



VNYUS ED610

VIDEONYSTAGMOSCOPE SYSTEM



OPERATING MANUAL

Rev 06 – 26/05/2021

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MANUFACTURER IDENTIFICATION

MEDI-CARE SOLUTIONS S.r.l.

Manufacturer:

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Facility:

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PRODUCT IDENTIFICATION

1. Control Box



2. B/W IR Camera



3. USB type C - USB type C cable



4. Cable



5. Stopper



6. Cable Rca/Bnc



SYMBOL MEANING

1.3 Symbols

Classification of the "BF" type machinery. "BF" 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 II machinery BF.



This symbol indicates: TO CLARIFICATION CONSULT THE ATTACHED DOCUMENTATION



This symbol indicates: ATTENTION! CONSULT THE ATTACHED DOCUMENTATION BEFORE USE THE UNIT



Symbol that indicate "generic warning".



Earthling contact of the machinery



Alternated current



Symbol discharge with normative



Symbol that indicate hot surface



Medical Device

CLASSIFICATION

CLASS II type machinery B:



DISPOSAL



The symbol of crossed out garbage bin (on the back of the equipment) indicates that the product at the end of its working life must be collected separately from other garbage. This refers to the following law:

art. 13 of D.L. 25 /07/2005, n.151: "Implementation of the regulations 2002/95/CE, 2002/96/CE and 2003/108/CE, about decrease of dangerous substances on electric and electronic equipments" and moreover it refers to garbage disposal.

The separate collection of rubbish of this equipment (felt into disuse) must be arranged and coordinated by the manufacturer. When the user wants to throw away the equipment, he will contact the Manufacturer Company that will indicate all procedures to follow for the disused equipment separate collection of rubbish.

Therefore, the appropriate separate collection of rubbish, aimed to actuate afterwards disused equipment recycling, treatment and to ambient garbage disposal, contributes to avoid possible bad effects on the environment and on the health. In addition, these procedures raise the reemployment and/or the recycling of the materials of which the equipment is composed.

The unauthorized garbage disposal, on the part of the holder, requires administrative law sanctions application.



CAUTIONS

1. Do not install the machinery in environments which are exposed to explosions or frost
2. The temperature of the environment in which the equipment is installed and used must be between 10 ° C and 30 ° C (max 40 ° C for storage).
3. The relative humidity environment of use or storage must be understood between 30% and 70%; pressure 500hpa at 1060hpa
4. During installing, check that the electrical tension on the sticker on the machine corresponds to that in use in order to avoid damaging.
5. The building, repairing, modifying, calibration and all the other operations that require the opening of the unit should be carried out by personnel authorized by MEDI-CARE SOLUTIONS.
6. The electric circuit in which the unit is connected to, should comply to the IEC 64.8 Sec. 710 regulation (regulation regarding electrical circuits in rooms used for medical purposes).
7. The machinery should be used exclusively following the instructions illustrated in this manual.
8. MEDI-CARE SOLUTIONS refuses any responsibility 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.
9. MEDI-CARE SOLUTIONS denies all responsibility which has nothing to do with faults in the material and non correct building.
10. Before installation and functioning check that there are not loose parts, burnt electric cables, or various anomalies and if they are evident please contact MEDI-CARE SOLUTIONS or authorized technical staff.
11. Mobile phones and radios can influence the good functioning of medical device
12. If during the use of the MD happen strange changes of performance or various anomalies we suggest to interrupt all operations, switch off the machine and contact authorised staff MEDI-CARE SOLUTIONS in order to avoid any kind of damage.
13. Do not install this unit in places exposed to the risk of explosions, rich in oxygen or exposed to frost
14. The DM is not protected against splashing water and foreign bodies: DEGREE IP20
15. WARNING!: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
16. WARNING!: There shall be no modification of this device
17. WARNING! The DM in question should not be used adjacent to or stacked with other equipment, if necessary use it close to or stacked with other equipment it is necessary to observe the DM to check whether, in the configuration in which it is used, its operation remains normal
18. WARNING! In the event of a serious accident occurring in relation to the device, it is necessary to report to the Manufacturer and the competent authority of your country
19. The MD can be transported and stored with the environment :
Temperature: da -10°C a 60°C;
Humidity: 10% - 90%;
Pressure = by 500hpa at 1060hpa



USE DESTINATION

VNYUS ED610 Videonystagmoscope system facilitates view and registration of Nystagmus reached by standard vestibular tests (both position and instrumental tests). This device allows to view patient eyes images on the monitor during the tests.



It 's not the intended use of the device in the surgery room

EQUIPMENT PLACEMENT

- Please, put the equipment on an horizontal surface that must be sufficiently large, solid and stable.
- Connect the power-supply cable to the plug;

Connect the USB-C cable only to a USB-C port of your PC/Laptop

ENVIROMENTAL COMPLIANCE

The environment in which the equipment is used must be hospital-type exempt from strong electric interferences and therefore far from high tension conductors, from large transformers, from x-ray implants, from diathermy and Marconi therapy generators.

Further inconvenience elements are elevator's contactors, automatic gear-cases, some lacks of the electric implant, such as conductors not perfectly fixed to the lamp-holders, to the current plugs, to the switches, etc.

In normal conditions the MD is capable of functioning without particular precautions. In critical conditions, that is when the inconveniences menace to compromise the performance of the good performance of the test, it is necessary to connect all equipment to a single efficient ground outlet.

The installation of the equipment must be made respecting the instructions of the following booklet of instructions.

The user should always make sure that the electric circuit complies to IEC values (in other words: 220/240 Vac, alternate monophase 50 Hz, the plant should comply with IEC 64.8 sec. 710 regulation).

It is advisable to insert the plug in a socket with a bipolar switch compliant to IEC and having the following technical characteristics:

230 Vac - 50 A contact opening of 3 mm.



It's not the intended use of the device in the surgery room

OPERATOR COMPLIANCE

The operator, in charge of use VNYUS ED610 Videonystagmoscope system, must have read and understood the instruction manual, therefore he must be able to recognize a potential malfunctioning and capable of following the procedure recommended in the manual.

The operator , in charge of use ED610 must be an ENT professional.

KIND OF FUNCTIONNING

VNYUS ED610 Videonystagmoscope system is an equipment with a continuous kind of working.

FUNCTIONING FAULTS

Not being an explosion-proof system, it is necessary the user not to use it near flammable anaesthetic.

Do not let VNYUS ED610 videonystagmoscope system let out to atmospheric factors. Do not let it unnecessarily turned on if nobody is using it.

Functioning faults are represented by specific situations when AD9240 mask is not preferably usable and, as a result, the device must be in case used with a defined limit, with regard to benefits/costs ratio that resting with the system in point.



The DM is not protected against splashing water and foreign bodies: DEGREE IP20



COUNTER EFFECTS

Counter effects are those specific situations in which VNYUS ED610 is not preferably usable and, as a result, the device must be in case used with a defined limit, with regard to benefits/costs ratio linked to system use.



WARNING, POSSIBLE UNDESIRE EFFECTS

Before starting to use VNYUS ED610 videonystagmoscope system, please, do not forget to make always a careful medical history to identify situations where it is advised against mask use for Nystagmus research.

MEDI-CARE SOLUTIONS S.R.L.**DESCRIPTION OF INSTALLATION AND/OR ASSEMBLING
PROCEDURE****ENVIRONMENT COMPLIANCE**

The environment in which the equipment is used must be hospital-type exempt from strong electric interferences and therefore far from high tension conductors, from large transformers, from x-ray implants, from diathermy and Marconi therapy generators.

Further inconvenience elements are elevator's contactors, automatic gear-cases, some lacks of the electric implant, such as conductors not perfectly fixed to the lamp-holders, to the current plugs, to the switches, etc.

In normal conditions the MD is capable of functioning without particular precautions. In critical conditions, that is when the inconveniences menace to compromise the performance of the good performance of the test, it is necessary to connect all equipment to a single efficient ground outlet.

The installation of the equipment must be made respecting the instructions of the following booklet of instructions.

The user should always make sure that the electric circuit complies to IEC values (in other words: 220/240 Vac, alternate monophasic 50 Hz, the plant should comply with IEC 64.8 sec. 710 regulation).

It is advisable to insert the plug in a socket with a bipolar switch compliant to IEC and having the following technical characteristics:

230 Vac - 50 A contact opening of 3 mm.

ACTIONS TO BE EXECUTED BEFORE SWITCHING THE SYSTEM ON

Push away all non-used cables and those near the system, they might cause encumbrance.

Furthermore, not being an explosion-proof system, it is necessary not to use it near flammable anaesthetic. Check all system device components integrity.

FIRST ACTIONS TO BE EXECUTED

1. After connecting USB-C plug into the USB-C socket, insert USB connector into the proper socket of PC/NOTEBOOK. Then, install DRIVER of camera using the CD about installation/video-acquisition.
2. Run VIEW/ACQUISITION PROGRAM; select the device; check green LED placed on the panel to be turned on: it means that software can interact with the camera.
3. If you are using EDM_Videocapture software, the camera will be automatically recognized.
4. Pressing the button I/O (placed on the system panel), check the lighting of red LED on the camera higher part.
5. Check that the USB cable is connected to the Power Supply if you use Analog Monitor

**EMERGENCY SIGNAL AND WARNING**

The green LED (placed on the fore panel) allows to view functioning condition about the two B/W Ir camera system. After connecting the camera, green LED lighting informs that camera drivers have been recognized by HARDWARE and by the used Software.

PERIODICAL START UP

The user must pay attention to the actions that are necessary to keep the device in good conditions, in order to make a "periodical start up" it in total efficiency:

- Check at sight the integrity of device and of its components (control box, mask, video camera, cables)
- place the device in an environment with the following features:

Temperature from	20° to 45°C
Relative humidity from	30 to 75%
Atmospheric pressure from	700 to 1060 hPa

- After checking disconnection of USB connector, take away the dust from the control box using an humid cloth.
- in case of prolonged inactivity, it is preferable to cover VNYUS ED610 videonystagmoscope together with its accessories (mask, camera, etc.) in a hiding place, after providing to a simple removal of the possible dust.
- Check to have the equipped power supplier of system electricity connection
- Require periodical checks (every years) c/o MEDI-CARE SOLUTIONS S.p.A..

MANUFACTURER RESPONSIBILITIES

VNYUS ED610 Videonystagmoscope system, manufactured by Medi-Care Solutions srl, is guaranteed against potential manufacture and/or material defects for one year from the purchasing date and according to the following conditions:

- The room interior wiring must comply with the current IEC regulations.
- The equipment must be used following the instructions and regulations as in the present manual.
- Installation, modifications and repairs must be executed by technicians authorized by Medi-Care Solutions srl Company.

The following voices are not under warranty:

- Defects caused by normal deterioration
- Parts subject to wearing out
- Malfunction caused by damaging (accidental causes), by maintenance or modifications executed by non-authorized people.
- Defects caused by the machine's use for different purposes from those it's been built for.

USE INDICATIONS

GENERAL DESCRIPTION

This manual describes VNYUS ED610 videonystagmoscope system functioning.

The equipment is composed of a small control box, a mask together with a camera, a USB-mini cable and a stopper.

After camera driver installation on PC/Notebook, using a visualization software, it will be possible to view and register the images reached by the camera.

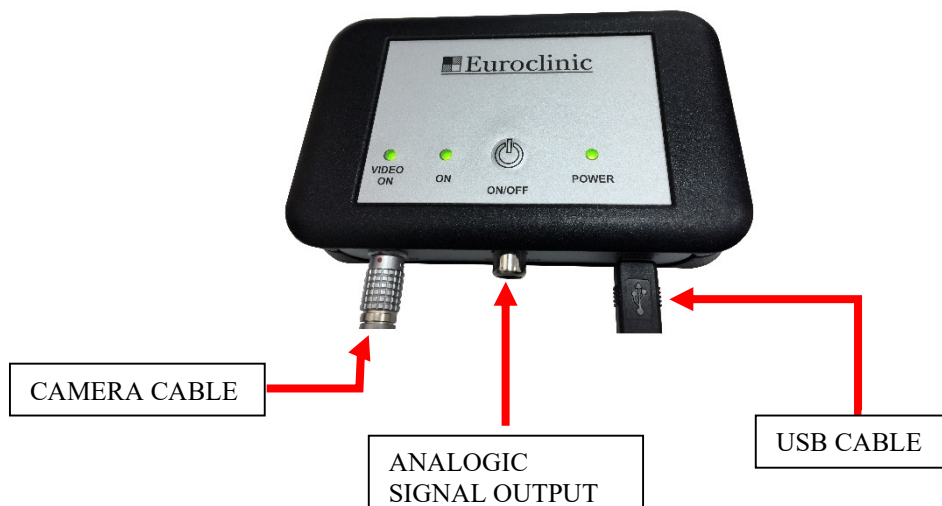
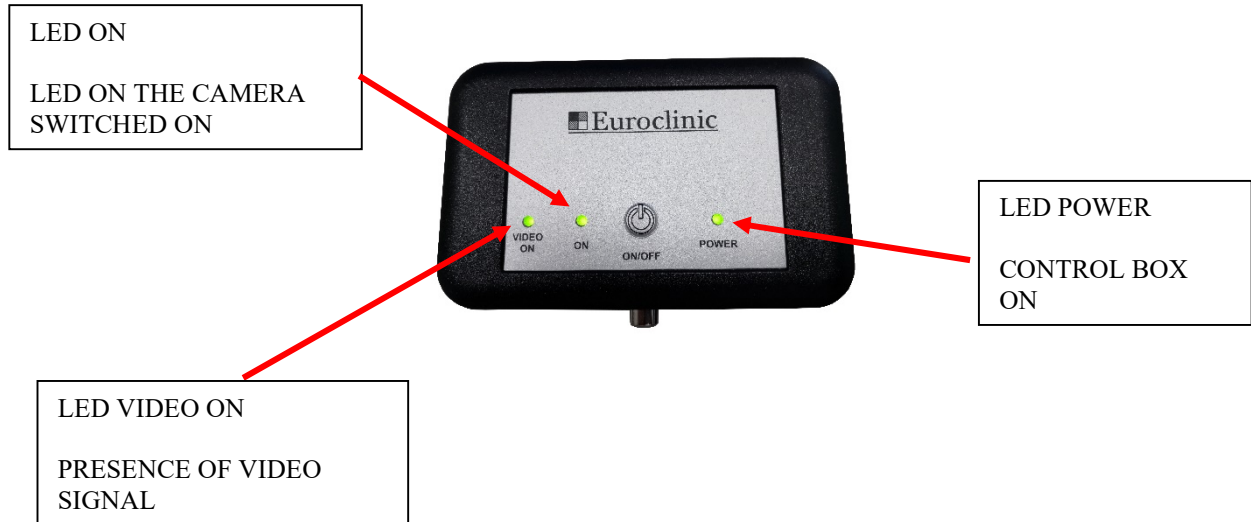
VNYUS ED610 videonystagmoscope system allows to start the red led inside the mask during tests, in order to make Visual Suppression Test using the button called I/O, placed on the control box.

If you use the VIDEONYSTAGMOSCOPE ED610 connected to an Analog Monitor you must be connect the USB-mini-USB cable to Power Supply. All you need is to connect the device analog output to the monitor using the video cable.

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CONTROLS DESCRIPTION

CONTROL BOX



CLEANING ED610

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 surfaces. The major damages are caused by the amount of time that these chemical products are left on the tops. It is important to immediately 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, ammonia or petrol

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



Cleaning and disinfecting products chart	
Disinfectants	Pharmaceutic products and cosmetics
+ bactol 5%	+ blood plasma
+ clorammina	+ sun tan lotion
- DDT	+ hydroplex
+ delegol 5%	= iodine dye
= dimammina 5%	+ lanolyn
= iodine dye	= mantolo 90% in alcohol
- fenic acid	-nail varnish
+ lysoform 2%	- solvent
- TB lysoform	+ mouth wash
+ bactol	+ periston R
+ merfen 2%	+ vaselyn
+ octozone	+ vicks rub
+ perydrol	
+ resorcina 1%	
= sagrotane 5%	
+ alcohol to be purely burnt	
+ mercury chloride	
+ trosilina G	
+ oxiginated water	
= zefirol	
CHART SIGNS	
+ compatible	
- non compatible	
= compatible but with caution	

TECHNICAL FEATUTURES

CONTROL BOX

Electrical tension:	5V DC (USB port)
Power absorbed:	max 2,5W
Weight	115 gr
Dimensions Max(in mm):	115 x80 x 23

MASK

Weight	115 gr
Dimensions Max(in mm):	180 x90 x 45

CAMERA

Weight	200 gr (with cable)
Dimensions Max(in mm):	56 x55 x 45

FAULTS RESEARCH

It is possible the equipment cannot reach the desired function.

Before calling assistance technician, please, try to solve the problem alone according to the following checking list, that could help to identify and eliminate faults.

THE EQUIPMENT DOES NOT START

- Make sure that USB cable plug is inserted on the USB socket of your PC/NOTEBOOK and check the socket to be active.
- Make sure to have opportunely installed camera drivers
- Call MEDI-CARE SOLUTIONS technical assistance service

NO IMAGES ON THE MONITOR

- Make sure that USB cable plug is inserted on the USB socket of your PC/NOTEBOOK and check the socket to be active.
- Make sure to have opportunely installed camera drivers
- Verify to have selected the device on the choices of your software

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- Call MEDI-CARE SOLUTIONS technical assistance service

GUIDE CHARTS AND CONSTRUCTOR DECLARATIONS

TABELLA 201 EMISSIONI ELETTROMAGNETICHE

Guida e dichiarazione del costruttore- Emissioni Elettromagnetica Guidance and manufacturer's declaration-electromagnetic immunity		
<p>Il DM in oggetto è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del riunito dovrebbe assicurarsi che esso venga usato in tale ambiente.</p> <p>The MD is intended for use in the electromagnetic environment specified below. The customer or the user of the Unit should assure that it is used in such an environment.</p>		
Prova emissioni Emissions test	Conformità Compliance	Ambiente Elettromagnetico-Guida Electromagnetic environment -Guidance
Emissione RF RF Emissions CISPR 11	Gruppo 1 Group 1	<p>Il DM utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini.</p> <p><i>The MD 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 .</i></p>
Emissione RF RF Emissions CISPR 11	CLASSE B CLASS B	<p>Il DM 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.</p> <p><i>The MD 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</i></p>
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	

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TABELLA 202 IMMUNITA' ELETTROMAGNETICA

Guida e dichiarazione del costruttore-immunità elettromagnetica Guidance and manufacturer's declaration-electromagnetic immunity			
Il DM è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del riunito dovrebbe assicurarsi che esso viene utilizzato in tale ambiente. The MD is intended for use in the electromagnetic environment specified below. The customer or the user of the unit 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) <i>Electrostatic discharge</i> (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%. <i>Floors should be wood ,concrete or ceramic tile. If floors are covered with sintetic material the relative humidity should be at least 30%</i>
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 ingresso/uscita <i>±1kV for input/output lines</i>	±2 kV per linee di alimentazione di potenza ±2 kV for power supply lines ±1kV per linee di ingresso/uscita <i>±1kV for input/output lines</i>	La qualità della tensione dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. <i>Mains power quality should be that of a tipical commercial or hospital environment</i>
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. <i>Mains power quality should be that of a tipical commercial or hospital environment</i>
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso di alimentazione <i>Voltage dips,short interruptions and voltage variations on power supply input lines</i> 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 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. <i>Mains power quality should be that of a tipical commercial or hospital environment.If the user of the Unit requires continued operations during power mainsinterruptions,it is recommended that the Unit powered from an uninterruptible power supply or a battery.</i>
Campo magnetico alla frequenza di rete (50/60 Hz) <i>Power Frequency</i> (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. <i>The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low</i>
Nota_ 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.			

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TABELLA 204 IMMUNITA' ELETTROMAGNETICA

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITA' ELETTROMAGNETICA

Il presente DM è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del riunito in oggetto dovrebbe assicurare che esso venga utilizzato in tale ambiente. The MD is intended for use in the electromagnetic environment specified below. The customer or the user of it 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 del DM, compresi i cavi, eccetto quando rispettano le distanze di separazione raccomandate calcolate dall'equazione applicabile alla frequenza del trasmettitore. <i>The communication sets radio-frequency portable and mobile should not be used near any part of unit, cables included, except when they respect the recommended separation distances calculated by the equation applicable to the frequency of the transmitter.</i> 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) <i>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)</i> 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 . <i>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</i> Si può verificare interferenza in prossimità di apparecchi contrassegnati dal relativo simbolo. <i>It could happen interference nearby equipments/sets signed by relative symbol.</i>

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 teoricamente 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'otocompact professional, supera il livello di conformità applicabile di cui sopra, si potrebbe porre sotto osservazione il funzionamento normale dell'otocompact professional. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento a posizione del otocompact professional. 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 Unit is used overcome the applicable conformity level specified before, the normal functioning of a 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 a Unit. The field intensity on a frequency range from 150 KHz to 80 MHz should be lower than 3V/m.*

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TABELLA 206 DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATILI E MOBILI E L'APPARECCHIO

Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili e mobili e il Dispositivo			
Recommended separation distances between portable and mobile RF communications equipment and the Device			
<p>Il DM è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore del DM in oggetto possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e il DM, come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.</p> <p><i>The MD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Device as recommended below, according to the maximum output power of the communication equipment.</i></p>			
POTENZA DI USCITA NOMINALE MASSIMA DEL TRASMETTITORE RATED MAXIMUM OUTPUT POWER OF TRANSMITTER <i>W</i>	DISTANZA DI SEPARAZIONE ALLA FREQUENZA DEL TRASMETTITORE SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER <i>m</i>		
	Da 150 KHz a _to 80 MHz <i>d=1,2 √P</i>	Da 80 MHz a _to 800 MHz <i>d=1,2 √P</i>	Da 800 MHz a _to 2,50 GHz <i>d=2,3 √P</i>
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
<p>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.</p> <p><i>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.</i></p>			

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.

TECHNICAL ASSISTANCE SERVICE**OF****MEDI-CARE SOLUTIONS SRL****TEL. / PHONE: +39 0542 642046****FAX: +39 0542 642355****E-MAIL: info@MEDI-CARE SOLUTIONS.it****!!!!!! VERY IMPORTANT ADVICE !!!!!!**

Before sending back the equipment, even if it is covered by its warranty, it is necessary to forewarn and require MEDI-CARE SOLUTIONS S.p.A. authorisation. Otherwise, the warranty could fall into decay.

In case, due to any reason, the equipment must be delivered to the technical assistance service, we suggest to use the original packing, in order to avoid eventual damages due to transport.

Therefore Medi-Care Solutions srl declines any responsibility in relation to these damages and will charge the new packing to be used for sending again the equipment to the customer.