

3901 S Fife Street, Suite 100 - Tacoma, WA 98409 - www.bioclearmatrix.com

Bioclear HeatSync-Mini Composite Heater

INSTRUCTIONS FOR USE: Please read completely before operating unit

1. Intended Use:

- The HeatSync-Mini Composite Warming unit is designed to heat composite materials, to 155°F (68°C). ***For best results, use a composite that has been specifically formulated for heating and gone through testing for both safety and performance when heated and cooled many times prior to dispensing.***
- The Compule Oven can warm compules, porcelain veneers, and onlays.

2. Precautions:

- Read these instructions carefully before use.
- Do not drop the unit.
- The HeatSync-Mini Composite Heater may be hot to touch.

Caution should be used to avoid touching the metallic surfaces on the unit.

3. HeatSync-Mini Setup:

- After unpacking the HeatSync-Mini, check that all components and accessories are included:
(1) Composite Warmer Unit (top and base), (2) Power cord and converter
- Connect power cord into the power converter making sure that it is correctly and firmly connected.
- Plug power cord into the back of the base of the HeatSync-Mini making sure it is completely seated.
- Turn system on by switching the ON/OFF switch on the front of the Composite Warmer base to the "On" position. The POWER ON LED will illuminate when the unit is on.
- The HeatSync-Mini requires a minimum 15 minute warm up period prior to inserting loaded composite syringes. ***If the unit is not to be used within an hour, it is recommended that the unit be turned off.***
- The Heating LED will illuminate while it is heating.

4. Daily Usage:

1. Insert compule into the composite syringe.
2. Insert composite and flowable syringes into the open slots in the HeatSync-Mini unit.
The compule oven in front of the unit will also heat any extra composite compules placed inside.
3. Heat compules in composite syringe for 10 minutes prior to completing the restoration.

5. HeatSync-Mini Maintenance and Disinfection:

- The entire top section of the unit (NOT including the Rubber Band) is autoclavable and can also be wiped with a disinfecting cloth.
- It is recommended to disinfect the unit between uses.
- DO NOT attempt to autoclave the "Base Warming Unit."
- Align the "X" mark at rubber band at front side of "Base Warming Unit" as shown Fig. 1.

6. System Components

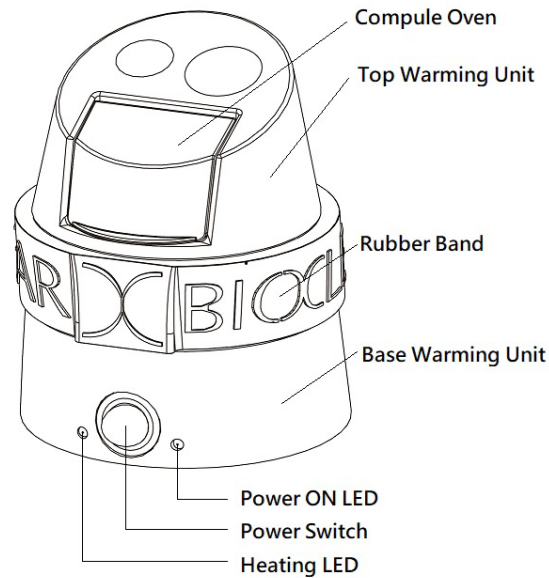


Fig. 1 System Components

7. Technical Specification

7.1 Electric Voltage :

Power Input Voltage : 100V~240V unit.

100-240 V AC 50/60Hz 1.0A (MAX)

Wattage Consumption MAX. 60W

7.2 Dimension :

Height : 10.2 CM

Width : 8.2 CM

Depth : 8.2 CM

Weight : 0.7 KG

7.3 Operation Environment :

Ambient Temperature : +10°C ~ +40°C

Relative Humidity : 30%~75%

Atmospheric Pressure : 700 hPa~1060 hPa










7.4 Transportation And Storage Environment:

Ambient Temperature : - 10°C~+70°C

Relative Humidity : 10%~90%

Atmospheric Pressure : 500 hPa~1060 hPa

8. Glossary of Symbols

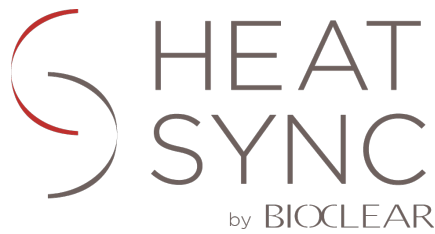
| | |
|---|---|
|  | Attention, Consult Accompanying Documents |
|  | Alternating Current |
|  | Power Off |
|  | Power On |
|  | Manufacturer |
|  | Date of Manufacture |
|  | Catalogue Number |
|  | The equipment complies with the requirements in the Medical Device Directive 93/42 EEC. |
|  | Icon to identify electric and electronic devices. The unit must be collected and disposed of separately. |

9. Package Content

| | |
|------------------|---------|
| Heater Main Unit | X 1 PCS |
| Power Cord | X 1 PCS |
| Power Adaptor | X 1 PCS |

10. Safety Warnings

- Before operating the unit, please follow and adhere to all warnings, safety and operating instructions located on the product and in this User Manual.
- Use only as specified by these operating instructions or the intrinsic protection provided by the unit may be impaired.
- Do not expose the product to water or moisture while energized.
- Do not allow moisture to penetrate openings in the case. If this occurs allow the unit to dry out unpowered before switching on again.
- Do not expose the product to extreme hot or cold temperatures.
- Do not expose the product to open flames.



- Do not allow objects to fall on or liquids to spill on the product.
- Do not replace detachable main supply cords by inadequately rated cords.
- If this equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

11. Regulatory Information

Limitation of Liability

HeatSync Minis are intended to be used by educated dental professionals, e.g., general dentists, dental assistants, dental hygienists, who have theoretical and practical knowledge on usage of dental products only. Any use not specified in the instructions is not recommended and will be the responsibility of the attending practitioner.

Any serious incident (defined in the regulation (EU) 2017.745 as an adverse event that results in death or serious deterioration in the health of the subject) that has occurred in relation to the use of this device should be reported both to the manufacturer immediately either by mail at the address above or by email to jennifer@bioclearmatrix.com as well as to the competent authority of the Member State in which the user or patient is established. After we receive the information on the incident, Bioclear will also report it to the FDA and the EU Competent Authority and follow up as necessary.

Manufacturer:



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USA
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Importer:

Find the importer for your country on our website at www.bioclearmatrix.com



EMERGO EUROPE B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



Harmonized Symbols:



The HeatSync Mini complies with RoHS 3 Directive 2015/863 (Restriction of Hazardous Substances)

IFU Revision Date: November 13, 2024