# ENA HEAT COMPOSITE HEATING CONDITIONER Ref. CHC3

## **INSTRUCTION MANUAL**



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DECLARATION OF CONFORMITY	4
CHAPTER 1	5
GENERAL REMARKS	5
GENERAL REMARKS  1.1 CONGRATULATIONS ON YOUR PURCHASE  1.2 PRODUCT DESCRIPTION AND INFORMATION	5
1.2 PRODUCT DESCRIPTION AND INFORMATION	5
1.3 GLOSSARY	5
1.5 GENERAL CONSIDERATIONS	0 8
CHAPTER 2	
HEATER SPECIFICATION	9
2.1 INTRODUCTION	9
2.1 INTRODUCTION 2.2 TECHNICAL DESCRIPTION OF THE MACHINE 2.3 TECHNICAL SPECIFICATIONS	
CHAPTER 3	
INSTRUCTIONS FOR USE	10
3.1 INTENDED USE	10
3.2 CONTROLS	10
3.3 HOW TO USE	
CHAPTER 4	13
CUSTOMER CARE & WARRANTY	13
4.1 CUSTOMER CARE	13
4.2 WARRANTY  4.3 TECHNICAL SERVICE  4.4 DEVICE DISPOSAL	14
4.4 DEVICE DISPOSAL	14 15
22.132.23. 33.12	
PICTURES INDEX	
Fig. 1: Ena Heat (front view detail)	10
Fig. 2: Ena Heat (back view detail)	11

#### CE DECLARATION OF CONFORMITY

WE

MICERIUM S.p.A. VIA G. MARCONI, 83 16036 AVEGNO (GE) ITALY

Tel.: (+39) 0185 7887870 Fax: (+39) 0185 7997970

DECLARE UNDER OUR EXCLUSIVE RESPONSIBILITY THAT THE PRODUCT:

## ENA HEAT COMPOSITE HEATING CONDITIONER Ref. CHC3

WHICH THIS DECLARATION IS REFERRED TO, IS IN COMPLIANCE WITH WHAT IS ESTABLISHED BY THE DIRECTIVES:

Medical device: 93/42/EEC (2007/47/ECC) - Annex VII

Annex IX, Rule XII, Class I

Electrical equipment:

Electromagnetic compatibility
Low Voltage
RoHS
2014/30/EU
2014/35/EU
2011/65/EU
WEEE waste electrical and electronic equipment 2012/19/EU

and further modifications

and to the armonized standard:

EN 61326-1 EN 61010 EN ISO 15223-1

Avegno (GE), November 2016



(Dr. Eugenio Miceli)

CHAPTER 1
GENERAL REMARKS

#### 1.1 CONGRATULATIONS ON YOUR PURCHASE

Congratulations for choosing this product.

You have purchased a product that has been manufactured with the highest precision and verified and tested with meticulous craftsmanship.

Since the 1980's Micerium S.p.A. has been introducing innovative products and receiving prestigious achievements in the dental industry.

Micerium S.p.A., to confirm its continuous involvement to fulfil its Customers requirements, applies from 1998, the most comprehensive quality system that ensures a good quality management in all the stages from design to development, manufacture, installation and service.

We want to thank You for choosing us and we are confident this new purchase will give You an efficient support for your job.

#### 1.2 PRODUCT DESCRIPTION AND INFORMATION

NAME: ENA HEAT COMPOSITE HEATING CONDITIONER

MODEL: CHC3

Ref. CHC3 with EC adapter Ref. CHC3-GB with UK adapter Ref. CHC3-US with US adapter

MANUFACTURER: MICERIUM S.p.A

Via G. Marconi 83

16036 Avegno (GE) - Italy

For more information, please contact the Micerium's sales offices at the followings:

- Phone number: (+39) 0185 78 87 880 (our sales offices are open all weekdays);
- Fax: (+39) 0185 78 87 970;
- E-mail: hfo@micerium.it

#### 1.3 GLOSSARY

The following symbols and their respective meanings are found in this instruction manual:



The caution symbol calls the attention to an operating procedure, practice or another similar measure that, if not properly followed or respected, can **seriously damage the functionality and the safety of the product**.



The warning symbol calls the attention to an operating procedure, practice or another similar measure that, if not properly followed or respected, can **CAUSE INJURIES**.

#### 1.4 GENERAL SAFETY DIRECTIONS



The unit can only be safely used after reading and understanding the instruction manual, the safety indications, all additional literature and strictly following the directions given.

The machine must be used only for the indicated purposes.

Failure to follow all instructions listed in both documents may result in electric shock, fire, and/or serious personal injury.

#### **KEEP THESE INSTRUCTIONS!**

#### **USER:**

- 1. This is a medical device intended for professional use only.
- 2. The equipment must be used only by one trained user. Tools are dangerous in the hands of untrained users.
- 3. Before using the device, please read the Instruction Manual carefully and completely. Please, learn the operation, applications and potential hazards related to the unit.

#### **INTENDED USE:**

Ena Heat Composite Heating Conditioner allows the use of composite at a clinically ideal temperature during its application in the oral cavity and in the laboratory. It can also be used to heat hypochlorite and anaesthetics. Any other use is forbidden.

#### **WORK AREA SAFETY:**

- 1. Do not use the electric device in wet or outdoor environments.
- 2. Keep work area clean and well lit. Cluttered benches and dark areas invite accidents.
- 3. Do not operate the device in explosive atmospheres, such as in the presence of flammable liquids, gases, or dust. Power tools create sparks which may ignite the dust or fumes.
- 4. Keep children, and visitors away from work area. The work area is forbidden to all these people. They are not understood of any instruction so they could have serious personal injuries. Furthermore, distractions can cause you to loose control.
- 5. Do not let visitors contact the tool or extension cord. Such preventive measures reduce the risk of injury.
- 6. Danger zone An area of at least 0.5 m around the unit has to be declared a danger zone, as this is the area in which the personnel does all work.

#### **ELECTRICAL SAFETY:**

- 1. Avoid to contact grounded objects such as tubes, radiators, refrigerators.
- 2. Do not use any adapter plugs.
- 3. Don't expose power tools to rain or wet conditions. Water entering a power tool will increase the risk of electrical shock.
- 4. Do not abuse cord. Never use the cord to carry the equipment or pull the plug from a socket. Keep cord away from heat, oil, sharp edges or moving parts.
- 5. Immediately replace the ACDC adapter when cord is waste or damaged. Damaged cords increase the risk of electrical shock.

- 6. Connect the tool to an AC power supply that matches the power unit specifications. Incorrect voltage supply can cause electrical shock or burns
- 7. Use only the supplied type of ACDC adapter. Other types than those listed may cause severe damage to the device and short-circuits to the electrical system.
- 8. Emergency Switch off the unit with the main switch and disconnect the plug from the wall socket.

#### **TOOL USE AND CARE:**

- 1. Do not insert metal objects or liquids into the device.
- 2. Do not use equipment if switch does not turn it ON or OFF. Any equipment that cannot be controlled with the switch is dangerous and must be repaired.
- 3. Disconnect plug from the power source before making any adjustments or storing the tool. Such preventive safety measures reduce risk of starting tool accidentally.
- 4. Always control that the tool isn't damaged Before using the unit, check with attention its efficiency and the perfect working of the safety devices and if necessary of damaged parts. Safety devices or damaged parts must be repaired or changed by an Authorized Center of Assistance it different indications aren't given. Many accidents are caused by poorly maintained tools.
- 5. If the device falls down, do not use it and send it to an authorized centers of assistance for the proper functional tests
- 6. Have qualified people to change the tools This electric unit is in conformity with the safety directions in force. The repair of electric tools must be done only by authorized centers of assistance
- 7. Inspect equipment, connection plug and cord periodically and replace the ACDC adapter if they are damaged.

#### **MAINTENANCE:**

- 1. Tool service must be performed only by qualified repair personnel authorized by Micerium S.p.A. Service or maintenance performed by unqualified repair personnel are not allowed and could result in injury.
- 2. When servicing an equipment, use only identical replacement parts. Follow instructions in the Maintenance Section of the Instruction Manual. Use of unauthorized parts or failure to follow maintenance instructions may create a risk of electrical shock or injury.

#### **CLEANING AND DISINFECTION**

The structure is of aluminium and plastic. For cleaning and disinfection is recommended to cut off the ACDC adapter and lightly rub the surface with a cloth dampened with alcohol (do not use acetone or other aggressive agents for plastics). Dry completely, including syringe and tips slots, with a dry cloth, if needed.



Do not dip any elements into liquids, nor pour liquids into the syringe and tips slots.

Do not autoclave.

Never spray disinfectant or cleaning agent directly onto the system.

For additional safety instructions, please read any enclosed information about the general operation of the machines.



## Read and follow safety labels on machine! Know the location and functions of all controls before using this tool

#### 1.5 GENERAL CONSIDERATIONS

This manual gives the indications about the recommended use of the machine and its maintenance. All personnel responsible for these activities should read and become familiar with this information.

This manual must be considered as an integral part of the machine and must be "kept for future reference".

If this manual is damaged or lost, please contact the Micerium's sales office to request a replacement copy.

Micerium S.p.A. reserves the right to update machinery and manuals without the obligation of updating any previous revisions, unless there is an exceptional change made in the instructions. The user can however request that Micerium's sales office provide an updated version of the manual and once it is received, the previous version should be discarded.

If you have any questions that are not answered in the manual, please contact the company directly for assistance.

If you decide to sell this machine, please provide the new owner with Micerium's contact information so assistance and training can be provided to the new owner.

If this contact information IS NOT provided to the new owner, the manufacturer is relieved of all responsibility linked to an improper use of the machine, and to all other information concerning the machine contained in this manual

## CHAPTER 2 HEATER SPECIFICATION

#### 2.1 INTRODUCTION

The use of Ena Heat CHC3 Composite Heating Conditioner is allowed only to well trained operators.

The machine must be connected to an <u>electrical system</u> (tension 100-240VAC 50/60Hz, 500mA) by using the provided ACDC adapter 12Vdc 1000mA 12W Class II (Ref. CHC3 with EC adapter, Ref. CHC3-GB with UK adapter, Ref. CHC3-US with US adapter).



Only use the enclosed ACDC adapter:

GM-120100 (CVE) type P2 EF, SW3, 12W, 100-240 V~, 50-60 Hz, 500 mA, class II).

#### 2.2 TECHNICAL DESCRIPTION OF THE MACHINE

Ena Heat CHC3 Composite Heating Conditioner consists of a cilinder body with recesses in two different sizes for placing syringes, vials and tips and an electronic control with an on-/off-switch, a led control, a temperature selector switch and a power supply unit.

#### 2.3 TECHNICAL SPECIFICATIONS

Power	Tension: 12Vdc stabilized	
	Current: 1A	
	Power: 12W	
Working temperature	$T_{\text{room}} > -20^{\circ}\text{C }(-4^{\circ}\text{F})$	
Selectable temperatures	T1: +39°C (102.2°F) +/-1%	
	T2: +55°C (131°F) +/-1%	
Heating times	T1: +39°C (102°F) ~ 16 min.	
at +20°C (68°F) T <sub>room</sub> .	T2: +55°C (131°F) ~ 55 min.	
	$T1 \Rightarrow T2 \sim 30 \text{ min.}$	
Signals	LED ON: green: on	
	LED T1 and T2: flashing yellow: heating	
	fix yellow: temperature reached	
	red: alarm	
Alarm conditions	a. T> +60°C (140°F)	
(LED ON turning red)	b. T<-20°C (-4°F)	
	c. temperature sensor failure or interrupted	
	d. ascent of temperature below 1°C (33.8°F)/200 sec.	
Active protections	Software protections	
Passive protections	2A quick-active fuse on power connection. 86°C (186.8°F) thermo - fuse	
Dimensions (mm)	115x110x125 (height, width, depth)	
Weight (gr)	750 (power unit included)	

## CHAPTER 3 INSTRUCTIONS FOR USE

#### 3.1 INTENDED USE

Ena Heat CHC3 Composite Heating Conditioner has been designed to keep composite (syringes and tips) at a clinically ideal temperature for its application in the oral cavity and in the laboratory. The first temperature (T1: 39°C = 102.2°F) is perfect to heat composite for build up and to heat anaesthetics and hypochlorite; the second temperature (T2: 55°C = 131°F) to heat composite for luting.



The <u>syringe heater</u> may <u>only</u> be used <u>with</u> composite which are suitable for temperatures of 39°C / 55°C (102.2°F/131°F), as <u>Enamel Plus HFO and HRi</u> (Ena HRi/HFO for US) and Tender Pink (except for Flow, OBN and other Tender colours). Please refer to manufacturer instructions for other composites. Please be sure that syringes/tips are perfectly closed.

To <u>heat hypochlorite</u> use <u>only airtight syringes or sealed vials</u> to avoid liquid entering in cavities of the unit.



All uses different from those described are not allowed. Do not use the machine with any other material which is not indicated for this machine.

#### 3.2 CONTROLS

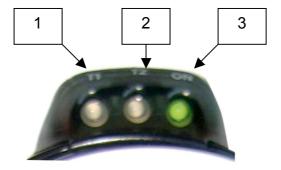


Fig. 1: Ena Heat (front view detail)

- 1. Led T1 for temperature 39°C (102.2°F) (flashing yellow = heating; fix yellow: temperature reached; red: alarm)
- 2. Led T2 for temperature 55°C (131°F) (flashing yellow = heating; fix yellow: temperature reached; red: alarm)
- 3. Led ON for switch on control (green: on)



Fig. 2: Ena Heat (back view detail)

- 1. On/off switch
- 2. T1/T2 temperature selector
- 3. Power supply

#### 3.3 HOW TO USE

- 1. Connect the ACDC adapter to the heating unit and connect it to a 110-240 V electrical socket.
- 2. Switch on the On/Off switch (the green led will light up). When the system works and the led On is lit, the surface of the system should soon begin to heat. This is a sign that the system works.



If the system is turned on, but the LED is not lit, please check the correct connection of the power unit and socket. If the problem persists, contact the manufacturer.

3. Regulate the temperature with the temperature selector: 55°C (131°F) for luting procedures and 39°C (102.2°F) for build up and to heat anaesthetics and hypochlorite. The selection of the temperature will be highlighted by the turning on of the flashing yellow LED. Before use, wait for the time necessary to achieve the ideal temperature: upon reaching the set temperature, the LED will become fixed.



T1: (corresponds to 39°C = 102.2°F)
To heat composite for build up, to heat anesthetics and hypochlorite.

T2: (corresponds to 55°C = 131°F)

To heat composite for luting



In table at Point 2.3 the mean times for heating at room-temperature of 20°C (68°F) are reported. Lower room-temperature will increase these times.

- 4. Insert syringes, vials or tips in the holes at least 10 minutes before using the material (20 min. for luting)
- 5. Once restoration is finished, remove the syringes or the tips from the unit. The unit can remain switched on even the whole day. If you are working at 55°C (131°F) please insert only the syringes and tips of the colour you need.

## CHAPTER 4 CUSTOMER CARE & WARRANTY

#### 4.1 CUSTOMER CARE

The control of all functions, both function and security, is operated by a microcontroller to supervise very clearly the proper conduct of the activities of heating and maintaining the temperature. During heating, the slope of the temperature curve is monitored to verify that the increment is at least 1° C (33.8°F) every 200 seconds. If this condition does not occur or is interrupted, there would be an alarm (red LED) and the shutdown of the machine (software protection). To remove the alarm condition (reset), you have to power cycle the machine by using the On-Off.



If the problem becomes repetitive, please return the machine to the assistance.

You can have reports of alarm (software protection), even in the following cases:

- a) exceeding a temperature of +60°C (140°F)
- b) below -20°C (-4°F)
- c) in case of failure of temperature control



In case of a) or c), you have to send the device to the assistance.

In addition, the following and other kind of passive securities have been introduced, that are independent of any control function of electronics:

- a) non-resettable 2A fuse on power supply as a protection against overcurrent or short circuit inside. The merger of the component makes the machine unusable.
- b) Thermo-fuse calibrated to +86° C in contact with the heating chamber to protect against overheating caused by a loss of electronics regulation. This component melts reaching the temperature setting, preventing the operation of the machine.



In both cases you have to send the device to the assistance.

#### **4.2 WARRANTY**

The unit is guaranteed for 12 months both for materials and construction.

This unit has been constructed and manufactured under consideration of all safety regulations. Should the unit show any manufacturing errors or irregularities during the guarantee period, the manufacturer according to our standards will fix them. For any guarantee claim, the invoice or delivery note must be provided as proof. The guarantee is limited to the replacement of the part or parts which show the manufacturing error or irregularity.

Excluded from guarantee are: personnel costs, expenses of the technical staff, transport costs, packaging, etc. Furthermore, errors or other problems that the manufacturer cannot be blamed for or parts that are subject to normal wear may not be claimed under guarantee.

Direct or indirect damage claims towards any persons or things may not be derived from this guarantee, even if the reason for the damage could be traced back to the unit. This guarantee will automatically be terminated, if the unit is repaired, changed or opened by force by the user/buyer or any unauthorized third party.

Should any problem occur during the guarantee period, the user/buyer have only to contact the manufacturer or an authorized service center named by the manufacturer.

The right to exchange the complete unit for a new one is excluded. Any parts replaced during the guarantee period must be returned to Micerium S.p.A., who will supply a new part. Should the replaced part not be returned, it will be billed to the user/buyer

#### 4.3 TECHNICAL SERVICE

Please contact Micerium S.p.A. at the followings:

- Phone number: (+39) 0185 78 87 880 (our sales offices are open all weekdays);
- Fax: (+39) 0185 78 87 970;
- E-mail: hfo@micerium.it

#### 4.4 SYMBOLS ON DEVICE and/or ON PACKAGE - DEVICE DISPOSAL

SEE INSTRUCTIONS FOR USE

 $\bigcap_{\mathbf{i}}$ 

PRODUCT REFERENCE

REF

**SERIAL NUMBER** 

First four digits: production year

SN

PACKAGE DISPOSAL

Carton



**DEVICE DISPOSAL** 



#### Information to Users

This product is covered by the European Directive 2012/19/UE, or the reduction of the use of hazardous substances in electrical and electronic equipment, and disposal of waste.

The symbol of bin crossed reported on your equipment or its packaging indicates that the product at the end of its useful life must be disposed separately from other waste.

A separate collection of this equipment arrived at the end of its life is organized and managed by the manufacturer. If you want to get rid of this equipment, please contact the manufacturer and follow the system that he has chosen to allow separate collection of the apparatus arrived at the end of its life.

A proper separate collection for the next launch of the disused equipment to recycling, treatment and environmentally compatible disposal helps to avoid possible negative effects on the environment and on health and promotes reuse and / or recycling of materials composing the equipment. The illegal disposal of the product by the holder includes the application of administrative sanctions provided for by law.



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