Euroclinic

POWER LED LIGHT SOURCE FOR ENDOSCOPY

WLS ED300

OPERATING MANUAL

Rev. 07 26/05/2021

CE

Euroclinic MEDICAL COMPONENTS DIVISION

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MANUFACTURER IDENTIFICATION

MEDI-CARE SOLUTIONS S.r.l.

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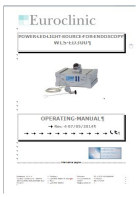
PRODUCT IDENTIFICATION

1. 12V DC Power supply

2. Led Handpiece complete with cable

3. Power supply control box

4. Operating manual



SYMBOL MEANING

Symbol indicating classification of type "B" equipment

Class I, II or III device, or device equipped with an internal electrical source, having a degree of protection against direct and indirect contacts with particular regard to:

- the permissible leakage currents
- The reliability of the ground contact.

This symbol indicates: FOR CLARIFICATION, SEE THE ATTACHED DOCUMENTATION

This symbol indicates:
WARNING! CONSULT THE ATTACHED DOCUMENTATION BEFORE USING THE MD

This Symbol indicates a general warning (read this user manual carefully)

This Symbol indicates a Class II device

This Symbol indicates: Direct Current

Disposal symbol according to regulations

Symbol indicating that the device is a Medical Device (following 2017/745 EU Rule)

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.

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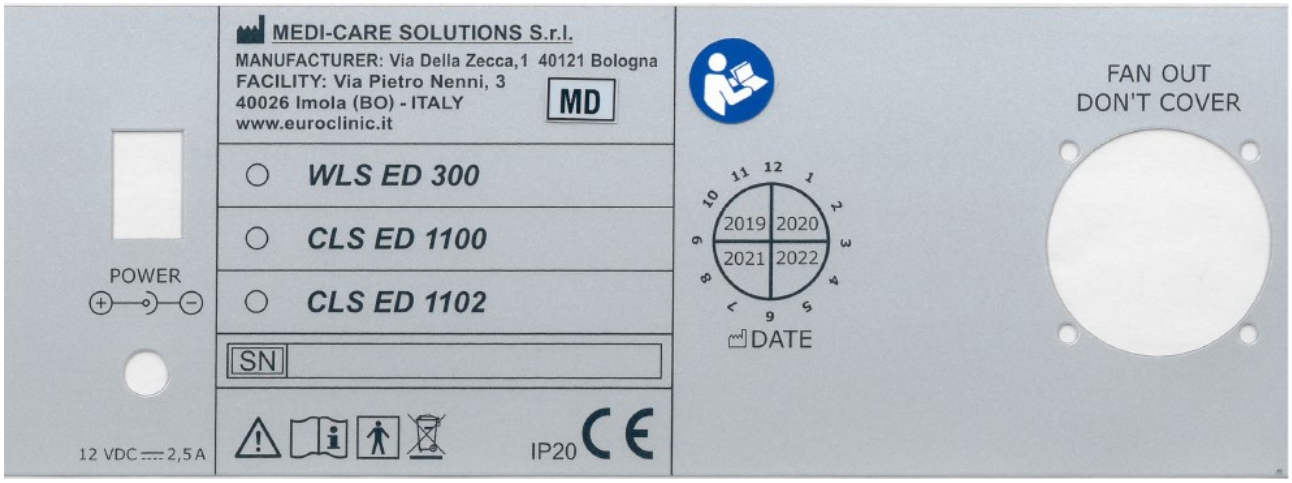
PRODUCT CLASSIFICATION

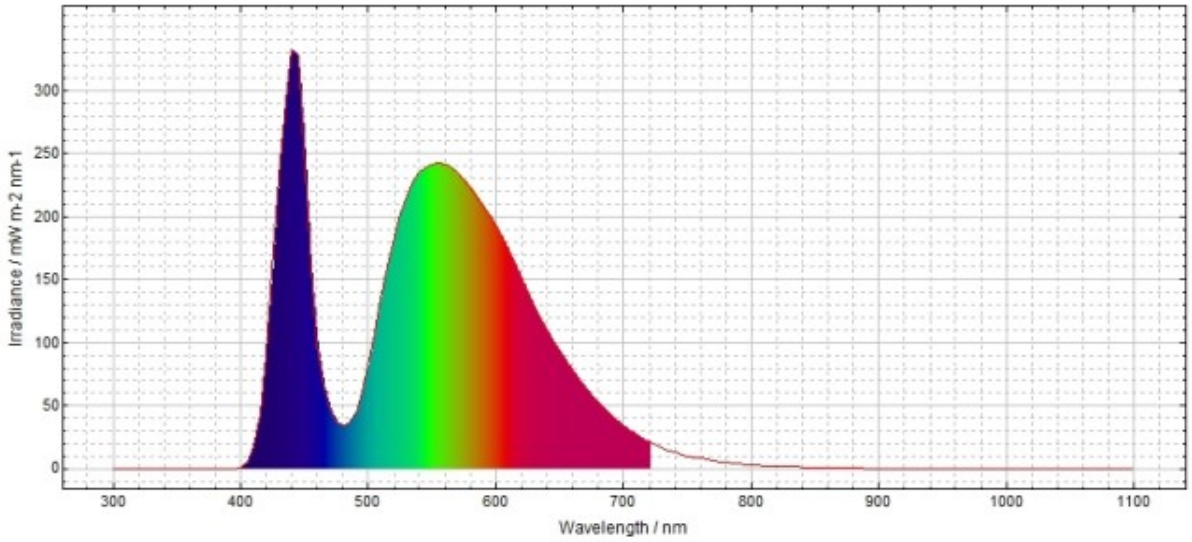
According to IEC 60601-1: Class I BF



PHOTOBIOLOGICAL RISK CLASS OF THE DEVICE

Emission limits for risk groups of continuous wave lamps									
Risk	Action spectrum	Symbol	Units	Emission Measurement					
				Exempt – RG0		Low risk – RG1		Mod risk – RG2	
				Limit	Result	Limit	Result	Limit	Result
Actinic UV	$S_{UV}(\lambda)$	E_s	W•m^{-2}	0,001	1,19E-06	-	-	-	-
Near UV		E_{UVA}	W•m^{-2}	0,33	3,49E-03	-	-	-	-
Blue light	$B(\lambda)$	L_B	W•m^{-2}•sr^{-1}	100	FAIL	10000	FAIL	4000000	4,50E+04
Blue light, small source	$B(\lambda)$	E_B	W•m^{-2}	0,01*	Not applicable	1,0	-	400	-
Retinal thermal	$R(\lambda)$	L_R	W•m^{-2}•sr^{-1}	28000/α= 7,00E+05	5,43E+05	28000/α	-	71000/α	-
Retinal thermal, weak visual stimulus**	$R(\lambda)$	L_{IR}	W•m^{-2}•sr^{-1}	545000 0,0017≤ α ≤ 0,011	Not applicable				
				6000/α 0,011≤ α ≤ 0,1	Not applicable				
IR radiation, eye		E_{IR}	W•m^{-2}	100	2,17E-01	570	-	3200	-
* Small source defined as one with α < 0,011 radian. Averaging field of view at 10000 s is 0,1 radian.									
** Involves evaluation of non-GLS source									

TEST RESULT	**RISK GROUP 2**



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 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 EUROCLINIC 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 authorized MEDI-CARE SOLUTIONS' staff 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! 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

18. 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
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

The WLS ED300 Led Light Source is an equipment that allows to generate cold light that will be transferred to endoscopy instruments.

WLS ED300 Light Source must be utilized only for the use it has been specifically planned and assembled for, every other use is improper and dangerous, therefore Medi - Care Solutions srl. denies liability for damages caused by improper use.

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 plug in a 220V, 50 Hz socket provided with efficient ground connection;

ENVIROMENTAL COMPLIANCE

The environment to use the equipment in 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 marconitherapy 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 machine 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.

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

OPERATOR COMPLIANCE

The operator, in charge of use WLS ED300 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 ED300 must be an ENT professional.

KIND OF FUNCTIONNING

WLS ED300 Light Source is a machine, whose operates in continuous way.

FUNCTIONING FAULTS

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

Do not leave the WLS ED300 Light Source exposed to atmospheric agents

Do not leave the WLS ED300 Light Source on if not used.

The limitations are specific situations in which the endoscopic visit a is not preferably advisable and in consequence the device must be used with a limitation related to the costs/benefits relation, deriving from the use of the system.

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

COUNTER EFFECTS

Counter effects are those specific situations in which test execution modalities can damage patient clinic conditions, always considering the costs/benefits relation, deriving from the use of the system.

WARNING, POSSIBLE UNDESIRED EFFECTS

Before using the Light Source, always remember to not address the handpiece towards anybodies eyes standing at 1 meter from the handpiece: the light might cause annoyance and blunder to the patient, causing a disagreeable sensation.

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 marconitherapy 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.

ACTIONS TO BE EXECUTED BEFORE SWITCHING THE SYSTEM ON

Do not connect to electric current; connect and check all connection cables .

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 use it near flammable anaesthetic.

Check at sight all system components integrity.

FIRST ACTIONS TO BE EXECUTED

Make sure that back switch (I/O) is on O position, insert power supply provider connector on the back panel (12V DC); after this, connect the power provider to power supply (220V~). After inserting led hand-piece connector into the forward-panel in L1 position, you must push I/O switch on I position and make sure that the display is on and also that the led hand-piece fan is working.

After this checking, you can connect your optic to led hand-piece and you can select the desired quantity, rotating the adjustment knob of light power towards the right side.

EMERGENCY SIGNAL AND WARNING

Always remember not to turn the hand-piece towards the eyes of any people present in 1 m. range from the hand-piece. In fact, the light issued could disturb and dazzle giving an unpleasant sensation. The forward-panel display not only gives the percentage of light power (issued by led power), but also it allows to view information about system condition. WLS ED300 system is adjusted by the microprocessor that controls and adjusts the most important functions and it indicates different functioning in comparison with the expected ones, through messages viewed on the display.

Messages that could appear on the display are the following ones:

--LL--:	low level battery
--HH--:	High temperature hand-piece – led hand-piece not connected
--E0--:	control box breakdown
--E1--:	overheated battery
--E2--:	fault battery (battery model)

--E3--: broken led or mistake in connecting the led hand-piece

--E4--: not working led adjuster

--E5--: Insufficient input tension to charge the battery

--E9--: Error memory Error parameters

--nC--: led hand-piece not connected

ACTIONS TO BE EXECUTED AFTER READING THE MESSAGES:

--LL--:

Connect WLS ED300 system to the power supply through (12V DC) power provider (supplied)

--HH--:

Automatically, the system interrupts the power supply to led power. Make sure that the fan placed inside the hand-piece is working. If not, disconnect power supply feeder (220V~) and put the switch O/I on O and call Technical Assistance of Medi - Care Solutions srl.

If the fan is working, please, wait the hand-piece temperature to come in the normal values ranges. Automatically, the led will start again to issue the light.

--E0--:

Disconnect power supply provider (220V~) and place the O/I switch into O, Call Medi - Care Solutions srl. Technical Assistance

--E1--:

Disconnect power supply provider from the electrical network (220V~) and place the O/I switch into O. Call Medi - Care Solutions srl. Technical Assistance

--E2--:

Disconnect the power supply provider (220V~) and place the O/I switch into O. Call Medi - Care Solutions srl. Technical Assistance

--E3--:

Make sure that the hand-piece connector is correctly inserted. If you remark that the led remains turned off, call Medi - Care Solutions srl. Technical Assistance

--E4--:

Disconnect power supply provider (220V~) and place the O/I switch into O

--E5--:

Make sure that you are using the power supply provider of standard production equipment you get together with the system. It must issue a at least 12V DC tension. Call Medi - Care Solutions srl. Technical Assistance.

--E9--:

Disconnect power supply provider from the electric network (220V~) and place the O/I switch into O. Call Medi - Care Solutions srl. Technical Assistance.

--nC--:

Make sure that the hand-piece connector is right inserted and screwed in its L1 Place. Call Medi - Care Solutions srl. Technical Assistance.

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:

- verify the integrity of device and of its components
- check that green Led, placed on the right of anterior panel, is on, while the device is working
- Always check that the hand-piece fan is working while the device is turned on 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

- Please, after making sure that I/O switch is in O position and the power supply provider (12 V DC) is connected, remove powders from control box using a humid cloth;
- in case of prolonged inactivity, it is preferable to cover VNYS ED600 together with its accessories (mask, camera and 12VDC power supplier) in a hiding place, after providing to a simple removal of the possible dust.
- Require periodical checks (every years) to Euroclinic Company in order to verify light power supply of the equipment.
- Check to have the equipped power supplier of system electricity connection

MANUFACTURER RESPONSIBILITIES

The **WLS ED300** light system produced by Medi - Care Solutions srl., is guaranteed against potential production 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 Euroclinic 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 persons.
- Defects caused by the machine’s use for different purposes from those it’s been built for , or modifications made by personnel not authorized by Medi - Care Solutions srl..

USE INDICATIONS

GENERAL DESCRIPTION

This document describes WLS ED300 light source functioning, light generator for endoscopy instruments. WLS ED300 new light source introduces 2 main new features: the usage of a power led (instead of the traditional incandescence light) and the led hand-piece direct connection to the optic (without the duty to use the standard optic fibres cable as inter-connection between the source and the optic. Power led temperature is 5.500 K°, therefore white light. The other innovation is the led placed on the hand-piece that allows to avoid the use of optic fibres cable, reducing the costs of the system. After you have made the operations described in the paragraphs "ACTIONS TO BE EXECUTED BEFORE SWITCHING THE SYSTEM ON" and "First actions to be executed" it will be sufficient to connect the Led hand-piece directly to the optic to use and adjust the light power through the knob place on the right of the equipment forward panel .

The display present on the panel consents to realize about light power percentage selected through the knob. The light power issued by the power led can be increased or reduced using the knob placed on the right side of the forward panel, otherwise, using the buttons + and - .

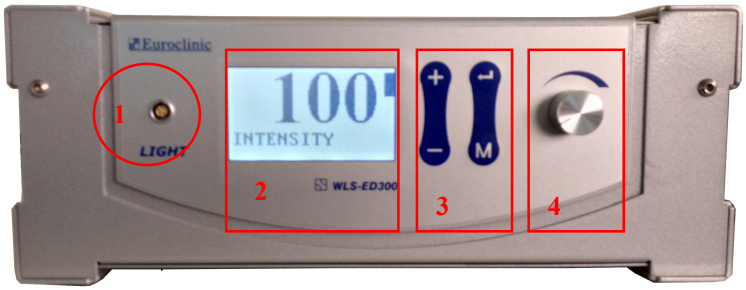
The button M is useful to call a power percentage previously saved; that value is the last adjusted and unchanged for 2 seconds

The button consents to reset to zero the value of the power percentage issued to the led.

The system autonomy (not connected to power supply , 220 V~) depends on the charge batteries and use 100% of light power can change from 1 to 2 hours.

CONTROLS DESCRIPTION

FORE PANEL MASTER STATION



1. Handpiece connector
2. Display
3. Increase/Decrease % power value and Enter buttons
4. Increase/Decrease % power value knob

CLEANING ED300

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% + 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	

TECHNICAL FEATURES

Electrical tension:	12V DC
Frequency:	50 Hz
Power absorbed:	25W
Weight	3.7 Kg
Dimensions Max(in mm):	300 x250 x 120

FAULTS RESEARCH

It could happen that the equipment could not execute the desired function. Tray to solve the problems alone, before calling Assistance technician. The following checking list could help to identify and cancel possible faults.

THE EQUIPMENT DOES NOT START

- Make sure that power supply cable plug is inserted on the outlet socket (that must be active 220V~)
- Make sure that I/O switch is ON
- Call Euroclinic technical assistance service
- Send the equipment to Technical assistance service

1. GUIDE TABLES AND MANUFACTURER'S DECLARATION

The electro-medical device requires special precautions regarding EMC (Electromagnetic Compatibility) and must be installed in accordance with the EMC information contained in the accompanying documents.
Portable and mobile radio-communication equipment can affect the operation of EUT (Equipment under test).
The use of accessories, transducers and cables other than those specified, with the exception of those sold by the manufacturer as spare parts for internal components, may cause an increase in emissions and a decrease in immunity.
The device or the system must not be used near other devices and, if it is necessary to use it near other appliances, the electro-medical device must be observed to check normal functioning in the configuration in which it is used.
The electro-medical device has been tested and founded in compliance with the emission and immunity limits of electromedical equipment according to IEC60601-1-2: 2014. These limits are
specifically designed to provide adequate protection against dangerous interferences in a typical medical room. However, there is no guarantee that interferences will not occur in a particular installation. If the electro-medical device, interacting with another one, causes or receives detectable interferences, the user is invited to limit them by adopting one or more of the following measures:
1. Reorient or relocate the receiving device;
2. Increase the distance between the appliances;
3. Connect the equipment to an outlet on a circuit different from the device (s) causing the interference;
4. Contact the manufacturer or local technician for assistance

<table>
<tr><th colspan="3">Guida e dichiarazione del fabbricante – emissioni elettromagnetiche/ Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">“ED420” è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il paziente o l'utilizzatore di “ED420” dovrebbe garantire che esso venga impiegato in tale ambiente / "ED420" is intended to operate in the electromagnetic environment below specified. The patient or user of "ED420" should ensure that it is used in such an environment.</td></tr>
<tr><th>Prova di emissione/Emission test</th><th>Conformità/ Conformity</th><th>Ambiente elettromagnetico/Electromagnetic environment</th></tr>
<tr><td>Emissioni a RF CISPR 11/RF CISPR 11 Emissions</td><td>Gruppo 1/ Group 1</td><td>“ED420” utilizza energia a radiofrequenza solo per il suo funzionamento interno. Di conseguenza le sue emissioni a RF sono molto bassa e verosimilmente non provoca alcuna interferenza negli apparecchi elettronici posti nelle vicinanze. / "ED420" uses radio frequency energy only for its internal operation. As a result, its RF emissions are very low and are unlikely to cause any interference in nearby electronic devices.</td></tr>
<tr><td>Emissioni a RF CISPR 11/RF CISPR 11 Emissions</td><td>Classe B/ Class B</td><td rowspan="3">“ED420” è adatto per l’uso in tutti gli ambienti compresi quelli domestici e da quelli collegati direttamente alimentazione di rete pubblica a bassa tensione che alimenta edifici utilizzati per scopi domestici. /"ED420" is suitable for use in all environments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Emissioni armoniche IEC 61000-3-2/IEC 61000-3-2 Harmonic Emissions</td><td>Classe A/ Class A</td></tr>
<tr><td>Emissioni di fluttuazioni di tensione/ Flicker emissions IEC 61000-3-3</td><td>Conformità/ Conformity</td></tr>
</table>

Guida e dichiarazione del fabbricante – immunità elettromagnetica
Guidance and manufacturer's declaration - electromagnetic emissions

Il DM è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il paziente o l'utilizzatore del DM dovrebbero garantire che esso venga utilizzato in tale ambiente. / The MD *is intended to operate in the electromagnetic environment specified below. The patient or user of the MD should ensure that it is used in such an environment.*

Prova di immunità/Immunity test	**Livello di prova della IEC 60601/IEC 60601 test level**	**Livello di conformità/ Conformity level**	**Ambiente elettromagnetico Electro-magnetic environment**
Scarica elettrostatica ESD/ Electro-static download (ESD) IEC 61000-4-2	± 8kV a contatto/in contact	± 8kV a contatto/in contact	I pavimenti devono essere in legno, calcestruzzo o in piastrelle di ceramica. Se i pavimenti sono rivestiti di materiale sintetico, l'umidità relativa dovrebbe essere almeno pari al 30%. / *Floors must be in wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30%.*
	± 2; 4; 8; 15 kV - air	± 2; 4; 8; 15 kV - air	
Transitori/sequenza di impulsi elettrici rapidi/ Fast electrical transients / pulse sequence IEC 61000-4-4	±2kV per le linee di alimentazione/ power feeding lines	± 2kV per le linee di alimentazione /power feeding lines	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. In caso di burst a 2 kV su linea di alimentazione si può verificare un lieve sfarfallio del display, che non pregiudica la sensibilità del touch screen o l'erogazione della terapia, né la sicurezza del paziente o l'operatore. / *The quality of the main voltage should be the one typically used in commercial or hospital environment. In the event of a 2 kV burst on the power supply line, the display may flicker slightly, which does not affect the sensitivity of the touch screen or therapy delivery, nor the safety of the patient or operator*
	± 1 kV per le linee di ingresso/uscita entrance/exit lines	± 1 kV per le linee di ingresso/uscita entrance/exit lines	
Sovratensioni/ Overvoltage IEC 61000-4-5	± 1kV tra le fasi/among phases	± 1kV tra le fasi/among phases	*La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. / The quality of the net voltage should be the one typically used in commercial or hospital environment.*
	± 2kV tra le fasi/among phases and earth	± 2kV tra le fasi/among phases and earth	
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione /Voltage dips, brief interruptions and voltage variations on the power input lines IEC 61000-4-11	0% U_T for 0,5 cycle	0% U_T for 0,5 cycle	*La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore di richiede un funzionamento continuato durante le interruzioni della tensione di rete si raccomanda di utilizzare il DM con un gruppo di continuità. / The quality of the main voltage should be the one of a typical commercial or hospital environment. If the user requires continued operation during power interruptions, it is recommended to use the MD with a UPS*
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	70% U_T for 25 cycle	70% U_T for 25 cycle	
	0% U_T for 250 cycle	0% U_T for 250 cycle	
Campo magnetico ad alta frequenza (50/60 Hz) / High frequency magnetic field (50/60Hz) IEC 61000-4-8	30 A/m	Non applicabile, il dispositivo non contiene componenti suscettibili ai campi magnetici. /Not applicable.	I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in un ambiente commerciale o ospedaliero. / Power frequency magnetic fields should have characteristic levels of a typical location in a commercial or hospital environment.

NOTE: UT è la tensione di rete in c.a. prima dell'applicazione del livello di prova
UT is the main voltage before applying the test level.

Guidance and manufacturer's declaration - electromagnetic emissions				
Il DM è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del DM dovrebbero garantire che esso venga utilizzato in tale ambiente. Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte di, compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore/ The MD *is intended for operation in the electromagnetic environment specified below. The customer or user of the MD should ensure that it is used in such an environment. Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.*				
Prova di immunità/Immunity test	**Livello di prova della IEC 60601/IEC 60601 test level**		**Livello di conformità/ Conformity level**	**Distantaza taccomandata d: Recommended distance d:**
RF Condotta/ Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz		3 Veff	**d= 30 cm**
RF Irradiata/Irradiate RF IEC 61000-4-3	3 V/m da/from 80 MHz to 2,5 GHz		3 V/m	**d= 30 cm**
Immunità a campi di prossimità da dispositivi di comunicazione RF wireless IEC 61000-4-3 / *Proximity field immunity from wireless RF communication devices IEC 61000-4-3*	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d= 30 cm**
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	

Euroclinic

TECHNICAL ASSISTANCE SERVICE

OF

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!!!!!! 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 srl. 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.