

PRODUCT GUIDE & **USER MANUAL**

RT-5100-05 Lithotomy AirShuttle™



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CH REP

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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.

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 Lithotomy AirShuttle has been designed to be operated by two people.

! WARNING! Take special care when setting up and transferring patients with protruding needles or applicators.

! WARNING! Take special care when completing a transfer to avoid unintended

! WARNING! Do not transport the patient on the AirDrive Trolley while the patient is in the insertion position.

! WARNING! Lithotomy AirShuttles manufactured before 1/1/24 have a maximum safe working load of 350 lbs.

! WARNING! The maximum safe working load for the Lithotomy AirShuttle (patient weight and accessories) is 204 kg (450 lbs). This does not include the weight of the Lithotomy AirShuttle (37 kg (82 lbs) when configured with Leg Extension A). Refer to the Instructions for Use of Receiving Systems and the AirDrive Trolley (P/N 2005112) for their maximum safe working loads.

! WARNING! Use caution when moving the Lithotomy AirShuttle to avoid patient or clinician injury. Extreme care has been taken to minimize trapping zones and other hazards associated with the Lithotomy AirShuttle. However, potential trapping zones include but are not limited to:

- · Between attached accessories and accessory rail
- · Between leg extension and accessory rail
- · Between the Lithotomy AirShuttle and AirDrive Trolley or Receiving System, e.g. CT,

! WARNING! Standing or sitting on the leg extension may damage the leg extension or cause injury.

! WARNING! Ensure all accessories including the transfer handles are secured to the AirShuttle™ prior to use.

- · Accessory rails have combined max load of 45 kg (100 lb).
- Each rail has max load of 23 kg (50 lb).

! CAUTION! Avoid tugging on hoses / monitor lines while transferring / transporting.

! NOTE! Do not attempt to reposition the AirShuttle with the air bearing deflated, as this can damage the air bearing.

! NOTE! Prior to transfer, ensure the AirShuttle is securely located on a suitable stretcher, gurney, or other wheeled patient support with sufficient max load capacity.

! NOTE! For surgical procedures, use sterile drapes to limit the risk of contamination from the transfer device to the patient and vice versa.

ENVIRONMENTAL CONDITIONS

Operating

- Temperature: 10°C to 40°C (50°F to 104°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

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the Lithotomy AirShuttle is MR Conditional. This device may be used with an MR system meeting the following conditions:

- The Lithotomy AirShuttle and leg extension may be placed in the bore of an MR system having a static magnetic field of 3T or less.
- Any attachments used with the device (e.g. stirrups, stepper) in an MR system must be MR Conditional or MR Safe for use in that system and used in accordance with

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

- · Static magnetic field of 3T or less.
- The MR system MRI table must be fixed or docked in place prior to patient transfers
- The AirDrive Trolley must be moved past the 160 mT (1600 G) boundary of the MRI scanner prior to scanning. If the spacial gradient of the magnetic field in your room configuration is not known, remove the trolley from the MR room prior to scanning.

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 Lithotomy AirShuttle prior to placing the AirShuttle into the bore of an MR system

! WARNING! Recommended maintenance and service, as well as use of only Offix-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.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.



INTENDED USE

The Lithotomy AirShuttle is for use as part of the AirDrive™ system to enable brachytherapy procedures, especially prostate and gynecological brachytherapy. The device is intended to support and transfer patients undergoing brachytherapy and related imaging procedures.

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

Patient Target Groups

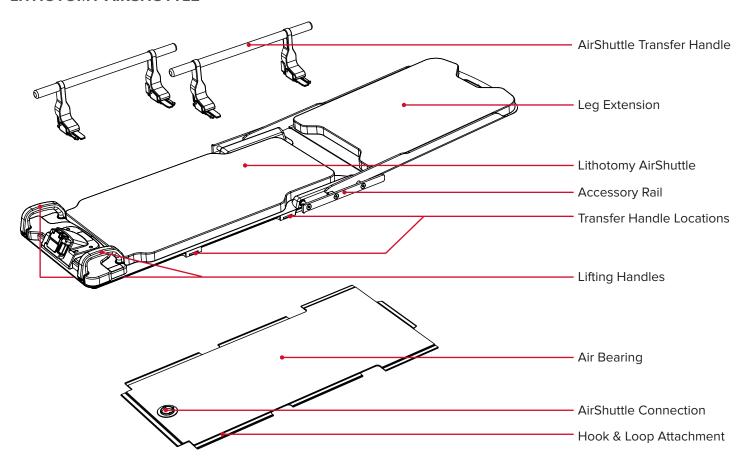
Patients undergoing radiation therapy, diagnostic imaging procedures, or other procedures involving transfer of a patient.

Intended Users

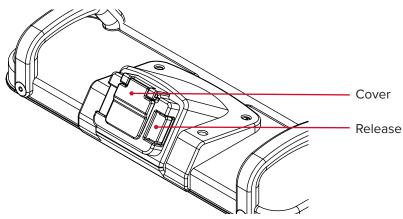
The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

GETTING TO KNOW YOUR LITHOTOMY AIRSHUTTLE

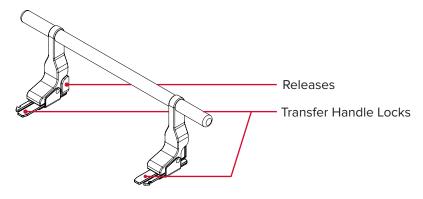
LITHOTOMY AIRSHUTTLE



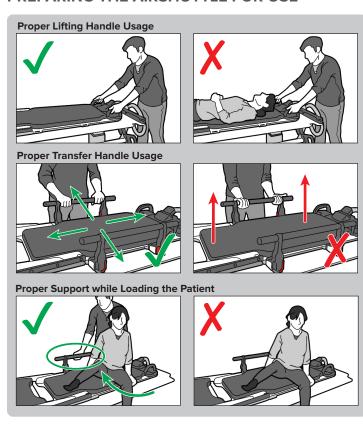
AIR INLET



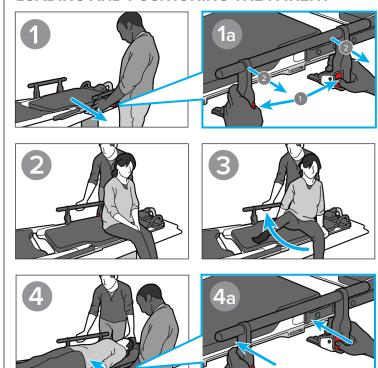
TRANSFER HANDLE

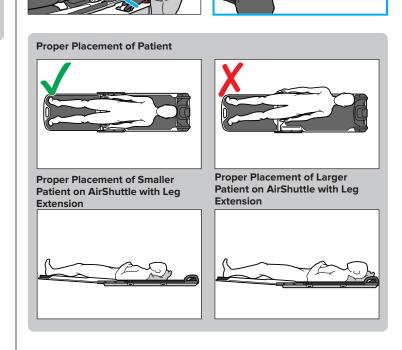


PREPARING THE AIRSHUTTLE FOR USE



LOADING AND POSITIONING THE PATIENT





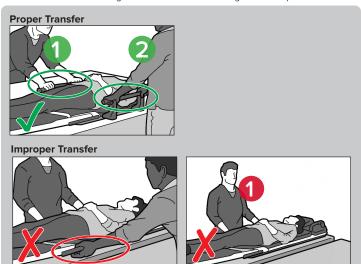
TRANSFERRING WITH AIRSHUTTLE



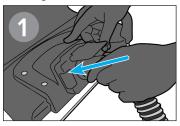
P/N 2005112, AirDrive Trolley

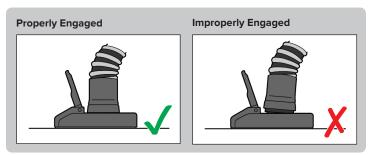
! WARNING! Performance may be degraded when transferring larger patients onto soft pads. Evaluate patient supporting surfaces prior to transfer and/or consider removing pads.

! WARNING! Position starting surface as close to receiving surface as possible..



Installing Transfer Hose



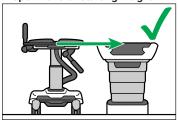


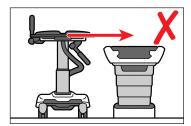
! NOTE! After activating the airsource, wait for the airbearing to fully inflate prior to attempting a transfer.

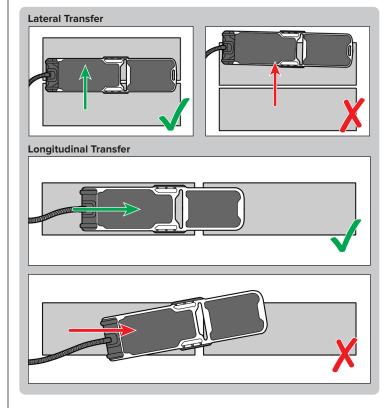
Transferring the Patient



Proper Transfer Starting Height







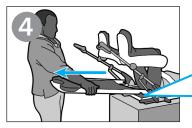
Attaching Stirrups

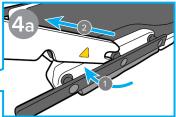


Stirrup Manufacturer



Removing the Leg Extension





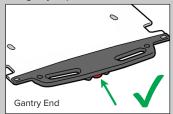
INSERTION ON THE AIRDRIVE TROLLEY



P/N 2005112, AirDrive Trolley

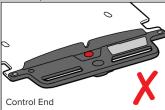
Insertion Compatibility

Insertion using the Lithotomy Overlay is compatible with Gantry End with emergency stop on the underside.

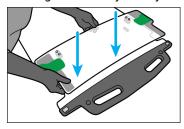


NOT compatible with Gantry End manufactured prior to 05/2020 (image not shown).

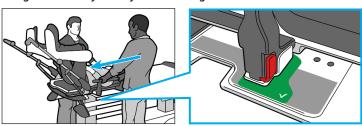
NOT compatible with Control End.

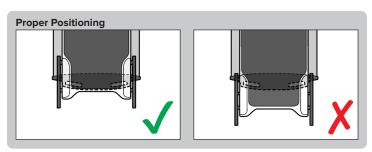


Installing the Lithotomy Overlay



Using the Lithotomy Overlay for Positioning into the Insertion Position

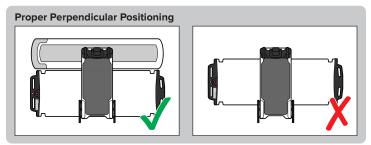




! WARNING! For patients in excess of 159 kg (350 lbs), patients must be positioned in the transport location on the trolley prior to adjusting the height of the trolley.

Perpendicular Positioning

In some instances, including tight workspaces, it may be preferable to achieve insertion position on the AirDrive Trolley by rotating the patient and the Lithotomy AirShuttle across both the AirDrive Trolley and another surface, positioning the patient in a perpendicular, cantilever position.



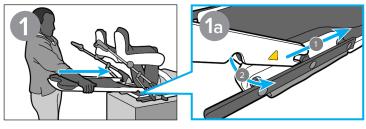
! WARNING! Ensure that both the AirDrive Trolley and the adjacent surface have brakes

! WARNING! Do NOT overextend either end of the AirShuttle beyond the outside edges of the AirDrive Trolley and the adjacent surface.

! WARNING! Do NOT adjust height of the trolley with the patient in the perpendicular position.

POST PROCEDURE INSTRUCTIONS

Attaching the Leg Extension



Removing Stirrups



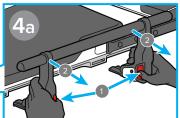
Transferring the Patient

! NOTE! Before transferring, ensure the Transfer Device is centered on the supporting surface and is not too close to the edge of the supporting surface. ! NOTE! Transfer only with one leg support system attached to the Lithotomy AirShuttle.



Unloading the Patient

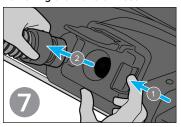








Removing the Transfer Hose



ACCESSING THE UNDERSIDE OF THE LITHOTOMY AIRSHUTTLE











MAINTENANCE

CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe the surface. Visually inspect the device, 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 material has been tested and found to be appropriate for cleaning the device.

- Water
- · Soap and Water

DISINFECTING THE SYSTEM

To disinfect the device surface, refer to specific instructions from the cleaning agent manufacturer.

- 10% Clorox® Bleach Solution
- · Isopropyl Alcohol

For proper operation of the air bearing, ensure no residue remains after cleaning. Perform final cleaning step with water, if necessary. Wait for air bearing to dry prior to next use.

! CAUTION! Fluids that enter the AirDrive Trolley, especially the trolley base or the AirShuttle, may cause device malfunction. DO NOT Spray directly onto the airdrive Trolley or the AirShuttle or allow liquids to flow into the trolley base.

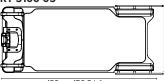
[⊗] REFERENCES

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

AirDrive, AirDrive Trolley, AirDrive Caddie, AirShuttle, and Lithotomy AirShuttle are trademarks of Qfix. Clorox is a registered trademark of The Clorox Company.

SPECIFICATIONS

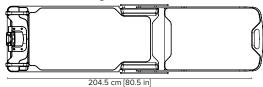
RT-5100-05



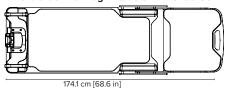
Configurable width to accommodate imaging system bore sizes down to 60 cm 53.3 cm, 54.7 cm, or 57.2 cm [21 in, 21.5 in, or 22.5 in]

129 cm [50.8 in]

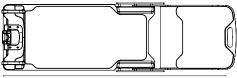
RT-5100-05 with Leg Extension RT-5100-50-A



RT-5100-05 with Leg Extension RT-5100-50-B



RT-5100-05 with Leg Extension RT-5100-50-D

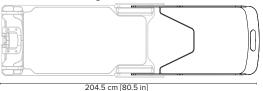


186.3 cm [73.5 in]

WEIGHT

Lithotomy AirShuttle RT-5100-05: 32 kg (71 lbs) Leg Extension RT-5100-50-A: 5 kg (11 lbs) Leg Extension RT-5100-50-B: 3 kg (7 lbs) Leg Extension RT-5100-50-D: 4 kg (9 lbs)

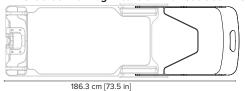
RT-5100-05 with Leg Extension with Cut Out RT-5100-50-A-CO



RT-5100-05 with Leg Extension with Cut Out RT-5100-50-B-CO



RT-5100-05 with Leg Extension with Cut Out RT-5100-50-D-CO



WEIGHT

Leg Extension with Cut Out RT-5100-50-A-CO: 3.45 kg (7.6 lbs)
Leg Extension with Cut Out RT-5100-50-B-CO: 2.44 kg (5.4 lbs)
Leg Extension with Cut Out RT-5100-50-D-CO: 2.27 kg (5 lbs)