

Next Generation Implantology

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Gen **WELD** *MK II*

Intraoral welder

User Manual

The instructions contained within this manual must be read carefully in order to ensure the correct and safe use of the device.

Contents of the user manual

Chap. Topic

1. Technical specifications
2. Functional indications and intended use
3. Regulations for safe use
4. System requirements
5. Moving the device
6. Operator and installation environment requirements
7. System malfunctions
8. Applied Standards
9. Device disposal
10. Packaging contents
11. Packaging label
12. Introduction to the device
13. Introduction to the accessories
14. Data label
15. Device connections
16. Instructions for using the device
17. Preventive functionality check
18. SetUp Section
19. Maintenance and periodic checks
20. Disinfection and sterilization
21. Errors and troubleshooting
22. Transport and storage
23. Technical assistance service

1. Technical specifications.

Rated Input voltage	110-230 Vac +/-10% - 50/60 Hz +/-1Hz sinusoidal single phase with automatic voltage selection
Input protection	Double input fuse accessible from the rear panel Luminous bipolar switch on the rear panel EMI/EMC filter with leakage current to GND max 500uA Capacitor thermal protection
Output characteristics	Selectable current pulse – max. current pulse of 2.5 kAmp at 100% power with pre-pulse heating.
User interface signals and features	LCD-TFT touch screen display Ready signal – visual and acoustic Welding in progress and welding concluded signals – visual and acoustic Best welding point detection – acoustic Welding power setting with the possibility of saving custom programs.
Output protection	Clamp open detection Capacitor temperature detection Residual welding charge detection
Hardware features	Activation footswitch Clamp sterilizable in an autoclave
IP protection rating	Device = IP40 LCD Display = IP64 (disinfectable using liquids).
Sound pressure	LpA = 59.57 dB(A) ₂ LpC-peak = 58.8 dB(C) ₃ = 0.35 Pa LwA = 69.14 dB(A)
Dielectric strength	Input / Clamp-Footswitch 1550 Vac 50Hz 1min Input / GND 1550 Vac 50Hz 1min Clamp-Footswitch / GND 1550 Vac 50Hz 1min Clamp-Footswitch-Input / touch screen 1550 Vac 50Hz 1min
Environmental operating conditions	Ambient temperature: -10° < Amb.Temp. < +40° Relative humidity : 0% / 90% Atmospheric pressure: 500/1060 hPa
Environmental conditions for storage and transport	Ambient temperature: -20° < Amb. Temp. < +60° Relative humidity : 10% / 100% - without condensation Atmospheric pressure: 500/1060 hPa
Input fuse	6.3A-T 250 Vac
Mechanical dimensions	28cm x 30cm x 14cmH
Weight	8.5Kg

Gen **WELD** MK II

2. Functional indications and intended use.

Foreword

The **Gen WELD MK II** is comprised of 2 electronic boards that serve the purposes of monitoring the device's components and generating the current pulses. These energy pulses serve to weld titanium wires of various diameters to dental abutments that are already in place, thus allowing the titanium wire itself to be attached between the abutments of dental implant systems. The system is controlled using an LCD touch screen display.

Welding methodology indications

The **Gen WELD MK II** provides for the fusion welding of two elements that are held in contact between two probes/electrodes. The welding is caused by the passage of a strong current within an extremely narrow conducting channel. This current causes the temperature inside the channel to abruptly increase, thus resulting in the two elements being melted and firmly welded together.

The welding quality depends upon the contact surface of the two elements: the narrower the surface, the better the quality and strength of the welding. This is due to the fact that a greater current density is obtained at the point, thus resulting in a higher melting temperature. The parameters that determine the welding energy are the following:

$I \times T \times R$ = Energy expressed in Joules, where I is the circulating current, T is the time during which the current flows, and R is the resistance posed by the material.

This current is transmitted through the tips of the clamp (electrodes).

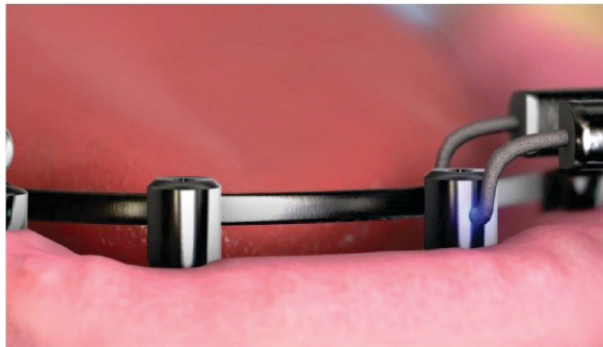
These electrode tips have been designed to provide for optimal positioning and pressure upon the parts to be welded, as well as to maintain constant pressure both prior to and during the welding operations. Lower pressure would result in gaps between the parts, which in turn could result in sparking. Both the clamp and the electrode-tips are made of a material that provides for excellent electrical and thermal conductivity. The former provides for an ample current flow channel and the latter allows the heat generated by the welding process to be discharged towards the clamp itself, rather than the abutment. The electrodes, clamp and relative connection cables with special connectors must all be kept in good condition. In order to maintain the equivalent resistance of the circuit involving the electrodes, the clamp, the cables and the connector significantly lower than that of the contact between the abutment and the wire, these elements must always be free of any dirt and/or other substances.

Gen **WELD** MK II

Welding stages

The intraoral welding process involves three stages:

1- Preparation stage: the ends of the electrodes are positioned next to the abutment (stump) and the titanium wire so that they make contact. Make sure there are no residues between the wire and the abutment. Position the clamp and the relative electrodes in a stable manner and let the clamp's springs exert their pressure. This pressure is necessary in order to keep the elements in contact and in order to maintain the proper position during the welding process.



2- Welding stage: upon pressing the footswitch, an electric current is emitted from the machine to the electrodes, thus generating an increase in temperature that results in the melting (syncrystallization) of the material. The main welding stage is preceded by an initial pulse for heating the material. The transfer of energy only lasts for a few milliseconds and the complete welding stage lasts for a total of approximately 3 seconds. The speed of this energy transfer thus ensures negligible residual heating.



3- Cooling stage: the clamp must be kept in contact until the end of the cycle, which is indicated by the device emitting a final acoustic beep and returning to its "Ready" status.

The *cooling stage*, which lasts approximately 3 to 4 seconds, is extremely important as it allows the heat generated by the welding process to be absorbed by the copper electrodes, which have a lower thermal resistance than the titanium. This ensures that the heat will not flow in the direction of the abutment and prevents the tissue itself from being heated. **It is nevertheless recommended to use one of the dental chair's cooling elements (water and/or air), above all for power levels in excess of 60% or with abutments of smaller diameters.**

Gen **WELD** MK II

Functional indications

The Gen **WELD** MK II intraoral welder makes use of energy accumulating components. This stored energy can be adjusted based on the type of material to be welded.

Upon pressing the footswitch, energy is accumulated that will allow for the welding operations to be carried out. This stage is repeated for each welding operation to be performed. During the system's pause/standby stages, a negligible current is absorbed from the electrical grid.

The stored energy is then instantaneously release in one or two different stages (one or two pulses are selectable by operator):

- *The first stage* (if two pulses was been selected) heats the material to be welded and prepares it for the main energy discharge during the subsequent welding stage. During the material preheating stage, less energy is applied with respect to that which is supplied during the Main stage. This energy is automatically regulated based on the selected welding power.
- *The main welding stage* applies the energy necessary to bond the materials in the best possible manner. This energy level can be selected upon the user interface and must be selected based on the material to be welded.

These two stages are automatically carried out in succession upon pressing the footswitch.

If one pulse stage is selected, only main welding stage will be performed.

The energy emitted by the Gen **WELD** MK II intraoral welder is instantaneous and causes the parts to be welded together: the abutment and the titanium wire. The extremely brief preheating period, combined with the heat dissipating effect of the electrodes, prevents the abutment itself from being heated up. The patient will not feel any sensation of heat. The low-voltage employed for generating the welding current is optimized in such a way so as to allow for the welding operation to be carried out in complete safety, with only a remote possibility of sparks being generated.

The operator has complete control over the amount of energy to be applied, selecting the desired energy level based on the material to be welded.

In fact, the user interface allows the operator to simply and intuitively select the material and the size of the wire to be welded.

The welding energy level is preselected by the Gen **WELD** MK II intraoral welder based on the type of material and its dimensions. This preselection determines the optimal energy level for the selected type of welding operation.

If the operator should require a different power level, he/she can use the touchscreen panel to adjust the welding energy level and to save the new value that has been inserted.

The Gen **WELD** MK II intraoral welder makes use of a visual and acoustic system that indicates the exact timing of the operations to be carried out, as well as any anomalies that may occur.

Gen **WELD** *MK II*

In fact, the operator is provided with "Ready", "In function" and "Wait" indications. These indications are clearly shown on the LCD display and can be identified by the number and length of the acoustic signals associated with them, thus allowing the operator to continuously focus his/her attention on the work being carried out.

The welding operations are carried out using an appropriate clamp.

This clamp has an ergonomic shape and is optimally predisposed to house the electrodes required for the welding stage.

Once positioned upon the material to be welded, the clamp maintains the correct position thanks to its retention springs. The pressure exerted by these springs can be adjusted as desired.

The clamp can be disconnected from the Gen **WELD** *MK II* intraoral welder in order to allow it to be sterilized in an autoclave. What's more, the touchscreen panel comes equipped with a protective casing that allows it to be thoroughly cleaned without compromising its functionality.

The Gen **WELD** *MK II* intraoral welder's user interface offers the user complete control of the system.

The ample LCD display provides the user with a clear view of the device's operating parameters, as well as the functions that are in progress.

The LCD touchscreen user interface allows the user to navigate the product menu, insert values and query the device itself by simply touching the screen.

Once the operator has accessed the menu, he or she can select the material size and type in order to allow the device to preselect the welding energy level. This energy level can be modified as desired in the event that the system and the field of application do not respond as expected. Such modifications can even be saved for subsequent use.

One section of the Gen **WELD** *MK II* intraoral welder's user interface allows for a number of the device's operating parameters to be detected and configured.

The parameters that can be consulted in the diagnostics section can be useful for resolving any malfunctions that may occur.

The Gen **WELD** *MK II* intraoral welder is equipped with a monitoring system that checks the system's status before, during and after the welding operation.

These checks are carried out in real time and detect:

- the opening of the clamp upon the activation of the welding stage, thus impeding it from being carried out.
- the temperature of the capacitor. If not within the safety range, the use of the welder will be impeded until the temperature has returned within the required safety limits.
- the presence of residual energy within the capacitor, indicating that a welding operation has been carried out incorrectly or else aborted.
- the absence of a charge within the capacitor.
- the presence of auxiliary voltages for monitoring and managing the system.

3. Regulations for safe use

This device has been developed and tested in compliance with the current national and international regulations and safety standards and therefore guarantees high levels of electrical safety.

Warning!



The user is required to carefully read these operating instructions before using the device and must observe all of the safety warnings and information contained within this manual. The instrument must be used correctly in order to ensure its safe functionality.

Warning!

The Gen **WELD** MK II intraoral welder **must only be used by Dental Surgeons and/or Dentists** who are aware of the device's applications, including the treatment parameters, the effects on the tissues, the possible side effects, the limitations, the contraindications, treatment of complications, etc.

The device must only be used in a medical/dental clinic

Warning!

The equipment and its relative accessories are not supplied in a sterile state. They must be properly cleaned, disinfected or sterilized before use.

Warning!

It is recommended to AVOID USING the device upon patients with PACEMAKERS or other types of ELECTRONICS SUPPORTS. The welder produces strong, yet brief, magnetic fields and electrical disturbances during peak welding.

Warning!

Avoid using the Gen **WELD MK II intraoral welder in conjunction with other electrical therapeutic or diagnostic devices.**
Electrical devices may cause interference with one another. If the use of another electrical device cannot be avoided, be sure to minimize the possibility of interference by positioning each device at a reasonable distance from the other.

NOTES ON INSTALLATION AND USE

Position the device in such a way so that the **electrical cable** and the electrical power supply connector on the rear panel are in an easily accessible location.

Do not use the equipment contained within the packaging in:

- areas at risk of explosion
- the presence of flammable anaesthetics or volatile solvents, such as alcohol, gasoline, etc.

Do not store or use the instrument in humid environments.

Avoid exposing the instrument to liquid sprays or drops: the instrument is not resistant to liquids.

Warning!

This device may not be altered in any way.

Do not alter this device without the manufacturer's express authorization.

If the device is altered in any way, appropriate tests and checks must be carried out in order to ensure that it can continue to be used in complete safety.

The manufacturer shall bear no responsibility for any damages due to tampering on behalf of unauthorized personnel; any such tampering shall invalidate the device's warranty.

Warning!

The use of any commands, adjustments or procedures other than those which are specified in this manual could result in unsuitable or poor quality processing.

Warning!

Always disconnect the device from its electrical power supply before opening it or changing any of its fuses.

Warning!

During the welding stage, it is recommended to use one of the dental chair's cooling elements (water and/or air), above all for power levels in excess of 60% or with abutments of smaller diameters.

4. System requirements

The following requirements must be respected both during and following installation.

- The voltage supplied by the electrical grid must correspond to the indications shown upon the instrument itself.
- The instrument must only be used in conjunction with its supplied power cable.
- All of the cables, outlets and plugs must comply if the current standards.
- Make sure that the clamp is properly connected to the device.

WARNING

In order to avoid the risk of electrical shock, this device must only be connected to a grounded electrical network.

WARNING

This medical device must only be connected to a sinusoidal electrical source with the following characteristics:

- it must not vary from the device's rated voltage (110-230 Vac) by more than $\pm 10\%$
- it must not vary from the device's rated frequency (50-60 Hz) by more than $\pm 1\text{Hz}$
- it must employ the protection measures outlined in IEC60364-4-41

Do not connect the device to the electrical network if these conditions are not met

5. Moving the device

Sudden temperature changes must be avoided when moving the device as these could result in condensation. **If the Gen **WELD** *MK II* intraoral welder is subjected to these types of sudden temperature changes, wait at least 3 hours before connecting the device to the electrical network and turning it on.** For indications regarding the transport of the product, please refer to the relative chapter.

6. Operator and installation environment requirements

The Gen **WELD** *MK II* intraoral welder must only be used in a dry environment and must never be exposed to rainfall or liquid spills.

Make sure that no concentrations of flammable gases or liquids are present during installation. These include adhesive solvents and disinfectant solutions with high alcohol content which, if used, must be allowed to evaporate before turning on the device.

Since the use of the device could result in sparks, the operator and the patient must make use of personal protective equipment, such as safety goggles and gloves.

7. System malfunctions

If any malfunctions that cannot be resolved using the instructions provided within this user manual are encountered while using the Gen **WELD** *MK II* intraoral welder, disconnect the device from its electrical power supply and contact the Manufacturer's Technical Assistance Service.

8. Applied Standards

The product meets the requirements of electrical safety class I, while its LF clamp accessory complies with the following standards if utilized in accordance with the indications provided below:

- CEI EN 60601-1:2006 Medical electrical equipment. General requirements for safety.
- CEI EN 60601-1-2:2010 Medical electrical equipment. Electromagnetic compatibility – requirements and tests.

Transceivers for telecommunications can affect the device’s functionality.

The cables that can be used in conjunction with the welder are the following:

- welding clamp cable Max. length 1.2 m.
- footswitch starter cable max. length 2 m.
- power cable max. length 2 m.

Longer cables could result in different emissions or immunity levels for the device.

Electromagnetic emissions		
Emission test	Conformity	Ambient
RF Emissions IEC EN 55011/A1/A2 CISPR11	Group 1	The Gen WELD MK II intraoral welder does not make use of RF energy, which can affect external equipment.
RF Emissions IEC EN 55011/A1/A2 CISPR11	Class B	The Gen WELD MK II intraoral welder is suitable or use in environments with AC electrical power supplies of the following values: <ul style="list-style-type: none"> - 230V +/-10% - 110V +/-10%
Harmonic Emissions IEC EN 61000-3-2	Class A	
Voltage fluctuation / flicker emissions 61000-3-3/A1	Compliant	

Electromagnetic immunity			
Immunity test	Test level	Compliance level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC EN 61000-4-2	+/- 6 kV by contact +/- 8kV by air	+/- 6 kV by contact +/- 8kV by air	Support surface made from wood or insulating material
Electrical fast transients IEC EN 61000-4-4/A1/A2	+/- 2kV for the power supply +/- 1kV for the inputs/outputs	+/- 2kV for the power supply +/- 1kV for the inputs/outputs	Mains power supply of similar quality to a household or clinical power supply
Pulses IEC EN 61000-4-5/A1	+/- 1kV in differential mode	+/- 1kV in differential mode	Mains power supply of similar quality to a

Gen **WELD** MK II

	+/- 2kV in common mode	+/- 2kV in common mode	household or clinical power supply
Interruptions and voltage dips IEC EN 61000-4-11/A1	0% of rated V (voltage dip of 100% for 10mSec) 40% of rated V (voltage dip of 60% for 100mSec) 70% of rated V (voltage dip of 30% for 500mSec) 0% of rated V (voltage dip of 100% for 5Sec)	0% of rated V (voltage dip of 100% for 10mSec) 40% of rated V (voltage dip of 60% for 100mSec) 70% of rated V (voltage dip of 30% for 500mSec) 0% of rated V (voltage dip of 100% for 5Sec)	Mains power supply of similar quality to a household or clinical power supply
Magnetic Field IEC EN 61000-4-8/A1	3A/m 1 minute	3A/m 1 minute	Check the device's functionality near other devices with intense magnetic fields.

Electromagnetic immunity			
Immunity test	Test level	Compliance level	Electromagnetic Environment
			Portable RF transceivers for communications should not be used in proximity to the intraoral welder. Observe the recommended separation distances
Conducted RF IEC EN 61000-4-6/A1	3kV eff. – 150kHz at 80 MHz	3kV eff. – 150kHz at 80 MHz	$D = 1.17 \times [P] \exp(1/2)$
Radiated RF IEC EN 61000-4-3	3V/m from 80 MHz to 2.5GHz	3V/m from 80 MHz to 2.5GHz	$D = 1.17 \times [P] \exp(1/2)$ from 80 to 1500 MHz – 12W $D = 1.23 \times [P] \exp(1/2)$ from 1500MHz to 2.5GHz – 12W
			Where P is the maximum power of the transmitter in Watts and D is the

Gen **WELD** MK II

			recommended separation distance in meters. Certain radio transmitter devices could have higher power levels than those which are declared. In such cases, verify the welder's proper functionality.
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Maximum transmitter power (W)	Recommended separation distance (m)		
	150kHz to 80 MHz $D = 1.17 \times [P]^{exp(1/2)}$	80 to 1500 MHz – 12W $D = 1.17 \times [P]^{exp(1/2)}$	1500MHz to 2.5GHz– 12W $D = 1.17 \times [P]^{exp(1/2)}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

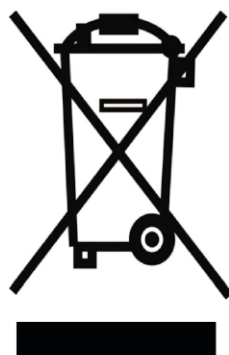
Use the formula shown in the tables for transmitters beyond the maximum power rating indicated.

9. Device disposal.

In accordance with Italian Legislative for electrical and electronic equipment (waste comprised of electrical and electronic equipment or WEEE) must be disposed of by means of sorted waste collection and sent to an authorized treatment facility at the end of its working life.

Intraoral welding equipment for medical use is classified as professional WEEE and as such must strictly be returned to the manufacturer at the end of its working life, who will collect the device at its own expense, will recover any reusable parts and will ensure that all remaining components are disposed of at appropriate disposal facilities.

Being subject to the provisions indicated above, the following symbol can be found affixed to the rear of the device itself:



This symbol indicates that the device was introduced to the market after August 13, 2005 and must be disposed of by means of sorted waste collection.

Due to the presence of hazardous substances inside the equipment itself, the disposal of WEEE as unsorted urban waste could be potentially harmful to the environment and to human health.

The unlawful disposal of such waste materials could result in administrative sanctions.

10. Packaging contents.

Pcs	Modello	Descrizione	Codice
1	Gen WELD MK II KIT	Complete Gen WELD MK II intraoral welder kit	8004
Il kit completo comprende I seguenti componenti			
1	Gen WELD MK II	The Gen WELD MK II intraoral welder device	8003
1	NB220 PEDALE	Activation footswitch complete with cable.	7967
1	Gen WELD MK II MANUALE	Cd User Instruction Manual	8010
1	NB151CABLE	Two cables to be connected to the clamp	8030
1	NB151CLAMP	Clamp complete with copper electrodes	7125
1	OMEGA - PZ 220 10 20	Power cable – Schuko plug IEC 23–50 S31 – COUPLER EN60320 - C13 (IEC 320) EEC 7/4 – Length 2 m	2024

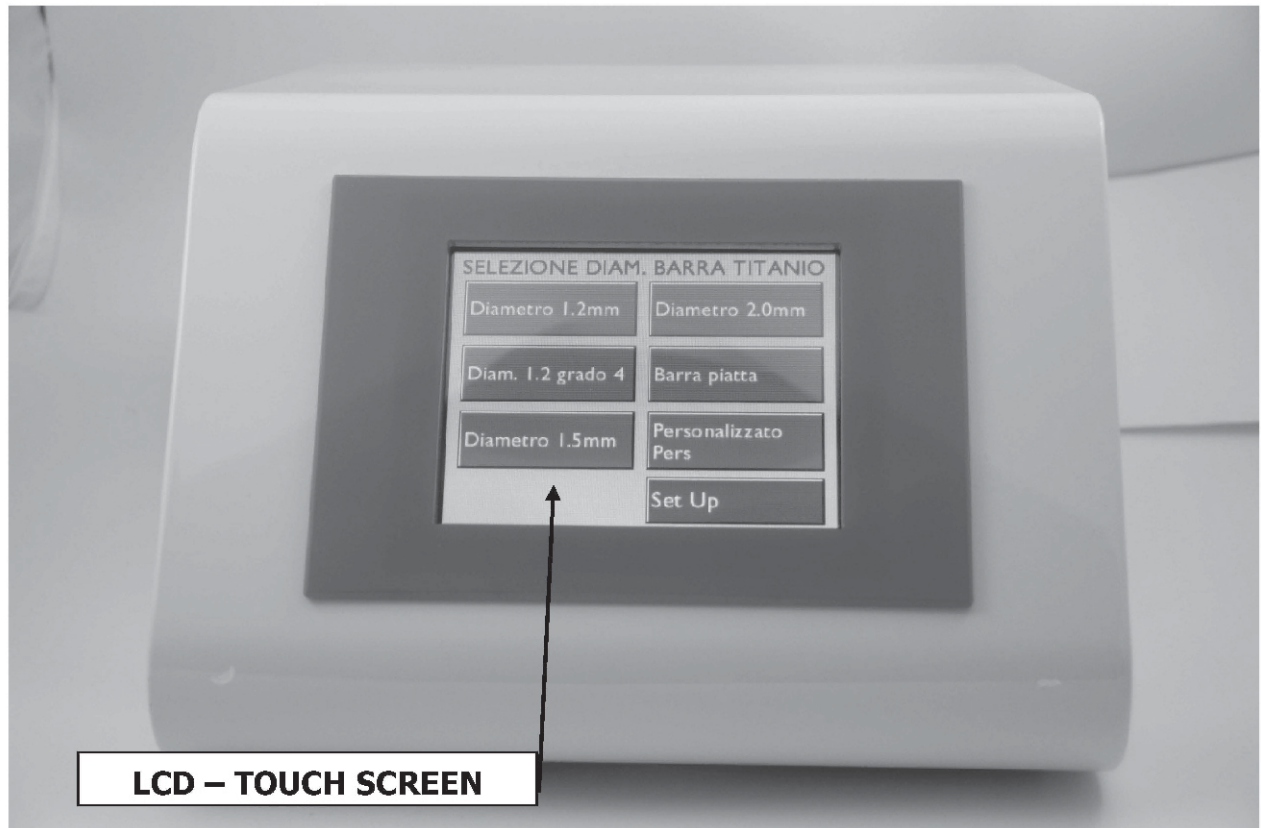
Warning

The use of materials that are not expressly indicated in this list could compromise the quality of the welding and the correct functionality of the welder.

cases, the warranty will be invalidated and the company srl will bear no responsibility for any malfunctions that may occur.

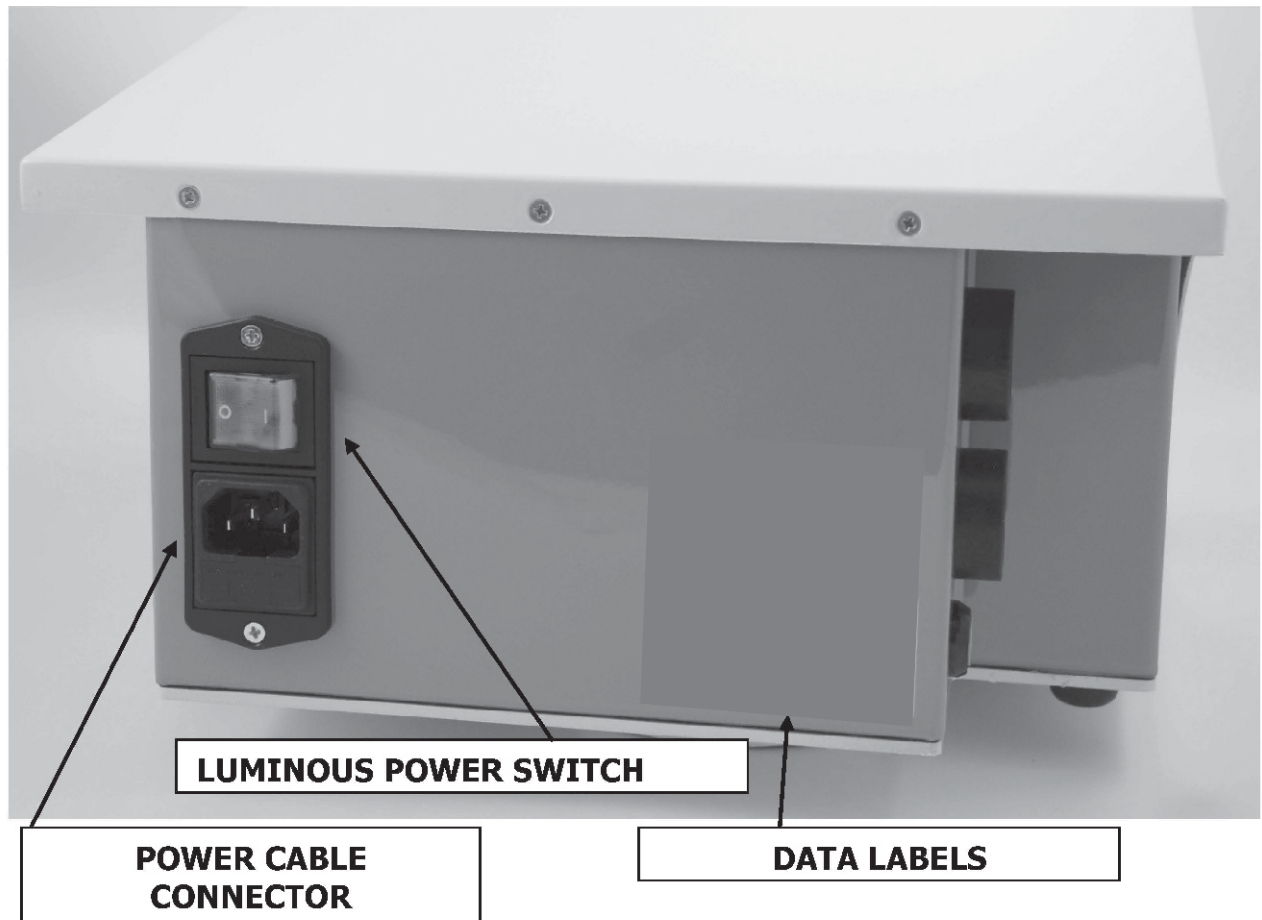
12. Introduction to the device

Frontal view of the intraoral welder cod.8003.



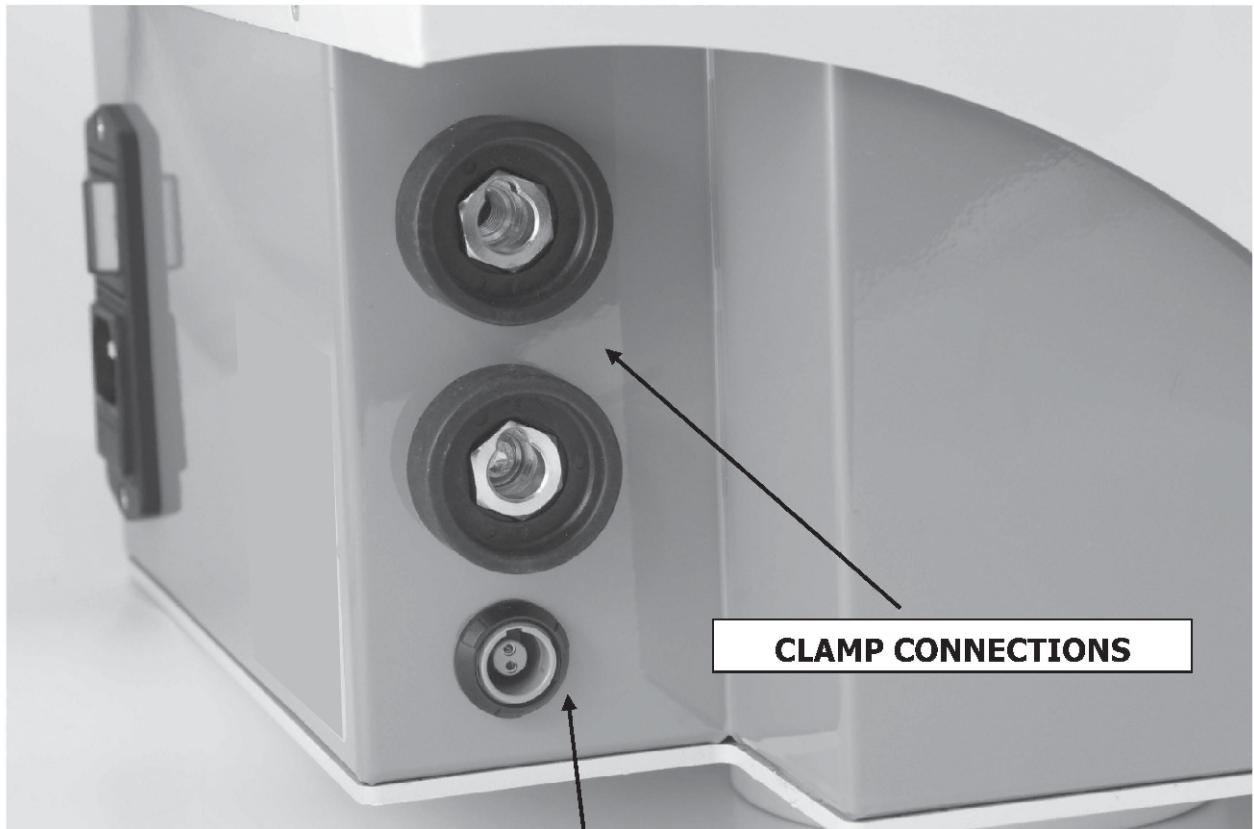
Gen **WELD** *MK II*

Rear view of the intraoral welder cod. 8003



Gen **WELD** *MK II*

View of the connections side of the intraoral welder cod. 8003



CLAMP CONNECTIONS

PEDAL CONNECTIONS

Gen **WELD** *MK II*

13. Introduction to the accessories



Clamp – cod. 7125 – LF type applied part



pair of clamp cables – cod. 8030



Gen **WELD** *MK II*

Footswitch – cod. 7967

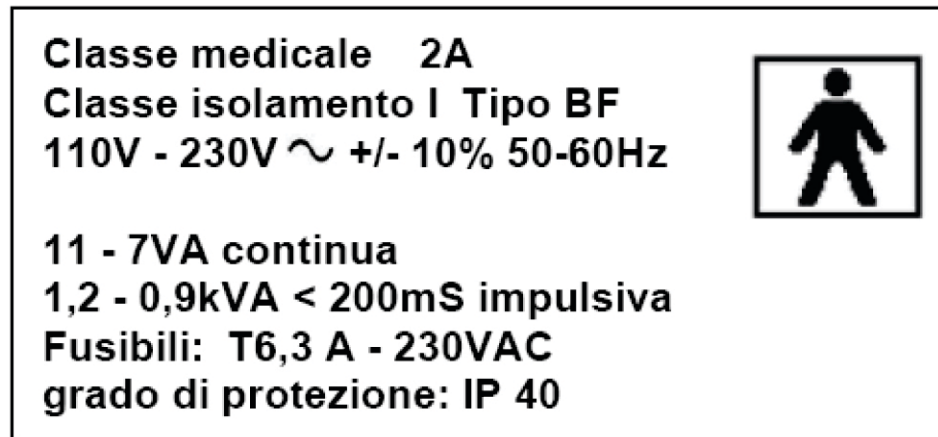


power cable – cod. 2024



Gen **WELD** *MK II*

WELDER LABEL B:



Descriptions of the symbols present upon the label:



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indicates that the device and its usage applications in relation to the patient and the operator are of an LF type, or rather that it meets the functional and safety requirements prescribed by the applied standards.

15. Device connections

Connect the various elements of the system as indicated and shown in the following images.

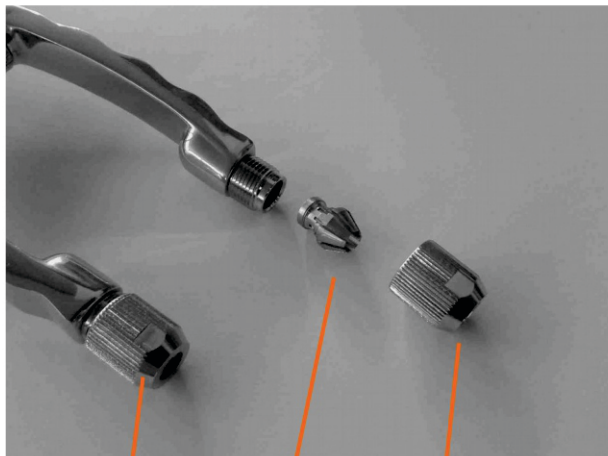
The connections must be performed in a secure manner, above all those in relation to the clamp/cables/welder circuit. In fact, the electrical current used to carry out the welding operations flows through this circuit.

The cable / clamp connection is obtained by inserting the male header of the cable inside the clamp and tightening the nut.

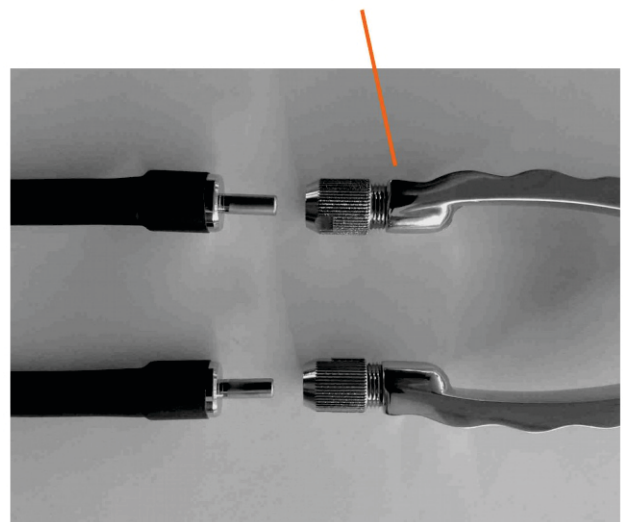
Connection cable / welder connection is obtained by inserting the male connector and turning clockwise the connector to lock it. Turn the clamp cable connectors in the opposite direction to release them.

cable / clamp connection

The cable connection to the clamp is done by inserting the male pin contact in the clamp after loosening the nut. To insert the male contact it is NOT required to remove the contact or conical ring from the clamp.

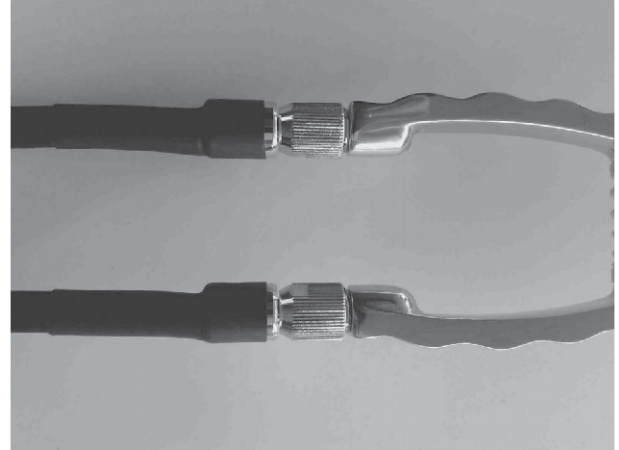
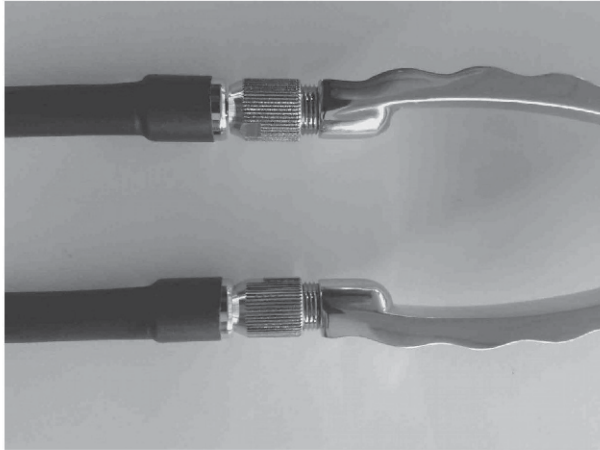


clamp – conical ring – nut



Gen **WELD** *MK II*

Insert the male contact in the clamp; turn the nut clockwise while maintaining it on place. To detach the cable, loosen the nut and remove the cable from the clamp header, it is not required to remove the nut or conical ring from the clamp header to extract the cable.



Clamp cable – welder connection

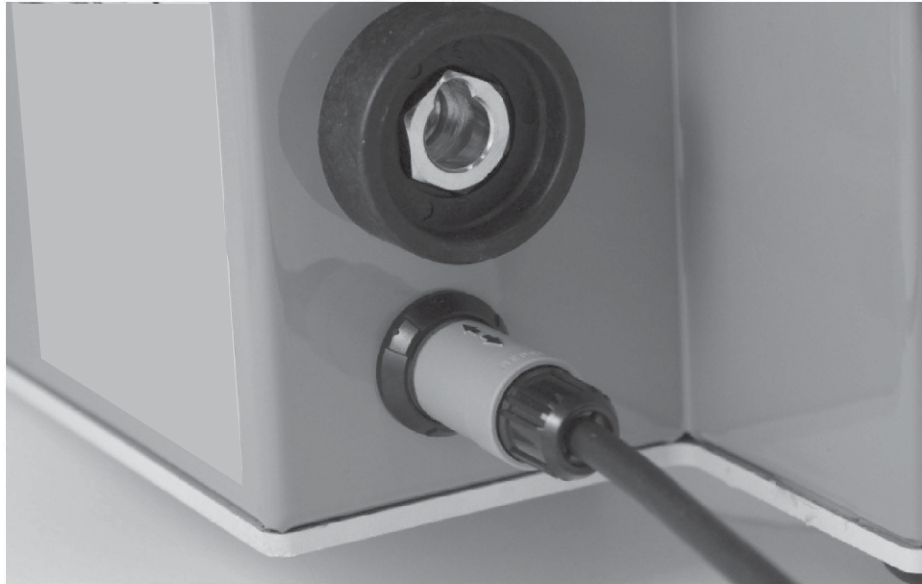
Connection cable / welder connection is obtained by inserting the male connector and turning clockwise the connector to lock it. Turn the clamp cable connectors in the opposite direction to release them.



Gen **WELD** *MK II*

Footswitch – welder connection

The footswitch control can be connected to the welder by inserting the relative connector until an audible “click” is heard. To release the connector, pull on it until it detaches from device.



16. Instructions for using the device

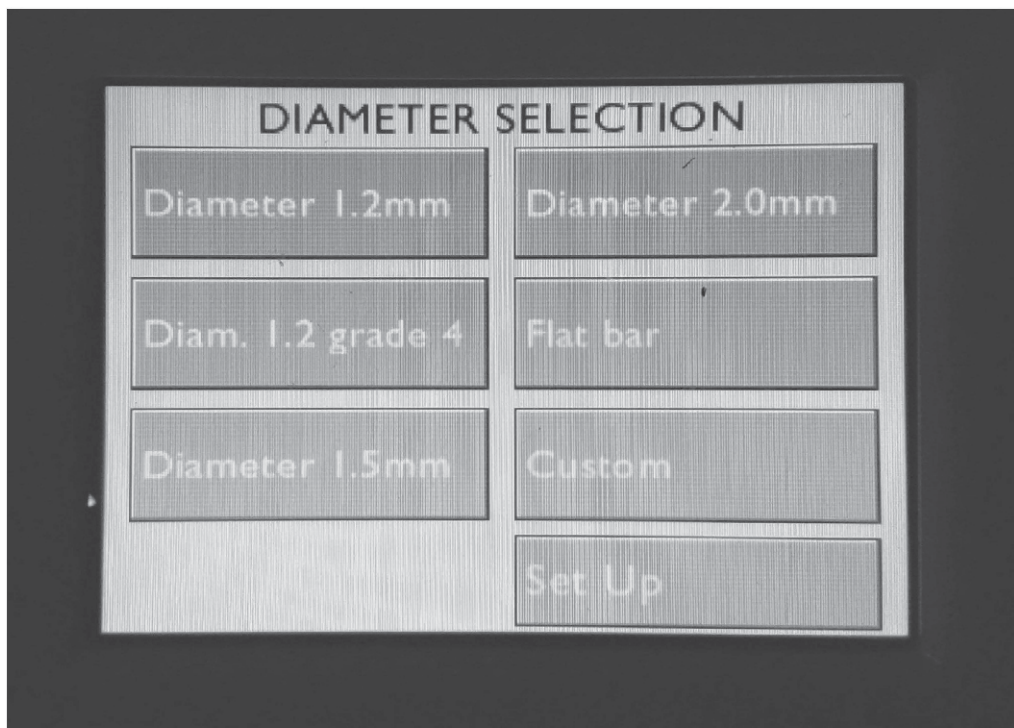
Activating the device

After having connected the power cable to the device and to an electrical outlet that complies with the safety characteristics indicated in the sections above, use the luminous switch on the device's rear panel to turn on the Gen **WELD** *MK II* intraoral welder.

After automatic check up of LCD panel, device will show the diameter selection windows.

Selecting the wire diameter

The system displays the screen for selecting the diameter of the wire to be used for the welding operations. The user can select the diameter of the wire to be used from the grid shown on the display.



Otherwise, if the desired diameter is not shown, the user may decide to set up a custom diameter by pressing the "Set up personal diameter" button.

SetUp navigation button

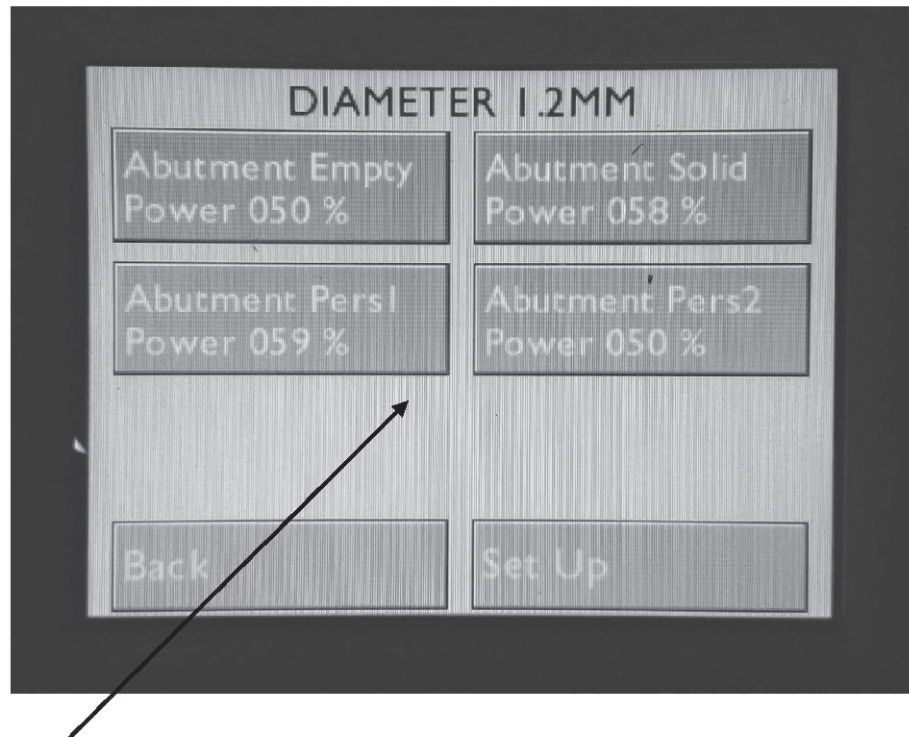


it is shown on various screens, allows the user to access the section of the software for setting up and detecting certain parameters. This section will be described subsequently in greater detail.

Gen **WELD** MK II

Selecting the type of abutment

After having selected the diameter, the system will display **two buttons** for selecting the material, whether solid or empty, and the **preset** welding power values

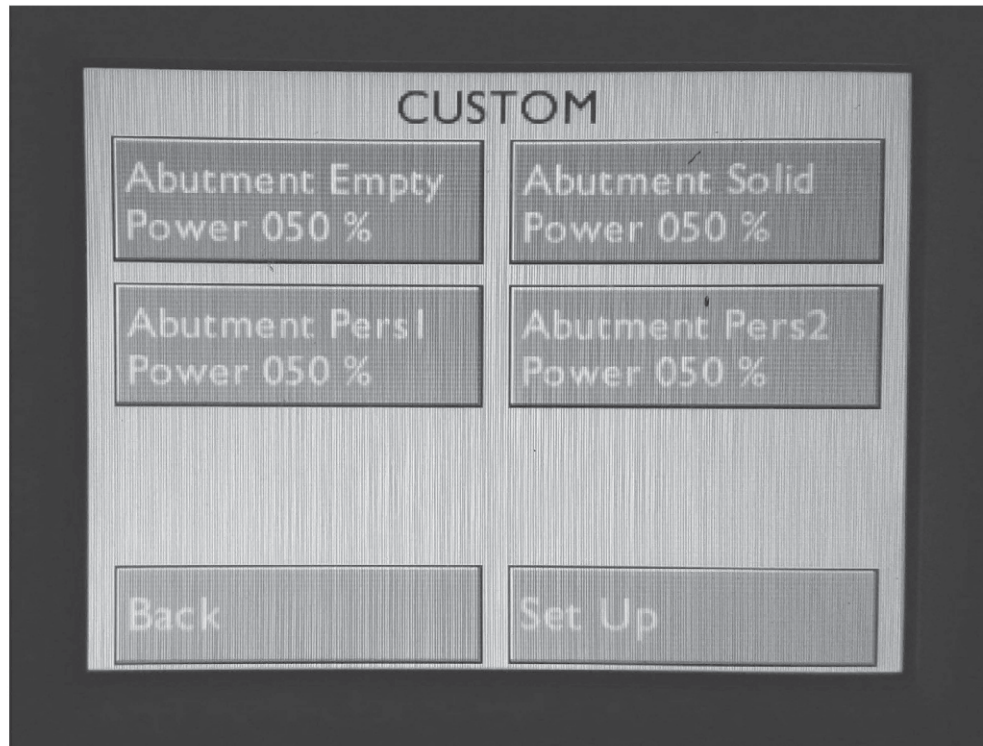


as well as **two buttons** with welding power values that **can be edited** and saved for subsequent use (procedure described subsequently).

After having selected the desired type of abutment, the system displays the actual operating screen.

Screen for customization of power.

After pressing Custom button, the screen below will be showed, power value in four dedicated button can be modified and stored for successive use.



Back navigation button

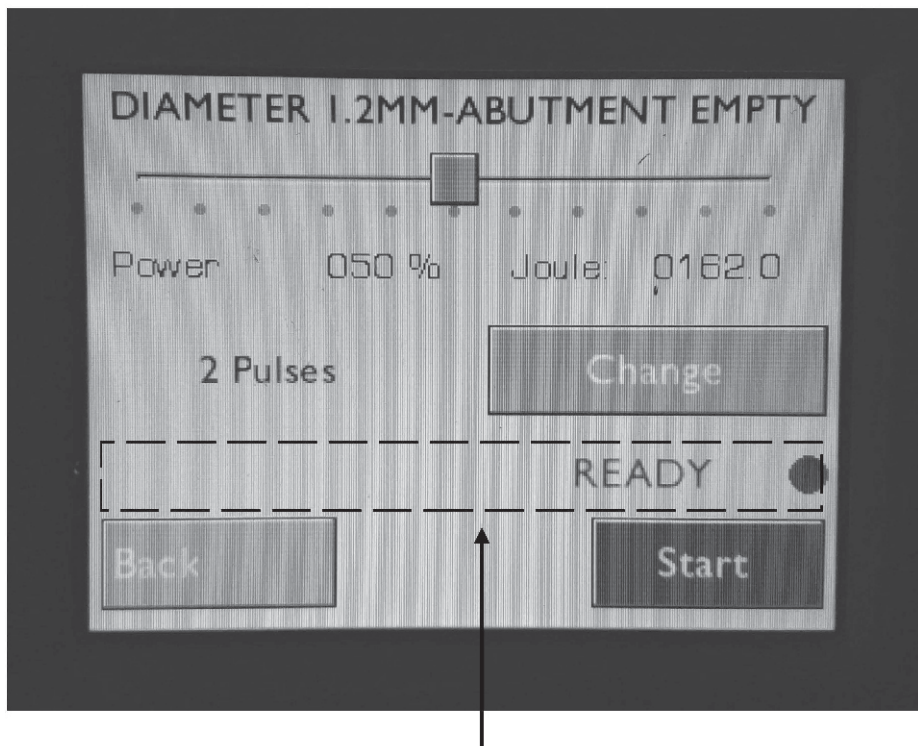
If the user should want to go back to the previous screen after selecting the parameters or during any subsequent operations, this can be done by pressing the following button:

Back

Gen **WELD** MK II

Operating screen

This screen displays the previously selected diameter and abutment type, along with the relative preset power parameters, welding pulse steps, start button, cursor for modify the power value.

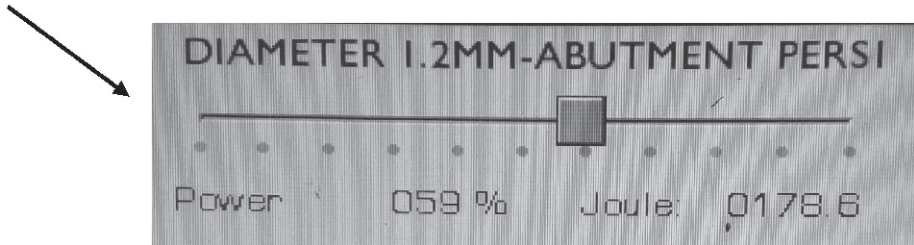


- This screen also contains a field (indicated with a dotted line in the image), which indicates the machine's status. The right hand portion of this field indicates the welding cycle, while the left hand portion (on the same line) indicates any error signals, which will be discussed later.

Gen WELD MK II

Central cursor.

The central cursor allows the user to customize the welding power by dragging the cursor towards the desired percentage.

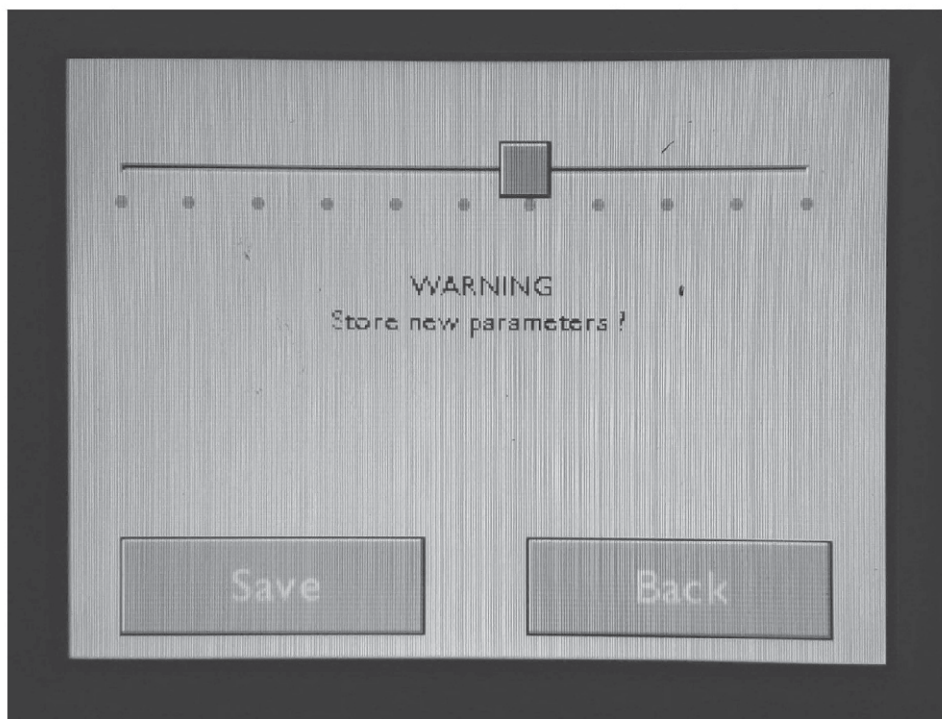


If the customizable type of abutment was selected, the central button will be shown as follows:



Upon pressing the "Store" button, the user will be prompted to confirm (RETURN button) or cancel the procedure (BACK button).

After saving, the same field will be able to be modified and saved as many times as desired.

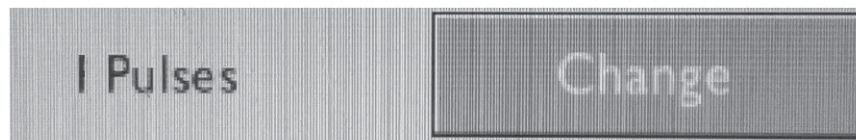


Number of step

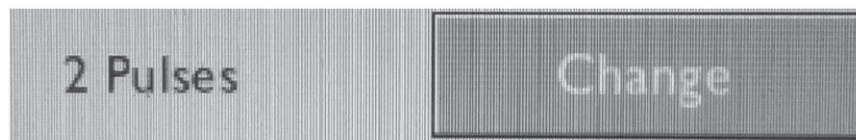
with "change" button, operator can select the number of step for each welding procedure.



1 pulse configuration



2 pulses configuration



The stored energy for welding is instantaneously release in one or two different stages (one or two pulses are selectable by operator):

- *The first stage* (if two pulses was been selected) heats the material to be welded and prepares it for the main energy discharge during the subsequent welding stage. During the material preheating stage, less energy is applied with respect to that which is supplied during the Main stage. This energy is automatically regulated based on the selected welding power.
- *The main welding stage* applies the energy necessary to bond the materials in the best possible manner. This energy level can be selected upon the user interface and must be selected based on the material to be welded.

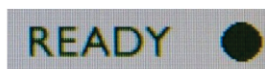
These two stages are automatically carried out in succession upon pressing the footswitch.

If one pulse stage is selected, only main welding stage will be performed.

Gen **WELD** *MK II*

Welding cycle

After having selected all of the parameters, the following message will appear on the display:

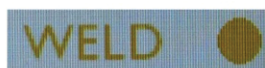


If no alarm signals are present, the user may proceed with the welding operations. Position the electrodes upon the components to be welded and press the footswitch one time.

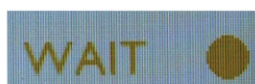
Once the footswitch is pressed, the welding cycle begins, indicated by an acoustic signal: **one brief beep** indicates the initial preheating pulse (if selected) or main welding stage, while a **double beep** indicates that the welding has been completed.

DO NOT MOVE CLAMP DURING WELDING PROCEDURE.

The progress of the welding cycle, during which these two acoustic signals take place, is indicated by the following message on the screen:



Once the cycle has completed without any alarms or malfunctions being detected, the following message appears on the display:

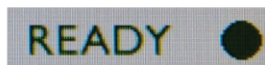


This indicates that the user must wait for the device to return to its "Ready" status before carrying out any subsequent welding operations.

WARNING

This waiting period allows the welder to restore optimal temperature parameters on abutment – high temperature will be absorbed by copper contact.

Once the device has returned to its ready state, the following message will appear on the display:



This message will also be accompanied by a **single brief acoustic beep**.

During the welding cycle, the footswitch does **not** need to be pressed more than once and does **not** need to be held down in order to conclude the two-pulse cycle. These will both be carried out automatically.

17. Preventive functionality check

A preventive functionality check can be carried out upon the system in order to exclude any functional anomalies.

This check requires a complete welding cycle to be carried out without any abutments or wire between the clamp's electrodes.

While the check can be carried out at any time, it is recommended that it be performed following **long periods of disuse**.

In order to carry out the cycle properly, close the clamp so that the electrodes make contact, initiate the welding cycle and check whether the system carries out the welding procedure without any functional errors being detected.

This simple check is sufficient in order to determine whether or not the machine is functioning within the desired safety and quality parameters.

By reading the generated values, in fact, the system is able to determine and signal any detected malfunctions using regular alarm signals.

18. **SetUp Section**

This portion of the menu contains the setup and control sections:

Welder data

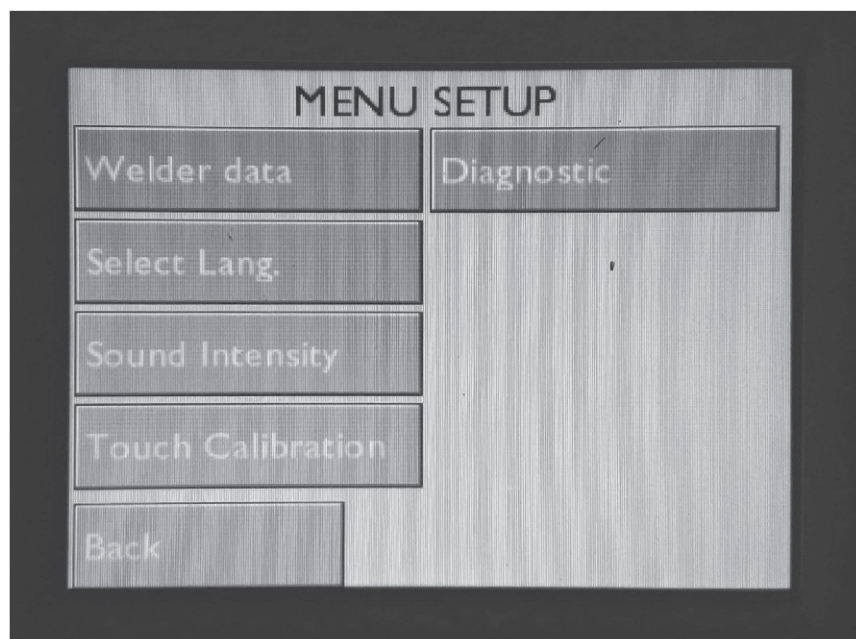
Select Language

Beep intensity

Touch calibration

Diagnostic

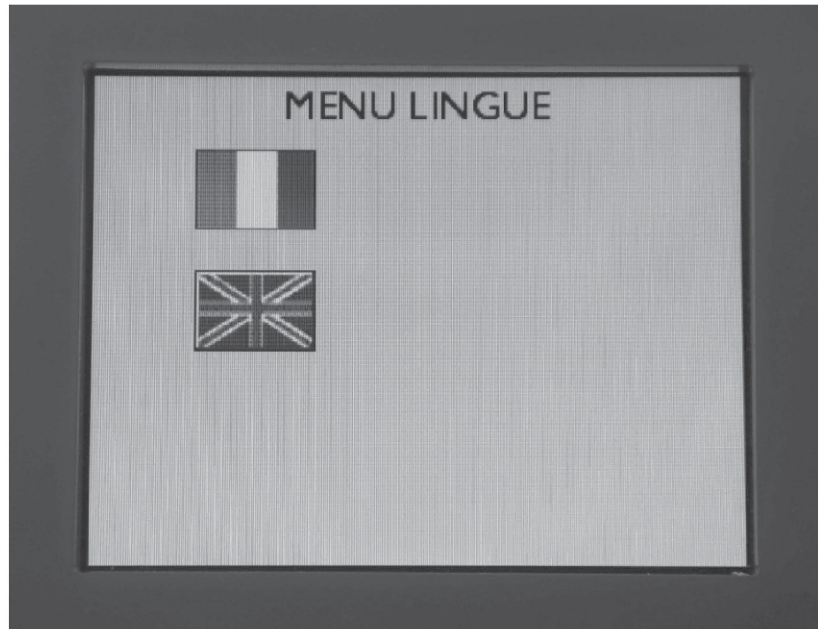
In order to return to the operating screen, press "Back".



Gen **WELD** *MK II*

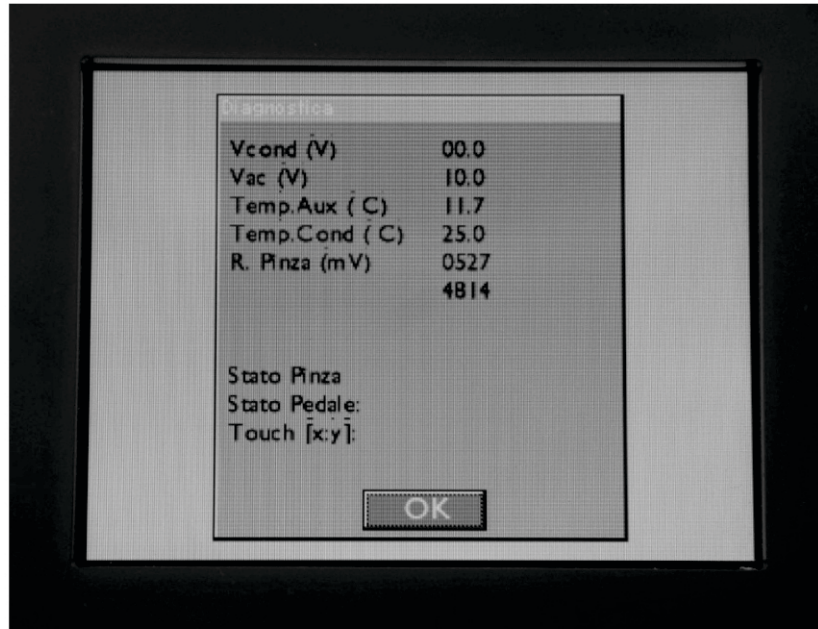
Select Language

The display language can be selected using the menu.

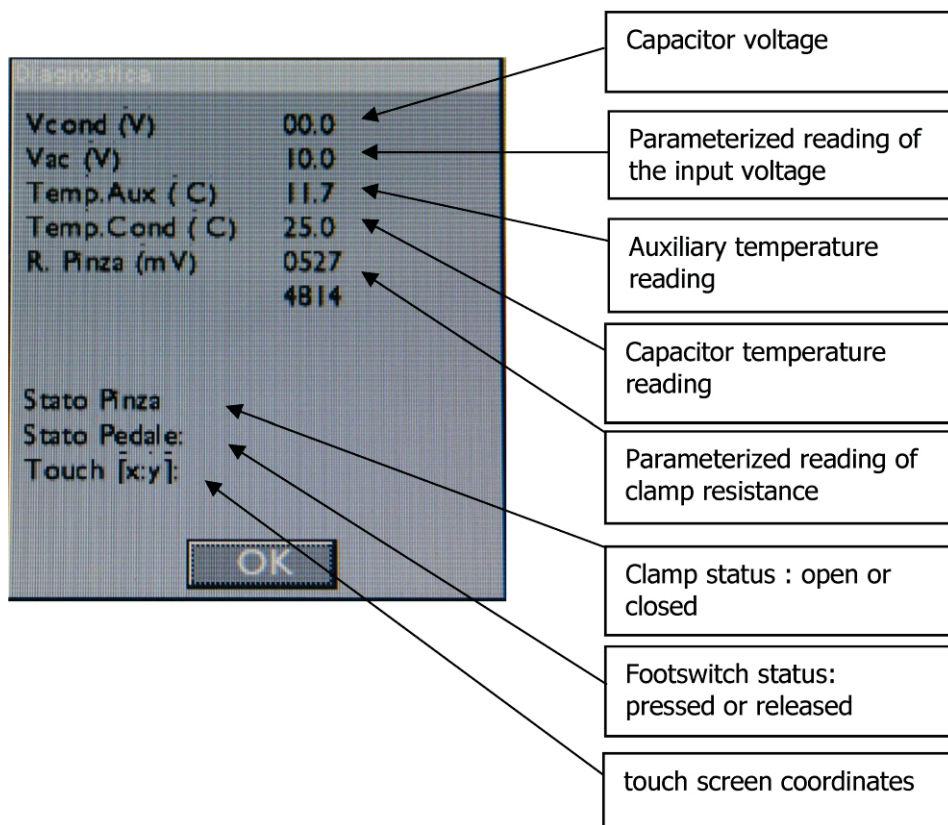


Gen WELD MK II

Diagnostics



The values shown offer a panoramic overview of the machine's status. In particular, they provide certain data that can be useful in the event of a malfunction. A concise description of the values and the points displayed is provided below

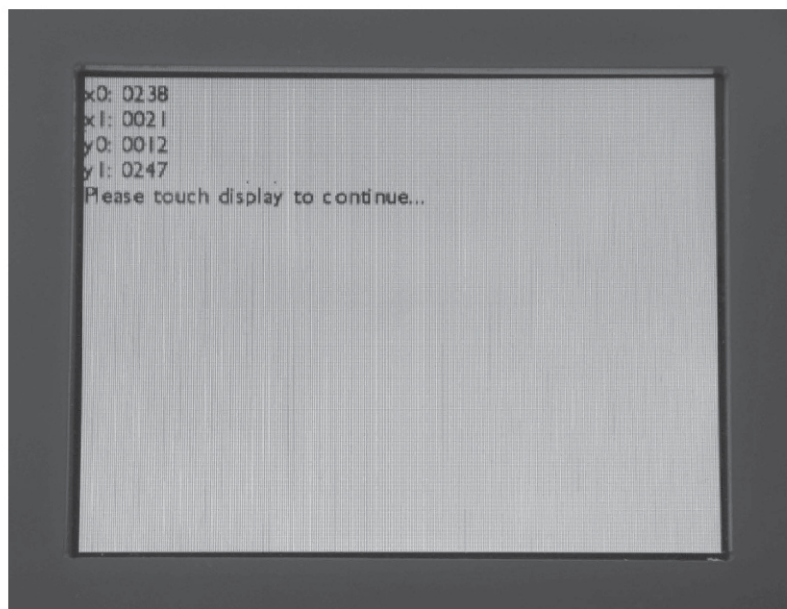


Touch calibration

The following procedure allows for any touchscreen precision errors to be corrected. Using an object with a rounded tip, touch the points that are indicated by the device during the various phases:



When finished, touch the screen to end the procedure.

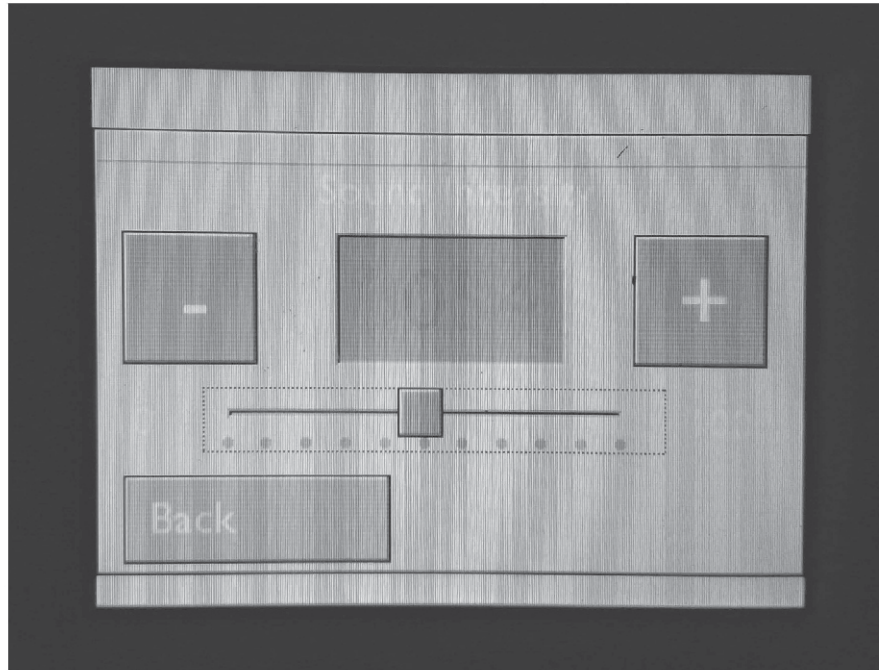


If the calibration was not carried out correctly, repeat the procedure from the beginning or switch off the device.

Beep Intensity

This button allows the user to adjust the volume of the buzzer that controls all of the machine's acoustic signals.

The cursor or the "+" and "-" buttons on the volume adjustment screen can be used to adjust the volume level.



After having adjusted the volume of the buzzer to the desired level, press the "*back*" button to return to the previous menu. The volume level setting will be maintained even after the welder has been turned off.

Welder data

This screen provides the following data:

- The device model.
- The installed software version.
- The number of welding operations that have been carried out.
- The name and information about the distributor.

19. Maintenance and periodic checks

The Gen **WELD** *MK II* intraoral welder does not require any special maintenance operations. Nevertheless, a number of periodic checks that are useful for avoiding malfunctions are described below.

- It is recommended to check the clamp cables and the main power cable for any cuts or incisions that could compromise their integrity. If any anomalies are encountered, replace the damaged cables immediately.
- Clean any surfaces that do not require disinfection using a damp cloth and a non-aggressive detergent diluted in water. Do not use solvents.

In addition to these checks to be carried out upon the accessories, the functionality of the Gen **WELD** *MK II* device itself can also be verified using the procedure described in the "**Preventive functionality check**" section. The components used to manufacture the product allow for it to be used for more than 10 years.

20. Disinfection and sterilization

Before and after each use upon a new patient, follow the instructions below in order to ensure the proper sterilization of the device parts:

CLAMP

In order to maintain the proper hygiene levels, the clamp must be disinfected and sterilized after each use. The clamp is manufactured with materials that allow for it to be **sterilized up to 1000** times using the values indicated below.

- For cleaning and disinfection, use gauze or cotton moistened with 70% ethyl alcohol

- The clamp can be sterilized in a **steam autoclave at 135°C, 2.2 bar for 20 minutes**, or else using other methods that comply with the current standards and/or protocols of the nation in which the machine is being used.

Before carrying out the sterilization procedure, do the following:

- disconnect the clamp from its cables
- **do not** use ultrasonic cleaning devices
- **do not** sterilize the device using dry heat sterilizers
- **do not** leave the clamp in the autoclave after the cycle has been completed
- Periodically check the autoclave according to the manufacturer's indications
- Sterilization temperatures beyond the indicated limits could damage the device

After the sterilization procedure, check to make sure that the clamp is completely dry. If not, dry it off thoroughly.

OTHER COMPONENTS:

Since the other parts that are contained in the packaging do not come into direct contact with the patient, they can be cleaned and disinfected using specific non-abrasive products or solvents. It is recommended to use a 70% solution of ethyl alcohol or a disinfectant of proven effectiveness

21. Errors and troubleshooting

With its internal microprocessor, the Gen **WELD** *MK II* intraoral welder is capable of detecting system malfunctions in order to guarantee the safe use of the device and ensure optimal welding quality.

These functional errors can be of different types and can have various effects upon the system, both while the anomaly persists as well as when it is reset.

The activation of the alarm is signalled both acoustically and visually.

The table below lists the error messages and their corresponding meanings, as well as the possible causes and solutions for the relative malfunctions.

If the problem persists, contact the Dentacare.

Any interventions on behalf of unqualified or unauthorized personnel will invalidate the warranty.

The manufacturer shall bear no responsibility for any damages due to tampering on behalf of unauthorized personnel; any such tampering shall invalidate the device's warranty.

ALARMS TABLE			
Detected error	Cause	How to reset the alarm	Corrective measures to be taken
CLAMP OPEN	the system has detected that the welding clamp was opened after the footswitch was pressed	The alarm resets itself automatically after the clamp is closed.	If the alarm persists, check to make sure that the cables are properly connected to the clamp - if the problem continues to persist contact the manufacturer's customer assistance service

Gen **WELD** MK II

WELDING ERROR	The system has detected that the welding cycle was not carried out properly due to residual voltage in the capacitor.	The alarm can only be reset by the operator touching the LCD display after the capacitor has been completely discharged. This ensures that the operator has taken note of the problem.	Carry out a welding operation with the clamp closed on its own (with no abutment) and check whether the problem persists. If the problem persists, contact the manufacturer's customer assistance service.
OVER TEMP	The system has detected an excessive capacitor temperature.	The alarm will reset itself automatically once the detected temperature falls back within the required range. The alarm cannot be reset by the operator	Shut off the welder and allow it to cool. If the problem persists once the welder has been turned back on, contact the manufacturer's customer assistance service.
ALL VAUX	The system has detected that the auxiliary voltage is outside of the required range.	The alarm will reset itself automatically once the voltage value falls back within the required parameters. The alarm cannot be reset by the operator	If the problem persists once the welder has been turned off and back on again, contact the manufacturer's customer assistance service.
POWER FAULT	The system has detected a lack of capacitor charge	The alarm can only be reset by the operator touching the LCD display. This ensures that the operator has taken note of the problem.	Carry out a welding operation with the clamp closed on its own (with no abutment). If the problem persists, contact the manufacturer's customer assistance service.

If the solutions proposed in this section are not sufficient to resolve the problems that have been encountered, the device must be shipped to the manufacturer or to an authorized centre for repair.

Upon receiving the request from the authorized repair centre, the manufacturer will provide all of the documentation required for the repair of the Gen **WELD** *MK II* intraoral welder.

22. Transport and storage

The Gen **WELD** *MK II* intraoral welder is an electronic device with a glass LCD display. For this reason, its original packaging must be kept in good condition and re-utilized each time the product needs to be transported.

The required accessories must also be included in the packaging during transport: clamp, cables and footswitch, taking care to ensure that they are properly arranged within the packaging along with the intraoral welder.

Do not use packaging materials that are unsuitable for transporting the product.

Follow the indications provided on the packaging label (see the relative chapter in the manual) regarding the proper relative humidity, temperature and atmospheric pressure levels for transport and storage.

23. Technical assistance service

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