

# LETTINI ELETTRICI PER TRATTAMENTI ELECTRIC HEIGHT ADJUSTABLE TREATMENT TABLE

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.



F 27628 - 27632 - 27633 - 27634 - 27635





M27628-M-Rev.3-04.25

#### WARNING

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 treatment, professional massages, diagnostic examinations and patient check-ups. The height of the beds can be adjusted electrically using a foot control. They feature a sturdy white metal painted frame. The backrest can be adjusted manually. Optional accessories: Paper roll holder, Mouth - nose hole plug.

(2)

## **COMPONENTS**

- 1. Padded backrest with manual adjustment
- 2 Padded seat
- 3 Painted metal frame
- 4 Motor kit:
  - A. Linear actuator
  - B. Power adaptor C. Foot control

THE BED IS SUPPLIED READY-ASSEMBLED. ONLY THE FOOT CONTROL **C** NEEDS TO BE CONNECTED TO THE ACTUATOR **A** 

Take care when making the electrical connections. Disconnect the power supply before moving the bed

#### **INSTRUCTIONS**

To adjust the bed, insert the free end of the foot control cable **C** in the actuator port **A**. Then, insert the power cable **B** in the power socket.

Once connected to the power supply, the height of the bed can be adjusted using the foot control: the left pedal (**UP**) raises the bed up while the right pedal (**DOWN**) lowers the bed towards the floor.

#### TECHNICAL DATA SHEET

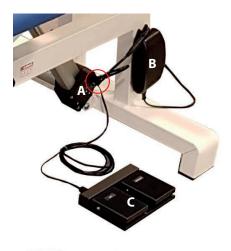
Power supply: 100-240 Vac 50-60 Hz. 1.5 A Measurements: 193 cm x 68 cm x variable h 65-91 cm (box 200x71x70) Weight: 54Kg (with box 63kg) Reclining backrest Max patient weight: 135kg Max safety weight: 170 kg Duty Cycle: 2 min ON / 18min OFF (10%)

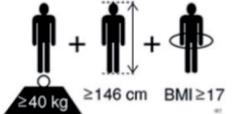
# Conditions of use, storage and transport

**Use:** Temperature 10 - 40°C / Humidity 20-60%/ Atmospheric pressure 98–105kPa / Max Altitude 2000m a.s.l. **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 that the cable cannot get damaged when the motor is running.
- · 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

- · Only use 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, bleaches and chemical cleaners or polishing sprays. N.B.: 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); Interruptions: 250 cycles (50Hz); 300 cycles (60Hz)
<ul> <li>Immunity to rf currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz</li> <li>6V modulation 80% 1kHz for the following frequency ranges:</li> <li>6.765 MHz ÷ 6.795 MHz</li> <li>13.553 MHz ÷13.567 MHz</li> <li>26.957 MHz ÷ 27.283 MHz</li> <li>40.66 MHz ÷ 40.70 MHz</li> </ul>
- 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			
50 V/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.

Portable RF communication devices (including peripherals, such as antenna cables and external antennas) should be used at a distance of no less than 30 cm (12 inches) with respect to any part of the [EM EQUIPMENT or EM SYSTEM], including 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	Distance (m) of separation according to the frequency of the transmitter			
power of transmitter (W)	<b>from 150kHz to 80MHz</b> $d = 1,2 \sqrt{P}$	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	0.1 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.

#### Symbols table

Ť	Keep in a cool, dry place	MD	Medical Device	1	Temperature limit
×	Keep away from sunlight	$\triangle$	Caution: read instructions (warnings) carefully	<u>(%)</u>	Humidity limit
REF	Product code		Manufacturer	\$•\$	Atmospheric pressure limit
LOT	Lot number	SN	Serial number	IP44	Covering Protection rate
Ŕ	Type B applied part	CE	Medical Device compliant with Regulation (EU) 2017/745	X	WEEE disposal
	Follow instructions for use	M	Date of manufacture	146 cm BMI≥17	Physical description of an adult
<u>○□</u> = 135 Kg	Maximum patient weight	<u></u> 170 Kg	Workload safely	UDI	Unique device identifier



**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.