MEDICAL DEVICES

# MRI Guard Agilia

Technical Manual


Agilia
Intuitive Generation

FRESENIUS
KABI
caring for life

## TM MRI Guard Agilia ENG ref. CC6078

**Applicable to devices with serial number from MGA0101 till...**

| Date | Revision | Chapter | Description |
|---|---|---|---|
| Nov. 9th, 2012 | 0 | All index "a" | Creation |
| July 22nd, 2013 | 1 | Index "b" | ■ Modification all chapters<br>■ Creation chapter "7.5.4 Quality Control Certificate" |
| Feb. 26th, 2014 | 2 | Index "c" | Update of:<br>■ the maximum alarm delay,<br>■ the EMC values in Tables 4 and 6. |
| Dec. 7th, 2016 | 3 | Index "d" | Update of:<br>■ 1.5.1 Intended positioning<br>■ 2.2.2 Switching on the MRI Guard Agilia: an information symbol is added.<br>■ 5.2.4 CPU specifications: only the Flash memory item.<br>■ 7.5.3: only the last sentence of the section<br>■ Intervention sheet no 1: only the first three sentences are modified. |

# 1 Introduction

The MRI Guard Agilia is intended to accommodate and power up to four infusion pumps of the Agilia range (**Injectomat Agilia**, **Injectomat MC Agilia**, **Injectomat TIVA Agilia**, **Volumat Agilia**, and **Volumat MC Agilia**). With the **MRI Guard Agilia**, these infusion pumps can be operated in a Magnetic Resonance Imaging unit.

The intended position in the MRI unit is as near as possible to the patient in the MRI unit with a limitation of 20 mT/200 Gauss as the maximum magnetic field density.

Due to its construction principle, the **MRI Guard Agilia** reduces the interferences between the **Agilia** IV pumps inside the device and the MRI Scanner as long as a trouble-free operation of all equipment is ensured. The operator is supposed to have a suitable qualification.

The use of **MRI Guard Agilia** does not change the standalone pump behaviour.

## 1.1 Description of symbols

DANGER

***Danger:***
*alert to an imminent hazard which could result in **serious** personal **injury** and/or product **damage** if the written instructions are not followed.*

***Warning symbol:***
*alert to a **potential hazard** which could result in **serious** personal **injury** and/or product **damage** if the written instructions are not followed.*

***Caution symbol:***
*alert to a **potential hazard** which could result in **minor** personal **injury** and/or product **damage** if the written instructions are not followed.*

***Information symbol:***
*recommendations to be followed.*

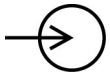
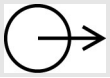
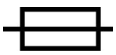
## 1.2 Glossary of terms

| Term | Description |
|---|---|
| A | Ampere |
| AC | Alternating Current |
| Agilia | Range of infusion pumps manufactured by Fresenius Kabi |
| Ah | Ampere hour |
| AM | Amplitude Modulation |
| CISPR | International Special Committee on Radio Interference |
| CPU | Central Processing Unit |
| DECT | Digital Enhanced Cordless Telecommunications |
| ECG | ElectroCardioGram |
| EEG | ElectroEncephaloGram |
| EMC | ElectroMagnetic Compatibility |
| ESD | ElectroStatic Discharge |
| FM | Frequency Modulation |
| GPL | General Public License |
| H/W/D | Height / Width / Depth |
| HF | High Frenquency |
| hPa | Hectopascal |
| Hz | Hertz |
| IEC | International Electrotechnical Commission |
| IFU | Instructions For Use |
| in | Inch |
| Injectomat<br>Injectomat MC<br>Injectomat TIVA | Syringe pumps belonging to the Agilia range and manufactured by Fresenius Kabi |
| IP | Ingress Protection |
| ISO | International Organization for Standardization |
| IT | Information Technology |
| IV | IntraVenous |
| Kg | Kilogram |
| Lb | Pound |
| LED | Light Emitting Diode |
| MRI | Magnetic Resonance Imaging |
| mT | milli Tesla (unit for magnetic field density) |
| RAM | Random Access Memory |
| RF | Radio Frequency |
| RFID | Radio Frequency IDentification |
| RS232 | Serial interface connector |
| S/N | Serial Number |
| UPS | Uninterruptable Power Supply |
| Ut | Test specification level |
| V | Volt |
| VA | Volt Ampere |
| Volumat<br>Volumat MC | Volumetric pumps belonging to the Agilia range and manufactured by Fresenius Kabi |

## 1.3 Device labelling

### 1.3.1 MRI Guard Identification label

Position: on back side of housing, next to Power / Mains connection

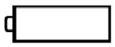
| Symbols | Description |
|---|---|
| REF | Product reference / part number |
| SN | Product serial number |
|  | Input terminal – connector |
|  | Output terminal – connector |
|  | Electrical fuses |
|  | Alternative Current (AC) |
|  | Protection against leakage current; type B applied part |
| IP21 | Index of protection against splashing liquids |
|  | Not to be used in residential area |
|  | Obligation for the user to refer to the Instructions For Use |
|  | Part included in a recycling process |
| CE 0123 | CE Marking |
|  | Name and address of the manufacturer / Date of manufacture |

### 1.3.2 Labels on the system

| Symbols | Position | Description |
|---|---|---|
|  | On the door lever | General warning sign |
|  | Near device identification label and inside the housing | MR conditional:<br>(The device does not cause any hazard in a specified MR Environment)<br>MRI Scanner: 1.5 Tesla and 3.0 Tesla<br>Magnetic Field: max. 20mT |
| **<4kg** | IV Pole | Maximum load < 4kg |
|  | Inside the housing | Push the **Agilia** IV pump firmly so that the locking mechanism secures. |

### 1.3.3 Label on Magnet Indicator's battery pack

Position: On Magnet Indicator's battery pack (Pos. 19)

| Symbols | Description |
|---|---|
|  | Battery pack |
| **REF** | Product reference / part number |
| **LOT** | Product batch number |
|  | Obligation for the user to refer to the Instructions For Use |
|  | Part included in a recycling process |

## 1.4 Scope

This technical manual is applicable to the **MRI Guard Agilia.**

For the **Link + Agilia** that **MRI Guard Agilia** is equipped with, please refer to the technical manual of the **Link + Agilia**.

***Warning:***

- *Check that this technical manual is applicable to the current **MRI Guard Agilia** software.*
- *The software version of the **MRI Guard Agilia** is printed on the identification label.*
- *The user must adhere to the instructions specified in this technical manual. Failure to adhere to these instructions may result in damages to the equipment.*

## 1.5 Intended use

***Warning:***

- *Before using the **MRI Guard Agilia** system, read all the accompanying documents provided with **MRI Guard Agilia**, **Agilia** IV Infusion pumps and accessories.*
- *Make sure to have fully understood how to use the device in order to assure your safety and the safety of the patient. Give a particular attention to the texts which are highlighted by a symbol.*

### 1.5.1 Intended positioning

The intended position of the **MRI Guard Agilia** is as near as possible to the patient in the MRI unit, but with the limitation of a maximum magnetic field density of 20 mT/200 Gauss which is equivalent to a distance of approximately 1.5 m by an active shielded 3 Tesla MRI Scanner.

### 1.5.2 Intended user population

***Warning:***

- ***MRI Guard Agilia** must only be used by qualified and trained medical staff.*
- *In order to be trained, please contact your **Fresenius Kabi** representative or a certified trainer.*

### 1.5.3 Intended patient population

***Warning:***

- *Make sure that all **Agilia** IV infusion pumps installed in one **MRI Guard Agilia** are only connected to a single patient.*
- *Never have several patients connected at the same time to the same **MRI Guard Agilia.***

**MRI Guard Agilia** in combination with **Agilia** IV Infusion pumps is intended to be used on the same patient population as the **Agilia** IV infusion pumps.

## 1.5.4 Intended conditions of use

### Contraindications

***Danger:***

DANGER

- ***MRI Guard Agilia*** *is not designed to be used in an explosive or flammable environment due to risk of ignition.*

***Warning:***

- ***MRI Guard Agilia*** *is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive or flammable environment or ultrasonic and ionizing radiation (eg: X-Ray) environments.*
- *Do not use drop sensor neither outside the* ***MRI Guard Agilia****, nor inside of the* ***MRI Guard Agilia****.*
- *Please refer to the "Use environment"and the "Technical specifications" sections in this document for additional information and requirements about the use environment.*

### Use environment

**MRI Guard Agilia** is intended to be used in the MR Environment.

***Information:***

- *Temperature operating range: 5°C (41°F) to 40°C (104°F).*
- *Storage temperature: -10°C (14°F) to +60°C (140°F).*
- *Pressure operating range: 700hPa (525mmHg / 10.15PSI) to 1060hPa (795mmHg / 15.37PSI).*
- *Storage pressure: 500hPa (375mmHg / 7.25PSI) to 1060hPa (795mmHg / 15.37PSI).*
- *Humidity operating range: 20% to 90%, no condensation.*
- *Storage humidity: 10% to 90%, no condensation.*
- *Altitude: max 3000m (9842.52ft).*

# 1.6 MRI Guard Agilia in MR Room

## 1.6.1 Get started in the MR Room

***Warning:***

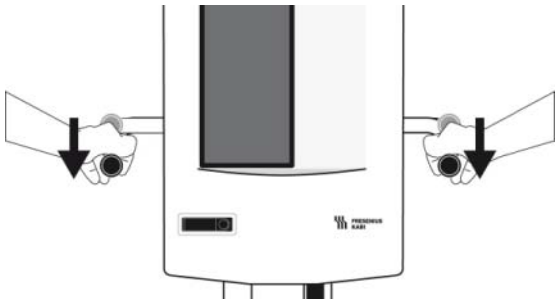
- *The **MRI Guard Agilia** is intended to be used at a maximum magnetic field of 20mT (= 200 Gauss).*
- *The **Agilia** IV infusion pumps can be used in the MR Environment only if they are installed in the **MRI Guard Agilia**.*
- *The door of the **MRI Guard Agilia** has to be locked during MR examination, otherwise the RF-Noise of the IV Pumps can lead to artefacts on the MR images.*
  *(Remark: door can be opened between different scans of the MR examination, if the MR Scanner is not imaging) (see also figure: Indicators for an open door).*
- *The **MRI Guard Agilia** and the Agilia infusion pumps have components with ferromagnetic parts that can be attracted if they are placed too close to the MR Scanner.*
- *Never place an IV pump on the patient table of the MR Scanner.*
- *The **Agilia** IV infusion pumps should be installed in or removed from the **MRI Guard Agilia** outside the MR Environment / Magnet Room.*
- *Observe the Magnet Indicator by positioning the MRI Guard Agilia in the MR Environment (refer to section 5.2 of the IFU). The **MRI Guard Agilia** should not be used with other devices.*
- *Sound alarm cannot be heard from the observation room.*
- *The external shield protects devices against electro-magnetic interferences but does not reduce the magnetic field.*
- *Before entering the MRI unit, check if there will is enough drugs in the Agilia infusion pumps for the entire procedure.*
- *Do not enter the **Agilia** IV infusion pumps alone into the room B.*

**General procedure to use MRI Guard Agilia:**

- "Room A" MR Control Room or preparation Room:
  - ☐ Install the **Agilia** IV infusion Pumps in **MRI Guard Agilia** rack.
  - ☐ Prepare the patient and adjust the **Agilia** IV infusion pumps for the MR examination.

***Warning:***
*Do not squeeze the infusion lines by closing and locking the door.*
*Please ensure no parts lay on the **MRI Guard Agilia** when you enter the MR Room.*
*Ferromagnetic parts can be attracted by the MR Scanner.*

- ☐ Disconnect power cable from mains.
- ☐ Press the two handles downwards to move the **MRI Guard Agilia** carefully into the MR unit.

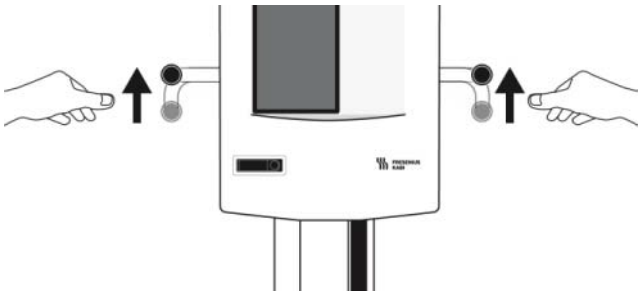


■ “Room B” MR unit (Magnet Room / MR procedure Room):

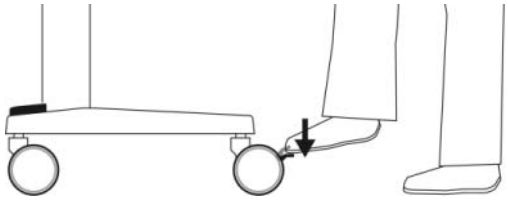
□ Approach the **MRI Guard Agilia** carefully closer to the MR Scanner and observe the Magnet Indicator until you reach the desired position in the MR Environment (max magnetic field ≤ 20mT): the Magnet Indicator should remain green. If the Magnet Indicator flashes yellow, move back the **MRI Guard Agilia** to the green position.
Position the **MRI Guard Agilia** so the front and the Cap User Interface (top) remains visible at all times from the control room.

***Warning:***
*At this position the door can be opened and the delivery rate can be set. The pumps should not be removed from **MRI Guard Agilia**.*
*Check the IV lines remain loose between the **MRI Guard Agilia** and the patient’s IV access.*

□ Once correctly positioned, carefully release the two handles.



□ Push the brakes of the castors in order to prevent any movement of the **MRI Guard Agilia**.



□ If a wall plug is available, connect the power cable of the **MRI Guard Agilia**. If no wall plug is available, the Cap user interface’s battery will ensure the correct lightning of the system, while the pumps will operate with their own battery back-up.

***Warning:***
*If used on battery, ensure **Agilia** IV infusion pumps have enough battery back-up to be able to operate for the expected duration of the infusion. To check battery life at current rate please refer to the respective **Agilia** pump IFU.*

□ Make sure the door of the **MRI Guard Agilia** is closed.

***Warning:***
*Do not squeeze the infusion lines by closing and locking the door.*

□ Start the MR examination.

***Warning:***
*The door of the **MRI Guard Agilia** has to be locked when MR Scanner is imaging but can be opened between different scans (when MR Scanner is not imaging).*
*In urgent cases the door can be opened also during MR Scanner is imaging, but this could lead to artefacts on the MR Images (not to malfunctions of the pumps). In this case the MR Scan has to be repeated.*

□ To remove the **MRI Guard Agilia** from the MR Environment to the MR Control Room or Preparation Room, lift the brakes to release the brakes of the castors, then push the two handles and move the **MRI Guard**.

■ "Room A" MR Control Room or Preparation Room:

□ Open the door of **MRI Guard Agilia** and remove the **Agilia** IV infusion pumps from **MRI Guard Agilia**.

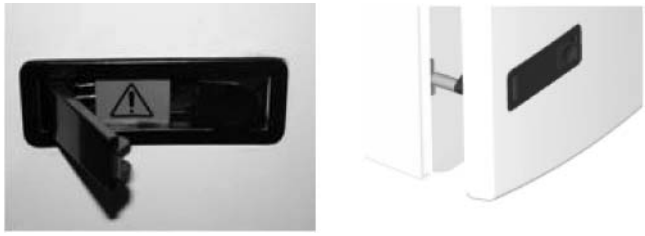


Figure: Indicators for an open door

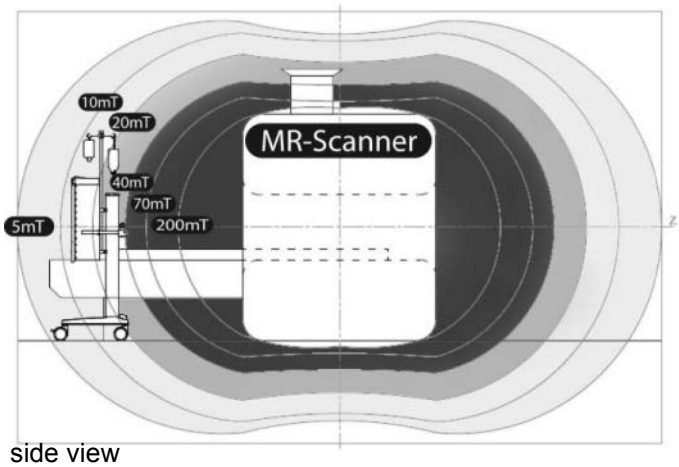
***Caution:***
*Before closing the door, make sure the infusion lines are properly placed in the outlets to avoid squeezing them and provoking occlusions.*

***Information:***

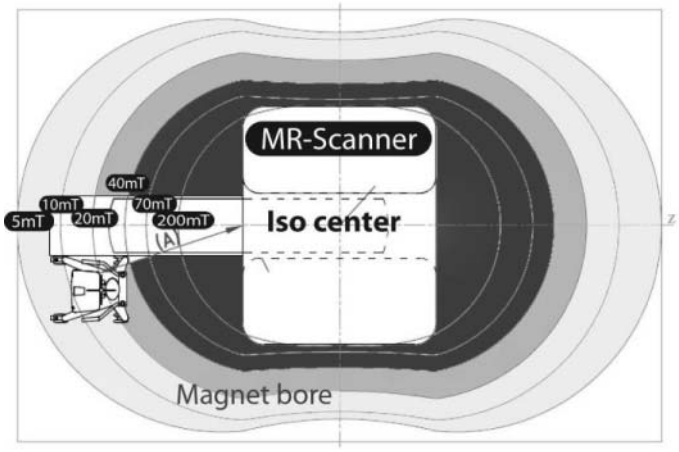
■ *MR Environment = Environment around an MR Scanner within the 0,5mT (5 Gauss) line of the three dimensional fringe field. The MR Environment includes the magnet bore and anywhere in the Magnet Room (MR procedure Room).*
■ *Fringe field or Spatial Gradient - The strong magnetic field within the magnet bore of the MR Scanner drops off with distance away from the magnet. The spatial distribution of the surrounding field from the MR Scanner is called Fringe field or Spatial Gradient.*

The following figure shows a typically spatial distribution of surrounding field (Fringe field) from an active shielded MR Scanner with a static magnetic field of 3.0 Tesla.

**MRI Guard Agilia** in MR Environment:




side view




top view

**MRI Guard Agilia** in MR Environment:

| Fringe field of MR Scanner | Typically values for approximately distances (A) in z-direction to opening of magnet bore | | Allowed position in MR Environment |
|---|---|---|---|
| | Static Magnetic field of MR Scanner: 3.0 Tesla | Static Magnetic field of MR Scanner: 1.5 Tesla | |
| 200mT / 2000 Gauss | 0.6m | 0.5m | No |
| 70mT / 700 Gauss | 0.9m | 0.8m | No |
| 40mT / 400 Gauss | 1.1m | 1.0m | No |
| 30mT / 300 Gauss | 1.2m | 1.1m | No |
| 20mT / 200 Gauss | 1.4m | 1.2m | Yes |
| 10mT / 100 Gauss | 1.7m | 1.5m | Yes |
| 5mT / 50 Gauss | 2.1m | 1.8m | Yes |

***Information:***
*Details to the MR Scanner, e.g. dimensions (length of magnet bore etc.) and the fringe field you can find in the IFU and the technical description provided by the Manufacturer of the MR Scanner. The technical description describes among other things the spatial distribution of surrounding field (Fringe field) with values of 0.5mT, 1mT, 3mT, 5mT, 10mT, 20mT, 40mT and 200mT as well as a distance scale and a superimposed outline of the magnet.*

DANGER

***Danger:***
*The dangerous area for the pumps regarding the magnetic field starts at 50mT. Never position the **MRI Guard Agilia** closer than 1m to the MR Scanner. The **Agilia** IV infusion pumps may be attracted towards the MRI scanner when positioned at this distance.*

## 1.6.2 Magnet Indicator

***Warning:***.


- *If no light is seen, do not use the **MRI Guard Agilia** within the MRI Room*
- *If the light on the Magnet Indicator is not green, immediately move the **MRI Guard** away from the MR Scanner until you get a green light.*
- *If the Magnet Indicator flashes red every 500ms, there is a System error (LED no. 4).*
- *Do not use the **MRI Guard Agilia** without the Magnet Indicator giving a visible sign.*

The Magnet Indicator is an integrated accessory to position the **MRI Guard Agilia** in the MR Environment.

The magnet indicator consists of the following components:

- Measuring unit with hall-sensors (x-, y-, and z- direction) and power management.
- Speaker for an audible signal.
- LEDs for a visual signal.
- Magnet indicator's Battery Pack to operate the Magnet Indicator independently from the power supply of **MRI Guard Agilia**.

***Information:***

- *The Magnet Indicator measures and indicates the magnetic field continuously.*
- *Warning events will be stored in the internal memory and can be read out by Technical Service.*
- *The Magnet Indicator is an accessory to place the **MRI Guard Agilia** as close as possible to the MR Scanner within the safe area.*
- *The Magnet Indicator's battery pack has to be replaced each 12 months and in case Low Battery (LED-No.5) is indicated or no light.*

| Color of Magnet Indicator | Green | Yellow | Red |
|---|---|---|---|
| Status |  |  |  |
| Action | Correct position | Move away from scanner to go to green | Move immediately away from scanner into green and get your pumps checked by a technician |


| LED No. | Positioning | Signal Priority | Color | Display | Instruction |
|---|---|---|---|---|---|
| 1 | Normal operation; Magnetic field < 20mT | -- | Green | LED flashes each 2 seconds | The unit is in a low level magnetic field and can be used safely. |
| 2 | Caution! Magnetic field 20 – 40mT | MEDIUM | Yellow | Yellow LED flashes each 1.5 second and speaker sounds an audible signal | Critical magnetic field is reached. Move the unit away to green level and do not approach the unit closer to the magnet bore. |
| 3 | Warning! Magnetic field > 40mT | HIGH | Red | LED flashes each 500ms and speaker sounds an audible signal. (Event is stored in the internal memory). | Maximum magnetic field is exceeded. Move the unit away immediately! |
| 4 | System Error (e.g. Watchdog failure / Measurement failure / Power supply error) | HIGH | Red | LED flashes each 500ms and speaker sound an audible signal | Function has to be checked by Technical Service |
| 5 | Battery Low. The Magnet Indicator operates for less than 10 days. | LOW | Yellow | LED flashes each two seconds and speaker sounds once an audible signal | Replace magnet indicator's battery pack immediately! |
| 6 DANGER | No light | -- | No light | No light | Do not use the device. Change the Magnet Indicator's battery pack |

***Information:***

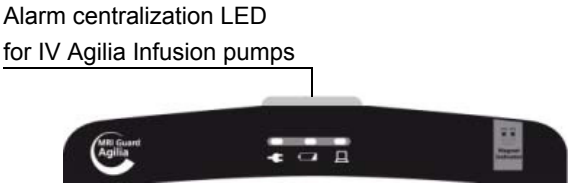
- *It is recommended to mark the critical magnetic field (20mT) on the floor.*
- *All Signals of the Magnet Indicator are non-latching.*
- *Low Battery (LED-No.5) appears at the same time as LED-No.: 1 or 2 or 3 if the Magnet Indicator operates only for less than 10 days. Please replace the magnet indicator's battery pack immediately.*

## 1.7 Signaling

### 1.7.1 Alarm and pre-alarm centralization for the IV Agilia Infusion pumps

***Warning:***

- ***MRI Guard Agilia*** *alarm and pre-alarm centralization display is NOT functional when system is booting, in maintenance mode or system error.*
- *Alarms, pre-alarms and notification events displayed by* ***MRI Guard Agilia*** *user interface are visual ONLY. Audible alarms are generated by the* ***Agilia*** *IV infusion pumps ONLY, so make sure the* ***MRI Guard Agilia*** *is positioned to ensure continuous visibility of the front and of the cap user interface situated on top of the device.*
- *The alarm and pre-alarm centralization system must not exempt the user from checking the patient status at the bedside.*
- *It is recommended that the user is located in front of the* ***MRI Guard Agilia****, so that from this location the Cap user interface's battery status and the alarm centralization display are visible.*




The **MRI Guard Agilia** provides the user with visual centralization of the alarms and pre-alarms of all connected pumps. The LEDs are located at the top of the device.

***Information:***
***When two alarms occur at the same time, the alarm of higher priority is displayed.***
*LED colors Information:*

- *Red: HIGH PRIORITY*
*(Indicating that immediate OPERATOR response is required)*
- *Yellow: MEDIUM PRIORITY (indicating that prompt OPERATOR response is required)*
- *or LOW PRIORITY (indicating that OPERATOR awareness is required)*

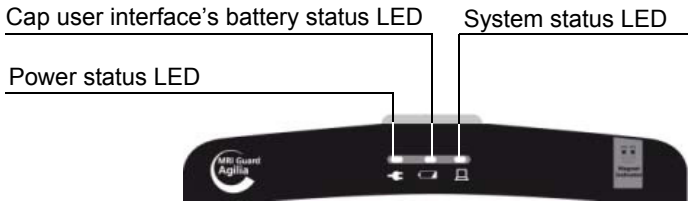
***Maximum alarm delay:***

- *For all alarms, the amount of time between the alarm audio and visual indicator on the pump and the alarm visual indicator on the* ***MRI Guard Agilia*** *is less than 5 seconds.*

Alarm Management:

| Event | Display color | Status |
|---|---|---|
| At least one connected infusion pump has a high priority alarm. | RED | Blinking |
| At least one connected infusion pump has a medium or low priority alarm (with no infusion pump on alarm) | YELLOW | Blinking |
| **MRI Guard Agilia** is operating on maintenance mode. | YELLOW | Fix |

### 1.7.2 Power supply, Cap User Interface's battery and system displays, status




The **MRI Guard Agilia** provides the user with visual information about the power supply, the cap user interface's battery and the system status indicated by a specific display located at the top of the device.

■ Power status LED

| Event | Display color | Status |
|---|---|---|
| Power is connected and present. | GREEN | FIX |
| No power, **MRI Guard Agilia** is operating on battery. | | OFF |

■ Cap user interface's Battery status LED

The following operating mode is used:

| Power supply status | Battery event | Display color | Status |
|---|---|---|---|
| Connected | Cap user interface's battery loaded / if the power supply is disconnected at this moment, the system has more than 1h battery life. | GREEN | FIX |
| | Cap user interface's battery is loading / If the power supply is disconnected at this moment, the system has between 20min and 1h battery life. | YELLOW | FIX |
| | Cap user interface's battery is loading / The system has less than 20min battery life and might fail if power is disconnected. | RED | FIX |
| | Cap user interface's battery error or absent / The system will fail if power is disconnected. | RED | BLINKING |
| Not connected | The system operates on Cap user interface's battery and has at least 1h battery life left. | GREEN | FIX |
| | The system operates on Cap user interface's battery and has between 20min and 1h battery life | YELLOW | BLINKING |
| | The system operates on Cap user interface's battery and has less than 20min battery life left - immediate reconnection of power supply is recommended | RED | BLINKING |

| Power supply status | Battery event | Display color | Status |
|---|---|---|---|
| | The system has detected a Cap user interface's battery error and might fail any time - immediate reconnection of power supply is recommended | RED | BLINKING |
| | Battery and power supply absent | OFF | OFF |

■ System status LED

The following operating mode is used:

| Event | Display color | Status |
|---|---|---|
| **MRI Guard Agilia** internal software is booting | YELLOW | FIX |
| **MRI Guard Agilia** internal software is running | GREEN | Fix |
| **MRI Guard Agilia** internal software error | RED | Fix |

## 1.8 Batteries and mains connection

**Batteries in MRI Guard Agilia:**

There are two batteries in the **MRI Guard Agilia**:

■ Cap User interface's: 

Mains power and integrated Cap user interface's battery.

Its rechargeable battery provides power to the cap user interface for about 1 hour. It can only be replaced by a **Fresenius Kabi** service technician.

■ Magnet Indicator's: 


Magnet Indicator's battery pack.

Its non-rechargeable battery provides power and lights to the magnet indicator at all times for about 1 year. This battery can be replaced by a **Fresenius Kabi** service technician or by a hospital qualified technician by following the instructions of this document.

### 1.8.1 Cap user interface's rechargeable battery precautions of use

***Danger:***

DANGER

***MRI Guard Agilia*** *uses a Lithium-ion rechargeable battery.*
*Incorrect handling of the battery by unqualified personnel or use of a battery other than that specified by the manufacturer may cause leakage, overheating, smoke, explosion or fire.*

***Caution:***

*Lithium-ion Cap user interface's rechargeable battery must be handled with care!*

- Do not use **MRI Guard Agilia** without battery connected.
- Do not disconnect battery when device operating on mains power or on battery: disconnect power cord from mains and power off device before disconnecting battery.
- Do not incinerate or place close to fire.
- Do not drop, crush, puncture, modify or disassemble battery.
- Do not use a battery that is severely scratched or damaged.
- Do not modify the battery.
- Do not expose to high temperature or very low temperature: refer to operating and storage conditions of use.
- Do not replace by a battery other than the one delivered by **Fresenius Kabi**.
- Do not charge or discharge otherwise than in the device.

### 1.8.2 Switching on and off

- The device switches ON when the power cord is plugged into mains power supply.
- The device switches OFF when:
  - Power is disconnected; the device operates then on battery for about 1 hour.
    - AND
  - No more pumps are switched ON or installed in the **MRI Guard Agilia** for at least 30 minutes.

***Information:***

- *There is no ON/OFF button on the **MRI Guard Agilia**.*
- *For **MRI Guard Agilia** storage (see "Precautions for storage" section).*

### 1.8.3 Cap user interface's battery operating mode

For additional information about Cap user interface's battery status indications, refer to the "*Signaling*" section in this document.

***Information:***

- *When the **MRI Guard Agilia** is used on battery, the **Agilia** IV infusion pumps will run with their individual batteries.*
- *In order to maximize the Cap user interface's battery lifetime and performance: during operation, leave the device plugged to the mains power supply to maintain the battery charged and at the maximum capacity.*

**Reset procedure:**

In case of severe malfunction of the **MRI Guard Agilia**, a reset can be done.

- Disconnect the **MRI Guard Agilia** from mains power supply until the Cap User Interface lights are off.
- Connect the **MRI Guard Agilia** to the mains power supply and observe if the device operates correctly (see also in the IFU the "*Quick check protocol*" section).

## 1.8.4 Magnet Indicator's Battery Pack

It is recommended to read "*Signaling*" section in this document.

***Danger:***

DANGER

*Magnet Indicator uses a Lithium battery (non rechargeable). Incorrect handling of the battery by unqualified personnel or use of a battery other than that specified by manufacturer may cause leakage, overheating, smoke, explosion or fire.*

***Caution:***

- *The Magnet Indicator's Battery Pack has to be installed before first use of **MRI Guard Agilia** in MR Environment.*

***Lithium magnet indicator's battery must be handled with care!***

- *Do not incinerate or place close to fire.*
- *Do not expose contents to water*
- *Do not drop, crush, puncture, modify or disassemble battery.*
- *Do not use a battery that is severely scratched or damaged.*
- *Do not modify the battery.*
- *Do not expose to high temperature or very low temperature: refer to operating and storage conditions of use.*
- *Do not replace by a battery other than the one delivered by **Fresenius Kabi**.*
- *Do not recharge.*
- *The Magnet Indicator's non rechargeable Battery Pack has to be installed by a technician.*

***Information:***

- *There is no ON/OFF button on the Magnet Indicator .*
- *The Magnet Indicator switches ON when cable is connected to the Battery Pack and vice versa.*
- *The Magnet Indicator's battery pack has to be replaced each 12 months and in case Low Battery (LED-No.5) is indicated*

# 1.9 Warranty

## 1.9.1 General conditions of warranty

**Fresenius Kabi** guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the batteries and the accessories.

## 1.9.2 Limited warranty

To benefit from the materials and workmanship guarantee from our Technical Service or agent authorized by **Fresenius Kabi**, the following conditions must be respected:

- The device must have been used according to the instructions described in the IFU and other accompanying documents.
- The device must not have been damaged when in storage, at the time of repair, or show signs of improper handling.
- The device must not have been altered or repaired by non-qualified personnel.
- The Cap user interface's battery must not have been replaced by a battery other than that specified by the manufacturer.
- The serial number (ID/N°) must not have been altered, changed, or erased.

***Information:***

- *In case of non-respect of these conditions, **Fresenius Kabi** will prepare an estimate for repair covering the parts and labour required.*
- *When a return and/or a repair of the device are required, please contact your **Fresenius Kabi** Technical Service.*

## 1.9.3 Warranty conditions for batteries and accessories

Batteries and accessories may have specific conditions of warranty.

Please contact your **Fresenius Kabi** sales representative for additional information.

# 2 MRI Guard Agilia and infusion pumps: installation and removal

## 2.1 Packaging content

***Warning:***
*Use ONLY recommended accessories.*
*Please refer to the "Ordering information" section for additional information.*

The **MRI Guard Agilia** package contains the following elements:

- 1 **MRI Guard Agilia** for up to 4 IV infusion pumps.
  - Instructions for use
  - 1 power cord
- IV Pole for bags and bottles (Pole with cross)
- Magnet Indicator's Battery Pack with two screws (M3-crossed slot) to fasten Battery Pack in housing of **MRI Guard Agilia.**

***Information:***

- *If the content of the packaging is not complete, please contact your **Fresenius Kabi** sales organization.*
- *If some parts are damaged in the packaging, please contact your **Fresenius Kabi** sales organization.*

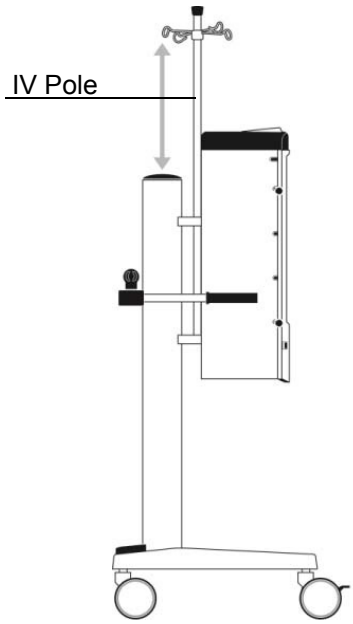
## 2.2 MRI Guard Agilia installation and removal

***Warning:***

- *All installations and removals have to be performed outside the MR Environment.*
- *When used with volumetric pumps and IV bags, respect the recommended distance between IV bags and **MRI Guard Agilia** with pumps. For more details, please consult the pumps IFU.*
- *It is recommended that the "Quick check protocol" be applied after installation and before use of the device on a new patient. Please refer to the IFU.*

### 2.2.1 IV Pole

Put the **IV Pole** in the holes between the column of the trolley and housing.




***Caution:***
*Do not install or remove **IV pole** with infusion bags.*

### 2.2.2 Switching on the MRI Guard Agilia

***Caution:***

- *Use ONLY the power cord supplied by the manufacturer.*
- *This device is intended to be powered ONLY by mains from 100VAC to 240VAC / 50-60Hz.*
- *The **MRI Guard Agilia** is an electrical class I device so must be earthed when connected to an AC power supply with power cord to ensure electrical safety requirements.*
- *When connected to mains power supply, a three-wire power cord (Live, Neutral, Earth) supply must be used with appropriate approvals and requirements by country.*
- *It is imperative that the user checks the quality of the earth (Building electric requirements) and the integrity of power cord.*
- *Do not replace fuses of type other than that specified by **Fresenius Kabi.***
- *Disconnect power cord from mains before changing the fuses.*
- *Be sure that the power supply network is insulated, protected and sized to support this medical device equipment.*
- *For additional information related to power requirements, refer to the "Technical characteristics" section in this document.*

MRI Guard Agilia and infusion pumps: ins-

1. Plug power cord to **MRI Guard Agilia** power connection.
2. Plug power cord into the wall power socket.
3. Check power status indicator is lit in green.

***Information:***
*The system status LED located on the upper side switches from yellow to green when the system is ready.*

### 2.2.3 Charging time of the Cap user interface's battery before first use

***Caution:***
*Before starting to use **MRI Guard Agilia**, connect the power cord to the mains power supply for approximately 15 hours without using the device.*

MRI Guard Agilia and infusion pumps: ins-

# 2.3 Agilia IV infusion pumps installation and removal

## 2.3.1 Compatible Agilia IV infusion pumps

***Caution:***

- *Do not try to connect IV pumps other than those recommended.*
- *The **MRI Guard Agilia** rack has 4 outlets to power **Agilia** IV infusion pumps devices. These outlets are connected to a functional earth.*
- *An internal switch cuts power on empty positions. This system does not guarantee protection against electric strokes in all cases, so usual caution must be applied.*

The **MRI Guard Agilia** is ONLY compatible with the following IV infusion pumps from **Fresenius Kabi:**

- **Injectomat Agilia**
- **Injectomat MC Agilia**
- **Injectomat TIVA Agilia**
- **Volumat Agilia**
- **Volumat MC Agilia**

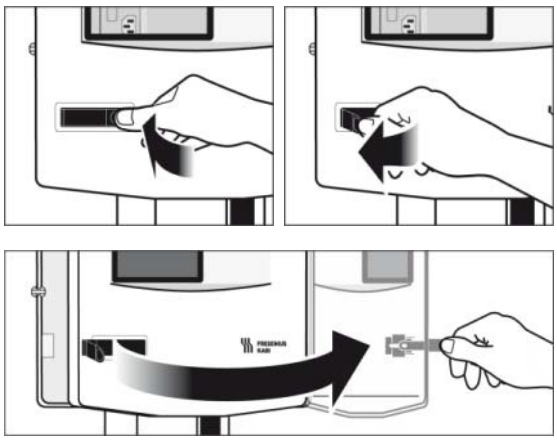
## 2.3.2 Installing an Agilia IV infusion pump

***Warning:***

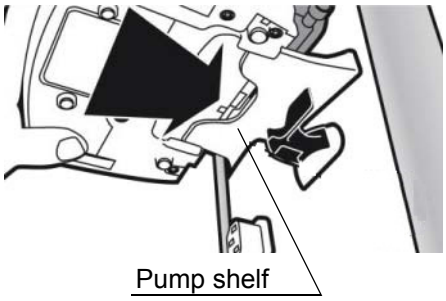
- *When used with volumetric pumps and infusion bags, respect the installation instructions as detailed in the pump's IFU (prefer the lowest positions for volumetric pumps).*
- *Do not force during pump installation. If you have to force excessively, do not use the devices and contact your Technical Service.*
- *During installation, be sure that IV sets are not squeezed, bent or cut when pump is mounted and door is closed.*
- *To avoid confusion between pumps and the associated infusion lines, we recommend that the infusion set is installed before another pump is mounted on the rack.*
- *Be sure that the pump is correctly mains powered after installation.*

MRI Guard Agilia and infusion pumps: ins-

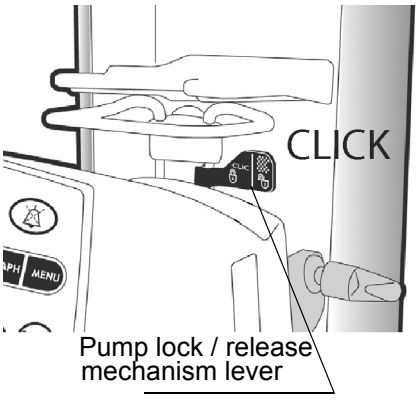
1. Press the door lever to release the door, then pull the lever to fully open the door of the housing.



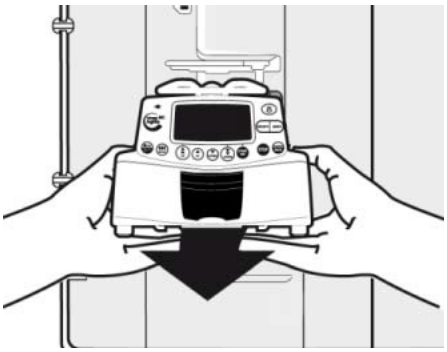
2. Ensure the pole clamp of the pump is folded up against the pump. Position the **Agilia** IV infusion pump in front of the **Link+ Agilia** and slide it carefully on the pump shelf slot.




3. Push the pump firmly so that the locking mechanism secures the pump (be sure to hear the "CLICK").

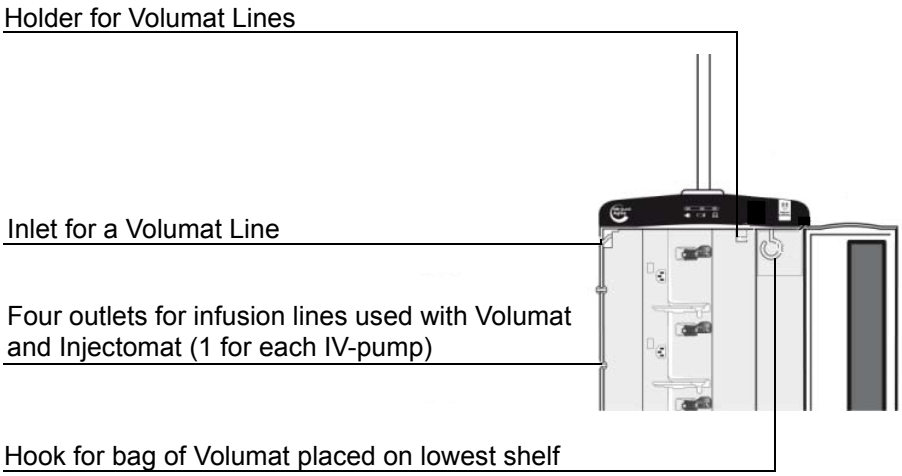



4. Pull the pump out to check if well installed.



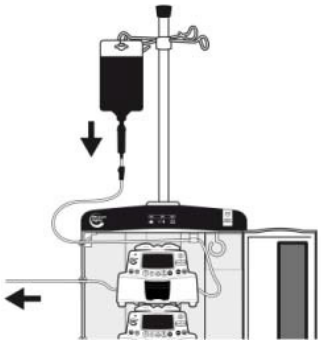
5. When the **MRI Guard Agila** is powered to the mains power supply, check on the pump display that the power display light is ON and listen to the audio pump signal.

**Infusion lines and bags installation:**



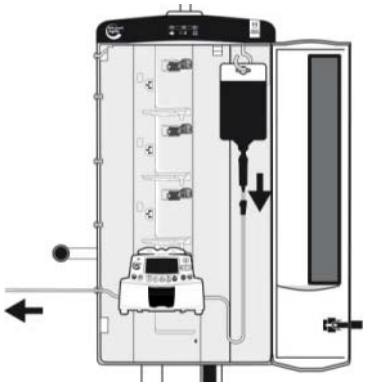

**Installation of Volumat Agilia pump in one of the 3 upper positions:**

***Information:***
*When **Volumat Agilia** pump is installed in one of the 3 upper positions, the infusion bag should be hunged outside the housing, from the pole. Volumat lines should be entered through the upper inlet and hooked in the holder.*

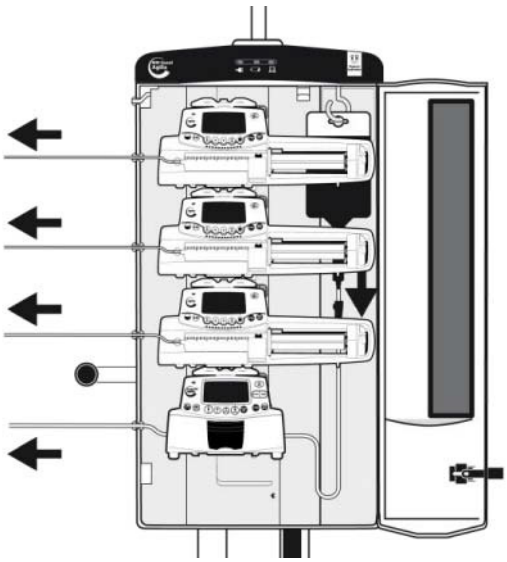


**Installation of Volumat Agilia pump at the bottom:**

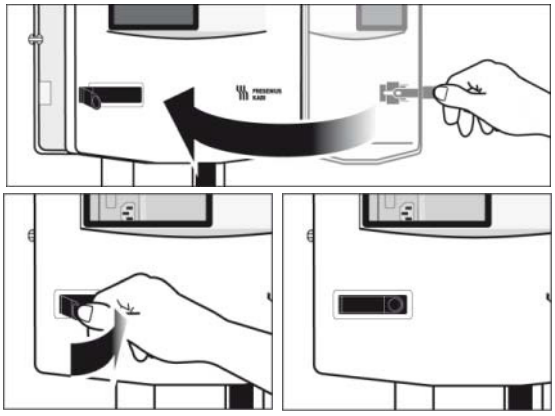
***Information:***
*When **Volumat Agilia** is installed at the bottom, the infusion bag should be hung from the upper hook inside the housing to avoid tensions.*



6. Place the IV lines in their respective outlets of the housing.

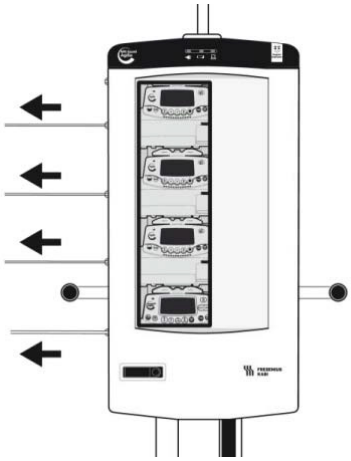


7. Turn the door towards the left and push it fully to close it. Push the door lever to lock the door.



***Warning:***

- *Do not use drop sensor neither outside of the **MRI Guard Agilia**, nor inside of the **MRI Guard Agilia**.*
- *Install the IV lines carefully at the outlets of the housing.*
- *Close the door carefully and do not squeeze, bent or cut the IV-Lines.*



For details on the use of **MRI Guard Agilia** with pumps in MR Environment and the general procedure see "***MRI Guard Agilia** in MR Room*" section in this document.

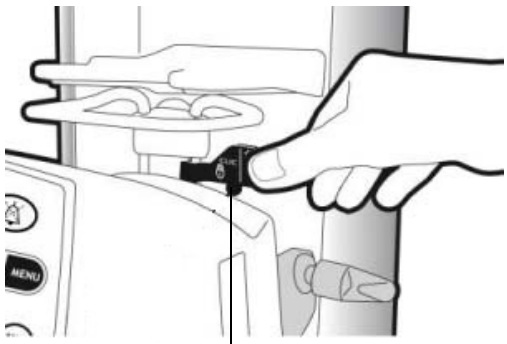
### 2.3.3 Removing Agilia IV infusion pump when infusion is ended

In order to remove an **Agilia** IV infusion pump, proceed as follows:

***Warning:***

- *Do not force during pump removal. If you have to force excessively, do not use the devices and contact your Technical Service*
- *During removal, be sure that IV sets are not squeezed, bent or cut.*
- *To avoid confusion between pumps and associated IV lines, we recommend that the IV set is removed before another pump is released on the* ***Link+ Agilia****.*

1. Press the door lever to release the door, then pull the lever to fully open the door of the housing.
2. Remove the IV set installed on the pump.
3. Hold the pump with one hand and push the release mechanism lever with the other hand.
4. Remove carefully the pump from the slot.
5. Store the IV pump according to the pump's IFU.




Pump release mechanism lever

MRI Guard Agilia and infusion pumps: ins-

# 3 Safety recommendations

***Warning:***

- *In case of any damage of the **MRI Guard Agilia**, the device must immediately be put out of service and sent to the maintenance.*
- *Be attentive to any damage of the power connector or the enveloping base.*

- **Fresenius Kabi** will not be liable for any damages or claims, medical or otherwise, of any nature whatsoever, whether direct or consequential, caused by improper use of this device.
- Special attention must be paid to the stability of the device. Use the device in horizontal position.
- The **MRI Guard Agilia** may only be connected to the power supply with the power cord supplied by the manufacturer. Check that the power supply voltage corresponds with the value indicated on the label placed on the back side of the housing, next to the power/mains connection. Do not exceed the permitted voltage on the different external connections.

# 4 Cleaning, transport, storage and recycling

## 4.1 Recommendations for cleaning

### 4.1.1 Prohibited cleaning agents

***Information:***
*Do not use cleaning agents incorporating the following substances:*

- *TRICHLOROETHYLENE,*
- *DICHLOROETHYLENE,*
- *AMMONIA,*
- *AMMONIUM CHLORIDE,*
- *CHLORINE,*
- *AROMATIC HYDROCARBON,*
- *ETHYLENE DICHLORIDE,*
- *METHYLENE CHLORIDE.*

*These substances could damage the plastic parts and cause device malfunction.*

### 4.1.2 Precautions for cleaning

***Warning:***

- *Before cleaning, disconnect and remove the power cable from the power supply and disconnect the other cables.*
- *Before cleaning, remove all **Agilia** IV infusion pumps.*
- *Do not place in an AUTOCLAVE or IMMERSE the device.*
- *Do not spray liquids directly on connectors; use a cleaning pad or disposable wipes.*

### 4.1.3 Recommended cleaning agents

Prefer to use ALCOHOL BASED SPRAY DILUTED UP TO 80% to clean the device.

Please contact the appropriate service of your hospital or your **Fresenius Kabi** sales organization for further details.

### 4.1.4 Cleaning guidelines and protocol

The device is part of the patient immediate environment. It is advisable to clean and disinfect the device's external surfaces regularly and especially before connecting a new patient and before any maintenance operation in order to protect the patient and the operator.

***Information:***
*Please follow the cleaning protocol hereafter or contact the hospital's appropriate department to perform regular device cleaning and disinfection.*

1 Disconnect the device from power supply.

2 Remove all connected **Agilia** IV infusion pumps.

3 Prepare the detergent-disinfectant solution.

4 Moisten the disposable cloth with the detergent-disinfectant solution, carefully wring out the cloth.
Repeat at each stage of the cleaning process.

5 Start by cleaning the bottom side of the device then the upper part.

6 Continue the cleaning on sides of the device without spraying liquids directly to the connectors (power inlet,etc.).

7 Complete the cleaning of the most exposed surfaces, the most critical zones and the power cord.

8 Do not rinse, leave to dry.

9 Protect and keep the device clean before reuse.

## 4.2 Transport, storage, recycling and disposal conditions

### 4.2.1 Precautions for storage

***Warning:***

- ***MRI Guard Agilia*** *must be handled with care during storage.*
- *If the device is not used during an extended period (longer than 2 months), it is recommended to remove the Magnet Indicator battery pack and store it as indicated in the storage conditions. It is recommended to charge the cap user interface's battery at least once a month, by leaving the device connected to the mains power supply for at least 15 hours.*
- ***MRI Guard Agilia*** *must be cleaned and disinfected prior to storage. Please refer to the "Recommendations for cleaning" section in this document.*

### 4.2.2 Storage and transport conditions

- Storage and transport temperature: -10°C (14°F) to +60°C (140°F).
- Storage and transport pressure:
  500hPa (375mmHg / 7.25PSI) to 1060hPa (795mmHg / 15.37PSI).
- Storage and transport humidity: 10% to 90%, no condensation.

***Information:***
*The storing area must be clean, organized and compliant with the storing conditions mentioned above.*

### 4.2.3 Preparing the device for storage

In order to prepare the device before storage, proceed as follows:

1. Be sure that no patient is being infused by the IV pumps inside the **MRI Guard Agilia**.
2. Switch pumps OFF and remove installed IV sets.
3. Remove connected IV pumps.
4. Disconnect **MRI Guard Agilia** power cord.
5. Clean the **MRI Guard Agilia**.
6. Handle the **MRI Guard Agilia** with care and store it in a compliant area.

**Note:** for detailed instructions, please refer to the related chapters in this document.

### 4.2.4 Installing the device after storage

***Information:***

- *If the Magnet Indicator battery pack has been removed for storage, please contact your biomedical department in order to reinstall it into the device prior to usage.*
- *We recommend charging the cap user interface's battery, by leaving the device connected to the mains power supply for at least 15 hours.*
- *We recommend that the "**MRI Guard Agilia** Quick check protocol" is performed when the device is installed after transport and before being used on a new patient.*

### 4.2.5 Recycling and disposal

*Before disposal, remove batteries from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations.*

It is recommended to keep the packaging for future transport of the device.

***Information:***
*For further information pertaining to waste processing regulations, contact your local **Fresenius Kabi** organisation or the local distributor.*

# 5 Technical characteristics

## 5.1 Compliance with standards

| | | |
|---|---|---|
| CE 0123 | Complies with the 93/42/ EEC Medical directive | |
| Safety of Electromedical equipments | Complies with EN/IEC 60601-1 | **IP21** protection against dust and splashing liquid<br>Type B applied part.<br>**Class I** with protective earth.<br>Agilia power outlets are wired on internal functional earth to reduce residual current that may disturb ECG or EEG devices. |
| EMC (ElectroMagnetic Compatibility) | Complies with EN/IEC 60601-1-2 | |

## 5.2 Technical data

### 5.2.1 Mains power input specifications

| Element | Description |
|---|---|
| Function | Primary power source for Agilia power outlets and for internal electronics of **MRI Guard Agilia** |
| Connector | Standard appliance inlet IEC type C14 - male - 3 poles |
| Power supply | 100V to 240VAC / 50 - 60Hz |
| Maximum power (with pumps) | 75VA |
| Protective fuses | 2 fuses, 2A timed with high breaking capacity - T 2AH 250V<br>Fuse holder is externally accessible on mains power inlet connector |
| Electric protection | Class I with protective earth, with 3-wire power cord |

### 5.2.2 Agilia pump power output specifications

| Element | Description |
|---|---|
| Function | Power source output for Agilia |
| Connector | Standard line outlet IEC type C13 - female - 3 poles |
| Power supply | 100V to 240VAC / 50 - 60Hz |
| Maximum power | 15VA per outlet |
| Protective fuses | Report to mains power input fuses |
| Electric protection | Earth pole is functional earth and Agilia's is class II with functional earth |
| On / Off power | Output power is ON when Agilia pump is locked and there is no power on empty power plug |

### 5.2.3 Cap user interface’s rechargeable battery specifications

| Element | Description |
|---|---|
| Function | Backup battery for mains power failures and displacement of the **Link$^{+}$ Agilia** |
| Access | Internal battery holder accessing with tool by qualified engineer |
| Characteristics | 7.2V / 2.2Ah - Lithium Ion rechargeable battery |
| Battery life | 1 hour minimum |
| Self protections | Over-current, over-discharge, over-voltage and over-temperature |
| Battery life | Highly dependent on conditions of use, but 300 cycles minimum charge / discharge is accepted:<br>■ capacity lost: 10% maximum<br>■ preventive replacement: after 3 years |

| Element | Description |
|---|---|
| Charging time | ≥ 15 hours, with integrated automatic charger, when the **Link+ Agilia** is plugged ion mains.<br>This is also applicable for a first use. |

### 5.2.4 Central Processing Unit (CPU) specifications

| Element | Description |
|---|---|
| Function | Data processing and communications |
| Processor | 32 bits, 400MHz |
| Central memory | 64 Mbytes, high speed RAM 266MHz |
| Flash memory | Non volatile 256 Mbytes |
| Operating system | Safety and flexible multitasking / multithreading operating system with GPL license |

### 5.2.5 Magnet Indicator's Non rechargeable battery pack

| Element | Description |
|---|---|
| Function | Battery to operate the Magnet Indicator independently from the power supply of the **MRI Guard Agilia** |
| Access | Battery is fixed with two screws. It can be replaced with tool by qualified engineer (technician) |
| Characteristics | 3.6V / 38Ah - Lithium battery (not-rechargeable) |
| Battery life | 1 year min by normal operation |
| Self protections | Over-current, over-discharge |

### 5.2.6 Use in MR Environment

| Element | Description |
|---|---|
| Magnetic field | maximum 20mT |
| MRI-Scanner | 1.5 Tesla and 3.0 Tesla |

### 5.2.7 Dimensions - Weight

**MRI Guard Agilia**

| Characteristic | Data |
|---|---|
| Height including IV Pole | 194cm (76,38in) |
| Dimensions (H x W x D) | 151cm (59.44in) x 62cm (24.41in) x 62cm (24.41in) |
| Weight | ~ 47kg |

## 5.2.8 Material characteristics

**Housing and base:**

| Component | Material |
|---|---|
| Base & cover housing incl. blank sheets and LED glasses. | Aluminium |
| Door Kit incl. Marks 101 - 108 | Aluminium |
| Door | Aluminium |
| Hinge | Stainless steel |
| Hinge cover | Aluminium |
| Hinge sheet | Stainless steel |
| Door lock | Zinc diecasting and stainless steel |
| Shielding strip | Copper-Beryllium |
| Door shield angle up and down | Aluminium |
| Side Door Shield | Aluminium |
| Shielded window | Polycarbonate and Copper |
| LED Glass Top | POM (Polyoxymethylene) |
| Hose Guide simple | POM (Polyoxymethylene) |
| Hose Storage | POM (Polyoxymethylene) |
| Hose Insertion | POM (Polyoxymethylene) |
| Cover for the **Link4$^{+}$ Agilia** | POM (Polyoxymethylene) |
| Film strip for Hinge Sheet | PVC (Polyvinylchloride) |
| Film strip for Side Door Shield | PVC (Polyvinylchloride) |
| Film strips for Door shield angle up and down | PVC (Polyvinylchloride) |

**Trolley:**

| Component | Material |
|---|---|
| Cap | ABS (Acrylonitrile Butadiene Styrene) |
| Trolley Holder assembled on the trolley | Aluminium |
| Trolley & IV pole Holder assembled on the housing (above) | Aluminium |
| Trolley & IV pole Holder assembled on the housing (below) | Aluminium |
| Allen screw DIN7984-M5 x 60-A2 for 6050133 and 6055003 | Stainless steel |
| Washer ISO6797-M5A2 for 6050133 and 6055003 | Stainless steel |
| Nut ISO4032-M5-A2 for 6050133 and 6055003 | Stainless steel |
| Allen screw DIN7984-M6 x 16-A2 for 6050132 | Stainless steel |
| Allen screw DIN912-M5 x 12-A2 for Holders fixation | Stainless steel |
| Handle | POM (Polyoxymethylene) |
| Lever Cover | POM (Polyoxymethylene) |
| Shelf 450 x 360mm | Aluminium |
| Double swivel castors Ø125mm, conductive, non-magnetic (only 2 front castors are replaceable in field) | Stainless Steel, PA (Polyamide), TPU (Thermoplastic Polyurethane) |

**Com and Power Versions:**

| Component | Material |
|---|---|
| Tesla Spy 2010 magnet indicator | FR4 TG 140 |
| Battery Pack Tesla Spy 2010 | Fuses:<br>Encapsulated, Epoxy-Coated Body; Solder Coated Copper Wire Leads.<br>Enclosure: Polystyren<br>Battery:<br>Lithium metal 7439-93-2 2 - 6 F, C 14/15-34<br>Thionyl chloride 7719-09-7 18 - 47 C 14-34-37<br>Aluminum chloride 7446-70-0 2 - 5<br>Lithium chloride 7447-41-8 1 - 2<br>Carbon 7440-44-0 2 - 5<br>Nickel-plated steel --- 35 - 73<br>Glass --- 0 - 2<br>PVC 9002-86-2 0 - 1<br>PMMA 9011-14-7 0 - 1<br>PTFE 9002-84-0 0 - 1<br>Mounting socket:<br>CuZn (brass)<br>CuSn (bronce)<br>Au (gold)<br>PA 12 (UL 94 HB)<br>Silicone: Elastosil E43<br>Hot melt adhesive : Polyamide<br>Self-cell rubber bands: cellular rubber APTK (SBR/EPDM), adhesive: Acrylate-Dispersion<br>Wiring: tinned copper wires, insulation: PVC |
| Magnet Indicator LED Board | FR4 TG 140 |
| Cable Battery Pack | Sheath: PVC<br>Flex: Tinned Copper<br>Pin: Brass, gilt<br>Contact Body: PA 12<br>Plug: Nylon with phosphorus-Bronze |
| LED Cable 3 pole | Sheath: PVC<br>Flex: Tinned Copper<br>Pin: Brass, gilt |
| LED Cable 4 pole | Sheath: PVC<br>Flex: Tinned Copper<br>Pin: Brass, gilt |
| Link_Extension-Cable | Sheath: PVC<br>Flex: Tinned Copper |
| LED board | FR4 TG 140 |

## 5.3 Electromagnetic compatibility

Elecromagnetic compatibility is assessed according to IEC 60601-1-2 : 2007. The **MRI Guard Agilia** has no "*essential performance*" according to this standard.

### 5.3.1 Electrostatic discharge (ESD) information

***Warning:***

- *Electronic components and semiconductors can be destroyed by electrostatic discharge (ESD). In particular, MOS components can be damaged from direct or indirect discharges. Damage caused by ESD is sometimes not immediately identifiable and malfunctions can even occur after a longer period of operation.*
- *Exceeding and / or repeating the test level attained in guidance & manufacturer's declaration on EMC may permanently damage the device and / or cause serious malfunctions as lost of communication and system reboot.*

***Caution:***

- *Connector panel symbol* 
- *All panel connector and communication ports are sensitive to electrostatic discharges; it is necessary to take precautions before touching connectors (pins or shield), connecting or disconnecting the associated cables.*
- *Touching communication ports without taking ESD precautions may result in potential fatal error and ESD protection failure.*
- *Points (e.g. screws) and surfaces that are only accessible for maintenance also require precautions.*
- *Points (e.g. battery contacts for battery replacement) and surfaces that are accessible only by intervention service users also require precautions.*

### 5.3.2 ESD precautions to be taken

The following instructions related to electrostatic sensitive components (ESD standards) must be observed: floor coatings made from wood, tiles and concrete, with relative humidity at least 40%.

If it is notpossible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and wearing of anti-static clothes.

The best precaution is the preliminary user discharge on a metal ground such as a metal rail, metal pole or metal part located at the rear of **MRI Guard Agilia**.

For maintenance operation performed on **MRI Guard Agilia**, the device must be placed on a conductive working surface and the operator must wear a special ESD conductive wristband.

### 5.3.3 Electromagnetic compatibility and interference guidance

**MRI Guard Agilia** has been tested in accordance with the electromagnetic compatibility standards applicable to medical devices. Its immunity is designed to ensure correct operation. Limitation of the emitted radiation avoids undesirable interference with other equipment.

**MRI Guard Agilia** is classified as a Class A device according to CISPR 11 emitted radiation and should not be used outside the hospital environment. If used outside the hospital environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

Use of accessories and cables other than those supplied with the **MRI Guard Agilia** by **Fresenius Kabi**, could result in increased emissions and / or decreased immunity of the **MRI Guard Agilia** system.

If **MRI Guard Agilia** is placed near devices such as HF surgical equipment, X-ray equipment, NMR, cell phones, DECT phones or wireless access points, portable RFID reader, large scale RFID reader and RFID Tags, it is essential to observe a minimum distance between the **MRI Guard Agilia** and this equipment (refer to "*Table 6 - Recommended separation distances between portable and mobile RF communication equipment and **MRI Guard Agilia***").

If **MRI Guard Agilia** causes harmful interference or if it is itself disrupted, the user is encouraged to try to correct the interference by one of the following actions:

- Reorient or relocate the **MRI Guard Agilia** or patient or disruptive equipment.
- Change the routing of cables.
- Separate power cables from the communication cables / signals.
- Connect **MRI Guard Agilia** mains plug on protected / backed-up / filtered supply or directly on UPS circuit (Uninterruptible Power Supply).
- Be careful with ground / earth loops formed by communication cables and / or power circuits: use class II powered systems or insulated bridges to break loops.
- Maintain earth potential at the same level between **MRI Guard Agilia** circuit and the circuit of the remote equipment.
- Increase the separation between the **MRI Guard Agilia** and patient or disruptive equipment.
- Connect the **MRI Guard Agilia** into an outlet on a circuit different from that to which the patient or disruptive equipment is connected.
- In any case, whatever the context, the user should conduct interoperability testing in a real situation to find the right setup and good location.

### 5.3.4 Table 1 - Guidance and manufacturer's declaration - Electromagnetic Emissions

***Warning:***

- *The **MRI Guard Agilia** rack system is intended to be used in the electromagnetic environment specified below.*
- *The customer or the user of the **MRI Guard Agilia** rack system should ensure that it is used in such an environment.*

| Emission test | Compliance obtained by the device | Electromagnetic environment - Guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | **MRI Guard Agilia** uses RF energy only for its internal operation. Its RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The **MRI Guard Agilia** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC61000-3-2 | Class A | |
| Voltage fluctuations Flicker emissions IEC 61000-3-3 | Complies | |

### 5.3.5 Table 2 - Guidance and manufacturer's declaration - Electro-magnetic Immunity

***Warning:***

- *The **MRI Guard Agilia** is intended to be used in the electromagnetic environment specified below.*
- *The customer or the user of the **MRI Guard Agilia** should ensure that it is used in such an environment.*

| Immunity test | IEC 60601-1-2 Test level | Compliance level obtained by the device | Electromagnetic environment - Guidance |
|---|---|---|---|
| Electrostatic Discharge(ESD) IEC 61000-4-2 | ± 6kV contact<br>± 8kV air | ± 6kV contact<br>± 8kV air | Floor coverings made from wood, tiles and concrete, with relative humidity level at least 30%, make it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and the wearing of antistatic clothing. |
| Electrical fast Transient / burst IEC 61000-4-4 | ± 2kV for power supply lines<br><br>± 1kV for input output lines | ± 2kV for power supply lines<br><br>± 1kV for input output lines | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV differential mode<br><br>± 2kV common mode | ± 1kV differential mode<br><br>± 2kV common mode | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5% Ut (> 95% dip in Ut) for 0.5 cycle | < 5% Ut (> 95% dip in Ut) for 0.5 cycle | Mains power quality should be that of a typical domestic, commercial or hospital environment.<br>For short and long interruptions (< than battery life) of power mains, the internal battery provides the continuity of service. |
| | 40% Ut (60% dip in Ut) for 5 cycles | 40% Ut (60% dip in Ut) for 5 cycles | |
| | 70% Ut (30% dip in Ut) for 25 cycles | 70% Ut (30% dip in Ut) for 25 cycles | |
| | < 5% Ut (> 95% dip in Ut) for 5s | < 5% Ut (> 95% dip in Ut) for 5s | |

| Immunity test | IEC 60601-1-2 Test level | Compliance level obtained by the device | Electromagnetic environment - Guidance |
|---|---|---|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 400A/m | If necessary, the power magnetic field should be measured in the intended installation location to assure that it is lower than compliance level. If the measured field in the location where the **MRI Guard Agilia** is used exceeds the applicable magnetic field compliance level above, the **MRI Guard Agilia** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating **MRI Guard Agilia**, or install magnetic shielding. |

Note: Ut is the A/C mains voltage prior to application of the test level.

### 5.3.6 Table 4 - Guidance and manufacturer's declaration - Electromagnetic Immunity

***Warning:***

- *The **MRI Guard Agilia** is intended to be used in the ectromagnetic environment specified below.*
- *The customer or the user of the **MRI Guard Agilia** should ensure that it is used in such an environment.*

| Immunity test | IEC 60601-1-2<br>IEC 60601-2-24<br>Test level | Compliance obtained by the device | Electromagnetic environment - Guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6 | 3Vrms<br>150kHz to 80MHz | 3Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the **MRI Guard Agilia** including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency. Recommended separation distance:<br>D = 1.2 √ P, for a frequency of 150kHz to 80MHz<br>D = 0.35 √ P, for a frequency of 80MHz to 800MHz<br>D = 0.7 √ P, for a frequency of 800MHz to 2.5GHz<br>where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than compliance level (b). Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF<br>IEC 61000-4-3 | 3V/m<br>80MHz to 2.5GHz | 10V/m | |

***Warning:***

- *Note 1: At 80MHz and 800MHz, the highest frequency applies*
- *Note 2: These guidelines may not apply to all situations. Absorption and reflection from structures, objects and people affect the electromagnetic propagation.*

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

*(b) Over the frequency range of 150kHz to 80MHz, field strengths should be less than 3V/m.*

### 5.3.7 Table 6 - Recommended separation distances between portable and mobile RF communication equipment and MRI Guard Agilia

***Warning:***

- ***MRI Guard Agilia*** *is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled.*
- *Users of* ***MRI Guard Agilia*** *may prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and* ***MRI Guard Agilia*** *as recommended below and according to the maximum output power of the communication equipment (transmitters).*
- ***MRI Guard Agilia*** *should not be used next to other equipment. If adjacent use is necessary,* ***MRI Guard Agilia*** *should be observed to verify normal operation in the configuration in which it will be used (pump with a mains cable, an RS 232 cable).*

| Rated maximum output power of transmitter (W) | Separation distance according to transmitter frequency in meters (m) | | |
|---|---|---|---|
| | 150KHz to 80MHz $d = 1.2 \sqrt{P}$ | 80MHz to 800MHz $d = 0.35 \sqrt{P}$ | 800MHz to 2,5GHz $d = 0.7 \sqrt{P}$ |
| 0.01 | 0.12 | 0.04 | 0.07 |
| 0.1 | 0.38 | 0.11 | 0.22 |
| 1 | 1.2 | 0.3 | 0.7 |
| 10 | 3.8 | 1.1 | 2.2 |
| 100 | 12 | 3.5 | 7 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, 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.

# 6 MRI Guard Agilia description

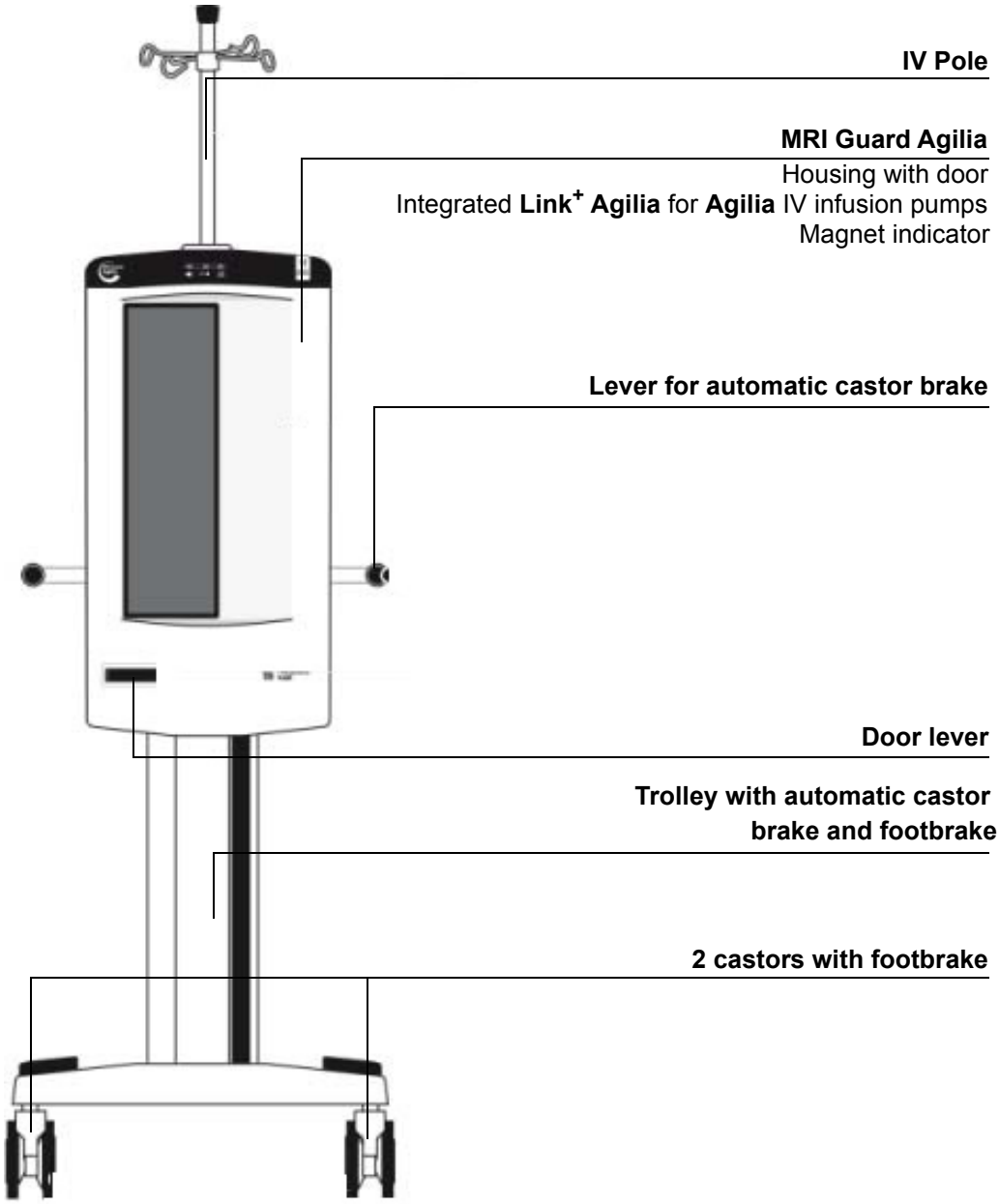
## 6.1 Physical description

### 6.1.1 MRI Guard Agilia system definition

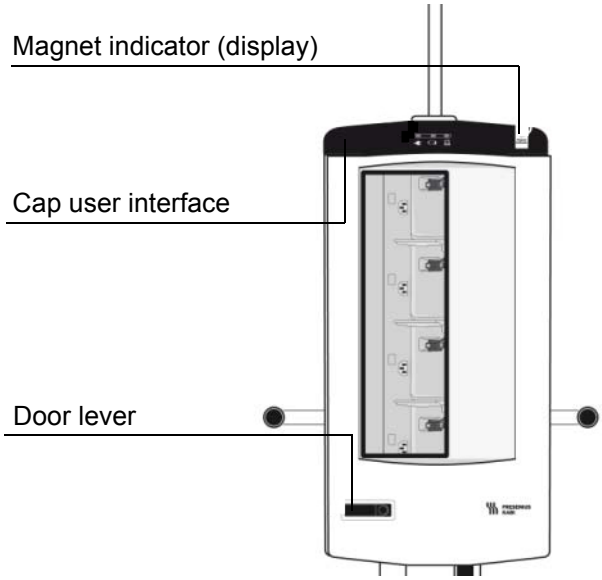
The **MRI Guard Agilia** system is composed of the following elements:

- 1 **MRI Guard Agilia** including 1 **Link+ Agilia** able to stack 4 **Agilia** IV infusion pumps with a power cord,
- Trolley with automatic castor brake and footbrake with IV Pole,

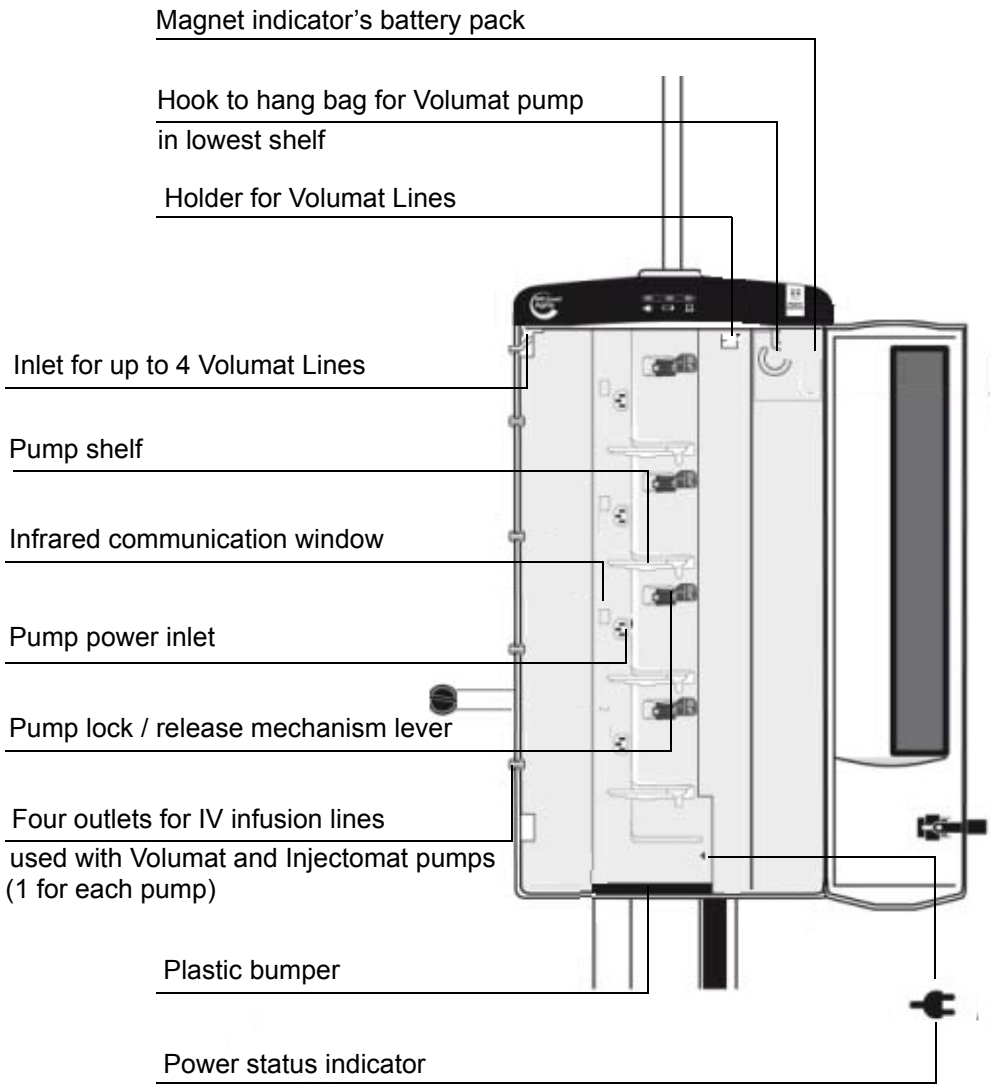
Up to 4 **Agilia** IV Infusion pumps with their respective accessories, disposables and documents



### 6.1.2 Front view (Door closed)

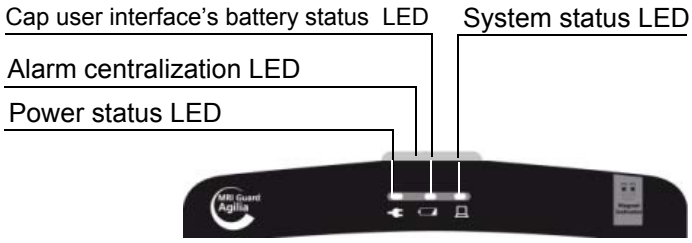


### 6.1.3 Front view (Door open)



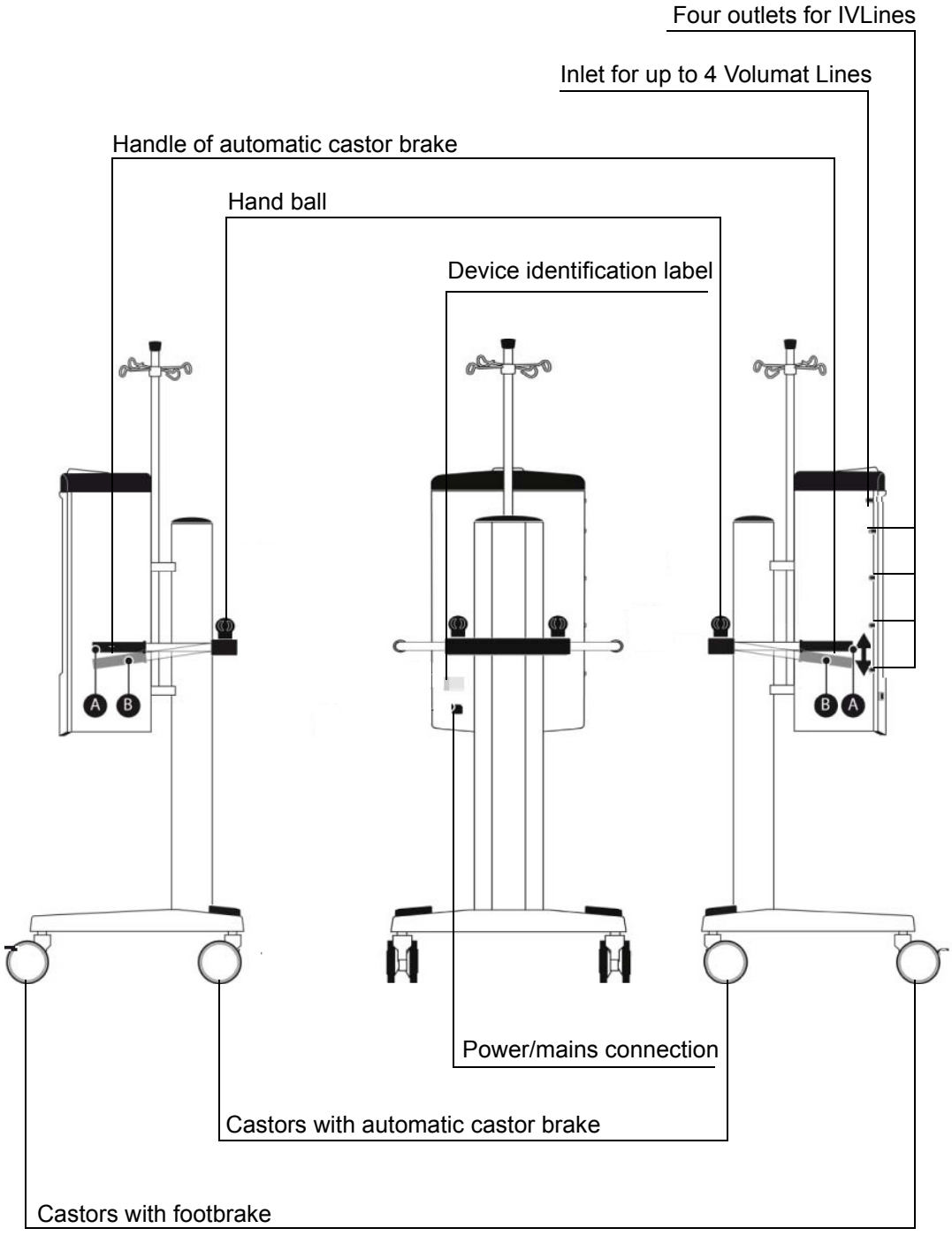

| Symbol | Location | Symbol description |
|---|---|---|
|  | On pump lock / release mechanism lever | Pushing area to lock and unlock pumps from MRI Guard |

### 6.1.4 Cap user interface




| Symbol | Location | Symbol description |
|---|---|---|
| | Cap user interface | Power status |
| | | Charge status of the Cap user interface's battery |
| | | System status |

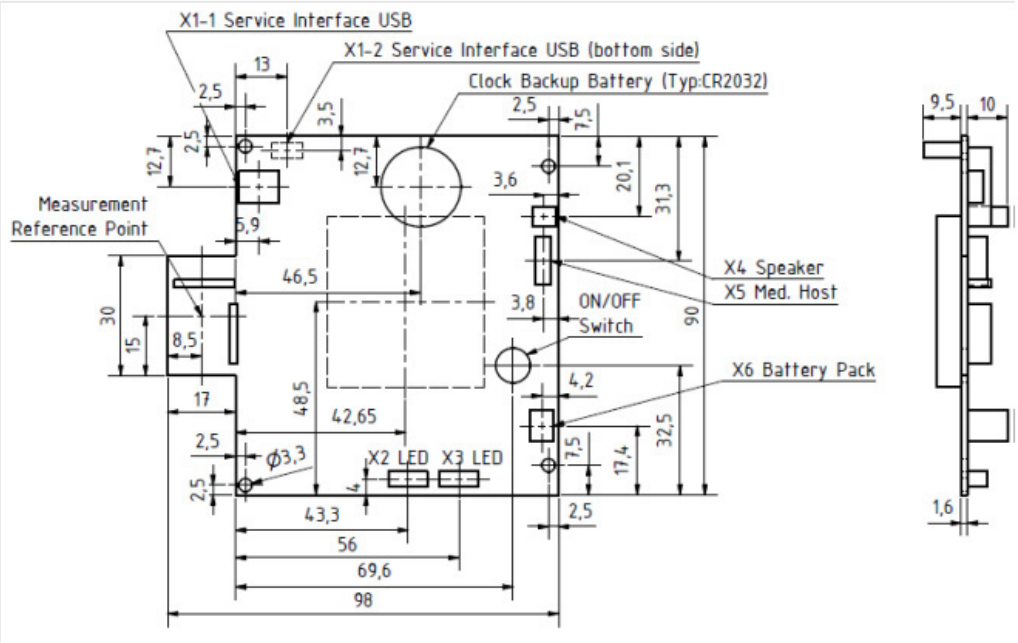
### 6.1.5 Right/Back/Left Sides




| Handle position | Position of automatic castor brake |
|---|---|
| A | STOP |
| B | MOVE |

## 6.1.6 Mechanical dimensions / interfaces Tesla SPY 2010 magnet indicator

Self test magnet indicator




### X1-1 Mini USB-B to personal computer

| Pin | Signal name | Voltage |
|---|---|---|
| 1-4 | Standard USB 1.1 | Standard USB 1.1 |

### X1-2 Mini USB-B to personal computer

| Pin | Signal name | Voltage |
|---|---|---|
| 1-4 | Standard USB 1.1 | Standard USB 1.1 |

### X2 ErNI Single Row Connector to Tesla (3 pole) Spy LED Board

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | VDD | 3.3V |
| 2 | LED_ERR | Cathode LED |
| 3 | LED_BAT | Cathode LED |

### X3 ErNI Single Row Connector to Tesla (4 pole) Spy LED Board

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | VDD | 3.3V |
| 2 | LED_green | Cathode LED |
| 3 | LED_yellow | Cathode LED |
| 4 | LED_red | Cathode LED |

MRI Guard Agilia description

**X4 Tyco/AMP (2 pole) to external speaker**

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | Speaker _- | 0...3.3V |
| 2 | Speaker _+ | 0...3.3V |

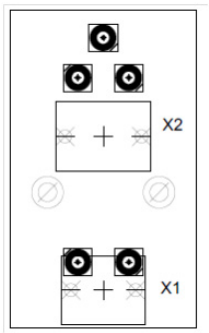
**X5 ErNI Single Row Connector (6 pole) to Medical host device**

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | V_Host | 9...30V |
| 2 | GND | GND |
| 3 | HOST_STATUS | 0...3.3V |
| 4 | EXT_RX | 0...3.3V |
| 5 | EXT_TX | 0...3.3V |
| 6 | NC | NC |

**X6 Tyco/AMP (3 pole) to Battery Pack**

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | Battery 1 | 9...12V |
| 2 | Battery 1 | 9...12V |
| 3 | GND | GND |

## 6.1.7 LED magnet indicator




**X1 ErNI Single Row Connector to Tesla (3 pole) Spy LED Board**

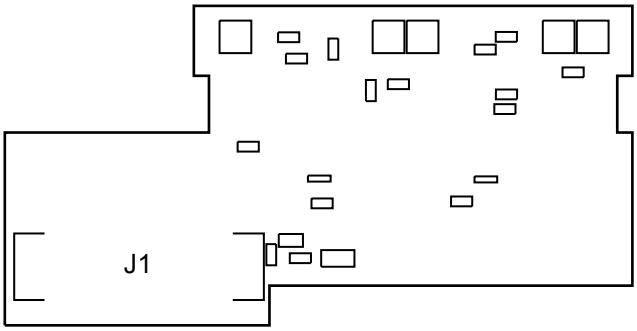
| Pin | Signal name | Voltage |
|---|---|---|
| 1 | VDD | 3.3V |
| 2 | LED_ERR | Cathode LED |
| 3 | LED_BAT | Cathode LED |

**X1-2 ErNI Single Row Connector to Tesla (4 pole) Spy LED Board**

| Pin | Signal name | Voltage |
|---|---|---|
| 1 | VDD | 3.3V |
| 2 | LED_green | Cathode LED |
| 3 | LED_yellow | Cathode LED |
| 4 | LED_red | Cathode LED |

### 6.1.8 LED board

The LED board ensures the visualisation of alarms and the status of the system.




**J1 connector to main board**

| Pin | Description |
|---|---|
| 1 | VCC +5V |
| 2 | VCC +5V |
| 3 | Ground |
| 4 | Ground |
| 5 | Ground |
| 6 | Power_status |
| 7 | Ground |
| 8 | LED_bumper orange |
| 9 | Ground |
| 10 | Battery_status_green |
| 11 | Ground |
| 12 | Battery_status_red |
| 13 | Ground |
| 14 | LED_bumper_red |
| 15 | Ground |
| 16 | Device_status_green |
| 17 | Ground |
| 18 | Device_status_red |
| 19 | Ground |
| 20 | Ground |

# 7 Maintenance

## 7.1 Service policy and rules

For warranty conditions see chapter "*Warranty*".

For further information concerning the device servicing or use, please contact our Technical Service or our Customer service.

***Information:***

- *If a device has to be returned for servicing, it is essential to first clean it and disinfect it. Then pack it very carefully, if possible in its original packaging, before shipping it.*
- ***Fresenius Kabi** is not liable for loss or damage to the device during transport.*

## 7.2 Maintenance requirements

***Warning:***

- *The qualified personnel must be informed if the device is dropped or if any malfunctions occur. In this case, the device must not be used. Please contact your biomedical department or **Fresenius Kabi**.*
- *Failure to comply with these maintenance procedures could damage the device and lead to a functional failure. Internal inspection of the device involves compliance with special procedures to avoid damage to the device.*
- *When replacing components, only use **Fresenius Kabi** spare parts.*

Preventive maintenance should be performed by a qualified and trained technical personnel in compliance with the technical manual and procedures.

To ensure the **MRI Guard Agilia** continues to operate normally, it is recommended that preventive maintenance **of the device and the Cap user interface's rechargeable battery** is performed **every 3 years**.

The Magnet Indicator's battery pack has to be replaced each year.

## 7.3 Training

For training please contact **Fresenius Kabi**.

The training levels, listed below, outline the specifics needed to maintain and preserve the device. They are defined below:

**Level 1** is intended to the user for on-site maintenance, using the technical documentation of the device and specific tools.

- Mechanical and electrical knowledge.
- Biomedical structures knowledge.

This degree of maintenance does not need an extensive inventory.

**Level 2** is intended to a technician specialized in maintenance performed through specific tools and procedures.

- Good mechanical and electronics knowledge.
- Two years experience minimum in a biomedical department.

**Level 3** is intended to a technician specialized in repair performed in the maintenance department using specific tools, procedures as well as measurement and adjustment instruments. Complete check-up according to this document.

- Good mechanical and electrical knowledge.
- Good computer knowledge.
- More than two years experience minimum in a biomedical department.

## 7.4 Maintenance schedule

### 7.4.1 Preventive maintenance

***Warning:***

- *The qualified personnel must be informed if the device is dropped or if any malfunctions occur. In this case, the device must not be used. Please contact your biomedical department or **Fresenius Kabi**.*
- *Failure to comply with these maintenance procedures could damage the device and lead to a functional failure. Internal inspection of the device involves compliance with special procedures to avoid damage to the device.*
- *When replacing components, only use **Fresenius Kabi** spare parts.*

Preventive maintenance should be performed by a qualified and trained technical personnel in compliance with the technical manual and procedures.

To ensure the **MRI Guard Agilia** continues to operate normally, it is recommended that preventive maintenance of the device and the Cap user interface's rechargeable battery is performed every 3 years.

The Magnet Indicator's battery pack has to be replaced each year.

### 7.4.2 Quality control

Upon request by the hospital, a **quality control** check can be performed on the **MRI Guard Agilia every 12 months**.

A regular quality control (not included in the guarantee) consists of various inspection operations listed in this document. Please refer to this document or contact your **Fresenius Kabi** Technical Service.

***Information:***

- *These control checks must be performed by a trained technical personnel and are not covered by any contract or agreement provided by **Fresenius Kabi**.*
- *For more information, please contact our Technical Service.*

## 7.5 Checking the MRI Guard Agilia and the Link+ Agilia

A quality control certificate is available at the end of this section.

The **MRI Guard Agilia** can ONLY be checked, serviced or repaired by **Fresenius Kabi** or by certified and approved technicians.

### 7.5.1 Visual check

- Check the **MRI Guard Agilia** is not altered or damaged on housing, connectors, IV pole and trolley with automatic castor brake.
  - ☐ No noise when the device is moved.
  - ☐ All labels are present.

### 7.5.2 Function of automatic castor brake check

- Brake can be released and brakes the castor on the backside of the trolley automatically.

### 7.5.3 AC power supply check

- Connect the power cord to **MRI Guard Agilia** and to the wall plug.
  - ☐ When connecting the **MRI Guard Agilia** to the mains power, check a bip generated by the **Link+ Agilia** sounds.
- The power indicator closed to the mains plug on the **Link+ Agilia** is on.
- The power status LED on the user cap interface is lit and green.
- Check the system status LED is yellow and becomes green.
- Check Cap user interface's battery status LED is lit and green.
- The **MRI Guard Agilia** connected to the mains power in normal mode OUTSIDE magnetic field.
  The magnet indicator's battery pack is connected.


- Check the right LED on the magnet indicator flashes green each 2 seconds.

  **This test has to be performed on every channel of the Link+ Agilia**.

- Connect a pump to the **Link+ Agilia**.
  - ☐ Check that the pump is locked correctly.
  - ☐ Check a "bip" sound is generated by the pump and the pump power LED is lit and yellow.

- Switch the pump ON and generate an alarm and check that:
  - ☐ A visual and audible alarm is displayed on the pump.
  - ☐ A visual alarm is blinking in red on the **MRI Guard Agilia** alarm centralization display (on the top).
  - ☐ Program the pump and generate a pre-alarm (eg: end of infusion pre-alarm).
  - ☐ A visual and audible pre-alarm is displayed on the pump.
  - ☐ A visual pre-alarm is blinking in yellow on the **MRI Guard Agilia** alarm centralization display (on the top).

- Remove the power cord from the power supply; **MRI Guard Agilia** is operating on battery. Check:
  - Power status indicator is OFF.
  - Power status LED on the cap is OFF.
  - Cap user interface's battery status LED is green fix.
  - System status LED is green.

- Switch pump OFF and remove the pump. Check:
  - The locking mechanism is functional and pump can be removed without difficulties.

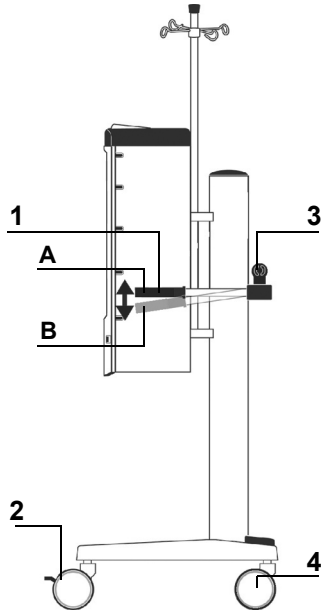
To complete the check list, checkups of the **Link+ Agilia** also need to be performed. Refer to the **Link+ Agilia** technical manual for a complete procedure which includes the battery test and the electrical test (this test has to be performed according to IEC 60601-1 or IEC 62353 standard. For further information, please contact your Technical Service).

### 7.5.4 Quality Control Certificate

Use this table to summarise the results of the various tests.

| Device type: | Product code: | Device serial N°: |
|---|---|---|

| N° | Inputs / Actions | Expected results | Conformity Yes | Conformity No |
|---|---|---|---|---|
| 1 | VISUAL CHECK OF THE **MRI GUARD AGILIA** | | | |
| | Initial conditions: Take the overall receiving **MRI Guard Agilia** and its packaging after shipment from **Fresenius Vial**.<br>NOTE : The test shall be proved by pictures of goods received (package and device) and to append these evidences at this checklist. | | | |
| | ■ Check the integrity of the housing, the cap, the connectors, the IV pole and the trolley with automatic castor brake. | Not altered or damaged. | | |
| | ■ Check the presence of broken or moving parts. | No noise when the device is moved. | | |
| | ■ Check the presence of labels. | All labels are present. | | |

| N° | Inputs / Actions | Expected results | Conformity Yes | Conformity No |
|---|---|---|---|---|
| 2 | AUTOMATIC CASTOR BRAKE CHECK | | | |
| | Initial conditions: Take the overall receiving **MRI Guard Agilia** after shipment from **Fresenius Vial**.<br>NOTE: The picture below shows the side view of the **MRI Guard Agilia** (right side) and indicates the automatic castor brake parts.<br>**1**- Handle of automatic castor brake<br>A- **STOP** position of automatic castor brake<br>B- **MOVE** position of automatic castor brake<br>**2**- Castor with footbrake<br>**3**- Hand ball<br>**4**- Castor of automatic castor brake<br>  | | | |
| | ■ Check the automatically locking of the castor brake (marker 4) | The castor of the trolley shall be blocked when the handle is in horizontal position (handle position A) | | |
| | ■ Check the releasing of the automatic castor brake (marker 4) | The castor of the trolley shall be released when the handle is pressed down (handle position B) | | |

| N° | Inputs / Actions | Expected results | Conformity Yes | Conformity No |
|---|---|---|---|---|
| 3 | FUNCTIONING CHECK | | | |
| | Initial conditions: Take the overall receiving **MRI Guard Agilia** after shipment from **Fresenius Vial**.<br>NOTE 1: The connection of the **MRI Guard Agilia** to the mains power shall be performed through the power cord in the wall plug.<br>NOTE 2: When the test concerns the connection of a pump on a channel of the rack (**Link+ Agilia**), every channel shall be tested. | | | |
| | ■ Connect the power cord of the **MRI Guard Agilia** to the mains **power.**<br>■ **Check the MRI Guard Agilia** behavior: | A "bip" sound is generated by the rack (**Link+ Agilia**) and the power indicator close to the mains plug on the rack is on | | |
| | | The system status LED is yellow and becomes green after 1 minute  | | |
| | | The power status LED on the user cap interface is lit and green  | | |
| | | The Cap user interface's battery status LED is lit and green after 1 minute  | | |
| | ■ The **MRI Guard Agilia** is connected to the mains power in normal operation outside magnetic field and the magnet indicator's battery pack is connected.<br>■ Check the magnet indicator behavior : | The right LED flashes green each 2 seconds  | | |
| | ■ The **MRI Guard Agilia** is connected to the mains power. Connect a pump to the **Link+Agilia**.<br>■ Check the **MRI Guard Agilia** behavior : | The pump is locked correctly | | |
| | | A "bip" sound is generated by the pump and the pump power LED is lit and yellow | | |
| | ■ The **MRI Guard Agilia** is connected to the mains power. A pump is connected to the **Link+Agilia**. Switch the pump ON and generate a pre-alarm on the pump (eg: end of infusion pre-alarm).<br>■ Check the **MRI Guard Agilia** behavior : | A visual and audible pre-alarm is displayed on the pump | | |
| | | A visual pre-alarm is blinking in yellow on the **MRI Guard Agilia** alarm centralization display (on the top) | | |
| | ■ The **MRI Guard Agilia** is connected to the mains power. A pump is connected to the **Link+Agilia**. Switch the pump ON and generate an alarm on the pump.<br>■ Check the **MRI Guard Agilia** behavior: | A visual and audible alarm is displayed on the pump | | |
| | | A visual alarm is blinking in red on the **MRI Guard Agilia** alarm centralization display (on the top) | | |

| N° | Inputs / Actions | Expected results | Conformity Yes | Conformity No |
|---|---|---|---|---|
| 3 | ■ The power cord is disconnected from the power supply. The **MRI Guard Agilia** is operating on battery.<br>■ Check the **MRI Guard Agilia** behavior : | The Cap user interface's battery status LED is green fix | | |
| | | The power status indicator is OFF  | | |
| | | The power status LED on the user cap interface is OFF  | | |
| | | The system status LED is green  | | |
| | ■ The power cord is disconnected from the power supply. The **MRI Guard Agilia** is operating on battery. Switch pump OFF.<br>■ Check the pump removal : | The pump can be removed without difficulties using a functional locking mechanism | | |

| **Name:** | **Date:** | **Visa:** |
|---|---|---|
| | | |

Observations:

# 8 Troubleshooting

## 8.1 Breaking guide

This section provides information to perform a first troubleshooting of the **MRI Guard Agilia**.

***Information:***
*For additional information about issues and troubleshooting, please contact your biomedical department or **Fresenius Kabi** Technical Service.*

| Issue description | Recommended action |
|---|---|
| **MRI Guard Agilia** is not stable when mounted. | ■ Check that castors of trolley are fastened. |
| **MRI Guard Agilia** is damaged, noisy, smoking or with an abnormally hot part. | ■ Remove power cable.<br>■ Donot use the device.<br>■ Contact immediately your biomedical department or **Fresenius Kabi** Technical Service. |
| Power status indicator is not lit. | ■ Check power cable connection to **MRI Guard Agilia**.<br>■ Check power cable connection to the mains.<br>■ Check Cap user interface's battery status LED.<br>■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |
| Cap user interface's battery status LED is red and blinking. | ■ Connect **MRI Guard Agilia** to the mains.<br>■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |
| System status LED is constant red after startup. | ■ Disconnect the **MRI Guard Agilia** from the mains until it automatically switches OFF. Reconnect the **MRI Guard Agilia** to the mains.<br>■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |
| Alarm centralization display is red and yellow at the same time. | ■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |
| Alarm centralization display is constant yellow without any pump pre-alarm. | ■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |
| Magnet Indicator flashes yellow, even out of MR environment.<br>Magnet indicator flashes green and yellow, even out of the MR environment. | ■ Battery is low: replace magnet indicator's battery pack. |
| Magnet Indicator never lights. | ■ Battery is empty: replace magnet indicator's battery pack. |
| Pump cannot be installed or removed from **MRI Guard Agilia**. | ■ Check pump locking mechanism operations.<br>■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |

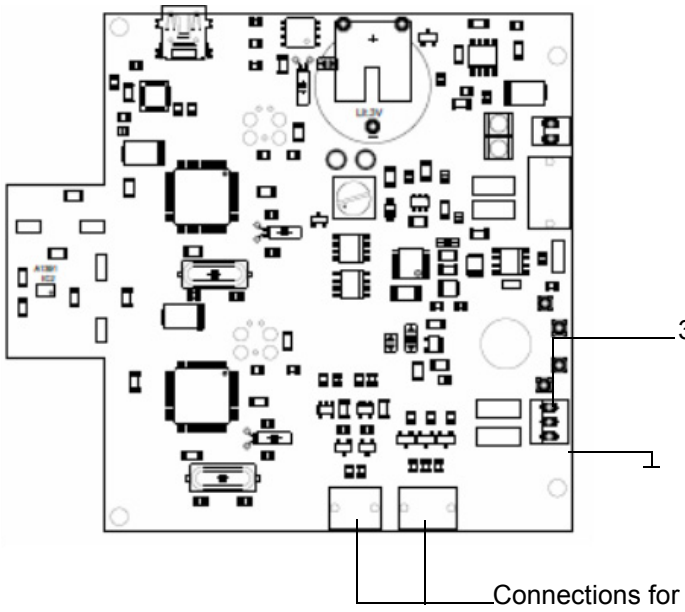
| Issue description | Recommended action |
|---|---|
| No sound is audible from pump when installed in **MRI Guard Agilia**. | ■ Check power status indicator.<br>■ Check **MRI Guard Agilia** is connected to mains power supply.<br>■ Contact your biomedical department or **Fresenius Kabi** Technical Service. |

Details about the troubleshooting and messages of Magnet Indicator are described in "*Magnet Indicator*" section.

## 8.2 Tesla Spy 2010 magnet indicator self-test

Valid for product version V1.

- Remove Tesla Spy 2010 magnet indicator from magnetic field.
- Connect Magnet Indicator to LED Board.
- Apply operating voltage.




- Tesla Spy 2010 magnet indicator starts self-test.
  - ☐ A beep sounds.
  - ☐ All LED light up.

- Self-test passed => acoustic signal off, all LED off.

Tesla Spy 2010 magnet indicator enters measuring mode => green LED lights up every two seconds.

- Self-test failed
  - ☐ Sensor error: self-test is running up to six times => red Error-LED flashes and provides an audible alarm.
  - ☐ If the red LED is defective, the test will not run at all, and the red LED does not switch on.
  - ☐ If the battery is defective, the test will not run at all and magnet indicator yellow LED lights on.

# 9 Intervention procedures

This chapter lists all procedures of disassembly and reassembly.

Service shall be done by approved and qualified technicians who have been trained.

***Warning:***

■ *Use ONLY recommended accessories and options delivered with the device. NO PART IS REPAIRABLE. When replacing components, only use* ***Fresenius Kabi*** *spare parts. Please refer to the "****Spare parts catalog****" for ordering.*

■ *Any instrument or device used for maintenance must be regularly checked or re-calibrated according to its specifications and local regulations.*

***Warning:***

*Any maintenance requiring a partial (battery change for example) or complete (main body) disassembling of the* ***MRI Guard Agilia*** *must be followed by a measurement of the leakage current according to IEC 60601-1.*

**Note:**

# N°1, Procedure: Link+ Agilia

## Safety:

***Danger:***

DANGER

- *For safety reasons, the technician should not intervene when the device is connected to the mains voltage.*
- *Disconnect the power supply cord from the mains.*
- *Switch off the device.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Torx TX-25 hexagon socket key.
- 1 Phillips PH1 screwdriver.
- 1 Phillips PH2 screwdriver.
- 1 socket wrench 5.5.
- 1 socket wrench 7.0.
- 1 hexagon socket screw key 4.
- 1 anti-static bracelet.

## Maintenance level:

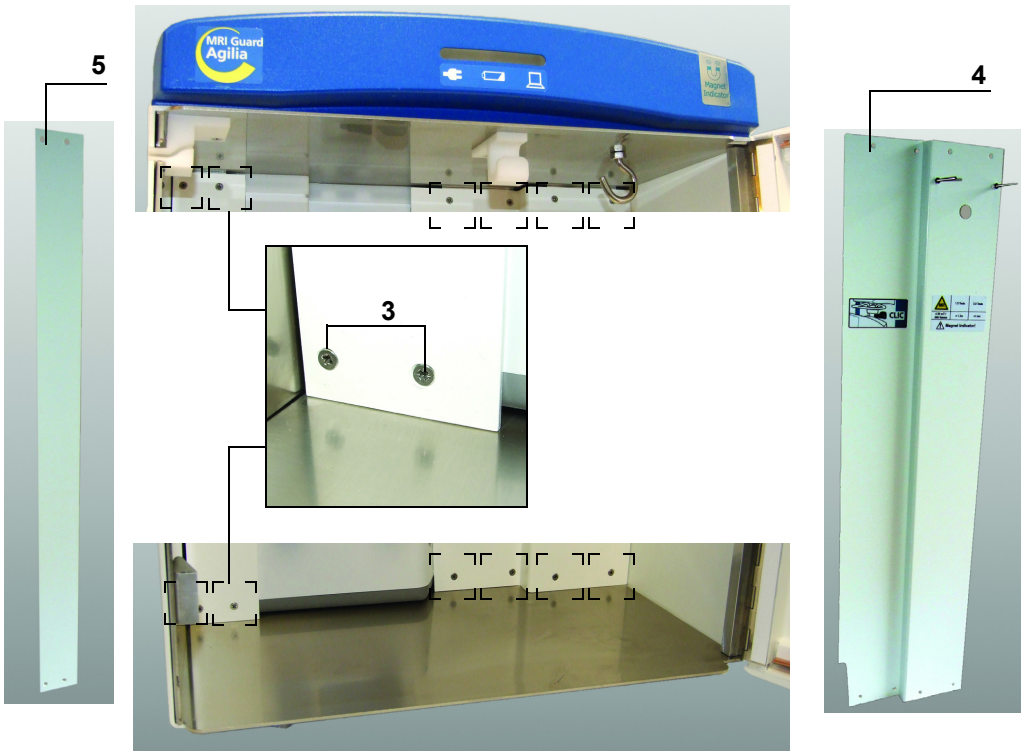
Level 2, specialist technician. A training program document is available upon request (please contact **Fresenius Kabi** service department).

## Procedure:

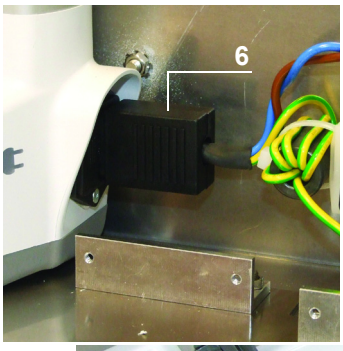
## Access

- Unscrew the 2 "Phillips" screws (marker 1) on the Battery Pack Tesla Spy (marker 2).
- Pull the Battery Pack Tesla Spy.
- Disconnect the Battery Pack.


- Unscrew all 12 "Phillips" screws (marker 3) on the front inside of the device and remove the right seal cover (marker 4) and left seal cover (marker 5).

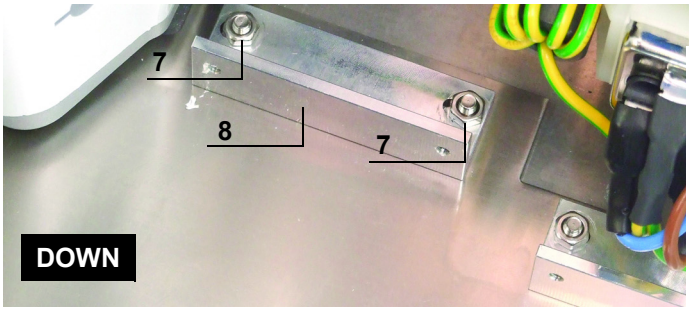


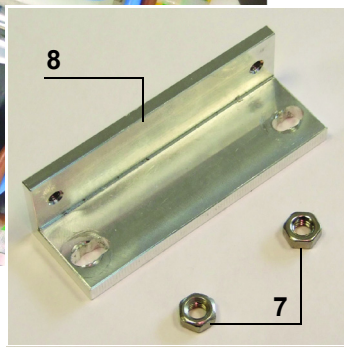
- Unplug the plug of the Power Line Filters (marker 6).
- Loosen the 2 M4 nuts (marker 7) on the bracket (marker 8) and remove them.
- Unscrew the 2 M4 Phillips screws (marker 9) on the bracket (marker 10) and remove it.







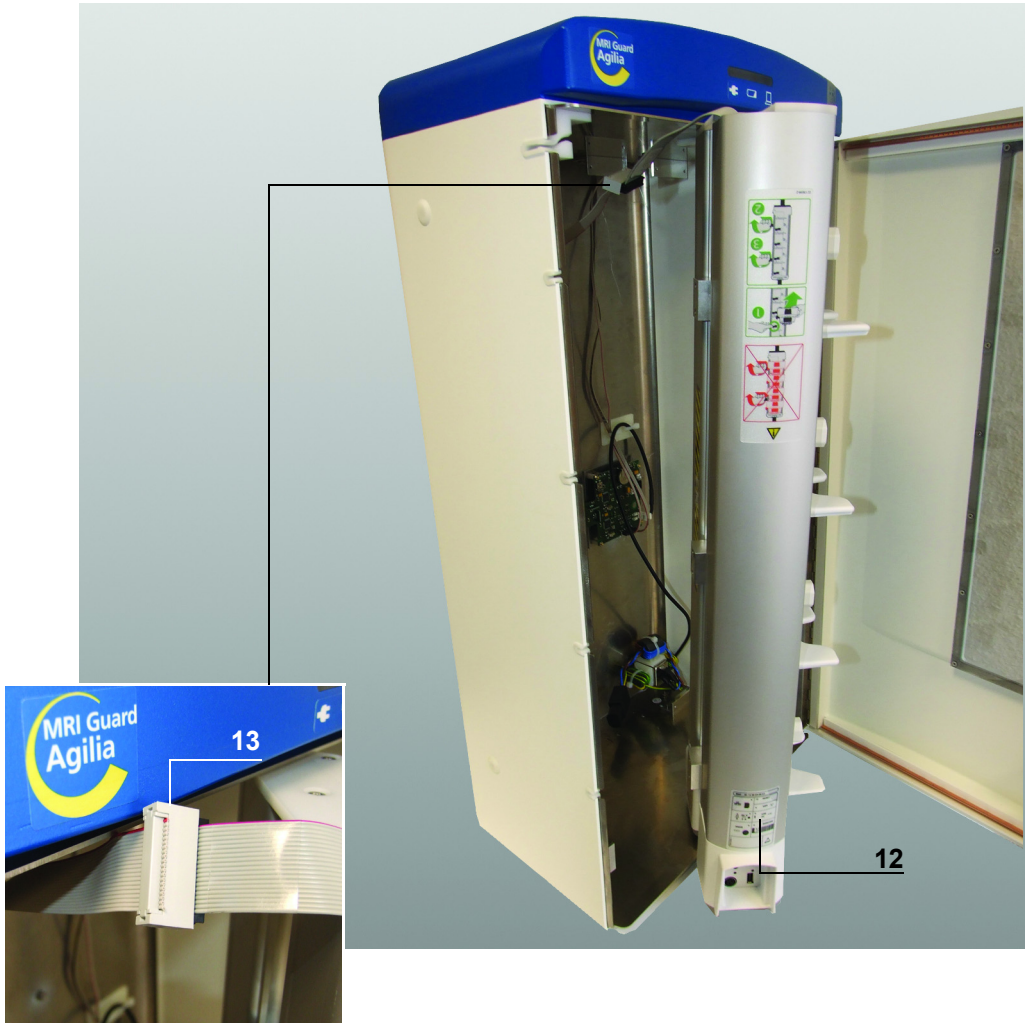


## Disassembly

- Unscrew the 6 "Torx" screws (marker 11) on the back of the base housing.

- Carefully pull out the **Link+ Agilia** (Marker 12).
- Disconnect the Link+ Extension Cable (Marker 13).




## Re-assembly

***Warning:***
*Each **Link+ Agilia** is equipped with its own main board. Specific information are recorded in each as MAC address, product code and serial number of the device.*

Pay attention to the ribbon cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 1) are refitted with a torque of 0.9 Nm.
  - Ensure the screws (marker 3) are refitted with a torque of 0.68 Nm.
  - Ensure the nut (marker 7) is refitted with a torque of 2.1 Nm.
  - Ensure the screws (marker 9) are refitted with a torque of 1.58 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°2, Procedure: LED Glass cap user interface, LED board, Magnet Indicator LED Board, Link+ Extension Cable, 3 pole LED cable, 4 pole LED cable

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Torx TX-25 hexagon socket key.
- 1 Phillips PH1 screwdriver.
- 1 Phillips PH2 screwdriver.
- 1 socket wrench 5.5.
- 1 socket wrench 7.0.
- 1 antistatic bracelet.

## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (please contact **Fresenius Kabi** service department).

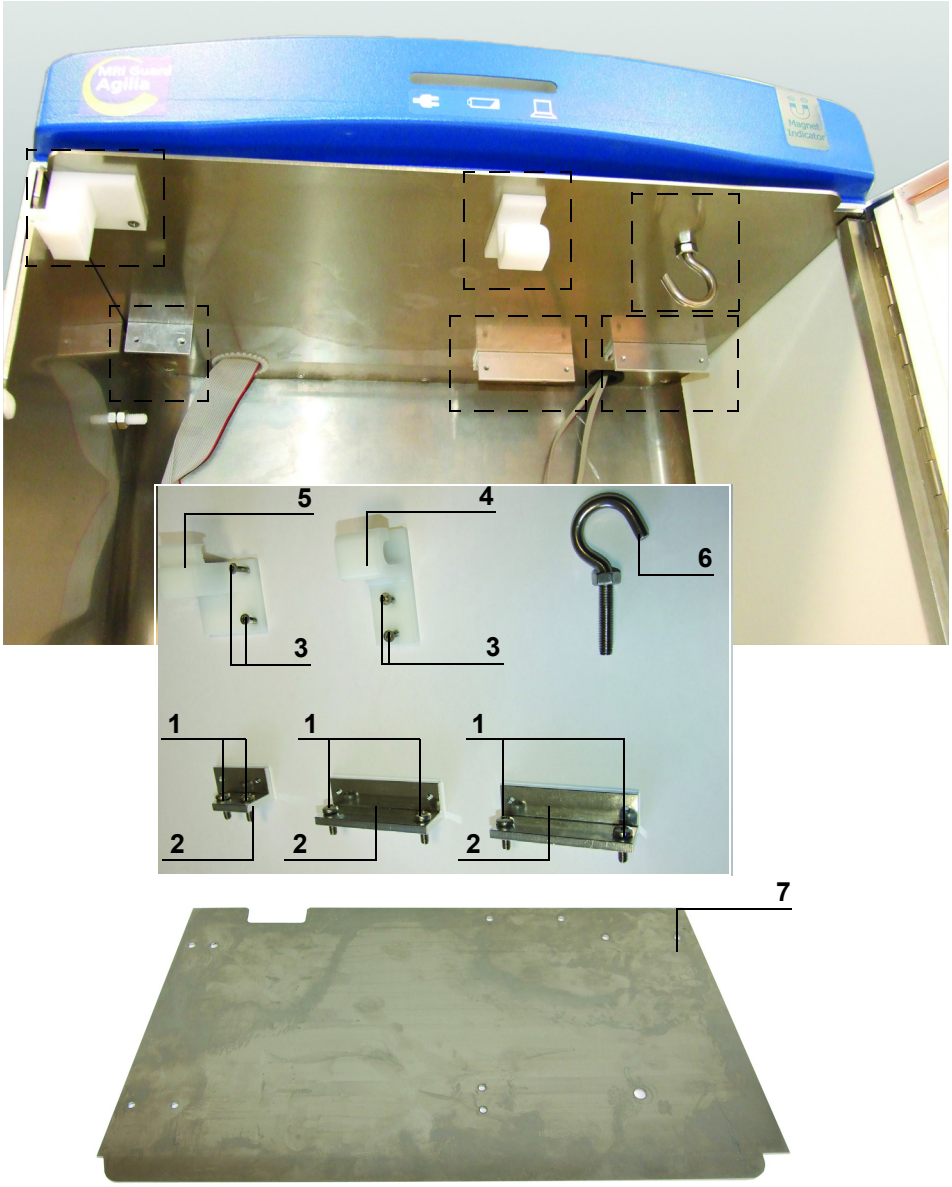
## Procedure:

### Access

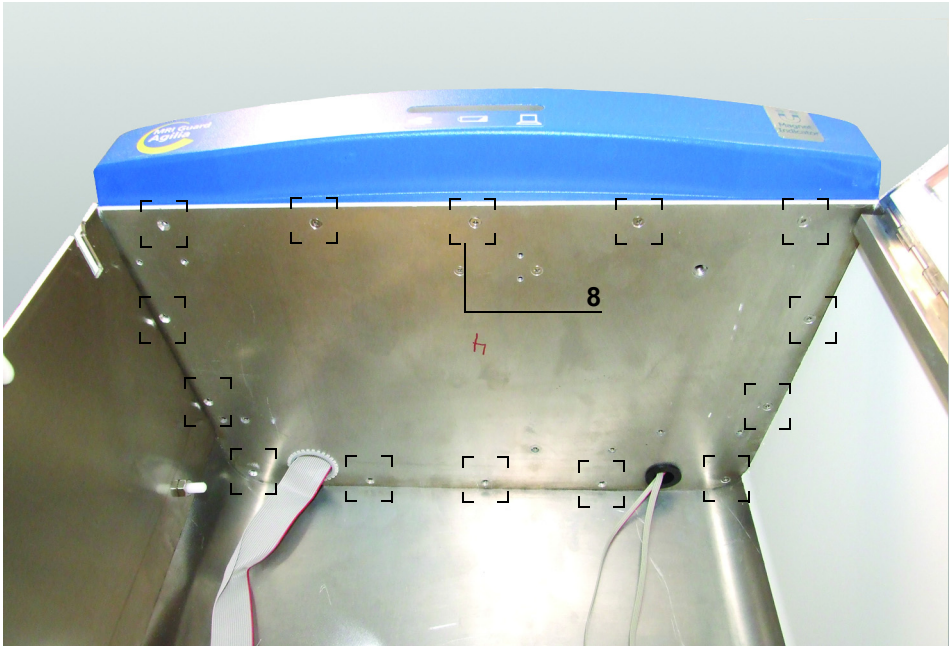
To access LED Glass cap user interface, LED board, Magnet Indicator LED board, Link+ Extension Cable, 3 pole LED cable or 4 pole LED cable, first remove the Link+ Agilia. Then, refer to the intervention sheet *"N°1, Procedure: Link+ Agilia"*: for detailed procedure (access and disassembly sections).

Once *"N°1, Procedure: Link+ Agilia MRI "* has been performed, continue with the following steps:

- Unscrew the 6 "Phillips" pan head screws (marker 1) and remove the brackets (marker 2).
- Unscrew the "Phillips" countersunk screws (marker 3), remove Volumat Line holder (marker 4) and the inlet Volumat (marker 5).
- Unscrew the infusion bottles hook (marker 6). You can use a small lever to unscrew it.
- After that, you can remove the contact plate (marker 7).

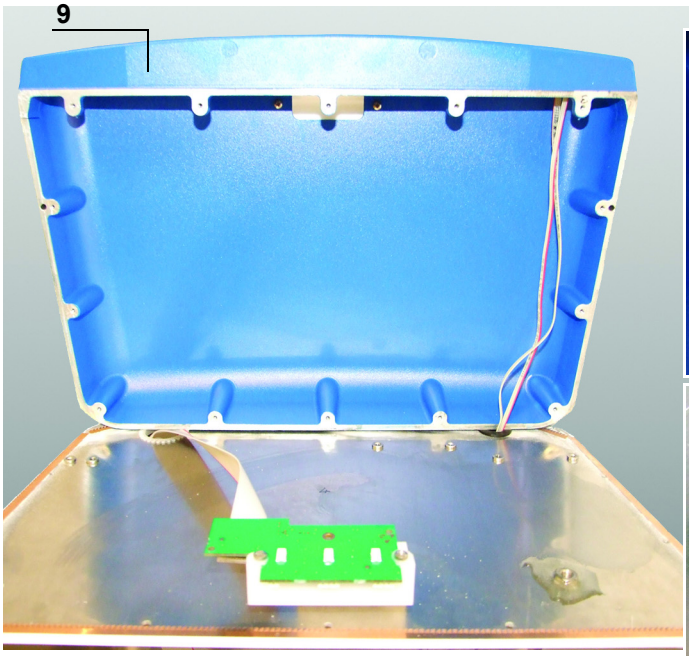


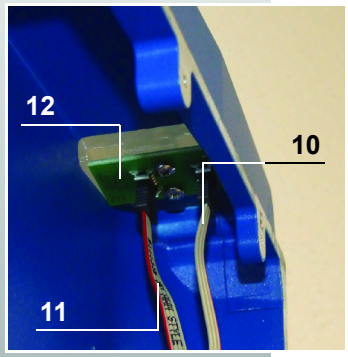
- Unscrew the 14 "Phillips" countersunk screws (marker 8).

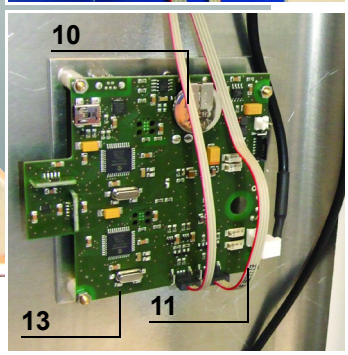



## Disassembly

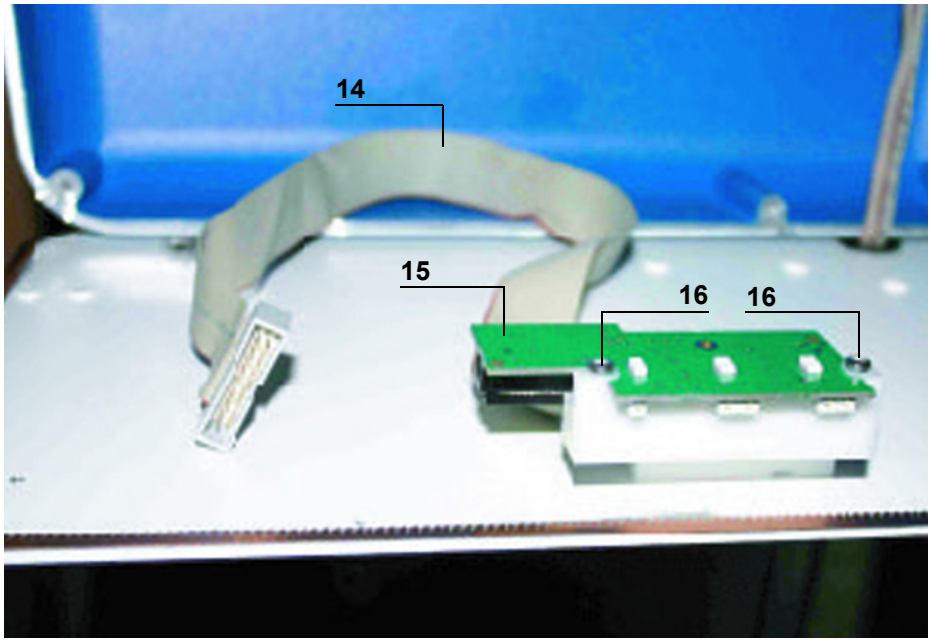
- Lift the housing cover (marker 9).
- To disassemble the 3 Pole LED cable (marker 10) or 4 Pole LED cable (marker 11), unplug it from the Magnet Indicator LED Board (marker 12) and at the Tesla Spy 2010 magnet indicator (Marker 13).
- To disassemble the Magnet Indicator LED Board (marker 12), unplug the 3 Pole LED cable (marker 10) and 4 Pole LED cable (marker 11).
- Remove the Magnet Indicator LED Board (marker 13).



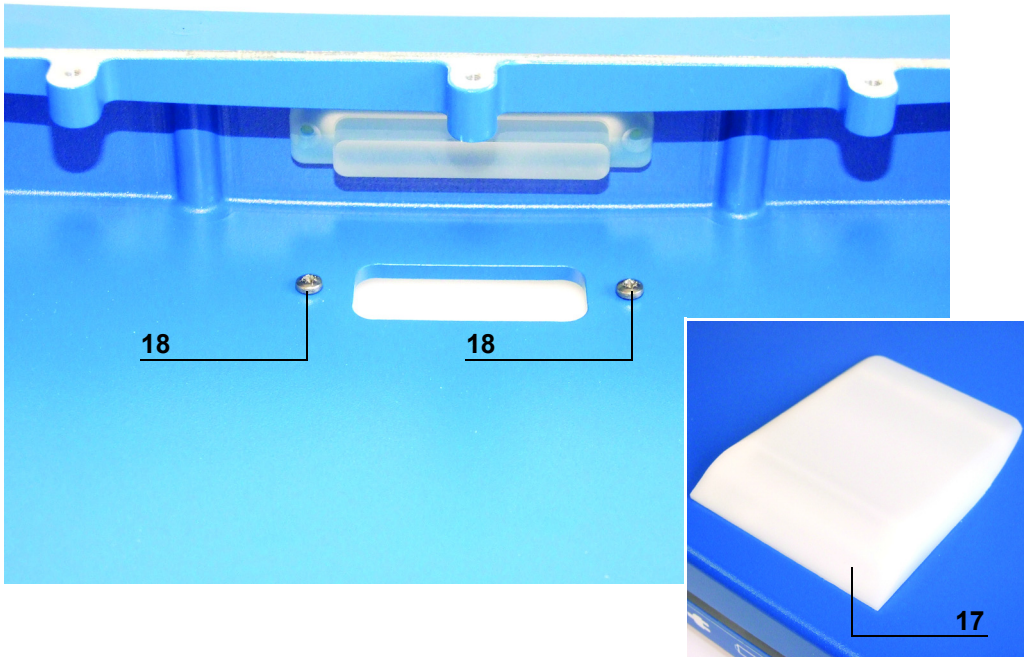



- To disassemble the Link+ Extension Cable (marker 14) unplug it from the LED board.
- To disassemble the LED board (marker 15) unplug the Link+ Extension Cable and unscrew the 2 "Phillips" pan head screws (marker 16).




- To disassemble the LED Glass cap user interface (marker 17), unscrew the 2 "Phillips" pan had screws (marker 18) and remove the LED Glass.



## Re-assembly

***Warning:***
*Each **Link+ Agilia** is equipped with its own main board. Specific information are recorded in each as MAC address, product code and serial number of the device.*

Pay attention to the ribbon cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (markers 1 and 6) are refitted with a torque of 1.58 Nm.
  - Ensure the screws (markers 3, 8, 16, 18) are refitted with a torque of 0.68 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°3, Procedure: Power line filters

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 socket wrench 7.
- 1 Phillips PH1 screwdriver.
- 1 anti-static bracelet.

## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

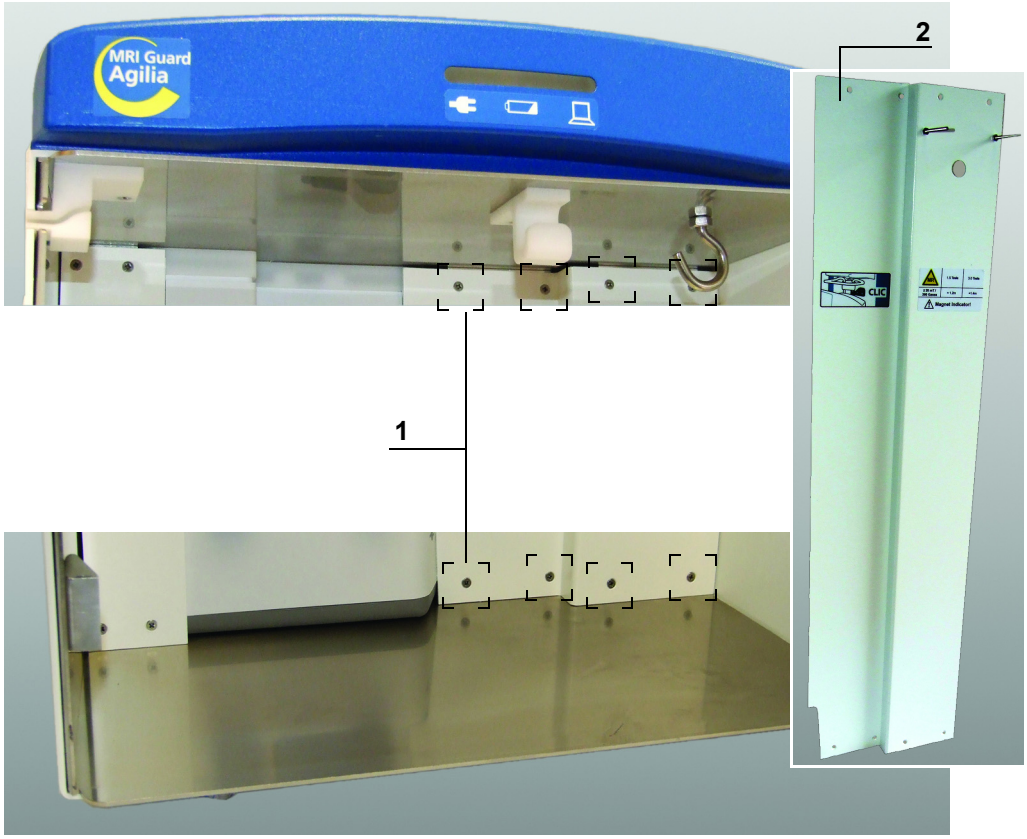
## Procedure:

### Access

To access Tesla Spy 2010 magnet indicator, first remove the Battery Pack and refer to the intervention sheet *"N°3, Procedure: Battery Pack Tesla Spy 2010"*, for detailed procedure (access and disassembly paragraphs).

Once *"N°3, Procedure: Battery Pack Tesla Spy 2010"* has been performed, continue with the following steps:

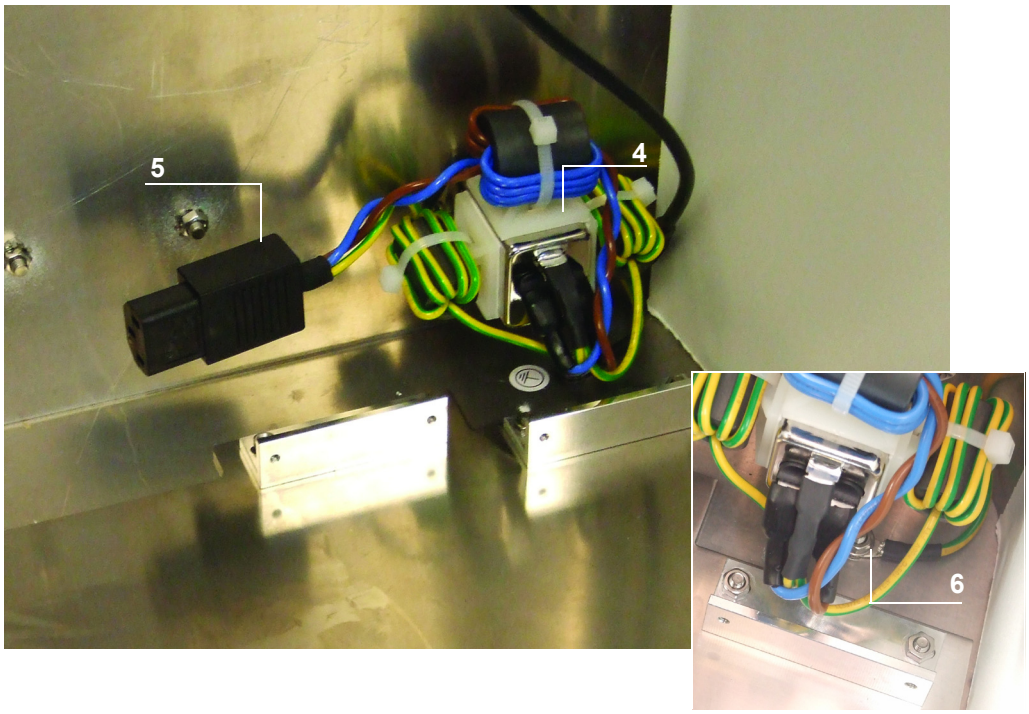
- Unscrew the 8 "Phillips" countersunk screws (marker 1).
- Remove the right seal cover (marker 2).



## Disassembly

- Unscrew the 2 "Phillips" countersunk screws on the back (marker 3).
- Remove the Power Line Filters (marker 4) from inside.

- Unplug the power plug (marker 5).
- Unscrew the PE terminal (marker 6).




## Re-assembly

Pay attention to the ribbon cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 1) are refitted with a torque of 0.68 Nm.
  - Ensure the screws (marker 6) are refitted with a torque of 1.58 Nm.
  - Ensure the screws (marker 3) are refitted with a torque of 0.9 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°4, Procedure: Cover of the Link+ Agilia

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Phillips PH1 screwdriver.
- 1 Phillips PH2 screwdriver.
- 1 anti-static bracelet.

## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

### Access

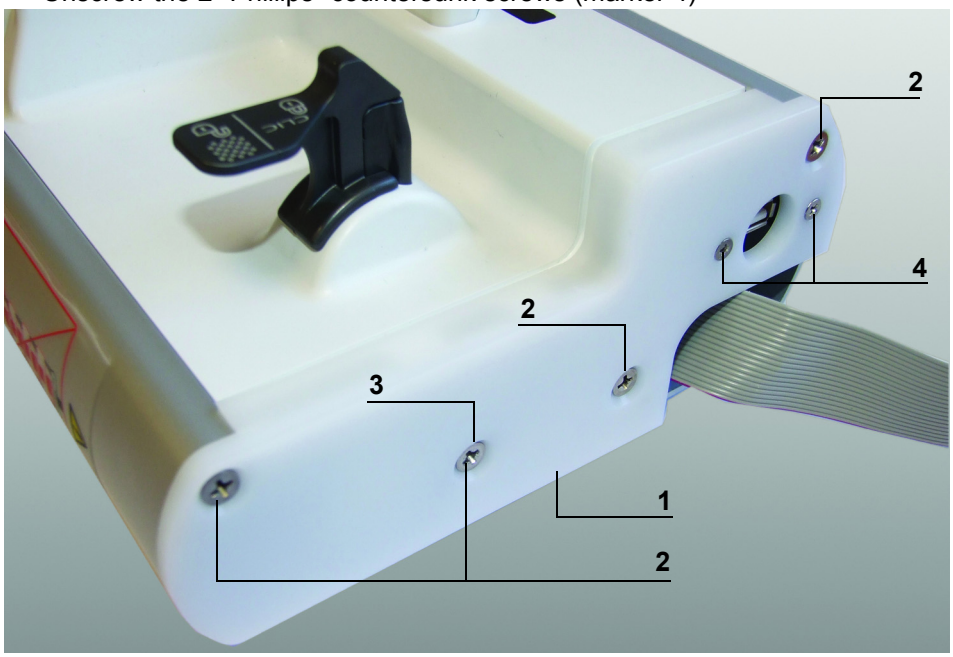
To access the Cover for the **Link+ Agilia** (marker 1), first remove the **Link+ Agilia**. Refer to the intervention sheet *"N°1, Procedure: Link+Agilia MRI "*, for detailed procedure (access and disassembly paragraphs).

Once *"N°1, Procedure: Link+Agilia"* has been performed, continue with the following steps:

- Unscrew the 4 "Phillips" countersunk screws (marker 2)

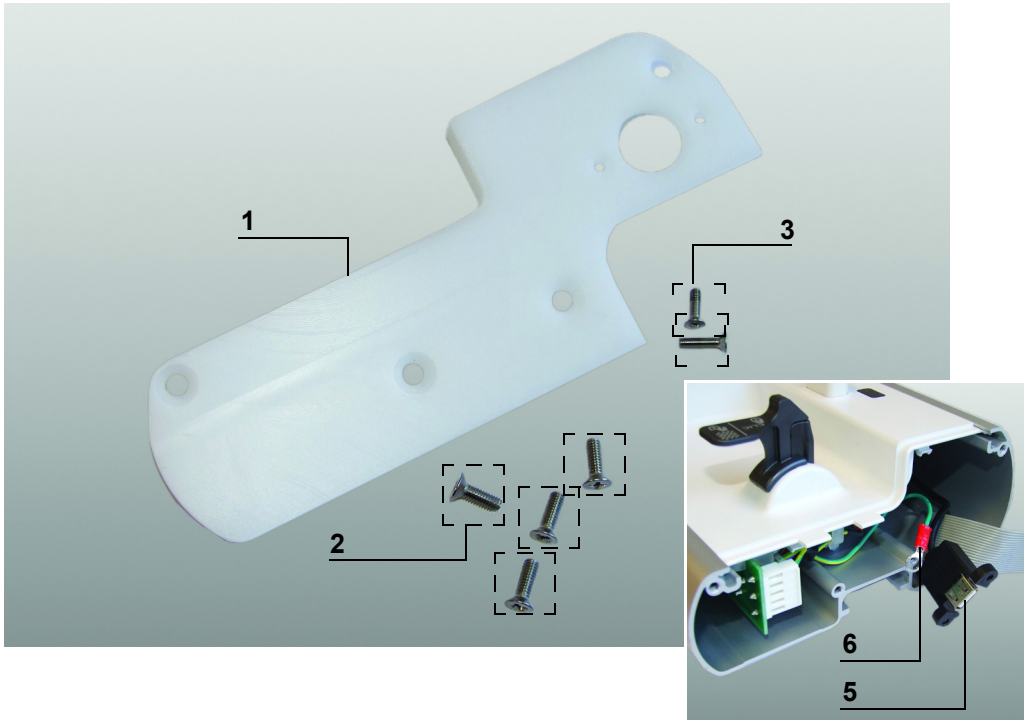
Be careful to the ground connector (marker 3).

- Unscrew the 2 "Phillips" countersunk screws (marker 4)




## Disassembly

- Remove the USB jack (marker 5).
- Remove the ground connector (marker 6).
- Remove the **Link+ Agilia** cover (marker 1).



## Re-assembly

***Warning:***
*Each* **Link+ Agilia** *is equipped ith its own main board. Specific information are recorded in each as MAC address, product code and serial number of the device.*

Pay attention to the ribbon cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 2) are refitted with a torque of 1.58 Nm.
  - Ensure the screws (marker 4) are refitted with a torque of 0.68 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

***Information:***
*For any intervention on the* ***Link+****, refer to the* ***Link+ Agilia*** *technical manual.*

# N°5, Procedure: Door Kit

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Phillips PH1 screwdriver.

## Maintenance level:

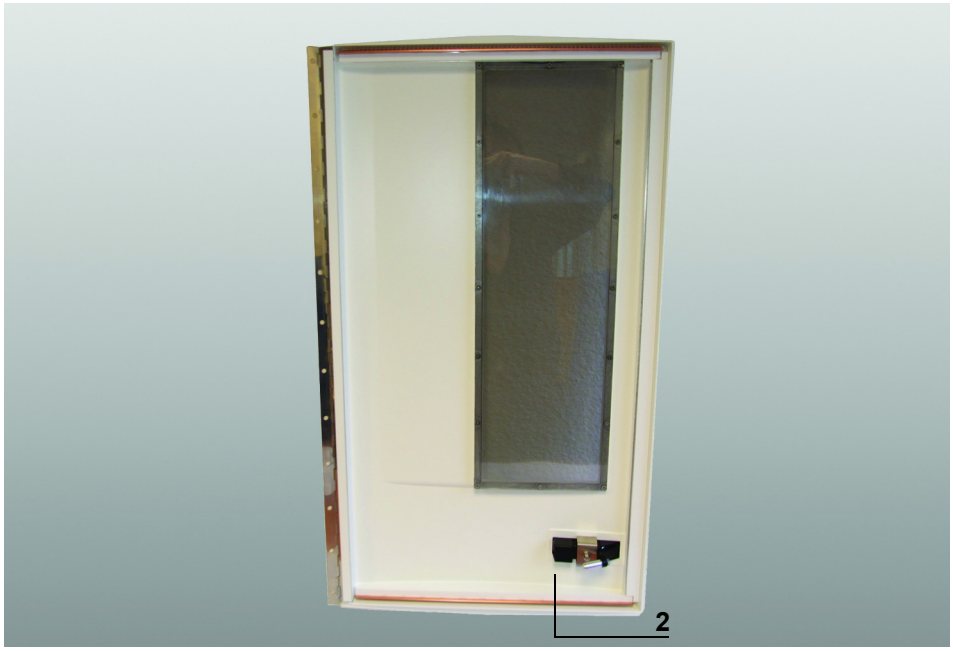
Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

### Disassembly

- Unscrew the 12 "Phillips" countersunk screws on the housing exterior (marker 1) holding the door (marker 2) and hinge sheet (marker 3) on the inside of the housing.


- Remove the Door Kit (marker 2) and place it on a suitable substrate.




## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 1) are refitted with a torque of 0.68 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°6, Procedure: Hinge

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Phillips PH1 screwdriver.

## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

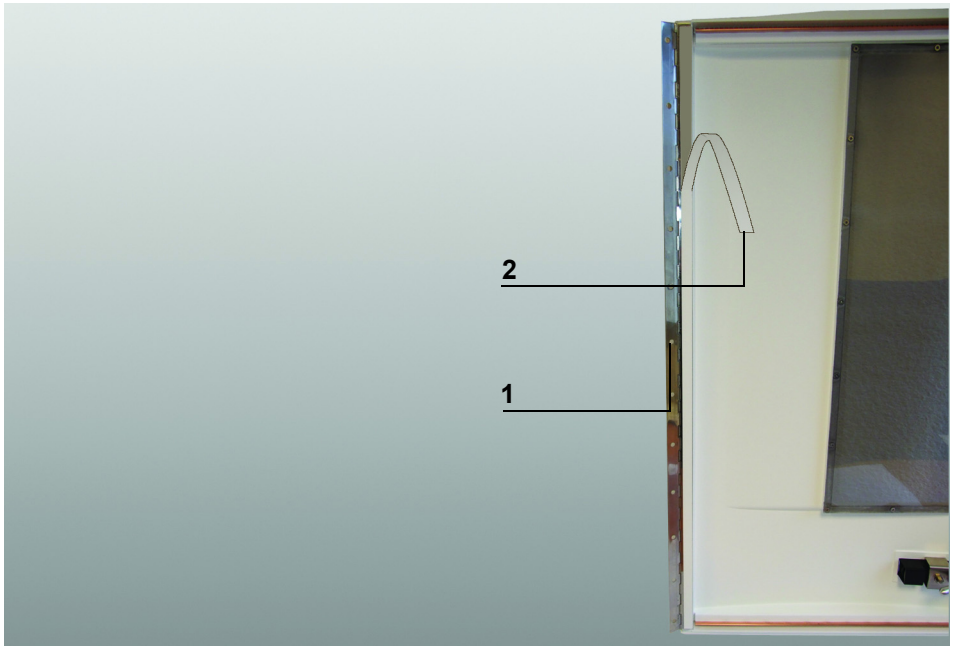
### Access

To access the Hinge (marker 1), remove the Door Kit first and refer to the intervention sheet *"N°8, Procedure: Door Kit"*, for detailed procedure (access and disassembly sections).

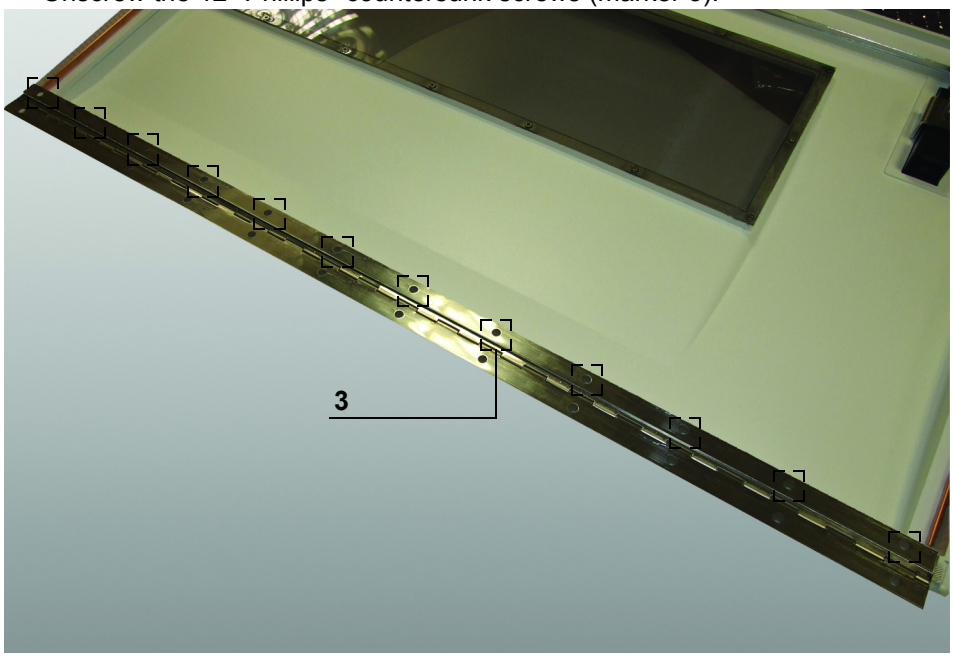
## Disassembly

Once *"N°8, Procedure: Door Kit"* has been performed, continue with the following steps:

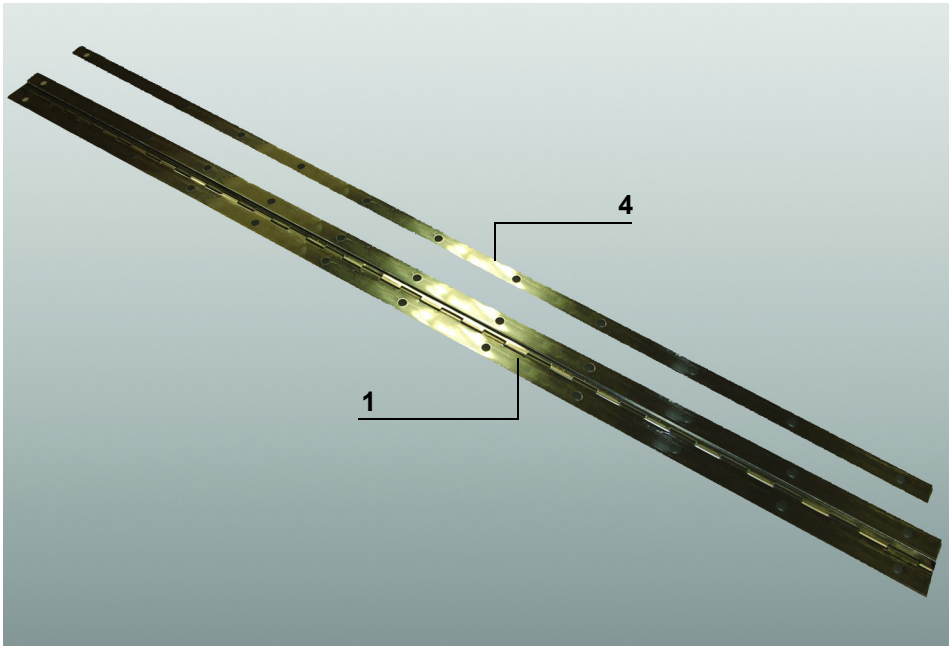
- Remove the film strip (marker 2).




- Unscrew the 12 "Phillips" countersunk screws (marker 3).



- Remove the hinge cover (marker 4).
- Remove the hinge (marker 1).




## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 4) are refitted with a torque of 0.68 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°7, Procedure: Door Lock

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Phillips PH2 screwdriver.
- 1 socket wrench 7.

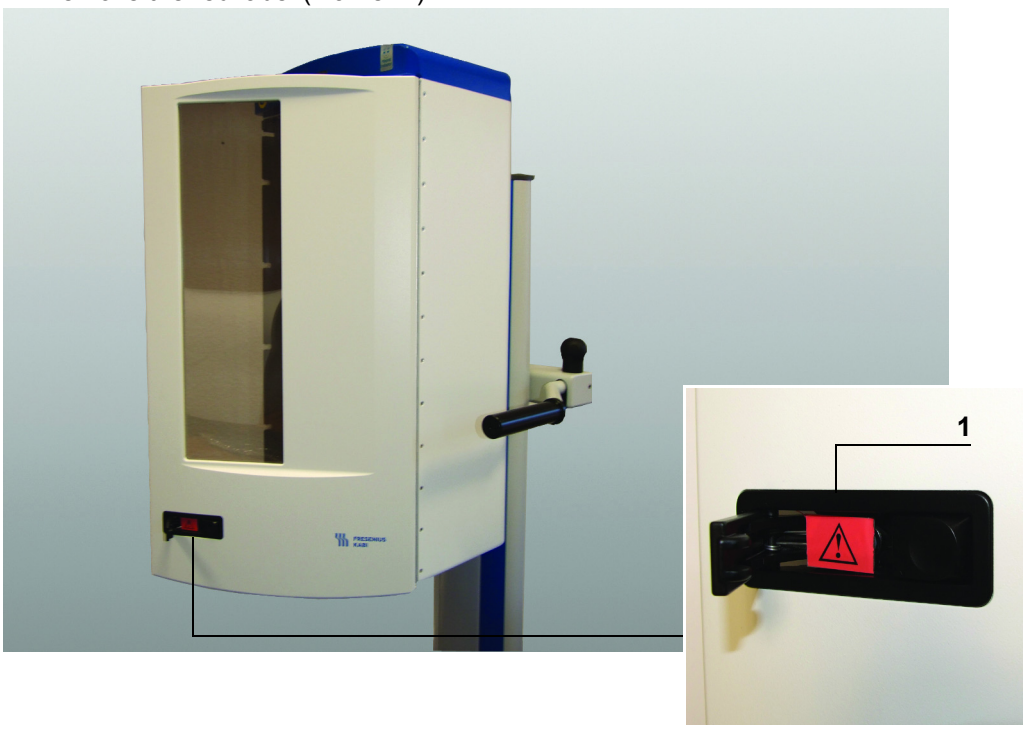
## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

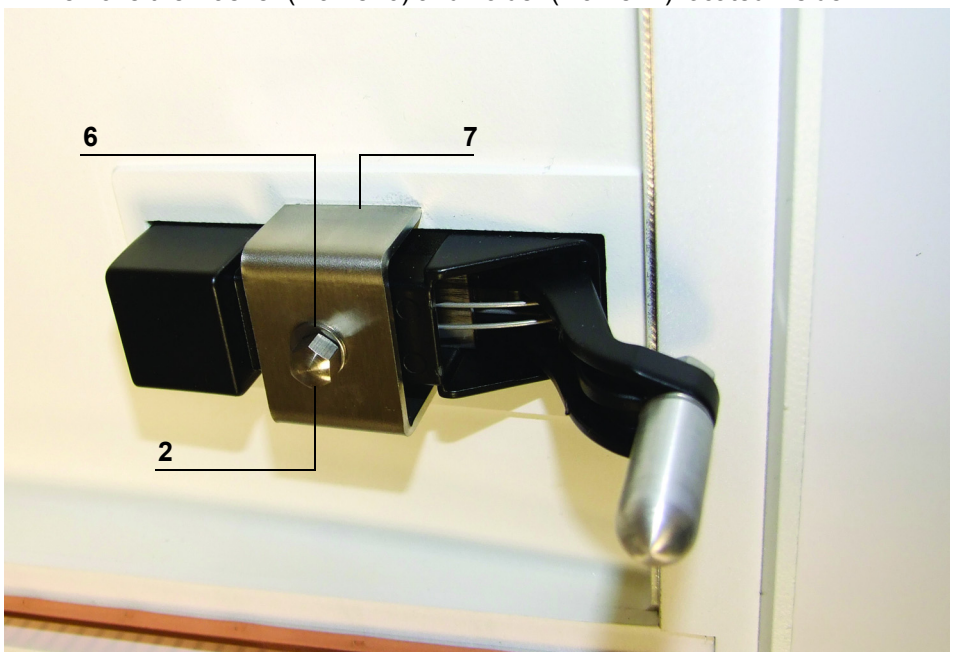
### Access

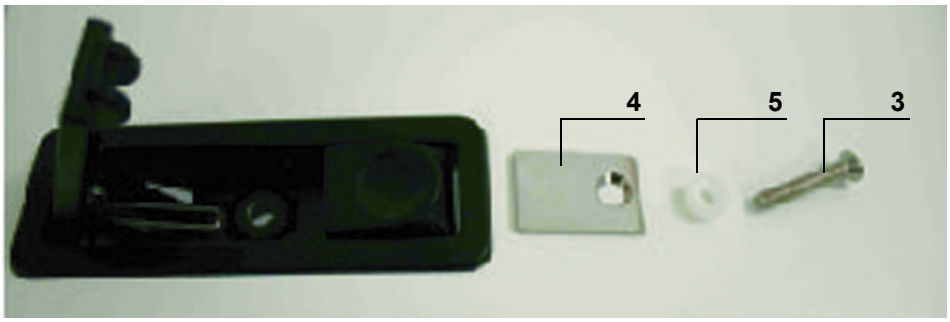
- Remove the red label (marker 1).



## Disassembly

- Loosen the M4 nut (marker 2) located inside and unscrew the "Phillips" countersunk screw (marker 3) on the front side.
- Remove the cover (marker 4) and spacer (marker 5) on the front side.
- Remove the washer (marker 6) and holder (marker 7) located inside.




## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - ☐ Ensure the nut (marker 2) is refitted with a torque of 2.1 Nm.
  - ☐ Ensure the screws (marker 3) are refitted with a torque of 2.1 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°8, Procedure: Shielded Window

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Phillips PH1 screwdriver.

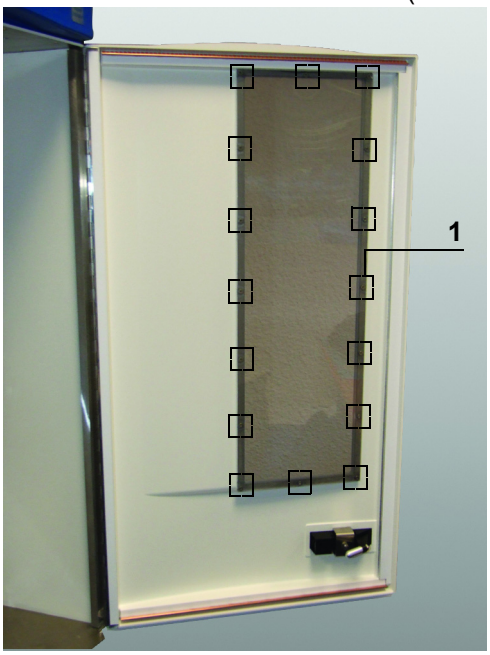
## Maintenance level:

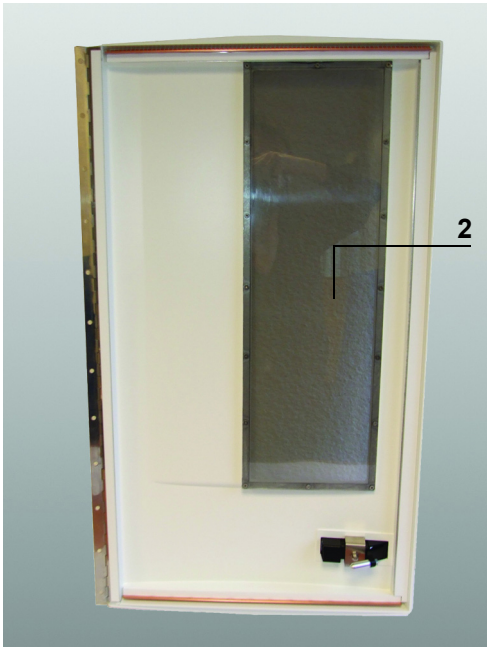
Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

### Disassembly

- Unscrew the 16 "Phillips" countersunk screw (marker 1).
- Remove the Shielded Window (marker 2).



## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 1) are refitted with a torque of 0.4 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°9, Procedure: Trolley with automatic wheel brake

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 hexagon socket screw key 4.

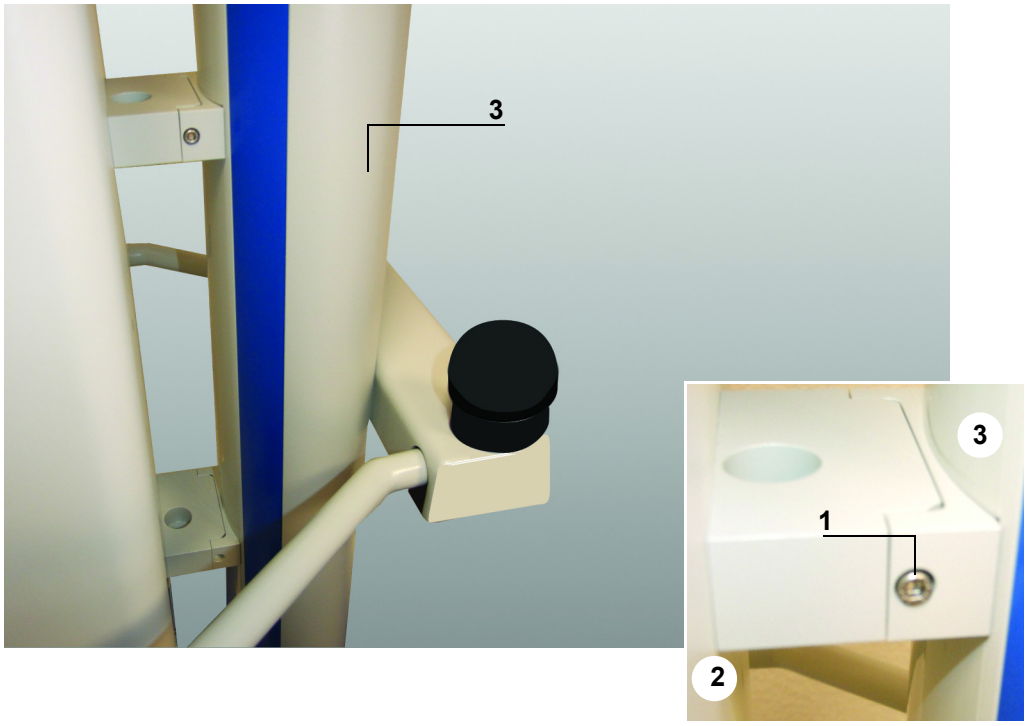
## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

## Disassembly

- Unscrew the 4 hexagon socket head screws (marker 1) on both sides of the trolley holder.
- Raise the base housing (marker 2) and place it on a suitable substrate.
- The Trolley (marker 3) is now separated from base housing.




## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 1) are refitted with a torque of 3.11 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°10, Procedure: Trolley Holder assembled on the trolley

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 hexagon socket screw key 3.
- 1 hexagon socket screw key 4.

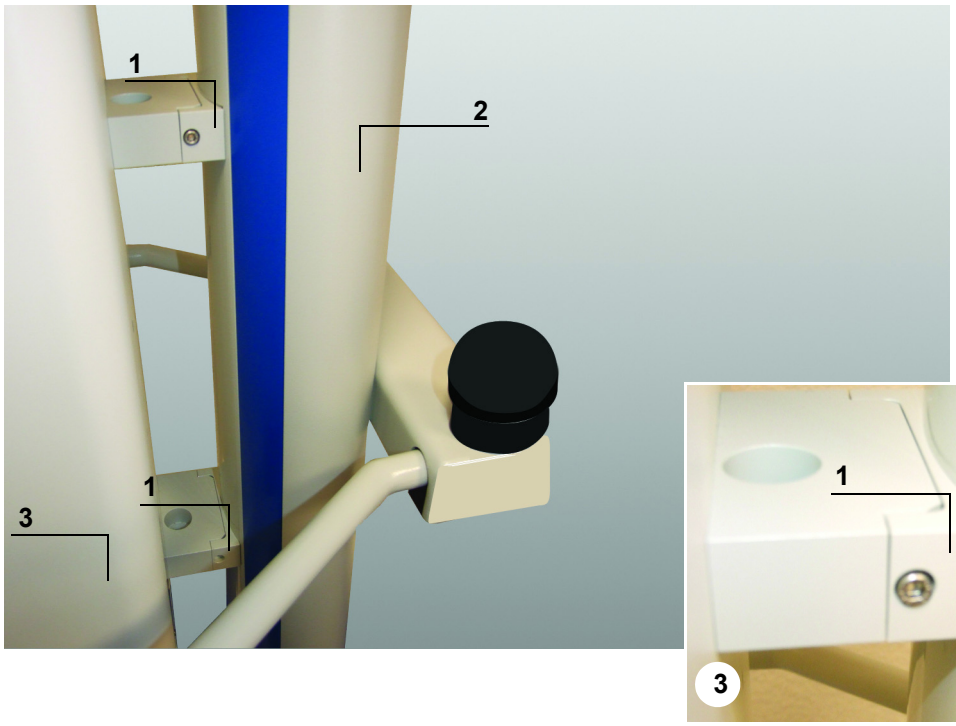
## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

## Access

To access the Trolley Holders assembled on the trolley (marker 1), disassemble the trolley (marker 2) from base housing (marker 3).
Refer to the intervention sheet *"N°12, Procedure: Trolley with automatic wheel brake"*, for detailed procedure (access and disassembly paragraphs).



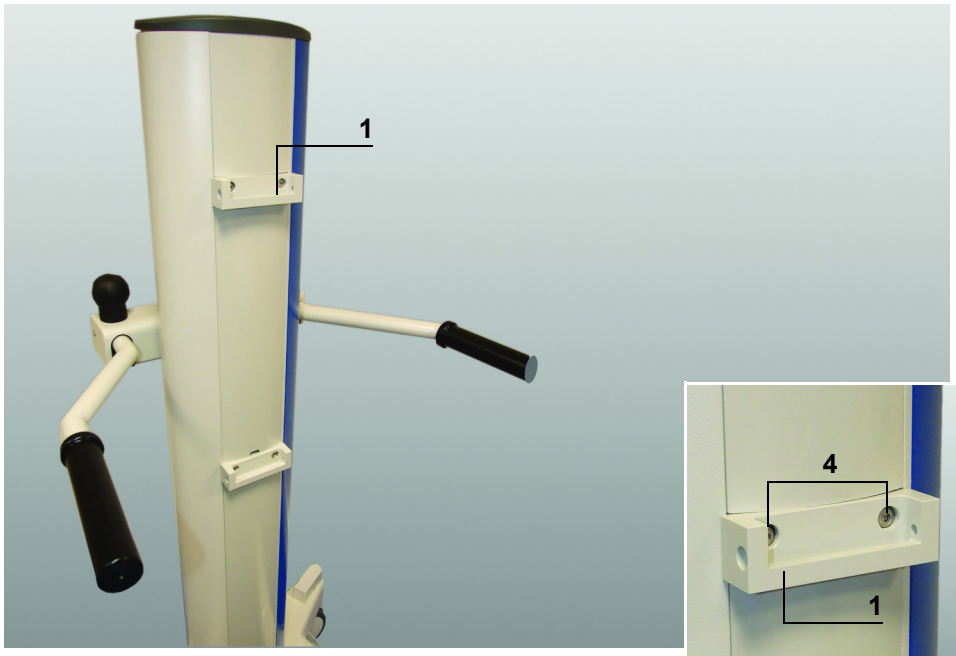




## Disassembly

Once " N°12, Procedure: Trolley with automatic wheel brake" has been performed, continue with the following steps:

- Unscrew the 4 hexagon socket head screws (marker 4).
- Remove the holders (marker 1).



## Re-assembly

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the screws (marker 4) are refitted with a torque of 0.73 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°11, Procedure: Trolley & IV pole Holder

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Hexagon socket screw key 3.
- 1 Hexagon socket screw key 4.
- 1 Socket wrench 5.5.
- 1 Socket wrench 7.0.
- 1 Socket wrench 8.0.
- 1 Torx TX-25 screwdriver.
- 1 Phillips PH1 screwdriver.
- 1 Phillips PH2 screwdriver.
- 1 anti-static bracelet.

## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

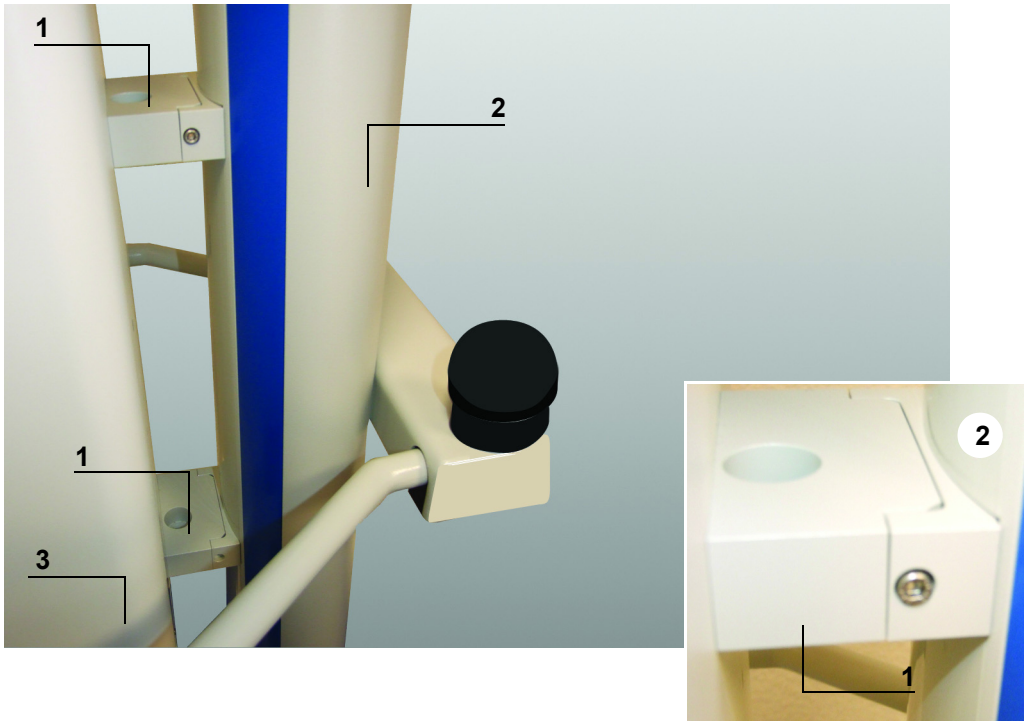
## Access

The **Link+ Agilia** must be removed.

Refer to the intervention sheet ***"****N°1, Procedure: Link+ Agilia"*, for detailed procedure (access and disassembly paragraphs).

To access Trolley & IV pole Holder (marker 1), disassemble the trolley (marker 2) from base housing (marker 3).

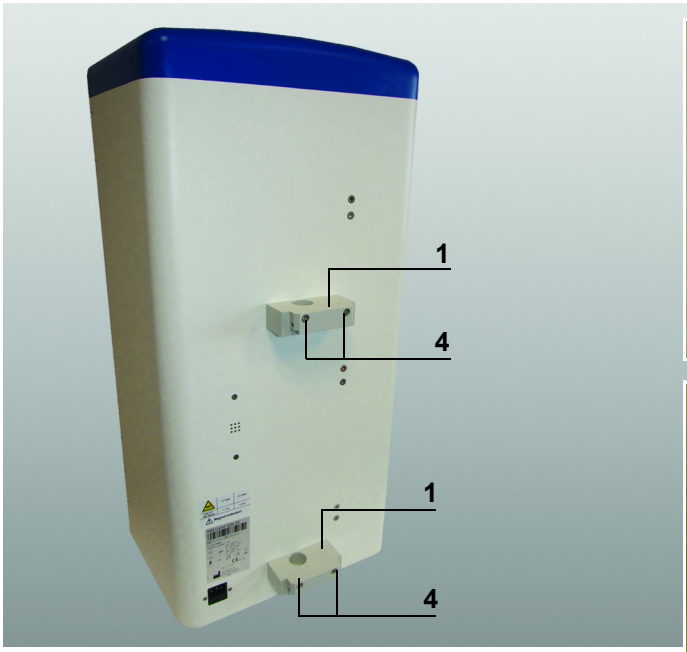
Refer to the intervention sheet *"N°12, Procedure: Trolley with automatic wheel brake"*, for detailed procedure (access and disassembly paragraphs).

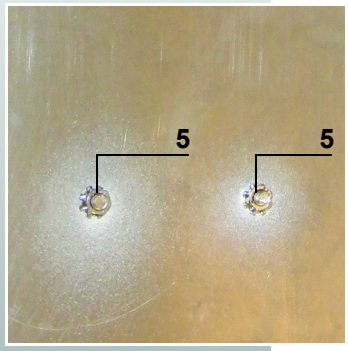


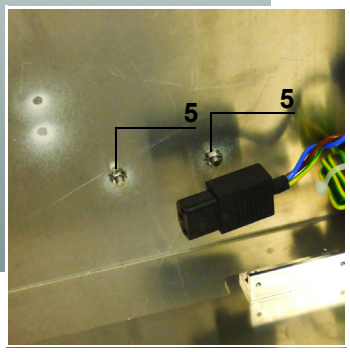
## Disassembly

Once *" N°12, Procedure: Trolley with automatic wheel brake"* has been performed, continue with the following steps:

- Unscrew the 4 hexagon socket head screws (marker 4) located outside the housing and 4 M5 nuts (marker 5) on located inside the housing.
- Remove the holders (marker 1).




## Re-assembly

***Warning:***
*Each **Link+ Agilia** is equipped with its own main board. Specific information are recorded in each as MAC address, product code and serial number of the device.*

Pay attention to the ribbon cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - ☐ Ensure the screws (marker 4) are refitted with a torque of 4.3 Nm.
  - ☐ Ensure the nuts (marker 5) are refitted with a torque of 4.3 Nm.

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°12, Procedure: Double swivel castors Ø125mm, conductive, non-magnetic (only 2 front castors are replaceable in field)

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning:***
*It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Required tools:

- 1 Wrench 22.

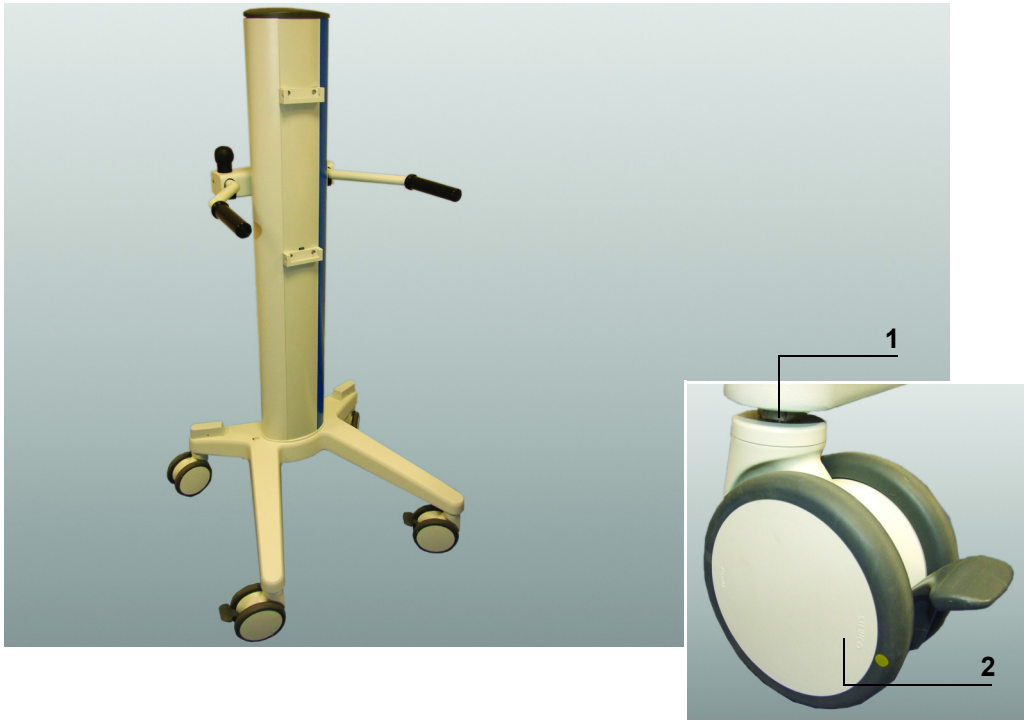
## Maintenance level:

Level 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

## Procedure:

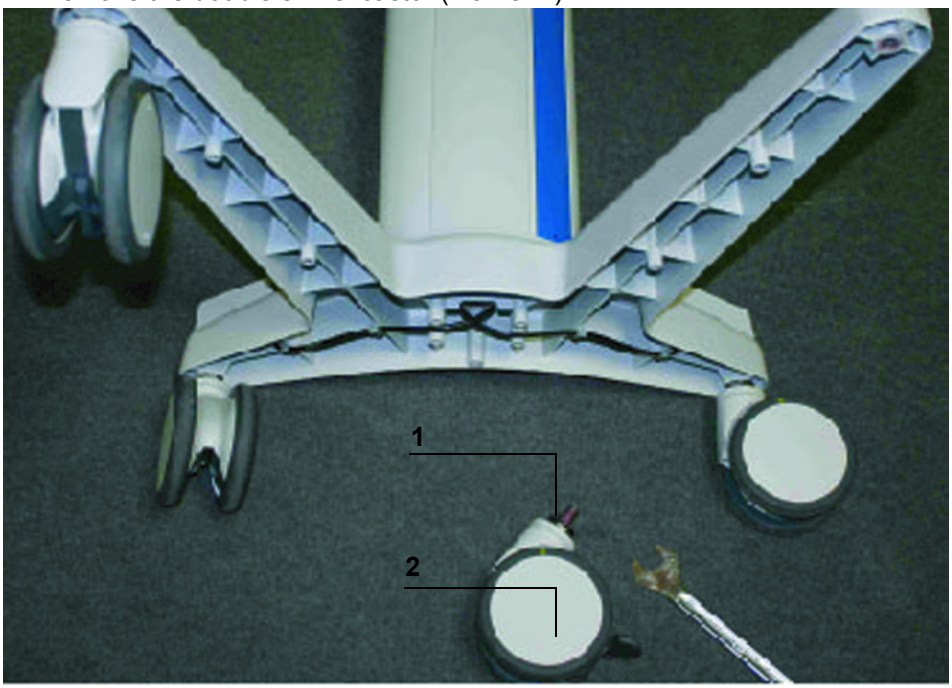
## Disassembly

- Loosen the nut (marker 1) of the double swivel castor (marker 2).




***Warning:***
*Only 2 front castors are replaceable by service technicians. If the back castors are damaged and need service, please contact* ***Fresenius Kabi*** *Technical Service, refer to the Useful addresses section.*

- Remove the double swivel castor (marker 2).




## Re-assembly

Pay attention to the cables connection direction during assembly.

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
  - Ensure the nut (marker 1) is refitted with a torque of 3.45Nm.
  - The screw of the castor must be provided with a thread lock (e.g. LOCTITE 248).

***Warning:***
*Carry out the regular servicing tests (see Quality Control Certificate).*

# N°13, Procedure: Battery

## Safety:

DANGER

***Danger:***
*For safety reasons, the technician should not intervene when the device is connected to the mains voltage. Disconnect the power supply cord from the mains.*

***Warning**:*
*It is advisable to clean and desinfect the device's external surfaces before any maintenance operation in order to protect the operator.*

## Material needed:

- 1 hexagon socket screws 3 key.

## Maintenance level:

Level 1 and 2, specialist technician. A training program document is available upon request (Please contact **Fresenius Kabi** service department).

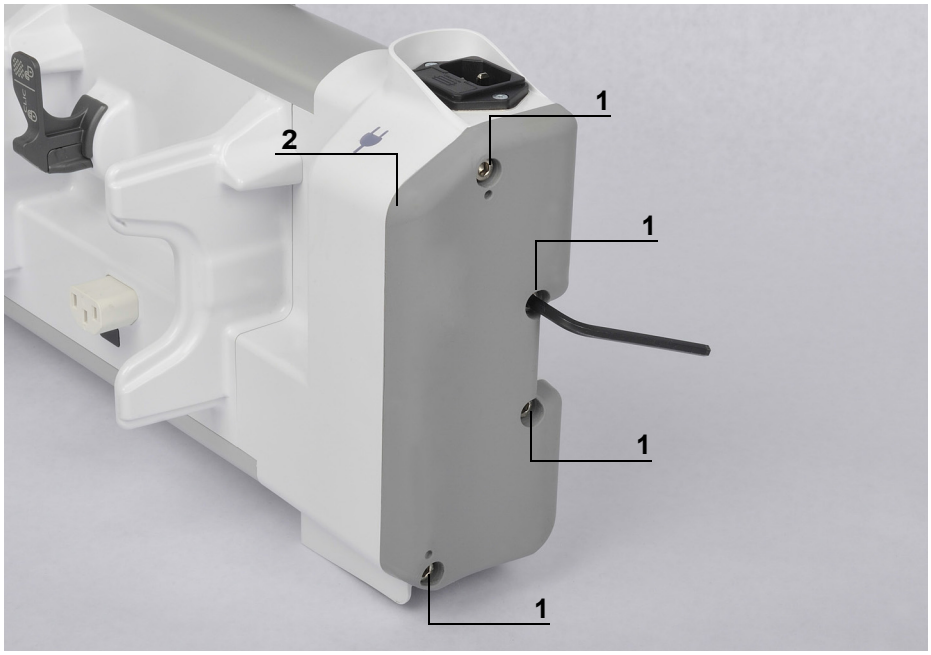
## Procedure:

### Access

To access the battery remove the **Link$^{+}$ Agilia.** Refer to the intervention sheet "*N°1, Procedure: Link$^{+}$ Agilia*", for detailed procedure (access and disassembly paragraphs).

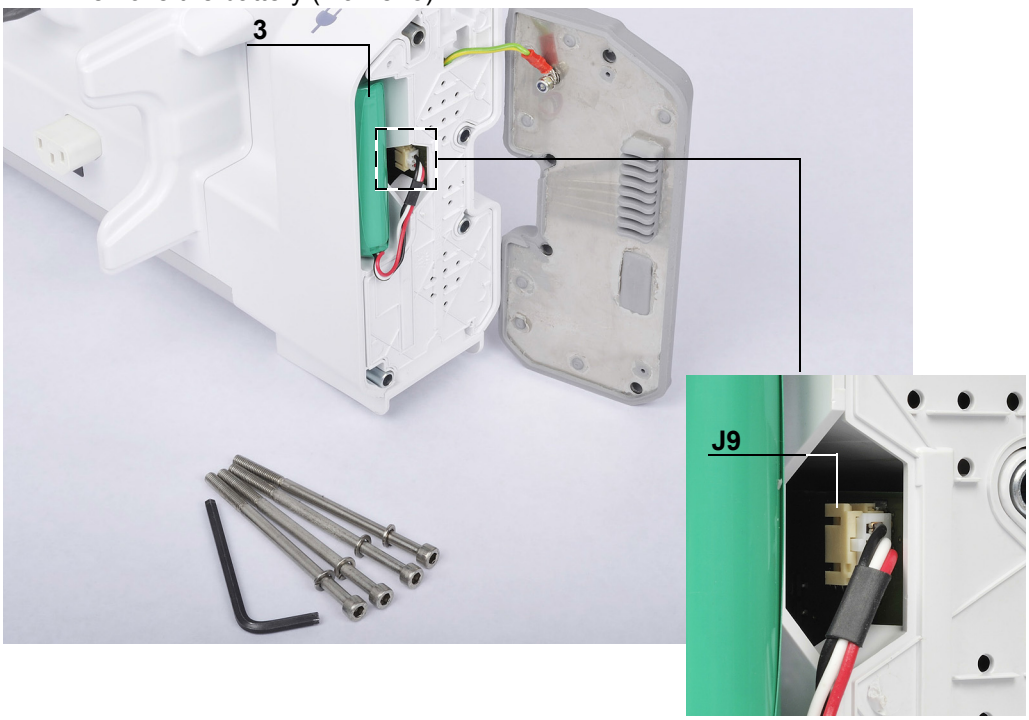
Once *"N°1, Procedure: Link+ Agilia"* has been performed, continue with the following steps:

- Unscrew the 4 hex socket head screws (marker 1) holding the bumper (marker 2) on the aluminium profile.
- Disassemble the bumper without removing it (grounding wire).



## Disassembling

- Take the battery (marker 3) out of its housing.
  - ☐ Disconnect the connector (J9) from the main board.
  - ☐ Remove the battery (marker 3).




## Re-assembling

- Repeat the disassembly operations in reverse order to reassemble.
- Recharge the battery.
  - ☐ Make sure when connecting the **Link+ Agilia** to the mains power, the cap indicators turn green.
- For further information, see test 4.3.2 in **Link+ Agilia** technical manual.
- Perform a complete check procedure *(see Quality Control Certificate)*.

***Warning:***
***After reassembling the battery, set the product date and time via the web Interface*** *(see chapter "Technical characteristics" in* ***Link+Agilia*** *technical manual).*

***Warning:***
***Before fixing the bumper on the aluminium profile, make sure that its thread is in good condition. If it is damaged, replace the aluminium profile.***

# 10 Ordering information

***Warning:***
*Use ONLY recommended accessories delivered with the device. When replacing components, only use* ***Fresenius Kabi*** *spare parts.*

## 10.1 MRI Guard Agilia packaging

The **MRI Guard Agilia** is a device to accommodate and power up to four **Agilia** IV pumps, thanks to the **Link4$^{+}$ Agilia** already mounted in the **MRI Guard Agilia**. With the **MRI Guard Agilia** these infusion pumps can be operated in a Magnetic Resonance Imaging unit.

Different part numbers are available depending on the requested language.

Please contact your **Fresenius Kabi** sales representative for ordering.

## 10.2 Spare Parts

### 10.2.1 Magnet Indicator's battery pack

| Part name | Part Description | Part Number |
|---|---|---|
| Battery pack | Magnet Indicator's non rechargeable battery pack | Z6450026 |

Please contact your **Fresenius Kabi** Technical Service to get the exhaustive list of available spare parts or for ordering.

# Useful addresses

**TRAINING DEPARTMENT / TECHNICAL ERVICE**

**Fresenius Kabi**
Le Grand Chemin
38590 Brézins
France

Tel.: +33 (0)4 76 67 10 76
or: +33 (0)4 76 67 60 73
Fax: +33 (0)4 76 67 11 22

**SPARE PARTS DEPARTMENT**

**Fresenius Kabi**
Le Grand Chemin
38590 Brézins
France

Tel.: +33 (0)4 76 67 10 34
Fax: +33 (0)4 76 67 11 88

**CUSTOMER SERVICE**

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38590 Brézins
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