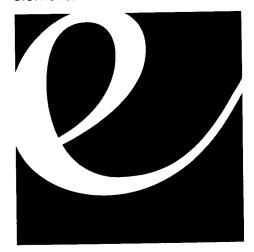
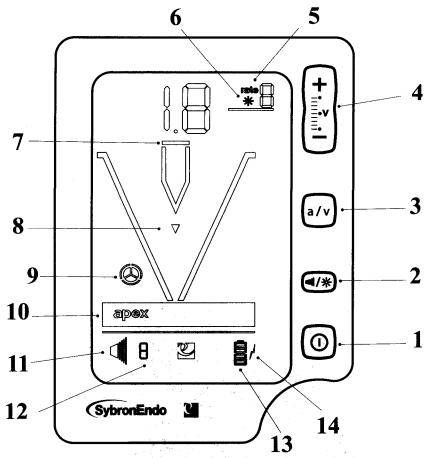
# elements



diagnostic





<b>English</b>	Français	Español	<b>Deutsch</b>	<u>Italiano</u>	<b>Dansk</b>
1. power	1.Alimentation	1. Alimentación	1.Ein	1.Alimentazione	1.Tænd/sluk
2. setup	2.Configuration	2.Configuración	2.Einrichtung	2.Impostazione	2.indstilling
3. mode	3.Mode	3.Modo	3.Modus	3.Modalità	3.Funktion
4. adjust	4.Réglage	4.Adjuste	4.Einstellen	4.Regolazione	4.Justere
5. vitality rate	5.Niveau de vitalité	5. Tasa de vitalidad	5. Vitalitätsrate	5.Grado di vitalità	5.Stimulushastighed
6. brightness	6.Luminosité	6.Brillo	6.Helligkeit	6.Luminosità	6.Kontrast
7. contact	7.Contact	7.Contacto	7.Kontakt	7.Contatto	7.Kontakt
8. carat	8.Carat	8.Carat	8.Carat	8.Carat	8.Trekantsymbol
9. constriction	9.Constriction	9.Constricción	9.Terminus	9.Costrizione	9.Indsnævring (isthmus)
10. apex	10.Apex	10.Ápice	10.Apex	10.Apice	10.Apex
11. volume	11.Volume	11.Volumen	11.Lautstärke	11.Volume	11.Volumen
12. audio mode	12.Audio Mode	12.Modo Audio	12.Klangmodus	12.Modalità	12.Lydsignal
13. battery level	13. Niveau de charge de la batterie	13.Nivel de la batería	13.Akkuladung	13.Livello della batteria	13.Batteriniveau
14. 100-240V	14.100-240V	14.100-240V	14.100-240V	14.100-240V	14.100-240V
<u>Português</u>	Nederlands	Suomi	Ελληνικα	<u>Norsk</u>	<u>Svenska</u>
1.Ligar/Desligar	1.Aan/uit	1.Virta	1.Ισχύς	1.På-bryter	1.Strömbrytare
2.Configurar	2.Instelling	2.Asetukset	2.Ρύθμιση	2.Oppsett	2.Knapp för initiala inställningar

<u>Português</u>	<u>Nederlands</u>	<u>Suomi</u>	<u>Ελληνικα</u>	<u>Norsk</u>	Svenska Svenska
1.Ligar/Desligar	1.Aan/uit	1.Virta	1.Ισχύς	1.På-bryter	1.Strömbrytare
2.Configurar	2.Instelling	2.Asetukset	2.Ρύθμιση	2.Oppsett	2.Knapp för initiala inställningar
3.Modo	3.Modus	3.Tila	3.Τρόπος λειτουργίας	3.Modus	3.Funktionsläge
4.Ajustar	4.Regelaar	4.Säädä	4.Προσαρμογή	4.Juster	4.Justering
5.Taxa de vitalidade	e 5.Stimulussnelheid	5.Elinvoima	5. Ρυθμός ζωτικότητας	5. Angivelse av vitalitet	5. Stimuleringshastighet för vitalitetstest
6.Luminosidade	6.Helderheid	6.Kirkkaus	6.Φωτεινότητα	6.Lysstyrke	6.Ljusstyrka
7.Contacto	7.Contact	7.Kontakti	7.Επαφή	7.Kontakt	7.Kontakt
8.Carat	8.Carat	8.Carat	8.Carat	8.Carat	8.Carat
9.Constrição	9.Constrictie	9.Kurouma	9.Στένωση	9.Innsnevring	9.Konstriktion
10.Àpice	10.Apex	10.Juuren pää	10.Κορυφή	10.Apeks	10.Apex
11.Volume	11.Volume	11.Äänenvoimakkuus	:11. Ένταση ήχου	11.Volum	11.Volym
12.Modo Àudio	12.Geluidssignaalmodus	12.Äänitila	12.Τρόπος λειτουργίας ήχου	12.Audiomodus	12.Ljudläge
13. Nivel de carga da bateri	a 13.Batterijniveau	13.Akun taso	13.Στάθμη μπαταρίας	13.Batterinivå	13.Batteristyrka
14.100-240V	14.100-240V	14.100-240V	14.100-240V	14.100-240V	14.100-240V

# 日本語

1.	電源	5.	生活率	9.	狭窄	13.	充電レベル
2.	設定	6.	輝度	10.	根尖	14.	100-240\
2	T V	7	拉车	11	立里		

モード 7. 接触 11. 音量
 調整 8. カラット 12. オーディオモード





# **Instruction Guidelines**

# **Cautions and Warnings**

DANGER: Not for use in the presence of flammable anesthetics.

**WARNING**: The diagnostic unit should NOT be used on a patient with a pacemaker.

**WARNING**: Do not plug any connectors or pins on the file clip or probes into any external power source, as it may cause a severe safety hazard to the patient.

WARNING: Only use the specified SybronEndo AC adaptor, adaptor plugs and SybronEndo battery pack replacement.

**WARNING**: Use of other accessories which are not authorized for use in connection with this device may cause malfunction and compromise patient safety.

CAUTION: This device has been investigated with regard to safety from electrical shock and fire hazard as well as electromagnetic compatibility (EMC). The device has not been investigated for other physiological effects.

CAUTION: For use by qualified and trained personnel only.

**CAUTION**: This device to be used in conjunction with other diagnostic procedures and not relied on exclusively.

CAUTION: Do not autoclave the Satellite

CAUTION: This device has been tested and found to comply with EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The device generates radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will occur in a particular installation. If this device does cause harmful interference with other devices, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving device
- Increase the separation between devices
- Connect the device into an outlet on a circuit different from that to which the other device(s) is connected.
- · Consult the manufacturer for help

**CAUTION:** To reduce the risk of electrical shock do not remove cover. Refer servicing to qualified service personnel.

**CAUTION:** U.S. Federal Law restricts this device to sale by or on the order of a health care professional.

#### **Parts List**

I AI IS LIST	
diagnostic unit	973-0300
diagnostic unit	973-0320 (International)
AC Adaptor	973-0302
Satellite Cord with Satellite	973-0303
Battery Pack	973-0305
Patient Lead Cord	973-0311
Bifurcated Probe	973-0307
File Clip	973-0310
Vitality Probe	973-0308
Crown Test Tip	973-0309
Optional Accessories	
Satellite Cord w/o Satellite	973-0304
Mounting Bracket	973-0306

# **Symbols**

### Front Panel

Adjustment of vitality rate, audio volume, LED bri			
a/v	Mode switch between Apex mode and Vitality mode		
<b>■</b> /※	Setup		
0	On		

#### Rear Panel

<b>C€</b> 0086	Corresponds to MDD 93/42 EEC Including EN 60601-1 and EN 60601-1-2.
© Us	CSA mark with "C/US" indicator for certified products.
$\overline{\Lambda}$	Attention! Consult manual before use

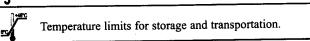


## Satellite Remote

1357	Do not autoclave.		

# Packaging / Handling Symbols

11	This way up.	
4	Fragile, handle with care.	
7	Keep away from rain.	·



# **Product Features**

The Diagnostic Unit combines a Vitality Scanner and an Apex Locator in one unit.

#### Apex Locator (AL) Mode

The Apex Locator calculates the distance from the tip of your endodontic file to the foramen by measuring changes in impedance between two electrodes. The first electrode is the lip clip. The second is the probe or file clip which makes contact with a file or plugger that has been inserted into the root canal.

The unit's advanced technology allows it to give accurate readings in the presence of sodium hypochlorite, anesthetic, alcohol, EDTA, blood, pus, etc., as well as in the presence of necrotic tissue.

#### Vitality Scanner (VS) Mode

The Vitality Scanner's patented pulsating stimulus allows pain-free determination of pulpal vitality. The stimulus strength automatically increases from a low value to prevent discomfort and is electronically stabilized to provide consistent results.

After a tooth is tested, the display retains its response level to facilitate recording of results. The unit automatically resets to aid rapid testing of multiple teeth.

### **General Instructions**

#### **Initial Setup**

Before your diagnostic unit is used for the first time, enter your desired settings. These may be readjusted at any time.

- Activate the unit by pressing the ① button. Once activated, the LCD segments will flash and return to the mode last used.
- Press and hold the ◄/\* button for 1 second placing the unit in volume adjustment mode as indicated by the flashing ◄ icon. Use the buttons to adjust the volume.
- 3. Momentarily pressing the <a>√\*</a> button again places you in sound adjustment mode. Adjust to the desired mode using the the buttons. A chart laying out each sound mode follows this section.
- 4. Pressing the ◄/\* button again allows you to adjust the Satellite Display brightness as indicated by the flashing number in the display's upper right corner. Use the buttons to adjust the brightness level. Note: Level "0" turns the Satellite Display off.
- The setup feature will timeout after five seconds of inactivity and the unit is ready for use.

#### **Sound Mode Options**

The number to the right of the symbol indicates the sound mode.

	Mode1	Mode2	Mode3
Unit powered on	✓	✓	
Elements network connection	✓	<b>√</b>	
Change VS/AL mode	✓	✓	
Change audio settings	✓	✓	
Battery low		✓	✓
Incremental apex steps (.1mm)	✓		
Close to apex (< .5mm)	✓	✓	✓
At apex	✓	✓	✓
Past apex	✓	$\checkmark$	✓
Vitality - circuit completed	✓	✓	
Vitality - circuit broken	· ✓	✓	
Vitality - increase (each 10 steps)	✓	✓	
Vitality - maximum	✓	✓	

#### **Device Power Off**

The unit will turn off after 60 seconds of non-use.

# Satellite Display

# Note: The Satellite Display is not autoclavable

A revolutionary Satellite Display is included with your diagnostic unit which gives a quick indication of the distance to the apex in AL mode and output level in VS mode. Use the strap provided to attach your Satellite Display to a chair, patient bib or microscope for ergonomic monitoring of status.

## Power Symbols

When the unit receives power from a wall outlet or the Elements Bus Connector, the / symbol appears in the lower right corner of its display. When running on battery power, the symbol appears. The diagnostic unit uses a rechargeable battery pack and can be used while charging. As battery strength is depleted, segments of the battery meter indicate remaining capacity. When the last segment of the battery meter begins to blink, recharge the unit immediately by plugging it into a wall outlet. Failure to do so can result in inaccurate readings. To maximize life, the battery pack should be fully discharged before each recharge. Should the battery pack require replacement, use only the pack expressly for this unit from SybronEndo (973-0305). There are no other user serviceable items within the unit.

#### **Apex Locator Mode**

# Numeric Display

The Numeric Display shows distance to the apical foramen from +3.0 mm to -0.5 mm in 0.1 mm increments. Beyond 1.5 mm from the foramen, readings are less reliable. When a file reaches the apical foramen, the numeric display will read "0.0". If the file has gone past the foramen, the display exhibits a negative number down to "-0.5"

#### **Graphic Display**

The display imitates your file moving toward the apex while its depth is indicated on the bar to the right. Upon coronal movement of the file, a  $\nabla$  remains for 15 seconds at the greatest depth reached near the apex. Upon reaching the apical foramen, the hollow file solidifies and the black "Apex" bar appears. If the file goes beyond the foramen, this bar will blink. The file should then be withdrawn approximately 0.5mm to reach the constricture. Segments of the 2 symbol will indicate you are nearing the correct position. Upon reaching the constricture, the segments of the constricture symbol will flash.

#### Satellite Display

The Satellite Display mirrors the Graphic Display. LED lights illuminate as the file progresses within the canal. Each segment represents 0.2mm. For example, when a file progresses from 0.4mm (from the apical foramen) to 0.3mm, the representative LED will illuminate dimly and then brightly upon reaching 0.2mm. When the foramen is encountered, the bottom green LED mimicking the "Apex" bar on the Graphic display will activate. If the file goes past the apical foramen, the LED's at the top and bottom of the satellite will flash alternately.

After reaching the foramen, the file is withdrawn 0.5mm to the constricture whereupon the representative segment turns green.

#### **Apex Locator Directions For Use**

NOTE: The Apex Locator should be used only as an adjunct to normal endodontic procedures. While the unit can reduce the number of radiographs necessary, an initial radiograph must be taken to estimate working length. Clinical judgment, including knowledge of root canal anatomy, is paramount when interpreting results.

- Grasping the Satellite Cord plug by its knurled section, line up the red dots and gently push it into its receptacle at the front of the unit. The cord may only be plugged in or removed by pulling the knurled section of the plug.
- 2. Place the Patient Lead Cord connector into the Satellite Cord receptacle.
- Insert either the Bifurcated Probe or File Clip into the Patient Lead Cord receptacle.
- 4. Power the unit by depressing the ① button.
- 5. Ensure the unit reads "apex" in the upper right hand corner confirming the unit is in Apex Locator mode. If not, press the a/v button to do so.
- Place the lip clip on the patient's lip. Direct contact between the mucosa and the lip clip must be made for proper function.
- Ensure the unit is functioning properly by touching the Probe tip to the gingiva. You should notice a change in the display.
- Touch the Bifurcated Probe or connect the File Clip to an endodontic file that is in the canal.
- Upon contact, the Numeric Display and small bar underneath it will appear until contact is broken.
- 10. Work the file apically until the Numeric Display reads "0.0", the Graphical Display exhibits a solid file, and the black "apex" bar appears. Note: The unit is sensitive and responds to minute changes in file position.
- 11. Pull back approximately 0.5mm to reach the constricture. As you do so, segments of the will appear. The complete symbol will flash at the constricture.
- 12. Set the desired working length by adjusting the position of the file stop.
- 13. When contact is broken, the Numeric Display will show two dashes and the file icon will disappear.

#### **Apex Locator Troubleshooting**

To correct erratic measurements:

- Ensure the lip clip fully contacts the patient's mucosa.
- · Check all connections.
- · Verify the unit turns on automatically when a circuit is completed.

Dry the canal with a paper point to increase accuracy when:

• Excessive conductive fluids form a conductive bridge between canals or with a metallic restoration or crown.

#### Other problem areas to check:

- Ensure the file barely goes through the terminus. A loose file will give inaccurate readings.
- If the apex is larger than .40mm there might not be ample constricture for accurate readings.
- Bone or periodontal ligament loss (indicated by a radiolucency on the film) can cause inaccurate readings.
- · If battery power is low, plug the unit into a wall outlet
- File or probe contact with a metal restoration will ground the circuit and inaccurately indicate the apex.
- If the canal is too dry, introduce NaOCl to the apical 1/2 of the canal.

# Vitality Scanner (VS) Mode Instructions

#### Numeric Display

Vitality response values range from 1 to 80. When the maximum value of 80 is reached, your Numeric Display flashes until contact is broken.

### **Graphic Display**

When a circuit is completed, a small horizontal bar will appear under the Numeric Display until the circuit is broken. A vertical bar corresponds to the numeric response value.

#### Satellite Display

The Satellite Display mimics your Graphic Display. The top LED segment indicates a completed circuit.

Vitality Scanner Directions for Use

- 1. Grasping the Satellite Cord plug by its knurled section, line up the red dots and gently push it into its receptacle at the front of the unit. The cord may only be plugged in or removed by pulling the knurled section of the plug.
- Place the Patient Lead Cord connector into the Satellite Cord receptacle.
- Insert either the Standard or the Mini Crown Test Probe into the Patient Lead Cord receptacle.
- 4. Power the unit by depressing the ① button.
- 5. Ensure the unit reads "vitality" in the upper right hand corner confirming the unit is in Vitality Scanner mode. If not, press the a/v button to do so.
- Adjust the rate of stimulus increase with the panel keys. This rate can be re-adjusted during testing.
- Place the lip clip on the patient's lip. Direct contact between the mucosa and the lip clip must be made for proper function.
- Dry the tooth to be tested.
- Dip the probe tip into a small amount of gel toothpaste or topical anesthetic and place it on the tooth. Do not contact the gingiva.
- 10. Upon contact, a small horizontal bar appears under the numerical display and remains until contact is broken.
- 11. Maintain contact with the tooth until your patient perceives a pulsating pressure, warmth, or tingling. A chart on normal responses follows this section.
- 12. If contact is broken and re-established within 1 second, testing continues without resetting. This feature avoids accidental resetting if momentary loss of contact occurs. The unit resets after 1 second of lost contact to aid rapid testing of multiple teeth.

Test Response

Normal test response ranges for vital teeth are:

Incisors 10-40 20-50 Bicuspids

30-70 Molars These are not absolutes and will vary from patient to patient.

- Vitality Scanner Usage Notes and Hints

   The unit automatically activates upon contact between probe and tooth. This ensures the patient initially receives the lowest output.
  - Begin testing on teeth adjacent to the subject tooth to provide a comparative basis.
  - The Mini Crown Probe allows access below the margin of a porcelain crown.
  - Lower resistance of metallic fillings produce readings considerably lower than natural tooth material.

Vitality Scanner Troubleshooting

A false negative occurs when a vital tooth does not respond to the maximum level of 80.

Causes include:

- Moisture on the surface of the tooth. False negatives can often be avoided by drying the tested tooth
- A metallic filling contacting periodontal tissue.
- Severe calcification of pulpal tissue.
- Immature apices.
- Severe trauma to the tooth.
- Other conditions resulting in degradation of neural response.

A false positive occurs when your patient perceives the stimulus on a necrotic tooth.

- Causes include: A patient sensing stimulation in an adjacent tooth in contact with the subject tooth.
- A patient sensing a periodontal neural stimulus instead of a pulpal nerve stimulus. The periodontal response is quite different than a pulpal response. Compare the sensation perceived on a tooth being vitality tested with the direct stimulation of periodontal tissue prior to vitality testing.

# **Expected Life of Accessories**

All accessories are reusable for a limited number of procedures. This number is highly dependent on how and for what duration the instrument is used and, therefore, will vary significantly from user to user. If the device function appears erratic, an accessory may have exceeded its useful life and should be replaced.

# Cleaning, Sterilization, and Maintenance

#### Cleaning

The Unit and Satellite should be wiped twice with CaviWipes or a clean cloth moistened with Cavicide (Metrex 714-516-7400) for cleaning and disinfecting. The first wipe will clean the instrument, the second wipe will disinfect. Do not submerge the device or allow liquid to enter the enclosure. Do not Autoclave the unit or satellite.

#### Sterilization

Probes, File Clips, and the Patient Lead Cord must be cleaned, sterilized, and inspected before every use:

1. Clean with CaviWipes or a clean cloth moistened with Cavicide or warm water. Dry thoroughly.

- 2. Double wrap the Probes, Clips, and Lead Cords using a typical central service wrapping technique and place into autoclave unit avoiding contact with other instruments.
- Operate sterilization cycle at 250°F (121°C) for 30 minutes or 270°F (132°C) for 25 minutes. Follow the instructions supplied with your autoclave unit for specific operating instructions.

# Technical Specifications

Dimension / Weight

### Weight

Main Unit: 0.9 kg Satellite Unit: 0.05 kg

#### **Dimensions**

#### Main Unit

Height 42 mm Width 96 mm

Depth 107 mm

#### Satellite Unit

Height 17 mm

Width 54 mm

Depth 65 mm

Classification: IEC 601-1 Class 2, Patient Contact

Mode of Operation: IEC 601-1 Continuous Operation

Degree of safety of application in presence of a flammable anesthetic mixture: Unit unsuitable for use in presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Conditions for use: +10 C to +35 C / 30% to 75% relative humidity

Storage and transport conditions: -10 C to +40 C / 10% to 95% relative humidity

SybronEndo Origin:

1332 South Lone Hill Ave. Glendora, CA 91740 USA

Model: elements - diagnostic

Power Supply: rechargeable NiMHi battery pack / 5 cells - 1,650mAh Isolated DC power supply from network voltage rail or wall transformer.

# Warranty and Returns

The unit is designed for lasting durability and predictable results. The unit comes with a one-year warranty. If the unit should fail to operate correctly, please contact your SybronEndo customer service representative at 1-800-346-7979 or contact your local dealer or supplier to coordinate the returns/repairs with SybronEndo.

Warranty repairs can only be performed by SybronEndo or by authorized agencies with original factory parts. Any unauthorized repairs will void the warranty

- 1. Use the original packaging when shipping or storing your unit.
- Many problems can be solved over the phone. Do not hesitate to contact us if you experience difficulties when using the unit.
- For returns, call us for a Return Material Authorization (RMA) number.
- Damages incurred during shipping due to improper packaging are not covered by the warranty. If the original box and/or foam packing are not available, please call SybronEndo for packing instruction.
- Mark all outer packaging with the RMA number, your name, address, and phone number.
- 6. Shipping costs are not covered by the warranty.

### **Disclaimer**

The responsibility of SybronEndo, as a manufacturer and distributor of electrical/medical devices, extends to the technical safety features of the device only if maintenance and repairs are carried out by SybronEndo or authorized agencies with original factory parts.

For safety reasons, this product should be used only with accessories manufactured and sold by SybronEndo. Any use of non-authorized accessories or not following any of the instructions for use is done so at the operator's risk and voids the warranty.

SybronEndo does not assume any responsibility for incorrect diagnosis due to operator error equipment malfunction.