



The Ortek-ECD[®]/ Electronic Caries Detector



Instructions for Use

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1 IMPORTANT INFORMATION

1.1 Indications for Use

The Ortek-ECD®/ Electronic Caries Detector (ECD) is for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

1.2 Warnings and Precautions



Federal law (USA) restricts this device to sale by or on the order of a licensed dental practitioner.

This device should not be used on patients with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic device.

Please read these instructions for use before using the product to avoid operator error and damage.

- Conductive handpiece (tip) is sharp and can penetrate skin or oral mucosa upon contact. Use common dental care practices when using the tip. Handle with care.
- Before use, gently tug the tip to ensure the tip is securely in place in the handpiece.
- Use caution when inserting the tip into patient's mouth.
- Practice caution when using the ECD with hyperactive patients.
- Do not use a damaged tip; an accurate caries measurement cannot be made with a damaged tip.
- Do not let any components of the ECD come into contact with an electric power source such as an electrical socket. This could damage the ECD.
- The lip hook could cause an adverse reaction if the patient has an allergy to stainless steel. Ask the patient about this before using the ECD.
- Do not let the tip make contact with the gums, lips or anywhere in the oral cavity except dry occlusal tooth surfaces. Moisture on these surfaces will cause the unit to beep and display an incorrect digital reading.
- Thoroughly air-dry pit and fissure surfaces of the tooth to be examined with at least a 4-second blast of dry air from the dental air syringe. If using an air/water syringe, make sure there is no moisture in the line. Moisture in the line will cause the unit to beep and display an incorrect digital reading.
- If using on patients with fixed orthodontic appliance, do not let the tip make contact with any metal part of the appliance as it will cause a false reading and not ensure a reliable measurement.
- The ECD should not be used in the presence of flammable material including anesthetic mixtures with air or with oxygen or nitrous oxide.
- No modification of the equipment is allowed.
- Do not open the ECD unit – there are no user serviceable parts inside.

1.3 Contraindications

The ECD cannot be used to assess the following:

- Secondary caries
- The integrity of a restoration
- Dental root caries
- The depth of an excavation within a cavity preparation
- Interproximal caries

The ECD should not be used when the occlusal tooth surfaces are covered with an excess of plaque, tartar and/or other debris. Ensure these tooth surfaces are cleaned and excess debris is removed.

1.4 Contact Information

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2 PRODUCT OVERVIEW

2.1 Introduction and Background

Dental caries remain one of the most common chronic diseases in humans and is caused by the action of acids on tooth enamel surfaces. Acid is produced when sugars from the diet react with specific types of bacteria present in the dental biofilm (plaque) on the tooth surface. Repeated acid attacks can lead to tooth enamel demineralization. Due to their morphology and anatomy, the pits and fissures located on the occlusal surfaces of posterior teeth account for approximately 80%-90% of tooth decay in permanent teeth.

2.2 The Ortek Electronic Caries Detector

The ECD is a patented noninvasive electronic caries detection device that helps dental professionals diagnose and monitor early cavitated lesions in the vulnerable pit and fissures located on the occlusal surfaces of posterior teeth. By measuring the conductivity of enamel at the bottom of pit and fissures, the ECD can instantly identify these very prevalent lesions usually before x-ray, visual and tactile evaluations. The ECD does not use ionizing radiation, is painless and not affected by stain.

The ECD is a small portable device that has a base unit with a digital display and a handpiece with a disposable single patient use conductive stainless steel tip. This novel tip is sized and dimensionally configured to fit deeply into the bottom of a pit or fissure. The tip ensures electrical contact with the dentinal fluid found at the bottom of a demineralized pit or fissure. When contact of dentinal fluid from the breached enamel site is made, an electrical circuit is completed and the device will beep. The digital display will increase from 01 to 100, depending on the size of the lesion. The tip should be disposed after every examination (it can be used on multiple teeth per exam). The ECD tip is paired with a reference electrode lip hook to complete the necessary electrical circuit. The lip hook rests on the patient's lower lip.

2.3 How It Works

If the dentin-enamel junction is breached by demineralization, hydrostatic pressure that exists within dentinal tubules will allow minuscule amounts of conductive dentinal fluid to enter the breached enamel site, allowing the ECD to complete an electrical circuit.

Loss of mineral from enamel as a result of caries activity increases porous size and enamel porosity. As this demineralization increases, more dentinal fluid enters the breached site. The more fluid detected results in lower resistance, a higher current and an increasing digital caries score that is digitally displayed from 01-100. (Figures 1 and 2)

Intact tooth enamel is a good insulator and is electrically non-conductive. When the enamel at the bottom of a pit/fissure is intact, the circuit path is opened and no current can flow, indicating non-cavitated lesion or a sound enamel site and a zero score. (Figure 3)

2.4 Box Contents

The purchase of the Ortek-ECD® includes the device main unit, a package of (20) non-sterile single patient use tips, a handpiece, a Y connector cable, two lip hooks and a 9V alkaline battery. (Figure 4)

Sterilize tips and lip hooks individually before use as per section 5. Tips are for single patient use and can be used on multiple teeth per exam. After use, dispose tips in an FDA-cleared sharps disposal container to reduce the risk of sticks, cuts or punctures from loose sharps. Do not resterilize the tips after use. Do not sterilize tips in the provided 20-count case.

- 1 - Electronic Caries Detector (ECD) Main Unit
- 2 - Conductive tips (Pkg/20)
- 3 - Handpiece
- 4 - Y connector cable
- 5 - Lip Hooks (2 included)
- 6 - 9V Alkaline Battery
(stored underneath Y connector cable)

Figure 1



Figure 2



Figure 3

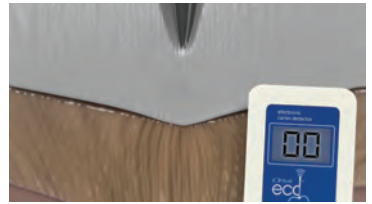


Figure 4





This device should not be used on patients with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic device.

Tip is sharp and can penetrate skin and oral mucosa upon contact. Use common dental care practices when using the tip. Handle with care.

Before use, gently tug the tip to ensure the tip is securely in place in the handpiece.

Use caution when inserting the tip into patient's mouth.

3 PREPARATION

3.1 The ECD

The ECD (*Figure 5*), when properly used, will detect early cavitated lesions in the pits and fissures located on the occlusal surfaces of posterior teeth.

- 1 - Electronic Caries Detector (ECD) Main Unit
- 2 - Conductive tip
- 3 - Handpiece
- 4 - Y connector cable
 - 4(A) Main unit cable plug
 - 4(B) Handpiece cable plug
 - 4(C) Lip hook cable socket
- 5 - Lip Hook

Figure 5



3.2 Getting Started

Before use, sterilize and clean ECD components as per section 5.

Tips must be sterilized before use. Do not sterilize tips in provided case.

- 1) Install a 9V battery¹ by sliding open the battery cover located on the bottom of the ECD main unit. (Figure 6)
- 2) Set the beeper volume switch to low or high.



Figure 6

- 3) Return the battery cover to its original closed position.
- 4) Connect the main unit cable plug [4 A] to the ECD Main Unit (1). (Figure 5)
- 5) Depress the on/off switch to turn on the ECD. The ECD will beep for 3 seconds while displaying "HOLD" and then it will stop beeping and will display "00" on the screen and will be ready for use.

¹ The ECD Device is compatible with most brand-name 9V alkaline batteries.

4 OPERATING THE ECD



This device should not be used on patients with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic device.

Use caution when inserting the tip into patient's mouth.

Tip is sharp and can penetrate skin and oral mucosa upon contact.

4.1 Component Connections and Operation

- 1) Connect the lip hook socket [4 C] to the lip hook (5) so that the lip hook is now connected to the main unit (1). (*Figure 5, page 4*)
- 2) Connect the handpiece cable plug [4 B] to the handpiece (3) so that the handpiece is now connected to the main unit (1).
- 3) Loosen top of handpiece (3) and fully insert the tip (2) into the handpiece (3) and securely tighten the handpiece after tip has fully bottomed. Before use, gently tug the tip to ensure the tip is securely in place in the handpiece. Remove silicone tubing from tip. If tip has residual moisture after sterilization, thoroughly dry all surfaces of the tip with an air syringe before use.
- 4) To ensure the accuracy of the detection of dental caries, the following steps must be taken prior to any measurements:
 - a. Remove any intra-oral removable appliances.
 - b. Clean occlusal surfaces of teeth to be examined to remove any debris or plaque. If prophylaxis paste is used, ensure it is all removed prior to making a measurement to avoid false readings.
 - c. Isolate the tooth to be measured and those in the immediate vicinity using cotton rolls and a saliva ejector.
- 5) Place Lip Hook in the patient's mouth.
- 6) Thoroughly air-dry pit and fissure surfaces of the tooth to be examined with at least a 4-second blast of dry air from the dental air syringe. The tooth must remain dry for the remainder of the examination. If using an air/water syringe, make sure there is no moisture in the line. Moisture in the line will cause the unit to beep and display an incorrect digital reading. After drying, make sure patient's tongue or any saliva does not contact occlusal surface of tooth being examined.

To ensure proper operation, place tip on the dried occlusal surface. If surface is completely dry, the ECD will display a zero score and you can proceed with the examination.

- 7) With little or no pressure, gently place the tip at the bottom of a pit or fissure. Do not explore the tooth by a conventional tactile examination, which can cause damage to the enamel surface.
- 8) When a beep is heard, hold the tip in position until the beep stops, then remove the tip. The beep indicates that a cavitated lesion has been detected due to the completion of the circuit as discussed in

Section 1. The ECD screen will display a numeric value for 3 seconds. See Table 1 to better understand the relation between the display results and lesion severity. If no beep is heard, move to the next site or tooth using the same tip.

- 9) If a lesion is detected, wait for the ECD screen to reset to zero before examining the next site or tooth. Repeat steps 6, 7 and 8 above. It is important to dry the occlusal surfaces of each new tooth to be examined.
- 10) When exam is complete, turn off unit and dispose tip in an FDA-cleared sharps disposal container to reduce the risk of sticks, cuts or punctures from loose sharps.

DO NOT REUSE TIP

4.2 Caries Detection and Evaluation

Table 1:

Relation between ECD Display Results, Beep Alerting and Enamel / Dentin Caries Status

Display*	Beep Alert	Enamel / Dentin Caries Status All readings are a guide to lesion detection and assessment.*
00	No	High probability of a sound enamel site.
01	Yes	Indication of initial caries lesion breaching the dentin-enamel junction.
02 – 03	Yes	Indication of caries lesion with the likelihood of dentin involvement.
04 – 20	Yes	Indication of caries lesion advancing into the dentin.
21 – 60	Yes	Indication of caries lesion progressing into the dentin.
61 – 100	Yes	Indication of an advanced caries lesion.

*Any final diagnosis and /or treatment decision is the responsibility of the dentist who should be integrating all the information available, particularly that from clinical visual and radiographic caries examination.

5 CLEANING AND MAINTENANCE

5.1 Cleaning

Universal cross-infection precautions should be observed.

The ECD cables should be cleaned after each use by using an EPA registered hospital disinfectant (intermediate level).



The ECD tips must be sterilized prior to use using a moist heat pre-vacuum cycle at 250°F (121°C) for 30 minutes, followed by a 15-minute dry time.

The tips have a maximum temperature resistance of 275°F.

The ECD tips are for single patient use only and should be discarded appropriately in a sharp's container after use. Do not resterilize the tips after use. Do not sterilize tips in the provided 20-count case. Silicone tubing covering tips can be sterilized. If tip has residual moisture after sterilization, thoroughly dry all surfaces of the tip with an air syringe before use.

The handpiece is sterilizable as per current CDC Guidelines, or a sheath or disposable barrier sleeve may be placed over the handpiece and any other non-sterilizable components during operation of the ECD. The sheath should be discarded and replaced after each patient and the handpiece should be cleaned after each use by using an EPA registered hospital disinfectant (intermediate level).

The lip hook should be cleaned and sterilized between each use. To clean, rinse the lip hook under running tap water for at least 1 minute to remove gross contamination. Fully immerse the lip hook in an enzymatic detergent and allow to soak for 5 minutes. While immersed, thoroughly brush the lip hook to remove visible contamination. Rinse the lip hook again under running tap water to remove detergent residue. The lip hook may be sterilized using a moist head pre-vacuum cycle at 250°F (121°C) for 30 minutes, followed by a 15-minute dry time.

5.2 Service

The ECD instrument contains no serviceable parts. If any problems arise, please contact your supplier.


5.3 Power Supply

Consists of 9V battery. Replacement is required when “Low Battery” is displayed on the battery indicator located on the ECD instrument. Battery is included. The ECD device is compatible with most brand-name 9V alkaline batteries.

5.4 Storage

Temperature Range/Ambient Temperature: 5°C to 30°C (41°F to 86°F)

Relative humidity: 5 to 95% 

Air pressure: 70 to 106 kPa 

6 TROUBLESHOOTING

ECD Not Working Properly

If the ECD device is not working properly, or the readings abnormally cause concern, the following steps should be followed to make sure the device is working as intended:


- Inspect the components of the ECD for damage. Check the Y connector cable, plugs and sockets. If damaged, the parts should be replaced.
- Make sure that each component is attached to the correct component and securely in place. Follow the steps in sections 3.2 and 4.1.
- Make sure that the occlusal surface of the tooth being examined is thoroughly clean and dry before using the ECD device.
- To ensure an accurate reading, hold the tip in position until the beep stops, then remove the tip. Wait for the ECD screen to reset to zero before examining the next site or tooth.
- Check the battery level on the device screen. If low, change the battery.
- If using an air/water syringe, check for water in the line.
- Make sure tip is not contacting moisture on lips or oral mucosa.
- If tip has residual moisture after sterilization, thoroughly dry all surfaces of the tip with an air syringe before use.

If the ECD is still not working as intended, contact your supplier.


7 LABELS AND SYMBOLS

 yyyy-mm-dd


Operating/
Storage Conditions:

 Temperature Limit

SN Serial Number


 Humidity Limit

LOT Lot/Batch Number

 Pressure Limit

REF Model Number

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(01)00858197004062(11)122319(10)231219A

REF Model Number


 Consult operating instructions for use


SN Serial Number

 Manufacturer

 Date of manufacture


LOT Batch Code


 Non-sterile

 Do not use if package is damaged


 Temperature Limit

 Humidity limitation

 Atmospheric pressure limitation

 Do not re-use

 Consult instructions for use

 Caution

FC Electromagnetic Safety

8 REPLACEMENT PARTS LIST



Y connector cable



Conductive tips (Pkg/20)



Handpiece



Lip Hook

9 TECHNICAL SPECIFICATIONS

Power Consumption: 9V

Weight: 2 lbs approximately

Operating Temperature Range: -20°C to 54°C (-4°F to 129°F)

10 EQUIPMENT STANDARDS

The device was tested and/or evaluated against and found compliant to the following standards/requirements:
IEC 60601-1-2 (2007) Ed. 3 (Electromagnetic Compatibility)

11 WARRANTY

Ortek Therapeutics, Inc. gives a limited two-year warranty to all original purchasers beginning from the date of purchase. During the warranty period, Ortek will repair or replace, at no charge, product or parts that prove defective because of faulty manufacture or material under normal use and maintenance.

This limited warranty does not cover any problems that are caused by conditions, malfunctions, or damage not resulting from defects in material or workmanship. Unauthorized alterations, wear and tear, abuse, improper use or failure to follow operating instructions supplied automatically voids all warranties. This limited warranty is not transferable.

In the event of a claim under this warranty, you must first contact Ortek to determine the problem and the most appropriate solution for you. Customer must return product for repair or replacement, carefully packaged, with postage and shipping pre-paid.

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