INSTRUCTIONS FOR USE (IFU)

ROOTBUDDY SYSTEM cordless dental device

1. Charge the RootBuddy for 24 hours after a battery pack change.

To extend the lifetime and re-activation of the batterypack, first charge the battery to its full capacity (e.g. 24 hours charge). Once fully charged, use your RootBuddy continuously to discharge the battery. If the battery is discharged, charge the battery again. Repeat if necessary.

Your device is now ready for use.

The intended use is to provide continuous heat and/or vibration at the tip of a dental instrument. RootBuddy is designed for processing dental material (applying, cutting, softening, spreading, compacting) and cutting plastic handles of obturators during a root canal treatment. The dental instrument heater can also be used for diagnosis the vitality of teeth by heat and/or vibration.

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CE 0344

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Welcome

Thank you for purchasing the RootBuddy device. The revolutionary RootBuddy device offers optimum functionality and quality. The cordless device is fully compatible with standard obturation techniques and is proven effective for downpack obturation of the root canal system.

The RootBuddy is a versatile endodontic device for use in the following root canal obturation techniques:
- Softening root canal filling material
- Spreading root canal filling material laterally and vertically
- Compacting root canal filling material using vibration and heat, separately or in combination
- Cutting points (cones) of root canal filling materials
- Cutting plastic obturator handles

This IFU provides detailed operating and setup instructions. It is important to read this IFU before operating the device. Store the IFU near the device for reference. Nikinc reserves the right to change this IFU or the product described herein at any time without notice. The most current version of this IFU may be downloaded from www.nikincdental.com.
Note: This IFU is not intended to substitute for accredited instruction or experience in dental/endodontic techniques.

1. Important safety instructions

To reduce the risk of injury and to maintain the RootBuddy device in good condition, always observe the precautionary information listed below as well as other warnings and cautions throughout this IFU. Read and familiarize yourself with these precautions and the rest of the IFU before using the device on patients.

Warnings indicate information which, if not observed, could result in injury to the patient, operator, or observers, and possibly damage the device.

WARNING
- The RootBuddy device is designed solely for heat softening and condensing root canal filling materials during root canal treatment and is intended exclusively for use by trained, qualified dentists and specialists only. Any other use or use beyond that specified in this IFU is deemed incorrect usage. The manufacturer accepts no liability for damage resulting from incorrect usage. All risks associated with the use of the device are borne solely by the user.
- Practice the technique and use of the device before using with patients.
- To reduce the risk of explosion, do not use in the presence of flammable anesthetics or in areas where there is a risk of explosion.
- The tips can reach temperatures up to 350° C (662° F) or slightly higher. To help prevent injury, do not allow the tip to contact the patient or operator when activated, other than in the appropriate performance of obturation procedures.
- To help prevent injury to the patient, do not keep a heated tip in the root canal for more than 4 seconds.
- New tips are not sterile and must be sterilized before use. Clean, disinfect, inspect, and sterilize tips using an autoclave before each use.
- Tip temperature is displayed in degrees Celsius only, not Fahrenheit.
- The maximum recommended temperature setting for NiTi Tips is the default 220° Celsius, for durability and to preserve NiTi memory characteristics.
- Do not use on patients with pacemakers.
- Use only the power adapter supplied with the RootBuddy device. Use of any other power adapter may damage the charger or handpiece, or result in risk of fire or electric shock, and will void the warranty.
- Use RootBuddy tips and accessories listed in §11 only. Use of any other tips or accessories may cause damage, injuries or loss of performance and will void the warranty.
- US federal law restricts this device to sale by or on the order of a healthcare professional.
- To reduce the risk of electric shock, do not attempt to open the handpiece other than to replace the battery pack. Do not attempt to disassemble the battery pack or charger.

Cautions indicate information which, if not observed, could result in damage to equipment.

CAUTION
- Before using the RootBuddy device for the first time, it must be charged continuously for 24 hours. Failure to fully charge the battery pack before first use may result in decreased battery pack life.
- When replacing the battery pack, insert the battery pack gently and do not attempt to disassemble the handpiece in a manner other than that as described in this IFU.
- Do not expose the power adapter, charger, handpiece, or battery pack to extreme temperatures or open fire. Operate in ambient temperatures ranging from +10°C to +40°C (50° F to 104° F).
- Do not submerge the charger, power adapter, or handpiece in liquid of any kind.
- Check the RootBuddy device and power adapter for damage before connecting to the electrical outlet. Contact your dealer for

replacement parts/ repair information.
- Before connecting the charger and the power adapter to the electrical outlet, ensure that the electrical current and voltage at the electrical outlet are compatible with that of the power adapter. Power adapters compatible with most common electrical systems are available.

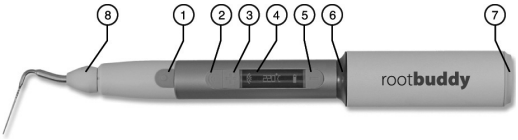
Notes provide information supplemental to the text.
Note: For more information on how to use the RootBuddy device in a root canal treatment, please review the separate technique guide.
Note: Read this IFU before using the RootBuddy device.

2. Package contents

As you remove each item from the box, check it against the items described below to make sure you have everything. If items are missing or damaged, contact your local dealer. Save the box for reuse if the product requires storage or must be returned to the manufacturer.
The package contents are: Handpiece, Charger, Power adapter, Instructions for use

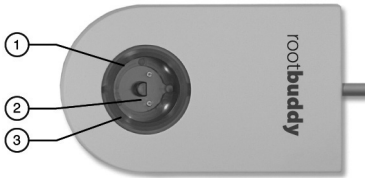
3. Product features

HANDPIECE: Cordless handheld obturation device that utilizes heat and/or vibration to precisely soften and compact obturation materials



1. Operation button: Press to initiate tip heat/vibration (if a temperature preference setting is selected and/or vibration button is pressed). Release to stop tip heat/vibration. Also used to program preferred settings.
2. Vibration button: Activates/deactivates vibration feature.
3. + Adjustment button: Increases tip temperature when pressed.
4. Display: See §5.1 for description.
5. – Adjustment button: Decreases tip temperature when pressed
6. Blue activation indicatorlights when tip is heated and/or vibrating.
7. Rechargeable Battery Pack (inside handpiece)
8. Tip: §11 lists compatible tips.

CHARGER: Charges handpiece battery pack when handpiece is placed in charger.



1. Charger port: Place handpiece in port when not in use to maintain battery pack charge.
2. Charger contacts: In order for battery pack to charge, handpiece contacts must align with charger contacts.
3. Blue indicator light:

- Lights dimly when charger is plugged into mains but handpiece is not inserted.
- Flashes brightly when charger is plugged in, handpiece is in charger port, and battery pack is charging.
- Lights brightly when charger is plugged in, handpiece is in charger port, and battery pack is fully charged.
- Off when charger is unplugged from mains or electrical power is not present.

4. Getting started

4.1. Connecting the charger
CAUTION
- For proper operation, the ambient temperature where the device will be installed and used must be in the range of +10° C to +40° C (50° F to 104° F).
- The power adapter and charger must be installed and used in a dry environment. If the charger becomes wet, unplug it immediately and dry completely before plugging it in and inserting the handpiece.
- Do not place the handpiece into the charger until it has reached room temperature. Humidity and condensation could damage the electronics.
- The power adapter is designed for use within a voltage range from 100-240 V AC, 50-60Hz. Ensure that the required voltage is available before connecting the charger to the power adapter. Failure to do so may damage the charger or the handpiece.
- Use only the power adapter supplied with the RootBuddy device.
- Do not use a power adapter other than the designated Nikinc model. Do not use the charger unless the power adapter plug is firmly inserted into the electrical outlet.

1. Plug the power cord plug into the receptacle in the charger.
2. Guide the cord through the cut-away in the charger housing.
3. Place the charger on a level and secure surface.
4. Insert the plug on the power adapter completely into the wall electrical outlet. Verify that the blue light in the charger illuminates when the power adapter is plugged in.

4.2. Charging the battery pack
CAUTION
- Before using the handpiece for the first time, allow the battery pack to charge for 24 uninterrupted hours.
- Ensure the handpiece end cap contacts touch the charger contacts.
- If the handpiece does not fit properly in the charger, do not force fit the handpiece.
- Approximate battery pack charge is indicated on the handpiece display. When the battery pack is discharged, the battery symbol appears empty and the handpiece will not operate. Place the handpiece in the charger as soon as possible to charge the battery pack. Allow the battery pack to charge for 24 uninterrupted hours before attempting to use the handpiece after an empty battery pack condition occurs.

Note: The handpiece will not operate while it is in the charger.

To charge the battery pack:
1. Place the handpiece vertically in the charger so its the RootBuddy-logo is oriented to the front side. The handpiece battery pack is charging whenever the handpiece is in the charger (and the charger is connected). The handpiece beeps when it is placed in the charger.
2. Observe that the brightness of the blue light in the charger increases when the handpiece is placed into the charger. The light flashes to indicate that the battery pack is charging.
3. Charging is complete and the handpiece is ready for use when the flashing stops and the charger light remains brightly lit.

4.3. Battery safety
WARNING
- To help prevent damage to the battery pack, charge only with the Nikinc charger provided with the RootBuddy device according to the instructions provided in this IFU.
- Do not open, incinerate, burn, or short circuit the battery pack. The battery pack may ignite, explode, leak, or overheat, which may result in personal injury.

- Do not drop, hit or otherwise abuse the battery pack as this may result in the exposure of corrosive chemicals in the battery pack.
- If fire or explosion occurs when handpiece is in the charger, unplug the charger immediately.
- In case of fire where NiMH batteries such as those used in the handpiece are present, apply a smothering agent such as METL-X, sand, dry earth, dolomite, or soda ash, or flood the area with water. Water may not extinguish burning batteries but will control the spread of fire. Burning batteries will burn themselves out. Virtually all fires involving NiMH batteries can be controlled with water.
- The battery pack is sealed. Do not open or rupture the battery pack. Opening the battery pack may result in leakage of battery pack contents, which are corrosive. Nickel, nickel compounds, cobalt, and cobalt compounds are listed as possible carcinogens by International Agency for Research on Cancer (IARC) or National Toxicology Program (NTP).
- Do not eat or swallow the battery pack. Contents of an open battery pack can cause serious chemical burns to mouth, esophagus, or gastrointestinal tract if swallowed. If battery pack or battery pack contents are ingested, do not induce vomiting or give food or drink. Seek medical attention immediately.
- Fumes from the contents of an open battery pack may cause respiratory irritation, or allergic pulmonary asthma in individuals with hypersensitivity to nickel. Provide fresh air and seek medical attention if exposed to fumes from a ruptured battery pack.
- Battery pack contents may cause skin irritation and/or chemical burns. Nickel, nickel compounds, cobalt, and cobalt compounds can cause skin sensitization and an allergic contact dermatitis. In case of contact with battery pack contents, remove contaminated clothing and wash skin with soap and water. If a chemical burn occurs or if irritation persists, seek medical attention.
- Battery contents may cause severe eye irritation and chemical burns. If contents of an open battery pack come into contact with the eyes, immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the chemical remains. Seek medical attention.

CAUTION
- Should a handpiece become disassembled, store the battery pack away from combustibles.
- Do not expose the battery pack to moisture.
- Dispose of the battery pack as chemical waste. Dispose in accordance with all applicable federal, state, and local regulations.

4.4. Inserting the tip
Note: Use RootBuddy device tips only.
Note: The tip may be placed in any of 8 different positions, each 45 degrees apart. The handpiece and tips are marked to indicate the 12 o'clock position.
Note: Do not activate the handpiece while inserting the tip.

1. Check that the tip and handpiece are clean and undamaged. See instructions accompanying the tip and "Cleaning and sterilizing the tips" on §8.
2. Carefully insert a tip that has been cleaned and sterilized into the handpiece, in the desired position.
3. Push the tip into the handpiece until it snaps securely into place.
4. Inserting a tip causes the handpiece to switch from OFF to operating mode. When this happens:
   - The handpiece beeps.
   - The RootBuddy name appears on the display.
   - The display then shows the default programmed temperature.
   - If the vibration feature is programmed, the vibration icon is also displayed.
   - The display will indicate battery charge level.
5. The handpiece is now ready for use.

5. RootBuddy device operation

Note: You may want to set operating preferences for the handpiece before using it on patients. The device's factory default settings remain in effect unless you program the preference settings. Your preference settings become the default settings each time the handpiece is powered on. For a list of the preference settings and instructions on how to set them, see "Programming preference settings" on §6.

Note: It is recommended that you follow the cleaning instructions for the tips and handpiece and place the handpiece in the charger as soon as possible after use. See "Cleaning" on §8.

5.1. Powering on
When the handpiece is off, its display is blank and the blue operation light is off. Pressing the operation button once causes the handpiece to beep and the display to light. If no tip is installed, the message "NO TIP" is displayed. The handpiece also turns on automatically when a tip is inserted.

If a tip is installed, the RootBuddy name appears on the display, followed by the programmed temperature, vibration icon (if selected) and battery charge indicator as shown below.

Note: If these indications do not occur as described, do not use the device. See "Troubleshooting" on §9.

The handpiece display is shown below and described in Table 1.

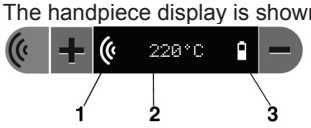


Table 1: Display indicators

Item	Description
1	Vibration icon: displayed when the vibration preference is set to VIBRATION ON and the Vibration button has been pressed. • If this icon is displayed, the tip will vibrate whenever the Operation button is pressed. • If this icon is not displayed, the tip will not vibrate.
2	Text area: During use, displays tip temperature setting (or "NO HEAT" if that is the preferred setting). During preference setup, programmable options and selections are displayed. See "Programming preference settings" on §6. Note: Tip temperature may be temporarily changed during use by pressing the + button or - button until the desired temperature is reached.
3	Battery charge icon: • When the handpiece is on, this icon displays one of 5 levels representing approximate battery pack charge remaining. When the battery pack is low, the battery charge icon appears empty and the handpiece will not operate. • The operation light on the handpiece flashes when the battery pack is low. Place the handpiece in the charger as soon as possible to recharge the battery pack if this occurs.

5.2. Operating the handpiece
WARNING
- Do not exceed 4 seconds in the root canal space.
- The tips can reach temperatures up to 350° C (662° F) or slightly higher. To help prevent injury, do not allow the tip to contact the patient or operator when activated, other than in the appropriate performance of obturation procedures.

CAUTION
- To facilitate cleaning, remove debris from tip as soon as possible after use.

The RootBuddy device is the most sophisticated heat and vibration controlled endodontic obturation device available in dentistry. The options to control and program this device enable you to set your personal preferences and settings as the default. Vibration can be switched on and off while temperature can be adjusted to related technique, use of materials, or tip styles and sizes.

- Root canal filling techniques vary and use of different filling materials can influence required temperatures. Also, root canal diameter, depth and total filling mass will influence the thermal characteristics

of the tips. During the obturation procedure, the device monitors and adjusts the programmed tip display to the required levels multiple times per second.
- While tip temperature is subject to numerous variables, and above all is strongly related to technique and personal preference, the RootBuddy device distinguishes the programmed display temperature as the approximate temperature of the tip during insertion in the gutta percha mass, which is lower than the temperature of the tip when measured in open air. Table 2 in this IFU indicates this relationship and variations thereof. Visit our website www.nikincdental.com for further details.
- While variation in tip temperature can also be generic to size and material, characteristics can change over time, so we recommend that you check new tips and older tips by cutting gutta percha or other filling material before use on patients.

Operation consists of tip heating and/or vibration, depending on the preference settings in effect, and is initiated when the user presses the operation button. During operation, the handpiece makes a sound and the blue operation light ring is lit. The + button and - button are disabled. The handpiece stops operating when the user releases the operation button or after a time-out of 60 seconds.

1. Depending on the preference settings, do one of the following to operate the handpiece:
   - Press and release operation button. The handpiece operates until you press operation button again to stop it.
   - Press and hold operation button to sustain operation. Release operation button to stop operation.
2. To initiate vibration, press the vibration button. The vibration preference must be enabled as indicated by the vibration icon on the display.

5.3. Adjusting tip temperature
The tip temperature can be adjusted up or down as required. The tip heats to the preferred tip temperature setting when operation button is pressed. Temperature adjustments remain in effect until the handpiece is powered off or the temperature is adjusted again.

To adjust temperature:
- Briefly press and release + button to increase or - button to decrease. Each keypress adjusts the temperature by one bar.
- To turn the tip heat off, press - button to reduce the temperature until “NO HEAT” is displayed.

5.4. Powering off
The handpiece turns off automatically after 60 seconds of inactivity (no buttons pressed). Do not touch the tip while the handpiece is still operating.

6. Programming preference settings

The settings listed in Table 2 can be set to the user’s preferences. The programmed preference settings become the default setting each time the handpiece is used. During use, the temperature can be temporarily adjusted at any time as required. Table 2 lists the programmable settings in the order they appear on the device, and describes the options available for each. The preferences may be reprogrammed at any time if desired.

Table 2: Preference setting options

Setting	Options	Description
Tip temperature	220°C (default)	Default temperature setting
	|||| 220°C	Lowest temperature setting (approximately 50° C)
	220°C ||||	Highest temperature setting (approximately 350° C)
	Variations between	Each bar gradually increases/decreases the temperature to the maximum/minimum temperature setting.
	NO HEAT	Indicates no tip temperature. Press - button until “NO HEAT” is displayed.
Vibration	VIBRATE ON (default)	Tip vibrates at a frequency of 100 Hz.
	VIBRATE OFF	Vibration icon is not displayed. Tip will not vibrate.
Sound	SOUND LOW (default)	Continuous soft tone whenever handpiece is operating.
	SOUND HIGH	Continuous louder tone whenever handpiece is operating.
	BEEP LOW	Soft beep every 4 seconds while handpiece is operating
	BEEP HIGH	Louder beep every 4 seconds while handpiece is operating
Activation Mode (Press or Hold)	HOLD MODE (default)	The user must press and hold operation button to initiate and continue handpiece operation. The handpiece operates as long as operation button is held. The handpiece stops operating when the user releases operation button or after 60 seconds have elapsed.
	PRESS MODE	The user must press and release operation button to start handpiece operation. Operation continues until the user either presses operation button again, or until 60 seconds have elapsed.
	DUAL MODE	In Dual mode, the user has two options to activate the handpiece: • Pressing and releasing operation button causes the handpiece to turn on and stay on for 60 seconds or until the user again presses and releases the operation button.
	DUAL MODE (continued)	• Pressing and holding operation button causes the handpiece to operate for as long as the operation button is pressed. Operation stops when the button is released, or when 60 seconds have elapsed.
Left or right handed use	R HANDED USE (default)	Text on the display is oriented for proper viewing when handpiece is held in the right hand.
	L HANDED USE	Text on the display is oriented for proper viewing when handpiece is held in the left hand. (text rotated 180 degrees).
Reset all options to factory default settings	RESET DEVICE	Restores all programmable settings to the factory default when selected.

6.1. Programming mode overview
Note: A tip must be inserted into the handpiece in order to enter programming mode.
Note: Preferred temperature and vibration settings apply to any tip inserted in the handpiece.

Program any or all preference settings when the handpiece is in programming mode. Place the handpiece in programming mode and change one or more settings at any time if desired. Use the programming menu to reset all options to the factory default settings if desired.

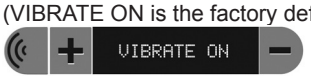
The following is an overview of the programming procedure.
1. To enter programming mode: press and hold + button and – button simultaneously for 1 second. The display flashes.
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. Press + button or – button until the desired setting is displayed. Refer to Table 2 for all options and available preference settings.
6. When the desired setting is displayed, press operation button again to confirm your selection. The display stops flashing.
7. Repeat steps 3 – 6 as necessary until all options have been set.
8. To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operating mode.

6.2. Setting temperature preference
WARNING
The handpiece displays temperature in degrees Celsius (° C) only. The maximum temperature the tip can reach is 350° C (662° F). Ensure the tip temperature setting is appropriate for the obturation techniques you will be performing with the handpiece.

1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows currently selected tip temperature preference (220° C is the factory default).

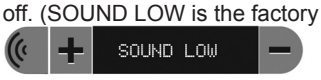
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. To change temperature:
   - Temperature can be set to clinician's preferred setting by pressing the + button or – button (when + button or – button is pressed, one bar above or below 220°C will appear on the display screen to indicate temperature setting.
   - To choose no tip heat as the preferred setting, press – button as many times as required to reduce the temperature until "NO HEAT" is displayed.
6. When the desired temperature is displayed, press operation button to confirm your selection.
7. Do one of the following:
   - To program the next option, press the + button.
   - To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operating mode.

6.3. Setting vibration preference
The Vibration icon is displayed when the vibration feature is enabled. (VIBRATE ON is the factory default).



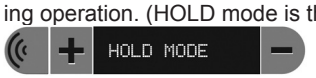
1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows the currently selected tip temperature preference.
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. Select the desired vibration setting using the + button or – button.
6. Confirm the setting by pressing operation button.
7. Do one of the following:
   - To program the next option, press the + button.
   - To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operatingmode.

6.4. Setting sound preference
The sound preference determines the audible tone emitted by the handpiece during operation. The sound cannot be turned completely off. (SOUND LOW is the factory default).



1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows the currently selected tip temperature preference.
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. To change sound: press + button or – button until selected sound preference is displayed.
6. When the desired setting is displayed, press operation button to confirm your selection.
7. Do one of the following:
   - To program the next option, press the + button.
   - To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operating mode.

6.5. Setting tip activation preference
(HOLD, PRESS, or DUAL MODE)
The Mode preference determines how the user activates the tip during operation. (HOLD mode is the factory default.)



1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows the currently selected tip temperature preference.
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. Press the + button or – button to select one of the three settings.
6. When the desired setting is displayed, press operation button to confirm your selection.
7. Do one of the following:
   - To program the next option, press + button the button.
   - To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operating mode.

6.6. Setting display orientation preference
(LEFT or RIGHT-HANDED)
The display orientation preference determines the orientation of the text on the display, allowing the display to be readable when held in the user's left or right hand (right-handed use is the factory default).

1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows the currently selected tip temperature preference.
2. Press + button to enter the option list. The display stops flashing and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. Press the + button or – button to select left or right-handed setting.
6. When the desired setting is displayed, press operation button to confirm your selection.
7. You have finished setting the operating preferences. To exit the programming mode, again press and hold + button and – button simultaneously for 1 second. The handpiece returns to the operating mode.

6.7. Restoring factory default settings
The RESET DEVICE option returns all programmable preference settings to the factory defaults listed in Table 2.

To restore the factory default settings:
1. Enter programming mode: Press and hold + button and – button simultaneously for 1 second. The display flashes and shows the currently selected tip temperature preference.
2. Press + button to enter the option list. The display stops flashing

and displays the first option, which is the currently programmed temperature preference.
3. Press + button to advance to the next programmable option as listed in Table 2.
4. To select an option for programming, press operation button. The option starts flashing.
5. Press operation button when RESET DEVICE is displayed to confirm your selection.
6. Press + button to confirm that you wish to reset all preferences to the factory default settings.

The factory default settings will take effect and the device will return to operating mode.

7. Replacing the battery pack

To remove/replace the battery pack:
1. Remove the battery pack by pressing the small pin on the bottom of the handpiece.
2. Pull the battery pack out of the handpiece.
3. Install the new battery pack by gently inserting it into the handpiece and snapping the circular bottom into place. The battery pack can only be inserted one way. The pin must snap into the housing.

For detailled replacement instructions look at www.nikincdental.com.

8. Cleaning

WARNING
- New tips are not sterile and must be sterilized before use. Clean, disinfect, inspect, and sterilize tips using an autoclave before each use.
- Do not submerge the handpiece or charger in liquids of any kind.
- Always disconnect the charger from the power supply before cleaning the charger.

CAUTION
- To prevent damage to the tips, do not clean the plastic tip handle with acetone or any cleaning products containing phenols.
- Do not expose tips to phenols, iodophors or dry heat sterilization.

8.1. Cleaning the handpiece
Remove handpiece from charger for cleaning. Clean the outer surface of the handpiece by wiping with a soft cloth dampened with pH neutral surface disinfection solution that does not contain phenols. Do not spray disinfection solution directly on the handpiece. Do not saturate the controls, display, or front portion of the handpiece.

8.2. Cleaning the charger
Remove the handpiece from the charger. Disconnect the charger from the power supply. Clean the outer surface of the charger by wiping with a soft cloth dampened with pH neutral surface disinfection solution that does not contain phenols. Do not spray disinfection solution directly on the charger base (do not saturate).

8.3. Cleaning and sterilizing the tips
Remove all visible soil from the tips, then clean using ultrasonic cleaner or thermo-disinfector and steam sterilize before each use. Steam sterilize for a minimum of 3 minutes at 134ºC (274ºF). Do not heat above 135ºC (275ºF).
Clean, disinfect, inspect and steam sterilize tips using an autoclave before each use. Follow the instructions provided with the cleaning/sterilizing equipment.

9. Troubleshooting

Table 3 lists troubleshooting for problems that may occur. Perform the corrective actions in the order listed. If the problem cannot be resolved using the information in Table 3, discontinue use and contact your local dealer.

Table 3: Troubleshooting

Problem	Corrective Action
Device will not operate. Display is blank except for empty battery charge indicator.	Battery pack charge is too low to power the handpiece. Charge battery pack as soon as possible for 2.5 uninterrupted hours before attempting to use handpiece.
Handpiece does not work	• Ensure battery pack has been charged for 2.5 uninterrupted hours before use. • Replace damaged tip. • Check charger and power adapter for proper operation. • Replace battery pack.
Charger does not work	• With the handpiece removed, ensure the charger light is on. If charger light is not on, do the following: • Check that power adapter is plugged into power outlet and that the outlet is providing current. • Check that cable from power adapter to charger is undamaged and is plugged firmly into charger. • If charger light is still not on, contact your dealer for charger service information. • If charger light is on, place the handpiece firmly into the charger and check that the charger light becomes brighter. The light starts flashing when the battery pack is charging.
Charger does not work (continued)	If the battery pack is fully charged, the charger light remains steadily and brightly lit while the handpiece is in the charger. • If charger light does not start flashing: • Ensure the handpiece is placed firmly into the charger base. • If battery contacts of handpiece and/or charger are wet, do not use product. Dry immediately with air or wait until contacts are thoroughly dry before placing handpiece in charger. In case of poor electrical contact, contact your local dealer service representative. • Replace the battery pack. See §7. • If the charger still does not work, contact your dealer for service.
Display reads “TIP BROKEN”	• Replace damaged tip.
Display reads “NO TIP” when tip is inserted	• Replace damaged tip.
Tip does not heat	• Charge battery pack for 2.5 uninterrupted hours before use. • If “NO HEAT” is displayed, temperature is not enabled. For instructions on changing the temperature, see §5.3. • Replace damaged tip. • Replace battery pack.
Tip does not vibrate	• VIBRATE ON is not activated. • Charge battery pack for 2.5 uninterrupted hours before use. • Replace damaged tip. • Replace battery pack.

10.Disposal

10.1. Handpiece and charger disposal
Remove battery pack before disposal. Dispose of electronic parts, including printed circuit boards, as electronic waste. (In Europe, according to the WEEE directive 2002/96/EC.) Dispose of all other parts according to the relevant regulations concerning waste disposal. The RootBuddy device or its components may also be returned to Nikinc for disposal.

10.2. Battery pack disposal
Dispose of the battery pack as chemical waste. Dispose in accordance with all applicable federal, state, and local regulations.

11.RootBuddy device part codes

Parts, accessories and tips listed in the following table are available separately from Nikinc and are compatible with all RootBuddy devices. For a complete list of tips and accessories, visit www.nikincdental.com or contact your local dealer.

Part Code	Description
NRBUS	RootBuddy device US/Japan/Canada
NRBEU	RootBuddy device Europe
NRBUK	RootBuddy device United Kingdom
NRBAU	RootBuddy device Australia
RBHPE	Handpiece (all regions)
RBCHR	Charger (all regions)
RBPUS	Power Adapter US/Japan/Canada
RBPEU	Power Adapter Europe
RBPUK	Power Adapter United Kingdom
RBPAU	Power Adapter Australia

RBTXFR	Tip Plugger XF (stainless) ISO 030/.02
RBTFR	Tip Plugger F (Stainless) ISO 030/.03
RBTFMR	Tip Plugger FM (Stainless) ISO 040/.05
RBTMR	Tip Plugger M (Stainless) ISO 050/.07
RBTLR	Tip Plugger L (Stainless) ISO 050/.09
RBTXLR	Tip Plugger XL (Stainless) ISO 070/.11
RBTFU	Tip Plugger F (UltraSoft) ISO 030/.03
RBTFMU	Tip Plugger FM (UltraSoft) ISO 040/.05
RBTMU	Tip Plugger M (UltraSoft) ISO 050/.07
RBTXFN	Tip Plugger XF (NiTi) ISO 030/.02
RBTFMN	Tip Plugger FM (NiTi) ISO 040/.02
RBTMN	Tip Plugger M (NiTi) ISO 050/.02
RBTCSS	Cutting Spoon Small CSS.01
RBTCSL	Cutting Spoon Large CSL.49

SN/LOT number date code

(241) XXXXX (11) YY MM DD (10) XXXXXXX XX
Date Code

12.Technical specifications

Table 4: Handpiece and charger specifications

Item	Specification
Product Name	RootBuddy cordless dental device
Part Code Number	See list above
Classification	Class II (U.S.), Class IIa (EU)
Electromagnetic Compatibility	This device complies with EN 60601-1-2:2002 Medical. Electrical Equipment-Part 1: General Requirements for Safety, Amendment No. 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests.
Input voltage	12 VDC
Current	300 mA
Dimensions	Handpiece length: 170 mm (6.67 in.) Handpiece width: 22.7 mm (0.895 in.) Charger length: 100 mm (4 in.) Charger width: 60 mm (2.36 in.) Charger height: 25 mm (1 in.)
Weight	91.7 grams (3.2 oz.)
Time to recharge battery pack	2.5 hours
Operating time on single battery charge	approximately 15 minutes
Tip vibration frequency	100 Hz
Operating temperature range	+10° C to +40° C (50° F to 104° F)
Storage temperature range	-20° C to +40° C (-4° F to 104° F)
Operating relative Humidity	45% to 85% (non-condensing)
Storage relative humidity	0% to 90% (non-condensing)
Classification: Handpiece and Tips	Type BF applied part
Tip temperature range	approx. 50° C to 350° C (122° F to 662° F)
Tip dimensions	See www.nikincdental.com
Battery pack	• GP Nickel Metal Hydride (NiMH) • Nominal voltage: 4,8 VDC • Typical capacity: 520 mAh • Minimal capacity: 500 mAh
AC/DC power adapter	Medical power supply. See Table 5 for details

Table 5: AC/DC Power adapter specifications

Item	Specification
Input voltage	• USA/Jap/Can (part code RBPUS): 100/120 V AC • EU (part code RBPEU): 220 V AC • UK (part code RBPUK): 230/240 V AC • AUS (part code RBPAU): 230/240 V AC
Input Frequency	• USA/Japan/Canada (part code RBPUS): 60 Hz • EU/UK/AUS (part code RBPEU, RBPUK, RBPAU): 50 Hz
Input Current	200 mA
Output voltage / current	12 V DC / 700 mA
Output connector	2.1 mm x 5.5 mm diameter DC plug, center pin + voltage
Output cord length	1.7 m (5.6 ft.)
Type	Wall plug-in
Cooling	Convection
Electromagnetic Compatibility	• FCC class B, CISPR 11 class B • EN 60601-1-2:2002

13.Warranty and service information

13.1. Limited warranty
Nikinc warrants the RootBuddy handpiece, charging base and power adapter to be free from defects in materials and workmanship for 12 months. RootBuddy tips are warranted against defects in materials and workmanship for 90 days. Nikinc will, at its sole option and as your exclusive remedy, repair or replace such defective products.

To obtain warranty coverage, please contact your local dealer representative. Products submitted for warranty coverage should be securely packed and shipped postage pre-paid and insured with tracking coverage. Your dealer will be responsible for shipping the repaired or replacement product to you.

NIKINC DISCLAIMS LIABILITY AND IS NOT RESPONSIBLE FOR THE PERFORMANCE OR REPLACEMENT OF PRODUCT THAT HAS BEEN MISUSED, TAMPERED WITH, MODIFIED, RETIPPED OR REFITTED IN ANY MANNER OR IS BEYOND THE EXPECTED LIFE OF THE INSTRUMENT.

Nikinc DISCLAIMS LIABILITY, UNDER ANY APPLICABLE WARRANTY OR OTHERWISE, FOR DAMAGES ARISING FROM (1) THE USE OF COMMERCIAL GRADE WASHERS; (2) THE USE OF DENTAL AUTOMATED WASHER-DISINFECTORS WHERE MANUFACTURER'S PROCESSING GUIDELINES ARE NOT FOLLOWED; (3) REPAIR OR MODIFICATION BY ANY UNAUTHORIZED TECHNICIAN; (4) USE OF TIPS AND ACCESSORIES NOT MANUFACTURED BY NIKINC; AND (5) IMPROPER SET-UP, INSTALLATION OR USE OF THE DEVICE.

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NOTWITHSTANDING ANYTHING ELSE TO THE CONTRARY, NIKINC SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES, AND NIKINC'S TOTAL LIABILITY ARISING AT ANY TIME FROM THE SALE, USE OR MISUSE OF THE PRODUCTS SHALL NOT EXCEED THE PURCHASE PRICE PAID FOR THE PRODUCT. THESE LIMITATIONS APPLY WHETHER THE LIABILITY IS BASED ON CONTRACT, TORT, STRICT LIABILITY OR ANY OTHER THEORY.

13.2. Service
If the device should fail to operate correctly, contact your local dealer service representative.
Disclaimer Nikinc assumes no responsibility for incorrect diagnosis or poor results due to operator error or equipment malfunction.

14.Symbol definitions

Table 6: Symbols on product labeling and packaging

Symbol	Meaning
	Attention, consult instruction IFU
	Type BF equipment - applied part (applies to handpiece and all tips)
CE 0344	This symbol represents adherence to Council Directive 93/42/EEC (14 June 1993) of the European Communities concerning medical devices. The handpiece is classified as a Class IIa product and bears the CE marking.
	Manufacturer: Nikinc Dental B.V. High Tech Campus 10, The Netherlands Made in the Netherlands
	Storage temperature: -20° C to +40° C (-4° F to 104° F)
	Symbol (WEEE 2012/19/EU) For product disposal, ensure the following: • Do not dispose of this product as unsorted municipal waste. • Collect this product separately. • Use collection and return systems available to you. • Bar below bin: Product distributed after August 13, 2005. For more information on return, recovery or recycling of this product, please contact your local dealer.

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