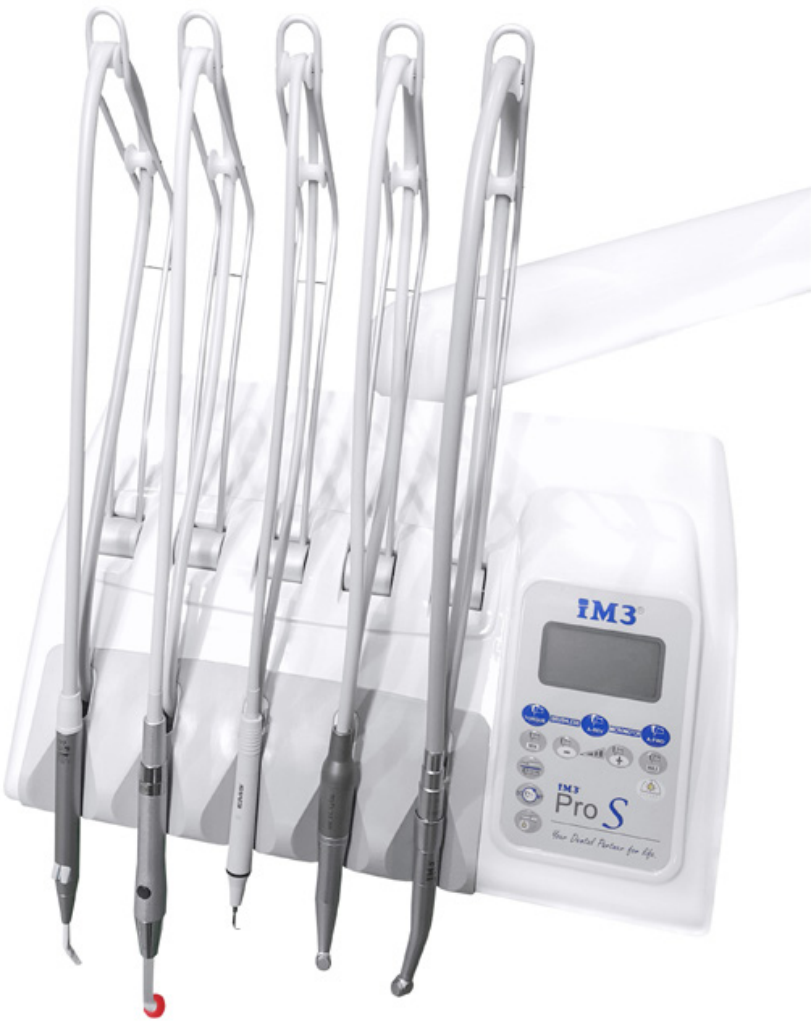
iM3® iM3 Pro S

INSTRUCTIONS FOR USE AND TECHNICAL MANUAL



FOR VETERINARY USE ONLY

WARNING!!

Before using the machine for the first time, please remember:

1. **The CE0051 certification refers only to the dental unit (dental chair, instruments & accessories are excluded). Ensure any additional medical devices used are in compliance with any existing regulations.**
2. **Carefully read and follow the User Instructions; if any questions, please ask the installation technician or contact iM3 Dental Support for further details.**
3. **Read all technical documents, in particular those relating to Instrument Manuals.**
4. **Carefully read the ProS and other equipment (instruments, dental chair, lamp and accessories) Warranty Conditions.**
5. **Check supplied accessories list.**
6. **The Installation technician must fill out an installation certificate and leave 2 copies with you. You must send 1 of these copies to iM3 Dental, within 10 days of the installation date.**
   (if not, the warranty will be considered void)
7. **Keep all unit and accessory related documents safe:**

   - **User Manual**
   - **All Manuals relating to instruments, dental chair, lamp and accessories**
   - **CE Conformity Assessment**
   - **Installation Certificate**
   - **Copy of shipping & delivery documents (transport document or invoice) with all S/N of system components (Unit, dental chair, instruments, lamp etc.)** (precondition for all components' warranty)

Table of Contents:

1 REFERENCE DATA

1.1 GENERAL INFORMATION

This manual is intended for personnel responsible for the installation & maintenance of the dental unit as well as persons involved with its professional use. Please read all the relevant sections carefully and follow the instructions, especially those pertaining to safety related guidelines.

The manual contains the following components;

- Technical information detailing the correct use of the equipment
- Equipment handling and positioning
- Operating functions
- Maintenance instructions

Please keep this manual in a safe and dry environment, close to the dental unit for easy access.

If the manual is damaged or misplaced, please contact iM3 Dental Ltd for a replacement copy.

1.2 WARNINGS

	**DANGER**: If a warning isn't carefully observed, there is a possible risk of damage to equipment or injury to operator.
	**WARNING**: FOR CORRECT USE, PLEASE REFER TO INSTRUCTION MANUAL

1.3 INTENDED USE

The ProS and its associated features are intended for use in the diagnosis, prevention, control, therapy or attenuation of veterinary medical oral diseases.

The Equipment is produced for the purpose of modification and/or re-establishment of oral function by means of dental treatment.

1.4 LIMITED WARRANTY

iM3 Dental will bear no responsibility in the following cases :

- Third party claims
- Improper equipment use
- Use that is not in compliance with country specific legislation or norms
- Faulty installation by Third Party
- Defective electric, pneumatic and/or water supply
- Unauthorized modifications and/or technical alterations
- Failure to follow proper procedures and instructions
- Any damage or economic loss caused by force majeure

1.5 EQUIPMENT WARNINGS

DANGER, PERMANENTLY LIVE _ 230V

WARNING! Do not remove this label or interfere with any parts associated with 230 VAC live voltage.
(Removable only by a qualified technician, after unit has been completely disconnected from mains supply)

1.6 SHIPMENT & STORAGE CONDITIONS

The Dental Unit should be shipped and stored in its original packaging under the following environmental conditions :

- Atmospheric pressure 600 – 1100mbar
- Temperature -10° to +40°C
- Relative humidity 10% min. to 90% max.

The Manufacturer's packaging must be kept intact until ready for installation. It is essential to:

- Check for any signs of damage on delivery.
- Ensure that the doors into the intended room are 70 cm wide at least.

1.7 OPERATING CONDITIONS

The Dental Unit, once installed in a suitable environment (dental room), should be operated under the following environmental conditions:

- Atmospheric pressure 600 – 1100mbar
- Temperature +15° to 35°C
- Relative humidity 30% min. to 70% max

1.8 MANUFACTURED BY

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20060 Gessate – Milano – Italia
Tel. +39 02 95781006 Fax. +39 02 95383707
www.idemriuniti.eu

1.9 TECHNICAL SPECIFICATIONS

Dimensions	Length :	500 mm
	Width :	500 mm
	Height:	750 - 900 mm
Weight	Total:	20 kg
Power supply	Voltage :	230V~ ± 10%
	Frequency :	50/60Hz
	Max current (unit):	2 A
	Max power (unit):	450 VA
Fuses	Primary Transformer Fuse (FL - SEA1 card) :	T 2,5 A
	Sec. Fuse VDC (F1 - SEA1 card) :	T5A
	Sec. Fuse. 12ac (F2 - SEA1 card) :	T3,15A
	Sec. Fuse Ac24g (F3 - SEA1 card) :	T6,3A
	Sec. Fuse. Ac24f (F4 - SEA1 card) :	T6,3A
	Lamp. Sec. Fuse (F5 - SEA1 card) :	T6,3A
	Auto-reset Fuse for M/M power supply card (F6 - SEA1 card):	Poly-switch 4A
Power supply transformer	Primary Safety Transformer:	230V – 450VA
	Secondary:	12/14/18/24 V - 450VA
Water supply	Pressure:	2,5 - 4 bar
	MAX flow N/l :	0,14L/min
Air supply	Pressure :	5 – 8 bar
	MAX flow N/l :	80L/min
Cooling systems	Handpieces :	Driven air & water

2 USER MANUAL

Foreword

Please note that in cases where the Dental Unit does not come with a specified configuration, the instructions will be "non applicable"

2.1 TOUCH PAD FUNCTIONS

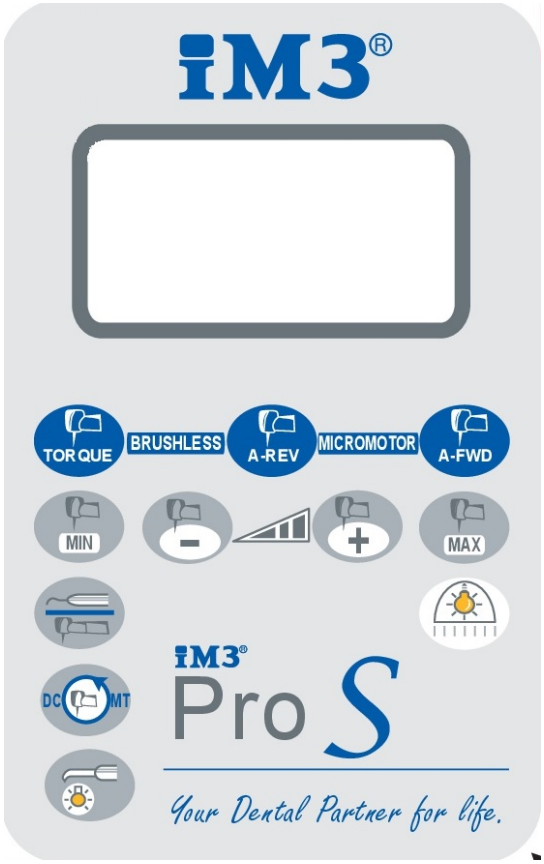
2.1.1 General Description

The basic functions of the Instrument console (PAD) display are:

- Main function display for Dental Unit Instruments
- Special functions display for units supplied with NSK induction micromotors

PAD display values are an indicative reference only, and cannot be used in therapies or treatments requiring precise measurements of instrument parameters.

2.1.2 Instrument table console keyboard

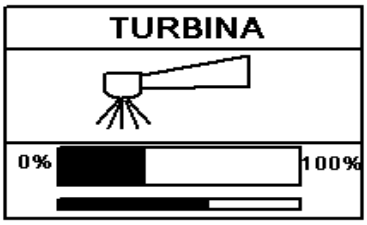


2.1.3 Symbol table

	**DC electric micromotor reverse rotation ON/OFF**
	**Instruments O.F. light ON/OFF**
	**Operator lamp ON/OFF**
	**Micromotor speed control**
	**Auto reverse & auto forward function selection**
	**Special functions activation: torque control, scaler power & contra-angle type**
	**Instrument status display**

2.1.4 Highspeed Turbine

When Selecting the highspeed instrument, the PAD will display:

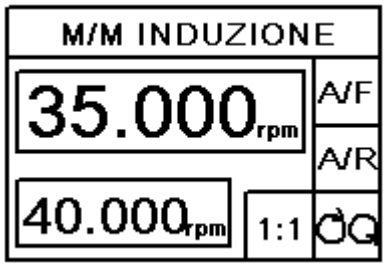


Dental Units supplied without a proportional control valve works as follows:
The lower progress bar shows max value. When the foot control on the dental unit is activated and the highspeed handpiece engaged, the upper bar moves from 0 to max.

Dental Units supplied with a proportional control valve works as follows:
The foot-control activates the instrument.
The handpiece speed is modified using the foot control and the variable speed is displayed as a percentage by the progress bar under the turbine logo.
(+) & (-) pushbuttons are used for pre-set speed values on the unit.
(MIN) & (MAX) pushbuttons automatically selects the minimum and maximum speed.
The pre-selected speed is constantly displayed by the lower progress bar.
The last selected speed is automatically recorded, even after the unit is switched OFF.

2.1.5 NSK electric Micromotor

The micromotor is automatically activated when selected (lifted) from the instrument control top and the PAD display will look as below:



The micromotor speed is controlled using the foot control. When the foot control is in max position, the micromotor will operate at its maximum pre-set speed.
The PAD displays the micromotor speed in the upper box, whilst the lower box displays the maximum pre-set speed. In most cases, the minimum speed is pre-set at 1000 rpm and intended for micromotor model "Nano"; while 100 rpm can be pre-selected for "Nano Plus" micromotors.
(+) & (-) push buttons allows for fine adjustment of the speed settings.
(MAX) or (MIN) push buttons are used to pre-set the maximum and minimum value required (max allowed 40.000 rps). Micromotor speed can only be adjusted when the instrument is selected (lifted) from the instrument control top. The last pre-set speed limit is recorded and saved until changed.

Min & max speeds, normally pre-set to 100, 1000 & 40000, are automatically adjusted based on the contra-angle selected. The displayed value is then divided into reduction ratio or multiplied for multiplication ratio.
E.g: with a green ring contrangle, 10:1, speed values will be min. 100rpm & max. 4000rpm. With a red ring contrangle, 5:1, speed values will be min. 5000rpm & max. 200.000rpm .

Pressing display button  will show the following table:

Choice of contra-angle:	
1:1	Standard blue ring
4:1	Speed reducing green ring
7,4:1	Speed reducing green ring
10:1	Speed reducing green ring
16:1	Speed reducing green ring
20:1	Speed reducing green ring
30:1	Speed reducing green ring
1:5	Speed increasing red ring

Scroll the options by pressing the "Max" or Min" buttons and select the appropriate value **(marked negative).**
To confirm selection, press the "reverse rotation" button and exit programming phase.
The last selected contrangle option will be saved, even after the dental unit is switched OFF. Speed & contra-angle can only be designated when the micromotor is selected (lifted) from the instrument control top.

The display have 3 icons relating to micromotor options.

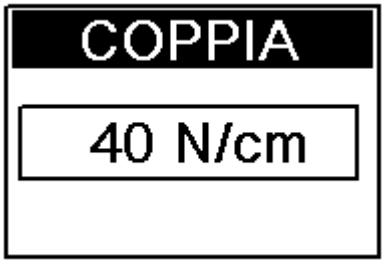
Lower icon controls Micromotor rotation direction. The direction can be reversed by pressing the button. This function in not permanently recorded and is reset when the unit is restarted. Nearby box shows pre-set contra-angle.

Upper icon “A/F” automatically pre-sets the instrument to "auto forward" and is activated by pressing the button. The function is disabled by pressing the button a second time. Bur rotation direction is automatically reversed when pre-set torque limit is reached

The central icon “A/R” selects for "auto reverse" mode and is activated by pressing the button. The function is disabled by pressing the button a second time. Bur rotation direction is automatically reversed when pre-set torque limit is reached.

“Nano Plus” micromotors also allows for torque selection

When the micromotor is activated, press button and the display will show the following options:



(+) & (-) pushbuttons allows for torque modifications **(0,1N/cm resolution)** of **0,5** to **4 N/cm intervals**. The displayed torque value is automatically adjusted in accordance with pre-set contra-angle reduction/modification ratio; e.g.:

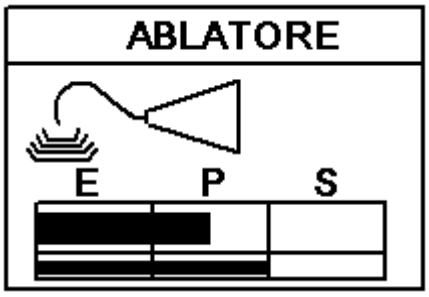
Type of contra-angle:		Full scale 4N/cm
Standard blue ring	1:1	4
Speed reducing green ring	4:1	16
Speed reducing green ring	7,4:1	29,6
Speed reducing green ring	10:1	40
Speed reducing green ring	16:1	64
Speed reducing green ring	20:1	80
Speed reducing green ring	30:1	120
Speed increasing red ring	1:5	0,8

If pre-set function is not possible, pressing the button 

will show the following message:

2.1.6 Piezoelectric Scaler

The scaler is automatically activated when the instrument is selected (lifted) from the instrument control top. The display will show:



The foot control activates the instrument.
3 power options are selectable, Endo-Perio-& Scaling (E-P-S)

By consecutively pressing the button “scaler-contra-angle”, the selection options will move from E to P & S. The reference table below details the setting chosen and power:

E	50% power
P	75% power
S	100% power

Each selected option can further be adjusted by using the (+) & (-) pushbuttons.
The (MIN) & (MAX) buttons immediately sets the scaler to the minimum and maximum power within the selected range.
The progress bar under EPS shows the selected option.
When an option is selected, the power is automatically set to the corresponding max limit.
The last selected power setting is automatically saved, even after the dental unit is switched OFF.

2.2 INSTRUMENT USE – GENERAL INSTRUCTIONS

Dynamic instruments are pre-selected and activated by moving the corresponding hose-carrying arm approximately 10° from its standby position or, with hanging cord instruments, lifting the instrument from its housing.

Single dynamic instruments are activated via an electronic control circuit which automatically prevents activation of all remaining instruments (excluding syringe and curing light).

 Single dynamic instrument activation initiates the function called “Active Stop”.

The pre-selected instrument is engaged and controlled by activating the foot control.

Chip-air function is available on rotating instruments. This results in a short burst of air blown from the handpiece into the operating field.

The coolant water for the handpieces is activated and controlled by a silver dial under the instrument control top. Turning the dial clockwise will reduce the flow. Turning the dial anti-clockwise will increase its flow.

The water supply to the highspeed turbine & micromotor is protected by an anti-contamination system called chip-blow. When coolant water is stopped in the handpiece, a high pressured burst of automatic air flow is pushed through the air pipe and allows for its cleaning (Venturi effect).

Instruments that utilise coolant water should have the gasket sealing and connection points checked regularly for leakage.

2.3 HIGHSPEED HANDPIECE

Foreword: This manual provides only basic information about this type of instrument. For specific technical details, please refer to the specific manufacturer’s user manual.

The highspeed turbine is activated by engaging the foot control.

If the dental unit has been equipped with a proportional valve for the highspeed turbine, the turbine speed can be controlled and adjusted by the pedal lever. If not, the turbine speed will always run at its maximum speed.

The speed can be manually adjusted and pre-set using the PAD control.

Please follow the manufacturer's disinfection and sterilisation protocols.

2.4 MICROMOTOR

Foreword: This manual provides only basic information about this type of instrument. For specific technical details, please refer to the specific manufacturer's user manual.

The micromotor is activated by engaging the foot control. Unless otherwise selected, the micromotor rotates clockwise and the speed (r.p.m.) is controlled by the foot pedal.

Maximum and minimum speed can be adjusted and pre-set using the PAD control display. Adjustments and selection of contra-angle functions can also be designated via the control display.

Auto forward and auto reverse can be selcted on the PAD display via pushbuttons.

O.F light can be switched on or off using the pushbutton on the PAD display.

Important: The micromotor is designed for integrated spray and it is important to use suitable handpieces for this purpose.

Please follow the manufacturer's instructions in terms of use, handling, disinfection and sterilisation.

2.5 PIEZOELECTRIC SCALER

Foreword: This manual provides only basic information about this type of instrument. For specific technical details, please refer to the specific manufacturer's user manual.

The scaler is activated by engaging the foot control.

Ensure coolant water flow is set correctly to keep the scaler tip cool.

The flow of coolant water can be controlled and adjusted using the silver dial on the underside of the dental unit control top. Twisting it clockwise decreases the flow, anti-clockwise increases the flow.
Coolant water is activated by depressing the foot pedal.

WARNING: Never use the scaler without coolant water unless using endodontic probes or amalgam condensation tips.

Power settings can be adjusted using the PAD control display.

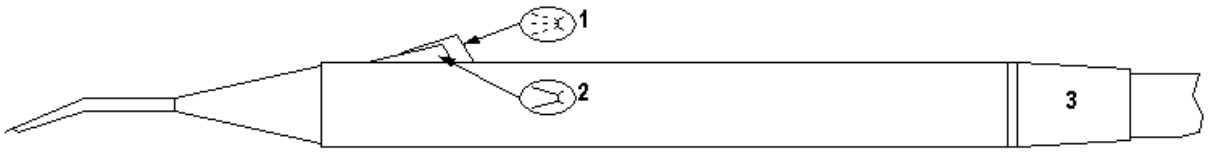
Please follow the manufacturer's instructions in terms of use, handling, disinfection and sterilisation.

2.6 SYRINGE

The 3-way syringe is equipped with two pushbuttons, No. 1 for air and No. 2 for water supply. When individually depressed, each pushbutton performs its own control function and if both are depressed simultaneously, a mist combining both air and water is produced.

Syringe tip can be removed by means of releasing pushbutton.

Please follow the manufacturer's instructions in terms of use, handling, disinfection and sterilisation.

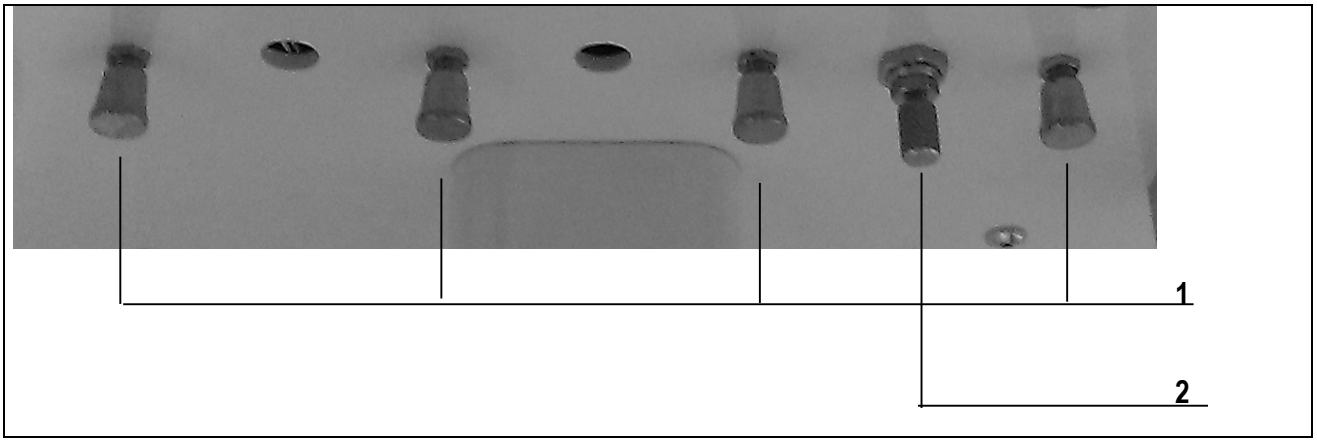


2.7 CURING LIGHT

Foreword: This manual provides only basic information about this type of instrument. For specific technical details, please refer to the specific manufacturer's user manual.

- Remove handpiece from its housing and position it close to where the composite is to be polymerized.
- Press the P pushbutton on the handpiece
- After 20 sec. the cycle will initiate. After 10 sec. the cycle will end and and the handpiece beeps.
- The cycle can be repeated following the same procedure again.
- Please avoid direct contact with non polymerized composites during the initial 10 seconds as residue on the curing light tip can lower its efficiency and compromise further polymerization work.

2.8 INSTRUMENT CONTROLS & PRE-SELECTION



1. Instruments coolant water controls.

2. Instruments air control.

2.9 CLEAN WATER/DISTILLED WATER

"Clean water" is a feature that enables the dental unit to provide clean or distilled water rather than water from the standard mains water supply.

Applicable liquids:

- Drinking water (in countries where standard water supply does not guarantee microbiologically pure drinking water)
- Softened water or distilled water (to prevent limestone formations in valves)
- A mixture of water and iM3 Straw sanitizer for antimicrobial and bactericidal effects

Sterile saline solutions should not be used in the "Clean Water" bottle for two main reasons:

- The physiological properties of Saline affects the dental unit valves, causing it to malfunction.
- The sterility of the Saline solution can no longer be guaranteed since "Clean Water" is poured into the bottle.

The bottle has a 1 liter capacity and must be manually refilled when empty.

The "Clean water" system consist of a replaceable and refillable bottle, mounted on a unit cuspidor and easily accessible without the need for opening any cover.
A ball valve underneath the instrument control top allows the alternative use of either demineralized "clean water" or mains water. This makes it possible to continue work without any interruption, even when bottle is empty.

WARNING!!!

There is not alarm on the dental unit alerting the user of an “Empty bottle”.
The operator will notice the bottle being empty when the system begins supplying water "puffs", and then air only.

Replacing/Refilling bottle

1. All the instruments must be in stand-by mode and the foot control idle.
2. Move the bottle toggle to its “OFF” position to depressurize the bottle.
3. Wait for 5 seconds before removing the bottle.
4. Fill the bottle with clean water or demineralised water.
5. Replace the bottle.
6. Move the bottle toggle to its "ON" position to pressurize the bottle.
7. Select the instrument you want to use and activate it using the foot control.
8. Clean water should be noticed after approximately 10 seconds of continuous operation.
9. The system is now ready for use.

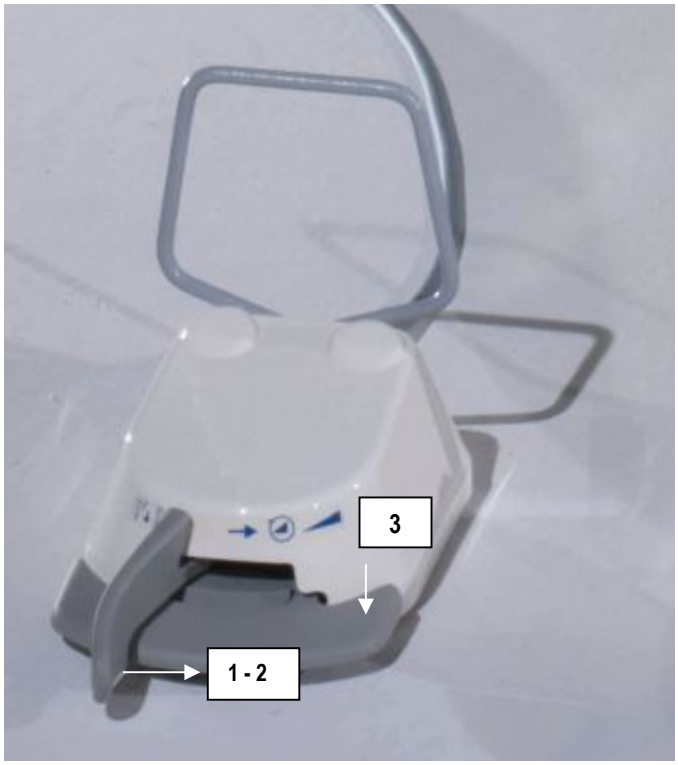
2.10 FOOT-CONTROL

Rheostat foot control

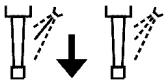
The foot control comprise a lever and a pedal.

The lever (1-2) works by pushing it horizontally left to right. pedal is activated by pressing downwards (3).

1. Dynamic instruments Start –Stop
2. Rotation speed control
3. Chip-air activation (when instruments are not in use), coolant water spray when in use.



Symbols

Dynamic instruments START With rotation speed control	
Chip-air activation (when instruments are not in use), coolant water spray	

Identification plate on the rheostat base plate:

MODEL RH 1 _ IPX1
FOOT CONTROL

3 MAINTENANCE

3.1 FOREWORD

Standard maintenance should be performed by the user.

Special maintenance and technical servicing should be carried out by an authorised service engineer.

 For ancillary equipment (instruments, chair, lamp, suction pump etc.), please follow the manufacturer's instructions and user manuals.

3.2 STANDARD MAINTENANCE

Between two patients:	Clean and disinfect all surfaces using a water-based non-alcoholic detergent
	Replace suction tip
	Clean, disinfect and sterilize handpieces
	Clean and disinfect all non single use equipment
At the end of the day:	Clean the surgical suction filter
	Remove and disassemble surgical suction parts and wash with a disinfectant as described
	Lubricate surgical suction terminals with silicon-based spray.
	Close air & water inlet taps, open mains switch.

3.2.1 Plastic Surfaces Cleaning

For low risk areas, use a water based non-alcoholic detergent to prevent damaging any plastic features.

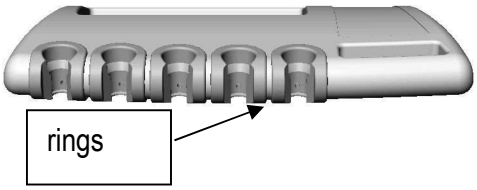
For high risk areas, use a product with a high level disinfectant. Avoid chemically aggressive products, which can damage the physical properties of plastics.

Carefully clean and disinfect the supports for the instruments on the control top. Avoid using products that can alter the physical properties of the material.

 **Unsuitable products can alter material and cause breakage**

A note on suitable and unsuitable cleaning products:

- Quaternary salts of ammonium based disinfectants, with low alcoholic percentage **SUITABLE**
- DÜRR DENTAL surface disinfectant type FD320 **SUITABLE**
- Cattani ECO-JET1 surface disinfectant **SUITABLE**
- High alcohol disinfectant **NOT SUITABLE**
- Synthetic diluents or nitro **NOT SUITABLE**
- All other products **NOT SUITABLE**



3.3 SPECIAL MAINTENANCE

Annually	Clean all water electro-valves
	Visually inspect all mechanical and electrical connections for all 230 V AC parts
	In accordance with the manual, ensure no 230 V AC components have been replaced with spare parts not original to or not compliant with the manufacturer's specifications
	Evaluate the function of all unit parts.
As needed	Replace Bulbs and Fuses.

PERIODIC MAINTENNACE REPORT	Date:
Customer:	Authorized technician:
Address:	Address:
Town:	Technician Sign/Stamp
Unmit S/N	

Controls & Measurements	Components cleaning	Replaced components
❑ Full final test	❑ EV H2O bicchiere	❑ Canula hoses ❑ Canula termionals
❑ Mains and ground check, fastening holding nuts	❑ EV H2O spittoon	❑ Main water filter ❑ Main Air filter
	❑ EV H2O general instruments	❑ Turbine oil filter ❑ EV H2O glass ❑ EV H2O spittoon
❑ instrumental check of ground circuit & leakage currents, according to EN62353	❑	❑ EV H2O gen.instrum ❑ EV H2O scaler ❑ EV H2O micromot.1
	❑	❑ EV H2O turbine 1 ❑ EV H2O turbine 2 ❑ EV H2O micromotor 2
Note:		

4 CLASSIFICATION & CE MARK

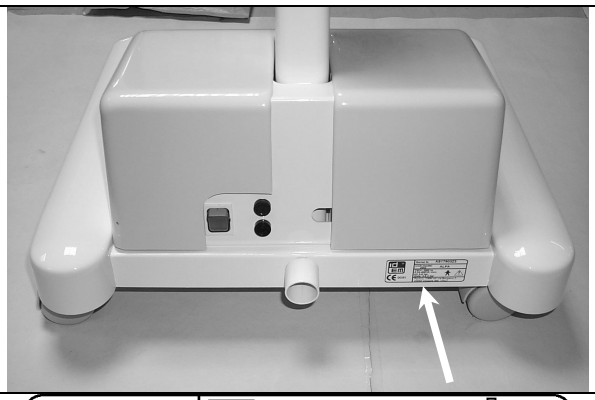
4.1 EQUIPMENT CLASSIFICATION EX ART. 9 OF 93/42/EEC DIRECTIVE & S.M.A. (2007/47/CE)

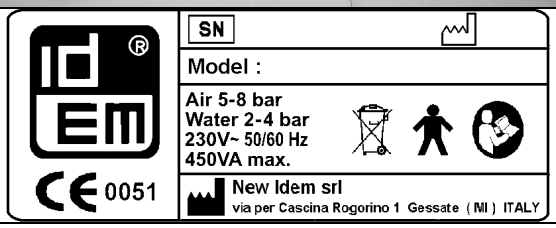
The ProS Galaxi Dental Unit is classified as a medical device **Class II a** when used in accordance with the manufacturer's instructions 93/42/EEC & s.m.i. (2007/47/CE)

4.1.1 EN 60 601-1 Classification

<5.1>Protection against electrical hazards	CLASS I – External power supply Protection against direct & indirect contacts is based on insulation and additional safety measure, i.e. equipment is connected via protection ground cable to power supply outlet and ensures accessible conductive parts cannot bear voltage caused by damaged to insulating parts.
<5.2>Protection level against direct & indirect contacts	B type applied parts Specific protection level against electrical hazards -Allowable leakage currents - Protection ground connection availability
<5.3>Protection level against water leakage.	**IPX 0** Equipment case isn't protected against water leakage
	IPX 1 Rheostat foot control case protected against vertical spill of water drops.
<5.4>Sterilization and/or disinfection methods allowed by manufacturer	For standard instruments, see paragraph 5.8 to 5.13 For non- standard instruments: see manufacturer's specifications
<5.5>Safety level in an environment of flammable anhaestetic gas mixed with air or oxygen or nitrogen protoxide.	Equipment **not suitable** for use in an environment of flammable anhaestetic gas mixed with air or oxygen or nitrogen protoxide
<5.6>Use conditions	**Continuous operations, intermittent loads** For recommended working times applicable to various equipment parts, please see related parts in the User Manual and refer to individual manuals of ancillary instruments.

4.2 IDENTIFICATION PLATE





4.2.1 Plate Data Description

SN	Internal code identifying equipment model/prod. Series/configuration, manufacturing and final testing dates
	Manufacturer name and addres
model	Model complete identifier
	Equipment disposal type
	Specific protection level against electrical hazards, Allowable leakage currents Protection ground connection availability.
	WARNING – For proper use, see related documentation
230V-50/60 Hz	External power supply 230V AC @ 50/60 Hz
450VA max	Max. electric power, with/without chair
Air 5-8 bar	Medical compressed air external supply @ 5 ÷ 8 bar
Water 2 - 4 bar	Potable water external supply @ 2 & 4bar
CE 0051	CE MARKING IN COMPLIANCE WITH ENFORCING NORMS. 0051 after CE (unit), identifies IMQ Notified Body. Certification and related CE mark are for unit only (chair, instruments, lamp etc. not included)
	New Idem Logo
	Manufacturer name and Factory addres

4.3 TRACEABILITY & FINAL TEST CERTIFICATIONS

A full test of functionality of the dental unit and all associated devices must be completed by the technical engineer upon completion of installation. Each unit comes supplied with a "FINAL TEST CERTIFICATION & INSTALLATION COMPLIANCE" form in 3 copies which must be filled out and signed by the engineer.

It is the customer's responsibility to return, within 10 days of completed installation, a completed and signed copy of the Certificate, together with a copy of unit delivery documents to the office of iM3 Dental.

Pls. Note that the CEE 93/42 Directive for Medical Devices requires the user to keep a "traceability" register of all medical devices. The Installation compliance certificate allows the manufacturer to keep a register of user data in case of "incidents".

By not submitting the Final Test Certification, the manufacturer is prevented from fulfilling enforced law requirements pertaining to medical device traceability and without return of such certificate, warranty is voided.

4.4 OTHER MEDICAL DEVICES

4.4.1 INSTRUMENTS (TURBINES-SCALER-MICROMOTORS-CONTRA-ANGLES-ETC.)

WARNING – Please refer to the individual manufacturer's Manuals for Installation, Use & Maintenance instructions

Instruments are separate Medical Devices.

As stand-alone devices, and according to existing legislation, Instruments are subject to their own Certification and Documentation:

- CE Conformity Assessment
- Installation, Use & Maintenance Manual
- Warranty Certificate

5 EQUIPMENT DISPOSAL

With reference to the European directives 2002/95/CE, 2002/96/CE, 2003/108/CE concerning “Electric & Electronic Equipment Waste (Italian acronym “RAEE”) disposal”, applicable from August ’05, any unit, at the end of its useful working life, must be prevented from further usability and must comply with following disposal procedure.

RAEE DEFINITION & RAEE SOURCES

RAAE acronym means “Electric & electronic equipment waste”.
“RAEE” includes all electric & electronic devices (both for home & professional use), which must be disposed of, at the end of their corresponding product lives.
New Idem, as an electro-medical devices manufacturer, must be considered a RAEE source.

LAW ENFORCEMENTS FOR MANUFACTURER, RE-SELLER & FINAL USER

Any manufacturer of electro-medical devices and RAEE sources, must contribute to its own equipment disposal costs, by means of special institutions, specifically constituted by competent Authorities.
According to enforcing norms, the manufacturer applies special labels to its devices, warning the user they’re RAEE, with a special disposal procedure requirement.
The re-seller (or user himself) with RAEE equipment for disposal, must strictly follow the disposal procedure in the next paragraph.
According to law, the manufacturer is not responsible whenever a user or re-seller do not comply with disposal procedures as outlined below.

EQUIPMENT DISPOSAL PROCEDURE

Before disposal, any electro-medical device must be prevented from further usability by taking the following measures:

- Remove all electrical, water and pneumatic connections
- Cut off all electrical connections from the equipment base plate to peripheral devices
- Cut off the transformer secondary output wires so that they cannot be recovered.

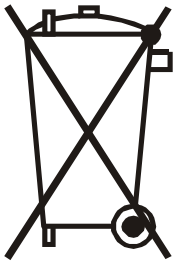
After device is rendered unusable, pack it with proper ecological materials and send it, free of charge, to (according to user or re-seller choice):

- Private or public disposal plant qualified to handle RAEE or
- To a local distributor of the manufacturer's units which, as a RAEE source, will send the device to a certified disposal plant.

The user or re-seller must keep evidence of RAEE device disposal procedure, by means of transport documents specifying special transport scope.

WARNING!!

The symbol on the equipment is a reminder that any other disposal procedure is strictly forbidden by law



6 WARRANTY

- iM3 ProS has a 24 month warranty relating to material and manufacturing defects valid from production month.
  (attached CE conformity declaration outlines production month).

- The warranty doesn't include parts subjected to normal wear and/or incorrect use, such as: Bulbs, Fuses, Ceramics, Hoses and external tubes, Surgical suction terminals, Plastic and/or other surfaces damaged by unsuitable chemicals

- The warranty is only valid with a correctly filled out, signed and returned installation certificate, sent to iM3 Dental within 10 days of the installation date.

- If the installation form is not returned correctly or on time, the warranty is immediately void. Note that in such circumstances, as the manufacturer cannot comply with legislation relating to medical device traceability, the buyer (re-seller or final user) will be held responsible for all aspects relating to the device.

- "Free of charge" repairs under warranty is carried out at the manufacturer's factory. Transport costs and any risks are considered the customer's responsibility.

- Warranty repairs on the premises of the customer can only be carried out by an authorized engineer. In such case, the customer is liable for any travel expenses incurred by the authorized engineer (provided that no other contract was entered with the re-seller and provided that manufacturer then is neither responsible nor liable for such private agreements).

- The nominated re-seller is primarily in charge for any technical/functional problem solutions and or technical intervention request made by the customer.

- The manufacturer does not acknowledge possible additional warranty clauses, stipulated by a re-seller.

- For medical devices connected to a iM3 ProS unit (e.g. handpieces, operating lamp, amalgam separators, surgical suction systems, etc.) please refer to the manufacturer's warranty conditions. In the case of malfunctioning handpieces (i.e. turbines, M/M, scalers, contra-angles, curing lights, etc.), the user must consult the relevant manufacturer in terms of warranty.

- The manufacturer has the absolute right to void any warranty in case of equipment tampering, deliberate damage, improper use, lack of correct maintenance or in the case where the damage occurred due to external causes or natural disasters.

- The current WARRANTY conditions are automatically considered accepted by the buyer, whenever the buyer fails to inform iM3 Dental by means of a registered letter within 10 days from installation date, about possible alleged claims.

7 CERTIFICATIONS

7.1 CE CONFORMITY DECLARATION

Each unit includes a single “CE conformity declaration”, specifying model & serial number.
When the unit is supplied together with New Idem, chairs, certification includes chair data.

IIIiIO IDC

DICHIARAZIOME DI CONFORMITA'

(Decisiooe t>I76B12008/CE del; QL.uglio 2008)

Prodotti:: Riun.iti Odontoiatri.ci

Marca: IDEM

IModello: GALAXI

L' aizienda New Idem S.r.l.,
con sede lega:le ill Vi1a per Cascina Rogorino, 1 - 20060 Gessate (MI) - ltaHa,
dichiara sotto la propria responsabilIta. che:

1. I summenzionati dispos.itivi sono realizzali OOl'lfurmement:e a quanto richiesto dalla Diretti11a 93142/CEE e s.m.i., S£:<XX1do quanto pre\tisto dalrAnegato Il (oortificato CE n. 092JMDD emesso daU'Q-ga:nismo Notilicato IMQ S.pA identificalivo n U051) attraverao !'app€C82ione delle norme di rirel1imerito:
   - EN 60601-1: 2007;
   - , EN 60601-1-2: 2014;
   - EN ISO 7494--1: 2011;
   - EN 1640: 2010;
   - EN ISO 9687:2015
   - IEC 80601-2--60:2012;
2. I summenzionati dispositivi sono considerati appartenenti a1ra Classe I.la in base alfa rag:ola 6 dell'Allegato JX della Direttiva 93142/CEE e s.m.i.;
3. I summenzionati dispos;itivl sono realizzali oonfurmemente a quanlo richiesto dalla Direttiva 20111651UE delrB qiuQ;m) 2011. sulla r € o n e deJruso di detetminate sostanze peticolose nelle appareccitiature etettnche ed elettrnniche "Rohs 2"
4. Tutta 11adocum.entaziane riguardante ta1i dispositivi € arcnr.iata nel fascioolo tecnico di prodotlo e oonseo-wta pet" tm per-iodo di alnleno 5 anni dalla data di ultima fabbnamooe del prodotto stesso;
5. Tu:tt:e ,le fasi della pruduzioooe dei summendon:ali dispositivi soddiisifano le prescrmoni indicate nel Sistema di Gestione per la Qualita aziendale coofom!emente a qµanto prescrilto nelrAllegato Il dells Direttiva 93/42/CEE e s.m.i.;
6. Tale Sistema di Geslione per ra Quatitii aziendale e confonne ai requisi:li specificati dalla oorma ISO 13485,:2012 ed € certificate dall'Organismo di Certific:Done CSQJJMQ (certificate n. 9124.IDR2);
7. L'Eenda New Idem S.r.L ha procedlllo nel notfficare all'Autorita Competente rinlmissione m comme1do dei surnmenziona:li disposilivi e a istiluire una procedllJOI sistematica airo soopo di garantime la sorvegUanza post--\\lendila..

La preseme d.ichiarazione viene rifasciata per ii dis:posim,ro caratterizato da:

Numero di Serie	Data Prod€ione
XXX XXX XX XX	XXIXX/XXXX

Gess.ate - Italia - MalZO 2018

Il !egale rappresentante
Un Amministratore