Model
Galaxy

Version
Kyri Water

Use & maintenance instruction

Rev.1 ***August 2017***
Translated by: *Rev.1 August 2017*
CE

SOMMARY:

1 REFERENCE DATA

1.1 MANUAL GENERAL INFORMATION

Manual is intended for people responsible of unit's installation & maintenance, and for people involved with equipment professional use.

Pls. thoroughly read all sections and carefully follow all instructions, especially when safety related.

Manual's technical information shows equipment's correct use, according to design & manufacturing scopes, and manufacturer's intended use.

In this manual, you can also find information about equipment moving, starting & maintaining, in accordance with manufacturer's assigned restrictions.

Instructions manual fully completes equipment and must be carefully preserved as long as unit is operative.

Manual must be kept in a safe, dry place, apart from direct sunlight, but as near as possible to equipment, because user must have it always accessible.

If manual is damaged, user must ask for a new copy to manufacturer, that's bound to supply it ASAP.

1.2 WARNINGS

	DANGER : This icon means that, whenever associated warning message isn't carefully observed, there's a possible risk of damage for operator and/or equipment.
	WARNING: FOR A CORRECT USE REFER TO INSTRUCTIONS MANUAL

1.3 INTENDED USE

Equipment 's intended use is the diagnosis, prevention, control, therapy or attenuation of human oral apparatus diseases.

Equipment is conceived in order to:

Modify and/or re-establish biologic functionality of mastication by means of teeth treatment.

Canalize saliva, water, blood and other water-based fluids, used as a coadjutant of local teeth treatment.

Allow treated zone cleaning.Allow suitable lighting of treated zone.

1.4 CASES RELIEVING MANUFACTURER'S RESPONSIBILITY

Manufacturer is relieved from any responsibility in following cases:

- equipment use: improper or by people not trained for professional use
- use not compliant with country applicable law and norms
- faulty installation, when supplied together with equipment
- defective electric, pneumatic and/or water supply
- grievous faults of manufacturer's prescribed maintenance
- unauthorized modifications and/or technical interventions
- not original or model specific spare parts
- total and/or partial instructions neglecting
- emergency events

1.5 APPLIED PARTS MATERIALS, CONTACTING PATIENT'S BODY

This class of parts includes :

- Burs
- Scaler tips
- Canulae.

NEW IDEM S.r.l does not supply them.

Manufacturer recommends to employ materials compliant with ISO10993-1.

1.6 SHIPMENT & STORING CONDITIONS

Equipment can be kept into its original package no longer than three months, if environmental conditions are within following limits:

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

Manufacturer's package must be kept untouched till its opening for installation in a dental study.
It is essential to:

- Check package does not show holes and/or other damages.
- Check that study doors are 70 cm wide at least.

Check unit general status.

1.7 OPERATING CONDITIONS

Equipment, installed in a suitable environment (dental study), must operate under environmental conditions within following limits:

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

1.8 SALES & MANUFACTURING

Marketing & sales responsible:

Tecno-Gaz S.p.a. – Strada Cavalli, 4
43038 Sala Baganza – Parma – Italia
Tel. +39 0521 8380 Fax. +39 0521 83391
www.tecnogaz.it

Manufacturer:

New Idem S.r.l. – Via Per Cascina Rogorino, 1
20060 Gessate – Milano – Italia
Tel. +39 02 95423704 Fax. +39 02 95423726
www.idemriuniti.it

1.9 TECHNICAL DATA

Dimension	Length :	500 mm
	Width :	500 mm
	Height :	800 - 900 mm
Weight	Total:	20 Kg
Power supply	Voltage :	230V~ ± 10%
	Frequency :	50/60Hz
	Max current absorption :	2 A
	Max power absorption:	450 VA
Fuses	Transformer's primary fuse:	T 2,5 A
	Sec. fuse 12ac (F3 S-Eco1 card) :	T2A
	Sec. fuse 24ac (F1 S-Eco1 card) :	T10A
	Sec. fuse 24ac (F2 S-Eco1 card) :	T2A
	Sec. fuse Lamp (F4 S-Eco1 card) :	T6,3A
Power supply transformer characteristics	Safety transformer primary:	230V – 450VA
	Secondary:	12/14/18/24 V - 450VA
Water supply	Pressure :	2,5 ÷ 4 bar
	MAX flow N/l :	4 l/min
Air supply	Pressure :	5 ÷ 8 bar
	MAX flow N/l :	80 l/min'
Surgical suction	Max allowed negative pressure (vacuum) :	120 mbar
	Air flow :	1250 l/mim
Cooling systems	Hand pieces :	Driven air/water

2 USE INSTRUCTIONS

2.1 PREMISE

It should be noted that in cases in which the configuration of the dental unit does not provide some of the parts described, the instructions of use means " not applicable ".

2.2 CERAMIC BASIN

Ceramic rotating basin can come close to patient, allowing for a comfortable rinse position. It is also removable to allow for an easier sanitation. Glass/spittoon spouts can be removed by pulling upward (see arrow) After removing spouts, it's possibile to remove spittoon too, pulling upward.	

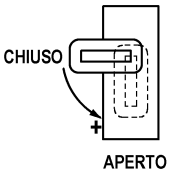
- Glass/spittoon spouts are autoclavable for sterilization
- Basin can be washed in cold with detergent / disinfectant or disinfected with a steam jet.

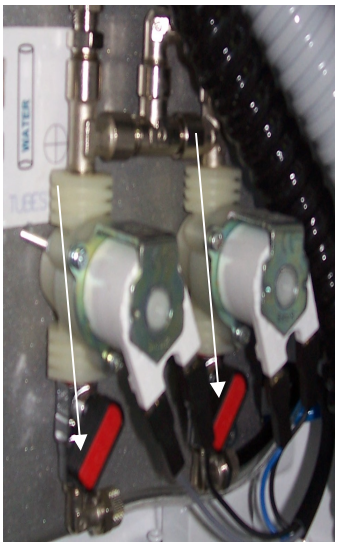
Basin is supplied with a filter for retaining solid particles, and a ceramic drain cover.

To clean the filter, remove it from the basin as shown in the figure below.

Timer for glass water is factory set to ab. 5 sec., that of the basin instead has a start command and one stop.

To calibrate water mass flow to glass/spittoon, move lever taps 1 (spittoon) & 2 (glass), within cuspidor.





2.3 KEYBOARDS

	GLASS WATER After pressing pushbutton, glass water supply is set ON for about 5 seconds.	
	SPITTOON WATER START Pressing pushbutton, spittoon rinse water supply is set ON.	
	SPITTOON WATER STOP Pressing pushbutton, spittoon rinse water supply is set OFF.	

2.4 ASSISTANT TABLE

A revolving arm connected with cuspidor supports assistant's table.

Assistant's table includes:

▪ Keyboard 3 functions ▪ Small canula (∅ 11) housing ▪ Large canula (∅ 17) housing ▪ Additional housing ready for 3 F Assistant's syringe (for details see instrument table syringe) ▪ Extracting canula from its housing, surgical suction pump (when supplied) automatically starts ▪ Inserting canula back into its housing, surgical suction pump automatically stops.	
	GLASS WATER After pressing pushbutton, glass water supply is set ON for about 5 seconds.
	SPITTOON WATER START Pressing pushbutton, spittoon rinse water supply is set ON.
	SPITTOON WATER STOP Pressing pushbutton, spittoon rinse water supply is set OFF.

2.4.1 Syringe

Syringe handpiece has two control pushbuttons, No. 1 for air and No. 2 for water supply: if pressed singly, each pushbutton performs its own control function, if pressed together, spray function is activated.

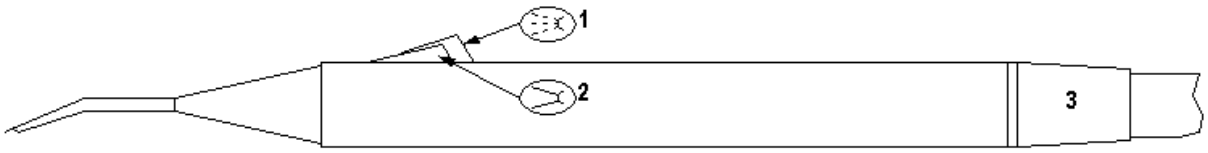
On 6 functions (hot) syringe there is a movable ring on handpiece back (detail No. 3) that, if turned around, switches ON & OFF air and water heating device; green led ON monitors heater operation.

Important: in a hot syringe, both water and air are necessary for handpiece cooling. In absence of water and/or air supply, heating stops automatically

This instrument is suitable for intermittent use, so conform to instructions in following table.

Syringe tip can be removed by means of releasing pushbutton.

Sterilization/disinfection must be compliant with manufacturer's instructions.



Technical specifications

	Luzzani Minilight 6 F syringe	**Siringa Luzzani Minimate 3F**
Air pressure/mass flow	4,5 bar - 10 N l/min	4,5 bar - 10 N l/min
Water pressure/mass flow	2,5 bar - 0,11 l/min	2,5 bar - 0,11 l/min
Power supply	24 V ~	n.a.
Max power.	103 W max.	-
Max. current	4,3 A max.	-
Working type	Intermittent	Continuous
Working time	10 sec. max.	-
Standby time	20 sec. @ room temperature	-

3 MAINTENANCE

3.1 FOREWORD

Standard maintenance is directly performed by user, or by user's qualified & authorized personnel.

Special maintenance is exclusively performed by technical personnel authorized by NEW IDEM srl.

For unit's auxiliary equipment(instruments, chair, lamp, amalgam separator etc.), follow manufacturer's instructions in specific user's manuals.

3.2 STANDARD MAINTENANCE

Between two patients	Clean & disinfect unit's surface with Pulidem, Ecojet Cattani or other water-based non-alcoholic detergents
	Replace suction canulae single-use terminals.
	Disinfect surgical suction canulae with suitable detergents
At working day's end	Clean surgical suction canulae filter
	Extract and disassemble surgical suction terminals, then 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 Suction Canulae Cleaning

Prepare and pour a small quantity of "Pulijet" Cattani or equivalent detergent liquid into a tepid water bucket, according to batching instructions of product label.
With unit and surgical suction pump ON, extract canulae terminals out of their housings.
Insert canulae into bucket with water & detergent, until bucket is completely empty.
Repeat steps 1 to 3, but with tepid water only.
Let canulae suck in air at least for 1 minute, so they can be dried.
Disassemble canulae terminals and carefully wash with suitable detergent/disinfectant

For operator's safety, it is advisable to use medical latex gloves during maintenance operations..

3.2.2 Plastic Surfaces Cleaning

For low contamination risk, surfaces cleaning, (upholstery, covers etc.), use Pulidem o similar non-alcoholic detergents , not harmful for plastic.
For high contamination risk surfaces cleaning, use products with high disinfecting power. Anyway, it is essential to avoid chemically aggressive products, which can modify physical properties of plastics, up to their sudden breaking.
Units use special plastic rings, which support instruments and surgical suction terminals of assistant's table.
In hanging cords configurations, same rings support table instruments. All these rings must be carefully cleaned and disinfected by means of suitable products, unable to modify material's physical characteristics.

Unsuitable products can alter material and then break rings.

Some indications about suitable and unsuitable products:

- Disinfectants based on quaternary salts of ammonium, with low alcoholic percentage SUITABLE
- DÜRR DENTAL type FD320 surface disinfectant SUITABLE
- **Surface disinfectant Cattani ECO-JET1 SUITABLE (Recommended)**
- High alcoholic percentage disinfectant NOT SUITABLE
- Synthetic diluents or nitro NOT SUITABLE
- All other products NOT SUITABLE

3.3 SPECIAL MAINTENANCE

Every year	Clean all water electro-valves
	Visually check mechanical hold and electric efficiency of protective ground connections for all unit parts at 230 V AC
	Following technical manual specifications, check all components at 230 V AC haven't been replaced with spare parts not original or not compliant with manufacturer's specifications
	Following use instructions of present manual, check functioning of all unit's parts.
After 10 years	According to D.P.R 224/1988, after the 10th year from manufacturing date, user only (so excluding manufacturer) is responsible for damages caused by unit's proper use. It is advisable an accurate unit's general test/overhaul performed by qualified & authorized personnel.
As needed	Bulbs/Fuses replacement. Check from time to time equipment safety, according to enforcing laws & norms. Unit's functional recovery, partially compromised by one or more failure events.

4 CLASSIFICATION & CE MARK

Equipment was positively tested both by New Idem's and Notified Body IMQ's test labs, in order to verify its compliance with EN 60601-1 and other related norms, applicable to European Medical Devices Directive 93/42/EEC & s.m.i. (2007/47/CE).

Equipment neither emits electro-magnetic fields nor is influenced by electro-magnetic radiations, in compliance with European Directive and related applicable harmonized norms.

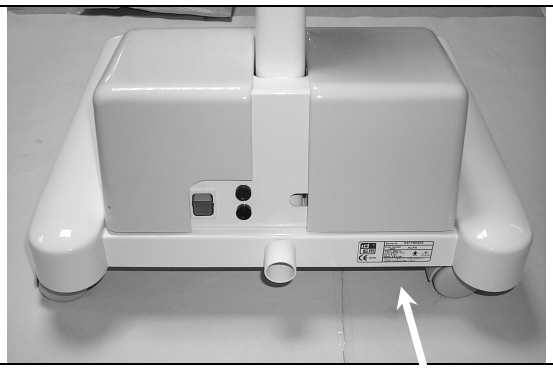
4.1 EQUIPMENT CLASSIFICATION EX ART. 9 OF 93/42/EEC DIRECTIVE & S.M.A. (2007/47/CE)

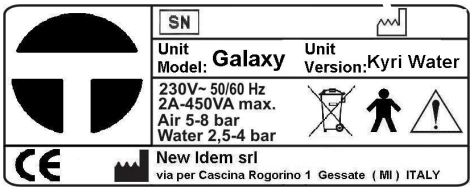
Actually implemented servicing functions are considered, in order to classify equipment in terms of applicability to reference Directive.
Series 2002 Units, when operating in accordance with Manufacturer's intended use, according to 93/42/EEC CEE & s.m.i. (2007/47/CE), Directive, are classified as Medical Devices of **Classe I .**

4.2 EN 60 601-1 CLASSIFICATION

<5.1>Protection against electrical hazards	CLASS I – External power supply As protection against direct & indirect contacts is not only based on fundamental insulation, but also on an additional safety measure, i.e. equipment is connected with protection ground cable of power supply plant, so that accessible conductive parts cannot bear voltage because of damaged fundamental insulation.
<5.2>Protection level against direct & indirect contacts	 With B type applied parts With a specific protection level against electrical hazards, namely: Allowable leakage currents Protection ground connection availability
<5.3>Protection level against water leakage.	IPX 0 Equipment case isn't protected against water leakage
<5.4>Sterilization and/or disinfection methods allowed by manufacturer	For table instruments: see manufacturers' 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 operation, intermittent working <2.10.3> As suitable to standard load operation for a fixed time, keeping temperature under norm prescribed limits.

4.3 IDENTIFICATION PLATE





4.3.1 Plate Data Description

SN	Internal code identifying equipment model/prod. Series/configuration, manufacturing and final testing dates.
	Identifies the Year of Production
Unit model/Unit version	Fully identifies equipment model
	Identifica la modalità di smaltimento dell' apparecchiatura
	With a specific protection level against electrical hazards, namely: Allowable leakage currents Protection ground connection availability
	WARNING – See related documentation
230V-50/60 Hz	External power supply 230V AC @ 50/60 Hz
4,2A-960VA max	Alternate current max 2 Ampere – 450Volt/ampere
Air 5-8 bar	Medical compressed air external supply @ 5 ÷ 8 bar
Water 2,5-4 bar	Potable water external supply @ 2, 5 & 4bar
CE	CE Mark complying with applicable enforcing laws & norms
	Tecno-Gaz Logo
	Manufacturer's Name and Factory address

5 COUPLIG WITH OTHER MEDICAL EQUIPMENT

5.1 FOREWORD

2002 Series units are normally supplied with an New Idem, or other manufacturers' chairs (provided that they fully comply with interfacing specifications of following paragraphs) and a number of instruments, chosen from New Idem Price list or of different Manufacturers (in this case, they must completely respect following interface specifications).

NEW IDEM srl denies any responsibility for damages to people and/or goods, whenever such specifications are not observed.

5.2 CHAIR

WARNING – For installation, use & maintenance instructions pls. refer to chair user's manual.

VERIFY compatibility between unit and chair, checking interface specifications below

Chair must be considered (according to 93/42/EEC Directive) as an Electro-Medical Device of Class 1.

It follows that chair, considered as a stand-alone device, must be supplied complete with applicable CE marking and with related documentation, in detail :

- CE conformity assessment (when supplied by manufacturer in compliance with Directive)
- Use, installation & maintenance manual
- Warranty Certificate

Chair must be fastened to floor in at least 2 points, by means of suitable expansion fasteners with 8 mm. min. diameter screws.

6 EQUIPMENT DISPOSAL

With ref. to European enforcing directives 2002/95/CE, 2002/96/CE, 2003/108/CE about "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, 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

New Idem, as an electro-medical devices manufacture and RAEE source, must contribute to its own equipment disposal costs, by means of special institutions, specifically constituted by competent Authorities.
According to enforcing norms, New Idem applies special labels to its devices, warning user they're RAEE, with a special disposal procedure.
Re-seller (or user himself) with RAEE equipment for disposal, must strictly follow disposal procedure of next paragraph.
According to law norms, NEW IDEM srl is not responsible in any cases, whenever user or re-seller do not comply with disposal procedure of next paragraph.

EQUIPMENT DISPOSAL PROCEDURE

Before disposal, electro-medical device must be prevented from further usability, with following operating procedure:

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

After device is completely 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 plants, qualified for RAEE wastes, or
- To New Idem local distributor[1] which, as a RAEE source, will send device to properly qualified disposal plants.

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

WARNING!! Symbol  on equipment reminds that any different disposal procedure is strictly forbidden by law!!

[1] **For EEC countries only: if IDEM device was sold before 08/13/2005, only when it replaces a newly bought equivalent IDEM device.**

7 WARRANTY

- New Idem 2002 Series equipment is guaranteed against materials and manufacturing defects for max 24 months since equipment was installed or (if shorter) 24 months since production month (equipment attached CE conformity declaration assesses production month).
- Warranty doesn't include all parts subjected to normal wear and/or incorrect use, such as:
- Bulbs
- Fuses
- Ceramics
- Upholstery
- Hoses and external tubes
- Surgical suction terminals
- Plastic and/or other surfaces damaged by unsuitable chemicals
- At par. 8.2 there is attached an installation form, that must be suitably compiled, stamped and signed by installation authorized technician; unit reseller or, in alternative, final user is bound to return filled form to New Idem within 30 days from installation date.
- Were not installation form returned by buyer, WARRANTY will be immediately voided. Note that in this case New Idem cannot comply with law enforcements regarding medical device traceability, and therefore buyer (re-seller or final user) will be claimed the only responsible for all respects.
- "Totally free of charge" repair is executed at New Idem factory; transport costs & risks are at customer's charge.
- Warranty repairs at customer's study can be performed only by New Idem authorized personnel, identified by an "Authorization Card". For such interventions customer will pay authorized technician corresponding traveling expenses (provided that no different agreement was stipulated with re-seller, provided that New Idem is neither responsible nor liable at all respects for such private agreements).
- Equipment re-seller is primarily in charge for any technical/functional problem solution and or technical intervention request at customer's study.
- NEW IDEM srl does not acknowledge possible additional warranty clauses, stipulated with a re-seller,.
- For medical devices connected with New Idem unit (e.g. handpieces, operating lamp, amalgam separators, surgical suction systems, etc.) directly refer to manufacturer's warranty applicable conditions. In detail, unit manufacturer reminds that, in case of handpieces' malfunctions (i.e. turbines, M/M, scalers, contrangles, polymerizing lamps, etc.), user must directly ask corresponding manufacturer to honor related warranty, according to its applicable conditions.
- In any cases, it is excluded the possibility to charge New Idem for any damage refund of unit total or partial working time loss.
- New Idem has the unobjectionable right to void warranty, in case of equipment tampering, damaging, improper use, lack of correct maintenance or in case of damages originated by external causes or natural disasters.

Present WARRANTY conditions are automatically fully accepted by buyer, whenever buyer doesn't inform NEW IDEM Srl, by means of a registered letter within 15 days from installation date, about possible alleged claims.

8 CERTIFICATIONS

8.1 CE CONFORMITY DECLARATION

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

DICHIARAZIONE DI CONFORMITA' — MOD. DC 0051

(Decisione N.768/2008/CE del 9 Luglio 2008)

Prodotti: Riuniti Odontoiatrici
Modello: Galaxy
Versione: Kyri Water

L' azienda New Idem S.r.l.,
con sede legale in Via per Cascina Rogorino,1 - 20060 Gessate (MI) - Italia,
dichiara sotto la propria responsabilità che:

1. I summenzionati dispositivi sono realizzati conformemente a quanto richiesto dalla Direttiva 93/42/CEE e s.m.i., attraverso l'applicazione delle norme di riferimento:
   - EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996;
   - EN 60601-1-2:2001 + A1:2006;
   - EN ISO 9687:1995;
2. I summenzionati dispositivi sono considerati appartenenti alla classe IIa in base alla regola 6 dell'Allegato IX della Direttiva 93/42/CEE e s.m.i.;
3. Tutta la documentazione riguardante tali dispositivi è archiviata nel fascicolo tecnico di prodotto e conservata per un periodo di almeno 5 anni dalla data di ultima fabbricazione del prodotto stesso;
4. Tutte le fasi della produzione dei summenzionati dispositivi soddisfano le prescrizioni indicate nel Sistema di Gestione per la Qualità aziendale conformemente a quanto prescritto nell'Allegato II della Direttiva 93/42/CEE e s.m.i.;
5. Tale Sistema di Gestione per la Qualità aziendale è conforme ai requisiti specificati dalle norme ISO 9001:2008 e ISO 13485:2012 ed è certificato dall'Organismo di Certificazione CSQ/IMQ (certificati n. 9120.IDRI e n. 9124.IDR2);
6. L'azienda **New Idem S.r.l.** ha proceduto nel notificare all'Autorità Competente l'immissione in commercio dei summenzionati dispositivi e a istituire una procedura sistematica allo scopo di garantirne la sorveglianza post-vendita.

La presente dichiarazione viene rilasciata per il dispositivo caratterizato da:

Numero di Serie	Data Produzione
XXX XXX XX XX	GG/MM/AAAA

Gessate - Italia - Febbraio 2015

Il legale rappresentante
Un Amministratore