



ADDENDUM

RT-5100-07 Alta™ AirShuttle™

This addendum to Product Guide & User Manual 2008272 contains additional instructions on the application of RT-4800-01 Alta Multipurpose Device when upgraded for use as Alta AirShuttle for transferring patients.



EC REP

Advena Limited
Tower Business Centre, 2nd Flr
Tower Street, Swatar, BKR 4013
Malta

Made in the USA by

Qfix
440 Church Rd,
Avondale, Pennsylvania, USA
+1 484-720-6053 www.Qfix.com

GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING ! THE UPGRADE OF RT-4800-01 ALTA MULTIPURPOSE DEVICE FOR USE AS RT-5100-07 ALTA AIRSHUTTLE SHALL ONLY BE PERFORMED BY QUALIFIED SERVICE PERSONNEL.

! 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 TECHSUPPORT@QFIX.COM.

SAFETY INFORMATION

To operate the Alta AirShuttle with either an AirDrive Caddie™ or an AirDrive Trolley™ accurately and safely, the operating personnel must have the necessary expertise in a hospital setting.

The Alta AirShuttle has been designed to be operated by two people when transferring a patient.

To ensure safe use of the patient transfer system, it is recommended that the users are educated and trained on the safe operation of the system prior to use.

The air source should never be engaged when loading a patient onto the Alta AirShuttle.

! NOTE ! Refer to the Product Guide & User Manual for the AirDrive Trolley (P/N 2005112) and the AirDrive Caddie (P/N 2008502) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the AirDrive™.

MRI SAFETY INFORMATION

MR Non-clinical testing has demonstrated **Alta AirShuttle** is MR Safe. This device may be used with an MR system.

MR Non-clinical testing has demonstrated the **InfinityLock™ Transfer Handles** are MR Safe. These devices may be used with an MR system.

! WARNING ! RECOMMENDED MAINTENANCE AND SERVICE, AS WELL AS USE OF ONLY APPROVED 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 AIRDRIVE AND AIRSHUTTLE PRODUCTS, INCLUDING ALTA AIRSHUTTLE SHOULD NEVER BE PERFORMED IN AN MR ENVIRONMENT.

Consult the Product Guide & User Manual for the AirDrive Trolley (P/N 2005112) and the AirDrive Caddie (P/N 2008502) for their MR compatibility.

ADDITIONAL PRECAUTIONS

When the air bearing is deflated during patient transfer, the InfinityEdge™ of the Alta AirShuttle can become a pinch point. Be sure that extremities are clear of this area during deflation.

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

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

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

When transferring, ensure that the patient is balanced left-to-right on the Alta AirShuttle to obtain a smooth transfer. If necessary, reposition the patient on the AirShuttle prior to performing a transfer

It is recommended to perform imaging studies on all transfer devices (such as the Alta AirShuttle) to characterize the physics properties and relative patient positioning, if necessary, prior to clinical use.

When cantilevering the Alta AirShuttle, ensure that the underlying support surface can properly support the AirShuttle in the cantilevered state.

! NOTE ! With the air bearing installed, the Alta AirShuttle can only be indexed to a couch top using AirShuttle Locating Bars.

! NOTE ! When setting up a patient for simulation and treatment, ensure that the position of the InfinityLock Transfer Handles and the AirShuttle Locating Bars are considered. For setups involving VacQfix™ vacuum cushions, the cushion may need to be formed carefully to accommodate these accessories.

! NOTE ! It may be necessary to move a patient's arms out of their immobilized position for patient comfort and to ensure access to the InfinityLock Transfer Handles during transfers.

! NOTE ! When using the Alta ArmShuttle™ Elite, it may be necessary to lower the patient's arms to their sides for transfers to keep the AirShuttle level with the air bearing inflated.

! NOTE ! Setups which position accessories or the patient's extremities outside of the perimeter of the AirShuttle should be avoided where possible.

! NOTE ! Patient transfers should only be performed using the InfinityLock Transfer Handles. Using other accessories to grip during transfers can increase transfer difficulty and could result in damage to the accessories.

WARNING LABELS & DESCRIPTIONS

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

	LOAD RATING The maximum safe working load for the Alta AirShuttle is 226 kg (500 lbs). Refer to the Instructions for Use of any supporting surfaces or devices for their maximum safe working loads and DO NOT exceed the lowest load rating.
	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.
	MR CONDITIONAL An item with demonstrated safety in the MR environment within defined conditions. Refer to the conditions as defined in the MRI Safety Information section.
	APPLIED PART TYPE B This symbol identifies Applied Parts Type B. These parts come in contact with the patient.
	LOCATING BAR STOP GUIDES These symbols are intended to be used to guide and align the Alta AirShuttle to the AirShuttle Locating Bars installed on the Receiving System during transfer.
	WARNING DO NOT extend the Alta AirShuttle off the end of the couch top beyond the orange cantilever line. Doing so may cause patient or personal injury. If cantilevering the device, the AirShuttle Locating Bars must be used.

GETTING TO KNOW YOUR ALTA AIRSHUTTLE

AIRSHUTTLE COMPONENTS

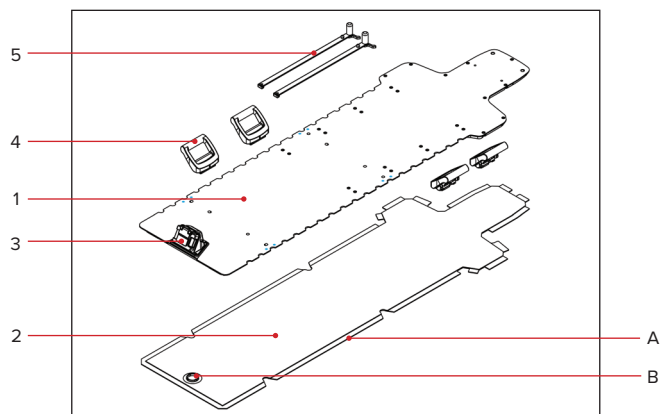


Fig. 1

1. ALTA AIRSHUTTLE

2. AIR BEARING

- (A) Hook and loop attachment
- (B) AirShuttle Connection

3. AIR INLET

4. INFINITYLOCK TRANSFER HANDLE (ACCESSORY)

5. AIRSHUTTLE LOCATING BAR (ACCESSORY)

ALTA AIRSHUTTLE LOCATING BAR ALIGNMENT

These markers are located on either side of the device and are intended to help guide the device to the alignment stops on the AirShuttle Locating Bar (Fig. 2).

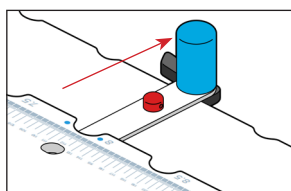


Fig. 2: View of Alta AirShuttle indexing with Locating Bar

AIR INLET

1. COVER

The air inlet is fitted with a cover to help keep contaminants out of the air bearing (Fig. 3). To insert the Transfer Hose, lift the cover to expose the air inlet. Push the hose into the air inlet (Fig. 4).

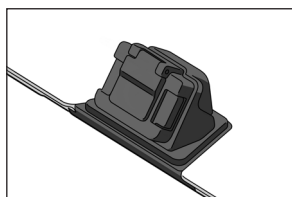


Fig. 3

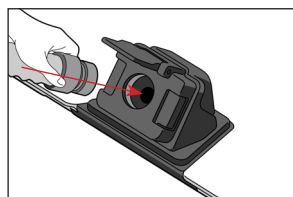


Fig. 4

2. RELEASE

The release is used to disengage the Transfer Hose from the air inlet on the device. Press the release and pull up on the Transfer Hose to remove (Fig. 5).

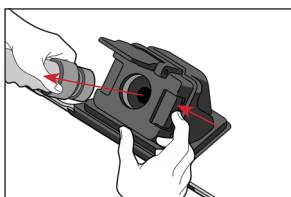


Fig. 5

INFINITYLOCK TRANSFER HANDLE

Patient transfers are performed with two InfinityLock Transfer Handles installed on each side of the Alta AirShuttle.

TO ATTACH

1. Ensure the lever is in the unlocked position (Fig. 6).
2. Firmly press the handle onto the InfinityEdge of the device until the handle clamp is completely seated (Fig. 7).
3. Use the blue indicator on the handle and the scale on the device to align the handle to the desired location (Fig. 8).
4. Rotate the lever to the locked position (Fig. 9).
5. For ease of transfer, follow the previous steps to attach two InfinityLock Transfer Handles to one side of the Alta AirShuttle in the recommended area (Fig. 10). The handles should be approximately shoulder-width apart from each other. Be sure to position the handles so as not to obstruct the AirShuttle Locating Bar positions or any other positioning devices.
6. Attach an additional pair of handles in the same locations on the other side of the AirShuttle (Fig. 10). Ensure that all four InfinityLock Transfer Handles are securely locked onto the InfinityEdge before transferring a patient.

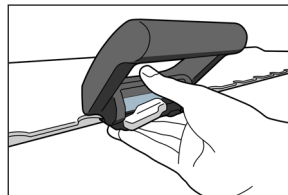


Fig. 6

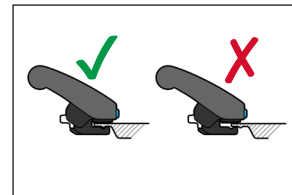


Fig. 7

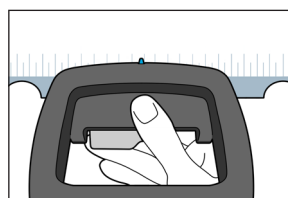


Fig. 8

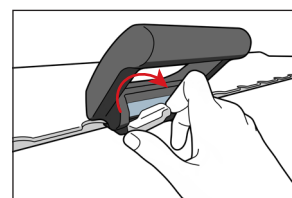


Fig. 9

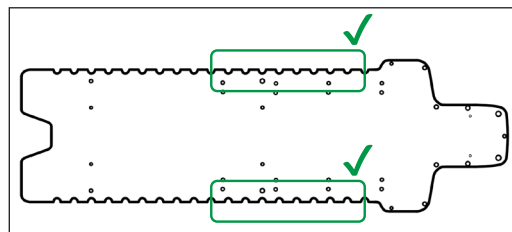


Fig. 10

TO REMOVE

Unlock by rotating the lever counterclockwise and remove from the device.

USING YOUR ALTA AIRSHUTTLE

PREPARING THE AIRSHUTTLE FOR USE

Inspect the Alta AirShuttle, including the air bearing, for damage prior to use.

Place the Alta AirShuttle onto an appropriate supporting surface. If using the AirDrive Trolley, stretcher, or other movable surface, lock the brakes.

LOADING & POSITIONING THE PATIENT

Attach any patient positioning devices to the top side of the Alta AirShuttle using an appropriate Locating Bar.

Lower the trolley / stretcher to an appropriate height if necessary. Set up the patient as needed for the imaging or treatment. Attach the four InfinityLock Transfer Handles as previously described. If forming a VacQfix vacuum cushion on the patient, consider the handle locations as well as AirShuttle Locating Bar positions when forming so as to avoid an interference.

MOVING & TRANSFERRING WITH THE AIRDRIVE TROLLEY

! NOTE ! Ensure the transfer target is locked or braked prior to initiating patient transfer.

For Instructions for Use on moving and transferring patients, refer to the Product Guide & User Manual for either the AirDrive Trolley (P/N 2005112) or the AirDrive Caddie (P/N 2008502).

UNLOADING THE PATIENT

If using the AirDrive Trolley, stretcher, or other movable surface, lock the brakes.

Remove the InfinityLock Transfer Handles from one side of the Alta AirShuttle.

Lower the trolley / stretcher, if necessary, and assist the patient off the AirShuttle.

MAINTENANCE

Refer to the Maintenance instructions provided in the Alta Multipurpose Device Product Guide & User Manual (P/N 2008272).

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