GIOCO

Integrated Hybrid Pressure Relief

G3 & G4
USER MANUAL

11810

Contents

G3 & G4

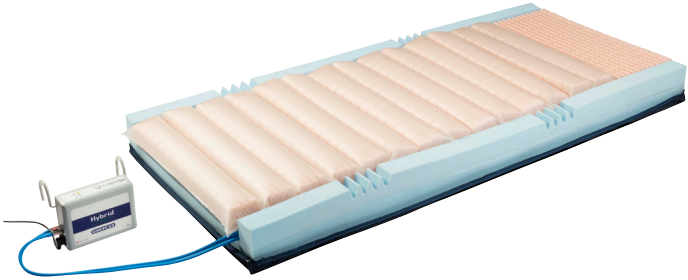
1. Introduction

The Gio-Form Integrated Hybrid Systems use a pressure relieving mattress suitable for patients at VERY HIGH RISK of pressure ulcer damage. Offering high levels of patient comfort, this unique system has the facility to “step up” to that of a dynamic mattress when clinically required. Similarly, the mattress’s function can be downgraded as the patient’s condition improves. These features make it particularly beneficial for use within the patient’s home or palliative care environment and help reduce logistic and decontamination costs.

The clinical benefits of a single system are equally applicable to those of a modern hospital setting. A higher maximum weight capacity, up to 39 stone (250kg), allows the product to meet the modern challenges of those heavier clients. All component parts are interchangeable and replaceable, maximising product life and reducing environmental impact.

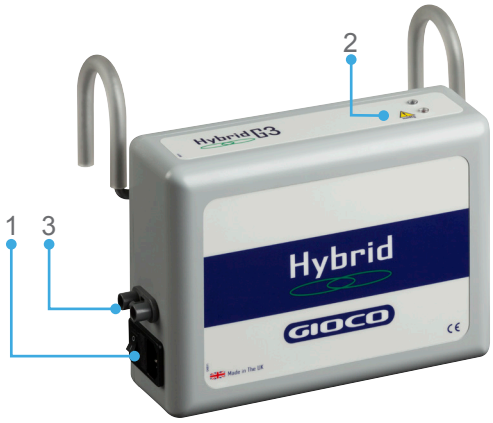
The Mattress consists of a foam head cell and series of 7 pairs of transverse air cells, each containing a unique foam profiled insert, which are in turn held within a foam U Core, all protected by a vapour permeable waterproof cover. The single pillow end consists of foam only. The transverse cells are arranged into alternate pairs of A and B cells which are filled and emptied in sequence.

When used without a pump, the mattress attains the pressure reducing properties of the Gio-Form Care Foam mattress (details available on request), whilst in alternating mode the mattress is able to offer similar properties to a pressure relieving dynamic system. It also maintains the air pressure within the mattress at the required level and controls the action of the audible/visual Audible Warning system in the event of mains supply failure or over or under inflation pressure. A CPR Valve located at the pump end of the umbilical hose permits the rapid deflation of the Mattress in an emergency.



2. Description of Controls

2.1. G3 Pump Controls



1. Power Switch (audible warning reset)

The power switch simply switches the mains power to the pump on and off. When the pump detects an audible warning condition, this can be silenced and reset by switching the pump off and then back on again.

2. LED Indicators

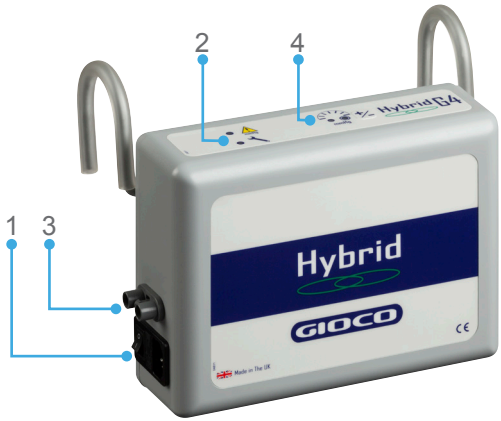
The top LED indicates the system power is turned ‘on’.

The yellow warning triangle indicates a pressure issue in the mattress. Refer to Section 3 for more information.

3. CPR Valve

Please ensure that the CPR connector is always placed fully home, prior to inflating the mattress. The mattress will NOT inflate properly should this not be the case. The CPR connector is only to be used in the event of a clinical emergency for priority use. However, disconnecting this function will cleverly deflate air rapidly from the mattress in readiness for transport / static mode.

2.1. G4 Pump Controls



1. Power Switch (audible warning reset)

The power switch simply switches the mains power to the pump on and off. When the pump detects an audible warning condition, this can be silenced and reset by switching the pump off and then back on again.

2. LED Indicators

The yellow warning triangle indicates a pressure issue in the mattress. Refer to Section 3 for more information.

The spanner symbol indicates a system fault. Please contact the supplier for more information.

3. CPR Valve

Please ensure that the CPR connector is always placed fully home, prior to inflating the mattress. The mattress will NOT inflate properly should this not be the case. The CPR connector is only to be used in the event of a clinical emergency for priority use. However, disconnecting this function will cleverly deflate air rapidly from the mattress in readiness for transport / static mode.

4. Pressure Settings

The +/- button is used to adjust pressure from low to high pressure. The left hand LED denotes low pressure. The right hand LED denoted high pressure.

3. Warning Modes

3.1. G3 Warnings

There is one LED which informs the user of potential problems with the mattress system.

The yellow warning triangle indicates a pressure issue in the mattress.

Low Pressure Alarm: The red LED will flash slowly whilst an audible alarm sounds. Check all hose connections for leaks.

High Pressure Alarm: The red LED will flash rapidly whilst an audible alarm sounds.

3.2. G4 Warnings

There are two red LED's which inform the user of potential problems with the mattress system.

The yellow warning triangle indicates a pressure issue in the mattress.

Low Pressure Alarm: The red LED will flash slowly whilst an audible alarm sounds. Check all hose connections for leaks.

High Pressure Alarm: The red LED will flash rapidly whilst an audible alarm sounds.

The spanner symbol indicates a system fault.

3.3. Audible Warnings

Audible warning conditions are indicated by flashing LED's accompanied by an alarm sound. In each case the user should respond by turning the power units switch off and investigating the cause.

High Pressure Audible Warning: This condition could be caused, for example, by a kinked umbilical hose or visitors, and others, sitting suddenly on the mattress.

Low Pressure Audible Warning: This may be triggered by, for example, incorrect fitting of the air inlet connector, opening of the CPR Valve or a leak in the Mattress due to a cut or puncture.

4.1. Power Unit (Pump)

Hang the Power Unit (Pump) onto the foot board. The mounting hooks are designed to suit the thickness of the foot boards or rails. Connecting the Umbilical Hose to the Power Unit (Pump), place the electrical plug into the wall outlet and switch on:

Attach the Blue Umbilical Hose to the Power Unit (Pump) by connecting the air connector at the end of the Umbilical Hose to the air inlet connector at the bottom left hand side of the pump. Ensure that the Red CPR Release Label is located on to Air Inlet connector so as can be easily read by user.

To shut down the pump, firstly REMOVE the patient from the mattress then switch the unit 'off'.

4. Operation

Attach the mains cable to the pump by inserting the "kettle" type connector into the recess located on the left hand side of the pump. The mains cable has been designed specifically as a removable part to aid easy replacement should it become damaged in use. The mains plug should be turned off and removed from wall socket as a means of isolation. Plug the mains cable into a suitable 230v mains socket and switch on the Power Unit using the on/off switch. After 'power on' the system will begin to reach operating pressure, this can take up to 30mins. The low pressure alarm may be activated during this period.

G3: Once the system has attained its initial operating pressure only the singular LED will be illuminated unless there is an error with the system. (See section 3)

G4: Once the system has attained its initial operating pressure only the low or high pressure should be illuminated unless there is an error with the system. (See section 3)

DO NOT PLACE PATIENT ON MATTRESS UNTIL UP TO OPERATING PRESSURE.

4.1. Pressure Settings

The G4 system has variable system pressure. To cycle between high an low pressure the user should press the '+/-' button. The left LED indicates the low pressure setting and the right LED indicates the high pressure setting is selected.

4.2. CPR Deflation

The CPR system consists of a manually operated button located on the Air Inlet connector attached to the pump. By pressing the Red Button to release the connectors locking mechanism, the user can remove the connector unit which will deflate the mattress system back to that of a static foam mattress.

Note: After a short period as the Mattress deflates the 'Low Pressure' Audible Warning is activated within the pump, this can be reset by switching the Power Unit off.

4.3. Troubleshooting

For assistance (if needed) in setting up, using or maintaining the Gioco G3 or G4 system, or to report unexpected operation or events, please contact Gioco Ltd. using the contact details on the reverse of this manual.

5. Transportation

To change the location of the mattress, disconnect the Umbilical cord from the pump unit and allow the mattress to return to its Static Mattress form. Switch off the Power Unit (Pump) using the On/Off switch and disconnect the electrical supply cable from the mains socket. The mattress can now be moved to a new location where it must immediately be reconnected to the mains electrical supply and the Power Unit (Pump) switched back on.

DO NOT PLACE PATIENT ON MATTRESS UNTIL UP TO OPERATING PRESSURE.

6. Audible / Visual Warnings

Audible / Visual Warning conditions are indicated by a flashing red display accompanied by an audible warning. In each case the user should respond by turning the Power Unit's switch off and investigating the cause.

6.1. High Pressure Warning

If the system pressure exceeds 100mmHg this warning will be activated. This may be triggered by, for example, a kinked Umbilical Hose or another person suddenly sitting on the Mattress.

6.2. Low Pressure Warning

If the system pressure falls below 15mmHg this warning will be activated. This may be triggered by, for example, incorrect fitting of the air inlet connector, opening of the CPR Valve or a leak in the Mattress due to a cut or puncture.

6.3. Mains Failure Warning

If mains power is lost then all LED lights will turn off. In such an event, the Mains Failure audible warning will sound and the Mains Failure LED will light up.

7. Maintenance Procedures

7.1. Safety Warning

Only qualified technicians trained or formally approved by Gioco Ltd. in the operation and maintenance of Gioco products may carry out maintenance, modification or repair work on the equipment. Unqualified personnel attempting to work on Gioco Power Units risk serious injury to themselves and others and possibly death by electrocution. Inlet fuse **NOT** to be replaced by operator or patient, to be replaced by service personnel **ONLY**.

Warning: Do not modify this equipment without authorisation from Gioco Ltd.

7.1.1 Servicing

Gioco Ltd. recommend that the Power Unit (Pump) should be serviced every year. The unit contains no user serviceable parts and should only be carried out by persons as described in section 8.1. Gioco will make available on request service manuals, component parts lists and other information necessary for any suitably qualified person (as in 8.1) to carry out repair or service the system. For Service, maintenance and any questions regarding any part of this system please contact Gioco Ltd.

7.2. Cleaning Procedures

Warning: Before cleaning the system make sure that the Power Unit (Pump) is disconnected from the mains electricity supply.

Do not immerse the Power Unit (Pump) in water or other fluids.

Do not autoclave, nor use phenol for cleaning.

Do wash hands before commencing the cleaning process.

Do wear appropriate protective clothing such as gloves, apron and a mask.

Do ensure all work surfaces are cleaned before and after contact with the mattress.

7.3. Warning – Cleaning the Power Unit (Pump)

The Power Unit can be cleaned by wiping with a cloth dampened with a detergent solution or Hypochlorite solution.
Also refer to symbol chart.

7.3.1 Warning

Ensure the Gio-Form Hybrid G3 + G4 System is not exposed to:

1. Excessive heat sources *e.g. fires, radiators etc*

2. Water, particularly immersion of the pump.

7.4. Warning – Cleaning the Mattress

1. Cleaning should take place after use or between patients.

2. With cover left on the Mattress disconnect the Mattress from the Power Unit (Pump).

3. Clean the surface of the wash down table with Hypochlorite solution or equivalent disinfectant.

4. Wash Mattress top using hot water (60 degrees C) containing detergent, then dry with a paper towel.

5. For heavy contamination use a Hypochlorite solution 1,000 parts per million available chlorine.

6. Using suitable brush, hot water, detergent or Hypochlorite solution, clean Umbilical Hose and CPR Valve. Dry with paper towel.

7. If required, the Mattress Cover may be removed and machine washed at a temperature of 80 degrees C, for no less than 10 minutes. The individual Air Cells can be wiped down with established disinfectants.

8. To avoid shrinkage of the cover line dry in an indoor clean environment or tumble dry on a low heat setting not exceeding 40 degrees C and for no longer than 10 minutes. Covers must be thoroughly dried before re-fitting to the mattress.

8. Technical data

9.1. Power Unit (Pump)	
Serial Number	As per label on rear of pump
Electrical Supply	220-240 volt, 50 Hz
Power Consumption	10 watts
Fuses	TA1H 250V
Protection against shock	Class 2
Noise Level	Approx. 25 dB (A)
Dimensions	235 x 180 x 80 mm
Weight	1.7 kg
Service Interval	12 months
Expected life	5 years
Shelf life of parts	5 years
Warranty (If serviced annually by Gioco Ltd)	5 years

9.2 Mattress	
Serial Number	Label on inside of mattress cover
Number of Air Cells	7 pairs of hybrid air cells
Dimensions	2000 x 900 x 150mm (Nominal)
Weight	14kg
Expected life of Mattress	5 years
Shelf life of Mattress parts	5 years

9. List of Accessories

G3 Mattress
G3 Pump Unit
G4 Mattress
G4 Pump Unit

EMC GUIDANCE AND DECLARATION

This guidance and manufacturer's declaration pertains to the Gioco range of pressure relief equipment which is listed at the back of this User Manual.

EMC Compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2007.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behaviour of medical electrical equipment.

The Hybrid G3 + G4 pump units comply with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate Hybrid G3 + G4 pumps in the presence of high-frequency surgical equipment.
- It is good practice to avoid using Hybrid G3 + G4 pumps in extremely close proximity to other equipment.

Electromagnetic Emissions

The Pulse Press range of pumps are intended for use in the electromagnetic environment explained below. The user should assure that they are used in such an environment.

Emissions test	Compliance	Environment guidance
RF emissions CISPR 11	Group 1	Pumps emissions are very low and unlikely to cause interference.
RF emissions CISPR 11	Class B	Pumps are intended for use by medical professionals only.
Harmonic Emissions EN 61000-3-2	Class B	If this equipment causes inference to near by devices then try to relocate or re-orient the device.
Voltage Fluctuations EN 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

The Hybrid G3 + G4 pump are intended for use in the electromagnetic environment explained below. The user should assure that they are used in such an environment.

Immunity test	**60601 Test**	**Compliance**	**Environment guidance**
Electrostatic discharge IEC 61000-4-2	+/- 4kV Contact +/- 8kV Air	+/- 4kV Contact +/- 8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV power supply lines +/- 1kV input output lines	+/- 2kV power supply lines +/- 1kV input output lines	Mains power quality should be that of a typical commercial or hospital.
Voltage Surge IEC 61000-4-5	+/- 2kV common mode +/- 1kV differential mode	+/- 2kV common mode +/- 1kV differential mode	Mains power quality should be that of a typical commercial or hospital. environment
Voltage Dips and Interruptions IEC 61000-4-11	30% Dip 25 cycle 60% Dip 5 cycle 100% Dip 0.5 cycle 100% Dip 250 cycle	30% Dip 25 cycle 60% Dip 5 cycle >95% Dip 0.5 cycle >95% Dip 250 cycle	Mains power quality should be that of a typical commercial or hospital. environment
Recommended Separation Distance			
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	d=(1.17) $\sqrt{P}$ 0.15 to 80MHz
Radiated RF	3 V/m	3 V/m	d=(1.17) $\sqrt{P}$ 80 to 800MHz
			d=(2.33) $\sqrt{P}$ 0.8 to 2.5GHz

Rated output power P of transmitter in Watts	**150kHz to 80MHz** d=1.17 $\sqrt{P}$	**80Mhz to 800 Mhz** d=1.17$\sqrt{P}$	**800MHz to 2.5 Ghz** d=2.33$\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.4
100	11.7	11.7	23.3

The device is intended for use in an electromagnetic environment in which the HF disturbances are controlled. The user can contribute to the avoidance of electromagnetic disturbances by adhering to the minimum distance required between portable and mobile HF telecommunications equipment (transmitters) and the device – depending on the output power of the communications device, as indicated below.
For transmitters whose maximum output power is not indicated in the above table, the recommended safety distance in meters (m) can be determined by using the formula that belongs to the same column, with P being the maximum output power rating of the transmitter in watts (W) according to the manufacturer's specifications.

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