

INSTRUCTIONS FOR USE (IFU)

USEFILL SYSTEM cordless dental device

1. Operate UseFill Heater

The UseFill Heater can only be activated when it is placed on the base station.

After the Heater is pre-heated (± 30 sec and 5 green LED's are bright) it can be transported to any place. The Heater can now be used stand-alone and is ready for use for at least 5 minutes.

The operation time can be extended by 5 minutes by pushing the operation button on the end of the 5 minute cycle indicated by a sound and a flashing operation button.

2. Charge UseFill Heater

After unpacking it is recommended to charge the Heater for 24 hours.

To extend the lifetime and re-activation of the batterypack, it is recommended to first charge the battery to its full capacity (e.g. 24h charge). Once fully charged, activate the UseFill Heater and take the Heater of the base station and let it run for 5 minutes. Then place the Heater back on the base station. Your device is now ready for use.

The intended use is to provide heat in an oven for heating obturators. UseFill Heater is designed for processing dental material (softening) during a root canal treatment.

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Table of Contents

1. Important safety instructions	1
2. Package contents	2
3. Product features	2
4. Installation	2
5. UseFill device operation	2
6. Replacing the Battery Pack	3
7. Cleaning	3
8. Troubleshooting	3
9. Disposal	3
10. UseFill device part codes	4
11. Technical specifications	4
12. Warranty and service information	4
13. Symbol definitions	4

Welcome

Thank you for purchasing the UseFill device. The revolutionary UseFill device offers optimum functionality and quality. The cordless device is fully compatible with standard obturator techniques. The UseFill is an endodontic device for use in the following root canal obturation techniques:

- Softening obturators

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.nikincedental.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 UseFill 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.

WARNING

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

- The UseFill device is designed solely for softening 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 inside of the Heater can reach temperatures up to 200° C (391° F) or slightly higher. To help prevent injury, do not remove the Lid when the Heater just has been activated. Let the Heater cool down before removing the Lid.
- Use only the Adapter supplied with the UseFill device. Use of any other Adapter may damage the Base Station or Heater, or result in risk of fire or electric shock, and will void the warranty.
- Use UseFill accessories listed in §10 only. Use of any other accessories may cause damage, injuries or loss of performance and will void the warranty.
- To reduce the risk of electric shock, do not attempt to open the device other than to replace the Battery Pack. Do not attempt to disassemble the Battery Pack or Base Station.
- 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 Heater is on the Base Station, unplug the Base Station immediately.
- In case of fire where NiMH batteries such as those used in the Heater 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

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

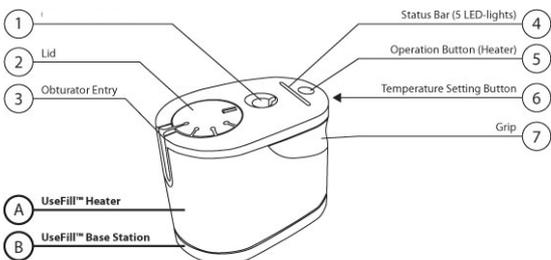
- Before using the UseFill device for the first time, it must be charged continuously for 24 hours. Failure to fully charge the Battery Pack before first use may result in decreased Battery Pack life.
- When replacing the Battery Pack disconnect the connector insert the Battery Pack gently and do not attempt to disassemble the Battery Pack in a manner other than that as described in §6 of this IFU.
- Do not expose the Adapter, Base Station, Heater 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 place the Heater on the Base Station until it has reached room temperature. Humidity and condensation could damage the electronics.
- Do not submerge the Base Station, Adapter or Heater in liquid of any kind.
- The Adapter and Base Station must be installed and used in a dry environment. If the Base Station becomes wet, unplug it immediately and dry completely before plugging it in.
- Check the UseFill Heater and Adapter for damage before connecting to the electrical outlet.
- Before connecting the Base Station and the Adapter to the electrical outlet, ensure that the electrical current and voltage at the electrical outlet are compatible with that of the Adapter. Adapters compatible with most common electrical systems are available.
- The 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 Base Station to the Adapter. Failure to do so may damage the Base Station or the Heater.

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 UseFill Heater-package contents are:

- Heater
- Base Station
- Adapter
- Instructions for use.



3. Product features

HEATER: Cordless handheld heating device.

1. (optional functionality)
2. Lid for placing 4 obturators
3. Obturator Entry to place in or take out of carousel
4. Status bar with five (5) green LED-lights
- 5a. Operation button: Press to start pre-heat of the oven to the desired temperature level. The Heater can only be activated when placed on the Base Station. When the Heater is used stand-alone the Operation button can be used to shut off the Heater.
- 5b. Operation button indicator light: When Operation button is white the Heater is standby for operation, and when Operation button is orange the Heater needs to be recharged. The Heater can be used on the Base Station, but must be charged before using stand-alone.
6. Temperature Adjustment button: For adjusting the temperature of the oven in five (5) different levels. Default temperature setting is position three (3), the middle position
7. Grip for a comfortable hold on the HEATER
8. Rechargeable Battery Pack (inside Heater)

BASE STATION: Charges Heater Battery Pack.

1. Base Station: Place Heater on Base Station when not in use to maintain Battery Pack charge.
2. Base Station contacts: In order for Battery Pack to charge, Heater contacts must align with Base Station contacts.

4. Installation

4.1. Connecting the Base Station

1. Plug the power cord plug into the receptacle in the Base Station.
2. Guide the cord through the cut-away in the Base Station housing.
3. Place the Base Station on a level and secure surface.
4. Insert the plug of the Adapter completely into the wall electrical outlet.

4.2. Charging the Battery Pack

1. Place the Heater correct aligned on the Base Station and the Heater will automatically be charged.
2. Approximate Battery Pack charge is indicated on the green status bar. When the Heater is placed on the Base Station the actual Battery Pack charge is indicated on the Status bar. The level is indicated by the 5 LED's which will light up. Five LED's is full battery charge and one LED is almost empty.
3. When the Operation button light is orange, then the Heater must be charged. With an orange Operation button light the Heater can only be used on the Base Station and cannot be used stand-alone.
4. When the Operation button light is white, the charging is complete and the Heater is ready for use and can be used stand-alone.

5. UseFill Device operation

WARNING

- In case (part of) an obturator is dropped into the heater turn of the device and let it cool down. Remove (part of) the obturator. If the inside of the heater can not be cleaned properly and safely or produces smoke, please contact your dealer. • The Lid can reach temperatures up to 70° C (158° F) or slightly higher. To help prevent injury, only rotate the carousel using the silicon handle. Do not touch the Lid surface when activated.



5.1. Standby-mode

When the UseFill device is installed and the Heater is charged and placed on the Base Station, the Operation button is emitting white light and the Heater is in the Standby-mode.

5.2. Pre-heat-mode

The Heater needs to be pre-heated before (stand-alone) use. The pre-heat of the Heater starts after activating the Operation button. The pre-heat will take approx. 40 sec. The timelapse of the pre-heat is indicated by the Status bar. The five green LED's are turning all green, starting with the first LED and flashing second LED until alle LED's are solid green. Then the Heater will beep twice and the Heater is in the Operation-mode (ready for use).

5.3. Operation-mode Heater

In the Operation-mode the Heater can be used standing on the base Station or it can be transported to another place and used stand-alone. Every 5 sec a beep indicates that the heater is in Operation mode. The timelapse of the Operation mode is indicated by the Status bar. The five green LED's are all solid green and every minute one LED will be turned off. The Heater in Operation-mode turns off automatically after 5 minutes. The Heater can also be turned off by pressing the Operation button. On the end of the 5 minutes cycle the Heater will beep twice and the Operation button will flash for 20 seconds. In this period the Operation button can be pushed to reactivate the Heater and start a new Operation-mode cycle of 5 minutes.

5.4 Charging-mode Heater

When the Heater is in use or not placed on the Base Station the battery charge can be too low to have sufficient capacity to provide enough power for stand-alone operation. In this case the Operation button will emit an orange light, indicating that the Heater needs to be recharged on the Base Station.

5.5. Programming Temperature Setting

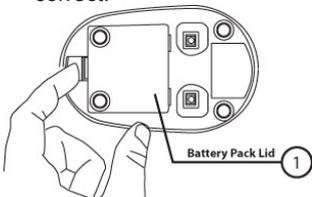
Note: You may want to set temperature setting preference for the Heater before using it on patients. The device's factory default settings are set to an average temperature setting, level 3 (the middle green LED of the Status bar indicates this level). Your preference settings become the default settings each time the Heater is powered on. The Heater temperature can be programmed in five (5) different temperature levels. By pressing the Temperature Setting Button the level can be changed. Every push on the button the level changes one level up or the loop will start again at level one.



6. Replacing the Battery Pack

To remove/replace the Battery Pack:

1. Remove the Battery Pack by removing the Battery Pack Lid on the bottom of the Heater.
2. Pull the Battery Pack out and disconnect the connector
3. Connect the new Battery Pack and gently inserting it into Heater.
4. Remount the Battery Pack Lid and make sure the clicker is snapped correct.



7. Cleaning

WARNING

- Do not submerge the Heater or Base Station in liquids of any kind.
- Always disconnect the Base Station from power supply before cleaning the Base Station.

CAUTION

- Make sure the Heater is cooled down before cleaning.

7.1. Cleaning the Heater

Remove Heater from Base Station for cleaning. Clean the outer surface of the Heater 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 Heater. Do not saturate the Operation button, Status Bar, Lid and the opening on top of the Heater.

7.2. Cleaning the Base Station

Remove the Heater from the Base Station. Disconnect the Base Station from the power supply. Clean the outer surface of the Base Station 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 Base Station (do not saturate).

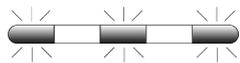
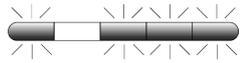
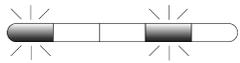
8. Troubleshooting

Table 1 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 1, discontinue use and contact your local dealer.

Table 1: Troubleshooting

Problem	Corrective Action
Device will not operate.	<ul style="list-style-type: none"> • Battery Pack charge is too low to power the Heater. Charge Battery Pack for 3 uninterrupted hours. • Check if adapter is connected to power outlet and cable-connector • Check if the power cord plug is plugged into the receptacle in the Base Station
Heater does not work	<ul style="list-style-type: none"> • Heater can only be activated when placed on the Base Station • Ensure Battery Pack has been charged for 3 uninterrupted hours before use. • Check Base Station and Adapter for proper operation. • Replace Battery Pack.
Operation button lights orange	<ul style="list-style-type: none"> • Place Heater on Base Station for charging the Battery Pack

Error Messages

- Error 1  Too Hot
- Error 2  No Lit
- Error 3  Contact dealer: NTC failure
- Error 4  Contact dealer: Wire failure
- Error 5  Fan Blocked

9. Disposal

9.1. Heater and Base Station disposal

Remove Battery Pack before disposal. Dispose of electronic parts, including printed circuit boards, as electronic waste. (In Europe, ac-

according to the WEEE directive 2012/19/EU.) Dispose of all other parts according to the relevant regulations concerning waste disposal. The UseFill device or its components may also be returned to Nikinc for disposal.

9.2. Battery Pack disposal

Dispose of the Battery Pack as chemical waste. Dispose in accordance with all applicable federal, state, and local regulations.

10. UseFill device part codes

Table 2: UseFill parts and accessories.

Part Code	Description
120 010	UseFill System Europe
120 011	UseFill System US/Japan/Canada
120 012	UseFill System United Kingdom
120 013	UseFill System Australia
120 014	UseFill Heater
120 015	UseFill 4 Obturator Lid
120 016	UseFill Base Station
120 017	UseFill Battery Pack
120 018	UseFill Adapter US/Japan/Canada
120 019	UseFill Adapter Europe
120 020	UseFill Adapter United Kingdom
120 021	UseFill Adapter Australia

SN/LOT number date code

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

11. Technical specifications

Table 3: Heater and Base Station specifications

Item	Specification
Product Name	UseFill cordless dental device
Part Code Number	See list above
Compatibility	This device complies with IEC61010-1, EMC EN 61326-1 and FCC Part 15B
Input voltage	15,0 VDC
Current	4,0 A
Dimensions	Device length: 130 mm (5,1 in.) Device width: 85 mm (3,3 in.) Device height: 110 mm (4,3 in.)
Weight	565 grams (19,9 oz.)
Time to recharge Battery Pack	2-3 hours
Operating time after pre-heat	approximately 5 minutes
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)
Battery Pack	• GP Nickel Metal Hydride (NiMH) • Nominal voltage: 9,6V • Typical capacity: 2250 mAh

Table 4: AC/DC Adapter specifications

Item	Specification
Input voltage	• USA/Jap/Can: 100/120 V AC • EU: 220 V AC • UK: 230/240 V AC • AUS: 230/240 V AC
Input Frequency	• USA/Japan/Canada: 60 Hz • EU/UK/AUS: 50 Hz
Input Current	1,7 A
Output voltage / current	15,0 VDC / 4,0 A
Output connector	2,5 mm x 5,5 mm diameter DC plug, center pin + voltage
Output cord length	1 m (3,3 ft.)
Type	Power Supply Table Top

12. Warranty and service information

12.1. Limited warranty

Nikincedental warrants the UseFill Device to be free from defects in materials and workmanship for 12 months. Nikincedental 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 CUTTING SPOON AND ACCESSORIES NOT MANUFACTURED BY NIKINC; AND (5) IMPROPER SET-UP, INSTALLATION OR USE OF THE DEVICE.

THE EXPRESS WARRANTIES DESCRIBED HEREIN AND ANY APPLICABLE IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS, ARE LIMITED AS HEREIN ABOVE STATED. EXCEPT AS SET FORTH HEREIN, DAMAGES FROM BREACH OF SUCH WARRANTIES ARE LIMITED TO THE COST OF REPAIR OR REPLACEMENT, AT NIKINC'S SOLE OPTION.

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.

12.2. Service

If the device should fail to operate correctly, contact your local dealer service representative.

12.3 Disclaimer

Nikincedental assumes no responsibility for incorrect diagnosis or poor results due to operator error or equipment malfunction.

13. Symbol definitions

Table 5: Symbols on product labeling and packaging

Symbol	Meaning
	Attention, consult instructions for use (IFU)
	This symbol represents adherence to Council Directive 93/42/EEC (14 June 1993) of the European Communities.
	Manufacturer: Nikincedental 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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