Loop™ LED Curing Light

CLK01

Instructions for use

Garrison®

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Prior to installation and start-up of the unit, please read these instructions carefully. The proper function and safe operation of this unit depend on the user's compliance with the standard safety procedures as well as the specific safety recommendations presented in these operating instructions. Do not discard these instructions for the duration of product use.

IMPORTANT: The unit must be fully charged for 3 hours prior to the first use. Refer to Section 4.10 "Charging and Batteries".

1. Product Overview

1.1 PRODUCT DESCRIPTION

Loop™ is a LED (Light Emitting Diode) light source for polymerization of dental materials for use by trained dental professionals. It is suitable for use with a broad range of light-cured dental materials including materials for restoratives such as light-cured and dual-cure cements, composites, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations such as ceramic inlays. Loop™ consists of a wireless handpiece and a charging base with an integrated calibration station. The device is a medical electrical device in accordance with IEC 60601-1-2.

Loop™ features a patented coaxial feedback sensing system that measures the actual irradiance, which is the light power striking the targeted tooth. The feedback data allows Loop™ to make corrective adjustments to the LED power output hundreds of times per second. This continually corrected "closed loop" operation ensures that the targeted surface of the restorative dental material receives the intended irradiance independent of operator-induced distance variations.

1.2 COMPONENTS

System components:

- 1 Loop™ LED curing light handpiece
- 1 Loop™ calibration and charging base
- 1 Loop™ universal power supply and adapters
- 1 Loop™ protective barrier sleeves pack
- 1 Loop™ protective light shield
- 1 Loop™ lens cleaning cloth (not shown)
- 1 Instructions for Use
- 1 Quick start guide

1.3 INDICATORS ON THE CHARGING BASE

A green light indicates that the charging base is receiving power.

1.4 INDICATORS ON THE CURING LIGHT HANDPIECE

A high-resolution OLED (Organic Light-Emitting Diode) color display screen will indicate the following:

1.4.1 Before the cure (powered up, but not curing):

Shipping lock screen

Power-up screen

Idle screen (closed-loop OFF)

Idle screen (closed-loop ON)

1.4.2 During the cure:

- Power bars show relative power output
- Cure time in seconds
- Progress bar shows passage of actual cure time

1.4.3 Immediately following the cure:

Successful cure and total joules delivered

1.5 OPERATING THE BUTTONS AND MODES

Turn on/Wake up: Press any button to turn on the handpiece.

Menu:  Press to select light irradiance or menu options.
Press & hold to cycle closed-loop ON/OFF.

Select:  Press to select cure time or setting options.
Press & hold to access preset settings.

Start/stop:  Press to start or stop a cure.
Press & hold to activate Tack mode

Turn off:  Press and hold simultaneously for 3 seconds (or until screen goes black) to force a shutdown and turn off.

Enter/Exit Settings:  Press and release both buttons simultaneously to enter or exit Settings.

1.5.2 Modes with Closed-Loop Operation

Direct Restorative Mode
(closed-loop ON)

1.5.3 Modes with Open-Loop Operation

Direct Restorative Mode
(closed-loop OFF)

Tack Mode

1.6 ACOUSTIC SIGNALS

Loop™ contains a resonate beeper. The volume can be set to on or off within the Settings. Refer to Section 4.3 "Settings". There are three types of beeps used in conjunction with the buttons and the OLED display screen during operation:

- Button press: a short beep indicates that a button press was recognized.
- Button hold: a second short beep indicates that a button hold was recognized
- Cure progress: while curing, the handpiece will beep every 5 seconds. One beep at 5 seconds, two beeps at 10 seconds, 3 beeps at 15 seconds.
- End of cure: a long beep will indicate the cure was successfully completed.
- Error: a series of five rapid beeps indicates the handpiece has timed out or an error occurred. Example: "Battery Low," "Dirty Lens," or "Service Error."

2. Safety

2.1 INTENDED USE

Loop™ is an LED based dental curing light that produces a localized and mildly dispersive beam of high-intensity blue light used for the rapid curing of light-cured dental materials. Loop™ is designed for short-term operation. The intended place of application is in the dental practice. The intended use also includes the observation of the direction and notes in these Instructions for Use. Loop™ is only for use in a dental office, hospital, or other professional healthcare facility environment.

2.2 INDICATIONS FOR USE

Indications for Use: Loop™ is a source of illumination for curing photo-activated dental restorative materials and adhesives.

With its multiband spectrum, Loop™ is suitable for the polymerization of all light cured dental materials activated in the wavelength range of 390-480 nm. It is suitable for use with a broad range of light-cured dental materials including materials for restoratives such as light-cured and dual-cure cements, composites, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations such as ceramic inlays.

2.3 CONTRAINDICATIONS

Materials for which the polymerization is activated outside the wavelength range of 390-480 nm (no materials known to date).

CAUTION: The use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: This device should not be used adjacent to or stacked with other equipment. If such use is unavoidable, the devices must be observed for normal operation in the configuration in which it will be used.

WARNING: This device should not be used near flammable anesthetics or mixtures of flammable anesthetics with air, oxygen, or nitric oxide.

2.4 SIGNS AND SYMBOLS

2.4.1 On Product & Packaging


Caution


Warning

RISK GROUP 2
CAUTION The light emitted may be harmful to the eyes Do not stare at the light source


Type BF Applied Part – Protection against electrical shock (Loop™ LED curing light handpiece and protective barrier sleeves are applied parts while Loop™ charging base is an accessible part)


Class II Electrical Protection – Double Insulation (device complies with safety class II)


Rx ONLY – Prescription use only, for dental use only!

Medical Device

Lot Number


Follow instructions for use


Temperature limit (0C/32F – 40C/104F)


Atmospheric pressure (500 hpa – 1060 hpa)

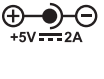

Storage humidity range (0% - 85%)


Fragile, handle with care


Keep dry


Recycle


Date of Manufacture



DC input


Manufacturer


WEEE Disposal of Waste Electronics - Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE). Do not dispose of electronic products in the general waste stream.

Loop™ is an electronic device and a medical product which. Conforms to ANSI/AAMI STD ES60601-1. Certified to CSA STDs C22.2# 60601-1, 60601-2-57. Certified to IEC STD 60601-1-6, 60601-2-57

The Unique Device Identifier (UDI) is found on the Loop™ packaging. It is provided as both text and a 2D-barcode that can be read with common barcode scanners or smartphone apps.

2.4.2 On OLED Display Screen

Idle: Refer to Section 1.4.1 "Before the Cure"

Time and irradiance settings

Curing: Refer to Section 4.1 "Operating States"

Curing in progress

Auto-Start: Tooth detection in progress

Battery Low: Refer to Section 4.10 "Charging & Batteries"

Battery too low for requested mode

Self-Check Dirty Lens Detection: Refer to Section 4.5 "Self-Check Dirty Lens Detection"

Self-Check Dirty Lens Detection – In progress

Self-Check Dirty Lens Detection – Success

Self-Check Dirty Lens Detection – Failure

Calibration is recommended

Calibration: Refer to Section 4.4 "Calibration"

Calibration – In progress

Calibration – Success

Calibration – Failure

Temperature Warning: Refer to Section 2.9 "Heat Development"

Temperature warning icon: the device needs to cool down

Service Error: Refer to Section 6 "Troubleshooting and Service"

Service Error

2.5 SAFETY WARNINGS AND PRECAUTIONS

CAUTION:

- **Read all instructions before operating this instrument. Use of the device is restricted to trained personnel in accordance with these instructions for use. The manufacturer accepts no liability resulting from improper use of this device or any damage resulting from the use of this unit for any other purpose.**
- **This product is specifically designed for use in dentistry and dental related applications for the cross-polymerization of dental materials. This system must only be used by a dental professional that is appropriately licensed and trained. The curing light should be put away and/or secured to protect against unauthorized use.**
- **Prior to installation of the unit make sure that the operating voltage stated on the rating plate is compatible with the available mains voltage. Operation of the unit at a different voltage may damage the unit.**
- **Ensure the unit has acquired the ambient temperature before use.**
- **Don't attempt to remove or fully rotate tip.**
- **This curing light produces high-output curing energy. A significant increase in curing energy may be possible compared with equipment previously used. Do not place light directly on or towards unprotected gingiva or skin. Adjust curing techniques in accordance with the increase in curing energy.**
- **Hazardous substances exist in electrical and electronic equipment and present potential risks to human health and the environment if disposed of in municipal landfills which are not designed to prevent migration of substances into the soil and groundwater. When disposing of electronic waste (i.e. devices, charging bases, batteries and power supplies) follow local waste and recycling guidelines. The Waste Electrical and Electronic Equipment (WEEE) Directive forbids the disposal of electrical and electronic equipment waste as unsorted municipal waste and requires that they be collected and recycled or disposed of separately.**

WARNING: No modification of this instrument is allowed.

WARNING: Use only original spare parts and accessories from Garrison® Dental Solutions to prevent improper operations, increased electromagnetic emissions or decreased electromagnetic immunity. The manufacturer does not accept liability for damage resulting from the use of other spare parts or accessories.

2.6 ASSUMPTION OF IMPAIRED SAFETY

CAUTION: If it must be assumed that safe operation is no longer possible, the unit must be taken out of operation and labeled accordingly to prevent third parties from inadvertently using a defective unit. This may be the case if the device is visibly damaged or no longer works correctly.

2.7 EYE PROTECTION

WARNING: The light emitted may be harmful to the eyes. Do not stare at the light source. Always use the supplied protective light shield or UV orange eye protection when operating this device within an ocular hazard distance of 20cm. Do not look at the light emission without proper eye protection. Do not use this device without suitable eye protection for the operator, assistant and patient. Direct or indirect exposure of the eyes must be prevented. Prolonged exposure to the light is harmful to the eyes and may result in injury.

Emission Aperture

Individuals who are sensitive to light, who have a history of photosensitive reactions, who take photosensitizing drugs, have undergone eye surgery, or people who work with the apparatus or in its vicinity for long periods of time should not be exposed to light from this unit.

Protect patient and user from high intensity reflections and scattered light by taking the appropriate precautions (e.g. light shields, goggles, or coverings). Using the supplied protective light shield is recommended. Refer to Section 4.8 "Light Shield".

2.8 BATTERY

WARNING: Use Loop™ batteries only! Use of other manufacturer's batteries or non-rechargeable batteries is a potential hazard and may damage the unit. Do not short circuit battery. Do not store at temperatures above 40°C / 104°F (or 60°C / 140°F for a short period). Always store batteries charged. The storage period must not exceed 6 months. May explode if disposed of in fire.

WARNING: Lithium-polymer batteries may react with explosion, fire, smoke development or other hazards if handled improperly, replaced by inadequately trained personal, or if it becomes damaged. Damaged lithium-polymer batteries must no longer be used.

The electrolytes and electrolyte fumes released during explosion, fire and smoke development are toxic and corrosive. In case of accidental contact with the eyes or skin, immediately wash with copious amounts of water. Avoid inhalation of fumes. In case of indisposition, see a physician immediately.

CAUTION: Never place the handpiece in the charging base without the battery inserted in the handpiece!

2.9 HEAT DEVELOPMENT

CAUTION: As is true for all modern high-power dental curing lights, the high intensity light emitted can result in significant heat development at the targeted surface. Additionally, the typical curing process of dental materials is an exothermic reaction. Any prolonged high irradiance exposure of treatment areas near tooth pulp or soft tissues, such as gingiva, cheek, tongue or lips, may result in irreversible pulp tissue damage that is not immediately evident.

The Loop™ handpiece will heat up during curing operation, especially during long cures at high irradiance settings. Unlike other curing lights, Loop™ has a predictive, automated temperature control to prevent the surface of the handpiece from reaching unsafe levels. It will not begin a cure if the selected time and irradiance setting would cause the surface of the handpiece to exceed 51°C during the cure. This prevents the cure process from being interrupted.

If the Temperature Warning icon (Fig. 1) is displayed when attempting to start a cure, wait for the device to cool or select a lower time and/or irradiance setting before trying to start the cure again.

Fig. 1 - Temperature warning icon: the device needs to cool down

CAUTION: For indications where the patient may be sensitive to temperature or when performing long or repeated high-irradiance cures, avoid prolonged contact to soft tissues.

The recommended curing times provided by the dental material manufacturer should be fully observed for curing. If performing multiple cures or long cures at high irradiance on a tooth, prevent over-heating tissue by blowing air on the cured area or allowing cooling time between cures.

3. Set-Up

3.1 INITIAL SET-UP

Remove all components from the packaging and inspect for damage. Immediately contact customer service if any components are damaged.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 5

Fig. 6

1. Plug the low voltage power supply output connector into the charging base. The socket is located at the bottom of the charging base (Fig. 1). Route the cord through the slot in the bottom of the charging base.

2. Plug the power supply into an appropriate electrical outlet (100-240VAC nominal, 50-60Hz). If necessary, use the proper adapter for your region. (Fig. 2) Refer to Section 4.9 "Power Supply & Adapters". The green light on the back of the charging base indicates that the charging base is plugged into the electrical outlet and receiving power. (Fig. 3)

3. Ensure that the charging base tip is in the lower position. (Fig. 4)

4. Ensure that the handpiece tip is rotated so the alignment marks are matched (Fig. 5) and insert it into the opening of the charging base. (Fig. 6) Loop™ will automatically start a Self-Check Dirty Lens Detection. A green circle with a checkmark indicates a clean lens.

   If the battery is too low, allow the battery to charge until the low-battery indicator has disappeared. When the battery is charged, remove and replace the handpiece on the charging base to automatically start a Self-Check Dirty Lens Detection.

   NOTE: The handpiece arrives in a locked state for shipping. Refer to Section 1.4.1 "Before the Cure" for shipping lock screen. Placing the handpiece in the charging base will automatically unlock the handpiece.

   NOTE: Keep the lens clean from skin oils and debris. If you receive a Dirty Lens Detection Failure, refer to Section 5.3 "Cleaning the Lens".

5. After the handpiece has properly charged, you may remove it from the charging base for normal use.

When not in use, the Loop™ handpiece should be stored in the charging base with power connected.

Refer to Section 4.2 "Normal Operation" to determine your desired mode of operation.

Refer to Section 4.3 "Settings" to change any settings.

Refer to Section 4.7 "Protective Barrier Sleeve" for application instructions.

Refer to Section 4.8 "Protective Light Shield" for application instructions.

CAUTION: Do not position the charging base so that it is difficult to disconnect the power cord.

WARNING: Do not touch the connector on the charger base and the patient simultaneously. The Charging Base must only be used with the power supply provided for the Loop™ charging base and connected with the appropriate supplied power adapter. Attempting to use another power supply may create a risk of electric shock to the operator or damage the product and will void the warranty.

3.2 CHARGING & BATTERIES SET-UP

It is recommended to fully charge the Loop™ handpiece before first use. This may take up to 4 hours. Refer to Section 4.10 "Charging and Batteries" for charging and battery operation.

3.3 INITIAL CALIBRATION

Once the Loop™ handpiece is fully charged, calibration is recommended at initial set-up and once a month thereafter. Complete the steps in section 4.4 "Calibration".

4. Operation

4.1 OPERATING STATES

There are four operating states:

4.1.1 Idle

Idle: The handpiece is idle when it is not curing or in sleep mode and the battery is charged. The user may cycle between curing irradiance and time settings by pressing the Menu or Select buttons. Curing cycles may also be initiated from the idle state by pressing the Start/Stop button.

NOTE: To conserve battery life, the display will dim after a period of inactivity.

4.1.2 Curing with Closed-Loop OFF:

Curing: A curing cycle is initiated by pressing and releasing the Start/stop button while the handpiece is idle. Once a curing cycle is started, the LED will be turned on and a progress beep will sound. A progress beep will sound every 5 seconds until the cycle is complete, at which time a final success beep will sound.

Curing

Start/stop:  Press to start a cure cycle.

Stopping a Cure: Pressing any button during a curing cycle will cancel the cure. The screen will return to Idle, showing the current irradiance and duration settings.

4.1.3 Curing with Closed-Loop ON:

Loop™ has the unique ability to measure and maintain a constant irradiance at the restoration surface. Controlling energy levels at the restoration surface ensures the operator that the cure time is consistent with dental materials manufacturer recommendations without requiring excessive time that may result in over-heating.

Turn closed-loop ON/OFF: Press and hold the Menu button for about 2 seconds to turn the closed-loop feature ON/OFF. When ON, the closed-loop arrows icons will appear at the bottom of the screen.

Closed Loop OFF

Closed-Loop ON

Curing: A curing cycle is initiated by pressing and releasing the Start/stop button while the handpiece is in Idle. A cycle will be started when the lens is positioned over a tooth and based on the selected curing mode. Once a tooth is detected, the LED will be turned on and a progress beep will sound. A progress beep will sound every 5 seconds until the cycle is complete, at which time a final success beep will sound.

Auto Start: When a cure cycle is requested with closed-loop ON, the LED will pulse at a low energy until the lens is properly positioned over the dental material to be cured, or similar surface. It will return to Auto Start when the device moves away from the tooth surface. Once a cure begins, movement away from the tooth will timeout after 3 seconds. If a cure is never started, a 10 second timeout will eventually cancel Auto Start.

To enter Auto Start, press the Start/stop button once while outside the mouth.

Auto Start

Start/stop:  Single press outside the mouth to enter Auto Start.

NOTE: If the center of the lens is directly over amalgam when the Loop™ is in Auto Start, the cure may not begin.

4.1.4 Sleep

Sleep: The handpiece goes to Sleep to conserve battery life after approximately 5 minutes of no activity. It can be awakened by pressing either the Menu or Select button once, at which time the handpiece will return to the idle state for the last mode used. While in Sleep, all LEDs are turned off and the handpiece goes into a low-power operating state.

4.2 NORMAL OPERATION

Loop™ has two operational modes for curing dental materials: Direct Restorative and Tack.

Direct Restorative is the default mode, and it can be used with the closed-loop either ON or OFF. See sections 4.1.2 and 4.1.3 for instructions on these features.

Tack is used to deliver a short burst of light (1,000 mW/cm^2 for 3 seconds) to the dental material for tacking adhesives. After completing a tack cycle, the handpiece immediately returns to the last-used Direct Restorative Idle screen.

NOTE: For curing bleached shades (e.g. bleached shade M1) and extra light surfaces, it is recommended to touch the lens directly on the surface immediately after the top layer is hardened. This allows the unit to recognize a bleached shade and adjust the delivered energy accordingly.

4.2.1 Direct Restorative Mode

Refer to sections 4.2.2 and 4.2.3 for information on curing with closed-loop ON or OFF

Direct Restorative mode can be operated in cycle times of 3, 5, 10, 15 or 20 seconds (depending on the selected irradiance). The factory preset time is 20 seconds. To change the time setting, press the Select button. See the dental material manufacturer's Instructions for Use when selecting the cure time.

The Direct Restorative mode can be operated with irradiance levels of 1,000, 2,000, or 3,000 mW/cm^2. The factory preset irradiance level is 1,000 mW/cm2. To change the irradiance level, press the Menu button.

There are two commonly used settings that can be quickly accessed by pressing and holding the Select button.

Press and hold the Select button to quickly jump between two available preset irradiance and duration presets.

Preset 1: 20 seconds, 1,000 mW/cm^2

Preset 2: 5 seconds, 2,000 mW/cm^2

Direct Restorative mode recommended technique:

1. Set the cure duration longer for deeper fillings, darker shades, or for specific materials.

2. Press the Start/Stop button to initiate the cure cycle.

3. Position the lens of the handpiece within 3 to 4mm of the center of the targeted surface during the cure cycle..

4. When closed-loop is ON, if the lens is positioned too far away, it will enter AutoStart (refer to Section 4.1.3 "Curing with Closed-Loop ON"). In this situation, move the lens closer to the surface (3 to 4mm) allowing the cure cycle to automatically start.

5. When closed-loop is ON, once the cure cycle is in process, Loop™ will actively adjust irradiance at the targeted surface regardless of the distance from the target until the maximum distance (approximately 8 to 10mm) is exceeded or the lens is moved over the gingiva.

6. Once the surface of the material is hardened, resting the lens directly on the surface ensures the most accurate cure.

NOTE:

- When closed-loop is ON if the lens is moved too far from the tooth or onto other tissues, Loop™ will enter Auto Start and automatically pause until returned to proper position over a tooth surface. Auto Start will be on for a limited time before canceling.
- During a cure, if any button is pressed, the cure cycle will be cancelled, and the handpiece will return to the Idle screen.
- If the restoration area is greater than 6mm across, the operator can pull the lens away from the tooth for more surface coverage. This may initiate an automatic addition of time to the cure cycle.

Refer to Section 2 "Safety" for details on safety.

4.2.2 Tack Mode

Tack mode is recommended to deliver a short burst of light (1,000 mW/cm^2 for 3 seconds) to the dental material for tacking adhesives. Tack mode does not use the closed-loop feature.

Press and hold the Start/Stop button for about 2 seconds to initiate Tack mode. This can be done from any Idle screen, regardless of the irradiance and time settings shown on the screen.

Tack mode recommended technique:

1. Before starting a tack cycle position the lens of the handpiece within 3 to 4mm of the center of the targeted surface.
2. Activate the tack cycle by pressing and holding the Start/Stop button for about 2 seconds. The device will beep, and the tack cycle will begin immediately.
3. Hold the light over the target surface for the 3 second Tack cycle.
4. After the tack cycle is complete, the screen will display the energy delivered, 3J (joules).
5. The screen will automatically return to Direct Restorative mode and the previously used settings will be shown on the Idle screen.

4.3 SETTINGS

Loop™ allows the user to custom configure several options in Settings including:

- Sound ON/OFF
- Information screen: Manufacturing Lot Number
- Protective barrier sleeve ON/OFF

How to enter or exit Settings:  (press and release both buttons simultaneously)

Menu:  Press to cycle through the main menu of settings.

Select:  Press to select setting options.

Settings Steps:

To enter Settings and configure the curing light, press and release both the Menu button and Select button simultaneously. This will allow Loop™ to enter Settings, displayed with all blue circle icons.

Press the Menu button to scroll through the menu options and press the Select button to change the setting options. After making a selection, press the Menu button and the selection is automatically saved.

To exit Settings, press and release both the Menu button and Select button simultaneously.

NOTE: Your selections will save automatically when you exit Settings.

Protective Barrier Sleeve

ON OFF

Protective Barrier Sleeve ON/OFF (preset to ON)

Press the Select button to configure Loop™ for use with or without a Protective Barrier Sleeve. If this setting is changed, it is recommended to do a calibration (refer to Section 4.4 "Calibration")

Sound Level

ON OFF

Sound ON/OFF (preset to ON)

Set Sound to ON or OFF (mute).

LOT Number

The LOT number can be found on the bottom of the charging base adjacent to the [LOT] symbol. The LOT number, for the handpiece, is also available on the display screen in Settings. In addition, the LOT number is visible inside the housing of the handpiece, under the battery cover.

4.4 CALIBRATION

Loop™ is the first curing light system with the ability to validate its delivery of irradiance to the tooth surface. To maintain like new performance, it is recommended to perform a monthly calibration which is completed in a few seconds.

The Loop™ calibration and charging base is a calibration tool that will automatically verify that the unit has precise power levels.

Initial and Monthly Calibration Steps:

1. Position the charging base on a flat stable surface and check that the green power indicator is on.
2. Check that the battery charge status icon on the handpiece OLED display screen is green.
3. Make sure there is not a protective barrier sleeve on the handpiece.
4. Check that the lens is properly cleaned and completely dry. If needed, clean the lens with the supplied Loop™ lens cleaning cloth. Refer to Section 5 for "Maintenance and Cleaning".
5. Ensure that the handpiece tip is rotated so the alignment marks are matched (Refer to Section 4.6 "Positioning the rotating tip").
6. Raise the charging base tip to the calibration position (Fig. 1).
7. Insert the handpiece into the charging base (Fig. 2). Verify that the lens is positioned securely within the white calibration area.
8. Loop™ will automatically perform a calibration. (Fig. 3) Upon successful completion, a green check mark (Fig. 4) will be displayed along with an audible beep. If a red X is displayed (Fig. 5), a failure has occurred, and you should repeat step 1 to 8. Should the failure persist, please contact customer service.
9. After a successful calibration, remove the handpiece from the charging base and lower the charging base tip to the normal position.
10. Loop™ is ready for use or may remain in the charging base until needed.

Fig. 1 Fig. 2

Fig. 3
Calibration –
In progress

Fig. 4
Calibration –
Success

Fig. 5
Calibration –
Failure

There is no harm in calibrating the device more frequently than the recommended monthly time period. You may calibrate more often for the following reasons:

- When a Self-Check Dirty Lens fails on repeated attempts. Refer to Section "4.5 Self-Check Dirty Lens Detection".
- After removing hardened dental material from the lens surface.
- When calibration was not conducted as scheduled.

4.5 SELF-CHECK DIRTY LENS DETECTION

A Self-Check Dirty Lens Detection is automatically performed each time the handpiece is seated in the charging base immediately after adequate battery charge is verified.

Self-Check Dirty Lens Detection Steps:

1. After use of the handpiece, remove the protective barrier sleeve and properly clean and dry before placing into the charging base. If needed, clean the lens with the supplied Loop™ lens cleaning cloth. Refer to Sections 5.2 "Cleaning after use" and Section 5.3 "Cleaning the lens".

2. Check that the tip is rotated so that the alignment marks are matched. Refer to Section 4.6 "Positioning the rotating tip".

3. Insert the handpiece into the charging base so that the lens is facing the black surface (Fig. 1).

4. Upon successful completion, a green circle with a check mark will be displayed along with an audible beep (Fig. 3). If the Dirty Lens Detection icon is displayed with a red X, a failure has occurred (Fig. 4).

If a failure occurs, check the items below:

- Is the tip rotated correctly so that the alignment marks are matched?
- Is the handpiece properly seated in the charging base?
- Is the charging base tip lowered to the normal position so that the lens is facing the black surface?
- Is the lens completely dry?
- Remove the handpiece and clean the lens. If needed, clean the lens with the supplied Loop™ lens cleaning cloth. Refer to Section 5.3 "Cleaning the lens."
- Clean the white calibration surface. 5.5 "Cleaning the Self-Check & Calibration Surfaces".

If all of these are correct, repeat Steps 1-4 above. If a success icon appears on the display (Fig. 3), Loop™ is ready for use. If a failure icon is once again detected (Fig. 4), clean Loop™ again and repeat Steps 1-4. If after repeated attempts the failure icon appears, contact customer service.

Fig. 1

Fig. 2
Self-Check Dirty Lens Detection – In progress

Fig. 3
Self-Check Dirty Lens Detection – Success

Fig. 4
Self-Check Dirty Lens Detection – Failure

If a calibration is recommended, a yellow check mark will be displayed (Fig. 5).

Fig. 5
Calibration is recommended

4.6 POSITIONING THE ROTATING TIP

The Loop™ tip rotates approximately 345 degrees. (Fig. 1) To prevent damage, do not try to rotate the tip past the stopping point. Rotate the tip into the desired position for use.

To make full use of the light intensity provided, place the tip as close to the tooth surface as possible while avoiding direct contact with the dental material. Keep the lens clean at all times to obtain full light intensity. A damaged tip or lens substantially reduces the light intensity and must be replaced immediately, sharp edges may cause serious injury!

NOTE: Before placing the handpiece in the charging base, always rotate the tip so that the marks align (Fig. 2).

Fig. 1

Fig. 2

4.7 PROTECTIVE BARRIER SLEEVE

Loop™ is designed to be used with a protective barrier sleeve to keep the device clean and functioning properly. The protective barrier sleeves are for single patient use only.

Using a Protective Barrier Sleeve has the following advantages:
- Prevents cross contamination between patients
- Helps avoid dental materials adhering to the lens
- Extends the Loop™ product life by reducing contact with harsh cleaning solutions
- Improves the accuracy of Auto-Start by preventing potential contamination on the lens from skin oils or debris

When using a Loop™ barrier sleeve, some irradiance is blocked, Loop™ will automatically adjust to deliver the intended irradiance to the tooth. This feature can be enabled or disabled in Settings based on protective barrier sleeve use. Refer to Section 4.3 "Settings".

To use a Protective Barrier Sleeve, follow these steps:

Fig. 1

1. In Settings, make sure that the Barrier Sleeve is set to ON (preset as the default). Refer to Section 4.3 "Settings".

2. If needed, clean the lens with the Loop™ lens cleaning cloth.

3. Slide a new barrier sleeve over a clean and dry handpiece until the end reaches the tip. Secure the barrier sleeve tightly over the lens. Ensure that there are no folds over the lens and that the barrier sleeve seam is not covering the lens. (Fig. 1)

4. Use Loop™ as normally directed. Refer to Section 4.0 "Operation".

5. Remove and dispose of the barrier sleeve after each use.

6. Clean Loop.™ Refer to Section 5 for "Maintenance and Cleaning."

Protective barrier sleeve is turned ON.

Protective barrier sleeve is turned OFF.

CAUTION: Ensure the barrier sleeve is snug fitting and lays flat against the lens.

CAUTION: Using a brand of barrier sleeve other than Loop™ may prevent the handpiece from functioning properly and an accurate output power cannot be ensured.

CAUTION: Not using a Loop™ barrier sleeve may reduce the accuracy of Auto-Start due to contamination on the lens from skin oils or debris. Do not touch the lens to skin or other surfaces. Keep lens clean.

If not using a Barrier Sleeve, follow these steps:

1. In Settings, make sure that the Barrier Sleeve is set to OFF. Refer to Section 4.3 "Settings".

2. Clean Loop™ ensuring the lens surface is clean. Refer to Section 5 for "Maintenance and Cleaning."

3. Use Loop™ as normally directed. Refer to Section 4.0 "Operation".

4.8 PROTECTIVE LIGHT SHIELD

Using a light shield protects the operator's eyes when viewing light output through the shield. The Loop™ protective light shield can be rotated for maximum efficacy. The shield can be used with or without a protective barrier sleeve.

To use the Protective Light Shield (Fig. 1), snap on the protective light shield avoiding the rotation joint. (Fig. 2)

Fig. 1

Fig. 2

4.9 POWER SUPPLY AND ADAPTERS

The Loop™ power supply is a 1.5m universal-input unit that accepts 100-240VAC nominal (50-60Hz).

WARNING: The Charging Base must only be used with the power supply provided for the Loop™ charging base and connected with the appropriate supplied power adapter. Attempting to use another power supply may create a risk of electric shock to the operator or damage the product and will void the warranty.

The power supply is preloaded with the 120V US - Type A adapter. Select the appropriate adapter for your region.

Power Supply and Adapters instructions:

1. Select the proper adapter for your region. Retain unused adapters for future use. The applications are as follows:
   - 120V US – Type A
   - Euro – Type C
   - UK – Type G
   - Australian – Type I

2. Insert the tip of the blade assembly into the power supply at a 30-60 degree angle (Fig. 1). The top edge of the blade assembly is flat and the bottom edge is U shaped. The power supply has the corresponding shapes.

3. Push the blade assembly into the power supply in a downward motion (Fig. 2).

4. Push the blade assembly down until the blade assembly locks in place. A clicking sound will occur (Fig. 3).

5. To check the AC Blade assembly for correct insertion, hold the power supply in one hand. Using another hand, pull up on the blade (Fig. 4).

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Removing the AC Blade assembly:

1. Using thumb or finger, slide the spring loaded locking key downward. It is marked with an arrow (Fig. 5).

2. Holding the locking pin down, pull upward on the AC blade to remove (Fig. 6).

Fig. 5

Fig. 6

NOTE: The blade assembly is "finger proof" which meets regulatory requirements against shock hazards

4.10 CHARGING AND BATTERIES

Loop™ LED curing light system has been designed to have the handpiece placed in the charging base after each use and cleaning. The charging base's smart charging circuitry removes any concerns regarding over-charging. When the handpiece is left inactive and disconnected from a charging base, it will power down and draw an insignificant amount of energy from the battery. Batteries will last longest in this condition when more than 50% charged.

Loop™ contains a powerful lithium-ion rechargeable battery. The lithium ion battery is designed to provide two to five years of use depending on frequency and severity of use.

- Battery pack life: 300 full charge/recharge cycles
- Output: 3.7 Volts nominal @ 2.5A-H capacity

CAUTION: The battery pack contains a Lithium ion (Li-ion) battery. Recycle or dispose of batteries according to national, state and local regulations.

When the Loop™ handpiece OLED display screen and operation is idle, the battery charge status icon is displayed. When the handpiece is seated on the charging base, the battery charge status icon will show the color that best represents the battery charge readiness. While charging, the white lightning bolt will slowly blink.

Battery Charge Status:

When the battery charge level drops below 25%, the red battery icon will appear on the Idle screen.

If the battery charge level is too low to complete a requested cure cycle, a battery warning screen will appear. The cure cycle will not start in this situation. Return to the charging base immediately. When the battery charge falls below 25%, the red battery-shaped indicator will appear in the bottom right corner of the screen.

Replacing the Battery

The Loop™ battery has been designed to be replaced in the field without requirement for factory re-calibration. A Loop™ battery replacement kit is available to order. It will include a new battery, star wrench, screw, washer and instructions.

TIMING: The battery should be replaced when any of the following conditions occur:

- The battery frequently drains from a full-charge to a low-battery within typical daily use.
- A 2 hour charge will not produce a green battery status.

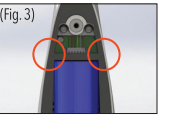
Battery replacement instructions:

1. Shutdown the handpiece by simultaneously pressing both the Menu button and Select button and holding for 3 seconds, or until the screen goes black.
2. To remove the plug covering the screw, use a small screwdriver or dental hand instrument.
3. To remove the screw, use the star wrench provided in the replacement kit.
4. Remove the battery cover (Fig. 1).
5. Carefully unplug the white battery connector from the white receptacle on the circuit board and remove the battery by holding the Loop™ handpiece housing with one hand and pulling the white battery connector away from the circuit board with fingers or forceps (Fig. 2). Do not pull on the wires. Do not apply excessive force or touch the circuitry. Remove the battery from the handpiece.
6. Take the new battery from the replacement kit and carefully plug the battery connector into the receiving connector on the circuit board. Slide the battery into the back end of the handpiece below the cross rib (Fig. 3) and rest the battery down against the housing. Ensure that the wires are not pinched.
7. Ensure that the rubber gasket surrounding the handpiece opening is not damaged or moved.
8. Replace the battery cover by first aligning the area around the charging pins (Fig. 4), then lower to align the screw hole, and over the rubber gasket to cover the unit. Ensure that the sides of the cover are flush and aligned with the sides of the handpiece.
9. Reattach the battery cover using the new screw and washer supplied in the replacement kit. Tighten the screw with the star wrench until it is snug. Do not over-tighten.
10. Replace the plug over the screw. Ensure the plug is positioned flush with cover. If the plug does not seat flush with the cover, use a thin composite instrument or similar tool to insert between the cover and the plug to release the trapped air beneath the plug.
11. Clean the lens. Refer to Section 5.3 "Cleaning the lens" in the instructions for use.
12. Place the handpiece in the charging base for 4 hours to fully charge the new battery for the first time.
13. Perform a Calibration. Refer to Section 4.4 "Calibration" in the instructions for use.

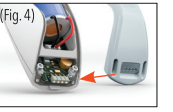
(Fig. 1)

(Fig. 2)

(Fig. 3)



(Fig. 4)



NOTE: Do not apply any adhesive to the screw or screw cover.

NOTE: Do not apply excessive force or touch the circuitry.

Disposal

The curing light must not be disposed of as normal household waste. Dispose unserviceable batteries and curing lights according to the corresponding legal requirements in your country. Batteries must not be incinerated.

4.11 USE WITH A RADIOMETER

The Loop™ LED Curing Light system functions as an internal radiometer that ensures an accurate, calibrated energy output. However, if you wish to test the handpiece on an external radiometer, operate the handpiece in Direct Restorative mode, with closed-loop turned off. To observe the closed-loop function on a radiometer, operate in Direct Restorative mode by first touching the lens to the radiometer surface before raising it to a distance to observe the closed-loop functionality.

5. Maintenance and Cleaning

5.1 CLEANING DURING USE

The Loop™ handpiece, charging base and light shield are not autoclavable and no portion can be sterilized. Only use approved disinfecting solutions. Refer to Section 5.2 "Cleaning After Use".

To keep the Loop™ handpiece clean and functioning properly, a new barrier sleeve should be used for each patient. Only use Loop™ barrier sleeves that are specifically designed for use with the Loop™ curing light.

The supplied Loop™ lens cleaning cloth should be used exclusively for drying the lens after cleaning.

5.2 CLEANING AFTER USE

Only use approved disinfecting solutions. If using a spray, do not spray the disinfecting solution directly on the device. Instead, spray or moisten a gauze or soft cloth with disinfecting solution and use it to wipe down and clean the unit. This ensures that significant amounts of disinfectant solution do not wick into the seams of the unit. When finished, dry any residual disinfectant solution remaining on the surface of the handpiece with a soft cloth. Do not use the supplied Loop™ lens cleaning cloth for anything other than drying the lens after cleaning.

Approved disinfectant solutions:
- Lysol® Brand III Disinfectant Spray
- Lysol® disinfectant or Lysol® concentrate (alcohol-based only)
- Cavicide™ non-bleach products
- Isopropyl alcohol
- FD 366 (Dürr Dental)

CAUTION: Do not use a metal edged instrument on the OLED display screen.

5.3 CLEANING THE LENS

Inspect the lens after each cleaning. If contaminates are found on the lens or the OLED Display Screen shows a failure for a Self-Check Dirty Lens Detection, carefully clean with the following method:

1. Clean the lens with a dry Loop™ lens cleaning cloth. If this does not clean the lens, then proceed to the next step.

2. Buff the lens surface with your regular disinfectant solution or isopropyl alcohol and a soft cloth using light pressure in a circular motion. If this does not remove the dental material or contaminant, then proceed to the next step.

3. Use a metal edged (non-diamond tipped) dental instrument to apply lateral pressure to the side and/or edge of the cured dental material that has bonded to the lens. Take care to not scratch the lens and avoid repeated scraping motions to clear away the cured dental material.

4. Repeat Steps 1-2. Surface is now ready for use.

5.4 CLEANING THE CHARGING BASE

Clean every few weeks or as needed. Carefully clean with the following method:

1. Temporarily disconnect the charging base from the power supply cord.

2. For cleaning, refer to Section 5.2 "Cleaning After Use."

3. Make sure that the charging pins and surrounding area are completely dry when finished. You may use compressed air or gentle use of a dry soft cloth. Take care to not bend the charging pins when drying.

4. Reconnect the power supply cord to the charging base.

5.5 CLEANING THE SELF-CHECK & CALIBRATION SURFACES

On the charging base, there are two calibration surfaces that should be cleaned. Clean once per year or if having problems with Calibration.

Black surface used for Self-Check Dirty Lens Detection: Clean the Self-Check Dirty Lens Detection surface with air blow-off only. Use sufficiently to remove all dust and debris. In most cases, nothing more will be required to keep the black surface functional. In cases of severe contamination, the use of a mild surface cleaner like Sparkle™ or Windex™ may be gently applied via a cotton swab if followed with a gentle rinse of distilled water and dried with clean compressed air.

White surface used for Calibration: Cleaning of the white calibration surface is rarely needed due to its protected location, but the process requires more care:

1. Carefully clean the white surface with the supplied Loop™ lens cleaning cloth. If this does not fully clean the surface, then proceed to the next step.

2. Do not use sprays or cleaners other than what is prescribed. Gently wipe with gauze or a towelette saturated with Sparkle™ or Isopropyl Alcohol. Wipe in a gentle circular motion.

3. Repeat the above step using distilled water.

4. Blow off with compressed air and allow 5 minutes additional dry time. Surface is now ready for use.

6. Troubleshooting and Service

Repairs are only to be performed by authorized service personnel. Garrison® will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information to eligible service personnel to repair parts that are repairable by service personnel only.

CAUTION: When returning units for repair or service, always follow the shipping instructions provided by the customer service representative.

Problem	Possible Solution
 Service Error on the display with a number.	Loop™ has failure detection built in and records issues. If a service error is observed during use, start the procedure again. If the service error continues to occur, contact customer service. The error number is useful to authorized service personnel. Note: The Loop™ equipment/system is not field repairable.
 Shipping Lock screen on the display.	The Loop™ handpiece is in a locked state for shipping. Check that the green power indicator on the charging base is lit and place the handpiece in the charging base to automatically unlock the handpiece. If the problem persists, contact customer service.
Charging base power indication does not turn on	Check that you are properly connected to a working electrical outlet and that the cables are secure. If the problem persists, contact customer service.
The handpiece OLED display screen does not turn on, when the Mode button is pressed.	Check that the green power indicator on the charging base is lit and place the handpiece in the charging base. If the display does not turn on immediately, contact customer service.
The OLED display screen does not respond to the buttons.	Check that the green power indicator on the charging base is lit and place the handpiece in the charging base. If the display does not turn on immediately, contact customer service.
The battery gauge level on the handpiece is red.	Check that the green power indicator on the charging base is lit and place the handpiece in the charging base until the gauge is green. If the gauge is not green within 4 hours, contact customer service.
The handpiece has not been used for a long time and now it cannot be turned on.	There is not enough charge in the battery to turn on the handpiece. Place the handpiece in the charging base to charge the battery.
Service Error during calibration.	Clean the lens and calibration surface. If you use a barrier sleeve, check that the Protective Barrier Sleeve Setting is ON. If you do not use a barrier sleeve, check that the setting is OFF. If the service error persists, contact customer service.
Temperature Warning Icon is displayed when trying to begin a cure.	The Loop™ handpiece has a predictive, automated temperature control to prevent the surface of the handpiece from reaching unsafe levels. It will not activate a cure if the selected time and irradiance setting would cause the surface of the Loop™ to become too hot. This prevents the cure process from being interrupted. If the Temperature Warning Icon is displayed, wait for the device to cool or select a lower time and/or irradiance setting before trying to start the cure again. If the service error persists after the Loop™ has reached ambient temperature, contact customer service.
Loop™ is excessively hot to the touch.	Loop™ monitors functional use and temperature to avoid harmful temperatures. After a long cure, the tip can become warm to the touch. After taking the handpiece off the charging base, the battery area can be warm to the touch. If the temperature is too hot to touch, remove the battery immediately and contact customer service.
The dental material does not cure completely.	Increase time or irradiance for the specified depth of cure according to the manufacturer's instructions.
Cure takes more time than selected amount.	Hold tip of wand closer to target during cure. When the wand is further away, it will adjust the power to a safe limit and add time.

7. Warranty

LIMITED WARRANTY

Garrison® Dental Solutions guarantees that the purchased Loop™ equipment listed below will be free from manufacturing defects for three (3) years from the date of purchase. This warranty shall not cover damage or defect caused by misuse, accident, ordinary wear incident to normal use, improper handling or actions contrary to those indicated in this manual, regardless of the date of purchase. This warranty applies solely to the Loop™ LED curing light handpiece and the Loop™calibration and charging base, and does not cover any accessory components such as the battery, power supply, adapters, light shield, barrier sleeves and lens cleaning cloth. Garrison® Dental Solutions reserves the right to repair or replace the product at its discretion. This warranty applies solely to the original purchaser and is not transferable.

Three (3) year limited warranty:

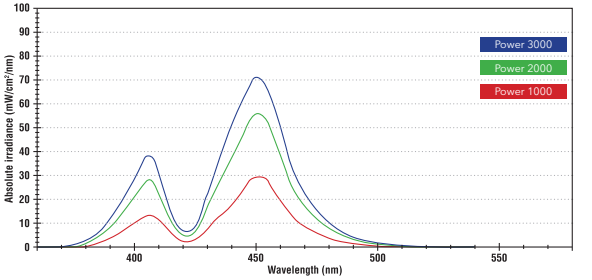
- Loop™ LED curing light handpiece
- Loop™ calibration and charging base

8. Specifications

8.1 CURING LIGHT HANDPIECE SPECIFICATIONS

Dimensions	Length = 209.6 mm Width = 35.5 mm Weight = 130 g
Wavelength Range/Light Spectrum	Effective Output Power: 390 - 480nm

Loop™ Spectrum Distribution in Operating Modes



Light Output	Closed-Loop ON: 5 20 Joules ± 15% [1,2,4] Closed-Loop OFF: 3 20 Joules ± 15% [1,2,3]	[1]See Section 4.11 for radiometer measurement instructions [2]Measured with a MARC LC radiometer [3]Relative to lens surface [4]Relative to the target surface [5]In closed-loop modes the irradiance at the lens is higher when the target is further away
Maximum Irradiance	At tooth surface: 3,000 mW/cm² ± 15%[1,2,3] At lens surface: 4,000 mW/cm² [1,2,5]	
Area of Effective Output Power	At 0 mm from lens: 74 mm² area, 9.7 mm diameter At 6 mm from lens: 117 mm² area, 12.2 mm diameter	

Battery	3.7 VDC Lithium Ion, 2500mAh, 9.25Wh IEC 62133 Rated
Operating Conditions	Ambient Temperature: 10˚C to 32˚C (50˚F to 90˚F) The light will not activate if the device surface temperature exceeds 51°C Relative Humidity: 0% to 85%, non-condensing Atmospheric Pressure: 700 hPa to 1,060 hPa
Storage and Transport Conditions	0˚C to 40˚C (32˚F to 104˚F) 0 to 85% RH, non-condensing Atmospheric Pressure: 500 hPa to 1060 hPa
Operating voltage	3.7 VDC with battery

8.2 CHARGING BASE SPECIFICATIONS

Dimensions	Length = 231.8 mm Width = 56 mm Weight = 270 g
Power Supply	Certified for IEC 60601-1 Mega Electronics Model: FJ-SW328D0502xxxx Input: 100-240VAC, 50/60 Hz, 0.4A Output: 5VDC, 2A
Operating Conditions	Ambient Temperature: 10˚C to 32˚C (50˚F to 90˚F) Relative Humidity: 0% to 85%, non-condensing Atmospheric Pressure: 700 hPa to 1,060 hPa
Storage and Transport Conditions	0˚C to 40˚C (32˚F to 104˚F) 0 to 85% RH, non-condensing Atmospheric Pressure: 500 hPa to 1060 hPa
Operating voltage	5 VDC

9. Electromagnetic Compatibility

ETL CLASSIFIED

Intertek
5031011

Loop™ is an electronic device and a medical product which Conforms to ANSI/AAMI STD ES60601-1. Certified to CSA STDs C22.2# 60601-1, 60601-2-57. Certified to IEC STD 60601-1-6, 60601-2-57

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Loop™ is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Notes**
RF Emissions CISPR 11	Group 1	Loop™ uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	Loop™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Loop™ is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+- 8 kV contact +- 15 kV air	+- 8 kV contact +- 15 kV air	Floors should be concrete or ceramic tile. If the floors are covered with synthetic material, the RH should be at least 30%.
Electrical fast transient/burst IEC 61000 4-4	+- 2 kV for Power Supply Lines +- 1 kV for I/O lines	+- 2 kV for Power Supply Lines N/A	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+- 1 kV differential mode +- 2 kV common mode	+- 1 kV differential mode +- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage, dips, shorts, interruptions, and variations on the power supply input lines IEC 61000-4-11	<5% U (>95% dip in U) for 0.5 cycle 40% U (60% dip in U) for 5 cycles 70% U (30% dip in U) for 25 cycles >5% U (>95% dip in U) for 5 seconds	<5% U (>95% dip in U) for 0.5 cycle 40% U (60% dip in U) for 5 cycles 70% U (30% dip in U) for 25 cycles >5% U (>95% dip in U) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment
Note - U is the AC main voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Loop™ is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of Loop™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = [\ 3.5/V\ ]\sqrt{P}$ $d = [\ 3.5/V\ ]\sqrt{P}$ 80 MHz to 800 MHz $d = [\ 3.5/V\ ]\sqrt{P}$ 800 MHz to 2,7 GHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Loop™ is used exceeds the applicable RF compliance level above, Loop™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Loop™. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

10. Accessories and Replacement Parts

System	SKU
Loop™ LED Curing Light System	CLK01

Replacement Parts	SKU
Loop™ LED Curing Light Handpiece	CLA01
Loop™ Calibration and Charging Base	CLA02
Loop™ Battery Kit	CLA03
Loop™ Universal Power Supply and Adapters	CLA04
Loop™ Protective Barrier Sleeves	CLA05
Loop™ Protective Light Shield	CLA06
Loop™ Lens Cleaning Cloth	CLA07

11. Contact Information

HEADQUARTERS
150 DeWitt Lane
Spring Lake, MI 49456
USA
888.437.0032

EUROPEAN OFFICE
Carlstrasse 50
D-52531 Uebach-Palenberg
Germany
+49.2451.971.409

www.GarrisonDental.com

For patent information, see www.garrisondental.com/patents

Garrison®

Company Headquarters
150 DeWitt Lane, Spring Lake, Michigan 49456 USA
Toll-Free (US and Canada): 888.437.0032
T 616.842.2244 • gds@garrisondental.com • garrisondental.com

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