Freedom Bath





WARNING

To avoid injury, always read this Instructions for Use and accompanied documents before using the product.



Mandatory to read the Instructions for Use

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Contents

Contents	3
Foreword	4
Intended Use	5
Safety Instructions	6
Preparations	7
Parts Designation	
Control Panel – External Water Supply	
Control Panel – Built-In Water Supply	
Product Description/Functions	
Power Operated Door	
Still Bath/Air Spa System	13
Control Panel	
Inflatable Door Seal	
Automatic Drain	
Lift-Accessible Model	
Maintenance Access	
Safety Belt (optional)	
Cleaning/Disinfection	
Emergency	
Power Assisted Door Operation	15
Standard	
Lift Accessible – LA (optional)	
Bathe/Shower Patient	
Air Spa System Operation (optional)	
Waste Water Pan	
Home Care Use	
Cleaning and Disinfection Instructions	23
Care and Preventive Maintenance	28
Troubleshooting	32
Technical Specifications	33
Labels	
List of Standards and Certificates	
Electromagnetic Compatibility	
Parts and Accessories	

Foreword

Thank you for purchasing Arjo Equipment.

Your FreedomTM bath is part of a world-wide family of quality products designed especially for assisted living facilities, group homes, retirement facilities, moderately dependent nursing care and in homes – wherever limited assistance or independent bathing equipment is desired.

Please contact us if you have any questions about the operation or maintenance of your *Freedom* bath.

Please read this *Instructions for Use* thoroughly!

Please read this *Instructions for Use (IFU)* in its entirety before using your *Freedom* bath. Information in the *IFU* is crucial to the proper operation and maintenance of the equipment, and will help protect your product and make sure that the equipment performs to your satisfaction. Some of the information in this *IFU* is important for your safety and must be read and understood to help prevent possible injury.

Unauthorized modifications on any Arjo equipment may affect its safety. Arjo will not be held responsible for any accidents, incidents or lack of performance that occur as a result of any unauthorized modification to its products.

Report Unexpected Operations or Events

Contact your local Arjo representative if any unexpected operations or events occur. The contact information appear on the last page of this *IFU*.

Serious incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Service and Support

A service routine must be performed on your *Freedom* bath every year by Arjo authorized service personnel to ensure continued safe operation of your product. See section *Care and Preventive Maintenance on page 28*.

If you require further information, please contact your local Arjo representative who can offer comprehensive support and service programs to maximize the long-term safety, reliability and value of the product.

Contact your local Arjo representative for replacement parts. Your service representative stocks the parts you will need. The contact information appears on the last page of this *IFU*.

Definitions in this IFU

WARNING

Means:

Safety warning. Failure to understand and obey this warning may result in injury to you or to others.

CAUTION

Means:

Failure to follow these instructions may cause damage to all or parts of the system or equipment.

NOTE

Means:

This is important information for the correct use of this system or equipment.



Means:

The name and address of the manufacturer.

Intended Use

This equipment must be used in accordance with these safety instructions.

Anyone using this equipment must also have read and understood the instructions in this *Instructions for Use (IFU)*.

If there is anything you are not sure about, ask your Arjo representative.

Freedom bath is intended for therapeutic bathing and showering of adult residents in care facilities or in home care environment.

The bath must be used by appropriately trained caregivers with adequate knowledge of the care environment, its common practices and procedures, and in accordance with the guidelines in the *Instructions for Use (IFU)*.

Indication for Use

This bath is used for general cleaning and relaxation and for hydrotherapy to relieve pain and itching.

This equipment should only be used for the purpose specified in this *Instructions for Use (IFU)*. Any other use is prohibited.

Resident Assessment

We recommend that facilities establish regular assessment routines. Caregivers must assess each resident according to the following criteria prior to use:

- The resident must be able to sit in an upright position, normally defined as active or semiactive.
- The resident's weight must not exceed 160 kg (352 lbs).
- The resident must understand and be able to respond to instructions to stay seated in an upright position.

If a resident does not meet these criteria an alternative equipment/system should be used.

Installation requirements

The equipment must be installed by appropriately trained personnel according to the Assembly and Installation Instructions. Requirements in the Assembly and Installation Instructions can only be superseded by local code.

Expected service life

The life time of this equipment is ten (10) years and the service life of the support strap (optional) is two (2) years. The life time and service life are stated providing that the preventive maintenance are being carried out in accordance with the instructions for care and maintenance in the *Instructions for use* (IFU).

This bath system must only be used for the purpose specified here.

Safety Instructions

WARNING

To avoid injury, make sure that the patient is not left unattended at any time.

WARNING

To avoid electric shock, never use other electrical equipment near this device.

WARNING

To avoid explosion or fire, never use the equipment in oxygen rich environment, in presence of heat source or flammable anaesthetic gases.

CAUTION

Never drop or insert any object into any opening.

Do not probe into the drain with any pointed or sharp object.

Do not force door down before bathtub empties and door seal deflates.

NOTE

Pressing the emergency seal release valve with water in the bathtub will cause the water to spill onto the bathroom floor.

If the door is not fully raised, the drain will remain open.

If the fully raised door is forced down, the drain will open.

The fully raised door will remain sealed as long as water remains in the bathtub and the emergency door seal release valve is not activated.

In the event of an AC power failure, the drain will open but the seal will remain inflated until the emergency seal release valve is activated.

Preparations

Site Preparations

Prior to installation of *Freedom* bath the floor and walls within the required area must be finished.

Material: The floor should be made of a slip-resistant material, free of bumps.

Floor slope: When using a floor drain, the slope towards the drain should not exceed 1:50.

Floor attachments: The floor construction must be suitable for anchoring the bolts.

Actions Before the First Use (9 steps)

- 1 Make sure that the bath has been installed according to the *Assembly and Installation Instructions*.
- 2 Check that all parts of the product are supplied. Compare with section *Parts and Accessories on page 43*. If any part is missing or damaged do NOT use the product.
- 3 Read the *IFU*.
- 4 Disinfect the product according to section *Cleaning and Disinfection Instructions on page 23*.
- 5 Perform a functionality test according to section *Care and Preventive Maintenance on page 28.*
- 6 Choose a designated area, where the *IFU* should be kept and is easily accessible at all times.

7 WARNING

To prevent scalding, make sure that the water mixer has been calibrated. Confirm that responsible organization has established calibration routines.

- 8 Make sure the thermostatic mixer has been calibrated according to the *Assembly and Installation Instructions* by an Arjo service technician.
- 9 Make sure to have a rescue plan ready in case of a patient emergency.

Actions Before Every Use (4 steps)

- 1 Check that all parts are in place. Compare to section *Parts and Accessories on page 43*.
- 2 Check bath and accessories for damage.
- If any part is missing or damaged do NOT use the product.

4 WARNING

To prevent cross-contamination, always follow the disinfection instructions in this *Instructions for Use.*

Before every use, make sure the *Freedom* bath is cleaned and disinfected according to section *Cleaning and Disinfection Instructions on page 23*.

NOTE

If you have any questions, please contact your local Arjo representative for support and service. The contact information (*Arjo addresses*) is listed on the last page of this *IFU*.

Parts Designation

Freedom bath

- Roll-Door 🛊
- Covers for service access (2 pcs)
- Low water level sensors (2 pcs)
- Emergency seal release
- Drain
- Assist handle
- Inflatable sealing system (inside the cover)
- 8 Seat
- Waste water pan (underneath the bathtub)
- 10 Shower
- 11 Bathtub fill spout
- 12 Thermostatic water control system (optional)
- 13 Control panel
- 14 High water level sensor (optional)
- 15 Surface overflow outlet
- 16 Safety belt (optional)

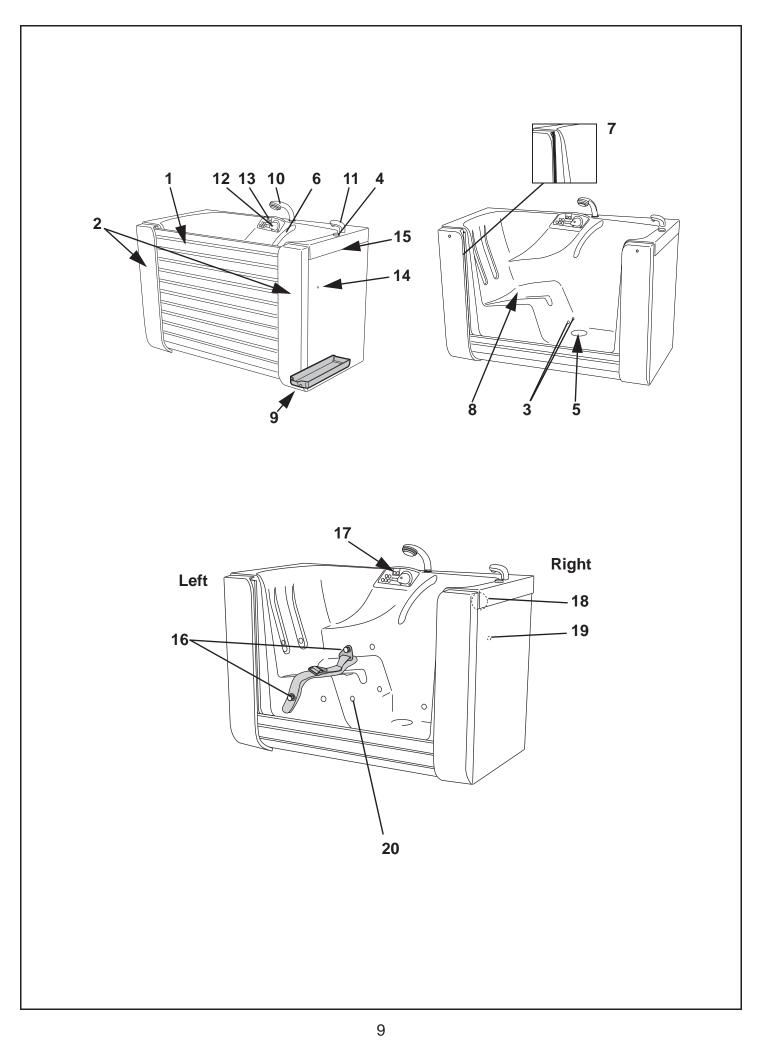
Air Spa system (optional)

- 17 Control panel
- 18 Disinfectant/rinse inlet for MultiClean unit (optional)
- 19 High water level sensor (1 pc)
- 20 Air nozzles (12 pcs)

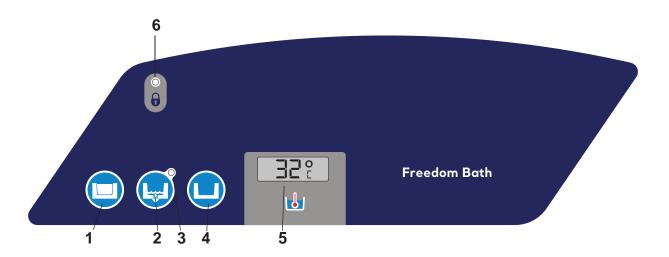


Applied part: Type B

Roll door. including the complete bathtub. Protection against electrical shock in accordance with IEC 60601-1.



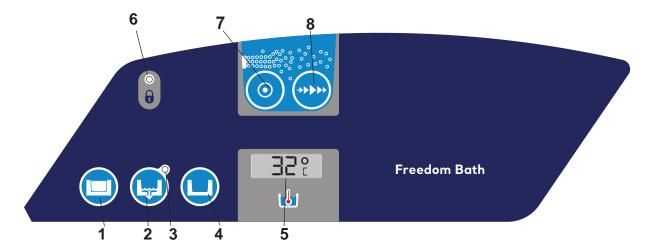
Control Panel – External Water Supply



Control Panel - Still Bath

- 1 Door UP
- 2 Door seal/ Drain
- 3 LED
 - flashes during sealing operation
 - steady green light when sealing is activated
- 4 Door DOWN

- 5 Shows water temperature in bathtub.
- 6 LED steady red light when all buttons are locked.
 Activates/releases when button 1 and button 4 are pushed at the same time for 1 s.

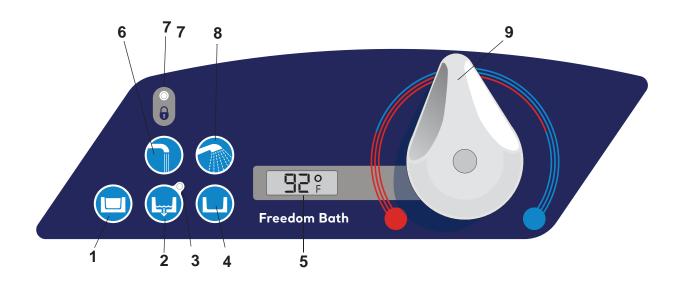


Control Panel - Air Spa System

- 1 Door UP
- 2 Door seal/drain
- 3 LED
 - flashes during sealing operation
 - steady green light when sealing is activated
- 4 Door DOWN
- 5 Shows water temperature in bathtub.

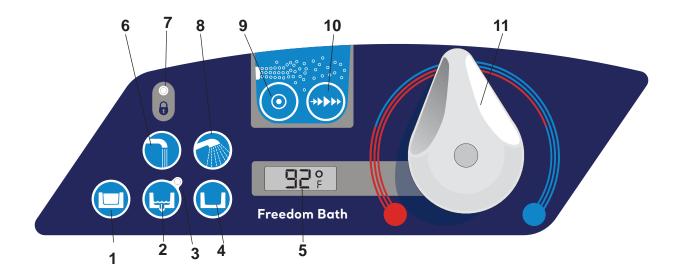
- 6 LED, steady red light when all buttons are locked. Activates/releases when button 1 and button 4 are pushed at the same time for 1 s.
- 7 Air Spa system ON/OFF. 20 minutes after the bathtub is emptied, the air blower activates for 1 minute (not for bath with option disinfectant/rinsing inlet for *MultiClean* unit).
- 8 Air Spa system INCREASE/DECREASE

Control Panel – Built-In Water Supply



Control Panel - Still Bath

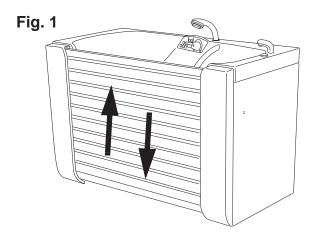
- 1 Door UP
- 2 Door seal/drain
- 3 LED
 - flashes during sealing operation.
 - steady green light when sealing is activated.
- 4 Door DOWN.
- 5 Shows water temperature (measured in the thermostatic mixer).
- 6 Bathtub filling
- LED steady red light when all buttons are locked.
 Activates/releases when button 1 and button 4 are pushed at the same time for 1 s.
- 8 Patient shower
- 9 Mixer knob INCREASE/DECREASE TUBWATER TEMPERATURE



Control Panel - Air Spa System

- 1 Door UP
- 2 Door seal/drain
- 3 LED
 - flashes during sealing operation.
 - steady green light when sealing is activated.
- 4 Door DOWN.
- 5 Shows water temperature (measured in the thermostatic mixer).
- 6 Bathtub filling.
- 7 LED, steady red light when all buttons are locked. Activates/releases when button 1 and button 4 are pushed at the same time for 1 s.
- 8 Patient shower.
- 9 Air Spa system ON/OFF. 20 minutes after the bathtub is emptied, the air blower activates for 60 s (not for bath with option disinfectant/rinsing inlet for *MultiClean* unit).
- 10 Air Spa system INCREASE/DECREASE AIR-SPEED.
- 11 Mixer knob INCREASE/DECREASE TUBWATER TEMPERATURE.

Product Description/Functions



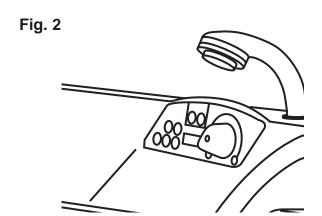
Power Operated Door

The power operated door has a gear motor which is operated from the control panel. The motor incorporates a push and hold feature and a safety clutch for user safety. The clutch disengages when the control button is released, permitting the door to be opened in a manual mode, but should only be used in emergency.

In case of power failure the door can be opened manually when pushing the emergency button. (See Fig. 1)

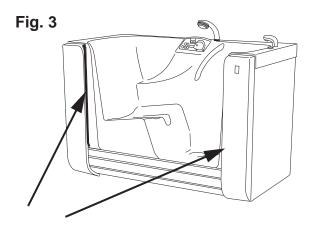
Still Bath/Air Spa System

The *Freedom* bath is available with or without an Air Spa system. A low-water sensor will prevent the Air Spa system from being activated until the water in the bathtub is at a proper operating level. See section *Air Spa System Operation (optional) on page 19*.



Control Panel

The control panel controls all bathtub functions and displays useful information such as bath temperature. (See Fig. 2)

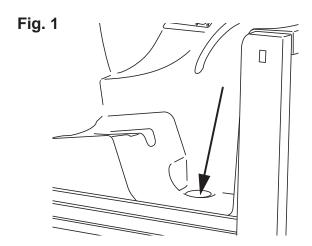


Inflatable Door Seal

An inflatable sealing system makes the door totally watertight. The sealing is operated by a button on the control panel and should be activated after the door is raised. (See Fig. 3)

NOTE

When the *Freedom* bath is not in use, it is best for the door to be left in the up (closed) position, with the seal not inflated.

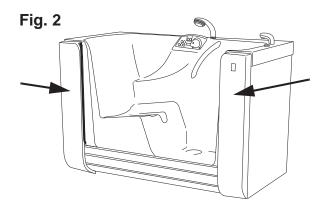


Automatic Drain

The drain is automatically activated in conjunction with the sealing system only when the door is fully raised. When the sealing system is deactivated, the drain is open. (See Fig. 1)

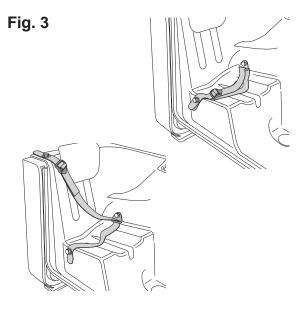
Lift-Accessible Model

The L-A model series accommodates the needs of both the ambulatory user and those requiring lift-transfer.



Maintenance Access

There are two openings with covers for service and cleaning access. (See Fig. 2)



Safety Belt (optional)

An optional safety belt is available to give the patient extra security when necessary.

There are two possible ways to fasten. (See Fig. 3)

Adjust the length by pulling the safety belt end by the clip.

Cleaning/Disinfection

Optional cleaning system is available as a separate system, *MultiClean* unit.

Emergency

If an emergency situation occurs when a patient is in the bathtub, press the emergency button to open the drain and release the door (the water will rush out around the door).

The door can now be manually pushed down.

Power Assisted Door Operation

Standard

- 1 To raise the door, press and hold the button (on the control panel. The door stops automatically when end position is reached.
- 2 To lower the door, press and hold the button on the control panel. The door stops automatically when end position is reached.
- 3 In an emergency situation the door may be pushed down manually after pressing the emergency seal release button.
- 4 The door will not operate in power mode if any of the following conditions exist:
 - The seal is ON.
 - The control panel is locked.

Lift Accessible - LA (optional)

Integration with Arjo standing and raising aid lifts such as *Stedy*, *Sarita*, *Sara*, *Encore* and *Chorus* is possible. The lift accessible area under the bathtub is shown in the illustration. (**See Fig. 1**)

- 1 To raise the door, press and hold the button on the control panel. The door stops automatically when end position is achieved.
- 2 To lower the door, press and hold the button () on the control panel. The door stops automatically in a low position. When docking with a patient lift, push the button () again and the door will proceed moving in under the bathtub and automatically stops in the end position.
- 3 In an emergency situation the door may be pushed down manually after pressing the emergency seal release button.
- 4 The door will not operate in power mode if any of the following conditions exist:
 - The seal is ON.
 - The control panel is locked.

WARNING

To avoid entrapment of the patient's or caregiver's legs or feet, make sure that they are kept clear of all obstacles. (See Fig. 2)

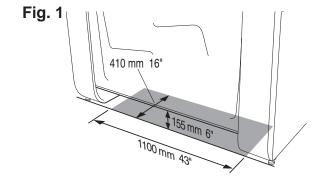
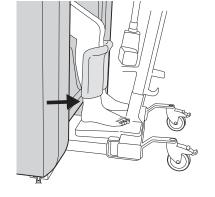


Fig. 2



Bathe/Shower Patient

Assisted Bathing



To prevent scalding, always check the water temperature with your naked hand before directing the water on the patient. Do note use gloves at it may insulate to the extent that the water temperature can be misjudged. Point the flow of the water away from the patient.

The *Freedom* bath is also ideal for assisted bathing. All controls are positioned for convenient use by the caregiver.

If necessary it is possible to lock the panel functions to avoid unauthorized use. See section *Control Panel – External Water Supply on page 10*.

Start the Bath/Shower (7 steps)

Arjo Liquid bathing products have been developed for use with the Freedom bath and are recommended.

1 WARNING

To avoid entrapment, make sure to keep the patients hair, arms and feet close to the body and use designated grab supports during any movement.

Lower the door to its lowest position. Clear all obstacles from the path of the door.

2 Help the patient to sit comfortably on the bath seat. (See Fig. 1)

Continue with the steps on the next page.

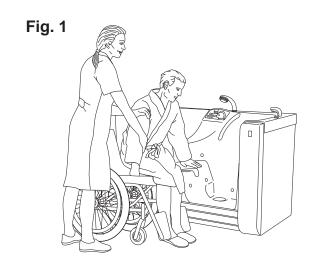


Fig. 2

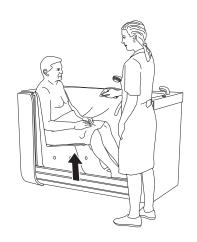
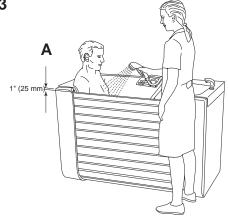


Fig. 3



3 **Bathe:**

Raise the door to the top position. (See Fig. 2)

Shower:

Raise the door but leave the door down at least an inch (25 mm) (A) from the top position to prevent the drain from closing. (See Fig. 3)

A lower position of the door will give more convenient access to the lower part of the bather. (See Fig. 4)

4 Momentarily press the door seal/drain button and the LED above the button will flash with a green light. When the door seal has reached proper inflation, the compressor will stop and a steady green light will indicate that the seal system is activated.

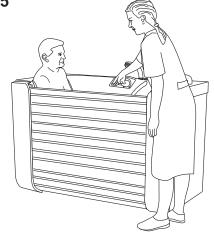
NOTE

Do not proceed with the operation if the compressor continues to run for longer than 60 s, or starts and stops frequently.

Fig. 4



Fig. 5



5 Bathe:

Press the bathtub filling button and fill the bathtub with water of desired temperature. (See Fig. 5)

NOTE

To accelerate the bathtub fill it is possible to start to fill 25 s after pushing the door seal/drain button by pushing the fill button.

(The 25 s delay is electronic and the fill and shower functions are locked out until 25 s has elapsed since the seal button was pushed).

If equipped with optional drain pan pump, this will start operating when the door seal is deflated. A varying sound level is normal during the operation.

Shower:

Press the patient shower button and shower the patient with desired temperature.

End the Bath/Shower

(4 steps)

- 1 At completion of bath, press the door seal/drain button. The drain will open and the water drains. The seal is still inflated and showering is suitable in this position with the door up.
- 2 Press the door seal/drain button again to deflate the seal. During the deflating process the LED above the button will be flashing green light.

NOTE

If the bather has both of their feet in contact with both of the water sensors at the same time, the seal may not deflate.

- 3 See that limbs of the patient are kept out of the sealing area and the door path.
- 4 To lower the door keep the door button pressed down.

Fig. 1 EMERGENCY



EMERGENCY

(2 steps)

- 1 In the event of medical emergency, open the lid covering the emergency seal release and push the button, then push down on the door. (See Fig. 1)
- 2 In the event of a power failure, wait for the bathtub to drain completely before activating the emergency seal release.

NOTE

The emergency seal release should only be used in emergency, because the water will spill out onto the bathroom floor.

Air Spa System Operation (optional)

Check Before Usage

- The door is fully raised.
- The bathtub is filled above the high water level sensor button.

NOTE

Only use emulsifying mineral oil.

Operating the air blower with soapy water in the bathtub is not recommended, as foaming of the bath water is likely to occur. Use clean water whenever possible.

- 1 Press the Air Spa system ON/OFF button on the display and the air blower will start in maximum speed. The air blower will stop by pressing the ON/OFF button again.
- 2 The intensity of the Air Spa system bubbling action can be reduced by pressing and holding in the air blower speed control symbol on the display. Release the button when the desired intensity is reached. The air blower speed can be changed at any time.
- 3 After completing the Air Spa system, wash & shampoo or drain the bathtub if bathing is complete.
- 4 Press the door seal/drain button to open the drain. Allow the water to drain below the low water level sensor buttons.

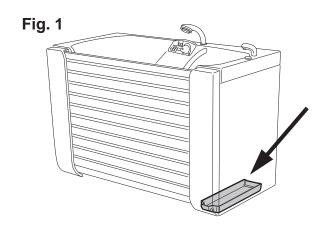
 Once again press the door seal/drain button and the seal will deflate and the door can be lowered.
- 5 Clean/disinfect the bathtub. See section *Cleaning and Disinfection Instructions on page 23*.
- 6 Bath without option disinfectant/rinsing inlet for *Multi-Clean* unit: 20 minutes after the bathtub is emptied, the air blower activates for 1 minute.
 - Bath with option disinfectant/rinsing inlet for *MultiClean* unit: the button ON/OFF has to be pushed to start the air blower, which then will activate for 1 minute.

NOTE

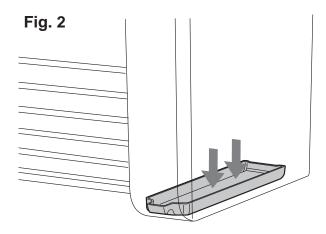
The air blower cannot be stopped during the 1 minute "dry" cycle, but the speed can be controlled during this time.

If the bather has both of their feet in contact with both of the water sensors at the same time, the seal may not deflate.

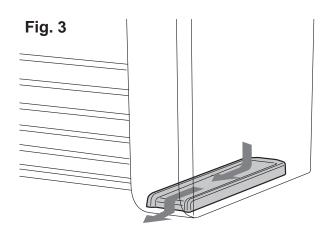
Waste Water Pan



The drain pan is placed on the right hand side of the *Freedom* bath. (See Fig. 1)



Placed in the normal position the drain pan will collect spilt / waste water. (See Fig. 2)



Placed upside down the drain pan will lead spilt water from *Freedom* bath onto the floor. (See Fig. 3)

NOTE

The water in the drain pan may be contaminated. Use caution when emptying.

Home Care Use

For Distributors and Renters

When transporting the *Freedom* bath to the customer with a van:

 Make sure the bath is properly secured during transport.

When delivering the *Freedom* bath make sure that:

- The requirements according to the site preparation instructions prior to installation are followed:
 Material: The floor should be made of a slip-resistant material, free of bumps.

 Floor slope: When using a floor drain, the slope towards the drain should not exceed 1:50.
 Floor Attachments: The floor construction must be suitable for anchoring the bolts.
- The bath is installed according to the *Assembly* and *Installation Instruction* by qualified personnel.

WARNING

To prevent scalding, make sure that the water mixer has been calibrated. Confirm that responsible organization has established calibration routines.

Make sure:

- The thermostatic mixer has been calibrated according to the *Assembly and Installation Instructions* by an Arjo service technician.
- You read this *IFU* together with the receiver (including relatives and caregivers).
- Show the features and intended usage described in the *IFU* with help of the real product.
- Read all the warnings to the receiver.
- The user has understood the cleaning and disinfection instructions.
- Perform a functionality test according to section *Care and Preventive Maintenance on page 28.*
- The environment fulfils all the requirements described in this *IFU*.

Use the Freedom Bath

Before using *Freedom* bath in home environment make sure that:

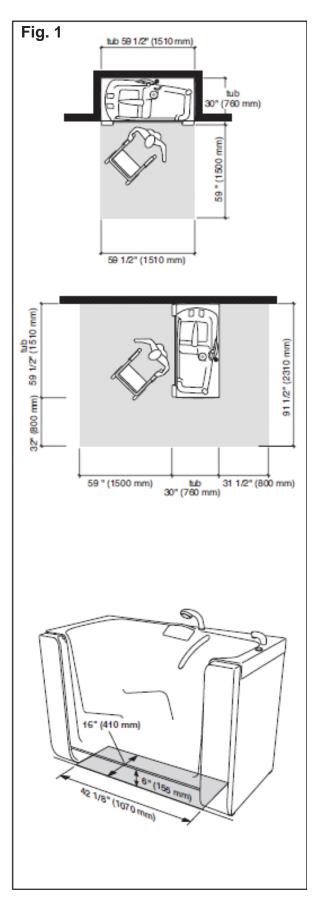
- All caregivers, including relatives, have read and understood the instructions in this *IFU*.
- The space requirements for the bath are followed. (See Fig. 1)

When the *Freedom* bath is not in use make sure that:

WARNING

To avoid strangulation, make sure to never leave children unattended near the equipment.

- No children can access the bath.
- No pets can come in contact with the bath.
- The storage environment fulfils the requirements specified in section *Technical Specifications on page 33*.



Space requirements around the bath

Freedom bath must always be installed according to recommended space requirements, this to provide optimal working conditions for personnel and patient. (See Fig. 1)

NOTE

Space for furniture and other personal items are not included in these measurements.

Available area for lift integration

The *Freedom* bath in lift accessible version (LA) allows the following area for lift integration, limited by the drain connections.

Cleaning and Disinfection Instructions

Thorough disinfection routines are necessary to prevent the build-up of bacteria on and in the equipment and to prevent cross-contamination. This is particularly vital in cases where the *Freedom* bath is in a shared facility.

WARNING

To avoid eye and skin damage, always use protective glasses and gloves. If contact occurs rinse with plenty of water. If eyes or skin becomes irritated, contact a physician. Always read the material safety data sheet of the disinfectant.

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this *Instructions for Use.*

WARNING

To prevent cross-contamination, the caregiver must always be present during the whole disinfection procedure to make sure it is performed correctly.

WARNING

To avoid eye or skin irritation, never disinfect in the presence of a patient.

CAUTION

To avoid damage on the equipment only use Arjo branded disinfectants.

Allowed Disinfectants

- Arjo Clean
- Arjo General Purpose Disinfectant
- Arjo Disinfectant Cleanser IV
- Arjo All Purpose Disinfectant (not for *MultiClean* unit)
- Arjo CenKleen IV

Accessories for Cleaning and Disinfection

- Protective glasses
- Protective gloves
- Disinfectant filled spray bottle or MultiClean unit
- Water filled spray bottle or MultiClean unit
- Cloths wet and dry
- Disposable towels
- Soft bristled brush
- Long handled soft bristled brush

Microbiological Formation Prevention

In order to enhance the on-site curative actions (chlorine or thermal shock), which do not guarantee a reduction of the contamination long term, make sure to follow the instructions below.

Installation precautions

In order to limit the growth of bacterial flora, it is necessary to take action at four levels:

- Avoid stagnating water and make sure proper water circulation;
- Take precautions against the formation of scale and corrosion based on the water quality;
- Maintain a high water temperature all the way from the hot water dispenser to the different distribution pipes;
- Mix hot and cold water as close as possible to the point of use.

Use

- Make sure that the water circulates in the bath and the shower on a daily basis even if the bathtub is not used; and particular to make sure to remove any water that may be left behind in the hose.
- Let the water flow approximately 5 minutes before the first bath of the day.
- Clean and disinfect the bathtub according to the IFU before the first bath of the day and after the bath of each patient.

Do not forget to contact Arjo for the annual Preventive Maintenance visit.

Clean and Disinfect bath without disinfectant/rinsing inlet for MultiClean unit (25 Steps)

For this procedure a spray bottle *or* a *MultiClean* unit can be used. For the *MultiClean* unit, refer to the *MultiClean* unit *IFU*.

Remove visual residue (Step 1-5 of 25)

- 1 Put on protective gloves and eye wear.
- 2 Make sure all functions are turned off.
- 3 Open the drain to empty any left over water.
- 4 Detach and place the neck pillow (if applicable) and the safety belt (if applicable) on the bottom of the bathtub.
- 5 Shower and rinse the bathtub, the neck pillow and the safety belt with water to remove visible residue. Turn the neck pillow and the safety belt and rinse again.

Clean (Step 6-14 of 25)

- 6 Spray disinfectant in the drain. Use a long handled brush to scrub the drain.
- 7 Close the drain by raising the door to the top position.
- 8 Spray disinfectant on all internal bath surfaces, the neck pillow and the safety belt at the bottom of the bathtub. Turn the neck pillow and safety belt and spray on the other side. Pay attention to parts, knobs and sensors attached to the bath surface such as safety belt knobs and surface overflow outlet.
- 9 Scrub all the surfaces of the bathtub, the neck pillow and the safety belt with a soft bristle brush or cloth (to remove any deposits, e.g. skin flakes).
- 10 Open the drain by pressing the door seal/drain button.
- 11 Rinse all parts clean with water with a temperature of approximately 25 °C (77 °F) to remove the disinfectant.
- 12 Soak a cloth in disinfectant.
- 13 Wipe all other contact areas such as the outside of the bathtub (particularly the surface were the head is), metal sensor knobs and door seals.
- 14 Wet a new cloth with water and remove all traces of disinfectant on the contact areas.

Disinfect (Step 15-25 of 25)

- 15 Spray disinfectant in the drain.
- 16 Close the drain.
- 17 Spray disinfectant on all internal bath surfaces, the neck pillow and the safety belt at the bottom of the bathtub. Turn the neck pillow and safety belt and spray on the other side. Pay attention to parts, knobs and sensors attached to the bath surface such as safety belt knobs and surface overflow outlet.
- 18 Soak a cloth in disinfectant.
- 19 Wipe all other contact areas such as the outside of the bathtub (particularly the surface were the head is), metal sensor knobs and door seals.
- 20 Allow an appropriate contact time of the disinfectant according to the instructions on the disinfectant bottle.
- 21 Open the drain.
- 22 Rinse all parts clean with water with a temperature of approximately 25 °C (77 °F) to remove the disinfectant. Use the shower to remove disinfectant.
- 23 Wet a new cloth with water and remove all traces of disinfectant on the contact areas.
- 24 Raise the door to the top position (do that always when the *Freedom* bath is not used.
- 25 Leave to air dry.

Clean and Disinfect bath with disinfectant/rinse inlet for MultiClean unit (43 Steps)

For this procedure a *MultiClean* unit shall be used. For the *MultiClean* unit, refer to the *MultiClean* unit *IFU*.

Remove visual residue (Step 1-5 of 43)

- 1 Put on protective gloves and eye wear.
- 2 Make sure all functions are turned off.
- 3 Open the drain to empty any left over water.
- 4 Detach and place the neck pillow (if applicable) and the safety belt (if applicable) on the bottom of the bathtub.
- 5 Shower and rinse the bathtub, the neck pillow and the safety belt with water to remove visible residue. Turn the neck pillow and the safety belt and rinse again.

Clean (Step 6-22 of 43)

- 6 Place the disinfection spray handle into the disinfectant/rinse inlet and turn either way to secure it (some force may be needed).
- 7 Press the trigger handle and hold it until the disinfectant flows from all Air Spa system nozzles.
- 8 Let it run for another 30 s.

NOTE

Disinfectant should be distributed through all Air Spa system nozzles, otherwise proper disinfection can not be guaranteed. Contact an Arjo technician if that problem occurs.

- 9 Release the trigger and remove the disinfection spray handle from the disinfectant/rinse inlet.
- 10 Place the water spray handle into the disinfectant/ rinse inlet and turn either way to secure it (some force may be needed).
- 11 Press the trigger handle and hold it until clean water flows from all nozzles.
- 12 Let it run for another 30 s.
- 13 Remove the shower handle from the disinfectant/rinse inlet.
- 14 Spray disinfectant in the drain. Use a long handled brush to scrub the drain.

- 15 Close the drain by raising the door to the top position.
- 16 Spray disinfectant on all internal bath surfaces, the neck pillow and the safety belt at the bottom of the bathtub. Turn the neck pillow and safety belt and spray on the other side. Pay attention to parts, knobs and sensors attached to the bath surface such as safety belt knobs and surface overflow outlet.
- 17 Scrub all the surfaces of the bathtub, the neck pillow and the safety belt with a soft bristle brush or cloth (to remove any deposits, e.g. skin flakes).
- 18 Open the drain by pressing the door seal/drain button.
- 19 Rinse all parts clean with water with a temperature of approximately 25 °C (77 °F) to remove the disinfectant.
- 20 Soak a cloth in disinfectant.
- 21 Wipe all other contact areas such as the outside of the bathtub (particularly the surface were the head is), metal sensor knobs and door seals.
- 22 Wet a new cloth with water and remove all traces of disinfectant on the contact areas.

Disinfect (Step 23-43 of 43)

- 23 Place the disinfection spray handle into the disinfectant/rinse inlet and turn either way to secure it (some force may be needed).
- 24 Press the trigger handle and hold it until the disinfectant flows from all Air Spa system nozzles.
- 25 Let it run for 30 s.
- 26 Release the trigger and remove the disinfection spray handle from the disinfectant/rinse inlet.
- 27 Allow an appropriate contact time of the disinfectant according to the instructions on the disinfectant bottle.
- 28 Spray disinfectant in the drain.

Continue with the steps on the next page.

- 29 Close the drain.
- 30 Spray disinfectant on all internal bath surfaces, the neck pillow and the safety belt at the bottom of the bathtub. Turn the neck pillow and safety belt and spray on the other side. Pay attention to parts, knobs and sensors attached to the bath surface such as safety belt knobs and surface overflow outlet.
- 31 Soak a cloth in disinfectant.
- 32 Wipe all other contact areas such as the outside of the bathtub (particularly the surface were the head is), metal sensor knobs and door seals.
- 33 Allow an appropriate contact time of the disinfectant according to the instructions on the disinfectant bottle.
- 34 Open the drain.
- 35 Place the water spray handle into the disinfectant/ rinse inlet and turn either way to secure it (some force may be needed).
- 36 Press the trigger handle and hold it until clean water flows from all nozzles.
- 37 Let it run for another 30 s.
- 38 Remove the shower handle from the disinfectant/ rinse inlet.
- 39 Rinse all parts clean with water with a temperature of approximately 25 °C (77 °F) to remove the disinfectant. Use the shower to remove disinfectant.
- 40 Wet a new cloth with water and remove all traces of disinfectant on the contact areas.
- 41 Raise the door to the top position (do that always when the *Freedom* bath is not used).
- 42 Press the button Air Spa system ON/OFF to start the air blower, which then will be activated for 1 minute.

NOTE

The air blower cannot be stopped during the 1 minute "dry" cycle, but the speed can be controlled during this time.

43 Leave to air dry.

Care and Preventive Maintenance

The *Freedom* bath is subject to wear and tear, and the following actions must be performed when specified to ensure that the product remains within its original manufacturing specification.

WARNING

To avoid malfunction resulting in injury, make sure to conduct regular inspections and follow the recommended maintenance schedule. In some cases due to heavy use of the product and exposure to aggressive environment more frequent inspections should be carried out. Local regulations and standards may be more stringent than the recommended maintenance schedule.

NOTE

Product cannot be maintained and serviced while in use with the patient.

PREVENTIVE MAINTENANCE SCHEDULE: Freedom bath

CAREGIVER OBLIGATIONS Action/Check	Between Patients	Every DAY	Every WEEK	Every MONTH	Every YEAR	Every 2:nd YEAR
Clean and Disinfect	Χ					
Clean door strip/seal and under the bathtub		X				
Visually check all exposed parts			X			
Check door seal			X			
Visually check hoses, pipes and connections			X			
Perform functionality test			Х			
Empty and clean pan under bathtub			X			
Visually check the safety belt, if any			Х			
Exercise the thermostat mixer				Χ		
Check/clean filters, incoming water				Χ		
Replace the safety belt						X
Yearly checks by qualified personnel only					X	
Check electrical installation (to be performed by authorized electrician)		Intervals a	ccording to	local requi	rements	

WARNING

To avoid injury to both the patient and the caregiver, never modify the equipment or use incompatible parts.

Caregiver Obligations

Caregiver obligations shall be carried out by personnel with sufficient *Freedom* bath knowledge following the instructions in this *IFU*.

Between patients

• Clean and disinfect:

Before every use, make sure the *Freedom* bath is cleaned and disinfected according to section *Cleaning and Disinfection Instructions on page 23*.

Every day

Clean door strip/seal and under the bathtub: Instruction for non lift accessible version of *Freedom* bath only: To make area at lower part of the door and under bathtub accessible for cleaning, perform following procedure: (See Fig. 1-2)

WARNING

To avoid injury, only use the emergency lowering when normal lowering is impossible. Use extreme care during lowering.

- 1 Hold the door up and door down buttons pressed simultaneously for 30 s, until the temperature display starts flashing.
- 2 Press the door down button. The door will move under the bathtub, leaving the lower part of the strip/seal and the area under the bathtub free for cleaning. Take caution at this operation as the crush protection is off. The protection is automatically activated again after one minute.

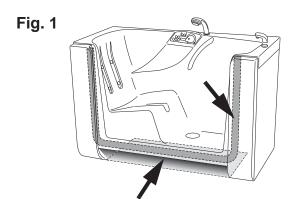
CAUTION

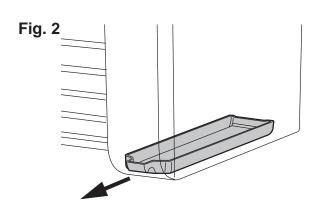
To avoid damage on the equipment only use Arjo branded disinfectants.

Every week

- **Visually check all exposed parts.** Make sure no cracks or sharp edges could cause the patient or caregiver injury.
- Check door seal: Check the seal for cracks or other damage. Check along the complete length that it is not twisted, shown as (B) in the illustration. Correct placement is shown as (A). (See Fig. 3)

Continue with the steps on the next page.





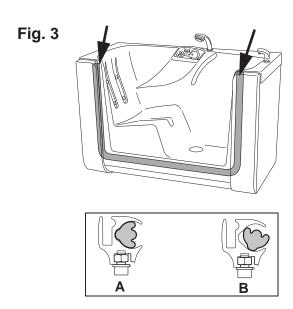
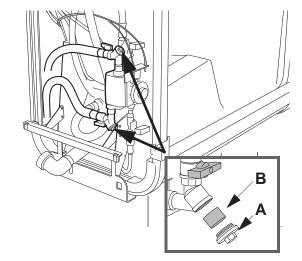
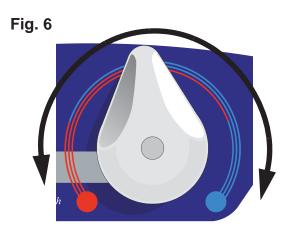


Fig. 4

Fig. 5





• Visually check hoses, pipes and connections:

Remove the left and right cover by removing the screws and lifting the covers upwards. (See Fig. 4)

Visually inspect for leaks of any kind on hoses, pipes, connection and drain.

- **Perform functionality test:** Test all panel functions and disinfection options. With water on: check shower hose and shower handle for damage replace if defect.
- Empty and clean accumulated water and dirt from the drain pan under the bathtub:

Clean the suction filter from dirt and/or lime build up on the surface of the net.

• Visually check the safety belt. Check the complete length for fraying, cuts, crack, tears, that no inner fabric is showing and that no other damage is visible. If the safety belt is found damaged, replace it.

Every month

• Check/clean filters incoming water (with mixer):

A rinsing valve with a filter is mounted on each of the two water supply hoses found under the left front cover. The filter should be rinsed in both valves as follows:

- 1 Remove the left cover by removing the screws and lifting it upwards. (See Fig. 4)
- 2 Close the valves. The handles (red for hot water and blue for cold) should be in a cross position (See Fig. 5).

WARNING

Pressurised system and risk of scalding. Make sure that the valve (A) is closed before removing the cap, this is especially important for the hot water valve.

- 3 Remove the cap (A) with a wrench. (See Fig. 5)
- 4 Pull out the filter (**B**) and clean it carefully in water. (See Fig. 5)
- 5 Reassemble the filter.
- 6 Fit the cap.
- Exercise the thermostat mixer:

Turn the temperature control knob back and forth over the whole temperature range. This is particularly important in areas with hard water. (See Fig. 6)

Yearly Checks by Qualified Personnel Only

The *Freedom* bath must be serviced once a year in accordance with the *Maintenance and Repair Manual*.

Contact your local Arjo service representative to sign for a service agreement.

WARNING

To avoid injury and/or unsafe product, the maintenance activities must be carried out at the correct frequency by qualified personnel using correct tools, parts and knowledge of procedures. Qualified personnel must have documented training in maintenance of this device.

NOTE

All Caregiver Obligations are to be checked when performing the Qualified Personnel Service. For details, see separate service instructions.

Troubleshooting

NOTE

Before starting the troubleshooting check: Power supply, Water supply and the LEDs on control panel. If the problem can not be solved with the problem solving actions below, please contact an Arjo authorized technician.

PROBLEM	ACTION
In the event of power failure during bath.	1 The bathtub drain is opened automatically.
	2 The door can be manually pushed down by pushing the emergency button.
Nothing happens when pressing a button on the panel. Function lock is activated – Red LED for function lock is on.	Release the function lock by pressing the 2 buttons DOOR UP and DOOR DOWN at the same time for 1 s.
It is not possible to stop a function by pressing a button.	Wait for one minute. The Air Spa system is in the dry cycle (option).
Air Spa system stops during operation (option).	1 Normal, if used more than 15 minutes.
	2 If used less than 15 minutes it may be overheated due to high ambient temperature or clogged filter. Can be started when cooled off.
	3 Power failure.
Water from shower and filling spout is slow.	1 In order to feel if any hot water is coming in feel the incoming hot water line to see if hot.
	2 Check and clean filter for incoming water according to section <i>Care and Preventive Maintenance on page 28</i> .
Auto fill function will not stop filling after reaching high water level sensor.	Metal sensor plugs need cleaning because of collected build up. See section <i>Cleaning and Disinfection Instructions on page 23</i> .

Technical Specifications

Ambient temperature

Atmospheric pressure

Relative humidity

A full technical description of the *Freedom* bath can be found in the service documentation, please contact Arjo for a copy. Contact information appears on the last page of this IFU.

General	
Dimensions – exterior	1510 x 760 x 1045 mm (59 1/2" x 29 3/4 " x 41 1/8")
Dimensions – seat	480 x 480 mm (18 7/8" x 18 7/8")
Colour	White
Weight - still bath	130 kg (286 lbs)
Weight with Air Spa system	140 kg (308 lbs)
Bathtub volume (with patient)	Approximately 320 I
Drain flow rate	130 l/minute
Drain flow rate with water trap	110 l/minute
Sound level	66 - 79.5 dBA
Maximum ambient temperature	40 °C (104 °F)
Pollution degree	2
SWL (Safe Working Load) (patient + water)	550 kg (1212 lbs)
Maximum patient weight	160 kg (353 lbs)
Maximum floor load	675 kg / 0.6 m ²
Maximum floor pressure	0.6 N/mm ²
Degree of protection	IPX4 IP: Ingress Protection X: The protection against contact and ingress of objects is not specified for this product. 4: Water splashing against the product from any direction does not effect safety or essential performance
Thermometer	
Range	10-50 °C (50-122 °F)
Accuracy	+/-1 °C (1.8 °F)
Resolution	0.1 °C (0.18 °F)
Operating Conditions	
Ambient temperature	10 °C (50 °F) to 40 °C (104 °F)
Relative humidity	Maximum 90% at 20 °C (68 °F)
Atmospheric pressure	800-1060 hPa
Transport and Storage Conditions	

-20 °C to 70 °C (-4 °F to 158 °F)

10% - 80% at 20 °C (68 °F)

500-1100 hPa

NOTE

All drainage, water and electrical installation work should be carried out by qualified personnel, in accordance with local and national regulations.

Electric Supply		
Voltage	230/240 V, single phase 120 V (US)	
Frequency	50 Hz	
Fuse	T 6.3 AL	
Ground Fault Circuit Interrupter (not included in delivery)	10 mA	
The unit must be continuously powered and cont	onnected via a ground fault circuit interrupter.	
The unit must be connected to protective earth (PE).		
Power supply cord	Replaced by qualified personnel	

Water Supply	
Cold/warm water connections, inlets and outlets	3/4"
CW temperature	2-20 °C (36-68 °F)
WW temperature	60-80 °C (140-176 °F)
Maximum inlet CW pressure	6 bar 600 kPa
Maximum inlet WW pressure	6 bar 600 kPa
Minimum inlet CW pressure	1 bar 100 kPa
Minimum inlet WW pressure	1 bar 100 kPa

Drainage

Bathtub drain – 1 1/2"

Floor drain – recommended to accommodate emergency user evacuation.

Mains Disconnection Device		
Permanently installed in wall. Visible and accessible at all times		
Mains transient voltage	4 kV*	
Creepage distance	3 mm*	
Air clearance	1.8 mm*	
Direction of movement	Up and down, right and left, clockwise and counterclockwise	
* If local regulations are higher, they must be met.		

Allowed Product Compatibility	
Freedom bath integrates with the following Arjo products:	Stedy, Sara Stedy, Sara Light, Sara Plus, Sara 3000 and MultiClean
No other combinations are allowed	

End of Life Disposal

- Equipment that has electrical and electronic components should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.
- Disinfection liquids if you have extra liquid, it's safe to pour it down the drain with running water. These products are water soluble and usually mixed with water when used for cleaning, your municipality will treat these cleaners the same way they would if you used them for cleaning.
- The packaging containers should be recycled according to the national or local regulations.

WARNING

To avoid electric shock, make sure that the equipment is connected to:

- Continuously powered supply mains with protective earth.
- Separate fuse and ground fault circuit interrupter (GFCI)
- A mains disconnection device
- Equipotential bonding point

All installations must be in accordance with local codes and regulations.

Labels

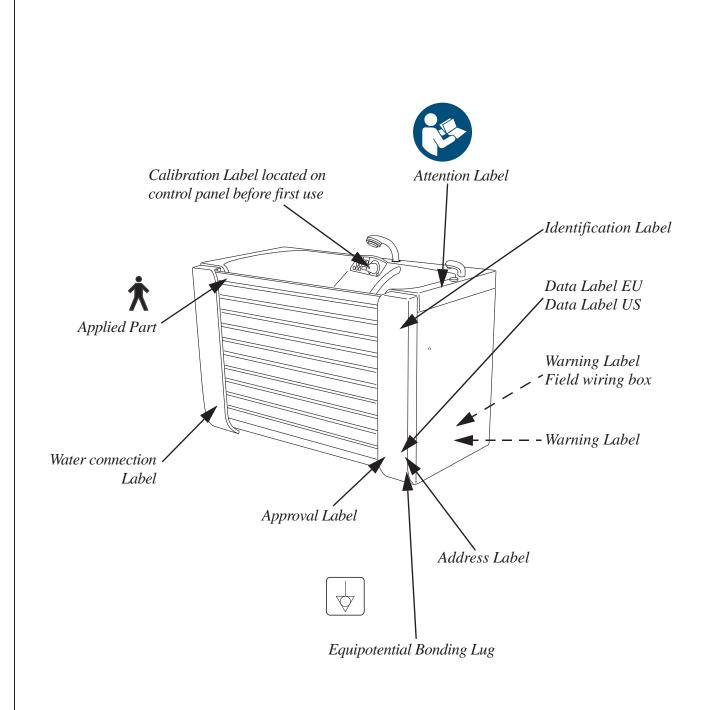
Label explanation

•		
Applied Part	Type B, Applied part: protection against electrical shock in accordance with IEC 60601-1.	
Attention Label	Important user information for correct use.	
Approval Label	States approvals for the current product.	
Calibration Label	States that a calibration has to be done before first use and after every installation. See <i>Assembly and Installations Instructions</i> and call an Arjo technician.	
Data Label	States technical performance and requirements, e.g. Input Power, Input Voltage and maximum Patient Weight etc.	
Identification Label	States the product identification, serial number and year and month of manufacturing.	
Water Connection Label	States the minimum/maximum temperature and pressure requirement of inlet water.	

Symbol	explanation
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	Label for equipotential connection point (bonding lug)
Max Patient Weight	Maximum weight of the patient
Max Total Load	Maximum weight of patient and water
Input Voltage	Voltage feed
Input Power	Power
Fuse F1 Fuse F2 Fuse F3	Identity of fuses
Class 1	Type of protection - grounded
IP X4	Degree of Protection (i.e. the product is protected against splashing water)
Air Spa system Duty Cycle	Time span of having Air Spa system turned ON and OFF.

Lift Duty Cycle	Time span of lifting the <i>Parker</i> bath and rest time.
	Read the IFU before use
	Separate electrical and electronic components for recycling in accordance with the European Directive 2012/19/EU (WEEE)
CERTIFIED SAFETY US-CA E347873	Classified by Underwriters Laboratories Inc. with respect to electrical shock, fire, mechanical, hazards and other specified hazards only in accordance with Approvals and List of Standards.
	Name and address of the manufacturer.



List of Standards and Certificates

STANDARDS/ CERTIFICATES	DESCRIPTION
EN/IEC 60601-1:2005 AMD1:2012	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
ANSI/AAMI ES60601-1 (2005) AMD 1 (2012)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
CAN/CSA-C22.2 No. 60601-1:14	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2	Electromagnetic Compatibility - Requirements and Tests
EN 60601-1-11:2015	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
ANSI Z124. 1-1995	Standards for Plastic Bathtub Units
ANSI/ASSE 1014-1989	Handheld Shower
ANSI/ASSE 1016-2005	Individual Thermostatic, Pressure Balancing and Combination Pressure Balancing and Thermostatic Control Valves for Individual Fixtures.

Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information below.

Portable and mobile RF communications equipment can affect Freedom bath.

WARNING

Stacking or placing other electrical equipment next to this device is not recommended, it can interfere with the equipment's operation and safety. Portable and mobile radio-frequency (RF) communications equipment can interfere with this equipment operation and safety.

WARNING

The equipment may cause radio interference or may disrupt the operation of nearby equipment.

It may be necessary to take action, such as reorienting, relocating the equipment or shielding the location.

Guidance and manufacturer's declaration - electromagnetic emissions

The *Freedom* bath is intended for use in the electromagnetic environment specified below. The customer or the user of the *Freedom* bath should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>Freedom</i> bath uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The <i>Freedom</i> bath is suitable for use in all establishments,
CISPR 11		including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic emission	Class A	network that supplies buildings used for domestic
IEC 61000-3-2		purposes.
Voltage fluctuations/flicker emission	Complies	
IEC 61000-3-3		

Guidance and manufacturer's declaration – electromagnetic immunity

The *Freedom* bath is intended for use in the electromagnetic environment specified below. The customer or the user of the *Freedom* bath should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance		
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV 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/burs IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines input/output lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.		
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth			
Voltage dips, short interruptions and voltage variations on power supply input lines	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycle	$<5\%$ U_T $(>95\%$ dip in U_T) for 0.5 cycle 40% U_T $(60\%$ dip in U_T) for 5 cycles			
IEC 61000-4-11	70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s			
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		
NOTE - U_T is the a.c. mains voltage prior to application of the test level					

Lift-functions, tilt-functions and temperature measurement were determined to be Essential Performance.

Guidance and manufacturer's declaration – electromagnetic immunity

The *Freedom* bath is intended for use in the electromagnetic environment specified below. The customer or the user of the *Freedom* bath should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Complian ce level	Electromagnetic environment – guidance	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of <i>Freedom</i> bath, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
Radiated RF	3 V/m	3 V/m	Recommended separation distance	
IEC 61000-4-3	IEC 61000-4-3 80 MHz to 2.5 GHz		d=0,35√P	
			$d=1,2\sqrt{P}$ 80 MHz to 800 MHz	
			$d=2,3\sqrt{P}$ 800 MHz to 2.5 GHz	
			Where <i>P</i> is the maximum output power rating of the transmitters in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).	
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b	
			Interference may occur in the vicinity of equipment marked with the following symbol: (((**)))	

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which *Freedom* bath is used exceeds the applicable RF compliance level above, the *Freedom* bath should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Freedom* bath.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and *Freedom* bath

The *Freedom* bath is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of *Freedom* bath can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Freedom* bath as recommended below, according to the maximum output power of the communications equipment

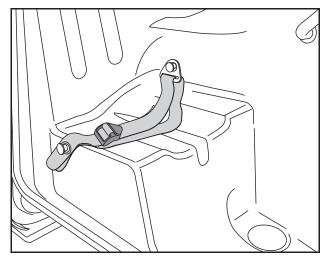
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m				
	150 kHz to 800 MHz d=0.35√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P		
0.01	0.04	0.12	0.23		
0.1	0.11	0.38	0.73		
1	0.35	1.2	2.3		
10	1.1	3.8	7.3		
100	3.5	12	23		

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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 transmitter manufacturer.

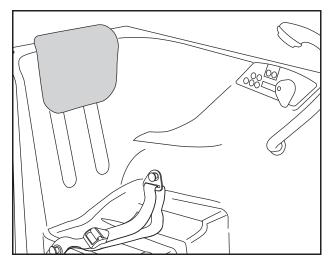
NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

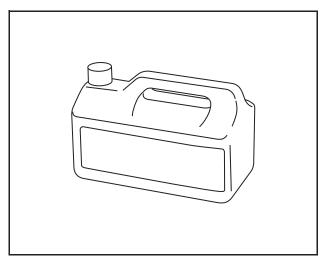
Parts and Accessories



S8662107-03 Safety belt



AFA0060 Neck pillow



For disinfectant contact the Arjo local representative

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AUSTRALIA Arjo Australia Building B, Level 3 11 Talavera Road

Macquarie Park, NSW, 2113,

Australia

Phone: 1800 072 040

BELGIQUE / BELGIË Arjo Belgium Evenbroekveld 16 9420 Erpe-Mere

Phone: +32 (0) 53 60 73 80 Fax: +32 (0) 53 60 73 81 E-mail: info.belgium@arjo.com

BRASIL

Arjo Brasil Equipamentos Médicos Ltda Rua Marina Ciufuli Zanfelice, 329 PB02

Galpão - Lapa

São Paulo – SP – Brasil CEP: 05040-000 Phone: 55-11-3588-5088

E-mail: vendas.latam@arjo.com E-mail: servicios.latam@arjo.com

CANADA

Arjo Canada Inc.

90 Matheson Boulevard West

Suite 300

CA-MISSISSAUGA, ON, L5R 3R3

Tel/Tél: +1 905 238 7880

Free: +1 800 665 4831 Institutional Free: +1 800 868 0441 Home Care

Fax: +1 905 238 7881 E-mail: info.canada@arjo.com

ČESKÁ REPUBLIKA Arjo Czech Republic s.r.o. Na Strzi 1702/65 140 00 Praha Czech Republic

Phone No: +420225092307 e-mail: info.cz@arjo.com

DANMARK

Arjo A/S

Vassingerødvej 52 DK-3540 LYNGE Tel: +45 49 13 84 86 Fax: +45 49 13 84 87

E-mail:

dk_kundeservice@arjo.com

DEUTSCHLAND Arjo GmbH

Peter-Sander-Strasse 10 DE-55252 MAINZ-KASTEL Tel: +49 (0) 6134 186 0 Fax: +49 (0) 6134 186 160 E-mail: info-de@arjo.com

ESPAÑA

ARJO IBERIA S.L. Poligono Can Salvatella c/ Cabanyes 1-7 08210 Barberà del Valles Barcelona - Spain

Telefono 1: +34 900 921 850 Telefono 2: +34 931 315 999 FRANCE Arjo SAS

2 Avenue Alcide de Gasperi

CS 70133

FR-59436 RONCQ CEDEX Tél: +33 (0) 3 20 28 13 13 Fax: +33 (0) 3 20 28 13 14 E-mail: info.france@arjo.com

HONG KONG

Arjo Hong Kong Limited

Room 411-414, 4/F, Manhattan Centre, 8 Kwai Cheong Road, Kwai Chung, N.T.,

HONG KONG Tel: +852 2960 7600 Fax: +852 2960 1711

ITALIA

Arjo Italia S.p.A. Via Giacomo Peroni 400-402 IT-00131 ROMA Tel: +39 (0) 6 87426211 Fax: +39 (0) 6 87426222

E-mail: Italy.promo@arjo.com

MIDDLE EAST

Arjo Middle East FZ-LLC
Office 908, 9th Floor,
HQ Building,North Tower,
Dubai Science Park,
Al Barsha South
P.O Box 11488, Dubai,
United Arab Emirates
Direct +971 487 48053
Fax +971 487 48072
Email: Info.ME@arjo.com

NEDERLAND

Arjo Nederland BV Biezenwei 21 4004 MB TIEL Postbus 6116 4000 HC TIEL

Tel: +31 (0) 344 64 08 00 Fax: +31 (0) 344 64 08 85 E-mail: info.nl@arjo.com

NEW ZEALAND

Arjo Ltd
34 Vestey Drive
Mount Wellington
NZ-AUCKLAND 1060
Tel: +64 (0) 9 573 5344
Free Call: 0800 000 151
Fax: +64 (0) 9 573 5384

E-mail: nz.info@Arjo.com

NORGE

Arjo Norway AS
Olaf Helsets vei 5
N-0694 OSLO
Tel: +47 22 08 00 50
Faks: +47 22 08 00 51

E-mail: no.kundeservice@arjo.com

ÖSTERREICH

Arjo GmbH

Lemböckgasse 49 / Stiege A / 4.OG

A-1230 Wien Tel: +43 1 8 66 56 Fax: +43 1 866 56 7000 **POLSKA**

Arjo Polska Sp. z o.o. ul. Ks Piotra Wawrzyniaka 2 PL-62-052 KOMORNIKI (Poznań)

Tel: +48 61 662 15 50 Fax: +48 61 662 15 90 E-mail: arjo@arjo.com

PORTUGAL

Arjo em Portugal MAQUET Portugal, Lda. (Distribudor Exclusivo) Rua Poeta Bocage n.º 2 - 2G PT-1600-233 Lisboa Tel: +351 214 189 815 Fax: +351 214 177 413 E-mail: Portugal@arjo.com

SUISSE / SCHWEIZ

Arjo AG
Fabrikstrasse 8
Postfach
CH-4614 HÄGENDORF

Tél/Tel: +41 (0) 61 337 97 77 Fax: +41 (0) 61 311 97 42

SUOM

Arjo Scandinavia AB Riihitontuntie 7 C 02200 Espoo Finland

Puh: +358 9 6824 1260

E-mail: Asiakaspalvelu.finland@arjo.com

SVERIGE

Arjo International HQ Hans Michelsensgatan 10 SE-211 20 MALMÖ Tel: +46 (0) 10 494 7760 Fax: +46 (0) 10 494 7761 E-mail: kundservice@arjo.com

UNITED KINGDOM Arjo UK and Ireland

Houghton Hall Park Houghton Regis

UK-DUNSTABLE LU5 5XF Tel: +44 (0) 1582 745 700 Fax: +44 (0) 1582 745 745 E-mail: sales.admin@arjo.com

USA

Arjo Inc.

2349 W Lake Street Suite 250 US-Addison, IL 60101 Tel: +1 630 307 2756

Free: +1 80 0 323 1245 Institutional Free: +1 800 868 0441 Home Care

Fax: +1 630 307 6195 E-mail: us.info@arjo.com

JAPAN

Arjo Japan K.K. 東京都港区虎ノ門三丁目7番8号 ランディック第2虎ノ門ビル9階 Tel: +81 (0)3-6435-6401 Fax: +81 (0)3-6435-6402

E-mail: info.japan@arjo.com

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ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden

www.arjo.com

