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INSTRUCTIONS FOR USE – PRINT SPECIFICATIONS

Instructions for Use – Elements IC - EU		
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	da-DANISH	DANSK
	sv-SWEDISH	SVENSKA
	el-GREEK	ΕΛΛΗΝΙΚΑ
	nl-DUTCH	NEDERLANDS
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	cs-CZECH	ČESKÝ
	tr-TURKISH	TÜRKÇE
	et-ESTONIAN	EESTI
	lt-LITHUANIAN	LIETUVIŲ
	sk-SLOVAK	SLOVENSKÝ
	ar-ARABIC	العربية
	bg-BULGARIAN	БЪЛГАРСКИ
	hr-CROATIAN	HRVATSKI
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	th-THAI	ภาษาไทย
SUPPLIER	American Solutions	

Kerr
ENDODONTICS

INSTRUCTIONS FOR USE

elements™ IC

OBTURATION SYSTEM

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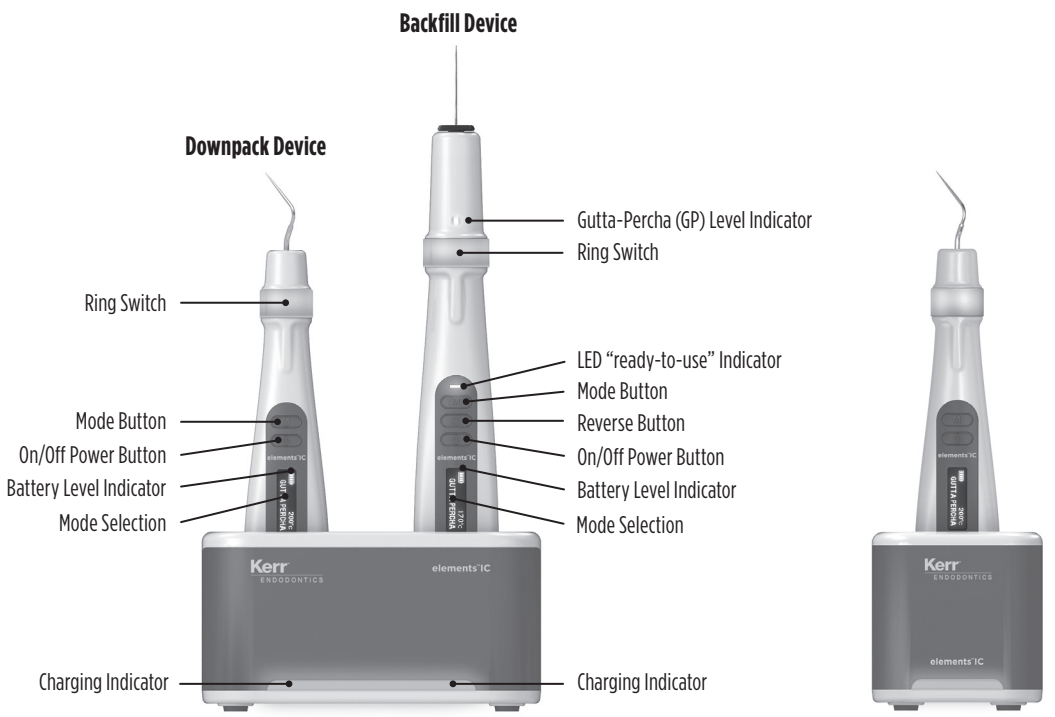
elements™ IC

OBTURATION SYSTEM

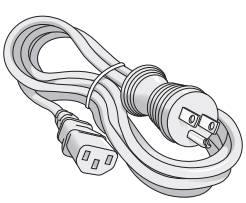
The cordless elements™ IC obturation system combines a Downpack heat source with a Backfill extruder. The Downpack device provides fast heating of the heat plugger with precisely controlled temperature and timing, making it suitable for single-motion downpack obturation of the apical portion of the root canal. Utilizing single-use gutta-percha cartridges, the ergonomic Backfill device has a motorized extruder system for precise temperature and speed control for a 3-dimensional obturation of the root canal system.

CONTENTS OVERVIEW

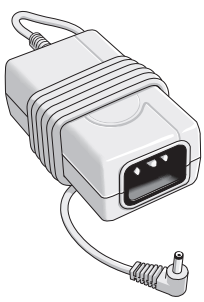


Dual Charging Base
Supplied only with combo unit

Single Charging Base



Power Cord



Transformer

Heat Plugger
Supplied only with Downpack and combo unit

Needle Bender
Supplied only with Backfill and combo unit

INDICATIONS FOR USE

The cordless elements™ IC obturation system is intended to be used in Endodontics to backfill and downpack gutta-percha during root canal obturation using warm vertical obturation technique.

CONTRAINDICATIONS

- Not for use in the presence of flammable anesthetics such as a mixture of oxygen, air and nitrous oxide.
- The obturation unit should NOT be used on a patient with a pacemaker.
- Do not use on patients with a known sensitivity to natural rubber latex or copper.

⚠ WARNINGS

Read the following warning before using this device.

- This device has been investigated with regards to safety from electrical shock and fire hazard as well as electromagnetic compatibility (EMC). The device has not been investigated for other physiological effects.
  Please contact Kerr Endodontics if you have any further questions regarding electrical safety or EMC.
- This device has been tested and found to comply with EMC limits for the Medical Device Directive 93/42/EEC. 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 not 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.

WARNING: This product can expose you to chemicals including Lead and Lead Compounds, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Treatment Procedure

- elements™ IC system can only be used with Kerr elements gutta-percha cartridges and heat pluggers.
- The heat pluggers and elements gutta-percha cartridges are designed to reach high temperatures. Inadvertent contact with patient and operator must be avoided to prevent accidental burns.
- Do not touch the cartridge needle within one minute after the device is turned off to avoid potential burn risk. Wait until the Backfill device is completely cooled down before touching the cap.
- Handle empty elements gutta-percha cartridges by the plastic locknut only. Other portions could be hot and could result in a serious burn.

Use, Repairs and Service

- For use by qualified and trained personnel only.
- U.S. federal law restricts the sale of this device by or on the order of a healthcare professional.
- To reduce the risk of electrical shock, do not remove charging cover. Refer servicing to qualified service personnel.
- Only use the specified Kerr Endodontics transformer and power cords.
- Use of other accessories that are not authorized for use in connection with this device may cause malfunction and compromise patient safety.
- No modification of this equipment is allowed.
- When transporting the device, use the original packaging provided by manufacturer to prevent accidental activation of the unit or any damage to the device itself.

Replacing or Shipping the Battery

- Only use Kerr Endodontics batteries designated for this system. Use of other batteries may damage the device(s) or cause a malfunction.
- Air or land transportation of the device is allowed if they are in the original packaging container.
- For shipping batteries within the United States or Internationally, consult the Department of Transportation's Pipeline and Hazardous Materials Safety Administration or the International Air Transport Association guidelines.

⚠ PRECAUTIONS

- Do not use in teeth with immature and/or over instrumented root canal apices unless the apex has been sealed.
- A protective dental dam is highly recommended when using this device.
- For the Backfill device, keep temperature setting above 150°C.
  Extruding material at lower temperatures will create more stress on the motor, and may shorten the device's life.
- Elements gutta-percha cartridges are for single-patient use.
- The electronic components should not be autoclaved as it will damage the circuitry.
- Do not spray the devices with any liquids as it may damage the circuitry.
- Do not immerse the gutta-percha cartridges in any liquid and do not autoclave them.
- Do not allow liquids to collect in the Charging Base or come in contact with the connector as it may damage the circuitry.
- Do not allow liquids to enter the openings for the heat plugger on the Downpack device or the elements gutta-percha cartridge on the Backfill device as it may damage the circuitry.
- Avoid multiple activations of the Downpack device while operating inside the root canal since prolonged exposure to the high temperatures may cause damage to the tissues surrounding the tooth (PDL or bone).

ADVERSE REACTIONS

None known.

SYMBOLS

SN	Serial Number
	Manufacturer
	Manufacturing Date
EC REP	Authorized Representative in the European Community
CE 0120	Corresponds to MDD 93/42 EEC Including EN 60601-1 and EN 60601-1-2
	This Way Up
C SA US 273015	CSA Mark with "C/US" Indicator for Certified Products
	Precaution/Warning
	Fragile, Handle with Care
12	Stack 12 Maximum
	Keep Dry
	Type B Applied Part
	Temperature Limits for Storage and Transportation
	Do Not Autoclave
	Humidity Limitation
	Do Not Throw into Trash
	Pressure Limitation
REF	Part Number
	Consult Accompanying Documents
Rx only* *for US law only	CAUTION: Federal law restricts this device to sale by or on the order of a dentist
IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°. Applies to Backfill and Downpack devices

STEP-BY-STEP INSTRUCTIONS

PRECAUTION
The components and devices of the elements™ IC have not been disinfected or sterilized prior to shipping. Please perform the necessary cleaning and disinfection steps prior to patient treatment.

GETTING STARTED

1 Initial Set-Up

a. Remove the device(s), Charging Base, transformer and wall cords from their packaging.
b. Connect the female end of the power cord into the transformer. Then plug the ends into the wall socket and the Charging Base.
c. Place the Downpack and Backfill devices into the Charging Base and confirm they are firmly seated.

2 Charging the Devices

a. Once the devices are firmly seated, the indication lights on the Charging Base will be either orange or blue.
b. The light will be orange when the battery is charging and will turn blue when the battery is fully charged.

Blue
means the unit is fully charged

Orange
means the unit is charging

3 Powering the Devices

a. To power on the device(s), press the On/Off Power button.

4 Set Temperature Mode

a. Devices come with two preset temperature modes. The following table shows their function and default temperature settings:

Setting	Description	Default Temp.	Temp. Range
Gutta-Percha	For use with gutta-percha	170°C (Backfill) 200°C (Downpack)	Not Editable
Custom	For use as an additional preset	200°C	100°C - 230°C (Backfill) 140°C - 400°C (Downpack)

b. Press the Mode button to toggle to the appropriate preset.

For instructions on changing the default temperature for a preset, see "Changing Temperature Presets" in the ADVANCED SETTINGS section.

5 Powering Off Device(s)

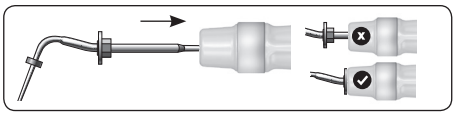
Hold 2 Seconds

Both devices will automatically shut down after approximately 5 minutes. If the device is seated into the charging dock, the Downpack device will automatically shut down after approximately 5 minutes and the Backfill device will automatically shut down after approximately 7 minutes. To manually turn off the device, hold down the Power button for approximately 2 seconds. The device will generate an audio signal to indicate it is powering down. Upon any power off of the Backfill device, the motor will automatically retract for a few seconds to relieve the pressure on the cartridge.

DOWNPACK DEVICE

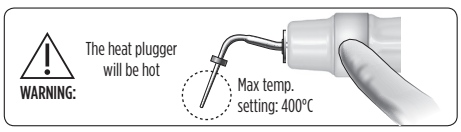
1 Installing the Heat Plugger

a. Align the hex nut to slide into one of six positions available.
b. Push the heat plugger until it is fully seated.



2 Activating the Downpack Device

Activate the Downpack device by depressing and holding the Ring switch. The heat plugger will heat instantly and a light under the Ring switch will illuminate.



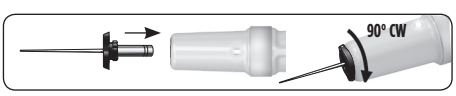
NOTE:
- To avoid overheating, the heat plugger will remain heated up to a maximum of approximately 4 seconds regardless of how long the button is depressed.
- Indicated temperature is the temperature the tip of the heat plugger reaches after activation in air. When the tip contacts other materials, its temperature may decrease depending on the nature of the contact.

PRECAUTION
The heat pluggers must be autoclaved between every patient to prevent cross-contamination. See the instructions in the CLEANING, DISINFECTION AND STERILIZATION section.

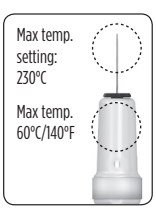
BACKFILL DEVICE

1 Inserting Elements Gutta-Percha Cartridge

a. Insert the large end of the Elements gutta-percha Cartridge into the device and rotate a quarter turn clockwise (CW) until it engages.



WARNING
Do not touch the cartridge needle within one minute after the device is turned off to avoid potential burn risk. Do not touch the cap of the Backfill device within 7 minutes after the device is turned off to avoid potential burn risk.



2 How To Tell When the Backfill is Ready for Use

a. Once powered on, the Backfill device will automatically begin to heat. The LED on the device will indicate whether or not the device is ready for use.

Flashing Light:
Device is still heating and is NOT ready for use.

Steady Light:
Device is fully heated and ready for use.

3 Activating the Backfill Device

Manual Run Mode:
a. Hold down the Ring switch to engage motor.
b. Release Ring switch to stop.

Continuous Run Mode:
a. Double-Click the Ring switch engage CR mode.
b. Press the Ring switch once to stop.

NOTE:
Before placing the cartridge needle in the canal, activate the motor until material extrudes out of the needle. If the motor is stopped before the cartridge is empty, the plunger will retract slightly to prevent excess material from discharging from the needle. Once the plunger reaches the end of the stroke, the cartridge is empty and the plunger will automatically retract.

4 Cartridge Level Indicator

a. The amount of gutta-percha in the elements gutta-percha cartridge can be checked by looking at the Gutta-Percha (GP) level indicator. The five increments indicator (4-3-2-1-0) provides the user with an estimate of the residual amount of gutta-percha in the cartridge:

Indicator	Gutta-Percha Level
4	Full
3	75%
2	50%
1	25%
0	Empty

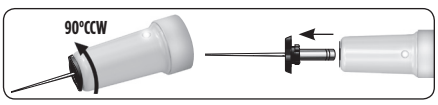
5 Retracting the Plunger

a. To retract the plunger before it reaches the end of its stroke, press the Reverse button. This will cause the plunger to fully retract to its "home" position.

6 Replacing the Elements Gutta-Percha Cartridge

a. To replace the elements gutta-percha cartridge before it is completely empty, first ensure that the unit is fully heated, then press the Reverse button to retract the plunger.

b. Remove the cartridge by turning the nut 90° counterclockwise (CCW), the pull the cartridge out of the device and dispose of properly.



WARNING

Handle empty elements gutta-percha cartridges by the plastic locknut only. Other portions could be hot and could result in a serious burn.

ADVANCED SETTINGS

1 Changing Temperature Presets

The device has two different preset temperature modes. (See the table in Step 4 of the GETTING STARTED section)

a. Press the Mode button to toggle to the temperature setting CUSTOM.

b. Hold down the Mode button for approximately 2 seconds to enter Temperature Control Mode.

c. Press the Mode button repeatedly to change temperature.

d. Once desired temperature is reached, hold down the Mode button (approx. 2 seconds) again or wait for 4 seconds (non-activity) to exit Temperature Control Mode.

PRECAUTION (BACKFILL ONLY)

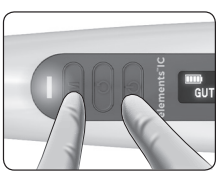
Keep temperature setting above 150°C. Extruding material at lower temperatures will create more stress on the motor, and may shorten the device's life.

2 Adjusting the Audible Signal Level

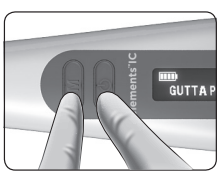
a. Change the audible signal level by simultaneously holding down the Mode and On/Off Power buttons for approximately 2 seconds. This will open Audible Signal Control Mode.

b. Press the Mode button repeatedly to change the audible signal level.

c. Once you have set your desired level, exit Audible Signal Control Mode by repeating the first step (a) above or wait for 4 seconds (non-activity).



Backfill - Hold 2 Seconds



Downpack - Hold 2 Seconds

3 Adjusting the Motor Speed

The motor of the Backfill device has two speed settings.

a. Press Reverse button for approximately 2 seconds to enter Speed Control Mode.

b. Press Reverse button repeatedly to change the motor speed (X1 - Standard speed, X2 - Double speed).

c. Once you have set your desired speed, exit Speed Control Mode by holding down the Reverse button (approx. 2 seconds) or waiting for 4 seconds (non-activity).

MAINTENANCE

1 Charging the Device(s)

The devices should be placed onto the Charging Base during and between uses.

2 Replacing the Battery

Contact Customer Care if the battery appears to be malfunctioning. To replace battery:

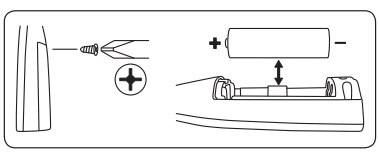
a. Remove silicon ball on the battery cover.

b. Remove screw on battery cover and remove battery.

c. Install new battery in same orientation.

d. Dispose of used battery per local regulations.

e. Cover the screw with the silicon ball.



PRECAUTION

Only use Kerr Endodontics batteries designated for this system. Use of other batteries may damage the device(s) or cause malfunction.

CLEANING, DISINFECTION AND STERILIZATION INSTRUCTIONS

elements™ IC obturation system, Cartridge Needle Bender and Heat Pluggers should be inspected prior to cleaning for the appearance of defects such as cracks, deformations, corrosion, which are indicators that the instruments are not in conditions to be re-used with the required level of confidence.

The use of automated cleaning devices or automated disinfecting devices is not recommended for the cleaning of the above components.

Health Care facilities are responsible for making sure that the sterilization equipment is calibrated according to the manufacturers manuals and specifications. In addition, health care facilities are responsible for training their staff on infection control, proper sterilization and disinfection procedures.

NOTE: make sure that the sterilization pouches are suitable for steam sterilization and comply with your national guidelines, standards and requirements.
- ISO 11607
- For USA: Use FDA-cleared accessories

PRECAUTION

- The electronic components should not be autoclaved as it will damage the circuitry.
- Do not spray the devices with any liquids as it may damage the circuitry.
- Do not immerse the gutta-percha cartridges in any liquid.
- Do not allow liquids to collect in the Charger Base or come in contact with the connectors as it may damage the circuitry.
- Do not allow liquids to enter the openings for the heat plugger on the Downpack device or the elements gutta-percha cartridge on the backfill device as it may damage the circuitry.

1 Cleaning the Backfill Device, Downpack Device and Charging Base

Preparation for the device cleaning:

- Carefully discard examination gloves, rinse and disinfect hands using an appropriate hand disinfectant solution and use a new pair of examination gloves.
- Remove the cartridge/heat plugger from the Backfill device/Downpack device prior to cleaning.
- Follow standard precautions for personal protection using cleaning agents/disinfectant solution as recommended by the manufacturer.

Clean and disinfect the elements™ IC obturation system immediately after each patient use following the cleaning and disinfection steps to prevent drying of soil and contaminants and to avoid the risk of cross-contamination between patients.

Cleaning:
Clean all the surfaces with CaviWipes™ or a cloth lightly moistened with other intermediate level disinfectant per manufacturer instructions. Use a cotton swab and a small, soft brush moistened with CaviCide™ or other intermediate level disinfectant to remove any soil that may have accumulated in crevices (e.g. between Ring Switch and the body of the device, between the LCD display and the body of the device). Wipe the device with additional CaviWipes™ or cloths lightly moistened with intermediate level disinfectant until no visible soil is detected on the cloth. Visually inspect the device/charging base to assure cleanliness. If any contamination is visible, repeat the cleaning steps. Use one more CaviWipes™ or a cloth moistened with disinfectant to ensure that no residual contaminants are left on the device.

Disinfection:
After performing the cleaning procedure above, complete disinfection of the device by using a new CaviWipes™ or a cloth lightly moistened with other intermediate level disinfectant. When using CaviWipes™, all device surfaces should remain visibly wet for at least three minutes. For other intermediate level disinfectant, refer to the disinfectant manufacturer's instructions for recommended contact time. Use a clean cloth lightly moistened with distilled water and wipe all device surfaces. Device is ready for reuse when all surfaces are visibly dry.

2 Cleaning and Sterilization of the Heat Plugger

The heat plugger must be cleaned and sterilized after each use.

Cleaning:
Remove the heat plugger from the Downpack device. Clean with water and mild, nonabrasive detergent such as dishwashing liquid using a soft bristled brush until all visible soil is removed. Rinse with clean running water for a minimum of 30 seconds.
Visually inspect for cleanliness and for any damage or contamination. If any contamination is visible, repeat the cleaning steps until there is no visible contamination. Dry with a clean, lint free cloth until there is no visible moisture.

Sterilization:
Place the heat plugger in a sterilization pouch suitable for steam sterilization. Sterilize the heat plugger using one of the cycles listed in section 4 - Recommended Sterilization Parameters.

3 Cleaning and Sterilization of the Cartridge Needle Bender

The Cartridge Needle Bender must be cleaned and sterilized after each use.

Cleaning:
Prepare an ultrasonic bath with an enzymatic cleaning solution at the concentration and temperature specified by the manufacturer of the enzymatic solution. Place Cartridge Needle Bender in the ultrasonic bath for 10 minutes. Remove the Cartridge Needle Bender from the bath and rinse with clean running water for a minimum of 30 seconds. Visually inspect for cleanliness and for any damage or contamination. If any contamination is visible, repeat the cleaning steps until there is no visible contamination. Dry with a clean, lint free cloth until there is no visible moisture.

Sterilization:
Place the Cartridge Needle Bender in a sterilization pouch suitable for steam sterilization. Sterilize the Cartridge Needle Bender using one of the cycles listed in section 4 - Recommended Sterilization Parameters.

4 Recommended Sterilization Parameters

Moist Heat Sterilization		
Cycle	**Gravity Displacement***	**Pre-Vacuum**
Temperature (°C)	121°C (250°F)	132°C (270°F)
Exposure Time (minutes)	30 minutes	4 minutes
Drying Time (minutes)	30 minutes	20 minutes

* The sterilization process of the Needle Benders was validated within fully loaded chamber using steam gravity displacement sterilization cycle.

STORAGE AND DISPOSAL

- After sterilization, place the pouches containing the devices in a dry and dark place such as a closed cupboard or a drawer.
- Follow the instructions provided by the pouch manufacturer regarding storage conditions and maximum allowed time in storage.
- For proper disposal always follow local and regional laws (i.e. The Waste Electrical and Electronic Equipment - WEEE).

TROUBLESHOOTING GUIDE AND TECHNICAL SUPPORT

If a problem occurs with your device, refer to the guide below. If this guide does not resolve the problem, contact Customer Care at 1-800-537-7123 (Available from 6:00am to 4:00pm PST). Outside of these hours, email us at KerrCustCare@kavokerr.com. Alternatively, contact your dealer or Kerr Endodontics sales representative.

Problem	Cause	Solution
Device(s) do not turn on	Battery out of charge	Place the devices on the Charging Base.
Charging base light(s) do not turn on	Base is not getting power	Ensure wall outlet has power. Check and adjust all connections: wall-outlet plug, power cord plug into the transformer and the small plug into the Charging Base.
Charging base light(s) repeat flashing	Device(s) may not be fully seated	Gently wiggle the devices to ensure proper seat.
Heat plugger on Downpack unit is not heating	Heat plugger not seated into Downpack device	See Step 1 in DOWNPACK section.
	Heat plugger tip is burned out	Replace the heat plugger.
	Battery is out of charge	Check battery level on display. If battery level indicator is low, place the device on the Charging Base.
Device(s) not heating	Battery is out of charge	Check battery level on display. If battery level indicator is low, place the device on the Charging Base.
Obturation material/ gutta-percha do not extrude	Motor is stuck or plugged due to gutta-percha in the Backfill device	Heat up the Backfill device. Press Reverse button. DO NOT disassemble the device(s).
	Temperature not set correctly	Adjust temperature setting. See Step 4 in the GETTING STARTED section; See "Changing Temperature Presets" in the ADVANCED SETTINGS section.
	Elements gutta-percha cartridge is empty or defective	Replace elements gutta-percha cartridge.
Unable to remove used elements gutta-percha cartridge from Backfill device	Plunger inside the Backfill device is stuck	Let the Backfill device heat up. Press Reverse button. DO NOT disassemble the device(s).

Problem	Cause	Solution
The light on charger fails to turn from orange to blue	Battery may be near end-of-life	Wait at least 4 hours. If unit fails to reach full charge, replace battery. Only use Kerr Endodontics battery.
Battery becomes exhausted quickly	Battery may be near end-of-life	Replace battery. Only use Kerr Endodontics battery. Note: On the Backfill device, battery has enough power for at least two procedures. It is recommended to place the device on the Charging Base between uses.
LED on the Charging Base blinks every two seconds (Or within seconds)	Incorrect charging	Remove device from the Charging Base and recharge. If the problem continues, then unplug the transformer from the dock and plug it again.
Device shows 'ERROR CODE' (ERROR CODE #1 ~ 5)	One or more internal components are not working properly	Contact Customer Care to get the device repaired.

SPECIFICATIONS

- Battery: 3.6 V, 1900 mAh Li-Ion, 6.8 Wh
- Adapter: Input: 100-240V~, 50/60 HZ, Output 9V == 2A
- Downpack: ~161mm x 33mm x 30mm (L x W x H), ~100 g
- Backfill: ~206mm x 33mm x 30mm (L x W x H), ~172 g
- Device: IEC 60601-1 Edition 3.1, Class I, patient contact, Type B Applied part
- Mode of Operation: Continuous Operation
- Wireless Charging Frequency:
  - Dual charger: 143.96kHz
  - Single charger (Backfill): 146.7kHz
  - Single charger (Downpack): 147.1kHz

Storage and Transport Conditions:	Conditions for use:
-20°C (-4°F) 50°C (122°F) Temperature	10°C (50°F) 35°C (95°F) Temperature
10% 90% Atmospheric Pressure	30% 75% Atmospheric Pressure
500 hPa 1400 hPa Atmospheric Pressure	697 hPa 1013 hPa Atmospheric Pressure
	0-10,000 ft. Altitude Limitation

WARRANTY

Kerr Endodontics warrants the system (excluding batteries) to be free from defects in materials or workmanship for period of 2 years from the original date of purchase. The batteries are warrantied for a period of 6 months from the original date of purchase. If the system shows any defect within the warranty period that are not excluded from this warranty, Kerr Endodontics shall, at its sole discretion, either replace or repair the device using suitable new or reconditioned parts. In the case other parts are used which constitutes an improvement, Kerr Endodontics may, at its discretion, charge the customer for the additional cost of these parts. If the warranty claim provides to be justified, the product will be returned to the user freight prepaid. Warranty claims other than those indicated herein, are expressly excluded.

EXCLUSIONS

Damage and defects caused by the following conditions are not covered by the warranty:

- Improper handling/disassembly/modifying, neglect, or failure to operate the unit in compliance with the instructions given in this manual.
- Force majeure or any other condition that is beyond the control of Kerr Endodontics.
- Damage caused by customer misuse or uses other than those specified.

DISCLAIMER

For safety reasons, this product should be used with accessories manufactured and sold by Kerr Endodontics. 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. Kerr Endodontics does not assume any responsibility for incorrect diagnosis due to operator error or equipment malfunction.

PART NUMBERS

Parts	Reorder Code
elements™ IC Obturation System	973-0600-TYPEX*
Downpack Unit	973-0602-TYPEX*
Backfill Unit	973-0604-TYPEX*
Dual Charger	973-0610
Single Charger	973-0612
Transformer	973-0615
Power Cord	973-0616-TYPEX*
Battery	973-0620
Heat Pluggers	**Reorder Code**
Medium Large (ML)	952-0007
Medium (M)	952-0006
Fine Medium (FM)	952-0005
Fine (F)	952-0004
Extra-Fine (XF)	952-0031
elements Cartridge	**Reorder Code**
Gutta Percha, Medium Body, 23 Gauge - SILVER	972-1002
Gutta Percha, Heavy Body, 23 Gauge - SILVER	972-1005
Gutta Percha, Light Body, 25 Gauge - SILVER	972-1003
Gutta Percha, Medium Body, 23 Gauge - GOLD	972-2500
Gutta Percha, Heavy Body, 23 Gauge - GOLD	972-2502
Gutta Percha, Light Body, 25 Gauge - GOLD	972-2501

Gutta Percha SILVER

Gutta Percha GOLD

NOTE:
Elements gutta-percha cartridges availability might be different depending on different regions of the world.

*X designates plug type		
Type B		
Type F		
Type G		
Type I		
Type N		

ELECTROMAGNETIC COMPATIBILITY

Medical Electrical Equipment requires special precautions regarding electromagnetic compatibility. elements IC needs to be installed and put into service according to the electromagnetic compatibility information provided in these instructions. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

⚠ WARNING:
The use of accessories and options other than those specified by the manufacturer may result in increased emissions or decreased immunity of elements IC. In the event of intermittent function of the device due to exposure to electromagnetic interference, power cycle the unit as per IFU instructions provided above.

In the event of permanent damage or display blackouts of the device due to electromagnetic interference, stop use of the unit. Contact Kerr Customer Care.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of elements IC. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – electromagnetic immunity

elements IC is intended for use in the electromagnetic environment specified below. The customer or the user of elements IC should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3* Vrms 0.15 MHz – 80 MHz 80% AM at 1 kHz	3* Vrms 0.15 MHz – 80 MHz 80% AM at 1 kHz	The distance between transmitting antenna and EUT was at least 3 meters for proximity field RF wireless communication equipment testing. The testing was performed with 1.85 m AC/DC adapter cable bundled to 1 meter
Radiated RF E M F i e l d s IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz, 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz, 80% AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity Fields from RF Wireless communications equipment IEC 61000-4-3	Table 9 of IEC 60601-1-2 ed. 4.0	Table 9 of IEC 60601-1-2 ed. 4.0	

NOTE 1: *6 Vrms in the ISM Bands and Amateur Radio Bands

The ISM band is 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

NOTE 2: elements IC unit was tested at 120 VAC/60 Hz, 230 VAC/50 Hz and 100 V 50/60 Hz.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Guidance and manufacturer's declaration – electromagnetic emissions

elements IC is intended for use in the electromagnetic environment specified below. The customer or the user of elements IC should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	elements IC uses RF energy only for its internal function. elements IC deliver energy to the patient in a form other than RF electromagnetic.
RF Emissions CISPR 11	Class B	elements IC is suitable for use install establishments with public low-voltage network that supplies buildings used for domestic purposes and professional healthcare facility environment (e.g. hospital) with dedicated power supply system.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

elements IC is intended for use in the electromagnetic environment specified below. The customer or the user of elements IC should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	elements IC complies antistatic material and synthetic material with relative humidity level as low as 10%.
Electrical fast transient/ burst (Power Lines) IEC 61000-4-4	±2 kV, 100 kHz repetition frequency	±2 kV, 100 kHz repetition frequency	elements IC is suitable for use in all establishments with public low-voltage network that supplies buildings used for domestic purposes and professional healthcare facility environment (e.g. hospital) with dedicated power supply system.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to ground	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to ground	elements IC is suitable for use in all establishments with public low-voltage network that supplies buildings used for domestic purposes and professional healthcare facility environment (e.g. hospital) with dedicated power supply system.
Voltage dips and Voltage interruptions on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at single phase (0°) Voltage interruptions: 0% UT, 250/300 cycle	Voltage dips: 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at single phase (0°) Voltage interruptions: 0% UT, 250/300 cycle	elements IC is suitable for use in all establishments with public low-voltage network that supplies buildings used for domestic purposes and professional healthcare facility environment (e.g. hospital) with dedicated power supply system.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m; 50 Hz or 60 Hz	30 A/m; 50 Hz and 60 Hz	elements IC is suitable for use in all establishments with public low-voltage network that supplies buildings used for domestic purposes and professional healthcare facility environment (e.g. hospital) with dedicated power supply system.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

IMPORTANT! Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

FCC Radiation Exposure Statement

The equipment complies with FCC Radiation exposure limits set forth for uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. To maintain compliance with FCC RF exposure compliance requirements, please follow operation instructions as documented in this manual. This equipment should be installed and operated with a minimum distance of 10 cm between the radiator and your body.

Industry Canada Statement

This device complies with RSS-216 of Innovation, Science and Economic Development Canada's rules. Operation is subject to the following two conditions:
(1) This device may not cause interference, and
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Radiation Exposure Statement

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment and meets the ISED radio frequency (RF) Exposure Guidelines. It is desirable that it should be installed and operated keeping the radiator at least 10 cm or more away from person's body.

Innovation, Science and Economic Development Canada Statement

This digital apparatus complies with CAN ICES-3(B)/NMB-3(B).

Manufactured for Kerr Corporation
200 S. Kraemer Blvd.
Brea, CA 92821 USA
1-800-KERR-123 | kerrdental.com

Distribution Facility:
Kerr Australia Pty. Ltd.
Unit 6, 12 Mars Road
Lane Cove West, New South Wales 2066
Australia
+61-2-8870-3000

META SYSTEMS CO., LTD.
#1214-18, Sicox tower 12F,
484, Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do,
13229, Korea

MADE IN KOREA

EC REP Meta Biomed Europe GmbH
Wiesenstr. 35, 45473
Mülheim an der Ruhr, Germany
Tel +49 208 30991910
Fax +49 208 30991999

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