

APEX LOCATOR

OSADA APIT 11

INSTRUCTION FOR USE



We thank you for your purchasing OSADA APIT 11.

This instruction manual is for how to operate and maintain the OSADA APIT 11 properly to get its best performance.

When you have any queries about this product, please contact the authorized OSADA distributor you purchased this product from or directly OSADA

FOR DANGER PREVENTION

Read carefully “Cautions for Handling the Device” in the instruction manual, and maintain with utmost care the good condition for the function, reliability and safety of the device.

In this instruction for use, the following marks are used for preventing the possible danger.

WARNING	There is a danger of serious injury to the user when mistakes in operations are made.
CAUTION	There is a danger of injury to the user when mistakes in operations are made which may lead to damage or functional troubles in the equipment.

FOR EXEMPTION CLAUSES

We are not responsible for:

1. The damages or troubles caused by the installation, transfer, maintenance, or repair handled by others who are not specified by us.
2. The damages and troubles caused by the other manufacturer’s product which we did not provide.
3. The damages and troubles caused by the maintenance, repair, etc. using the parts which are not the genuine parts specified by us.
4. The damages and troubles caused by the negligence of the necessary cautions or proper operations which are explained in this instruction manual.
5. The damages and troubles caused by the improper environmental conditions indicated in this instruction manual including the condition of electricity source and installation environment.
6. The damages and troubles caused by the natural calamities such as Fire, Earthquake, Flood, Lightning, etc.

WARNING	Do not remodel the equipment.
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FOR REPAIRS

Please contact the authorized OSADA distributor or OSADA (Tokyo) for repairs. When contacting, please inform the product name, serial (manufacturing) number and the kind of the trouble with the equipment.

CAUTIONS FOR HANDLING THE DEVICE

For using the OSADA APIT 11 safely, read carefully the instruction manual beforehand and follow strictly the instructions and cautions.

If there are points which are not understandable, before utilizing the device, please contact the authorized OSADA distributor or directly OSADA (Tokyo) to clarify.

● PRECAUTIONS (INSTALLATION)

CAUTION	<ol style="list-style-type: none">(1) Avoid the place where water affects the device.(2) Place the device on the surface with less than 1 degree inclination.(3) Do not be subject to strong shock, as when dropped. Besides that, be careful not to drop on foot.(4) Remove the dry batteries from the device if it is not expected to be used for a long time or when the device must be transported to another location.(5) Be careful about electromagnetic disturbance, in case of using in combination with other devices.
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● PRECAUTIONS (IN USE)

WARNING	<ol style="list-style-type: none">(1) Do not use the device other than the dentist.(2) Do not use the device for any purpose except measurement of the root canal length.(3) Do not use if the patient is using a Pacemaker, in consideration of safety.(4) Do not use in combination with an electro-surgery unit, as there is danger of damage to the device.(5) If the abnormality is felt on the position which meter is indicating, always confirm the position of K-file or reamer by the X-ray film without fail.(6) The buzzer sound tells when the K-file or reamer reaches W.L. (working length). When it happens, not only relying on the sound, always double check with the meter indication without fail.(7) Use the rubber dam not to swallow, by mistake, the lip clip, K-file or reamer.(8) To prevent the infections, sterilize the lip clip and file holder cord by the steam autoclave before using them.
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●PRECAUTIONS (IN USE)

CAUTION	<ul style="list-style-type: none">(1) Use the device in enough luminance to read the meter indication.(2) When the ambient temperature is low, it may happen that the symptoms like the indications appear on the display panel rather slow, etc. Use the device in appropriate environmental temperature, 10~40°C.(3) Use an AA-size alkaline dry battery or AA-size nickel-hydrogen battery as the electric power source. Do not use a manganese dry battery.(4) Dry batteries are not set up in the device at the time of delivery. Please load dry batteries properly in the device with the specified manner.(5) Be careful about electrical leakages due to cervical caries and/or metallic fillings in the patient's tooth.(6) Use the K-file or reamer with the plastic handle. The metallic handle can not be used.(7) Measure the root canal which is filled with normal saline or sodium hypochlorite as conductive solutions.(8) Do not use strong acidic water, as there is danger of corroding the device.
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●PRECAUTIONS (AFTER USE)

CAUTION	<ul style="list-style-type: none">(1) After use, wipe both the inside and outside surfaces of the metallic clipping end of the file holder cord with a cotton dipped in ethanol
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●PRECAUTIONS (DISINFECTION/STERILIZATION)

CAUTION	<ul style="list-style-type: none">(1)Take care of getting sufficient aeration to prevent the side effects from the remaining gas of EOG sterilization, such as headache, dizziness, nausea, faint, respiratory arrest, etc. by inhaling. Be careful of the skin wound by touching the solution.(2)High pressure steam sterilization is possible for the file holder cord and lip clip only and if others are given the method of sterilization other than EOG sterilization, (for example, high pressure steam sterilization), it may cause the damage to them or they will not be able to perform well with sufficient efficiency.
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● PRECATIONS (CHECKUP AND MAINTENANCE)

Be careful about the followings at the time of checkup, maintenance or exchange of expendables.

WARNING	<p>(1) Work after turning off the power switch. There is a danger of electrical leakage or shock. ※After the work, etc or when needed, turn on the power switch to confirm.</p> <p>(2) Do not modify this equipment without authorization of the manufacturer.</p>
CAUTION	<p>(1) Make periodical checkup and maintenance.</p> <p>(2) Wipe the surface of the Apit body with a soft cloth dipped in neutral detergent which should then be followed by a wiping with a cloth dipped in water. (Wiping with the OSADA Unit Cleaner is also acceptable, in this case.) Do not use thinner, benzine or other chemical solutions, in this case. Wipe immediately when dirtied by a medicament solution.</p> <p>(3) Exchange for new batteries when the battery power indication shows one level out of 3 levels.</p> <p>(4) First check the device under 6.2 “Checkup” and then use it, when the device is not used frequently,</p>

※When the device gets out of order, do not try to repair by yourself, after indicating about it properly, call for the authorized Osada distributor.

● PRECAUTIONS (STORAGE)

CAUTION	<p>(1) Storage conditions are as follows. Ambient Temperature -10—60°C Relative Humidity 10—90% Atmospheric Pressure 700—1060hPa ※When storing the device in the carton box for a long time, keep it in the room.</p> <p>(2) Store the device at the place where water or medical solutions do not affect.</p> <p>(3) Check the device before use when the device has been stored for a long time.</p>
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● PRECAUTIONS REGARDING DISPOSAL

CAUTION	<p>Do not dispose or treat the device as household waste but must process to Directive 2002/96/CE. Should you wish to definitively dispose the device, please comply with the regulations which apply in your country.</p>
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1 FEATURES

1. Accurate Measurement can be obtained.

Due to the measurement under relative value method using two different measuring frequencies (1kHz and 5kHz.), the accurate measurement can be obtained.

2. Adjustment Function is incorporated.

The fundamental of precise measurements of Osada Apit 11 is to make adjustment (zero adjustment). Osada Apit 11 incorporates two adjustment modes, auto and manual, which can be selected by the dentist, depending on the preferred technique.

Root canals with subgingival caries, residual pulp, etc. which are liable to cause electric leakage and not easy to measure, may be measured by pressing the ADJ. switch, as the result, measurable clinical cases are widened.

3. File Holder Cord has become easier to use than before.

A part of the file holder cord which can be put in the mouth is 10mm longer, so to approach the molar has become easier. The metal clipping end has become 0.5mm thinner, so the length of the K-file (or reamer) is used efficiently.

4. Reliable and Safe Treatment

- 1) The checker function is incorporated, so the device actuation can be checked periodically and safely operated.
- 2) The measuring current is less than 2 microamperes at the maximum, and very safe for the patient.

5. Environmentally Friendly

- 1) The battery-life has become longer, it approximately lasts 150 hours and the trouble of the battery exchange has become less.
- 2) The rechargeable nickel hydride battery (AA-size) lasts approximately 100 hours by one full charge, which can be used repeatedly, is also usable.

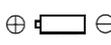
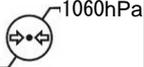
6. Easy to Understand

The large colored-liquid crystal display is easy to read and understand the device conditions from the icon indicated on the display.

2 PURPOSE OF UTILIZATION

Osada Apit 11 is an electronic root canal measuring device. It measures the root canal length by the impedances between the electrodes of the file holder cord and lip clip in the root canal.

3 SYMBOL DEFINITIONS

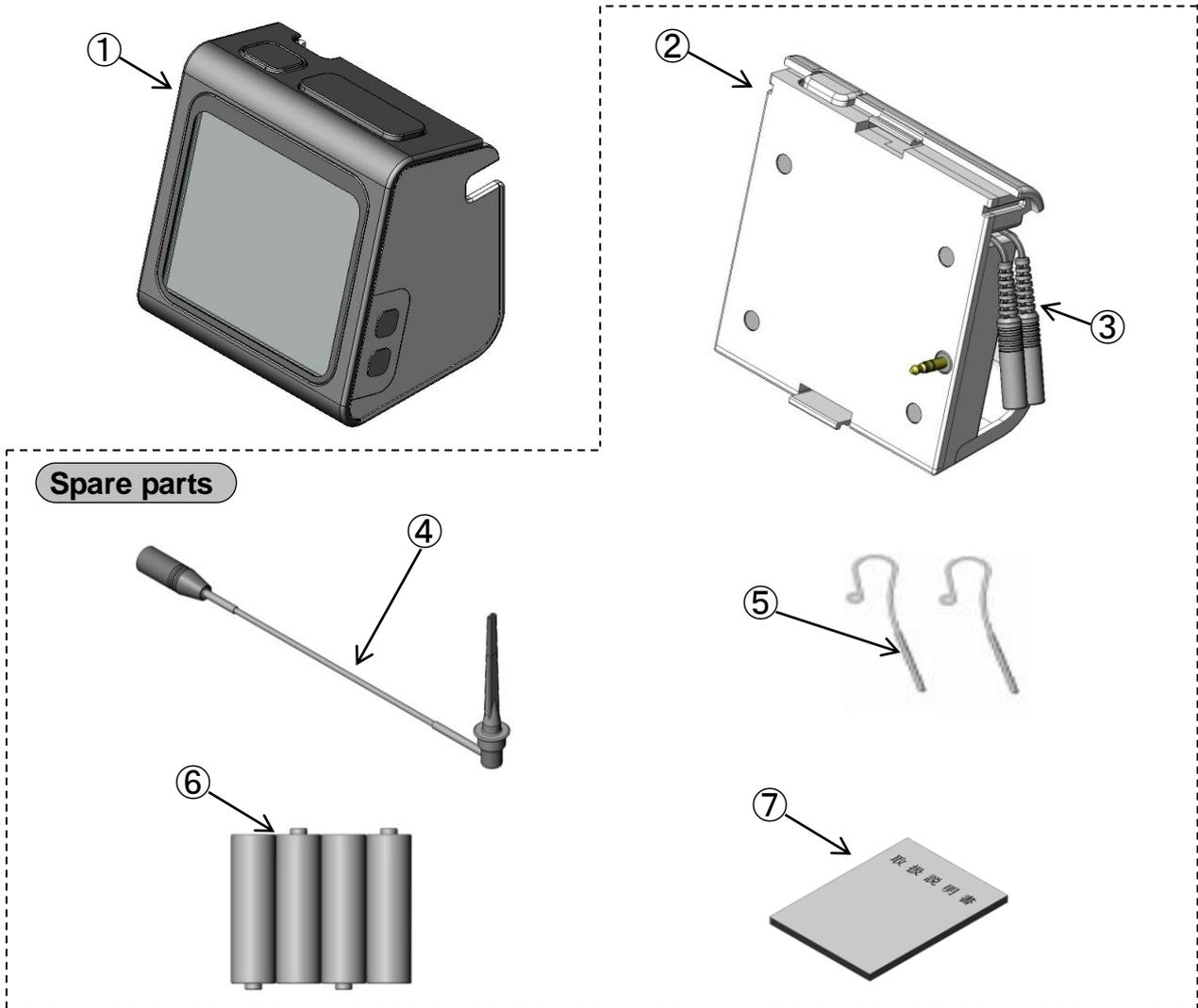
					
ON/OFF (Push-Push)	ADJ. Switch	Start-up Position of Intermittent Buzzer Sound	Volume of Buzzer Sound	Set Icon	Auto- Winding
					
Auto Adjustment Icon	Manual Adjustment Icon	Zero Adjustment Icon	Working Length Icon	Apical Foramen Icon	Battery Level Icon
					
Warning/Caution Consult accompany- ing documents	Warning/Caution Consult accompany- ing documents	Type“BF” Applied Part	Dry Battery Indication	CE Marking	Authorised Representative in the European Community
					
Manufacturer	Date of Manu- facture	Serial Number	Not to be Disposed of as Household Waste	Temperature Limitation	Humidity Limitation
					
Atmospheric pressure Limitation	Fragile , handle with care	Keep dry			

4 SPECIFICATIONS

ITEM	SPECIFICATION	REMARKS
1. Product	Osada Apit 11	
2. Model (Model Number)	EM-S11	
3. Classification according to the type of protection against electric shock	Internally powered equipment	EN60601-1
4. Classification according to the degree of protection against electric shock	Type BF applied part Applied part : File Holder Cord, Lip Clip	EN60601-1
5. Classification according to the degree of protection against water permeability	IPX0	
6. Operating Mode	-Continuous operation -The device meant to be used as transient (the continuous duration is limited to less than 60 min.)	
7. Precautions against flammable atmospheres	This device is not suitable to be used in the air/flammable anesthetic gas, oxygen, nitrous oxide, or flammable anesthetic gas.	
8. Power Source①	Power Voltage	DC 6 V
	Applicable Battery	4 pcs. of AA-size alkaline dry batteries
	Power Input	15mA
9. Power Source②	Power Voltage	DC 4.8 V
	Applicable Battery	4 pcs. of AA-size rechargeable nickel hydride batteries
	Power Input	20mA
10. Body Dimensions	100 (W)mm x 79 (D)mm x 101 (H)mm	
11. Body Weight	420 grams (excluding batteries)	
12. Environmental Conditions (IN USE)	Ambient Temperature... 10 ~ 40°C Relative Humidity..... 30 ~ 75% Atmospheric Pressure...700 ~ 1,060hPa Less than 2,000m altitude	
13. Software Version	Ver 1.00	
14. User (Dentist)	-The dentist who has normal vision and normal audibility (the dentist who has the slight impairment in vision or audibility or the vision corrected to more than log MAR0.2 (6/10 or 20/32) or audibility corrected to be able to hear 30dB is accepted.). -No particular education or training required for operating the device. -Should read and understand English and the Arabic figures.	

5 NAME OF THE PARTS

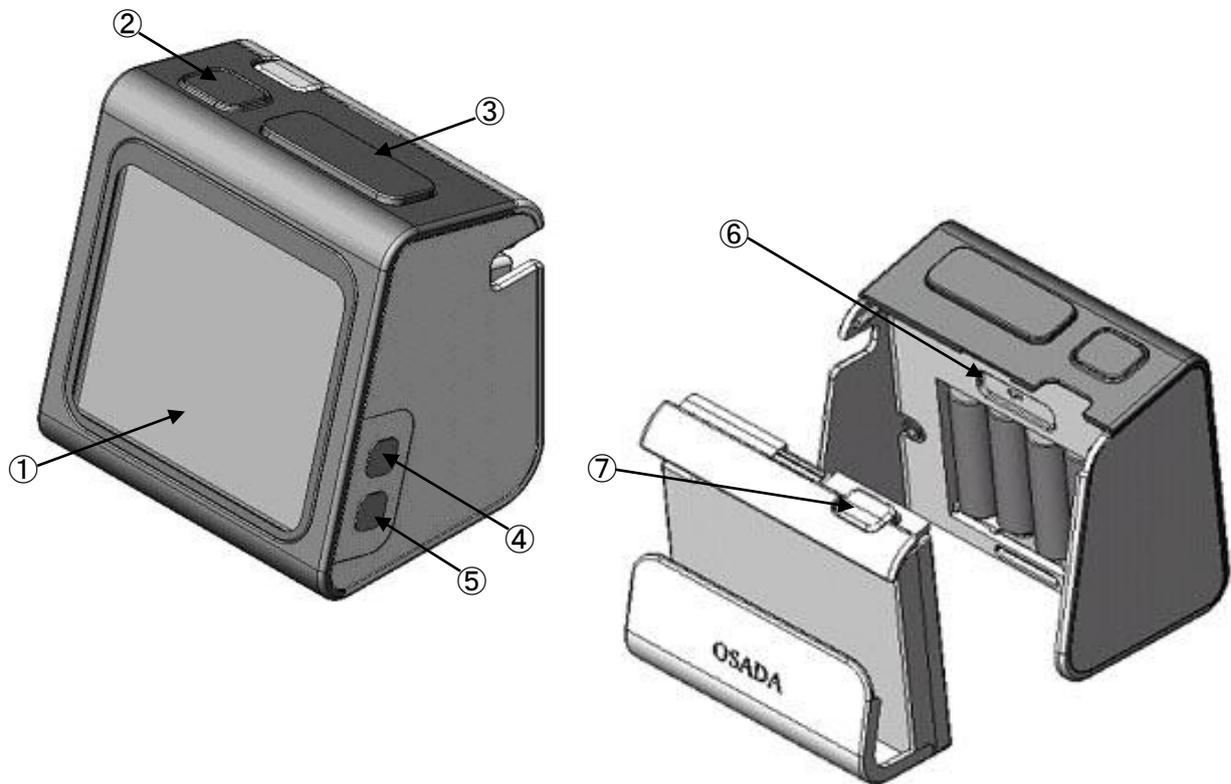
NAME OF STANDARD COMPONENTS



NO.	NAME	QTY.	REMAKRKS
①	Osada Apit 11 Body	1	
②	Probe Cord Auto-Winding Module	1	
③	Probe Cord (inside the module)	1	Expendable item
④	File Holder Cord	1	Expendable item
⑤	Lip Clip	2	Expendable item
⑥	AA-size Dry Battery	4	
⑦	Instruction for Use	1	

5 NAME OF THE PARTS

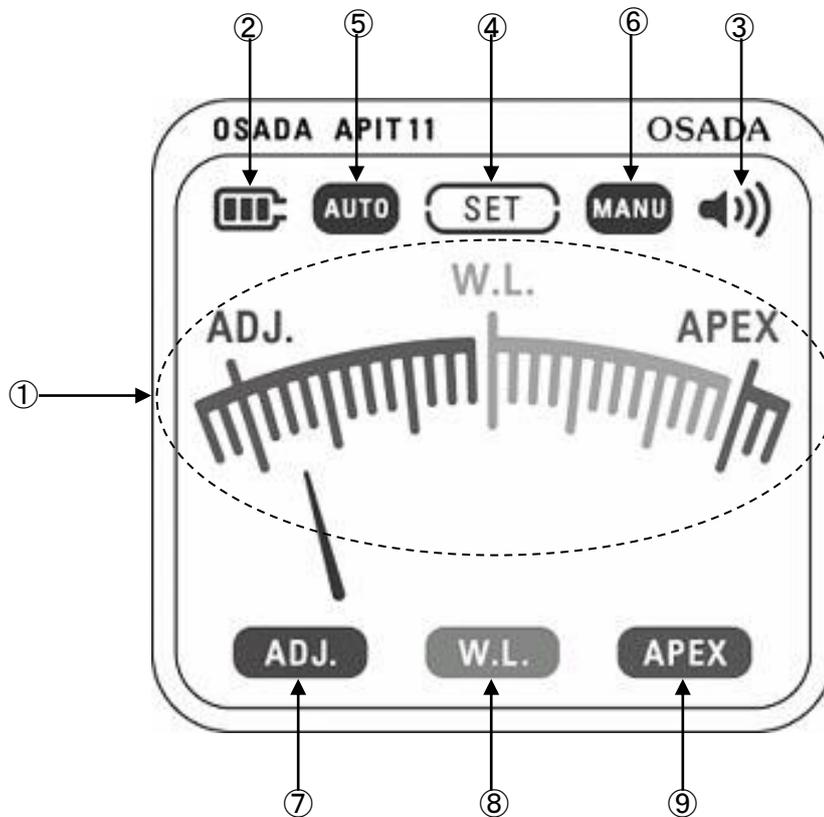
NAME OF OSADA APIT 11 BODY AND FUNCTIONS

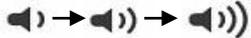


NO.	NAME	FUNCTIONS
①	Digital Display	Displays performance on screen. For details refer to Page 11.
②	Power Switch	On-Off switch of the power.
③	ADJ.(adjustment) Switch	When the K-file (or reamer) is inserted into the root canal and the ADJ. switch is depressed, the meter needle on the display panel falls on "ADJ." it means, zero adjustment was made.
④	Buzzer Switch	Adjusts the volume of the buzzer sound.
⑤	Set Switch	Changes the start-up position of the intermittent buzzer sound. For details refer to Page 14.
⑥	Checker Switch	Checks functions of the body. For details refer to Page 23.
⑦	Probe Auto-Winding Button	Is used for winding the probe cord. For details refer to Page 22.

5 NAME OF THE PARTS

NAME OF OSADA APIT 11 DIGITAL DISPLAY AND FUNCTIONS

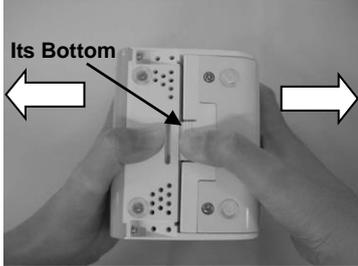


NO.	NAME	FUNCTIONS
①	Display Meter	Can view the changes of the distance to the apical foramen with the movement of the meter needle.
②	Battery Level Icon	Shows the remaining battery power in 3 levels. 
③	Buzzer Sound Icon	Shows the volume of the buzzer sound in 3 levels. 
④	Set Mode Icon	Shown when start-up position of the intermittent buzzer sound is set by the set switch being depressed.
⑤	Auto-Adjustment Mode Icon	Shown when the auto-adjustment mode is selected.
⑥	Manual-Adjustment Mode Icon	Shown when the manual-adjustment mode is selected.
⑦	ADJ. (adjustment) Icon	Shown when zero adjustment is made.
⑧	W.L. (working length) Icon	Shown when the tip of the K-file or reamer reaches the working length (W.L.).
⑨	APEX (apical foramen) Icon	Shown when the tip of the K-file or reamer reaches the apical foramen (APEX).

6 OPERATIONS

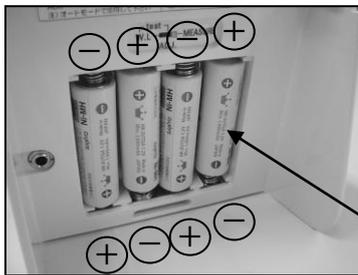
6.1 ATTACHMENT OF PARTS

1. Detach the Auto-Winding Module.



Detach the auto-winding module from Osada Apit 11 body by pressing its bottom.

2. Loading Dry Batteries.

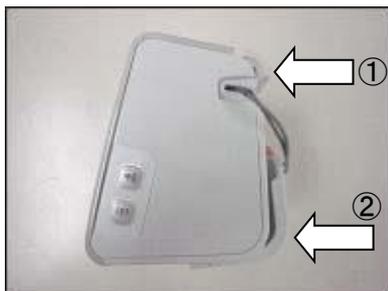


Load dry batteries to the Osada Apit 11 body, in accordance with the (+) and (-) polarity indications on the dry battery. The spring side in the battery case of the body is (-) polarity side.

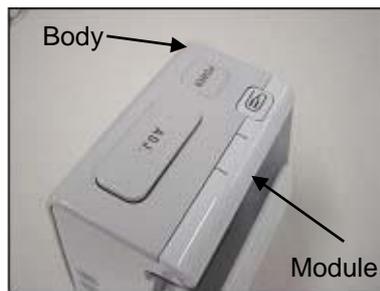
WARNING	Do not use with (+) and (-) polarity indications on the dry batteries reversed. The device can be damaged. There is also danger of the batteries heating up, the liquid leaking and/or the batteries exploding, due to the abnormal reaction by charging batteries.”
CAUTION	<ol style="list-style-type: none"> 1) Do not use batteries which mix new batteries with used batteries or mix up different types of batteries. There is danger of the batteries heating up, the liquid leaking and/or the batteries exploding, due to the difference in characteristics. 2) Take out used-up batteries immediately from the device. If the used-up batteries are left in the device for a long time, there is danger of the batteries heating up, liquid leaking out, the batteries exploding and/or damage the device due to the gas generated by its high electric discharge from battery. 3) For using a device, read carefully the cautions for the charger of the rechargeable nickel hydride battery (AA-size) and also for how to charge the battery.

3. Attaching Auto-Winding Module.

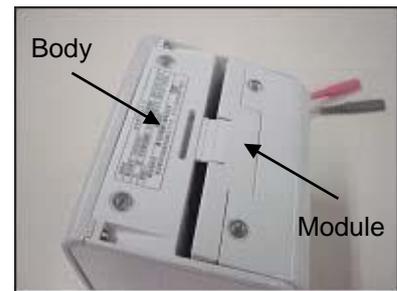
First, insert the upper part ① of the auto-winding module into Osada Apit 11 body and set in toward the arrow-indication by pushing the lower part ② of the auto-winding module.



Side View



Top-Down View



Reverse View

6. 2 CHECKUP**1. Checking Before Use (Please do it before use)**

1) Confirm the connection.

Confirm if the auto-winding module, file holder cord and lip clip are properly connected.

2) Confirm the actuation.

Confirm if the power switch can be turned on and off.

Confirm if the remaining battery power shows more than 1 levels.

2. Checking After Every Use

1) Confirm the connection.

Confirm if the auto-winding module, file holder cord and lip clip are properly connected.

2) Confirm the actuation.

Confirm if the power switch can be turned on and off.

Confirm if the remaining battery power shows more than 1 levels.

3. Checking Occasionally

1) Confirm by the checker.

Confirm the actuation by using the checker incorporated in the Osada Apit 11 body.

For details of how to use refer to Page 23.

2) Confirm the actuation.

① Confirm if the metal clip of the file holder cord is not corroded or dirtied.

② Confirm if the meter needle swings out when lip clip and the metallic clipping end of the file holder cord is in contact.

4. Checking Before Use After Long Storage

1) Confirm standard components.

Provide Osada Apit 11 body, auto-winding module, file holder cord and lip clip.

2) Confirm the connection.

Confirm if the auto-winding module, file holder cord and lip clip are properly connected.

3) Confirm the actuation.

Confirm if the power switch can be turned on and off.

Confirm if the remaining battery power shows more than 1 levels.

4) Confirm by the checker.

Confirm the actuation by using the checker incorporated in the Osada Apit 11 body.

For details of how to use refer to Page 23.

5. Checking Periodically.

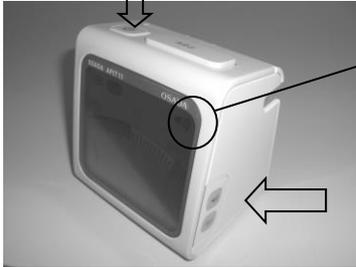
It is recommended to check the device periodically in order to maintain the device in the normal condition. Regarding items and contents of the checkup, please contact the authorized Osada distributor you purchased or directly Osada Electric Co., Ltd.

6 OPERATIONS

6.3 HOW TO SET UP

1. How to adjust the Buzzer Sound.

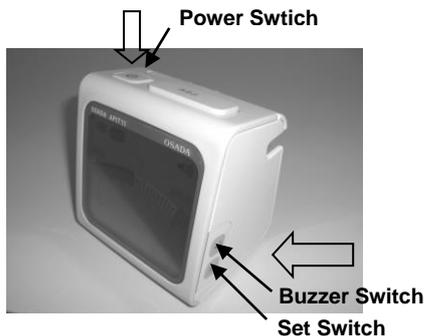
(At the time of factory-delivery, the buzzer sound is preset to the maximum.)



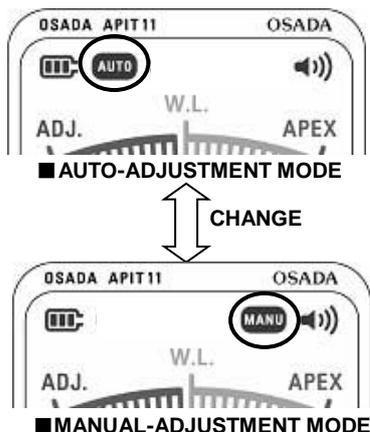
- 1) Switch ON the power switch on the upper part of Osada Apit 11 body by pressing it
- 2) Depress the buzzer switch on the side of Osada Apit 11 body and adjust the buzzer volume as you want.
- 3) The buzzer volume can be adjusted in three (3) levels as above by pressing the buzzer switch repeatedly.

2. How to change the Adjustment Mode from Auto Adjustment Mode to Manual Adjustment Mode.

(In the factory default, the adjustment mode is preset in the auto adjustment mode.)



- 1) First, turn off the power switch, and then depress the power switch again while depressing the buzzer switch and set switch on the side of Osada Apit 11 body at the same time.



- 2) By doing so, the adjustment modes can be changed over from the auto adjustment mode to the manual adjustment mode and vice versa.

At the time of factory delivery, Osada Apit 11 is preset in the auto-adjustment mode, therefore, by doing the above, the adjustment mode can be changed to the manual adjustment mode.

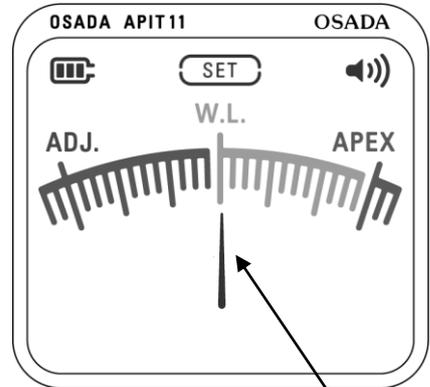
6 OPERATIONS

6.3 HOW TO SET UP

3. How to change the Start-up Position of the Buzzer Sound (intermittent).

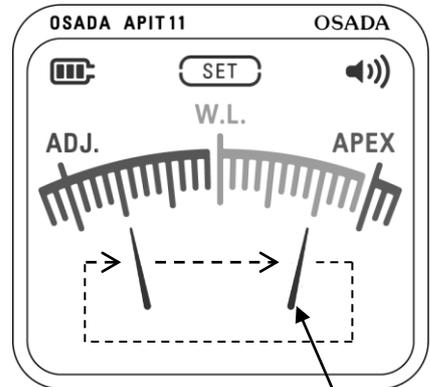
(At the time of factory delivery, the starting position is preset to the working length (W.L.).)

- 1) Depress the set switch once on the side of Osada Apit 11 body. The set mode icon, **SET**, is indicated on the display panel, at the same time, the meter needle blinks.



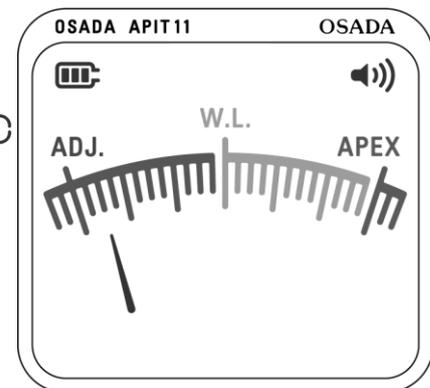
Meter Needle

- 2) When the set mode icon, **SET**, is indicated and the meter needle is blinking, by depressing the set switch again, the meter needle makes one scale move to the right by one time depressed within the range shown in the right figure and the start-up position of the buzzer sound can be changed. When keep depressing, the meter needle moves faster.



Meter Needle

- 3) After the start-up position of the buzzer sound (intermittent) is set, release the set switch on the side of Osada Apit 11. body start-up position is inputted and the set mode icon, **SET**, will disappear from the display panel after three seconds.



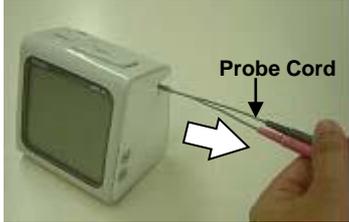
WARNING	Do not measure when the set mode icon, SET , is indicated on the display panel. Always use after the set mode icon, SET , disappears from the display panel.
CAUTION	The volume of the buzzer sound, changeover of the auto/manual adjustment modes and start-up position of the buzzer sound are memorized even if the power switch is turned off.

6 OPERATIONS

6.4 PREPARATION BEFORE USE

1. How to pull out the Probe Cord from the Auto-Winding Module.

- 1) Pull out the probe cord in the horizontal direction.



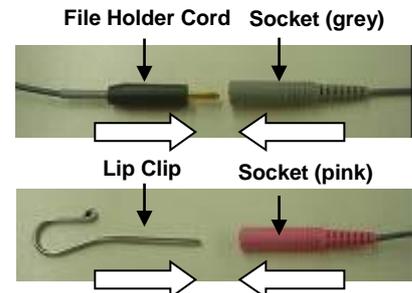
Probe Winding Button



- 2) If the probe cord is pulled out too long, retract it a little by depressing the probe winding button.

2. How to attach the File Holder Cord and Lip Clip.

- 1) Insert the plug of the file holder cord into the socket (grey) of the probe cord.
- 2) Insert the lip clip into the socket (pink) of the probe cord.



CAUTION

- 1) Do not use the file holder cord and lip clip made by other manufacturer. If those items made by other company are used, it is possible that sufficient accuracy of measurement can not be gained.
- 2) Insert the plug of the file holder cord and lip clip fully into the socket.
- 3) To prevent infections, sterilize the lip clip and file holder cord by steam-autoclave before use.

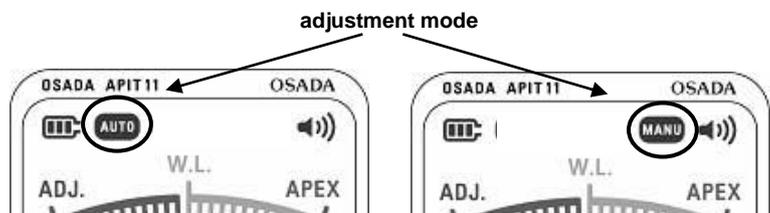
3. Turning on the Power and Confirming the Setup.

- 1) Turn on the power by depressing the power switch on top of Osada Apit 11 body.

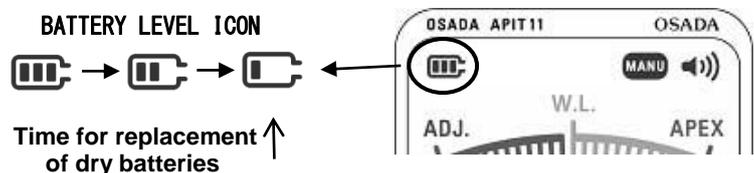
Power Switch



- 2) Confirm the adjustment mode.
(When changing the adjustment mode, refer to 6.3 2. "How to change the Adjustment Mode from Auto Adjustment mode to Manual Adjustment Mode" of Page 14.)



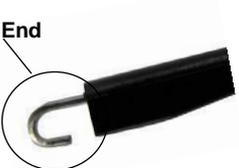
- 3) Confirm the battery level icon (the remaining battery power).



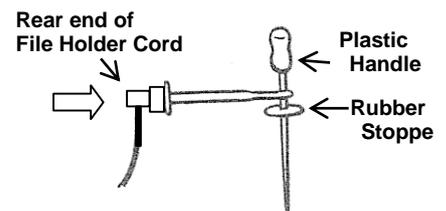
6 OPERATIONS

6.4 PREPARATION BEFORE USE

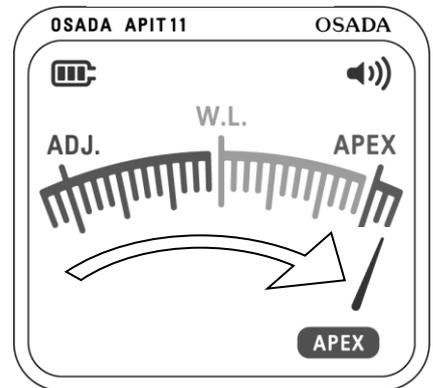
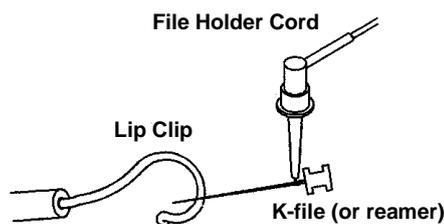
4. Confirm the Faulty Connections and Cord Disconnection.

CAUTION	<p>1) In order to assure stable measurements, wipe the metallic clipping end of the file holder cord with cotton dipped in ethanol before measurements.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Metallic Clipping End</p> </div> <div style="text-align: center;">  <p>File Holder</p> </div> </div> <p>2) In order to prevent the faulty connection, confirm the metallic clipping end of the file holder cord in which the K-file (or reamer) is clipped for corrosion or accumulation of dirt.</p> <p>3) In order to prevent electrical leakage, do not use the K-file (or reamer) with the metallic handle.</p>
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- 1) Attach the K-file (or reamer) to the metallic clipping end of the file holder cord.



- 2) Contact the lip clip with the metallic part of the K-file (or reamer) and confirm that the meter needle on the display panel swings into the right side beyond the APEX position.



CAUTION	<p>In case of the auto-adjustment mode, the zero adjustment may take place automatically when contacting the lip clip with the metallic part of the K-file (or reamer). In this case, confirm that the meter needle indicates the end of the left side and the adjustment icon, ADJ., disappears when the lip clip and the metallic part of the K-file (or reamer) is released.</p>
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6 OPERATIONS

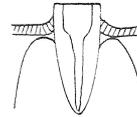
6.5 HOW TO USE

Measurement by Auto-Adjustment Mode

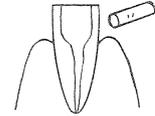
1. Moisturizing the Root Canal.

- 1) The tooth which is being measured should not be wet. Use a rubber dam or cotton rolls for prevention from moisture.
- 2) Fill the root canal with a medicinal solution.
(Uniform the condition inside the root canal.)

Rubber Dam

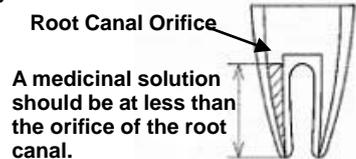
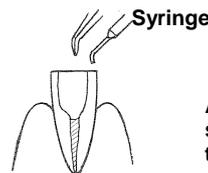


Cotton Roll



- Fill the solution up to the orifice of the root canal with pincers or a syringe. In this case, medicinal solution should not overflow.

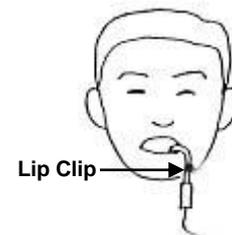
Pincers



- In general, the normal saline solution is used as medicinal solution. The medicinal solution of good conductivity such as sodium hypochlorite, EDTA, etc. can be used as well. In case of treating a residual root, the medicinal solution tends to overflow and may leak from the margin around tooth structure, as the result, the zero adjustment becomes unstable. In this case, dry and clean the medicinal solution with paper points and change the solution to normal saline solution if it was not so.

WARNING	Always use a rubber dam for patient not to swallow the K-file (or reamer) or lip clip by mistake.
CAUTION	As hydrogen peroxide (H ₂ O ₂) is not the medicinal solution of good conductivity, the measurement will show unstable state.

- 3) Hang the lip clip on the patient's lip.



2. Inserting the K-file (or Reamer) into the Root Canal.

- 1) Insert the tip of the K-file (or reamer) into the root canal which is filled with the medicinal solution.
- 2) After inserting the K-file into about till the middle of the root canal, clip it with the metallic clipping end of the file holder cord.

The zero adjustment takes place automatically, at the same time, the adjustment icon, **ADJ.**, appears on the display panel. It means that the condition inside the root canal has been inputted.

While the zero adjustment is in work, it can be cancelled in three (3) seconds after detaching K-file from the metallic clipping end of the file holder cord or extracting the K-file from the root canal, as it means the electric circuit is blocked off.

CAUTION	During use, do not depress the probe winding button. There is a danger that the tip of the probe cord may hit the body.
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6 OPERATIONS

6.5 HOW TO USE

Measurement of Auto-Adjustment Mode

3. When the Zero Adjustment does not take place automatically.

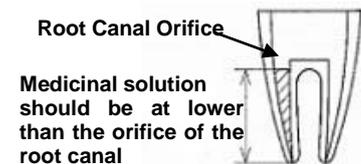
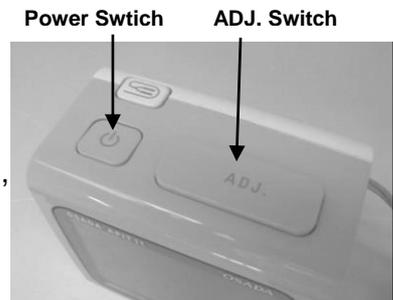
When the zero adjustment does not take place automatically, even if the meter needle swings widely, make the following 1) and 2) steps:

- 1) If there are any uncertain electric leakages, there is a chance to be able to measure the root canal by depressing the ADJ. switch. If the zero adjustment can take place by depressing the ADJ. switch, at the same time, the adjustment icon, **ADJ.**, is indicated on the display panel, it means that the condition inside the root canal has been inputted.

When canceling the zero adjustment, wait for three (3) seconds or blocking the electric circuit, or switch off the power.

When turning on the power switch again, the zero adjustment is cancelled and ready for the next measurement.

- 2) There are cases that the medicinal solution overflows from the orifice of the root canal and leaks to the gingival. In this case, measure again after wiping it with cotton rolls, etc. When the medicinal solution overflows, accurate measurement is not possible.



CAUTION

When gutta percha, etc remains in the root canal, the meter needle does not swing and the accurate measurement is not possible.

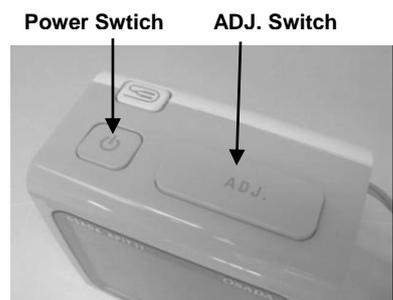
Measurements of Manual-Adjustment Mode

4. Moisturizing the Root Canal.

Refer to 6.5 1. Moisturizing the Root Canal of Page 18.

5. Inserting the K-file (or Reamer) into the Root Canal.

- 1) Insert the tip of the K-file (or reamer) into the root canal which is filled with the medicinal solution.
- 2) After inserting the K-file till about the middle of the root canal, clip it with the metallic clipping end of the file holder cord and depress the ADJ. switch, at the same time, the adjustment icon, **ADJ.**, appears on the display panel. It means that the condition inside the root canal has been inputted. In case the zero adjustment is to be canceled, turn off the power switch once. When the power switch is turned on again, it works again in the condition of the manual adjustment being canceled.



CAUTION

During use, do not depress the probe winding button. There is a danger that the tip of the probe cord may hit the body.

6 OPERATIONS

6.5 HOW TO USE

6. Measuring the Working Length.

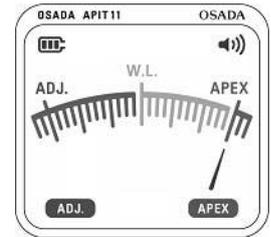
- 1) When inserting the K-file (or reamer) into the root canal, the meter needle on the display panel swings to the right and reaches the working length (W.L.) position, and, at the same time, the buzzer sound (intermittent) starts. This position is to be noted as the working length.

The position indicated as W.L. on the display panel should be considered as a criterion for the working length. The actual working length differs depending on the root canal conditions. W.L shown on the panel should be the point about 0.7mm less distance to reach the apical foramen.

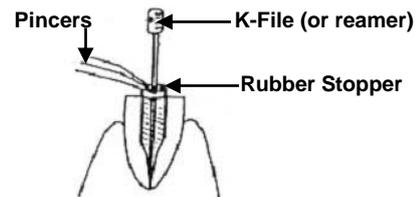


WARNING	<ol style="list-style-type: none"> 1) If the abnormality is felt on the position which the meter needle shows, confirm the position of the K-file (or reamer) by the x-ray. 2) The buzzer sound tells when the K-file (or reamer) reaches the working length (W.L.). However, not only relying on the buzzer sound, always confirm the indication of the meter needle on the display panel also.
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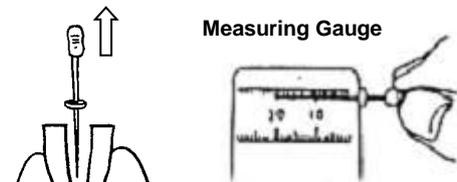
CAUTION	<p>When the K-file (or reamer) is moved farther into the root canal, the meter needle on the display panel reaches the APEX, at the same time, the buzzer sound becomes a steady continuous sound. When determining the working length from this position, it should be about 0.7mm shorter. Watch discreetly the meter needle on the display panel, as it has very high sensitivity in the vicinity of the apical foramen (APEX). (Refer to the drawing on the needle position, though it depends on cases.)</p>
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- 3) Mark the working length on the K-file (or reamer)
Move the rubber stopper down to the working length by using pincers.



- 4) Pull the K-file (or reamer) out of the root canal and measure the distance to the position of the rubber stopper with measuring gauge.



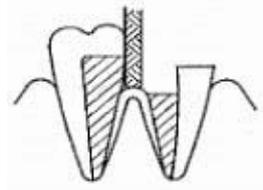
- 5) Please determine the working length in view of your procedure.

6 OPERATIONS

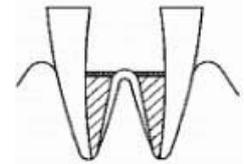
6. 6 METHODS FOR MEASUREMENT IN DIFFERENT TREATMENTS AND THE PROCEDURES

1. Measuring the Working Length when Dental Pulp remains in the Radicular Pulp.

1) Remove the roof of the pulp chamber and the prepare a sufficient flare.

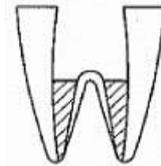


2) Wipe away excess blood and prevent overflow from the root canal orifice. If the blood overflows from the pulp chamber, the meter needle swings out and the accurate measurement is not possible.



2. Measuring the Working Length of the Tooth with an Infected Root Canal.

1) Remove any remaining filling materials such as gutta percha from the root canal with a multi-purpose ultrasonic device.



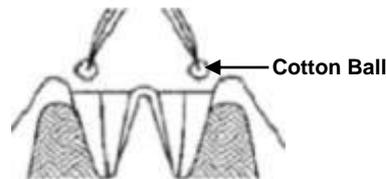
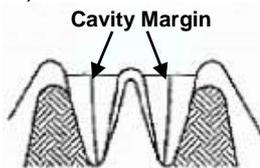
2) After irrigating the root canal thoroughly, measure the root canal.

If filling materials remain in the root canal, the meter may not move and the accurate measurement is not possible.



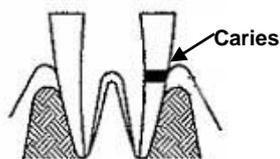
3. Measuring the Working Length of the Tooth with a Residual Root Condition.

Wipe the cavity margin (between the root canal interior and the gingival) with cotton balls to insulate the tooth and prevent leakage of electricity and then, measure the root canal. If the cavity margin is wet, the meter needle swings out and the accurate measurement is not possible.

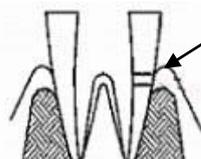


When measuring the working length of the tooth with cervical caries or metallic restorations, the electricity will leak through the periodontal membrane. Therefore, the proper measurement may not be possible. In this case, first, move cervical caries or metallic restorations, then temporarily seal with resin, stopping, etc. or insulating type of materials; which should make the measurement possible.

CAUTION



1) When there are caries or restorations in the cervical region.



2) Remove caries or restorations.



3) Temporarily seal with an insulating type of materials.

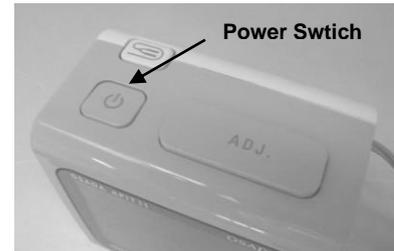
4) Measure the root canal.

6 OPERATIONS

6.7 PROCEDURES AFTER USE

1. Turning off the Power.

Confirm that the display panel disappears when the power switch is depressed.

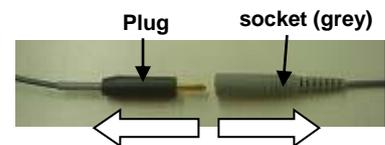


CAUTION

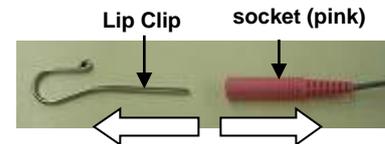
The device is kept operating if the power is not turned off. By the auto off function, the device will be turned off automatically after five (5) minutes since its final operation, but it is important to switch off the power in order to reduce power consumption.

2. How to attach the File Holder Cord and Lip Clip.

1) Pull out the plug of the file holder cord from the socket (grey) of the probe cord.



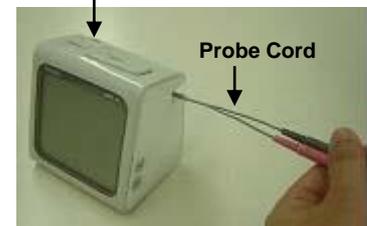
2) Pull out the lip clip from the socket (pink) of the probe cord.



3. How to store the Probe Cord to the Auto-Winding Module.

1) Store the probe cord to the auto-winding module by depressing the probe winding button. The probe cord is stored to the auto-winding module automatically.

Probe Winding Button



CAUTION

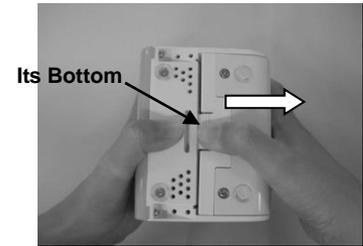
Always hold the probe cord with your fingers when storing it by depressing the probe winding button. When storing the probe cord without holding it, there is a danger that the tip of the probe cord may hit the body.

6 OPERATIONS

6.8 HOW TO USE CHECKER SWITCH

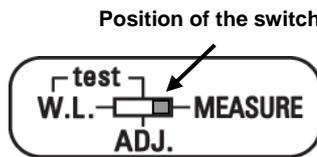
1. How to detach the Auto-Winding Module.

Detach the auto-winding module from Osada Apit 11 body by pressing its bottom.

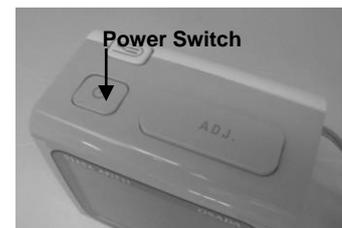


2. How to use the Checker Switch.

1) Confirm the checker switch behind the Osada Apit 11 body is on the "MEASURE" position.



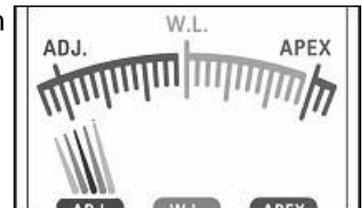
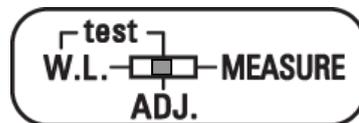
2) Turn on the power by depressing the power switch.



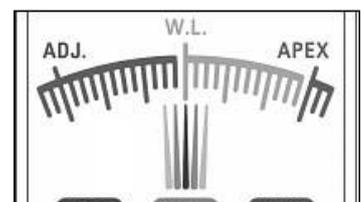
CAUTION

The checker functions with the auto-adjustment mode and the manual adjustment mode.

3) Slide the checker switch to the ADJ. position. Press the ADJ. switch set on the body and confirm if the meter needle on the display panel is pointing within ± 2 scale range from the ADJ. position, as shown in the right figure.



4) Next, move the checker switch to the W.L. position and confirm the meter needle on the display panel if it points within ± 2 scale range from the W.L. position on the display panel, as shown in the right figure.



CAUTION

Do not skip 3) above, always take both steps of 3) and 4) consecutively. If you go to the step 4) directly, the checker does not function properly.

7.1 CLEANING AND DISINFECTION

- 1) Items which can be cleaned with neutral detergent are to be referred to the list of "CLEANING" on Page 25.
Wipe off the dirt with moistened gauze with neutral detergent and then, wipe with dry gauze.



Osada Apit 11 Body

Auto-Winding Module
(the probe cord is built-in)

File Holder Cord



Lip Clip

CAUTION

- 1) Do not scrub the surface of the above items with hard materials.
- 2) The above items cannot be immersed in liquid. To be wiped off only.

- 2) Items which can be disinfected are to be referred to the list of "DISINFECTION" on Page 25.
Every time after use, wipe off the foreign particles such as body fluids, tissues, etc. with moistened gauze with dehydrated alcohol or alcohol for disinfection (70 to 90%) .



File Holder Cord



Lip Clip

CAUTION

- Medicinal solutions mentioned below cannot be used for wiping.
- 1) Halogen compound (especially, sodium hypochlorite)
Do not use as it causes metal corrosion.
 - 2) Aldehydes or phenols.
Do not use as it causes plastic discoloring or cracks.
 - 3) Aqualeate or highly acidic water
Do not use as it causes metal corrosion, etc.

7 CLEANING, DISINFECTION AND STERILIZATION

7.2 STERILIZATION

Steam Autoclave

Items which can be steam-autoclaved are to be referred to the list of “**STERILIZATION**” on Page 25.



File Holder Cord



Lip Clip

TEMPERATURE	DURATION
121°C	20 min. and more
132°C	5 min. and more
135°C	3 min. and more

Regarding the possibility to re-sterilize the lip clip and file holder cord, they can be steam-autoclaved up to two hundred fifty (250) times.

CAUTION

Always put in a sterilization bag when Steam Autoclave is given. Do not utilize the drying process

7.3 METHOD FOR CLEANING, DISINFECTION AND STERILIZATION (REFERENCE CHART)

ITEM \ METHOD	CLEANING	DISINFECTION	STERILIZATION
	WIPING WITH NEUTRAL DETERGENT OR WATER	WIPING WITH ETHANOL	STEAM AUTOCLAVE
Osada Apit 11 Body	O	X	X
Auto-Winding Module	O	X	X
Probe Cord*	O	O	X
File Holder Cord	O	O	O
Lip Clip	O	O	O

8 EXPENDABLE ITEMS

8.1 LIST FOR EXPENDABLE ITEMS

ITEM	TO BE EXCHANGED BY			HOW TO CHANGE	REMARK (P/NO.)
	USER	DISTRIBUTOR	OSADA FACTORY		
Probe Cord	-	-	O	-	53321
File Holder Cord	O	O	-	Refer to Page 22.	53322
Lip Clip	O	O	-	Refer to Page 22.	53323

*The probe cord is built in the auto-winding module.

9 WARRANTY PERIOD EXCEPT EXPENDABLE PARTS

9.1 WARRANTY

*Usable life of Osada Apit 11 is seven (7) years.

*Expendable items are excluded. Refer to "8 EXPENDABLE ITEMS"

WARRANTY	PRODUCT	EXCLUDED ITEMS
One(1) year	Osada Apit 11 Body	Expendable items (but the cases of coloration, discoloration of the items by contact or contamination with chemicals, etc.)

■Exceptional rules of repairs without charge

The repairs will be charged according to the following conditions even if the period is within the warranty period.

- 1) The damages and troubles caused by the installation, shifting and repairs done by people who are not specified by us.
- 2) The damages and troubles caused by the other manufacturers' products or parts which were not provided by us.
- 3) The damages and troubles caused by the repair parts which are not our genuine parts or not specified by us.
- 4) The damages and troubles caused by the negligence of the cautions or proper operations which are explained in the instruction for use.
- 5) The damages and troubles caused by the improper conditions of usage without following indications in the instruction for use including the condition of electricity source and installation environment.
- 6) The damages and troubles caused by the natural calamity such as fire, earthquake, flood, lightning, etc.
- 7) The expendable items for replacement or replenishment.

10 HIGH-PRESSURE STEAM STERILIZATION

1. Possible Range of High-Pressure Steam Sterilizer

The file holder cord and lip clip can be steam autoclaved within the range of temperature not beyond 135°C, but do not make a drying cycle.

2. Quality Deterioration by High-Pressure Steam Sterilizer

By steam autoclave sterilization (heat, pressure, steam , etc.), rust, corrosion , quality change and discoloration of components will occur on the file holder cord and lip clip. This leads to deterioration in performance and function gradually.

3. Prevention of Rapid Deterioration from High-pressure Steam Sterilizer

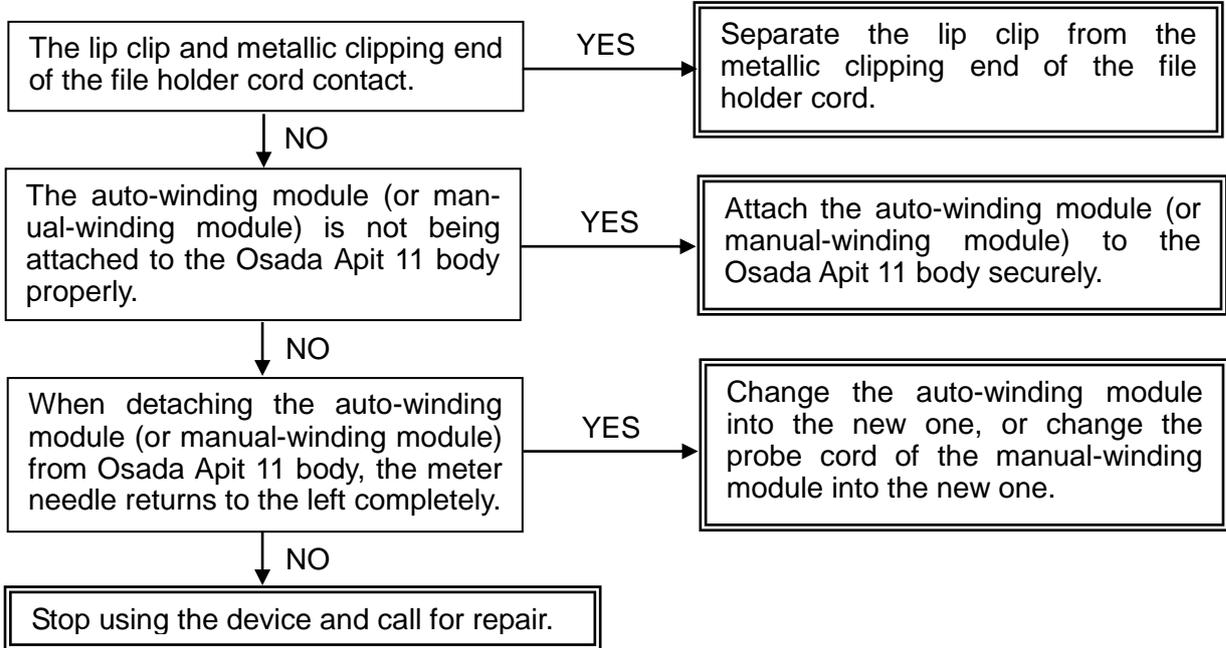
- 1) Observe the cautions written in the instruction for use strictly.
- 2) Do not use the autoclave equipment whose container gets higher temperature or has possibility to get higher temperature than specified temperature(temperature in the chamber).
- 3) When giving steam autoclave sterilization, keep instruments in the sterilization bag. It prevents the transfer of the rust to instruments from the equipment.
- 4) Use distilled water or purified water for steam autoclave sterilization.
Depending on the area, water contains different quantity of chlorine, iron, and other variable impurities. Those impurities may give bad influences.
- 5) Clean instruments more perfectly before steam autoclave sterilization.
If medical solution or blood is adhered to instruments, it forms rust, brings discoloring or is hardened in the course of sterilization. It brings the deterioration and less work efficiency.
- 6) Water becomes dirty by steam autoclave sterilization. Change water more often than once a week. (Refer to the instruction for use for each high-pressure steam sterilizer)

11 REFERENCE

11.1 GUIDE FOR REPAIRS

The meter needle on the display panel swings so soon as the power is turned on.

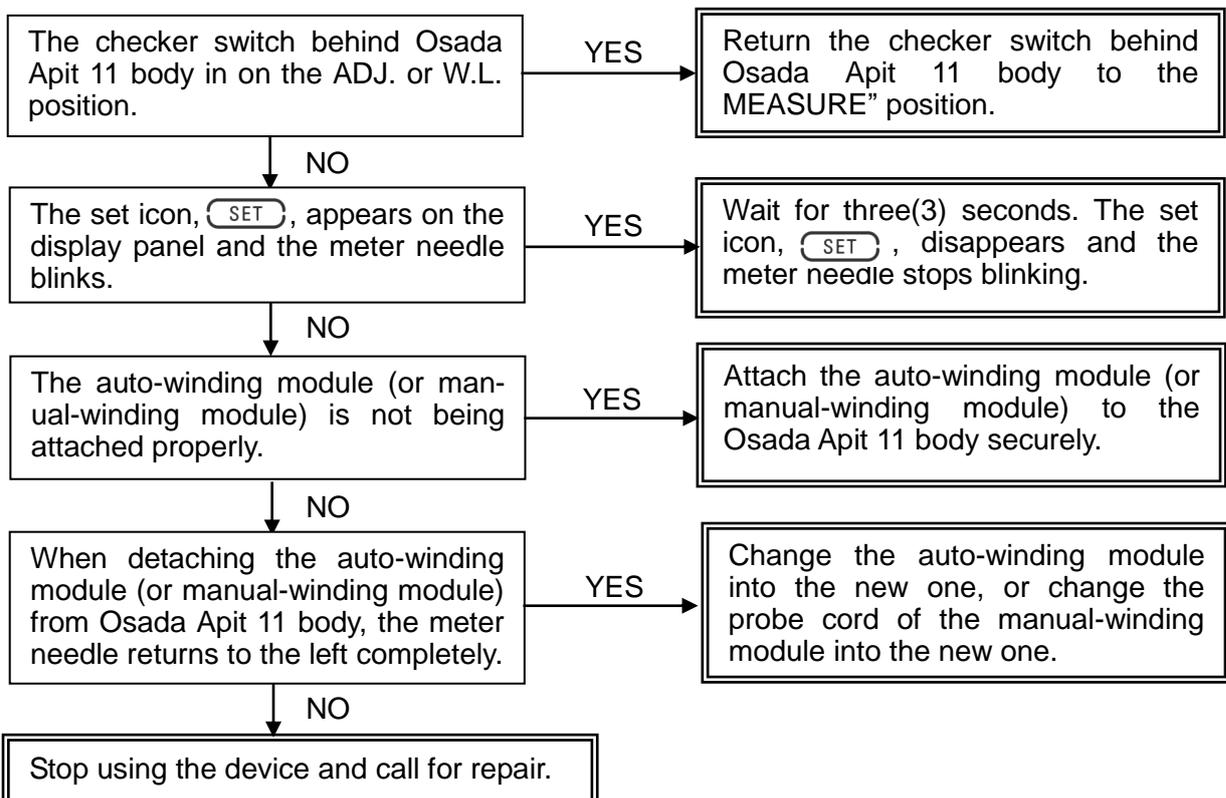
1) The meter needle on the display panel swings out.



CAUTION

The probe cord of the manual-winding module can be changed by you, while the probe cord of the auto-winding module cannot be changed by you.

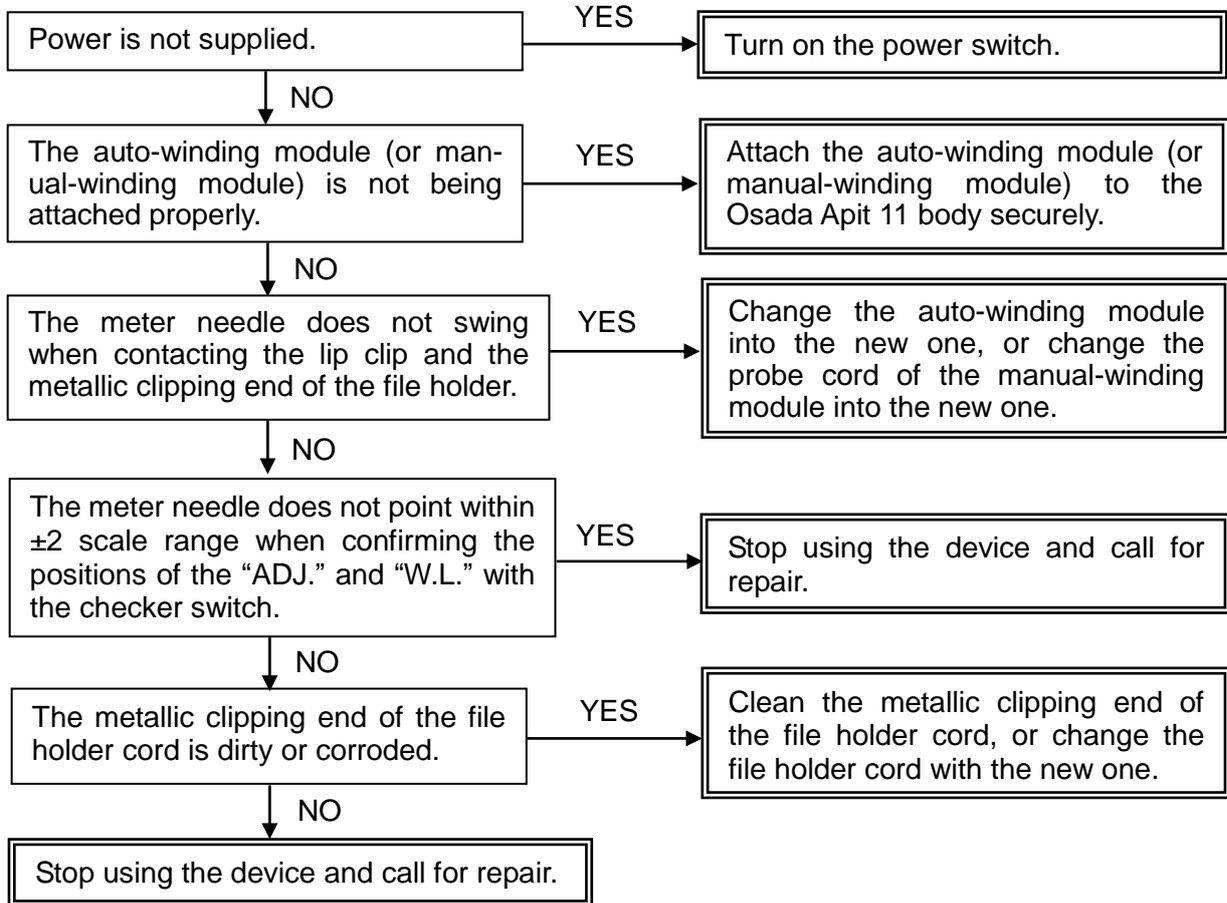
2) The meter needle on the display panel stops in the middle and does not move at all.



11 REFERENCE

11.1 GUIDE FOR REPAIRS

3) The meter needle on the display panel does not swing or swings less.



11 REFERENCE

11. 2 DISPOSAL AND RECYCLING

This symbol  means that this product should not be disposed off or treated as household waste but must be processed according to Directive 2002/96/CE.

Please comply with the regulations which apply to your country as well.

11. 3 GUIDANCE AND MANUFACTURER'S DECLARATION

The Osada Apit 11 complies with current Electromagnetic Compatibility standards according to EN 60601-1-2:2007. However, the user should ensure that any possible electromagnetic interference does not present an additional risk of interfering with or damaging the device or any other electronic devices in the vicinity.

<group 1, class B, for use in hospitals and doctor's office>
<not LIFE-SUPPORTING>

The product is intended for the use in the electromagnetic environment specified in the next page. The customer or the user of the product should assure that it is used in such environment.

11. 4 ELECTROMAGNETIC EMISSIONS

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Field Intensity EN 60601-1-2:2007 CISPR11:2009+A:2010	Group 1 Class B	The Osada Apit 11 uses RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic device.
Power Terminal Disturbance Voltage EN 60601-1-2:2007 CISPR11:2009+A:2010	Group 1 Class B	Refer to (1).
High-frequency Emissions EN 60601-1-2:2007 IEC61000-3-2:2005+A1:2008+A2:2009	N/A (1)	
Voltage Fluctuations/Flicker Emissions EN 60601-1-2:2007 IEC 61000-3-3:2008	N/A (1)	

(1) The above mentioned test items are not applicable for battery operated devices (without battery charging function).

11 REFERENCE

11. 5 ELECTROMAGNETIC IMMUNITY

1. Electromagnetic Immunity

IMMUNITY TEST	EN60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic Discharge (ESD) EN 60601-1-2:2007 IEC 61000-4-2:2008	±2kV, ±4kV, ±6kV Contact Discharge ±2kV, ±4kV, ±8kV Aerial Discharge	±2kV, ±4kV, ±6kV Contact Discharge ±2kV, ±4kV, ±8kV Aerial Discharge	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 Transient/Burst EN 60601-1-2:2007 IEC 61000-4-4:2004 +A1:2010	±2kV Power Port ±1kV Signal Port	N/A (2)	Refer to (2).
Surge EN 60601-1-2:2007 IEC61000-4-5:2005	±0.5kV, ±1.0kV ±2.0kV Common Mode ±0.5kV, ±1.0kV Normal Mode	N/A (2)	Refer to (2).
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines EN 60601-1-2:2007 IEC61000-4-11:2004	Dips:5%U _T /0.5 Cycle, 5%U _T /0.5 Cycle, 5%U _T /0.5 Cycle Instant Stop: 0%U _T /5 sec. U _T is for a rated voltage of the device.	N/A (2)	Refer to (2).
Power Frequency (50/60Hz) Magnetic Field EN 60601-1-2:2007 IEC61000-4-8:2009	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

(2) The above mentioned test items are not applicable for battery operated products, without battery charging function, DC power supply lines and interface cable length, of less than 3m (for input/output lines).

11 REFERENCE

11.5 ELECTROMAGNETIC IMMUNITY

2. Electromagnetic Immunity

IMMUNITY TEST	EN60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
<p>Conducted Field Intensity EN 60601-1-2:2007 IEC61000-4-6:2008</p>	<p>3Vrms 150kHz to 80MHz</p>	<p>3Vrms 150kHz to 80MHz</p>	<p>Portable and mobile RF communications device should be used no closer to any part of Osada Apit 11, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = 2.3 \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <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).</p>
<p>Radiated Radio-Frequency Field Intensity EN 60601-1-2:2007 IEC61000-4-3:2006 +A1:2007+A2:2010</p>	<p>3Vrms 80MHz to 2.5GHz</p>	<p>3Vrms 80MHz to 2.5GHz</p>	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of device marked with the following symbol:</p> 
<p>(1) At 80 MHz and 800MHz, the higher frequency range applies.</p> <p>(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 OSADA APIT 11 is used exceeds the applicable RF compliance level above, the OSADA APIT 11 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			



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