

# LETTINO DA VISITA ELETTRICO AD ALTEZZA REGOLABILE CON BARRA PERIMETRALE ELECTRIC HEIGHT ADJUSTABLE TREATMENT TABLE WITH FOOTBAR DIVAN DE TRAITEMENT ÉLECTRIQUE RÉGLABLE EN HAUTEUR AVEC SYSTÈME D'ÉLÉVATION PÉRIPHÉRIQUE

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

# REF 44520 - 44521 - 44522 - 44525



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M44520-M-Rev.0-07.21

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# CAUTION

It is important to read the following instructions carefully in order to use the bed correctly. The manufacturer declines all responsibility for any consequences resulting from using the device for any uses other than the ones described in these operating instructions. The product is a Class I medical device compliant with Regulation (EU) 2017/745.

# DESCRIPTION

The beds are intended for outpatient use in hospitals, community centres, care homes and medical centres.

They are suitable for physiotherapy treatments, professional massages, diagnostic tests and patient monitoring. The device is an examination bed with electric height adjustment by means of a perimeter bar, fitted with a headrest that can be adjusted by means of a gas pump lever. It has a sturdy, epoxy powder-coated metal structure.

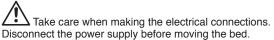
# DESCRIPTION OF COMPONENTS

- Structure: Sturdy painted metal structure
- Standard linear actuator connected to the control bars
- Mattress with fireproof faux leather cover,
- supplied with mouth-nose hole plug, colour on request.
- Optional accessories: Paper roll support

with possibility for installation at the head or foot.

## **COMPONENTS**

- 1. Backrest
- 2. Seat
- 3. Painted frame
- 4. Motor kit:
- A. Linear actuator
- B. Transformer
- C. Control bar
- D. Height adjustment ON/OFF



THE BED IS SUPPLIED READY-ASSEMBLED. INSERT THE POWER CORD CONNECTED TO THE TRANSFORMER **B** IN THE POWER SOCKET TO ACTION THE BED.

#### **INSTRUCTIONS FOR USE**

For safety reasons the controls have been inverted: TO LIFT  $\rightarrow$  PRESS THE BAR DOWNWARDS TO LOWER  $\rightarrow$  PUSH THE BAR UPWARDS

Before using the electric bed for the first time, check that it is properly positioned with sufficient space around it to perform the necessary height and backrest adjustments, and to allow the patient to climb on without any obstructions.

1. Completely lower the bed before getting the patient to lay down. To action the perimeter bar, push it upwards.

2. Once totally lowered, get the patient to lay down.

3. To lift the bed, press the bar downwards.

4. To lift the backrest, press the lever located in the rear part and release it in the desired position.

5. To lower the backrest, press the lever and push the backrest down firmly

**Caution!** DURING MOVEMENT AND REGULATION OF THE BED AND BACKREST, ALWAYS MAKE SURE THERE ARE NO OBSTACLES IN THE MOVEMENT AREAS.

# TECHNICAL DATA SHEET

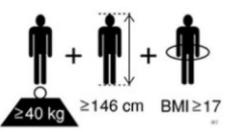
Power supply: 100-240 Vac 50-60 Hz. 1.5A Maximum dimensions 195 x 59.5 x h min 54 - max 71 cm Max inclination 51°, Max H 94 cm with headrest fully raised Box 200x71x70 cm Weight: 65Kg (with box 74kg) Reclining backrest Max patient weight: 135kg Max safety weight: 170 kg Duty Cycle: 2 min ON / 18min OFF (10%)

# Conditions of use, storage and transport

**Use:** Temperature 10 – 40°C/ Humidity 20-60% Atmospheric pressure 98–105kPa / Max altitude 2000m asl **Transport and storage:** Temperature -10 – 50°C / Humidity 20-90% Atmospheric pressure 98–105kPa

# **INSTRUCTIONS FOR USE**

- · Make sure that the fastening nuts are properly tightened.
- · Comply with the maximum weights indicated in the technical data sheets.
- · Avoid direct contact with open wounds.
- Not suitable for outdoor use.
- When the height of the bed and the backrest are adjusted, make sure that no-one puts their hands, legs or anything else in the adjustment area: RISK OF CRUSHING!









- Move the bed without lifting it off the ground.
- · The device may interfere with other electronic devices and, in turn, may receive interference from other electronic devices in the vicinity.
- The plug must always be accessible during use so that it can be easily pulled out in case of danger.
- The power cable must be positioned so that it does not get dragged away, trodden on or damaged when the bed is in use.
- Before moving the bed, make sure that the plug is disconnected from the power socket and store the cable so that it cannot fall onto or drag on the floor.
- Make sure the cable cannot be damaged when the motor is in use.
- · Position and operate the foot control to ensure that the patient is protected from any unexpected motorised movements.
- Do not, under any circumstances, use extension cords or plug power strips under the bed. Extension cords and/or plug power strips should never be used.
- Check the foot control cable and the power cable for wear every three months. If worn and/or frayed, the damaged cable must be replaced immediately.
- Every six months, check that no unusual sounds or vibrations are emitted when operating the bed which could be a sign of actuator and/or mechanical faults. After the above-mentioned operations, complete the inspection by passing the work cycle test to raise the bed with the maximum safety load.
- · Periodically, or after intensive use, check that the screws, bolts and pins are tightened; make sure there are no cracks or structural defects.
- · Periodically check the state of the cover.
- · The bed should be lowered when the patient cannot be monitored.
- · Do not bend, tangle or crush the power cable.
- Do not crush the power cables of other devices with the bed frame.
- Do not sit on the headrest of the bed.
- Never use accessories and cables that differ from those specified or supplied with the bed.
- · Consult the technical data section to make sure that the current complies with the technical specifications of the bed.
- · Before using the bed, consult the technical data section to make sure that the room complies with the environmental conditions.
- · Avoid exposure to direct sunlight, UV rays, excessive dirt, humidity, vibrations and impacts.
- · Do not move the bed with a person or a weight on it. Only move the bed on a flat surface.
- The "safe working load" of the bed is 135 kg. i.e. the total weight to which the bed is subjected (the weight of the patient plus other loads, e.g. the therapist's manipulations) must not exceed 170 kg.

#### MAINTENANCE AND CLEANING

- · Use only original spare parts.
- · Periodically check all fixing points.
- To ensure its efficient, long-term use, it is advisable to avoid prolonged exposure to sun rays, contact with saline environments and storage in very damp environments.
- · Wash the stainless steel surfaces with soapy water and use suitable disinfectants.
- · Rinse with a damp cloth and dry carefully.
- · Do not pour chlorine- or ammonia-based detergents or greasy and oily substances on the surfaces.
- · Do not use metal tools for cleaning. If disinfection is required, only use suitable non-corrosive products.

#### Instructions for cleaning the fabric

 Clean with a damp and soapy cloth and rinse well with clean water. Do not use solvents, bleach and chemical detergents or sprays to polish. Attention: In general, the light colours of the faux leather should not come into contact with clothes with unfixed dyes (e.g. jeans and similar) to avoid stains or marks which cannot be removed

# ELECTROMAGNETIC COMPATIBILITY

#### LEVELS OF COMPLIANCE WITH THE EN 60601-1-2:2015 STANDARD

ESD immunity 15kV in air and 8kV on contact (EN 61000-4-2)	
Burst immunity 2kV/100kHz (EN 61000-4-4) power supply/1kV signals	
Surge immunity (EN 61000-4-5): 1kV common mode/2kV differential mode	
Magnetic field (EN 61000-4-8): 30A/m	
Dip Immunity: 0% 0.5 cycles; 0% 1 cycle; 70% 25 cycles (50Hz) and 30 cycles (60Hz); Breaks: 250 cycles (50Hz); 300 cycles (60Hz)	
Immunity to RF currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz 6V modulation 80% 1kHz for the following frequency ranges: 6.765 MHz ÷ 6.795 MHz 13.553 MHz ÷ 13.567 MHz 26.957 MHz ÷ 27.283 MHz 40.66 MHz ÷ 40.70 MHz	
CISPR 11 class A emissions	
EN 61000-3-2 class A Harmonic currents	
PST, DT, DC Flickers	

RF FIELD IMMUNITY (EN 61000-4-3):					
FIELD (V/M)	FREQUENCY	MODULATION			
3	80MHz÷2700MHz	1kHz AM 80%			
27	380MHz÷390MHz	18Hz PM 50%			
28	430MHz÷470MHz	18Hz PM 50%			
9	704MHz÷787MHz	217Hz PM 50%			
28	800MHz÷960MHz	18Hz PM 50%			
28	1700MHz÷1990MHz	217Hz PM 50%			
28	2400MHz÷2570MHz	217Hz PM 50%			
9	5100MHz÷5800MHz	217Hz PM 50%			

## CONFORMITY LEVEL ACCORDING TO EN 60118-13:2011 STANDARD

TEST LEVEL					
FIELD	MOD.	FREQUENCY			
90V/M	AM 80% 1KHZ	800MHZ-960MHZ			
50V/M	AM 80% 1KHZ	1.4GHZ-2GHZ			
35V/M	AM 80% 1KHZ	2GHZ-2.48GHZ			

#### WARNINGS:

Even if it complies with EN 60601-1-2, the medical device may interfere with other devices in the vicinity. The device should not be used next to or stacked with other equipment. Install the device away from other equipment which radiates high frequencies (short waves, microwaves, electrosurgical units, mobile phones).

The use of this device near to or placed on other appliances should be avoided, as this can lead to its incorrect operation. In these cases, the device and the other equipment should be kept under observation to verify their normal operation.

Transportable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no less than 30 cm (12 inches) away from any part of the [EM EQUIPMENT or EM SYSTEM], including the cables specified by the MANUFACTURER. Otherwise, performance degradation of this equipment may occur".

The device is designed to operate in an electromagnetic environment in which RF radiated disturbances are under control. The customer or the operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of the radio communication devices.

Rated maximum output power	Distance (m) of separation according to the frequency of the transmitter			
of transmitter (W)	from 150kHz to 80MHz $d = 1,2 \sqrt{P}$	from 80MHz to 800MHz $d = 1,2 \sqrt{P}$	from 800MHz to 2.5GHz $d = 2,3 \sqrt{P}$	
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	

For transmitters whose rated maximum output power is not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the rated maximum power transmitter output in Watts (W) according to the transmitter manufacturer.

Notes:

(1) The higher frequency range applies at 80 MHz and 800 MHz.

(2) These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and by the reflection from structures, objects and people.

Ť	Keep in a cool, dry place	MD	Medical Device	<b>J</b>	Temperature limit
×	Keep away from sunlight	$\triangle$	Caution: read instructions (warnings) carefully		Humidity limit
REF	Product code		Manufacturer	(*)•(*)	Atmospheric pressure limit
LOT	Lot number	SN	Serial number	~~	Date of manufacture
×	Type B applied part	CE	Medical Device compliant with Regulation (EU) 2017/745	X	WEEE disposal
8	Follow instructions for use	146 cm BMI≥17	Physical description of an adult	= 170 Kg	Workload safely
<u>○</u> = 135 Kg	Maximum patient weight				

#### Index of Symbols



**Disposal:** The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

#### GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.