COMFORT FIXED HEIGHT

USER MANUAL









INTRODUCTION

COPYRIGHT

This user manual is supplied with the purchase of a bath and is intended to provide information on its correct and safe use. Copying it for these purposes is only permitted if it is copied in its entirety to ensure all the pertinent health and safety related information along with the user information is retained together as a whole. Copying part of the manual for the purposes detailed above is not permitted under any circumstances © 2024.

Gainsborough Healthcare Group Ltd., 10 & 11, The Oaks, Clews Rd, Redditch, England B98 7ST.



Contact: Gainsborough Healthcare Group 01527 400022

PREFACE

Additional reading and related information can be obtained upon request, including Circuit Diagrams, Component Parts Lists, Descriptions, Calibration Instructions, and other information that will assist service personnel.

If an alternative format of this or any other documentation is required, please contact your authorised representative or **Gainsborough Healthcare Group Ltd.** on 01527 400022.

INTENDED USE

This equipment is intended to facilitate the bathing of residents in care facilities or in a home care environment. The product is designed to help people who struggle with getting in and out of a bath, especially those with physical limitations. It's useful for both hygiene and relaxation purposes.

The bather sits on a low-positioned seat outside the bath, which is already filled with water. Then, operated by the bath handset, the motorised mechanism lifts the seat vertically. When the mechanism reaches its highest point, it rotates the seat until it's directly over the bathtub. This way, the user can enjoy their bath comfortably and easily.

RECYCLING

The following materials are used in the manufacture of the bath. Separate the materials and dispose of them at a recycling centre in line with your local authority's recommendations.

- Metal and Acrylonitrile Butadiene Styrene (ABS) plastic
- Packaging: Wood, Cardboard and Plastics
- Glass Reinforced Plastic (GRP) and Wood
- Batteries and other Electrical Components as applicable

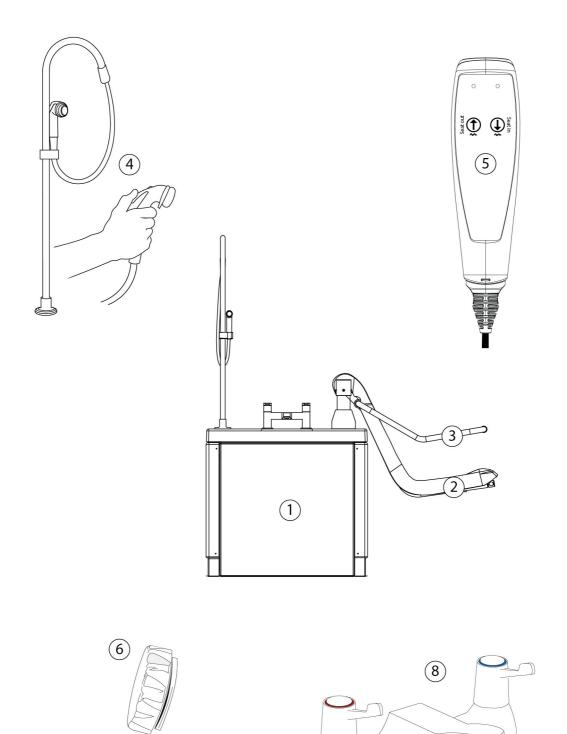
FUTURE PRODUCT DEVELOPMENT

Gainsborough Healthcare Group Ltd operates a policy of continuous product development and reserves the right to change specifications and designs without prior notice.

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BATH AND EQUIPMENT OVERVIEW





Key: Refer to Fig 0448

- I Fixed height bath
- 2 Powered seat
- 3 Arms moveable
- 4 Shepherd's Crook shower system
- 5 Remote handset
- 6 Pop-up waste release
- 7 Pop-up waste
- 8 Twin lever bath filler

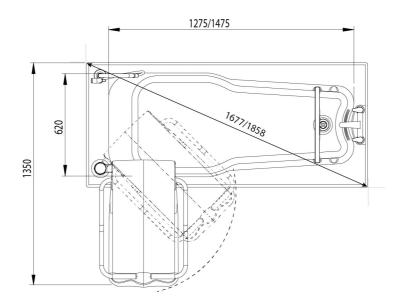
SPECIFICATIONS AND DIMENSIONS

SPECIFICATIONS

Maximum User Weight:	165kg
Water Capacity:	1500mm - 200 litres, 1700mm - 230 litres
Approximate Bath Weight (empty):	1500mm - 115kg, 1700mm - 119kg
Approximate Bath Weight (full):	1500mm - 315kg, 1700mm - 349kg
Typical Mechanical Operation Times:	Seat - 232secs/cycle
Class I Electrical Device	
Power Supply:	Mains 230V to be supplied via 30mA RCD
Operating Voltage:	24V
Battery Backup:	24V DC (lead acid), for emergency use only
Actuator Duty Cycle:	Max. 10% or 2min continuous use followed by 18min not in use The life cycle test has been performed with a stabilised power supply (10% duty cycle) on a 20mm stroke actuator at max. load for 10,000 cycles at ambient temperature.
Water Supply:	Unblended hot and cold water at Ibar min., 3.5bar max. pressure
Hot Water Temperature:	55°C to 65°C
Cold Water Temperature:	5°C to 20°C
Flow Rate:	10 litres per minute
'A' weighted sound emission:	<60dB(A)
Ambient temperature range:	5°C to 50°C
Relative humidity range:	10-80%
Atmospheric pressure range:	50kPa to 106kPa

DIMENSIONS

Comfort Fixed Height 1500 and 1700mm



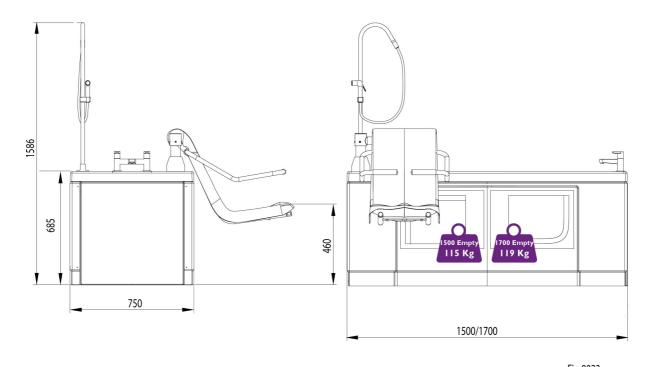


Fig 0023

Dimensions in millimetres (mm). Right-hand example (handing of a bath is indicated by the exit point of the bath when in a seated position).

SAFETY INFORMATION



WARNING RISK OF ELECTROCUTION/FIRE/ENTRAPMENT:

Modifying the bath/equipment could cause serious injury or prove fatal. Under **NO CIRCUMSTANCES** should you modify the bath/equipment.

Your bath, supplied by the **Gainsborough Healthcare Group Ltd.**, is part of a range of products designed and built for bathers in care homes, hospitals and other specialist care environments.

Please ensure that you read and thoroughly understand this user manual. This information is vital for the correct operation of the bath, ensuring the safety of both bather and operator at all times.

Please use this bath in the manner specified in this manual. **Gainsborough Healthcare Group Ltd.** do not take any liability if the product is misused.

To ensure best practice and safety the bath must be operated only by a trained professional with adequate understanding of the specific environment, its common practices and processes. It is vital that regular assessments of the bather are undertaken to ensure the bath remains suitable. **Gainsborough Healthcare Group Ltd.** does not take responsibility for individual product suitability. This is the duty of the care facility.

Any detachable parts must be used as described in this user manual and must not be modified or used with other equipment not specified in this user manual.

This bath is for hygiene and relaxation purposes only. DO NOT use for any other purpose.

To avoid entrapment, make sure that the path of movement is free from obstacles. Make sure the bather retains a comfortable and safe position. To avoid injury, do not leave the bather at any time. **Gainsborough Healthcare Group Ltd.** does take any liability if misused in this manner.

Any modifications to the bath or significant changes to its surrounding environment and installation may affect important safety and performance related functions. **Gainsborough Healthcare Group Ltd.** is not responsible for any safety incidents or functional performance issues arising as a result of any modifications that have not been approved in advance by **Gainsborough Healthcare Group Ltd**.



If you have any questions regarding the user manual or operation of the bath, feel free to contact your authorised representative or **Gainsborough Healthcare Group Ltd.** on 01527 400022.

PURPOSES OF WARNINGS, CAUTIONS AND NOTES

Warnings, Cautions and notes used throughout this manual have the following meanings:



WARNINGS: Warnings used throughout this manual **MUST** be followed carefully failure to do so, could result in serious bodily injury or could be fatal.



CAUTIONS: Cautions used throughout this manual **MUST** be observed to avoid damage to your bath.



NOTES: Notes used throughout this manual contain important information and useful tips on the operation of this product.

HEALTH AND SAFETY WARNINGS

The following warnings and any additional warnings used throughout this manual **MUST** be followed carefully failure to do so, could result in serious bodily injury or could be fatal.



WARNING RISK OF ENTRAPMENT: Operating the bath without appropriate training in its safe use could cause serious injury or be fatal by entrapment. Ensure persons operating the seat have been trained, read this manual and understand its safe use.



WARNING RISK OF ENTRAPMENT: Operating the bath when people are nearby could cause serious injury or be fatal by entrapment. Ensure nobody is close to moving equipment during its operation.



WARNING RISK OF ELECTRIC SHOCK: Using electrical appliances near to the bath could cause electric shock which may be fatal. **DO NOT** use electrical appliances within 3 metres of the bath.



WARNING RISK OF ELECTRIC SHOCK: Inappropriate wiring can cause an electric shock which may be fatal. Ensure the bath is installed by a qualified electrician using current legislation, the equipment must only be connected to a supply main with protective earth.



WARNING RISK OF SLIPPING: Water left on the floor could cause serious injury or be fatal by slipping. Ensure the floor area around the bath is always free from water. Clean and dry **ANY** spillages immediately.

HEALTH AND SAFETY CAUTIONS

The following cautions and any additional cautions used throughout this manual **MUST** be observed to avoid damage to your bath.



CAUTION: Bath could be damaged, which may be irreparable, if objects/ equipment is trapped during operation. Ensure there are no objects/equipment left under the seat that could become trapped.



CAUTION: Remote handset could be damaged which may be irreparable. Ensure the remote handset is **ALWAYS** returned to its holder after use.



CAUTION: The bath and any additional equipment could be damaged if used for anything other than its intended use, which may be irreparable. **NEVER** use the bath for anything other than its intended use.



CAUTION: The bath and any additional equipment could be damaged, which may be irreparable, if abrasive cleaners, bleach or scourers are used. Use cleaning methods outlined in the Maintenance and Cleaning section only.



CAUTION: Do not exert excessive pressure on the bath panels as this may cause them to become ill-fitting or damaged over time.

HEALTH AND SAFETY NOTES

The following notes and any additional notes used throughout this manual contain important information and useful tips on the operation of this product.



NOTE: The system batteries must be charged for 24 hours prior to using the bath. You may test the bath seat operation empty to ensure it is working correctly.



NOTE: If this unit is to be utilised by many different bathers, we would strongly recommend that it is cleaned regularly with a medical disinfectant as well as following the strict cleaning routine outlined in the Maintenance and Cleaning section.



NOTE: In the event of mains failure during use of the bath, back-up batteries will enable the bather to exit the bath. The bath seat will then be disabled until mains power is restored.



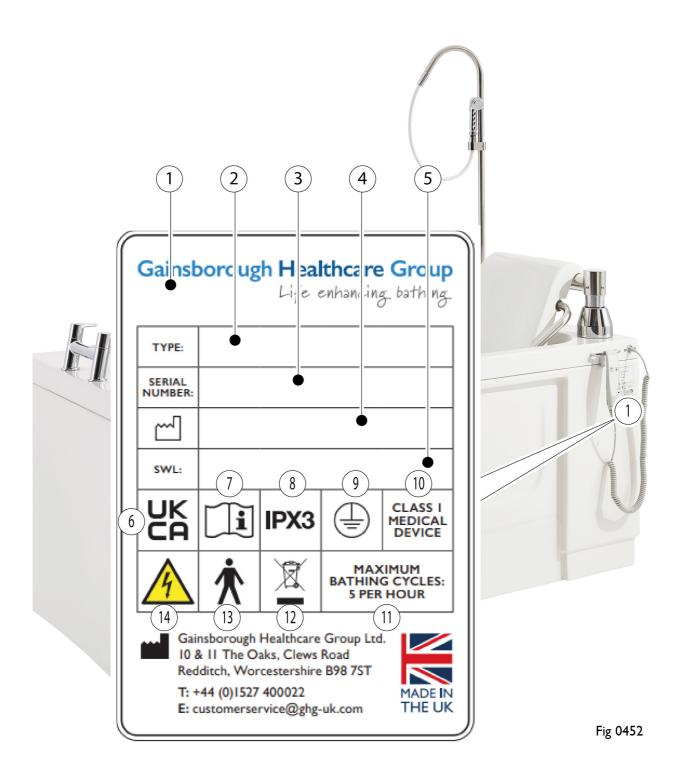
NOTE: If any serious incident occurs in relation to the device this should be reported to the manufacturer and the competent authority in which the user and/ or patient is established.



NOTE: Expected lifetime of this product is 8 years and approximately 5 years for the battery back-up system, when adhering to our service and maintenance guidelines.

VERSION 1.4 ~ 06.24

LABELS



IDENTIFICATION LABEL



NOTE: The Identification label attached to your bath contains critical information! **DO NOT** remove it from its location. The serial number is required for maintenance, information or spare parts. It is recommended that you make a note of it below for future reference.

KEY (Refer to Fig 0452)

- I Identification label and its location
- 2 Type of bath this user manual refers to
- 3 Unique identification number (this is needed for maintenance, information or spares)

Serial Number:

- 4 Manufacturing location
- 5 The Safe Working Load
- 6 UK Conformity Assessed marking
- 7 Read instruction manuals and accompanying documents
- 8 Ingress Protection (IP) rating (Protected against direct moisture spray at an angle of 60° from the vertical)
- 9 Type of protection: Class I
- 10 Class I medical device
- II Maximum number of baths allowed per hour
- No domestic waste. Separate electrical and electronic components for recycling in accordance with European Directive 2012/19/EU (WEEE)
- 13 Application part 'Type B' according to DIN EN 60601-1
- 14 This product is powered. Warning dangerous voltage

USER INFORMATION

The following steps are a pre-requisite before using the bath in **ANY** capacity.

- I. Read the entire user manual.
- 2. Ensure you have received appropriate training in its safe and proper use for the bath (this should be done following installation hand over).
- 3. Ensure the bath back up batteries have been fully charged for a minimum of 24 hours prior to use.
- 4. Inspect the bath for any cracks or damage.
- 5. Test the bath and all safety devices/equipment (empty without a bather) prior to its first use and periodically afterwards in line with the maintenance recommendations, see <u>maintenance and cleaning, page 22</u>.
- 6. Operate the **Seat out** function. The seat should raise up to its maximum height, turn outside the bath and lower without excessive noise.
- 7. Operate the **Seat in** function. The seat should raise up to its maximum height, turn inside the bath and lower without excessive noise.



If you are in any doubt or you cannot answer yes to **ALL** the above steps, then seek advice from your authorised representative or contact **Gainsborough Healthcare Group Ltd.** on 01527 400022.

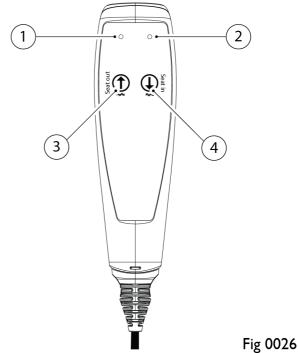
REMOTE HANDSET



CAUTION: If submerged in water, the remote handset could be damaged irreparably. Ensure the remote handset is **ALWAYS** returned to its holder after use.

The remote handset has two control buttons and two LEDs as shown in Fig 0026 and is located in the holder on the side of the bath.

- LED illuminates to indicate that mains power is supplied (1).
- LED flashes when mains power is lost (2).
- Positions seat outside of the bath (3).
- Positions seat inside of the bath (4).
- I. To operate either of the buttons, press lightly and hold. Releasing it at any time will stop the operation.
- 2. Operations automatically stop once they have reached their maximum extent; when the seat is fully inside the bath, for example.
- 3. It is completely safe to operate the handset with wet hands, but it should never be immersed in water, so always return to the holder after use.





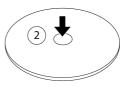
NOTE: In the event of a power cut, the system is protected by Battery Back-Up, so the user can still safely exit the bath. In Battery Back-Up mode, the seat will operate at half speed. When the Battery Back-Up begins to lose power, there is an audible beep each time a button is pressed on the handset.

CLOSE THE POP-UP WASTE

The bath comes with a pop-up waste as standard.

I. Refer to Fig 0196. Turn the chrome handle (I) anti-clockwise and the pop-up waste plug (2) closes.





FILL THE BATH

Fig 0196



WARNING RISK OF SCALDING: Not checking the water temperature could cause serious injury or be fatal. The temperature of the hot water is limited to 43°C for safety. Use a thermometer to observe the temperature whilst filling and again before transferring the bather into the bath.

- 1. Fig 0442 shows the twin lever bath filler (1).
- 2. Open the hot tap (2) and fill the bath to half full, checking the temperature with a thermometer.
- 3. Where necessary adjust the temperature using the cold tap (4). The bath is now ready for the bather.

Topping up the bath will be carried out when the bather is in position. This aids the carer to observe the depth of water.

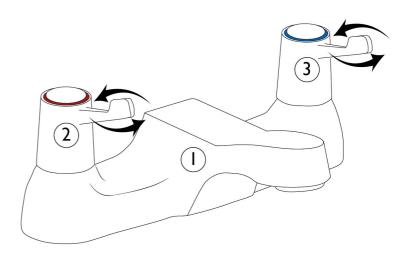


Fig 0442



CAUTION: Do not exert excessive pressure on the bath panels as this may cause them to become ill-fitting or damaged over time.

TRANSFER BATHER INTO THE BATH



NOTE: The arms lift to allow easier access for the bather.



CAUTION: DO NOT attempt to use this equipment if you have not been fully trained. Escalate to your local representative or contact Gainsborough Healthcare Group Ltd. on 01527 400022 and ask about product training sessions.



WARNING RISK OF ENTRAPMENT: Operating this bath/equipment when the bather is unsecured/unattended could cause serious injury or be fatal by entrapment. Ensure the bather is **NOT** left unattended and is seated properly with the safety lap strap **ALWAYS** secured.

1. Refer to Fig 0428. Allow or assist the bather to transfer onto the seat. The safety lap strap should be clipped securely around them and the arm rests should be down with the bather holding the handle grips. The bather's arms and legs should be positioned securely within the seat.

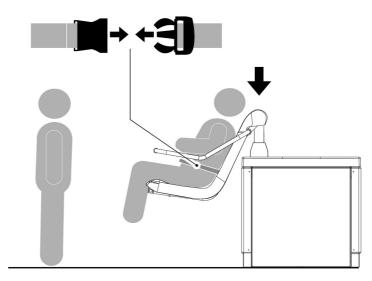


Fig 0428

2. Observe the bather at all times. Press the Seat in button and the seat will start to lift. Please see <u>remote</u> handset, page 16 for details. The seat may be stopped at any time by releasing the button.

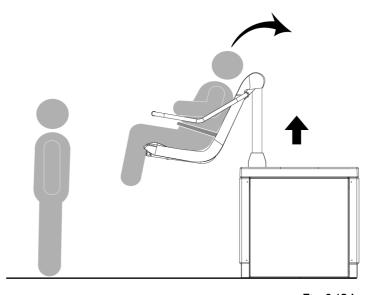


Fig 043 I



WARNING RISK OF ENTRAPMENT: Ensure that the bather is able to lift their legs over the edge of the bath whilst the seat is being moved into position. If they are unable to do this themselves, then they must be assisted in doing so to avoid potential serious injury by entrapment.

- 3. Continuing to press the Seat in button, the seat will now raise to its maximum height and will turn into position over the bath.
- 4. Continue to press the Seat in button until the operation is complete and the bather is in the bath.

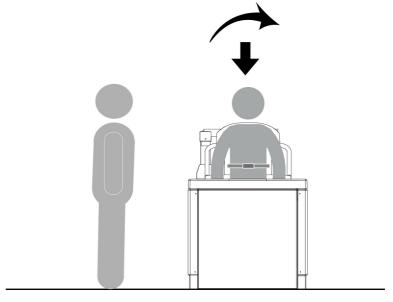


Fig 0423



CAUTION: Do not exert excessive pressure on the bath panels as this may cause them to become ill-fitting or damaged over time.

SHEPHERD'S CROOK SHOWER

The shower system operates as follows:

- I. As shown in Fig 0020, remove the shower head (I) from the holder and turn the shower control (2) anticlockwise fully. The temperature on the shower valve is controlled by a thermostatic valve and is factory set at 38°C for safety.
- 2. With the shower head directed into the bath, press the trigger spray (3) on the shower head to release the water. Check the temperature is safe with a thermometer and by hand. Release the trigger at any time to stop the water.
- 3. When showering is complete, turn shower control clockwise fully.
- 4. Press the trigger spray to depressurise the shower and return the shower head to its holder.

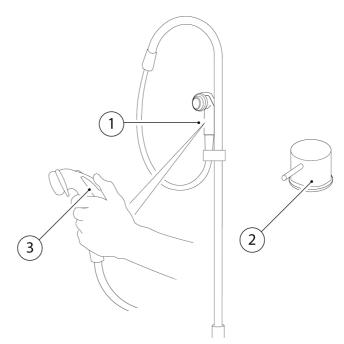


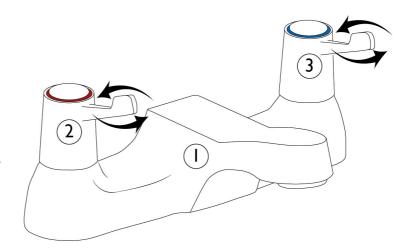
Fig 0020

TOP UP THE BATH



WARNING RISK OF SCALDING: Not checking the water temperature could cause serious injury or be fatal. The temperature of the hot water is limited to 43°C for safety. Use a thermometer to observe the temperature whilst filling and again before transferring the bather into the bath.

- 1. Fig 0442 shows the twin lever bath filler (1).
- 2. Whilst observing the bather, open the hot tap (3) and top up the bath checking the temperature with a thermometer.
- 3. Where necessary adjust the temperature using the cold tap (4).



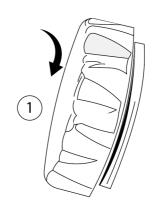
TRANSFER BATHER OUT OF THE BATH

- I. Ensure the bather is positioned in the seat with the safety lap strap fitted and the seat arms in the lowered position. The bather's arms and legs should be positioned securely within the seat.
- 2. Observe the bather during all operations. Press the Seat out button (3). Please see <u>remote</u> <u>handset, page 16</u> for further details. The seat may be stopped at any time by releasing the button.
- 3. This operation will raise the seat out of the bath to its maximum height. The seat will then turn out and lower the bather outside the bath.
- 4. Raise the seat arms, release the safety lap strap and the bather can then exit the seat.

EMPTY THE BATH

The bath comes with a pop-up waste as standard.

I. Refer to Fig 0438. Open the pop-up waste by turning the chrome handle (I) clockwise. The waste plug (2) then opens to drain the bath.



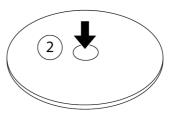


Fig 0438

MAINTENANCE AND CLEANING



CAUTION: The bath and any additional equipment could become damaged or wear prematurely if thorough, regular, cleaning and maintenance is not carried out. Contact bath supplier for clarification or additional assistance if required.



NOTE: Ensure your bath is cleaned, serviced and maintained regularly. Maintenance and cleaning information is provided for maintenance staff employed to look after the bath equipment supplied.



Contact: Please ask for details of the of Gainsborough Healthcare Group Ltd. Service and Maintenance Agreement on 01527 400022.

It is of the utmost importance to follow the Health and Safety information (see <u>safety information</u>, <u>page 9</u>), before carrying out any cleaning or maintenance procedures. The following routines are a minimum requirement. Where a high volume of use occurs, increase the frequency as appropriate.

In addition to the maintenance and cleaning requirements detailed here, it is the responsibility of the equipment operator/provider, under the Provision and Use of Work Equipment Regulations 1998 (PUWER) to ensure, where applicable, that periodic Lifting Operations and Lifting Equipment Regulations (LOLER) testing is undertaken.

DAILY

Routine	Method
Visual inspection (before use)	 Inspect the bath for broken equipment, leaks or any general issues
Seat operation	 Use the handset to take the seat through a full cycle of motion, both into and out of the bath
Minor clean (after use)	 Wipe bath whilst draining with a soft damp cloth, clean with disinfectant and wipe dry

WEEKLY

Routine	Method
Major clean (after use)	 Use cleaning mousse/washing-up liquid/warm water and a soft cloth, stubborn stains may require a non-scratch liquid cleaner, disinfect and wipe dry
Inspect handset/cable	 Inspect handset and cable for ANY signs of damage
Check water temperature	 Using a calibrated thermometer operate the hot tap and check the water temperature does NOT exceed 43°C

MONTHLY

Routine	Method
Remove Lyme/Calcium deposits	 Water stain deposits or minor scratches may be removed using a mild cutting fluid such as T-Cut or Brasso
Inspect cables	 Check there are no loose/damaged/frayed cables
Check for leaks	 Check water, waste pipes and all plumbing connections for leaks
Check remote handset operation	 Operate ALL bath controls ensuring all operations are as expected and free from unusual noises see <u>remote handset</u>, <u>page</u> <u>16</u>
Test RCD	 Operate the Residual Circuit Breaker (RCD) press the test button and reset
Inspect Shepherd's Crook shower	 Ensure the shower pole is fixed/secure and vertical, inspect hose, trigger operation hanger and control see <u>shepherd's crook</u> <u>shower, page 20</u>

SIX MONTHLY

Routine	Method
Visual inspection	 Visually inspect bath ensure there is NO damage
Panel inspection	 Check all external bath panels are secure with all screws/ fixings in place
Inspect waste pipes	 Ensure ALL waste fitting are secure free from leaks and drain efficiently

ANNUALLY

ANNOALLI		
Routine	Method	
Servicing	 Servicing by Gainsborough Healthcare Group Ltd or a trained approved company with guidance 	

It is of the utmost importance to follow the Health and Safety information (see <u>safety information</u>, <u>page 9</u>), before carrying out any cleaning or maintenance procedures. The following is a typical schedule for the average user. Where a high volume of use occurs, increase the frequency as appropriate.

Maintenance Schedule Minimum Frequency	Day	Week	Month	6 Month	Year
Visual inspection (before use)	Х				
Seat operation	Х				
Minor clean (after use)	Х				
Major clean (after use)		Х			
Inspect handset/cable		Х			
Check water temperature		Х			
Remove Lyme/Calcium deposits			Х		
Inspect cables			Х		
Check for leaks			Х		
Check remote handset operation			Х		
Test RCD			Х		
Inspect Shepherd's Crook shower			Х		
Visual inspection				Х	
Panel inspection				Х	
Inspect waste pipes				Х	
Servicing					Х

TROUBLESHOOTING

The following is a basic troubleshooting guide in the event of failure, it is not intended as a comprehensive diagnostic routine. If the bath or equipment fail to operate as intended following these basic checks, please contact your authorised representative or a **Gainsborough Healthcare Group Ltd.** service support engineer on 01527 400022.

PROBLEM	POSSIBLE CAUSE	
	 Mains power supply failure - the top right LED on the handset will flash in this case 	
Bath Inoperative	 Check condition of handset cord and it is securely connected to the bath 	
	 Check 5 Amp fused spur (fuse) 	
	 Check Residual Current Device (RCD) has power and has not tripped 	
	Check there are no obstructions on or around the bath	
Bath Judders	Check bath fixings are secure	
	Check bath is level	
	Check there are no obstructions on or around the seat	
Bath Noisy	 Check if pipework, cables or anything else is obstructing the seat during operation 	
	Visually inspect for bath damage	
Water Leaking/Less	 Inspect flexi-hoses pipework 	
Water Leaking/Loss	Inspect hot and cold supply pipework	
	Inspect waste pipework	
Bath Uneven	Check bath is level - adjust feet as appropriate	
Seat Operating At Half Speed	 Bath mains power supply failure - if so the top right LED on the handset will flash - check power is supplied - check fused spur (fuse) 	
Items Visibly Damaged	 Any obviously damaged items should be reported and decommissioned immediately 	
Audible Beep When	Battery Back-Up is running low	
Operating Handset	 Bath mains power supply failure - check power is supplied check fused spur (fuse) 	

WARRANTY

For information on the warranty supplied with this bath, please refer to separate warranty documentation.



Contact: Please ask for details of the of Gainsborough Healthcare Group Ltd. Service and Maintenance Agreement on 01527 400022 or email warranties@ghg-uk.com.

DECLARATION OF CONFORMITY

Gainsborough Healthcare Group



Declaration of Conformity

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Manufacturer's name:

Gainsborough Healthcare Group Ltd 10 & 11 The Oaks Clews Road Redditch

Manufacturer's Address:

Worcestershire

Equipment Type: Bath Chassis with Powered Seat

Gainsborough Healthcare Group Ltd solely declares that the below products comply with the essential requirements and fulfil the provision of the CE marking.

Bath Model	UDI	Part No	umbers
Gentona 1500 – Height Adjustable Bath with Powered Seat	(01)05060968110260	BGEW5LHFS	BGEW5RHFS
Gentona 1700 – Height Adjustable Bath with Powered Seat	(01)05060968110277	BGEW7LHFS	BGEW7RHFS
Gentona 1500 DTS – Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110284	BGEW5LHGT	BGEW5RHGT
Gentona 1700 DTS – Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110291	BGEW7LHGT	BGEW7RHGT
Ezion 1500 – Height Adjustable Bath with Powered Seat and Leg Lift	(01)05060968110307	BEZW5LHFS	BEZW5RHFS
Ezion 1700 – Height Adjustable Bath with Powered Seat and Leg Lift	(01)05060968110314	BEZW7LHFS	BEZW7RHFS
Talano 1500 – Fixed Height Bath with Powered Seat	(01)05060968110321	BTAW5LHFS	BTAW5RHFS
Talano 1700 – Fixed Height Bath with Powered Seat	(01)05060968110338	BTAW7LHFS	BTAW7RHFS
Talano 1500 DTS – Fixed Height Bath with Detachable Transfer Seat	(01)05060968110345	BTAW5LHGT	BTAW5RHGT
Talano 1700 DTS – Fixed Height Bath with Detachable Transfer Seat	(01)05060968110352	BTAW7LHGT	BTAW7RHGT
Alera 1500 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110369	BALW5LHFS	BALW5RHFS
Alera 1700 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110376	BALW7LHFS	BALW7RHFS
Torin 1500 – Height Adjustable Bath	(01)05060968110246	BTOW5LH	BTOW5RH
Torin 1700 – Height Adjustable Bath	(01)05060968110253	BTOW7LH	BTOW7RH
Comfort 1500 – Height Adjustable Bath with Powered Seat	(01)05060968110475	CVW5LHFS	CVW5RHFS
Comfort 1700 – Height Adjustable Bath with Powered Seat	(01)05060968110482	CVW7LHFS	CVW7RHFS
Comfort 1500 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110536	CVW5LHGT	CVW5RHGT
Comfort 1700 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110543	CVW7LHGT	CVW7RHGT
Comfort 1500 – Fixed Height Bath with Powered Seat	(01)05060968110499	CFW5LHFS	CFW5RHFS
Comfort 1700 – Fixed Height Bath with Powered Seat	(01)05060968110505	CFW7LHFS	CFW7RHFS
Comfort 1500 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110512	CLW5LHFS	CLW5RHFS
Comfort 1700 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110529	CLW7LHFS	CLW7RHFS

The products correspond to Class 1 Medical Device Directive

The following standards and European Directives apply:

- 2006/42/EC Machinery Directive MDR 2017-745/EU Class 1 Medical Device ROHS Restriction of Hazardous Substances

- IEC 60601
 BS EN 60601-01-11 General requirements for basic health and safety and essential performance Home healthcare
- BS EN 60601-1-6 General requirements for basic safety and essential performance
- BS EN 62366-1 Application of usability engineering to medical devices
 BS EN ISO 10535 :2021 Assistive products Hoists for the transfer of persons Requirements and test methods
- BS EN ISO 10993-1 2022 Biological Evaluation of medical devices
 BS EN ISO 21856-2022 Assistive products General requirements and test methods



Peter Eckhardt

For and on behalf of Gainsborough Healthcare Group Ltd

Date of issue; 15/12/2021

Registered in England No. 10433373 | VAT No. 254046128





Declaration of Conformity

Gainsborough Healthcare Group Ltd 10 & 11 The Oaks Clews Road Redditch Manufacturer's name:

Manufacturer's Address:

Worcestershire B98 7ST

Equipment Type: Bath Chassis with Powered Seat

Gainsborough Healthcare Group Ltd solely declares that the below products comply with the essential requirements and fulfil the provision of the UKCA marking.

Bath Model	UDI	Part No	umbers
Gentona 1500 – Height Adjustable Bath with Powered Seat	(01)05060968110260	BGEW5LHFS	BGEW5RHFS
Gentona 1700 – Height Adjustable Bath with Powered Seat	(01)05060968110277	BGEW7LHFS	BGEW7RHFS
Gentona 1500 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110284	BGEW5LHGT	BGEW5RHGT
Gentona 1700 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110291	BGEW7LHGT	BGEW7RHGT
Ezion 1500 – Height Adjustable Bath with Powered Seat and Leg Lift	(01)05060968110307	BEZW5LHFS	BEZW5RHFS
Ezion 1700 – Height Adjustable Bath with Powered Seat and Leg Lift	(01)05060968110314	BEZW7LHFS	BEZW7RHFS
Talano 1500 – Fixed Height Bath with Powered Seat	(01)05060968110321	BTAW5LHFS	BTAW5RHFS
Talano 1700 – Fixed Height Bath with Powered Seat	(01)05060968110338	BTAW7LHFS	BTAW7RHFS
Talano 1500 DTS - Fixed Height Bath with Detachable Transfer Seat	(01)05060968110345	BTAW5LHGT	BTAW5RHGT
Talano 1700 DTS – Fixed Height Bath with Detachable Transfer Seat	(01)05060968110352	BTAW7LHGT	BTAW7RHGT
Alera 1500 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110369	BALW5LHFS	BALW5RHFS
Alera 1700 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110376	BALW7LHFS	BALW7RHFS
Torin 1500 – Height Adjustable Bath	(01)05060968110246	BTOW5LH	BTOW5RH
Torin 1700 – Height Adjustable Bath	(01)05060968110253	BTOW7LH	BTOW7RH
Comfort 1500 – Height Adjustable Bath with Powered Seat	(01)05060968110475	CVW5LHFS	CVW5RHFS
Comfort 1700 – Height Adjustable Bath with Powered Seat	(01)05060968110482	CVW7LHFS	CVW7RHFS
Comfort 1500 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110536	CVW5LHGT	CVW5RHGT
Comfort 1700 DTS - Height Adjustable Bath with Detachable Transfer Seat	(01)05060968110543	CVW7LHGT	CVW7RHGT
Comfort 1500 – Fixed Height Bath with Powered Seat	(01)05060968110499	CFW5LHFS	CFW5RHFS
Comfort 1700 – Fixed Height Bath with Powered Seat	(01)05060968110505	CFW7LHFS	CFW7RHFS
Comfort 1500 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110512	CLW5LHFS	CLW5RHFS
Comfort 1700 – Fixed Height Bath with Powered Seat and Leg Lift	(01)05060968110529	CLW7LHFS	CLW7RHFS

The products correspond to Class 1 Medical Device Directive

The following standards and European Directives apply:

- 2006/42/EC Machinery Directive MDR 2017-745/EU Class 1 Medical Device ROHS Restriction of Hazardous Substances
- BS EN 60601-01-11 General requirements for basic health and safety and essential performance Home healthcare BS EN 60601-1-6 – General requirements for basic safety and essential performance

- BS EN 62366-1 Application of usability engineering to medical devices
 BS EN 61366-1 Application of usability engineering to medical devices
 BS EN ISO 10535:2021 Assistive products Hoists for the transfer of persons Requirements and test methods
 BS EN ISO 10993-1 2022 Biological Evaluation of medical devices
 BS EN ISO 21856-2022 Assistive products General requirements and test methods



Peter Eckhardt

C.E.O

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ELECTROMAGNETIC COMPATIBILITY

Electrical medical equipment is subject to special precautionary measures with regard to EMC and must be installed and operated in accordance with the EMC instructions included in the accompanying documents.

For the devices and systems from **Gainsborough Healthcare Group Ltd.**, no special measures must be observed.



NOTE: Portable and mobile HF-communications equipment can interfere with electrical medical equipment.

The product standard applied to Gainsborough Healthcare Group Ltd. are;

- BS EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic disturbances Requirements and tests.
- BS EN 61000-3-2: 2014 Electromagnetic compatibility EMC. Limits. Limits for harmonic current emissions (equipment input current < 16A per phase).
- BS EN 61000-3-3:2013 Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current < 16A per phase and not subject to conditional connection.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The Bath Chassis with Powered Seat has been designed for use in the following listed electromagnetic environments. The customer or the user of the Bath Chassis with Powered Seat must ensure that the appliance is used in such environment.

Emission Measurements	Compliance	Electromagnetic Environment Guidance		
High frequency (HF) Radiated Emissions to BS EN 55011	Group I - no internally generated electromagnetic radiation	The Bath Chassis with Powered Seat does not use HF radiation for internal functions. Therefore, the HF radiation of the device is very low and any interference with adjacent electrical equipment is unlikely.		
High frequency (HF) Radiated emissions to BS EN 55011	Class B	The Bath Chassis with Powered Seat is intended for use in any		
Conducted Emissions to BS EN 55014	Class B	type of facility including living quarters and those that are directly connected to a public		
Harmonics to IEC 6100-3-2	Class A	mains network that supplies		
Voltage fluctuations / flicker to IEC 6100-3-3	Compliant	residential buildings and buildings used for domestic purposes.		

ELECTROMAGNETIC COMPATIBILITY

Immunity Testing	BS EN 60601 - Test Level	Compliance Level	Electromagnetic Environment Guidance
Discharging of static electricity (ESD) to BS EN 61000-4-2	+- 8kV contact discharge. +- 15kV air discharge	+- 8kV contact discharge. +- 15kV air discharge	The floor must be in wood, concrete or ceramic tiles. In case of floors in synthetic material, the relevant air humidity must be at least 30%.
Rapid transient interference pulses/ burst BS EN 61000-4-4	+-2kV for power supply cables	+-2kV for power supply cables	The quality of the supply voltage should match that of a typical business or hospital environment.
Overvoltage (Surges) BS EN 61000-4-5	+-1kV Mains cable connection differential mode +-2kV Mains Cable common mode	+-1kV Mains cable connection differential mode +-2kV Mains Cable common mode	The quality of the supply voltage should match that of a typical business or hospital environment.
Voltage drops, short interruptions and voltage fluctuations in the power supply input cables IEC 61000-4-11	<5% Ut (>95% drop of Ut) For 0.5 period <5% Ut (>95% drop of Ut) For 0.5 period <70% Ut (>30% drop of Ut) For 25 periods <5% Ut (>95% drop of Ut) For 5% drop of Ut) For 5s	<5% Ut (>95% drop of Ut) For 0.5 period <5% Ut (>95% drop of Ut) For 0.5 period <70% Ut (>30% drop of Ut) For 25 periods <5% Ut (>95% drop of Ut) For 5% drop of Ut) For 5s	The quality of the supply voltage should match that of a typical business or hospital environment.
Radiated RF Field Immunity	3 V/m 80MHz - 2700MHz Spot check frequencies in accordance with BS EN 60601-1-2 requirements	3 V/m	

ELECTROMAGNETIC COMPATIBILITY

Immunity Testing	IEC 60601 - Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF BS EN 61000-4-6	3 Vrms 150 kHz up to 80 MHz 6 Vrms at spot frequencies	3 Vrms 150 kHz up to 80 MHz 6 Vrms at spot frequencies	Portable and mobile HF communications equipment should be used no closer to any part of the Bath Chassis with Powered Seat including cables, than the recommended separation distance calculated in accordance with the equation applicable to the frequency of the transmitter Recommended separation distance D=0.35√P D=1.2√P 80 MHz up to 800 MHz D=2.3√P 800 MHz up to 800 MHz With P as the rated output of the transmitter in Watt (W) in accordance with the manufacturer's specifications and d as the recommended separation distance in meter (m). The field strength of fixed HF-transmitters as determined by an electromagnetic field survey - should be less than the compliance level in each frequency range.
		//\\	In the vicinity of



equipment marked with this symbol, interference may occur.



NOTE: This manual could possibly not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The field strength of fixed RF transmitters, such as base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radios as well as radio and television broadcast media cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength measured in the environment where the Bath Chassis with Powered Seat is to be used, exceeds the applicable HF compliance level, special care should be taken that a normal operation of the Bath Chassis with Powered Seat can be guaranteed. In case anomalies are identified, additional measures could be required, such as different alignment or a change of the location of the Bath Chassis with Powered Seat. In the frequency range from 150 kHZ to 80 MHz, the field strength must be less than 3 V/m.

Rated Output of the Transmitter	Separation Distance Depending on the Transmitting Frequency in m			
	150 kHz to 800 MHz D=0.35√P	80 MHz to 800 MHz D=1.2√P	800 MHz to 2.5 GHz D=2.3√P	
0.01	0.04	0.12	0.23	
0.1	0.11	0.38	0.73	
I	0.35	1.2	2.3	
10	1.1	3.8	7.3	
100	3.5	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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 specifications given by the transmitter manufacturer.



NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.



NOTE: These guidelines could not apply to all situations. The dispersion of electromagnetic waves is affected by absorption and reflection from structures, objects and persons.

Gainsborough Healthcare Group Life enhancing bathing





CUSTOMER TRAINING RECORD CUSTOMER DETAILS

Date:			
	I		
Address:			
Postcode:			
PRODUCT(S)	DISCUSSED	AND DEMONSTRATED	
Bath Ty	⁄pe	Serial Number	Bath Location
Trainer's Name:			
Trainer's Signatur	e:		

TRAINING ATTENDEES

I agree that I have read and understood the User Manual and that I have been trained on how to use this bath safely and correctly.

Attendee Name	Signature	Position
	se products are Class I medica	



CAUTION: These products are Class I medical devices and should only be used by the above trained people in accordance with the manufacturer's User Manual provided.

A copy of the manufacturer's User Manual has been left with:

• •	
Name:	
Signature:	
Position:	