



PRODUCT GUIDE & USER MANUAL

RT-5100-S AirDrive Caddie™

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 <p>Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6053 www.Qfix.com</p>	<p>CH REP Raditec Medical AG Schlossberg 5a 5454 Bellikon Switzerland</p>

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING ! No modification of this equipment is allowed. If any part of this device experiences a catastrophic load, appears damaged or functions improperly, discontinue use immediately and contact Qfix at +1 484-720-6053 or tech support@qfix.com.

! WARNING ! Follow your local regulations for disposal for the AirDrive Caddie and its components.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

SAFETY INFORMATION

The air source should never be operated when loading or unloading a patient on AirShuttle device.

ENVIRONMENTAL CONDITIONS

Operating

- Temperature: 10°C to 35°C (50°F to 95°F)
- Humidity: 10% to 90% non-condensing
- Atmospheric: 700–1060 hPa

Storage

- Temperature: 0°C to 50°C (32°F to 122°F)
- Humidity: 0% to 95%
- Atmospheric: 700–1060 hPa

Shipping

- Temperature: -29°C to 60°C (-20°F to 140°F)
- Humidity: 0% to 95%
- Atmospheric: 700–1060 hPa

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the **AirDrive Caddie** is MR Conditional. This device may be used with an MR system only under the following conditions:

- Static magnetic field of 3T or less.
- The GaussAlert™ module is installed and operational on the AirDrive Caddie.
- Both the AirShuttle device and the underlying patient support (e.g. trolley, stretcher, table) is MR Conditional or MR Safe for the MR environment.
- The **AirDrive Caddie** shall not be moved closer to the MR system than the 30 Gauss boundary. Identify the 30 Gauss boundary prior to bringing the **AirDrive Caddie** into the MR environment.
- The user does not lift the **AirDrive Caddie** off the floor of the MR room.
- The patient support is in a braked or otherwise fixed condition prior to patient transfers taking place.

Non-clinical testing has demonstrated the **AirShuttle Transfer Handles** are MR Conditional. These devices may be used with an MR system meeting the following conditions:


- Static magnetic field of 3T or less.
- The **AirShuttle Transfer Handles** must be removed from the device prior to placing the device into the bore of the MR system.

Non-clinical testing has demonstrated the **AirDrive Charging Cable** is MR Conditional. This device may be used with an MR system meeting the following conditions:

- Static magnetic field of 3T or less.
- The **AirDrive Caddie** must not be on charge in the MRI room when imaging. Doing so could result in MR image artifacts.

Non-clinical testing has demonstrated the **AirDrive Pendant Switch** is MR Conditional. This device may be used with an MR system meeting the following conditions:

- Static magnetic field of 3T or less.

 Non-clinical testing has demonstrated the **AirDrive Pneumatic Foot Switch** is MR Safe. This device may be used in an MR environment.

! WARNING ! Not adhering to the conditions described above when using **AirDrive Caddie** and other components of the AirDrive system in the MR environment may result in injury to the patient or clinician.

! WARNING ! Recommended maintenance and service, as well as use of only Qfix-provided accessories, components, and replacement parts, are necessary to ensure the safety, performance, and MRI compatibility of the product(s), as well as to maintain applicable warranties.

! WARNING ! Use of unapproved MR accessories may result in:

- Injury to patient
- Patient burns
- Damage to equipment

Use only proven MR Safe or MR Conditional accessories, tested and approved for your MR system.

Consider the MR compatibility of accessories prior to use on your MR system.

! WARNING ! Maintenance and other service of qfix products should never be performed in an MR environment.

ELECTRONIC EMISSIONS

The AirDrive Caddie is classified as Emissions Class A and has been tested to Immunity to RF Electromagnet Fields at a level of 3 V/m per IEC 60601-1-2. The AirDrive Caddie is an electronic device that may interfere with other electronic devices. If the AirDrive Caddie interferes with other electronic devices, move the AirDrive Caddie away from affected device(s).

! WARNING ! The AirDrive Caddie may be affected by emissions from nearby electronic devices, including devices adjacent to or placed on the AirDrive Caddie. Emissions may affect control of the AirDrive Caddie, rendering them inoperable. In the event that control of AirDrive Caddie is impaired, separate the AirDrive Caddie and the emitting devices by a sufficient distance. If electronic devices are to be used on or adjacent to the AirDrive Caddie, this equipment and the AirDrive Caddie should be observed to verify that they are operating normally.

! WARNING ! Use of accessories and cables other than those specified or provided by Qfix could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

! WARNING ! Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AirDrive Trolley. Otherwise, degradation of the performance of the trolley could result.

ADDITIONAL PRECAUTIONS

! CAUTION ! The AirDrive Caddie is electrically powered. To prevent injury, this system's electronics, internal fuses, and internal battery should be serviced by Qfix-approved service personnel only.

The use of additional immobilization devices may create additional trapping zones not described in this Product Guide and User Manual.

Use of the charging cable and the transfer hose may create a tripping hazard. Take care in managing the charging cable and the transfer hose to avoid potential tripping and snag scenarios.

When using the AirDrive Caddie, avoid tugging on the hose. Doing so could pull the hose out of the AirDrive Caddie, cause the AirDrive Caddie to roll, or cause the AirDrive Caddie to tip over, potentially damaging the device and harming users.

When moving the AirDrive Caddie, take care not to roll over feet or park the AirDrive Caddie such that it can pinch someone's foot.

Be cognizant of location when parking the AirDrive Caddie or leaving it unattended, as it may become a trip hazard.

Ensure charging system of AirDrive Caddie is connected to equivalent receptacle marked 'Hospital Only' or 'Hospital Grade'.

! WARNING ! To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

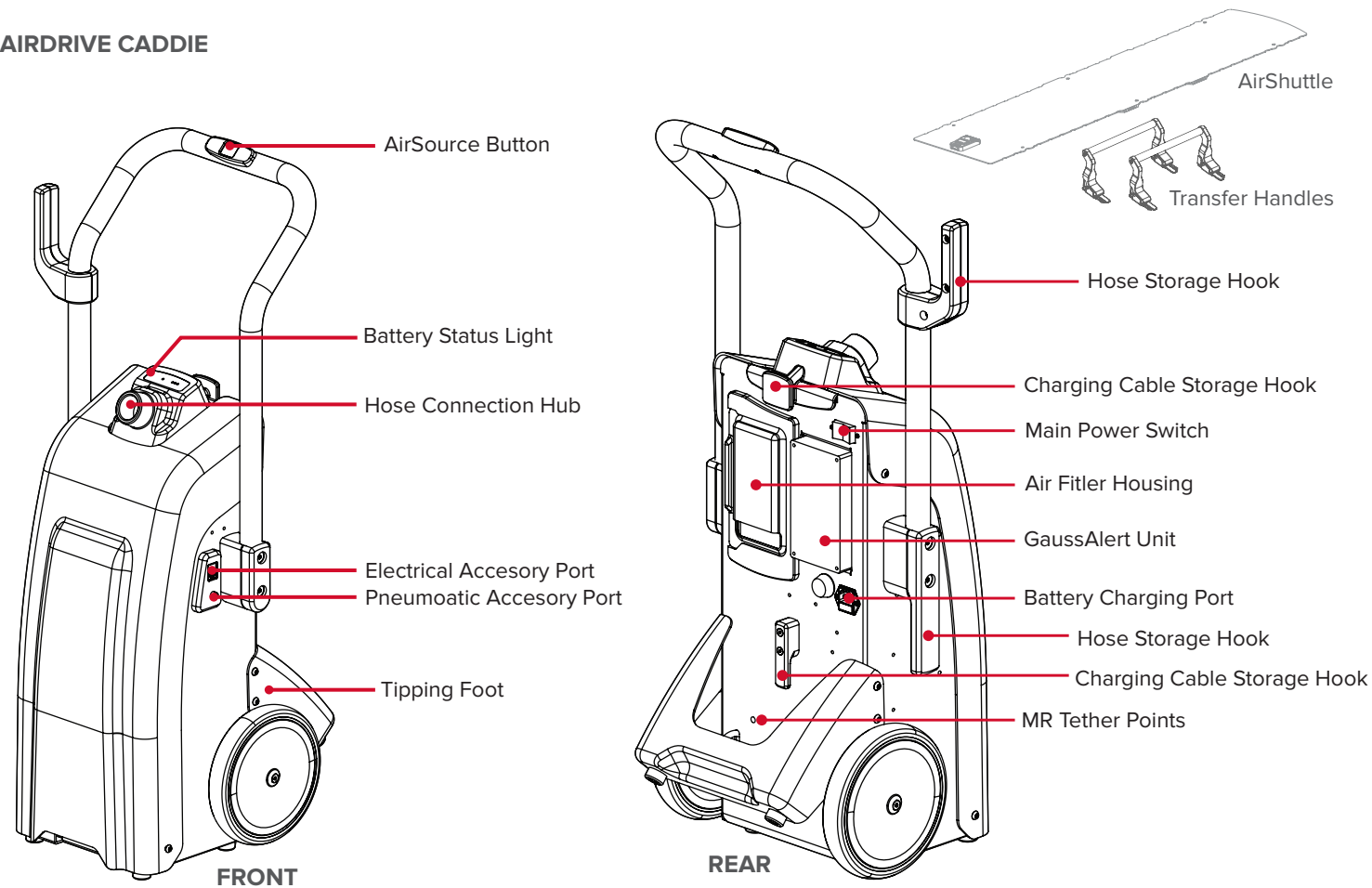
Any tables, stretchers, or other patient supporting surfaces used for the patient transfer must be fixed, braked, or docked in place prior to patient transfers taking place.

Ensure that the air hose is properly seated in both the AirShuttle device air inlet as well as the hose connection point in the AirDrive Caddie prior to use of the air source.

! CAUTION ! The AirDrive Caddie is not intended for use in oxygen rich environments or with flammable agents.

GETTING TO KNOW YOUR AIRDRIVE CADDIE

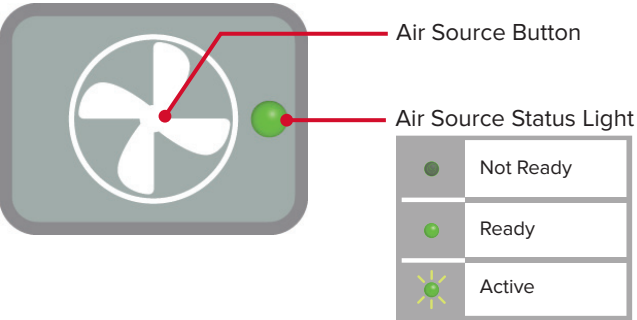
AIRDRIVE CADDIE



BATTERY STATUS LIGHTS

	Charging (flashing in sequence)
	Fully Charged
	Partially Charged • 1 or 2 green lights illuminated
	Low Charge • Critically Low (flashing with alarm)

AIRSOURCE BUTTON



INTENDED USE

The AirDrive Caddie is intended to aid in transfer of a patient when used with compatible AirShuttle devices, including during imaging and treatment.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

Patient Target Groups

Patients undergoing radiation therapy, diagnostic imaging procedures, or other procedures involving transfer of a patient.

Intended Users

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

GETTING TO KNOW YOUR AIRDRIVE CADDIE

GAUSSALERT



The AirDrive Caddie has been designed with an integrated GaussAlert alarm system. The GaussAlert is a magnetic field detector and audible alarm alerting the user when AirDrive Caddie has entered a magnetic field of approximately 30 Gauss or greater. This unit is self-contained with its own power source and will remain functional even when the AirDrive Caddie is not powered.

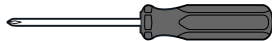
! WARNING ! The functionality of the GaussAlert should be tested on a regular basis by holding a strong magnet to the unit's cover. If the GaussAlert is non-functional, its battery should be replaced and functionality demonstrated before using the AirDrive Caddie in the MR environment. Contact your Qfix service representative for a replacement battery or assistance.

! NOTE ! The GaussAlert's dedicated 9V battery must be replaced at least every 5 years to maintain functionality. If the battery requires replacement, do not use a standard 9V battery. Instead, request a GaussAlert Battery Replacement Kit from Qfix.

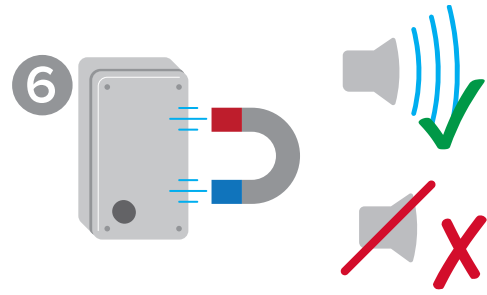
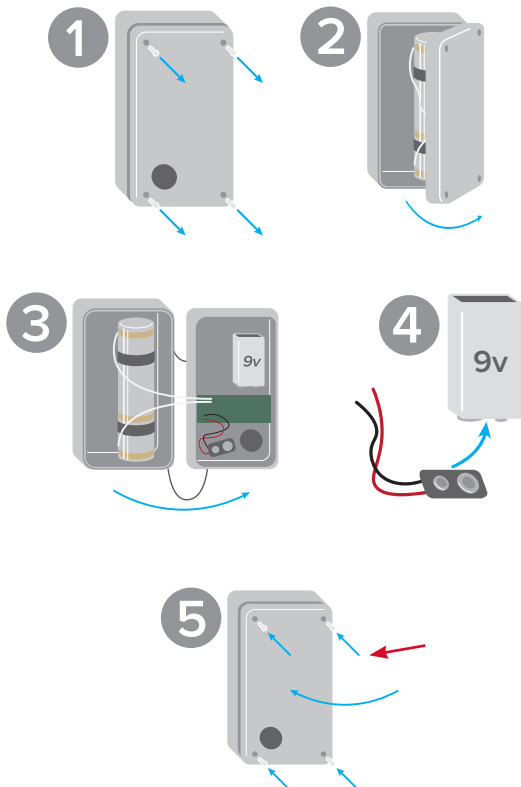
INSTALLING AND REPLACING THE GAUSSALERT BATTERY

! CAUTION ! Prior to use in an MR environment, the included GaussAlert unit must be operational.

If connecting the GaussAlert's battery for the first use, remove the cardstock with instructions covering the GaussAlert and main power switch.



Tool Needed: Cross-head Screwdriver

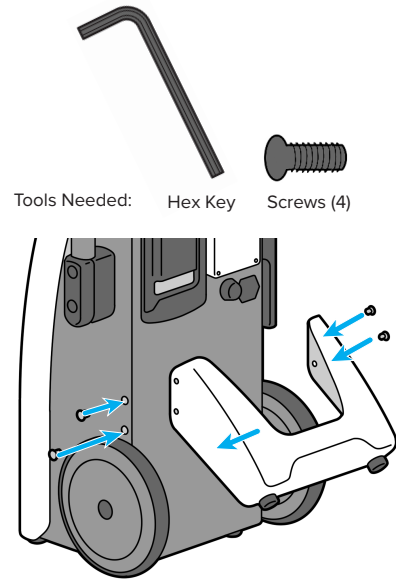


If, after installing the battery, a strong magnet does not trigger the alarm, try a stronger magnet and check the battery connection. If the GaussAlert remains nonfunctional, contact a Qfix service representative for assistance.

! CAUTION ! Do NOT use AirDrive Caddie in an MR environment until the GaussAlert is demonstrated to be functional.

INSTALLING THE TIPPING FOOT

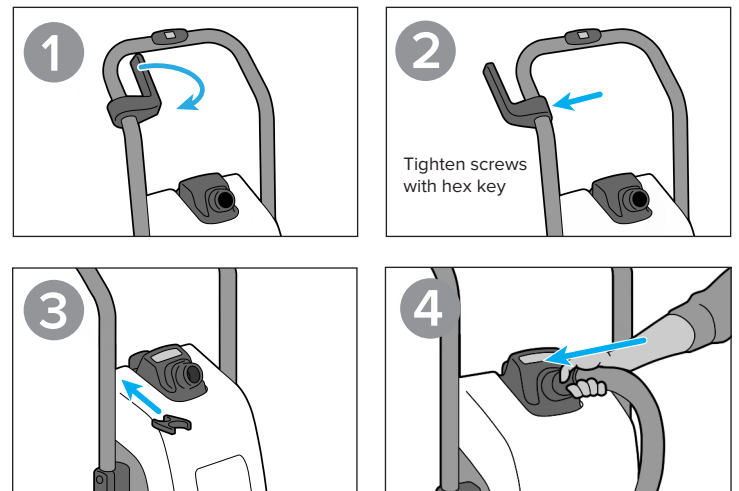
! CAUTION ! Ensure installation of the Tipping Foot to prevent toppling the unit.



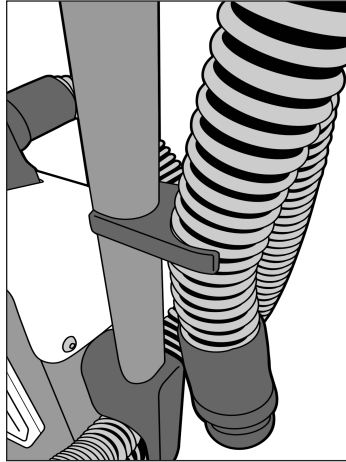
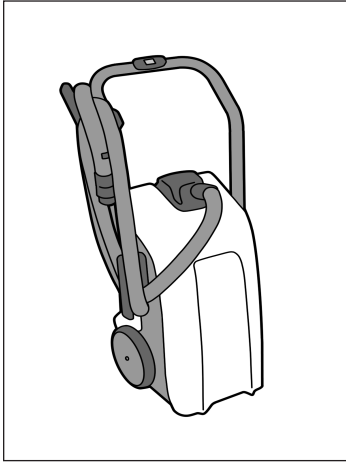
INSTALLING THE TRANSFER HOSE



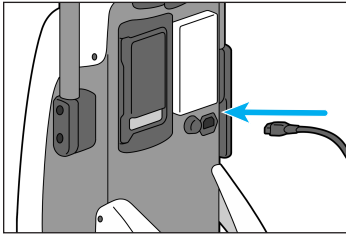
Tool Needed: Hex Key



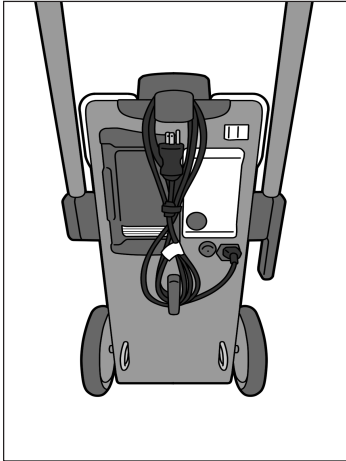
STORING THE TRANSFER HOSE



INSTALLING THE CHARGING CABLE



STORING THE CHARGING CABLE



! NOTE ! The air source is disabled while charging.

! NOTE ! The AirDrive Caddie is not operational when charging.

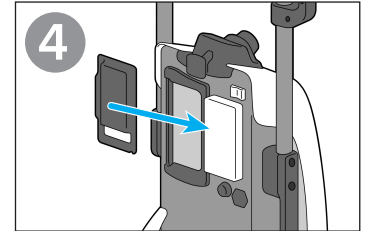
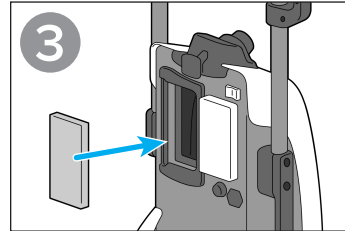
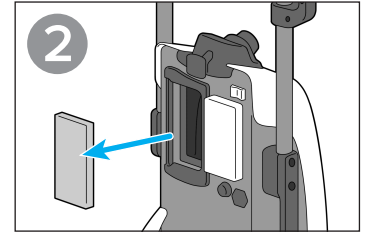
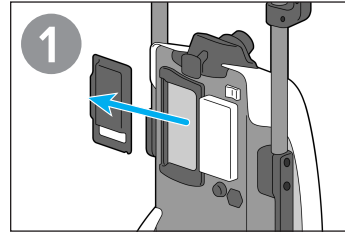
! NOTE ! Use only the supplied cable for charging.

! NOTE ! Position the AirDrive Caddie close to the charging outlet in a way that does not impede disconnecting the charging cable from the wall or device.

! NOTE ! To prolong the life of the batteries and ensure availability of the AirDrive Caddie when needed, charge the AirDrive Caddie at the end of every workday. The system may be left on charge indefinitely without incurring damage to the battery.

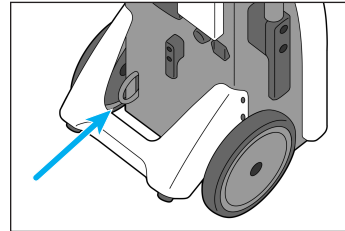
AIR FILTER

The air filter should be inspected regularly and replaced as needed, but at least once per year, by following the procedure described below. Replacement air filters may be purchased from Qfix.



MR TETHER POINTS

If a tether is utilized, it should be sized and positioned appropriately to prevent the AirDrive Caddie from entering a field with strength greater than 30 Gauss. Tethers should be routed over the tipping foot when attaching to the tether point.

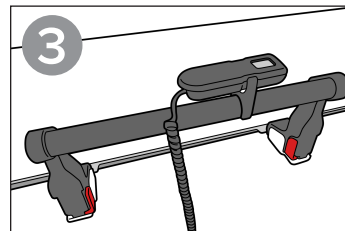
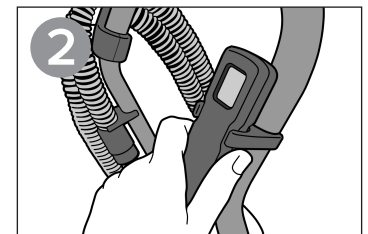
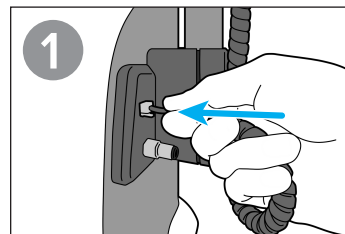
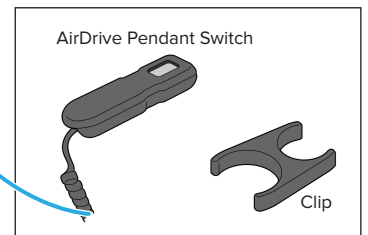
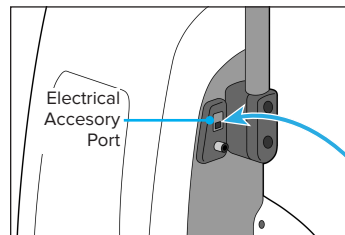


! NOTE ! When using the AirDrive Caddie in an MR environment, ensure that all conditions of use in MR are met. Refer to MRI Safety Warnings.

ACCESSORY PORTS

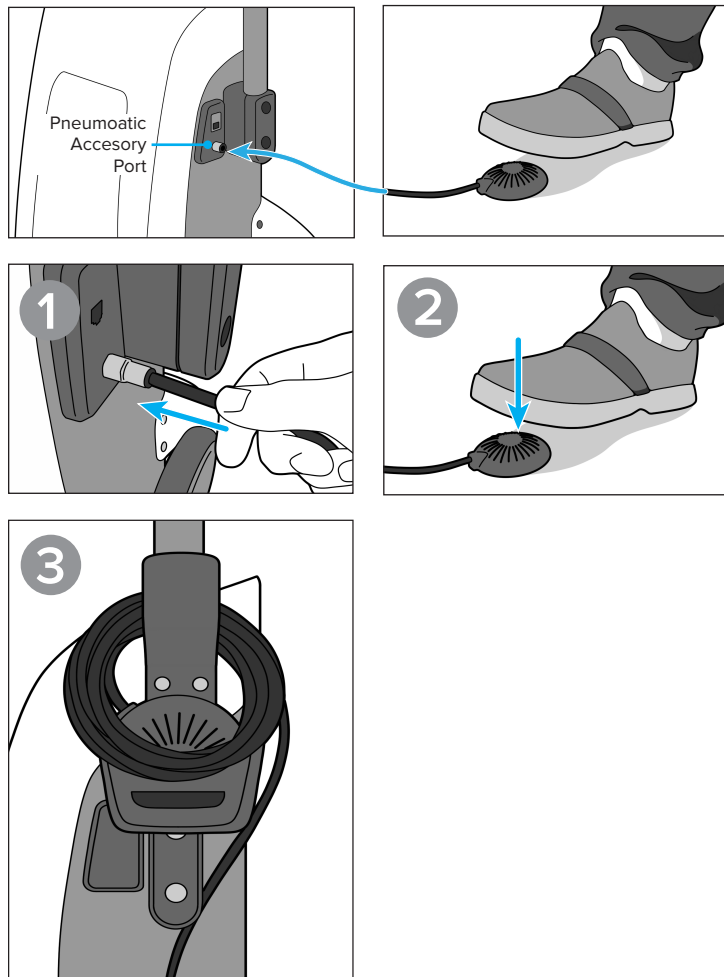
RT-5100-42, AirDrive Pendant Switch

The button on the AirDrive Pendant Switch may be used to activate the AirDrive Caddie's air source instead of, or in combination with, the button on the AirDrive Caddie Handle.



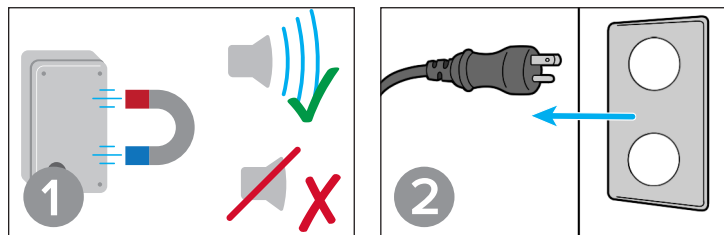
RT-5100-43, AirDrive Pneumatic Foot Switch

The AirDrive Pneumatic Foot Switch may be used to activate the AirDrive Caddie's air source instead of, or in combination with, the button on the AirDrive Caddie Handle



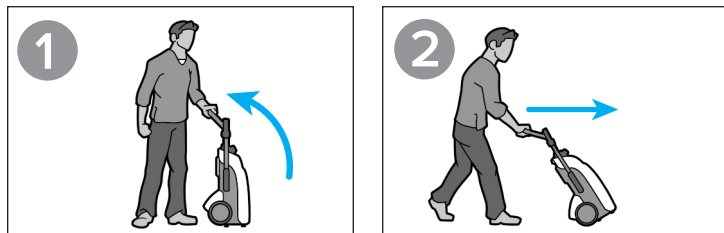
! NOTE ! Use of the AirDrive Pneumatic Foot Switch may create a tripping hazard. Take care in managing the hose to avoid potential tripping and snag scenarios.

PREPARING THE AIRDRIVE CADDIE FOR USE



! NOTE ! If the alarm is not triggered, refer to the *Troubleshooting* section of this manual.

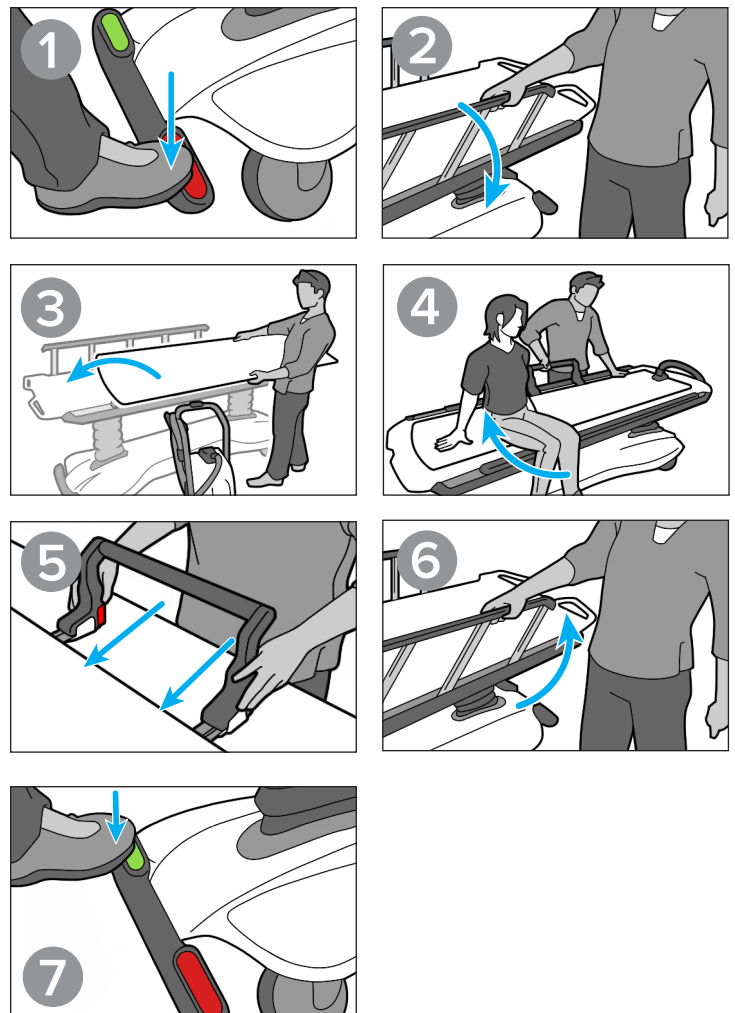
MOVING THE AIRDRIVE CADDIE



! CAUTION ! Avoid parking the AirDrive Caddie in a location where it can become a bump or trip hazard.

LOADING & POSITIONING THE PATIENT

Refer to Product Guide and User Manual for the selected AirShuttle for additional details.



TRANSPORTING THE PATIENT

To transport the patient while positioned on an AirShuttle device, the patient and the AirShuttle device should be located securely on a suitable stretcher, gurney, or other wheeled patient support with a sufficient maximum load capacity.

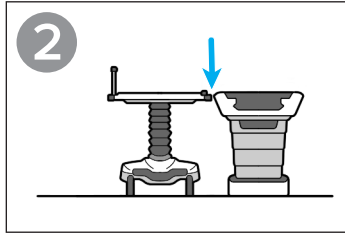
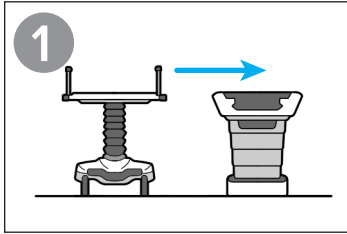
! NOTE ! The AirDrive Caddie transfer hose should not be attached to the transfer device when transporting the patient on a stretcher or other wheeled, patient support.

! WARNING ! If entering an MR environment, ensure the patient support is appropriate for the MR environment.

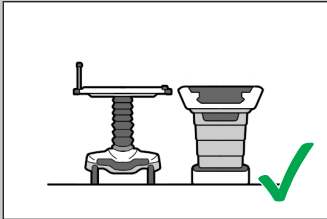
SETTING UP PATIENT TRANSFER WITH AIRDRIVE CADDIE



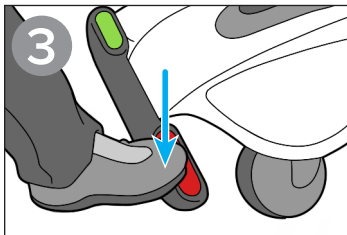
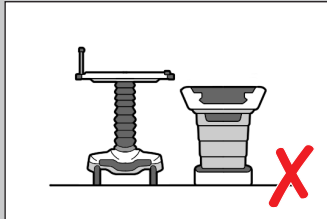
Refer to Product Guide and User Manual for the selected AirShuttle for more details on the use of AirShuttle Locating Bars, if applicable.



Proper Height



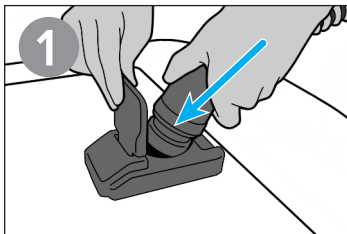
Improper Height



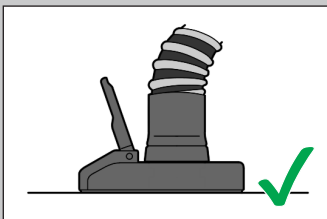
PERFORMING PATIENT TRANSFER

! CAUTION ! Horizontal trapping zones exist. Check that clinicians' and patient's appendages are not in the way of horizontal trapping zone.

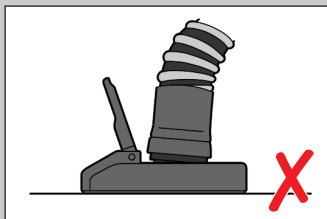
! CAUTION ! Avoid pulling the hose taut during transfer due to risk of topping the AirDrive Caddie.



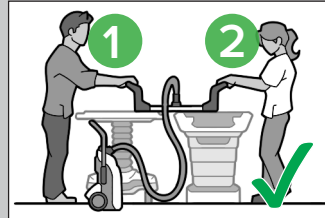
Properly Engaged



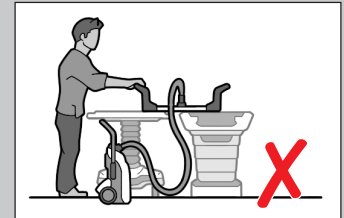
Improperly Engaged



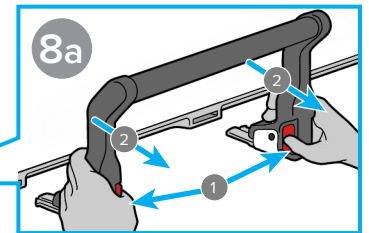
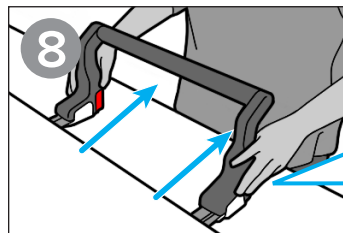
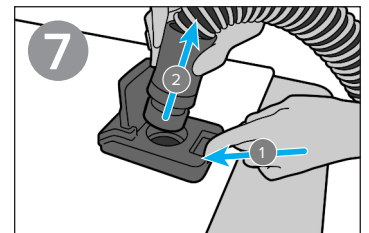
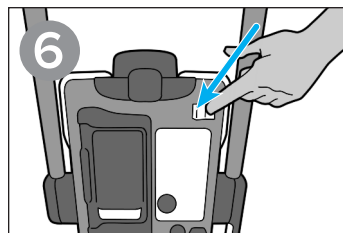
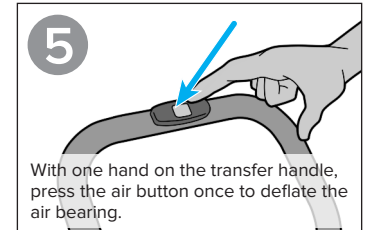
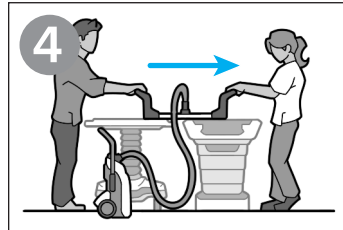
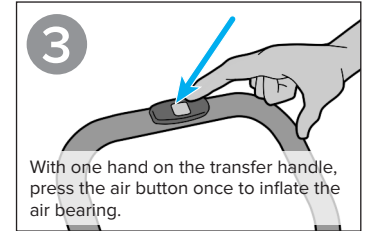
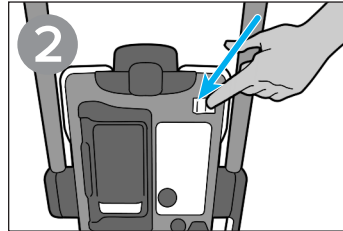
Proper Transfer



Improper Transfer



! NOTE ! Position the AirDrive Caddie nearby, ensuring that the air source button will remain within reach of at least one of the operators during the transfer process.



! NOTE ! To prolong the life of the batteries and ensure availability of the AirDrive Caddie when needed, it is recommended that the system is placed on charge at the end of every workday. The system may be left on charge indefinitely without incurring damage to the battery.

MAINTENANCE

USER REPLACEABLE PARTS

The following parts are replaceable by the user. In the event that a replacement part is needed, contact Qfix or your distributor and reference the associated part number listed below.

Part Number	Description
8003294	Air filter
8003295	GaussAlert replacement battery
8003296	Tipping foot
8003297	Rubber feet
8003298	Charging port fuses
8003299	Upper hose hook
8003300	Hose clip
8003301	Filter cover

Use only Qfix-provided replacement parts.

! NOTE ! Parts not listed, including internal components, should be serviced only by Qfix-authorized service personnel.

AIR FILTER REPLACEMENT

The air filter should be replaced as needed, but at least annually. For instructions, refer to Air Filter.

FUSE REPLACEMENT

The two fuses at the AC power inlet may be accessed using a flat blade screwdriver directly under the charging port. Replace as necessary with (2x) 5 x 20 mm F5AH, 250V fuses supplied by Qfix. Contact a Qfix service representative for help in troubleshooting the cause.

CLEANING THE SYSTEM

The AirDrive Caddie and accessories can be cleaned with a mild, non-abrasive cleaning solution. To clean the unit, apply solution to a clean cloth and wipe external surfaces. Visually inspect the device and, if it is not clean, repeat the previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe the device to remove any cleaning agent residue. To dry, wipe the device with a clean, dry cloth.

The following cleaning materials have been tested and found to be appropriate for cleaning the Symphony Patient Transport System:

- Water
- 10% Clorox® Bleach Solution
- Soap and Water

DISINFECTING THE SYSTEM

To disinfect the AirDrive Caddie, use a 70% isopropyl alcohol solution applied to a clean cloth. Wipe the surface of the device with the cloth and allow the device to dry before use.

! CAUTION ! Fluids that enter the AirDrive Caddie or its accessories may cause device malfunction. DO NOT spray directly onto the Airdrive Caddie or the airshuttle or allow liquids to flow into the enclosure of the AirDrive Caddie.

TROUBLESHOOTING

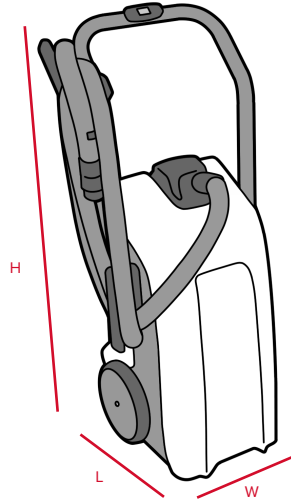
Gauss Alert is not alarming when exposed to strong magnet	<p>If the GaussAlert does not give an audible alarm when exposed to a strong magnetic field:</p> <ul style="list-style-type: none">• Check the battery connection using the same steps described in Installing and Replacing the GaussAlert Battery. <p>! NOTE ! If the battery requires replacement, do not use a standard 9V battery. Instead, request a GaussAlert Battery Replacement Kit from Qfix.</p>
AirDrive Caddie not turning on	<p>If both the air source status light and the battery status lights are not illuminated:</p> <ul style="list-style-type: none">• Ensure the Main Power Switch is in the "ON" position.• Plug in the Symphony Charging Cable to charge the batteries.• Check and replace the fuses. (Refer to previous section, Maintenance.)
Air Bearing Does not inflate	<p>Check the hose connection at the AirShuttle.</p> <p>Check the transfer hose connection at the AirDrive Caddie..</p> <p>Inspect the air filter and replace if necessary.</p> <p>Check that hose fittings are secure on the hose. The fittings screw tight in the counter-clockwise direction.</p> <p>Inspect the hose and the air bearing for damage.</p>

If the issue cannot be resolved, contact Qfix service representative.

REFERENCES

REF	DEVICE	PRODUCT GUIDE & USER MANUAL
RT-5100	AirDrive Trolley	2005112
RT-5100-S	AirDrive Caddie	2008502
RT-5100-01	Slate AirShuttle	2007235
RT-5100-02	Portrait AirShuttle	2007236
RT-5100-04	BoS AirShuttle	2007614
RT-5100-07	Alta AirShuttle	2008315

SPECIFICATIONS



DIMENSIONS AND WEIGHT

Length (L): 37 cm [14.5 in]

Width (W): 44 cm [17.4 in]

Height (H): 100 cm [39.5 in]

Mass: 27 kg [60 lb]

DUTY CYCLE

Air Source: 5 mins ON / 5 mins OFF

POWER REQUIREMENTS

Input: 100–240 V[~] ± 10%, 50/60 Hz

Max Input Current: 2.1 Amps

AirDrive, AirDrive Trolley, AirShuttle, and Slate AirShuttle are trademarks of Qfix.

Symphony is a registered trademark of Qfix.

Clorox is a registered trademark of The Clorox Company.

GaussAlert is a trademark of Kopp Development, Inc.

ETL CLASSIFIED












Intertek












5018847

Conforms To
AAMI STD ES60601-1
IEC STD 60601-1-6
Certified To CSA STD
C22.2 # 60601-1


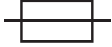

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.2
	Conformité Européene (European Conformity)	CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC.	N/A
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.7
	Refer to Instruction Manual/Booklet	To signify that the instruction manual/booklet must be read.	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-M002
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.2
	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.	ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.1
	Overbalance	The AirDrive Caddie may overbalance when aggressively pushed or pulled, including when pulling on the hose.	N/A	N/A
	Do Not Lift	The unit is not to be lifted during normal use.	N/A	N/A

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.4
	Fragile, Handle With Care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.1
	This Way Up	To indicate correct upright position of the transport package.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-6023
	Temperature Limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-6032
	Medical Device	Indicates the product is a medical device.	N/A	N/A
	Keep Away From Sunlight	To indicate that transport package shall not be exposed to sunlight.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-0624
	Direct Current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-5031
	Alternating Current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-5032
	“ON” for a part of equipment	To indicate the “ON” condition for a part of equipment, if the symbol 5007 cannot be used, for example, to identify the “ON” position of a switch.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-5264
	“OFF” for a part of equipment	To indicate the “OFF” condition for a part of equipment, if the symbol 5008 cannot be used, for example, to identify the “OFF” position of a switch.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-5265
	Atmospheric Pressure Limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-2621

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Center of Gravity	To indicate the centre of gravity of the transport package which will be handled as a single unit.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-0627
	Fuse	To identify fuse boxes or their location.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-5016
	Mass; weight	To indicate mass. To identify a function related to mass.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-1321B