Euroclinic

OTOPLUS

OTOPLUS

CE

0476

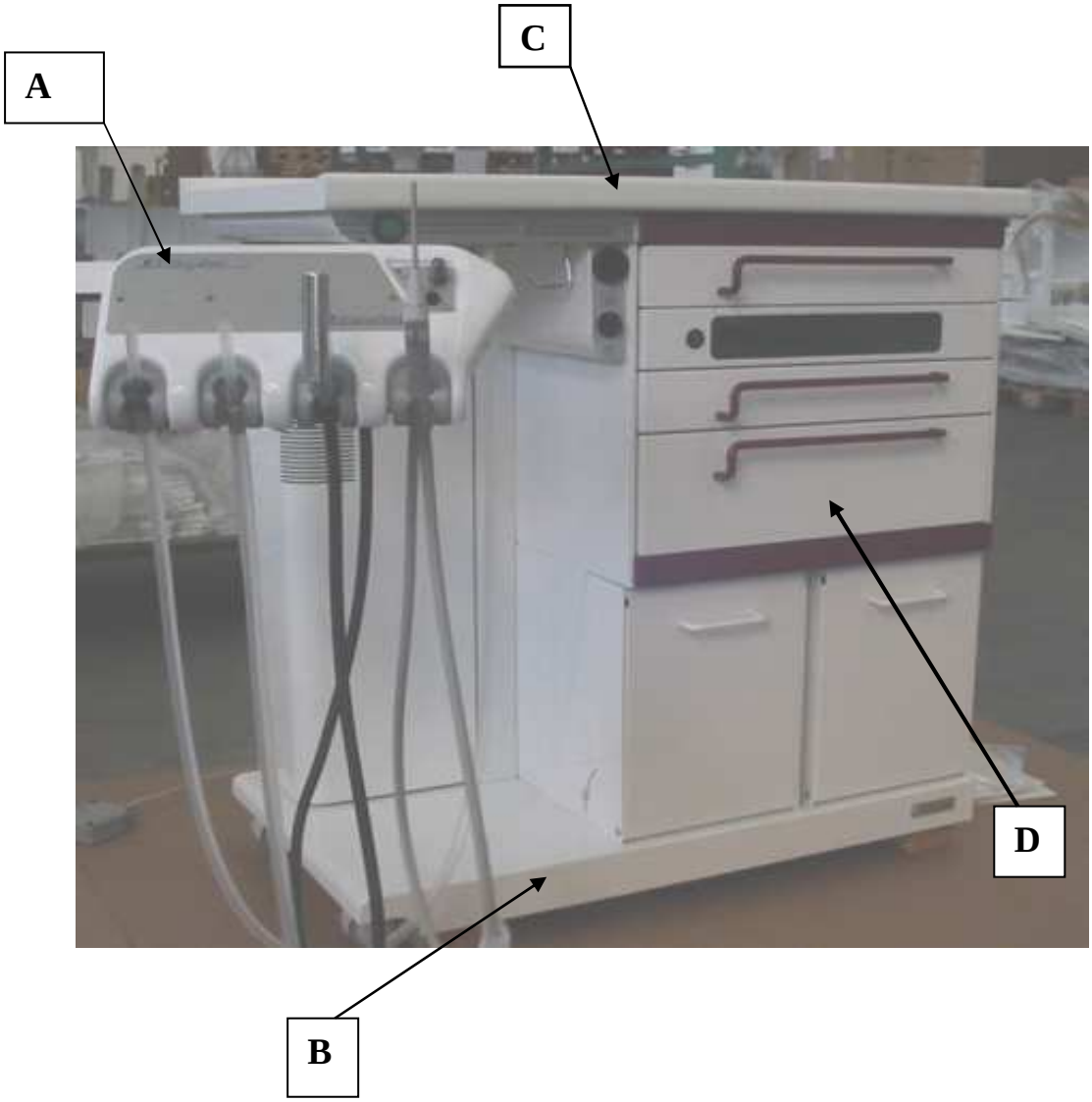
Libretto di istruzioni
Instruction manual

1	**2**	**3**	**4**	**5**	**6**		**06**	**07**
7	**8**	**9**	**10**	**11**	**12**		**08**	**09**
n°matricola								

English

These instructions apply to all the versions of the OTOPLUS unit and all the related accessories. For this reason, not all the paragraphs of this manual will refer to the equipment you have bought.

EUROCLINIC will provide the authorised service center with all the information necessary to install and repair the equipment.


A
C
D
B

1. INTRODUCTION

1.1 General characteristic and identification of the parts

Unit for otorhinolaringology completely autonomous and mobile on castor wheels composed of:

A) Instrument tray holder wich is able to hold up to a maximum of 4 instruments. It has articuled arms wich enables one to position it in the most confortable of ways.

B) Suction instruments holder

C) Duropall working bench complete with waterproof back panel: a back panel which houses different sockets is available by request.

D) Housing for the auxillary instruments complete with a series of drawers & spaces of various sizes and dimensions according to one's choice

1.2 CAUTIONS

1) Do not install the machinery in environments which are exposed to explosions or frost.

2) The temperature and relative humidity and environmental temperature in which the machinery is installed should be respectively included between 10℃ and 40℃, 30% and 75%, 700 mBar and 1060 mBar.

3. During installing, check that the electrical tension on the sticker on the machine corresponds to that in use in order to avoid damaging.

4) The building, repairing, modifying, callibration and all the other operations that require the opening of the unit should be carried out by technical staff authorized by EUROCLINIC.

5) The electrical circuit in which the unit is connected to, should comply to the IEC 64.4 regulation (regulation regarding electrical circuits in rooms used for medical purposes).

6) The machinery should be used exclusively following the instructions illustrated in this manual.

7) EUROCLINIC refuses any responsability for the following: damages or accidents caused by the carelessness of the user, the non compliance to the safety rules, a non correct use of the machine, a use of the machine which is different to that of its purpose. EUROCLINIC denies all responsability which has nothing to do with faults in the material and non correct building.

8) Before installation and functioning check that there are not loose parts, burnt electric cables, or various anomalies and if they are evident please contact EUROCLINIC or authorised technical staff.

9) Mobile phones and radios can influence the good functioning of medical device OTOPLUS.

10) If during the use of unit OTOPLUS happen strange changes of performance or various anomalies we suggest to interrupt all operations, switch off the machine and contact authorised staff EUROCLINIC in order to avoid any kind of damage.

1.3 Symbols

Classification of the “B” type machinery.
“B” type machinery (machinery of the type I,II,III or machinery housing an internal electric source with a protection degree against direct and indirect contact and in particular for:
- permitted current dispersion
- reliability of the ground contact)

Class I machinery.

This symbol indicates: FOR FURTHER INFORMATION CONSULT THE ATTACHED DOCUMENTATION

This symbol indicates: ATTENTION !!! CONSULT THE ATTACHED DOCUMENTATION

If the sockets situated on the back panel are used for feeding other instruments different to the unit, it is advisable to check that they comply with the IEC 62,5 law and that they need the following current: 220/240 V AC 4A

Earthing contact of the machinery

Alternated current

Symbol discharge and scrap

2. INSTALLATION

The installation of the equipment must be made respecting the instructions of the following booklet of instructions. It must be mate by authorised staff Euroclinic, or thanks to the simplicity of operations also by the user themselves under their responsibility.
The user should always make sure that the electric circuit complies to IEC values (in other words: 220/240 V, alternate monophase 50 Hz, the plant should comply with IEC 64.4 regulation). The operations are:

- Full the tank but not to the rim
- Insert the plug in a socket

It is advisable to insert the plug in a socket with a bipolar switch compliant to IEC and having the following technical characteristics:
230 V
50 A
contact opening of 3 mm.
To check that the installation has been properly made it is enough to check that the switch on button is properly lit up (SEE PICTURE 1) and that no acoustic signal is present.

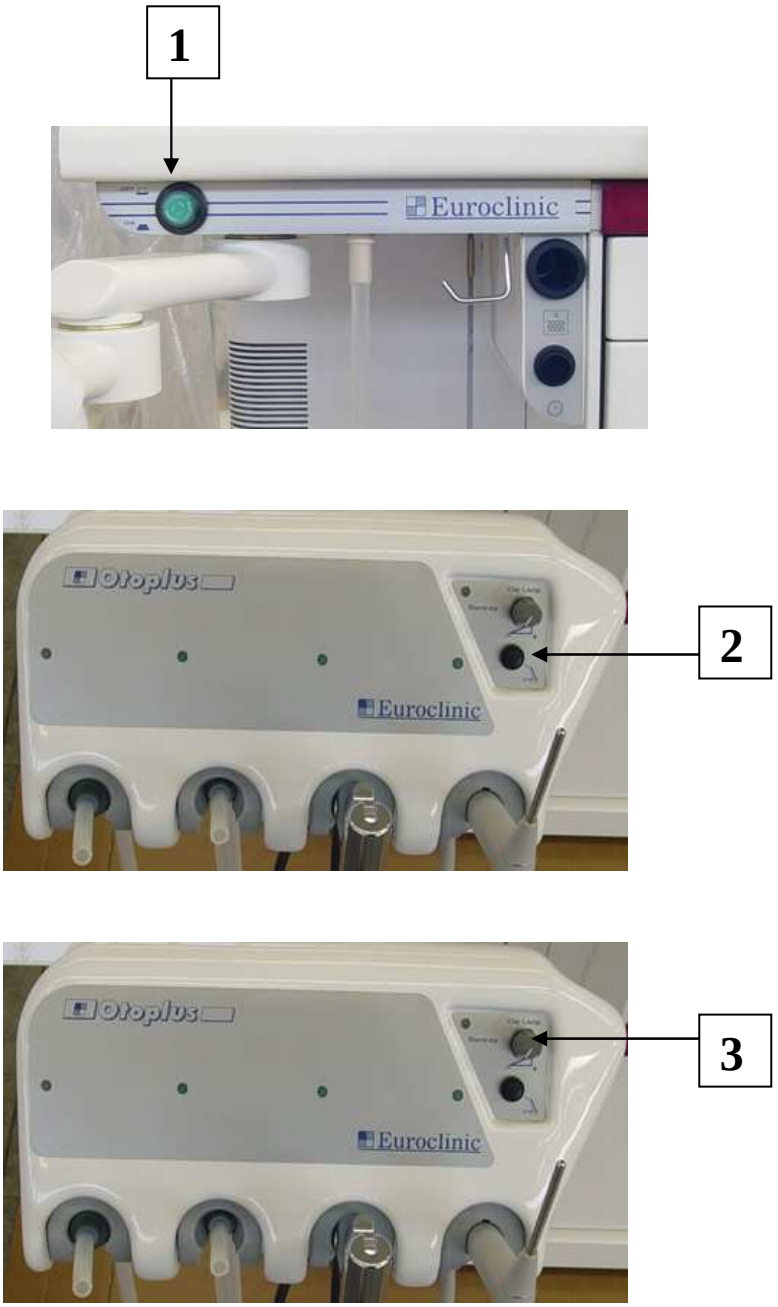


Figura 1
Picture 1

3. USE OF THE INSTRUMENTS

In order to use the instruments of the machine it is necessary to proceed with the switch on of the machine by pressing the button 1 on front of the work bench. When the green light is on, this means that the machine is working. Turn it off by pressing the same switch again.

3.1 Frontal comands

The following comands are present on the instruments board of the unit: it is possible to use them only after turning the general switch on (see picture 1)

1- general switch

2- water heating switch

3- potentiometer for Clar lamp.
By turning it clockwise the light increases by turning it the opposite way it decreases

3.2 Insufflator

For a correct use of the instrument it is advisable to work according to the following periods:
work 5 min
pause 10 sec

The functioning of the instrument stars when it is taken out of its housing and pushing the pedal.
When the corresponding light on the instrument holder is on, this means that the instrument is working.
In order to vary the intensity of air, one should adjust it with the lever behind the cannula holder.

3.3 Ear washings syringe

For a correct functioning of the instrument we suggest to use it according to the following periods:
Work 5 min
Off 10 sec

Before using the syringe it is necessary to fill up, not completely full, the tank.
The functioning of the instrument is activated by taking it out of its housing. When the corresponding indicator-light on the instruments tablet is lit up, this means that the instrument is functioning.
For obtaining warm water flux, firstly turn on the warm water switch placed in the front of the unit (see section 3.1): the led stand-by on the tablet starts blinking. When the right temperature is reached, the led is lit up and the acoustic sign is activated. Now it is possible to push one of the two buttons placed in the syringe hand-piece.
N.B. Use only spare parts by EUROCLINIC.

N.B. <u>The First cycle of heating lasts approximately 15 minutes</u>
N.B<u>. During the first heating cycle or after a prolonged pause with the unit off, as soon as the right temperature is reached, it is always necessary to make overflow from the syringe a water jet for 10 second, in order to settle the unit.</u>

N.B. In case that the water temperature overcome the set value, a safety thermostat blocks automatically the ear washing syringe and a fix acoustic advising signal is activated, until the normal cycle is not re-activated.

WARNING!! In case of reserve please immediately switch off the equipment and fill up the tank.

Insufflatore / insufflator

Siringa / syringe

Aspiratore / suction

Nebulizzatore medicinali /
Medicaments atomizer

Fig. 2
Pic.2

3.4 Suction (See Pic. 2)

For a correct use of the instrument it is advisable to work according to the following periods:
Work 5 min
Off 10 sec

The starting of the instrument is obtained by taking it out of its housing. When the corresponding light on the tray is on this means that the instrument is working. To vary the intensity of the aspiration it is necessary to adjust the lever placed on the end of the cannula holder. (see previous picture)
NB: Use only spare parts by EUROCLINIC.

3.4.1. Accessori x Aspiratore

The unit Otoplus is set with a pulling-out neck headed by a piece of silicone pipe (see pic. 3.4.1)); moreover together with the machine is supplied an apposite Kit for setting the funnel for secretions collecting (see pic. 3.4.2) – which contains a pipe fitting to be coupled to the suction pipe + funnel (see assembling phase).

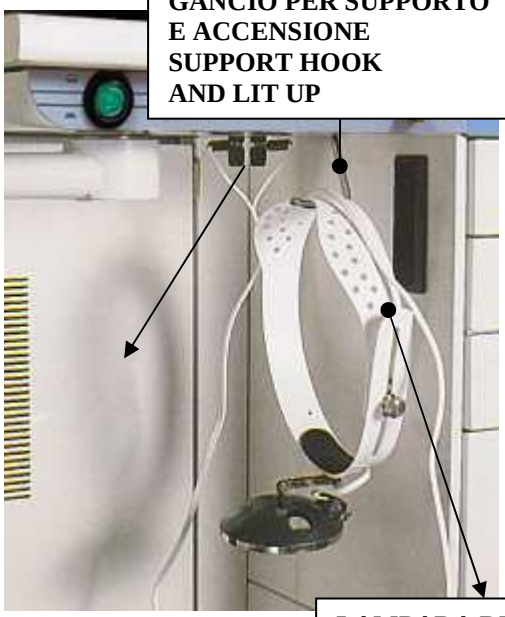
Antimicrobial hydrophobic filter

On the Unit is planned an antimicrobial hydrophobic filter on suction (see pic. 3.4.2), in order to ensure the killing (99%) of any bacteria that come from the suction system. The replacement **is advisable** every 10 – 15 working days.

3.5 Medicaments Atomizer (See Pic. 2)

For a correct use of the instrument it is advisable to work according to the following periods:
Work 5 min
Off 10 sec

The functioning of the instrument is obtained by taking it out of its housing and pushing the pedal. When the corresponding light on the tray is on this means that the instrument is working. In order to obtain the nebulization of the medicine products it is necessary to adjust the handpiece of the instrument. (see previous picture).
N.B. Use only spare parts EUROCLINIC.


GANCIO PER SUPPORTO
E ACCENSIONE
SUPPORT HOOK
AND LIT UP
LAMPADA DI CLAR/
CLAR LAMP


SUPPORTO OTTICHE
Fixed Holder for endoscope


VANO GERMICIDA/
GERMICIDE COMPARTMENTS
INTERRUTTORE
ACCENSIONE
SWITCH ON
BUTTON


Euroclinic
INTERRUTTORE
ACCENSIONE SCALDA SPECCHIETTI
SWITCH ON BUTTON MIRROR
WARMER

Fig. 3
Pic. 3

4. USE OF THE ACCESSORIES

4.1 Socket back panel

When installing the machine, the plugs are automatically connected to the electric system.
Check that other instruments connected to supplementary sockets can function with 220-240 V alternated monophase Hz.
Always take the plugs of these other instruments out after their use and during cleaning: do not connect more then one instrument to each socket.

4.2 Germicide compartments (See Pic.3)

On request, the machine can be equipped with this auxiliary drawer, that permits only the maintenance in hygienically conditions of the instruments already sterilized.
The functioning of the UV lamp is obtained by turning the general switch of the unit on (see chapter 3).
The germicide lamp can be turned on and off by a switch placed on the side of the drawers turns the lamp off automaticaly if the germicide compartment is accidentally opened, and it will turn the lamp on again when the drawer is closed.
WARNING! We repeat once more that the germicidal space does not constitute substitutive element of the sterilization process, but function only as co-adjuvant and supporter.
NB: do not use lamps with technical features different from those indicated by EUROCLINIC.
N.B. We suggest to substitute the lamp each 500 hours of functioning

4.3 Clar Lamp (Pic. 3)

The lamp is turned on automatically by taking it from its housing, to turn it off it is necessary to place it back.
The adjusting of the intensity of the light is obtained by adjusting the potentiometer placed on the instruments board (see chapter 3.1)

4.4 Mirror-warned larinx

The functioning of the mirror-warned larynx is obtained by pressing the switch placed next to the fan (see figure).
Place the surgical instrument in front of the warm air flux and wait a few seconds.

⚠ WARNING !

N.B. When overused, the system has a thermal safety switch which stops the air flow until normal values of temperature are reached again; it is necessary in that case to wait for some minutes before using it again.

5. MAINTENANCE

Attention! The following proceeding have to be carried out when the machine isn't plugged into the mains.

5.1 Empty of the condense filter

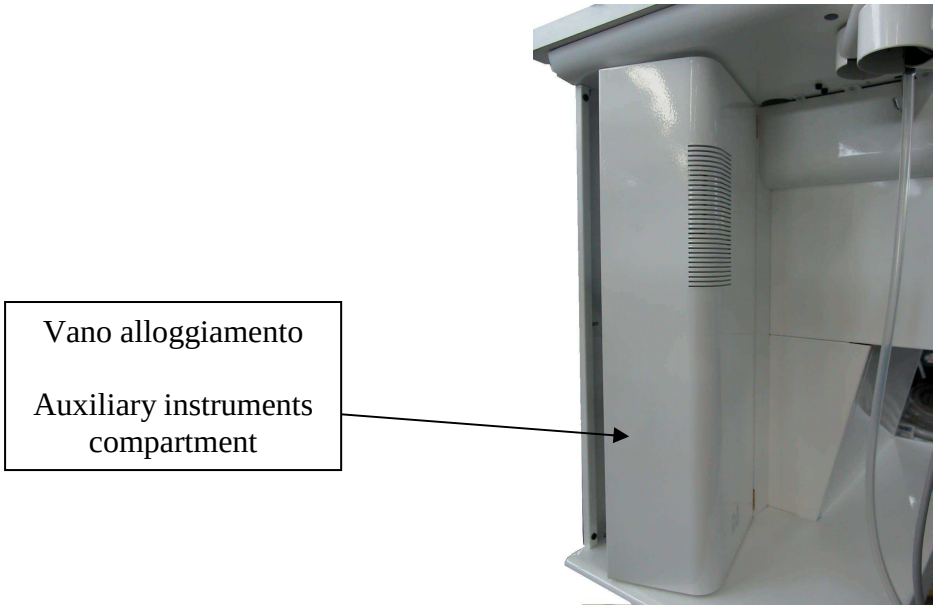
⚠ Near the panel there is a filter for collecting the condense created by the compressor; in case it is filled it is necessary to empty it; place a glass under the filter, turn the knob and pull downside the knob, empty the condense and close again the knob!
Warning! If the knob is not closed the compressor leaks air through it!

5.2 Filling the water tank

In acoustic case of signal intermittent it means that it is intervened the reserve of the tank and that it is necessary to fill it up. In order to fill the tan please proceed in the following way:

1- take the plug out of the machine
2- open the door of the auxillary instruments compartment
3- take the tank out, unwind the tap and with a funnel pour the water,without reach the maximum level .
4- close the tap and the door
5- plug the machine in again

Notice: We suggest you to use only distilled water



Aprire lo sportello

Open the door

Svitare il tappo

Unwind the tap

Immettere acqua nel recipiente (no max)

Introduce distilled water in the tank (no max)

5.3 General maintenance and spare parts

To grant the correct functioning of the machinery EUROCLINIC suggest to proceed with a complete revision of the unit each 2 years.
EUROCLINIC declines any responsibility for damages, hitches or inefficiencies due to the substitution of NON ORIGINAL spare parts.

5.4 Cleaning of the secretion tank

At the end of a days work it is necessary to clean the tank where all the secretions gather. In order to carry out this operation, proceed in the following way:

1- unplug the unit
2- open the door where the tank is housed
3- unwind the tank by turning it anticlockwise to separate it from the tap which is fixed
4- empty the tank and clean it thoroughly
5- re-attach the tank to the tap close the door and plug the unit it again

5.5 Cleaning the unit

The choice of materials used for building the unit has been carefully taken in order to correspond to the cleaning and disinfecting needs.
Given the big differences between chemical products used in a medical study, it is possible to ruin the tops. The major damages are caused by the amount of time that these chemical products are left on the tops. It is important to immediatly dry the interested parts with a damp cloth.
To clean the painted or metal parts, use a specific product for these materials which doesn't damage their composition.
IMPORTANT! Do not use products with alcohol, amonia or petrol

5.6 Cleaning and maintenance of secretion tank

The tank which contains the aspirated liquids can be cleaned with water and detergents which are compatible with the materials (see chart) used and/or sterilized in an autoclave at 135°C. Separate the main parts of the tank befo re the sterilization, insert the glass upside down in the autoclave and do not place anything on top of it whilst disinfecting.

DO NOT USE SOLVENTS OR ALCOHOL FOR CLEANING AND DISINFECTING. THE USE OF THESE PRODUCTS CAN DAMAGE THE PLASTIC PIECES OF THE SYSTEM.

⚠ Always substitute the damaged or faulty parts with original spare parts.

In case of cleaning in autoclave strictly respect the timing chart explained in section 5.6.

5.7 Svuotamento condensa
Vicino l'anta è presente un filtro per la raccolta della condensa creata dal compressore; nel caso esso si riempia è necessario svuotarlo; posizionare un bicchiere sotto al filtro girare e tirare verso il basso il pomolo,svuotare la condensa e richiudere il pomolo!
Attenzione! Se il pomolo non viene chiuso il compressore sfiata l'aria attraverso di esso

5.8 Discharge and scrap
The unit does not contain dangerous or toxic elements and can therefore follow normal discharging and scraping procedures in law in the Country where it has worked.

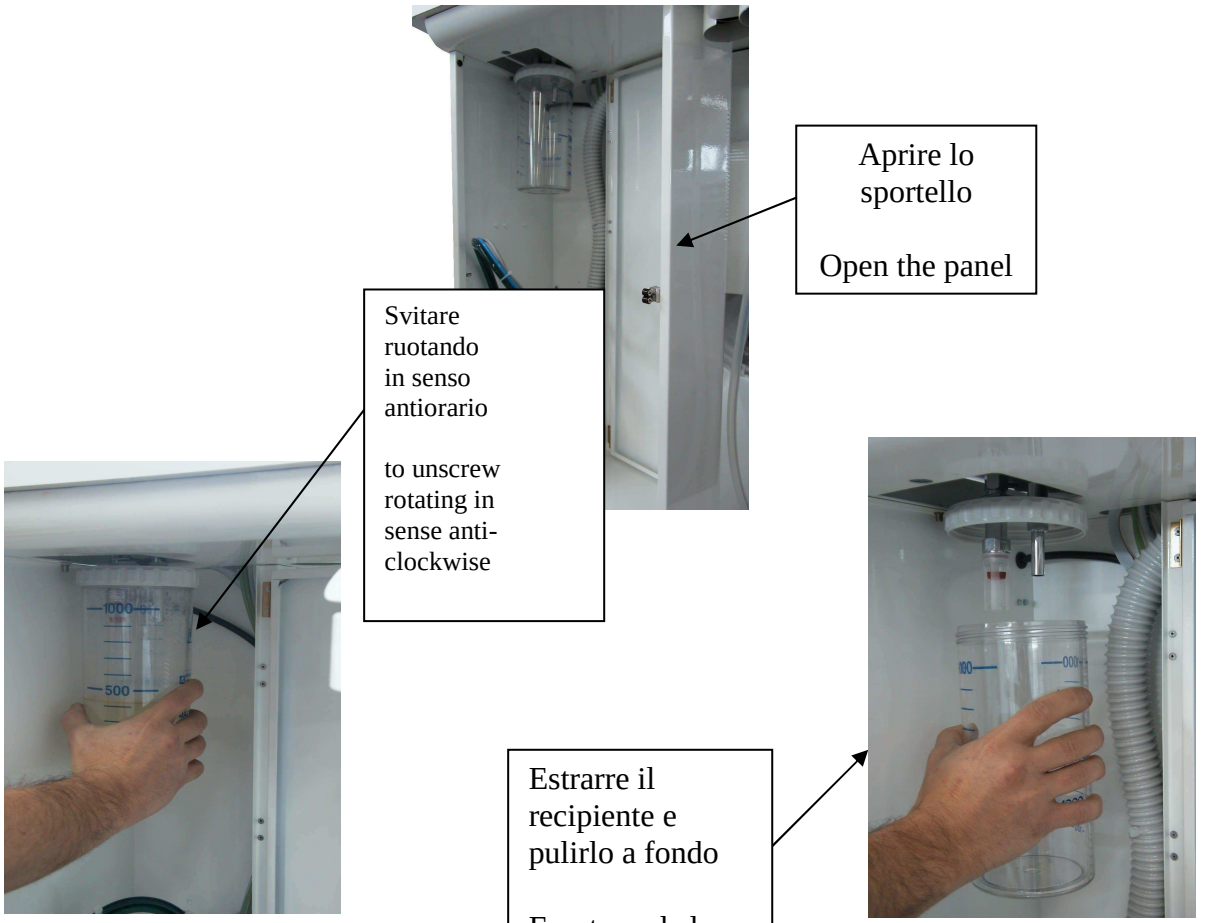


Fig. 4
Pic. 4

5.8 Tabella prodotti per pulizia e disinfezione

Tabella sterilizzazione strumentario		
STRUMENTO	TEMP	TIPO DI STERILIZZAZIONE
Impugnatura siringa	135°C	In autoclave 5 – 7 min
Terminale nebulizzatore	135°C	In autoclave 5 – 7 min
Cannula insufflatore	135°C	In autoclave 5 – 7 min
Cannula aspiratore	135°C	In autoclave 5 – 7 min

Tabella prodotti per pulizia e disinfezione	
Disinfettanti	Prodotti farmaceutici e cosmetici
+ bactol 5% + clorammina - DDT + delegol 5% = dimammina 5% = tintura di iodio - acido fenico + lisoformio 2% - TB lisoformio + bactol + merfen 2% + octozono + perydrol + resorcina 1% = sagrotane 5% + alcool da bruciare puro + cloruro di mercurio + trosilina G + acqua ossigenata = zefirol	+ plasma sanguigno + latte solare + hydroplex = tintura di iodio + lanolina = mantolo 90% in alcool - smalto per unghie - solvente + sciacquo per bocca + periston R + vaselina + vicks vaporub
LEGENDA + compatibile - non compatibile = compatibile con riserva	

5.8 Instrument strerilization chart

Instrument sterilization chart		
INSTRUMENT	TEMP	KIND OF STERILIZATION
Syringe handpiece	135°C	In autoclave 5 – 7 min
Nebulizer terminal	135°C	In autoclave 5 – 7 min
Insufflator cannula	135°C	In autoclave 5 – 7 min
Aspirator cannula	135°C	In autoclave 5 – 7 min
Cleaning and disinfecting products chart		
Disinfectants		Pharmaceutic products and cosmetics
+ bactol 5% + clorammina - DDT + delegol 5% = dimammina 5% = iodine dye - fenic acid + lysoform 2% - TB lysoform + bactol + merfen 2% + octozone + perydrol + resorcina 1% = sagrotane 5% + alcohol to be purely burnt + mercury chloride + trosilina G + oxiginated water = zefirol		+ blood plasma + sun tan lotion + hydroplex = iodine dye + lanolyn = mantolo 90% in alcohol -nail varnish - solvent + mouth wash + periston R + vaselyn + vicks rub
CHART SIGNS + compatible - non compatible = compatible but with caution		

6. CARATTERISTICHE TECNICHE

6.1 Tabella dati tecnici

Tensione di alimentazione		220/240 V
Frequenza		50 Hz
Potenza assorbita (secondo la configurazione)		1200 VA
Peso Max		80 Kg
Numero massimo di strumenti		4 pz
Massima pressione dell'aria		2.2 Atm
Portata aria		26 l/m
Max pressione acqua		2.2 Atm
Portata acqua		0.4 l/m
Dimensioni (in mm)	Altezza piano lavoro	850 mm
	Larghezza	850 mm
	Profondità	540 mm

Tabella potenze assorbite

DESCRIZIONE	ASSORBIMENTO	TENSIONE	SERVIZIO
Lampada germicida	8 W	230 V ac	Continuo
Aspiratore	70 W	230 V ac	Continuo
Compressore	70 W	230 V ac	Continuo
Pompa	48 W	230 V ac	Continuo

6.2 Riepilogo tempi di funzionamento degli strumenti

STRUMENTO	LAVORO	RIPOSO
Siringa	5'	10"
Insufflatore	5'	10"
Aspiratore	5'	10"
Nebulizzatore	5 '	10"

Riepilogo identificazione apparecchiatura

1	**2**	**3**	**4**	**5**	**6**		**05**	**06**
7	**8**	**9**	**10**	**11**	**12**		**07**	**08**
n°matricola								

6. TECHNICAL FEAUTURES

6.1 Technical data chart

Electrical tension	220/240 V
Frequency	50 Hz
Power absorbed by the unit (according to the configuration)	1200 VA
Weight Max	80 Kg
Maximum number of instruments	4 pcs
Maximum air pressure	2.2 Atm
Air capacity	26 l/m
Maximum water pressure	2.2 Atm
Water capacity	0.4 l/m
Dimensions (in mm)	
Height of the working bench	850 mm
Width	850 mm
Depth	540 mm

Absorbed power chart

DESCRIPT.	ABSORB.	TENSION	SERVICE
Germicide Lamp	8 W	230 V ac	Continuos
Aspirator	70 W	230 V ac	Continuos
Compressor	70 W	230 V ac	Continuos
Pump	48 W	230 V ac	Continuos

6.2 Summary of the working periods of the instruments

Device identification summary

INSTRUMENT	WORK	OFF
Syringe	5‘	10”
Insufflator	5‘	10”
Aspirator	5‘	10”
Nebulizer	5 ‘	10”

Caratteristiche principali –
Most important feautures:

1	**2**	**3**	**4**	**5**	**6**		**02**	**03**
7	**8**	**9**	**10**	**11**	**12**		**04**	**05**
n°matricola								

Tensione di alimentazione Electrical tension	230 V ac 50/60 Hz
Potenza Nominale Power absorbed by the unit	1200 VA
Cavo di alimentazione Electrical cable	3 x 1,5 mm lunghezza - Lenght: 1400 mm
Fusibili di protezione *(uno per fase)* Fuse	250 V 6,3A
Serbatoio H_2O Reservoir H_2O	5 l
Dimensioni Dimensions	Altezza - Height: 850 mm Profondità - Depth: 540 mm Larghezza - Width: 850 mm
Peso[1] Weight	80 kg
CARATTERISTICHE DI USCITA OTOPLUS – OTOPLUS OUT FEAUTURES	
siringa con tempertaura fissa a 37°C 37° fix temperature Syringe	Portata - Capacity 0,4 L/m
TOP Antigraffio in Duropall Duropall working plane	850x540 mm
insufflatore (optional) Insufflator (optional)	Portata max – Maximum Capacity : 26 L/m
Aspiratore di base Basic Suction	Vuoto Massimo - Maximum Empty: 650 mm Hg **Flusso – Flow: 25 lpm**
Capacità del vaso aspiratore Suction reservoir capacity	1 litro / *1 litre*
Predisposizione per lampada di Clar (optional) Clar Lamp Provision (optional)	Tensione d'uscita regolabile - Out Adjustable tension : 3-6 VDC
Cassetto con impianto U.V. (optional) UV Drawer (optional)	
Scaldaspecchietti temporizzato(optional) Mirror-warmed larynx	

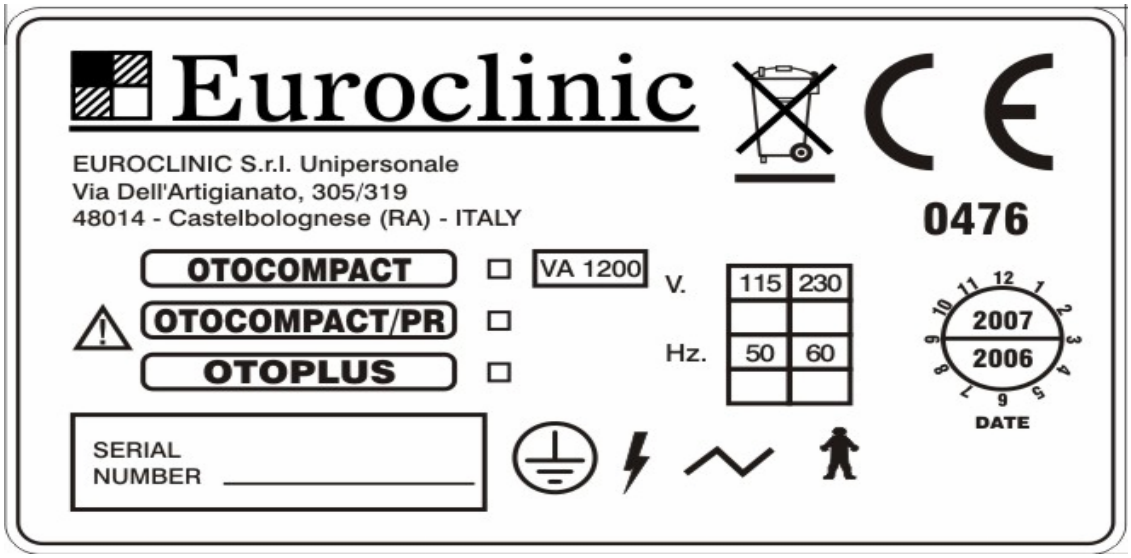
[1] Il peso si riferisce alla macchina con tutti i serbatoi scarichi
Weight refers to the unit with all empty reservoirs

7. TARGHETTA IDENTIFICATIVE

7.1 TARGHETTA MATRICOLA

La targhetta matricola si trova nella parte posteriore del riunito, i dati riportati sono:
The label of the serial number is located in the back part of the unit, and the details are:

- Tipo di riunito – UNIT MODEL
- Tensione nominale – NOMINAL TENSION
- Frequenza nominale – NOMINAL FREQUENCE
- Potenza massima assorbita – MAXIMUM POWER ABSORBED
- Numero di serie – SERIAL NUMBER
- Anno e mese di fabbricazione – YEAR AND MONTH OF FABRICATION



7.2 IDENTIFICAZIONE MASSA

All'interno della macchina la massa di protezione è indicata con il seguente simbolo adesivo :
Inside the machine the protection mass is indicated with following sticking label:

8. TABELLE GUIDA E DICHIARAZIONE DEL COSTRUTTORE

8.1 TABELLA 201 EMISSIONI ELETTROMAGNETICHE

Guida e dichiarazione del costruttore- Emissioni Elettromagnetica Guidance and manufacturer's declaration-electromagnetic immunity		
L'**OTOPLUS** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato.Il cliente o l'utilizzatore dell' **OTOPLUS** dovrebbe assicurarsi che esso venga usato in tale ambiente The **OTOPLUS** is intended for use in the electromagnetic environment specified below. The costumer or the user of the **OTOPLUS** should assure that it is used in such an environment		
Prova emissioni **Emissions test**	**Conformità** **Compliance**	**Ambiente Elettromagnetico-Guida** **Electromagnetic environment -Guidance**
Emissione RF RF Emissions CISPR 11	Gruppo 1 Group 1	L'Otoplus utilizza energia RF solo per il suo funzionamento interno.Perciò le sue emissioni RF sono molte basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. *The* Otoplus *uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment* .
Emissione RF RF Emissions CISPR 11	CLASSE B CLASS B	L' Otoplus è adatto per tutti gli edifici,compresi gli edifici domestici, e quelli direttamente collegati alla rete di alimentazione pubblica in bassa tensione che alimenta edifici per usi domestici. *L'* Otoplus *is suitable for use in all establishment, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes*
Emissioni armoniche Harmonic emission IEC 61000-3-2	CLASSE A CLASS A	
Emissioni di fluttuazioni di tensione/flicker Voltage fluctuations/flicker emissions IEC 61000-3-2	Conforme Complies	

8.2 TABELLA 202 IMMUNITA' ELETTROMAGNETICA

Guida e dichiarazione del costruttore-immunità elettromagnetica
Guidance and manufacturer's declaration-electromagnetic immunity

Il riunito otorinolaringoiatrico **OTOPLUS** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato.
Il cliente o l'utilizzatore del riunito **OTOPLUS** dovrebbe assicurarsi che esso viene utilizzato in tale ambiente.
The **OTOPLUS** is intended for use in the electromagnetic environment specifed below. The costumer or the user of the **OTOPLUS** should assure that it is used in such an environment

Prova immunità **Immunity test**	**Livello di prova** **IEC 60601** **IEC 60601** **test level**	**Livello Conformità** **Compliance level**	**Ambiente elettromagnetico-guida** **Electromagnetic environment- guidance**
Scariche elettrostatiche (ESD) *Electrostatic discharge (ESD)* **IEC 61000-4-2**	±6 kV a contatto_ contact ±8 kV in aria_air	±6 kV a contatto_ contact ±8 kV in aria_air	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno del 30%. *Floors should be wood ,concrete or ceramic tile. If floors are covered with sintetic material the relative humidity should be at least 30%*
Transitori/treni elettrici veloci Electric fast transient/burst **IEC 61000-4-4**	±2 kV per linee di alimentazione di potenza ±2 kV for power supply lines ±1kV per linee di ingreso/uscita *±1kV for input/output lines*	±2 kV per linee di alimentazione di potenza ±2 kV for power supply lines ±1kV per linee di ingreso/uscita *±1kV for input/output lines*	La qualità della tensione dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a tipical commercial or hospital environment*
Impulsi Surge **IEC 61000-4-5**	±1 kV in modo differenziale ±1 kV differential mode ±2 kV in modo comune ±2 kV common mode	±1 kV in modo differenziale ±1 kV differential mode ±2 kV in modo comune ±2 kV common mode	La qualità della tensione dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a tipical commercial or hospital environment*
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso di alimentazione *Voltage dips,short interruptions and voltage variations on power supply input lines* **IEC 61000-4-11**	<5% UT (> 95% buco di_dip in UT) for_per 0,5 cicli_cycle 40% UT (60% buco di_dip in UT) for_per 0,5 cicli_cycle 70% UT (30% buco di_dip in UT) for_per 0,5 cicli_cycle <5% UT (> 95% buco di_dip in UT) for _per 5 s	<5% UT (> 95% buco di_dip in UT) for_per 0,5 cicli_cycle 40% UT (60% buco di_dip in UT) for_per 0,5 cicli_cycle 70% UT (30% buco di_dip in UT) for_per 0,5 cicli_cycle <5% UT (> 95% buco di_dip in UT) for _per 5 s	La qualità della tensione dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero.Se l'utilizzatore del riunito otorino Otoplus richiede un funzionamento continuo anche durante l'interruzione della tensione di rete , si raccomanda di alimentarlo con un gruppo di continuità (UPS) o con batterie. *Mains power quality should be that of a tipical commercial or hospital environment.If the user of the* Otoplus *requires continued operations during power mainsinterruptions,it is recommended that the* Otoplus *powered from an uninterruptible power supply or a battery.*
Campo magnetico alla frequenza di rete (50/60 Hz) *Power Frequency (50/60 Hz) magnetic field* **IEC 61000-4-8**	3A/m	3A/m	Il campo magnetico alla frequenza di rete dovrebbe essere misurato nel locale della prevista installazione per assicurarsi che esso è abbastanza basso. *The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low*

Nota_e UT è la tensione di rete in c.a. prima dell'applicazione del livello di prova
UT is the c.a. mains voltage prior to application of the test level.

8.3 TABELLA 204 IMMUNITA' ELETTROMAGNETICA

GUIDA E DICHIARAIZONE DEL COSTRUTTORE – IMMUNITA' ELETTROMAGNETICA

L' **OTOPLUS** è previsto per funzionare nell'ambiente elettromagnetico sotto specificato.

Il cliente o l'utilizzatore dell' **OTOPLUS** dovrebbe assicurarsi che esso venga utilizzato in tale ambiente.

The **OTOPLUS** is intended for use in the electromagnetic environment specified below. The costumer or the user of the **OTOPLUS** should assure that it is used in such an environment

PROVA DI IMMUNITA' IMMUNITY TEST	**LIVELLO DI PROVA IEC 60601 LEVEL OF TEST IEC 60601**	**LIVELLO DI CONFORMITA' LEVEL OF CONFORMITY**	**AMBIENTE ELETTROMAGNETICO – GUIDA GUIDING ELECTRO-MAGNETIC ENVIRONMENT**
RF condotta - conducted IEC 61000-4-6	3 Veff da 150 kHz a 80 MHz	Veff	Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati vicino a nessuna parte dell'otoplus , compresi i cavi, eccetto quando rispettano le distanze di separazione raccomandate calcolate dall'equazione applicabile alla frequenza del trasmettitore. *The communication sets radio-frequency portable and mobile should not be used near any part of OTOPLUS unit, cables included, except when they respect the recommended separation distances calculated by the equation applicable to the frequency of the transmitter.* **Distanze di separazione raccomandate** **Separation distances recommended** d=1,2 √P
RF irradiata - irradiated IEC 61000-4-3	3 V/m Da 80 MHz a 2,5 GHz	3 V/m	d=1,2 √P da 80 MHz a 800 MHz d=2,3 √P da 800 MHz a 2,5 GHz Ove **P** è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e **d** è la distanza di separazione raccomandata in metri (m) *Where **P** is the maximum rated power in out coming of the transmitter in Watt (W) according to the manufacturer of the transmitter and **d** is the recommended separation distance in meters (m)*

			L'intensità del campo dei trasmettitori a RF fissi, come determinato in un'indagine elettromagnetica del sito[a], potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza[b]. *The field intensity of the fixed radio-frequency transmitters, as determined by an electro-magnetic enquiry of site[a] , could be less of conformity level in each range of frequency[b]* Si può verificare interferenza in prossimità di apparecchi contrassegnati dal relativo simbolo. *It could happen interference nearby equipments/sets signed by relative symbol.*

A 80 MHz e 800 MHz si applica l'intervallo della frequenza più alta.
Queste linee guida potrebbero non applicarsi in tutte le situazioni.
La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone. Le intensità di campo per trasmettitori fissi come le stazioni di base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM ed FM e trasmettitori TV non possono essere previste teoreticamente e con precisione. Per stabilire un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa un l'otoplus, supera il livello di conformità applicabile di cui sopra, si potrebbe porre sotto osservazione il funzionamento normale dell' otoplus. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento a posizione dell' otoplus. L'intensità di campo su un intervallo di frequenza da 150 KHz a 80 MHz dovrebbe essere minore di 3 V/m.

At 80 Mhz and 800 Mhz is to apply the higher frequency range.
These guidelines could not be applicable to every situation.
The electro-magnetic propagation is influenced by absorption and reflection of structures, objects and people. The field intensities for fixed transmitters as base-stations for radio-telephones (mobiles and cordless) and earth radio-mobiles, radio-amateurs sets, radio transmitters in AM or FM and TV transmitters cannot be forecasted with absolute certainty and precision. To detect an electro-magnetic environment caused by RF fixed transmitters, an electro-magnetic inquiry of the site itself should be considered.
*If the field intensity measured in the place where a **SURPLUS** is used overcome the applicable conformity level specified before, the normal functioning of **SURPLUS** unit could be placed under observation. If strange performances are noticed, it could be necessary to proceed to further measures, like a different positioning and orientation of the **SURPLUS**. The field intensity on a frequency range from 150 KHz to 80 MHz should be lower than 3V/m.*

8.4 TABELLA 206 DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATITLI E MOBILI E L'APPARECCHIO OTOPLUS

Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili e mobili e L' OTOPLUS

***Recommended separation distances between portable and mobile RF communications equipment and the* L'OTOPLUS**

L'OTOPLUS è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo I disturbi irradiati RF.
Il cliente o l'operatore dell **'** **OTOPLUS** possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e l' **OTOPLUS**, come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

The **OTOPLUS** *is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the* **OTOPLUS** *can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the* **OTOPLUS** *as recommended below, according to the maximum output power of the communication equipment.*

POTENZA DI USCITA NOMINALE MASSIMA DEL TRASMETTITORE *RATED MAXIMUM OUTPUT POWER OF TRANSMITTER* ***W***	DISTANZA DI SEPARAZIONE ALLA FREQUENZA DEL TRASMETTITORE *SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER m*		
	Da 150 KHz a _to 80 MHz d=1,2 √P	*Da 80 MHz a _to 800 MHz* d=1,2 √P	*Da 800 MHz a _to2,50 GHz* d=2,3 √P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Per I trasmettitori con potenza nominale massima di uscita sopra non riportata, la distanza di separazione raccomandata in metri (m) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, ove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore.

For transmitters rated at a maximum output power not listed above, the recommended distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Nota/Note:
1) A 80MHz e 800 MHz si applica l'intervento della frequenza più alta. *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*
2)Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone. *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*