New Idem srl Gessate (MI) Italy

Galaxy

S2002

USER INSTRUCTION MANUAL

CSQ MED UNI EN ISO 13485 : 2004 — IQNet CSQ UNI EN ISO 9001:2008	REV. 4 – DICEMBER 2012
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SUMMARY

1 REFERENCE DATA

1.1 MANUFACTURER

NEW IDEM srl – via Per Cascina Rogorino, 1
20060 Gessate (MI) Italy
Tel. 02/95423704 Fax. 02/95423726
www.idemriuniti.com - email : info@idemriuniti.it

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 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	Transformer Primary 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 characteristics	Safety Transformer primary:	230V – 450VA
	Secondary:	12/14/18/24 V - 450VA
Water supply	Pressione :	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

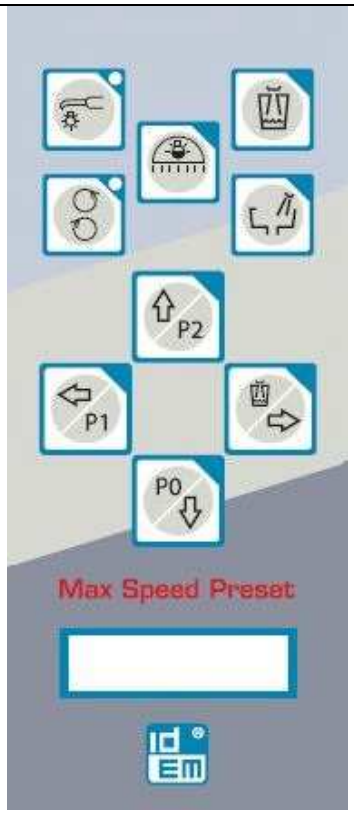
2 USE INSTRUCTIONS

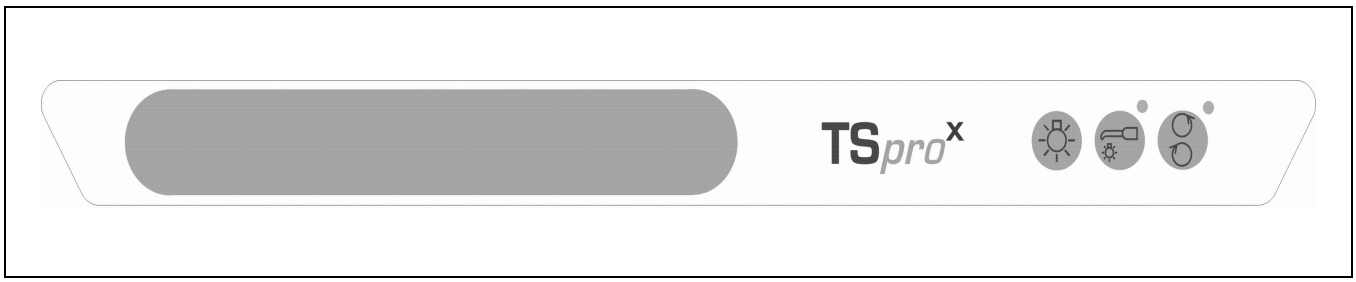
2.1 FOREWORD

Units use instructions are valid for all 2002 Series models.

Pls. note that, in case an unit does not include a specific part/sub-system, related instructions must be intended as "not applicable".

2.2 KEYBOARD

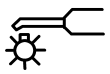




2.2.1 Symbol table.

Symbol	Description
	• SEATREST DESCENT (all chairs) Manual movement control pushbutton. As long as it's pressed, seatrest keeps going down. • "ZERO Position" Program (all chairs) Automatic movements control pushbutton. If pressed, automatically seatrest moves downward, and backrest completely upward. Seatrest bottom position is factory calibrated, as it's considered the most suitable for patient access to chair. Pressing chair descent pushbutton, seatrest goes down a little more (some centimeters), depending on actual chair model.
	• BACKREST ASCENT (all chairs) Manual movement control pushbutton. As long as it's pressed, backrest keeps going up. • RINSE & LAST POSITION Program (Prima & Tecno chairs only) *Chair without memories* Press pushbutton to start "Zero position" program. *Chair with memories* Pressing pushbutton, backrest automatically moves up to top position. Pressing pushbutton again, , backrest automatically returns to previous working position.
	• BACKREST DESCENT (all chairs) Manual movement control pushbutton. As long as it's pressed, backrest keeps going down. • PROGRAM 1 (all chairs) Automatic movement control pushbutton. *Chair without memories* Press pushbutton to start "Zero position" program. (Prima & Tecno chairs only) *Chair with memories* Pressing pushbutton, backrest automatically moves to user-programmed position.
	• SEATREST ASCENT (all chairs) Manual movement control pushbutton. As long as it's pressed, seatrest keeps going up.

	• PROGRAM 2 (all chairs) Automatic movement control pushbutton. *Chair without memories* Press pushbutton to start "Zero position" program. (Prima & Tecno chairs only) *Chair with memories* Pressing pushbutton, backrest automatically moves to user-programmed position.

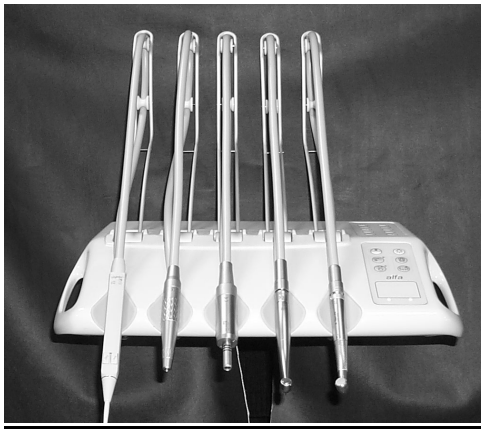
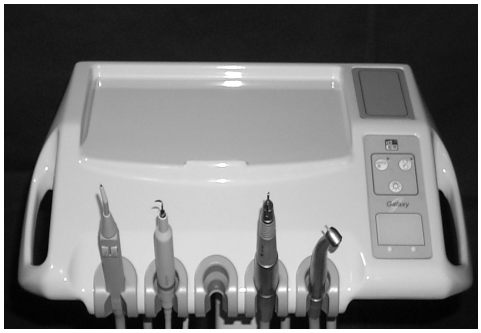
Symbol	Description
	**OPERATOR LAMP** Lamp is controlled by means of a bi-stable switch. When lamp own switch is ON, lamp is switched ON pressing once pushbutton; pressing pushbutton again, lamp i s switched OFF. At every unit-startup, lamp is switched OFF. Pls. note: Lamp can be controlled independently; if the case, check installation with an authorized technician.
	**O.F.** O.F. for all applicable instruments is controlled by means of a bi-stable switch. O.F. is switched ON pressing once pushbutton (LED is ON); pressing pushbutton again, O.F. i s switched OFF (LED is OFF). At every unit-startup, O.F. is switched OFF.
	**MICROMOTOR INVERSION** Rotation inversion of electric M/M is controlled by means of a bi-stable switch. Inversion is switched ON pressing once pushbutton (LED is ON); pressing pushbutton again, inversion i s switched OFF (LED is OFF). At every unit-startup, inversion is switched OFF.
	**X-VIEWER** X-viewer bi-stable control pushbutton. Pressing pushbutton once X-viewer lights ON; pressing again X-viewer is OFF. At each equipment's startup, X-viewer is OFF.

DISPLAY	**DISPLAY** Using potentiometer under instrument table keyboard a value 0÷40,000 is displayed. That's the max setting of M/M rotation speed (when value is zero, i.e. min. speed).

2.3 INSTRUMENT TABLE TYPES DEFINITION

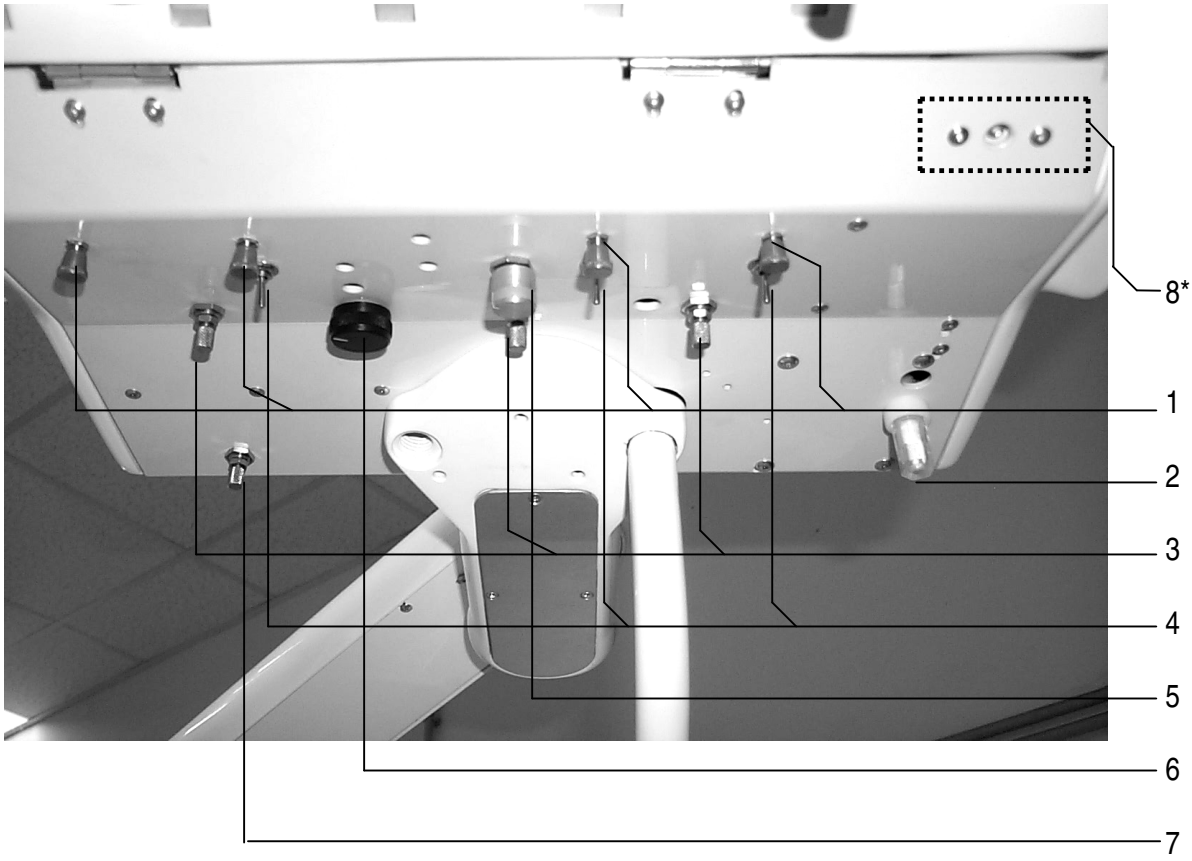
Dentist normally works with the help of a specific type of instruments table.

2002 series units can use 3 different models of instrument table:

SPRIDO Instrument table • Ready for 5 instruments max. • Instrument recovery by spring operated mechanical arm. • Complete with plastic-coated consoles for table functions control. • With single instrument calibration devices	
HANGING CORDS Instrument Table • Ready for 5 instruments max. • Instruments with special housing bushes. • Instrument cords needing no recovery spring. • Complete with plastic-coated consoles for table functions control. • With single instrument calibration devices.	
HANGING CORDS Instrument Table • Ready for 5 instruments max. • Instruments with special housing bushes.	

- Instrument cords needing no recovery spring.
- Complete with plastic-coated consoles for table functions control.
- With single instrument calibration devices
- Space tray wider

2.4 INSTRUMENTS CALIBRATION & PRE-SELECTION



1. Instruments spray water calibration taps.

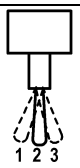
2. Turbine oil recovery filter; one per each turbine(optional).

⚠ Filter is a small glass cup, with a small amount of cotton wool.screwed to table bottom; when cotton becomes yellow, or at least once a month, it must be replaced, with an equivalent small amount of cotton wool; if too much cotton is used, and pressed inside the cup, turbine rotates slower and bur cuts less.

3. Instruments air calibration taps:
   - Spray air (syringe)
   - Motor air (turbine)

- Cooling air (micromotor)
- Scaler: n.a.

4. ⚠ Spray selection switch:

	Position 1= Instrument spray starts pressing spray lever of rheostat foot-control. Position 2= Instrument spray is always OFF. Position 3= Instrument sprayautomatically starts pressing start lever of rheostat foot-control.

5. Micromotor speed manual calibration potentiometer; pre-sets electric micromotor max. accessibile speed.Max. rotation speed is controlled by rheostat foot-control related lever.

⚠ WARNING: if potentiometer is set to min. value, rheostat foot-control lever cannot modify micromotor rotation speed, which will always remain at its bottom level.

6. Scaler power calibration potentiometer (Scaler power cannot be controller by rheostat foot-control lever).

7. Spray air calibration tap; one for all instruments.

8. As shown in foll. Fig.,there is a potentiometer, setting a value 0÷40,000 (displayed on lower instrument table keyboard), corresponding to M/M max. rotation speed.

M/M rotation speed pre-setting potentiometer

2.5 CLEAN WATER

Clean Water is an instrument water supply system, using a plastic bottle (accessible to operator) with a liquid replacing standard water supply.

Following liquids can be used:

- Distilled water (to prevent valves calcareous scales)

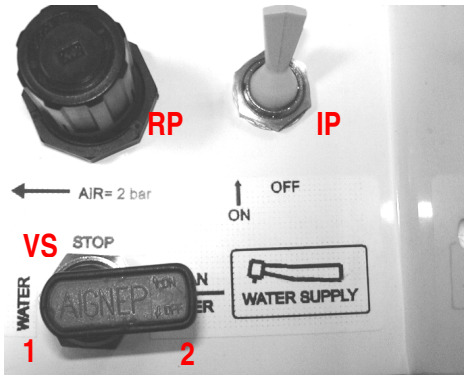
- 1 % Calbenium powder diluted in drinkable water (acting as anti-scale and germicide and cicatrizing at the same time)

- Mixture of drinkable water and of a liquid tested and certified as suitable for handpieces spray.

Equipment's autonomy is ab. 100cc; then it must be manually re-filled with selected liquid, unscrewing bottle cap, after internal pressure release

N.B: Sterile physiological liquid (for micro-surgery or implantology operations) cannot be user with Clean water because physiological liquid is not granted as sterile since it is poured into Clean-water tank, and also because it's easily "crystallized", and so can damage pass-through tubes and valves.

2.5.1 Operating instructions



VS ball valve/tap supplies instruments either with mains water or >Clean Water bottle liquid.
Position 1= mains water
Position 2= Clean-water liquid
IP pneumatic switch supplies liquid bottle with compressed air, to keep proper internal pressure.
IP switch must be set ON for liquid supply; when set OFF, bottle can be disconnected and re-filled.
RP knob controls bottle internal air pressure.
RP is normally factory calibrated at 2 bar; an authorized technician, using a manometer, can perform possible new calibration.

Note: The ball valve in question is located under the quiver.

WARNING: air excessive pressure can damage bottle and its functionality.

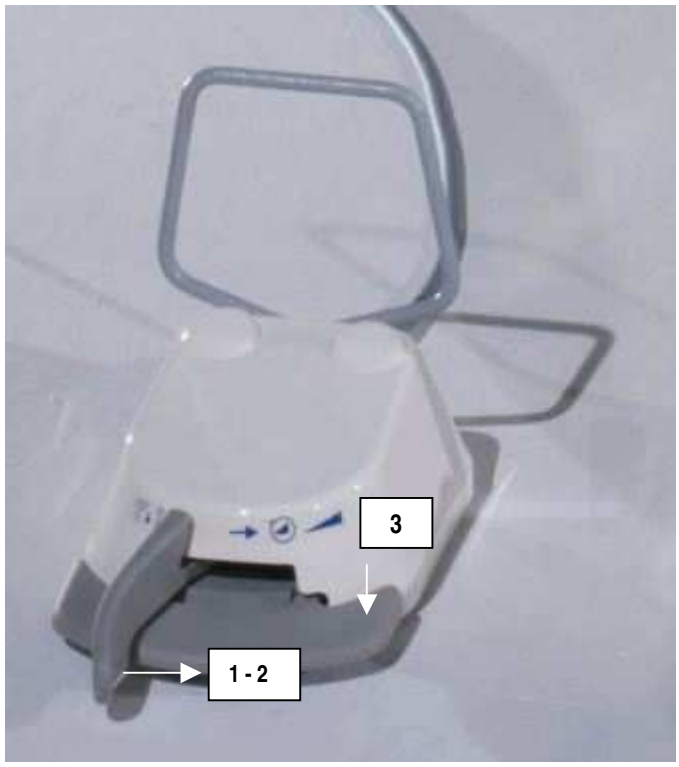
2.6 PEDALE REOSTATO

RH Rheostat (without push button)

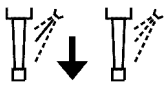
Rheostat is controlled by 2 levers and a Joystick.

The first lever (1-2) works rotating horizontally left to right; the second one must be pressend downwards (3).

1. Dynamic instruments Start –ST–
2. Rotation speed control
3. Chip-air activation (when instruments are not working), spray activation in other case



2.6.1 SYMBOLS

Function (with selected instruments)	**Symbol**	**Function (only with supplementary functions card and instruments NOT selected)**
Dynamic instruments START With rotation speed control.		Operator lamp and last position synchronous control
Chip-air activation (when instruments are not working), spray activation in other case		Glass and spittoon water supply or glass only

2.7 INSTRUMENTS DEFINITION

Unit's instruments are partially considered as unit's parts and partially as stand-alone electro-medical devices .
Instruments can be housed 5 max. on instruments table and 2 max on assistant's table.
Available instruments are:

Cold or hot water SYRINGE	(A) Unit's part
Standard or O.F. ELECTRIC M/M	(B) Stand-alone electro-medical device
M/M HANDPIECES standard or contrangle	(B) Stand-alone electro-medical device
Standard or O.F. TURBINE	(B) Stand-alone electro-medical device
PIEZO SCALER	(B) Stand-alone electro-medical device
POLYMERIZING LAMP	(B) Stand-alone electro-medical device

 New Idem recommends, for all dynamic instruments, tips and burs complying with ISO 10993-1.

 All instruments marked (B) can be supplied separately from unit, if they are compliant with interface specifications of this Manual and with CE marking according to 93/42/EEC Directive.

WARNING: INSTRUMENTS WITHOUT CE MARKING ARE NOT PERMITTED

2.8 INSTRUMENTS USE - GENERAL INSTRUCTIONS

Dynamic instruments are pre- selected moving corresponding hose-carrying arm a few cm. from standby position or, with hanging cord instruments, lifting instrument from its housing.

Single dynamic instrument activation, by means of an electronic control circuit, automatically prevents activation of all remaining instruments (excluding syringe and polymerizing lamp).

 Single dynamic instrument activation starts operation of a function called "Active Stop"

It prevents all chair movements until an instrument is active (such function is assured only when both unit and chair are manufactured or marketed by New Idem).

Pre-selected instrument activation is controlled by activation of Start control of rheostat foot-control.

Chip-air function is available on rotating instruments, i.e. an air blow from handpiece into operating field, by means of handpieces and of rheostat/foot-control.

2.9 TURBINE

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

Agendo sulla leva del pedale reostato, si ottiene l'attivazione della turbina .

Turbine speeds varies proportionally with pedal lever shift, only when unit is complete with turbine proportional module; otherwise turbine speed is always the maximum available.

Spray control is performed by means of a throttle/tap on instruments table bottom; clockwise screwing decreases flow, anti-clockwise increases.

Instrument water supply system includes a chip-blower device, providing a high pressure air automatic blow, purging (Venturi effect) water pipe, every time spray stops.

As there is always water inside handpiece, to prevent dripping check packing tightness and verify that handpiece is firmly fastened with its hose.

Taking instrument out of its housing, after pressing the related pushbutton of instrument table console, switches Optical Fibers light ON.

To disconnect a turbine from its unit, unscrew anti-clockwise bottom ring (before hose cover).

This instrument is manufactured for discontinuous use, so follow applicable user instructions of turbine's Manufacture.

For these instruments use autoclave with sterilization program of 16 minutes @ 135 °C – pressure 1,9/2,1 bar.

2.10 MICROMOTOR

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

Moving rheostat foot-control lever, micromotor rotates clockwise and its speed (r.p.m.) is controlled.

On instruments table bottom, corresponding with M/M module, there is M/M speed manual control potentiometer, to pre-set max allowable speed.

⚠ **WARNING:** if potentiometer is set to min. speed, rheostat foot-control cannot modify M/M speed, that will remain at min. value.

Rotation inversion is controlled by setting ON/OFF a lever switch under corresponding instrument control module, on bottom cover of instrument table.

Spray control is performed by means of throttle/tap on instruments table bottom; clockwise screwing decreases flow, anti-clockwise increases.

Instrument water supply system includes a chip-blower device, providing a high pressure air automatic blow, purging (Venturi effect) water pipe, every time spray stops.

As there is always water inside handpiece, to prevent dripping check packing tightness and verify that handpiece is firmly fastened with its hose.

Taking instrument out of its housing, after pressing the related pushbutton of instrument table console, switches Optical Fibers light ON.

To disconnect M/M from unit, unscrew anti-clockwise bottom ring (before hose cover).

Important: M/M is designed for integrated spray, therefore it is essential to adopt handpieces with corresponding spray type.

This instrument id suitable for intermittent use, so conform to instructions in manufacturer's user manual.

2.11 PIEZO-ELECTRIC SCALER

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

Moving rheostat foot-control lever, scaler is activated.

Scaler tip must be constantly cooled by water flow, so specific spray selection lever must be pre-set accordingly.

Spray control is performed by means of throttle/tap on instrument table bottom; clockwise screwing decreases flow, anti-clockwise increases.

Power control is performed by means of a potentiometer under instrument table bottom.

⚠ WARNING: it is strictly forbidden to stop water flow completely, unless endodontic probes or amalgam condensation tips are in use.

Power control is performed by means of potentiometer under instrument table bottom.

⚠ This instrument is suitable for intermittent use, so conform to instructions in manufacturer's user manual.

Sterilization must be performed inserting scaler tips and handpiece into an autoclave programmed for a 4 minutes sterilization at 135 ° C @ 2 bar. or 20 minutes at 121 ° C @ 2 bar.

2.12 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.

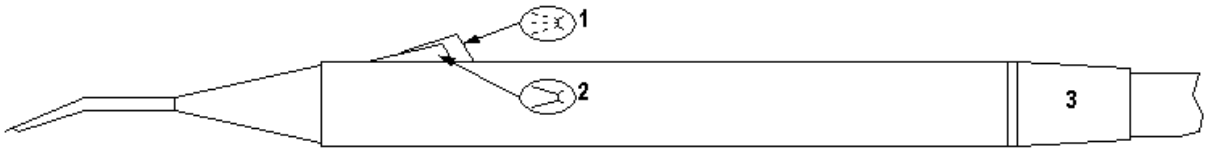
On 6 functions (hot) syringe there is a movable ring on handpiece bottom (detail No. 3) that, if turned around, switches ON & OFF air and water heating device; green led ON monitors heater operation.

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 must be performed inserting syringe shell into an autoclave programmed for a 32 minutes sterilization at 121 ° C @ 1÷1,15 bar.



2.12.1 Technical characteristics

	Luzzani Minilight 6 F syringe

Air pressure/mass flow	4,5 bar - 10 N l/min
Water pressure/mass flow	2,5 bar - 0,11 l/min
Power supply	24 V ~
Max power.	103 W max.
Max. current	4,3 A max.
Working type	Intermittent
Working time	10 sec. max.
Standby time	20 sec. @ room temperature

2.13 POLYMERIZING LAMP

Foreword: present manual provides only basic information about Mectron Starlight S or P lamps. For installing other lamps or specific technical details, refer to manufacturer's corresponding user manuals.

⚠ Starlight P lamp can be used only when a Mectron Compact Piezo Scaler is installed.

Remove scaler handpiece from its hose, insert lamp handpiece and check scaler power control potentiometer (under instrument table) is set to max power.

Use instructions:

- Remove handpiece from its housing (on instrument or assistant's table) and move it near to part where composite must be polymerized
- Press P pushbutton on handpiece (only S model)
- Activate foot-control instrument start for at least 20 sec. (only P model)
- 20 sec. cycle starts. After 10 sec. and at cycle end device beeps
- At the end of each polymerization cycle, it is possible to repeat operations many times, following previous procedure (according to specified standby times)
- Pls. note: during initial 10 sec. of each cycle, prevent contact between O.F. terminal tip and un-polymerized composite. Composite scraps on O.F. lower lamp efficiency, compromising following polymerizations.

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

After use, clean handpiece using a cloth wet with a neutral PH detergent/disinfectant.

Sterilization is only possible for O.F. C and its cover, which must be removed from handpiece.

⚠ Sterilization must be performed before each single use (EN554 norm), inserting O.F. into an autoclave programmed for a 20 minutes sterilization at 135 ° C @ 1,9/2,1 bar.

2.13.1 Technical characteristics

	Mectron Starlight Polymerizing lamp
Power supply	24 V AC
Max power.	9 W
Light Radiation	470 nm
Working type	Intermittent
Working time	40 sec. max.
Standby time	60 sec. min.
Sterilization method	Autoclave @ 135°/ 2,1 bar max. – 20 min.'

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.
	Suitably sterilize unit's handpieces.
	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..

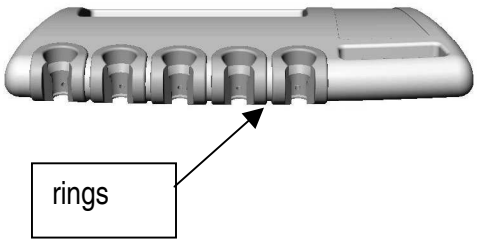
3.2.2 Plastic surfaces cleaning

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 MANUTENZIONI STRAORDINARIE

Ogni 6 mesi	Sostituire i Tubi delle cannule di aspirazione
	Sostituire i terminali delle cannule di aspirazione
	Pulire il vaso miniseparatore se presente sul riunito
	Sostituire i filtri aria ed acqua generali
	Sostituire la batteria alcalina tipo LR6 1,5 V del sistema MAC
Ogni anno	Pulire tutte le elettrovalvole con passaggio di acqua
	Controllare visivamente la tenuta e l'efficienza dei collegamenti di terra e delle connessioni relative alle parti sottoposte a tensione di rete 230V.
	Controllare con l'ausilio del manuale tecnico che i componenti sottoposti a tensione di rete non siano stati sostituiti da componenti non originali ovvero non conformi alle specifiche tecniche del costruttore.
	Effettuare una verifica, seguendo le istruzioni d'uso del presente manuale, di funzionalità di tutte le parti del riunito
Dopo 10 anni	In base al D.P.R 224/1988, dopo il 10° anno di età dalla data di costruzione, le responsabilità di danni causati dall'apparecchiatura non sono più imputabili al costruttore ma solo all'utilizzatore. Si consiglia pertanto di fare eseguire una accurata revisione generale da personale autorizzato e qualificato.
Secondo la necessità	Sostituzione delle lampadine e/o dei fusibili Verifiche periodiche relative alla sicurezza in conformità alle leggi vigenti. Ripristino della funzionalità dell'apparecchio, parzialmente compromessa da uno o più guasti verificatisi .

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.

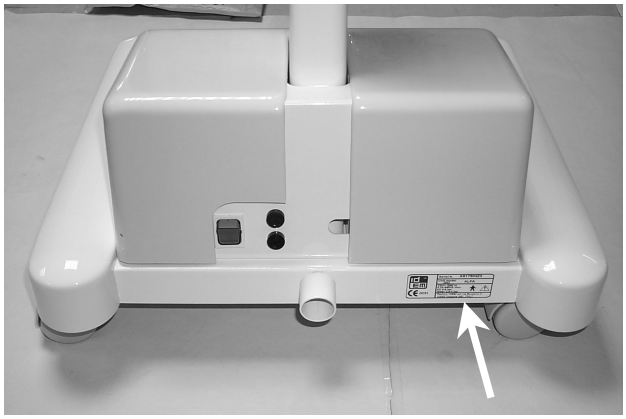
4.1.1 Equipment Classification ex Art. 9 of 93/42/EEC Directive & s.m.a. (2007/47/CE)

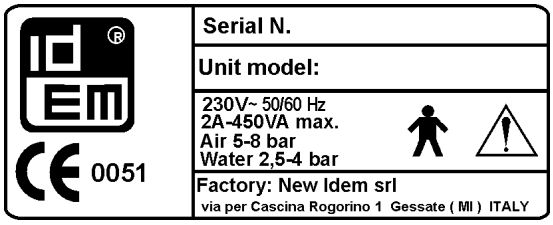
Actually implemented servicing functions are considered, in order to classify equipment in terms of applicability to reference Directive.
Series 2002 Units, including BRIO & BRIO KART units, when operating in accordance with Manufacturer's intended use, according to 93/42/EEC CEE & s.m.i. (2007/47/CE),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

4.1.2 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 <5.1>Protection against electrical hazards	Continuous operation, intermittent working <2.10.3> As suitable to standard load operation for a fixed time, keeping temperature under norm prescribed limits.

4.2 IDENTIFICATION PLATE





4.2.1 Plate data description

Serial N.	Internal code identifying equipment model/prod. Series/configuration, manufacturing and final testing dates.
Unit model	Fully identifies equipment model
	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 0051	CE Mark complying with applicable enforcing laws & norms. "0051" after CE mark identifies IMQ Italian Notified Body in charge
	New Idem Logo
Factory	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.

5.3 APPLICABLE INSTRUMENTS

⚠	WARNING – For use & maintenance instructions, pls. refer to instrument specific user manual. VERIFY compatibility between unit and instrument using "instrument interface technical specifications"

Applicable instruments (turbines, M/M's, contrangles, scalers, prophylactic units and polymerizing lamps) must be considered, according to 93/42/EEC Directive, as Electro-Medical Devices of 2 A Class. Instruments/Devices of M.D. Class over 2 A are not allowed.
It follows that instruments, considered as stand-alone devices, 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

5.4 INSTRUMENTS INTERFACE TECHNICAL SPECIFICATIONS

5.4.1 **TURBINES :** standard 3 or 4 ways hose connections (with – w/o O.F.)

MOTOR AIR		COOLING AIR		SPRAY AIR		SPRAY WATER		O.F. POWER SUPPLY	
Consumo Nl/min	**Pressione bar**	**Consumo l/min**	**Pressione bar**	**Consumo Nl/min**	**Pressione bar**	**Consumo l/min**	**Pressione bar**	**tensione Vcc**	**corrente A**
30 ÷ 40	2 ÷ 3	---	---	15	3	0.14	2.5	3 ÷ 3.5	0.5 ÷ 1

5.4.2 **PNEUMATIC MICROMOTORS & SCALERS:** standard 3 or 4 way hose connection (with or without O.F.)

N.B: Instrument works properly only with enhanced power modules

MOTOR AIR		COOLING AIR		SPRAY AIR		SPRAY WATER		O.F. POWER SUPPLY	
Flow l/min	**Pressure atm**	**Flow l/min**	**Pressure bar**	**Flow l/min**	**Pressure bar**	**Flow l/min**	**Pressure bar**	**Voltage V Dc**	**Current A**
30 ÷ 50	2 ÷ 3,3	---	---	15	3	0.14	2.5	3 ÷ 3.5	0.5 ÷ 1

5.4.3 ELECTRIC MICROMOTORS (complete with hose)

MOTOR AIR.		COOLING AIR.		SPRAY AIR		SPRAY WATER		O.F. POWER SUPPLY	
Flow l/min	**Pressure atm**	**Flow l/min**	**Pressure bar**	**Flow l/min**	**Pressure bar**	**Flow l/min**	**Pressure bar**	**Voltage V Dc**	**Current A**
15	3	15	3	0.14	2.5	0 ÷ 24	65Wmax	3 ÷ 3.5	0.5 ÷ 1

5.4.4 PIEZO SCALERS complete with hose & driver card

TAKE-OFF CONTACT		COOLING WATER		POWER SUPPLY	
35V DV max.		**Flow l/min**	**Pressure bar**	**Voltage V AC**	
5 A max	Normally Open	0.14	2.5	24	50 W max

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. Sample copy follows, valid for all products of 2002 Series.

DICHIARAZIONE DI CONFORMITA' - DECLARATION OF CONFORMITY
DECLARACION DE CONFORMIDAD - DECLARATION DE CONFORMITE'
KONFORMITÄTSBESCHEINIGUNG

CE 0051

Applicazione della direttiva CEE 93/42 (DISPOSITIVI MEDICI) & s.m.i. (2007/47/CE)
Application of EEC directive 93/42 (MEDICAL DEVICES) & s.m.i. (2007/47/CE)
Conforme a la Directiva CCE 93/42 (EQUIPOS MEDICOS) & s.m.i. (2007/47/CE)
Application a la Directive CEE 93/42 (DISPOSITIFS MEDICAUX) & s.m.i. (2007/47/CE)
Anwendung der EWG Vorschrift 93/42 (MEDIZINPRODUKTE) & s.m.i. (2007/47/CE)

Norme applicate/ constructions Standard

UNI EN ISO 9687	1996	Attrezzatura Dentale - Simboli Grafici Dental Equipment - Graphical Symbols
CEI-EN 60601-1	1998	Medical Electrical Equipment General requirements for safety
CEI-EN 60601-1-2	2003	EMC
UNI-EN 1640	2010	Dispositivi medici per odontoiatria Odontoiatry medical devices
UNI EN ISO 7494-1/2	2006/2003	Unità dentali/ dental Equipment

Nome del fabbricante
Name of manufacturer
Nombre del fabricante
Nom du fabricant
Name des Herstellers

New IDEM S.R.L.

Indirizzo del fabbricante
Address of manufacturer
Direccion del fabricante
Adresse du fabricant
Adresse des Herstellers

Via per Cascina Rogorino, 1 - 20060 GESSATE (MI) - ITALIA

Descrizione del materiale
Description of goods
Descripcion del material
Description des marchandises
Warenbezeichnung

Riuniti per Odontoiatria e Podologia
Podiatry and Dental Units

Modelli
Models
Modelo
Modele
Modell

serie 2002 - Brio, Alfa, Alfa Young, Alfa Ortodontico, Alfa Podologico, Penta, Colibrì, Galaxy.

Il sottoscritto dichiara che il materiale di cui sopra è conforme alla direttiva 93/42 CEE.
The undersigned hereby declares that the abovementioned goods are compliant with 93/42/CEE directive.
El declarante afirma que el material arriba indicado es conforme a la directiva CEE 93/42.
Le soussigne declare que le material cité ci-dessus est entièrement conforme à la directive 93/42 CEE.
Der unterzeichnete erklärt dab die obengenannte ware vollständing die vorschrift 93/42 der EWG entspricht.

Costruito a
Made in
Fabricado in
Fabrique à
Hergestellt in

GESSATE - ITALY

MAGGIO/MAY 2011
Addì - Date - Fecha - Le - Datum

Firma - Signature - Firma - Signature - Unterschrift

PONZANO VINCENZO
Cognome e nome - Surname and name
Nombre apellidosy - Nom et prénom - Nach - und Vorname

AMMINISTRATORE
Funzione - Position - Cargo -Fonction - Stellung

Modello: Model:	#N/D	N°serie: Serial No:	#N/D	000	#N/D	#N/D	Data prod: Mfg.Date:	#N/D