to use the equipment.

- Do not use this 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, 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. FKG 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 the Film viewer which use an inverter can cause the S-Apex to operate erratically. Do not use the S-Apex 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.
- Do not perform maintenance while using the instrument for treatment.

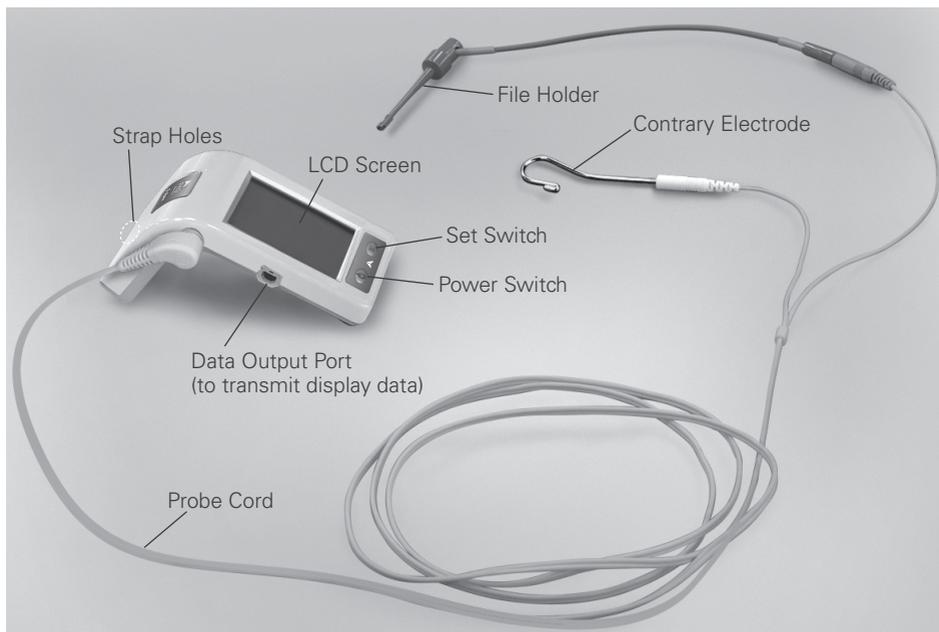
* FKG is not responsible for any accidents or other types of trouble that are caused by not following the warnings and important precautions noted above.

Indications for Use

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

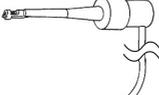
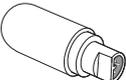
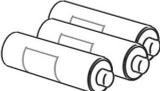
Parts Identification and Accessories

Parts Identification



Accessories

Standard Accessories

Probe Cord (1)	File Holder (3)	Contrary Electrode (5)	Tester (1)	Alkaline Dry Cells (3)
				

Optional Accessories

Long File Holder (1)


Usage

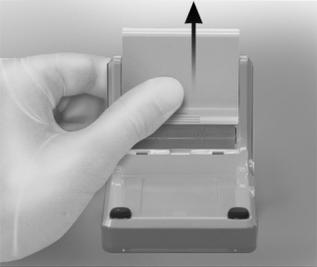
1. Before Using the Unit



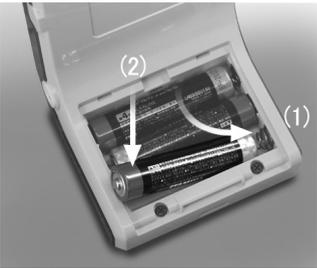
Check the following before using the instrument.

- Have autoclavable components been sterilized? Refer to page 24 “Sterilization”.

Installing the Batteries

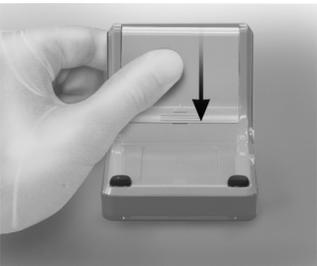


1. Slide the cover in the direction by the arrow in the illustration and remove it from the S-Apex.



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.

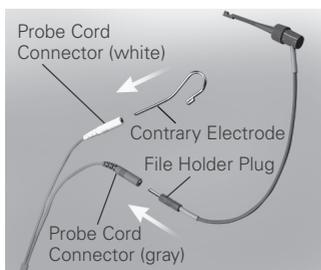
CAUTION

- The S-Apex 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 S-Apex.



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.



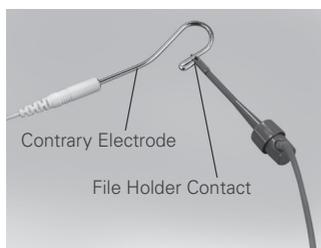
Checking the Function



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.

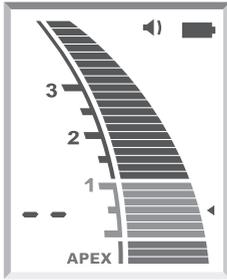


2. Check that the probe cord is properly plugged into the jack.
3. Check that the file holder and contrary electrode are properly connected to the probe cord.
4. Touch the metal part of the file holder with the contrary electrode. Check that all the meter indicator bars on the display light up.

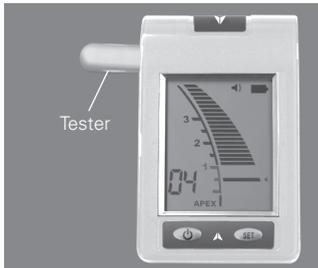
CAUTION

- Handle the S-Apex 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

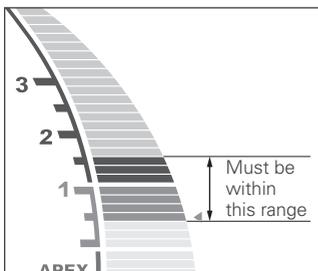


Check the S-Apex's performance with the tester once a week.

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 FKG.



WARNING

- Check the S-Apex 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

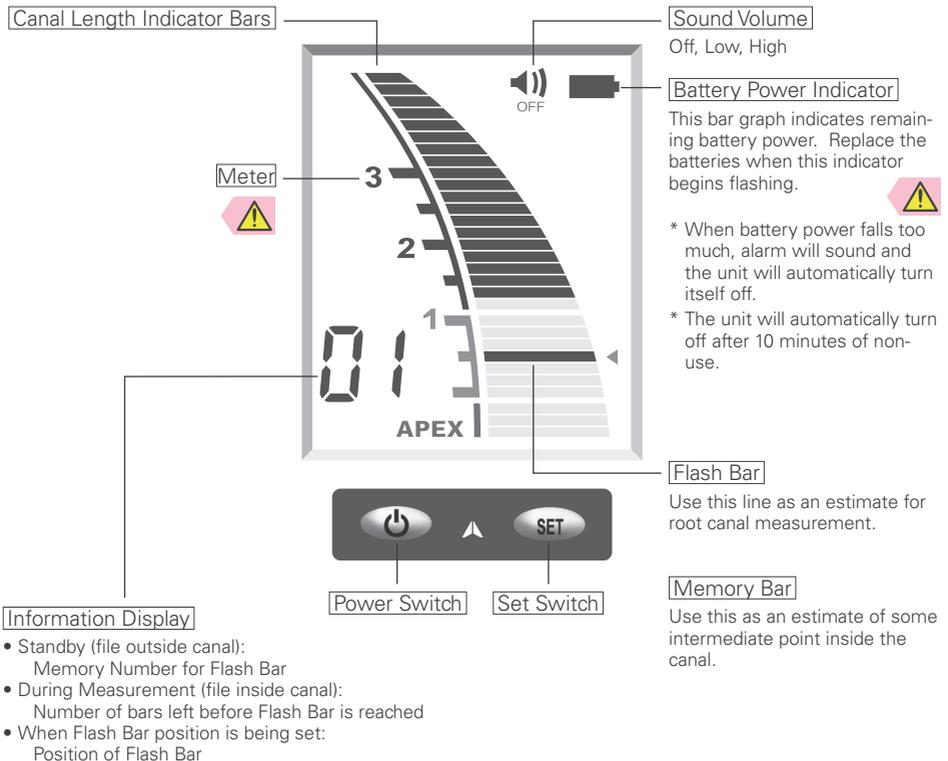
Operation Conditions for the main unit

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

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



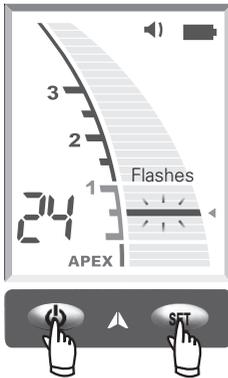
Operation Panel Display and Switches



WARNING

- Never connect the S-Apex to any device not approved by FKG.
- 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 it is 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

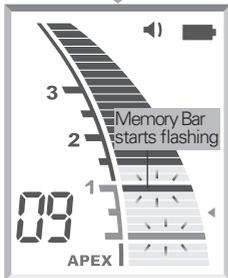
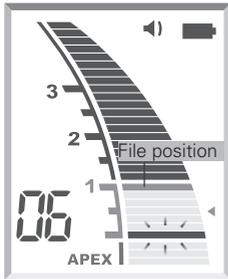
When the file is not inserted, hold down the Power Switch and then press the Set Switch at the same time. Each press of the Set Switch will move the Flash Bar one bar towards the Apex. The position will be automatically memorized.



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 than 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 S-Apex 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.



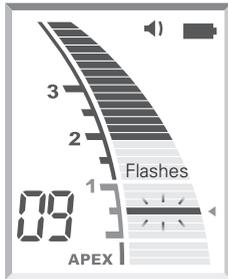
WARNING

- 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.

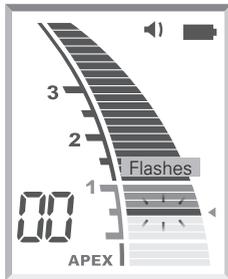
CAUTION

- 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 S-Apex 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

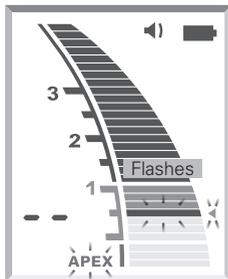


The position of the file tip is shown by the canal length indicator bar on the display. The Flash Bar flashes on and off once file is inserted into the root canal.



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.

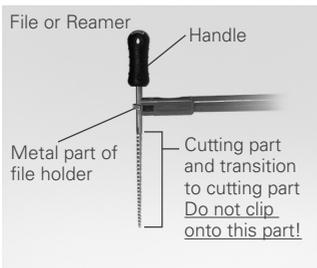
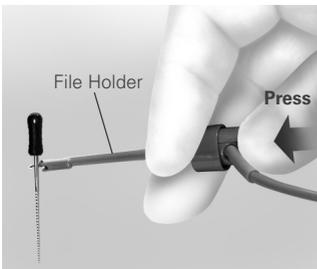
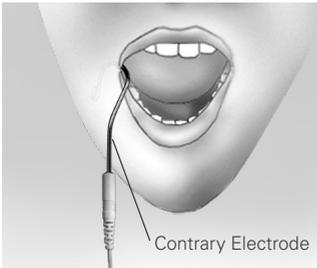
WARNING

- 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.

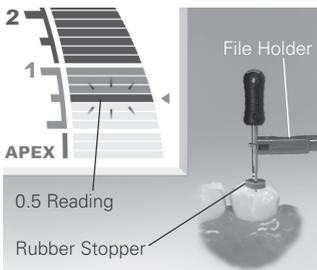
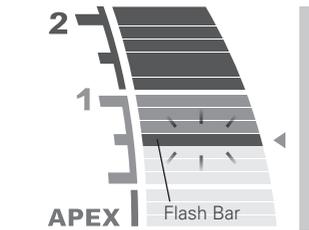
CAUTION

- 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.

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

* 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.



When using the long file holder instead of the file holder



Long File Holder (Option)



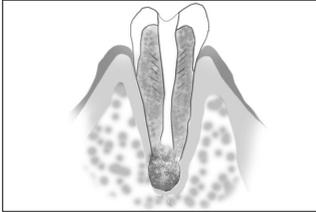
CAUTION

- 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

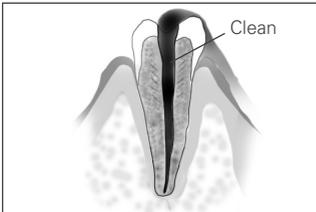
Accurate measurement cannot be obtained with the root canal conditions shown below.

There may be cases other than these where an accurate measurement cannot be made.



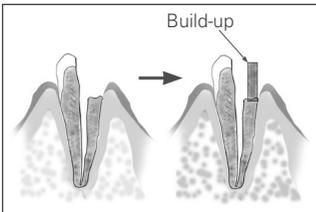
Root Canal with a large apical foramen

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.



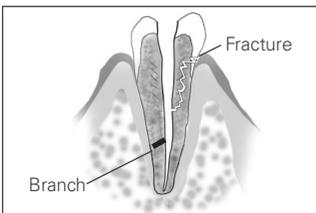
Root Canal with blood, saliva or a chemical solution overflowing from the opening

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.

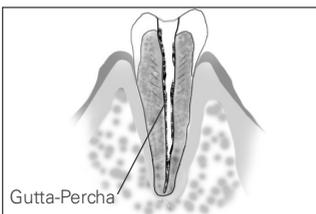


Fractured tooth

Leakage through a branch canal

Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.

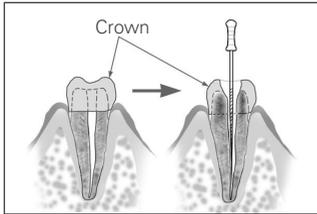
A branch canal will also cause electrical leakage.



Re-treatment of a root filled with gutta-percha

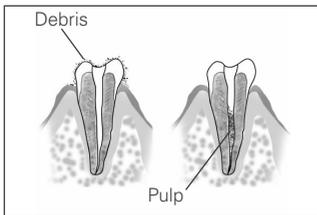
The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.

Root Canal not suitable for Electronic Measurement



Crown or metal prosthesis touching gingival tissue

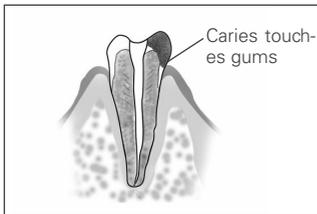
Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.



Cutting debris on tooth

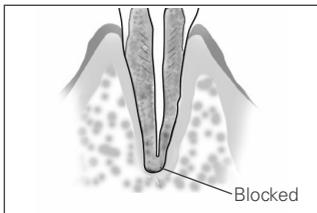
Pulp inside canal

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



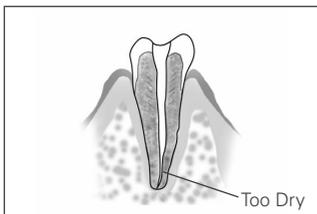
Caries touching the gums

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.



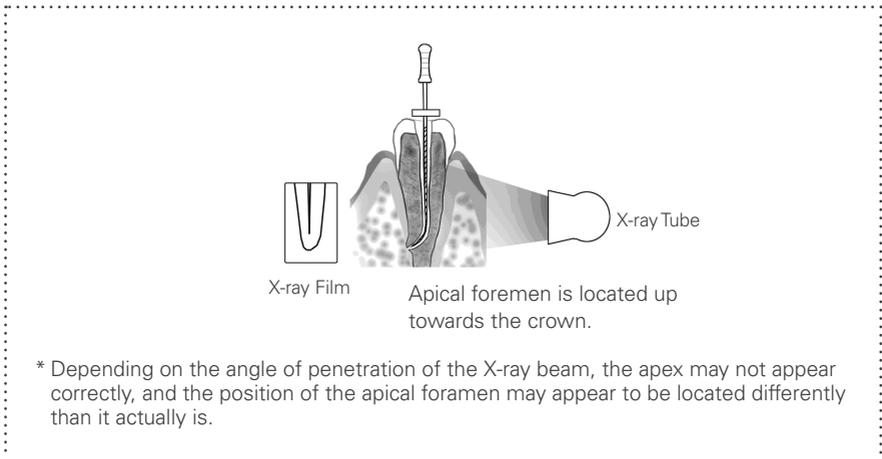
Extremely dry canal

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.

S-Apex Meter Reading and Radiography

Sometimes the S-Apex meter reading and the x-ray image will not correspond. This does not mean that the S-Apex 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.

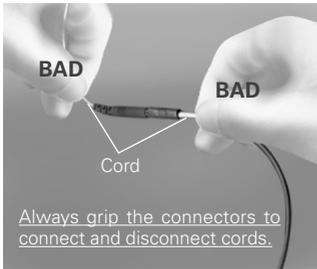


3. After Using the Unit

1. Turn the unit off.

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

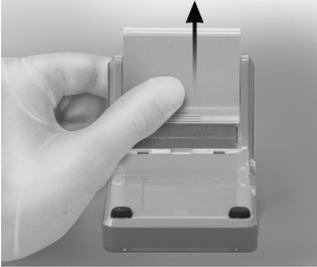
2. Disconnect the probe cord and other cords or cables.



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

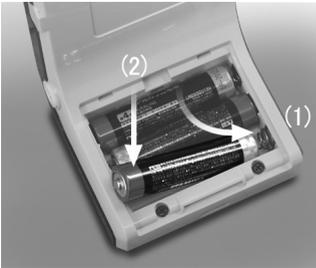


Replace the batteries as soon as the battery power indicator starts flashing.



* 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 S-Apex.



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.

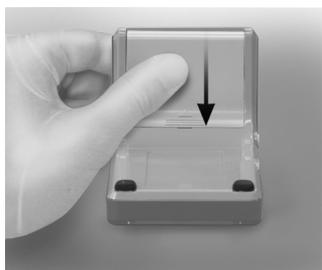


WARNING

- 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

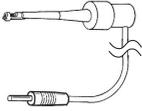
- After installation, give the cover a light tug to confirm it is securely attached.
- Always use LR03 alkaline, Oxyride™, or manganese dry cells. (Manganese dry cells will not last as long as Oxyride™ or alkaline dry cells.) Never use rechargeable nickel-hydrogen or nickel-cadmium batteries.
- All the 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.

Maintenance

Be sure to follow the procedure below when performing daily maintenance.



- Components maintained this way:



File Holder



Conrany Electrode



Long File Holder (option)

- ! Take out the file before cleaning the file holder.
- ! Other than the components listed above, refer to page 23 "Disinfection (other components): Wipe with Ethanol" for how to disinfect 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.

CAUTION

- Be careful to avoid cross contamination when performing maintenance.

Disinfection



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

- ❗ Never wipe the contra angle with any solution other than Ethanol for Disinfection (70 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 hypochlorite, 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.

Disinfection (other components): Wipe with Ethanol

Components Disinfected with Ethanol : Main Unit, Probe Cord

Dampen a piece of gauze with ethanol, wring it out and then wipe these components with it.

- ❗ Never wipe components with any solution other than Ethanol for Disinfection (70 to 80 vol%). Other solutions could cause cracking and discoloration.
- ❗ 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.
- ❗ Avoid spilling chemical solutions used for treatment on the any components. These chemicals could damage, deform or discolor plastic and metal. Use extra caution to avoid spilling formalin cresol (FC) and sodium hypochlorite as they are quite strong. Wipe up any chemical spills immediately. (Some chemicals may leave traces even if wiped up immediately.)
- ❗ 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 S-Apex.
 - 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.

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.



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.

- ! Do not sterilize the autoclavable components by any method other than autoclaving.
- ! 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 long file holder before autoclaving.
- ! Clean everything thoroughly 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

- The file holder, long file holder, and contrary electrode are extremely hot after autoclaving; do not touch until they cool off.

Replacement Parts, Transport and Storage Conditions

Replacement Parts

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

Transport and Storage Conditions

Transport and Storage Conditions:

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 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.

Inspection and Warranty

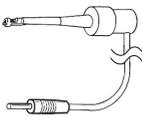
- Maintenance and inspection are generally considered to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, contact FKG for details.
- Replace the parts listed in the Parts Lists as necessary depending on degree of wear and length of use.
- 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 List

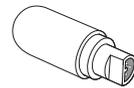
File Holder
Code No. 08.911.00.002.FK



Contrary Electrode
Code No. 08.911.00.003.FK



Function Tester
Code No. 08.911.00.004.FK



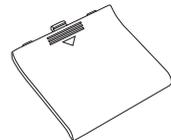
Probe Cord
Code No. 08.911.00.005.FK



Long File Holder
Code No. 08.911.00.006.FK



Battery Cover
Code No. 08.911.00.007.FK



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 S-Apex should be repaired and serviced by J. MORITA's authorized technicians. Please contact and call FKG's local dealer for more details.

Warranty

■ 2 Year Limited Warranty

1. FKG 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 FKG.
2. Warranty repair and service: in the event of a claim under this warranty, please contact with FKG's local dealer.
3. In the case of damage caused by wear and tear, careless handling and repairs not carried out by FKG, 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. 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 equipment himself or if the equipment fails to work properly after being adjusted or after parts are replaced, contact FKG.

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
<p>Canal Length Indicator overreacts or is too sensitive. (Measurements are too short, poor accuracy or erratic results.)</p>	<p>Are there lateral canals or is the tooth fractured?</p> <p>Does a broken crown allow leakage of electric current?</p> <p>Is there a lesion at the apex?</p> <p>Is the file holder broken or dirty?</p>	<p>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.</p> <p>Build up an insulating barrier to stop the leakage.</p> <p>A lesion can destroy the apical foramen through absorption and an accurate measurement cannot be obtained.</p> <p>Replace or clean the file holder.</p>
<p>Canal Length Indicator does not move at all or only when the file tip is close to the apical foramen.</p>	<p>Is the canal blocked?</p> <p>Is the apical foramen very large and open?</p> <p>Is the canal extremely dry?</p>	<p>Open the passage all the way through the apical constriction first and then take the measurement.</p> <p>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.</p> <p>Moisten the canal with oxydol or a saline solution.</p>
<p>Cannot set Memory Bar for file tip at desired point.</p>	<p>Is desired indicator bar lit up?</p> <p>Did you press the Set switch?</p> <p>Has file tip gone beyond Apex Bar?</p>	<p>Advance file to desired point.</p> <p>Press Set switch firmly.</p> <p>Move file tip up above the Apex Bar.</p>

Technical Specifications

Specifications

*Specifications may be changed without notice due to improvements.

Name	S-Apex
Model	RCM-7
Degree of Protection (IEC 60529)	IPX 0
Protection against Electric Shock	Intenal powered ME equipment / Type BF applied part
Intended Use	The S-Apex 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 × Width 60 × Length 103 mm
Weight	Approx. 110 g
Applied Part	File holder, Contrary electrode

Symbols



Serial Number

E.g.) F A XXXX



- ① Year of Manufacture
E.g.) F: 2017, G:2018, H: 2019...
- ② Month of Manufacture
E.g.) A: Jan., B: Feb., C: March...
- ③ Lot No.
0001, 0002, 0003...

E.g.) K315 XXXXXX K



- ① Lot No.
000001, 000002, 000003...



Reference number

E.g.) 08.911.00.001.FK



Attention, consult accompanying documents.



Manufacturer



Type BF applied part (Contrary electrode and File holder)



Date of manufacture



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



CE(0197) marking

Conforms with the European Directive, 93/42/EEC.

CE marking

Conforms with the European Directive, 2011/65/EU.



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



Keep away from rain



This way up



Fragile



Consult Instructions for Use



Temperature limitation



Atmospheric pressure limitation



Humidity limitation



Direct current

Appendix – Electromagnetic Declaration

The S-Apex (hereafter the RCM-7) conforms to IEC 60601-1-2: 2007, the relevant international standard for electromagnetic compatibility (EMC). The following is the “Guidance and Manufacturer’s Declaration” which is required by IEC 60601-1-2: 2007, the relevant international standard for electromagnetic compatibility.



Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The RCM-7 is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7 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 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 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	

WARNING

- The RCM-7 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- Portable and mobile RF communications equipment can affect the RCM-7.
- Use of parts other than those accompanied or specified by FKG may result in increased EMC emissions or decreased EMC immunity of the RCM-7.
- The RCM-7 should not be used adjacent to with other equipment. If adjacent use is necessary, the RCM-7 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The RCM-7 is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7 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 not 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 is intended for use in the electromagnetic environment specified below. The customer or the user of the RCM-7 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3.15 V</p> <p>3.5 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the RCM-7, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.11 \sqrt{P}$ $d = 1.00 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.00 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment 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 is used exceeds the applicable RF compliance level above, the RCM-7 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RCM-7

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.

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

Basic Performance:

None

Probe Cord:

Length: 1.7 meters



⚠ WARNING

- Use of the parts other than those accompanied or specified by FKG may result in increased EMC emissions or decreased EMC immunity of the S-Apex.



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swiss endo

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