



positioning
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PRODUCT GUIDE & USER MANUAL

RT-5100-04

Symphony® BoS™ Headframe Transfer
Device





<div>EC</div> <div>REP</div>		<p>Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta</p>	<div> Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 610-268-0585 www.Qfix.com</div>
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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 TECHSUPPORT@QFIX.COM.

SAFETY INFORMATION

In order to operate the Symphony® Patient Transport System accurately and safely, the operating personnel must have the necessary expertise in a hospital setting.

The Symphony has been designed to be operated by two people.

To ensure safe use of the Symphony Patient Transport System, it is recommended that the user is educated and trained on the safe operation of the system prior to use.

Air source should never be engaged when loading a patient onto the Symphony Patient Transport System.

! NOTE ! Refer to the Product Guide and User Manuals for the Symphony® Patient Transport System (P/N 2005112) and Symphony® Transfer Device(s) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Symphony® Patient Transport System and the Symphony® Transfer Device(s).

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.

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

GENERAL PRECAUTIONS

MRI SAFETY INFORMATION

 Non-clinical testing has demonstrated the **Symphony® BoS™ Headframe Transfer Device** is MR Safe. This device may be used with an MR system.

 Non-clinical testing has demonstrated the **Symphony Patient 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 taking place.**
- **The Symphony Patient Trolley must be moved past the 160 mT (1600G) 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 **Symphony 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 Symphony Transfer Handles must be removed from the Symphony Transfer Device prior to placing the transfer device into the bore of an MR system.**

 **! WARNING ! RECOMMENDED MAINTENANCE AND SERVICE, AS WELL AS USE OF ONLY SYMPHONY 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 burn**
- **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 SYMPHONY PRODUCTS SHOULD NEVER BE PERFORMED IN AN MR ENVIRONMENT.**

Consult the Symphony Patient Transport System (P/N 2005112) and Symphony Transfer Device(s) Product Guide and User Manuals (IFUs) for their MR compatibility.

ELECTRONIC EMISSIONS

The Symphony Patient Trolley is an electronic device that may interfere with other electronic devices. If the Symphony interferes with other electronic devices, move the trolley away from affected device(s).

GENERAL PRECAUTIONS

ADDITIONAL PRECAUTIONS

When the air bearing is deflated during patient transfer, the edge of the Symphony Transfer Device 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 and User Manual.

Use of the Symphony Charging Cable may create a tripping hazard. It is recommended that users position the Symphony Patient Trolley as close to the charging outlet as possible and in a way that does not impede disconnecting the charging cable from the wall or device.

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 Transfer Device Air Inlet as well as the hose connection point in the Symphony Trolley Handle prior to use of the air source.

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

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

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



LOAD RATING

The maximum safe working load for the BoS Transfer Device is 159 kg (350 lbs). Refer to the Instructions for Use of Receiving Systems and the Symphony® Patient Transport System (P/N 2005112) 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.



TRANSFER HANDLE INTERFACE

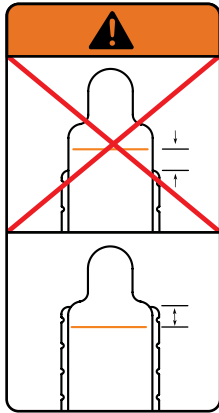
These symbols indicate where the Symphony Transfer Handles attach to the Symphony Transfer Device.



LOCATING BAR STOP GUIDES

These symbols are intended to be used to guide and align the Symphony® Transfer Device to the Symphony Locating Bars installed on the Receiving System during transfer.

GENERAL PRECAUTIONS



WARNING

DO NOT extend the Symphony® BoS Transfer Device off the end of the couch top beyond the orange cantilever line. Doing so may cause patient or personal injury.

If cantilevering the device, Symphony Locating Bars must be used.

INTENDED USE

The Qfix® Symphony® BoS Transfer Device is indicated to aid in the support, positioning, and transfer of a patient for head and neck procedures involving imaging, including MRI; and external beam radiation therapy treatment with electrons, photons or protons; and other general procedures requiring transfer of a patient. The Symphony BoS Transfer Device is designed to interface with other positioning devices, such as couchtops, inserts, thermoplastic masks and positioning pads. This device allows for a patient to be cantilevered for head and neck treatments.

! 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.

SYMPHONY® PATIENT TRANSPORT SYSTEM

DESCRIPTION

The Qfix Symphony Patient Transport System (the Symphony) is designed to maximize workflow efficiency and throughput. The Symphony is a fully integrated transport system consisting of a trolley system and interchangeable patient transfer devices designed for ease of use. Patient positioning and immobilization can be performed on a Symphony Transfer Device, enabling users to transport patients seamlessly to multiple imaging modalities and treatment systems.

SYMPHONY SYSTEM COMPONENTS

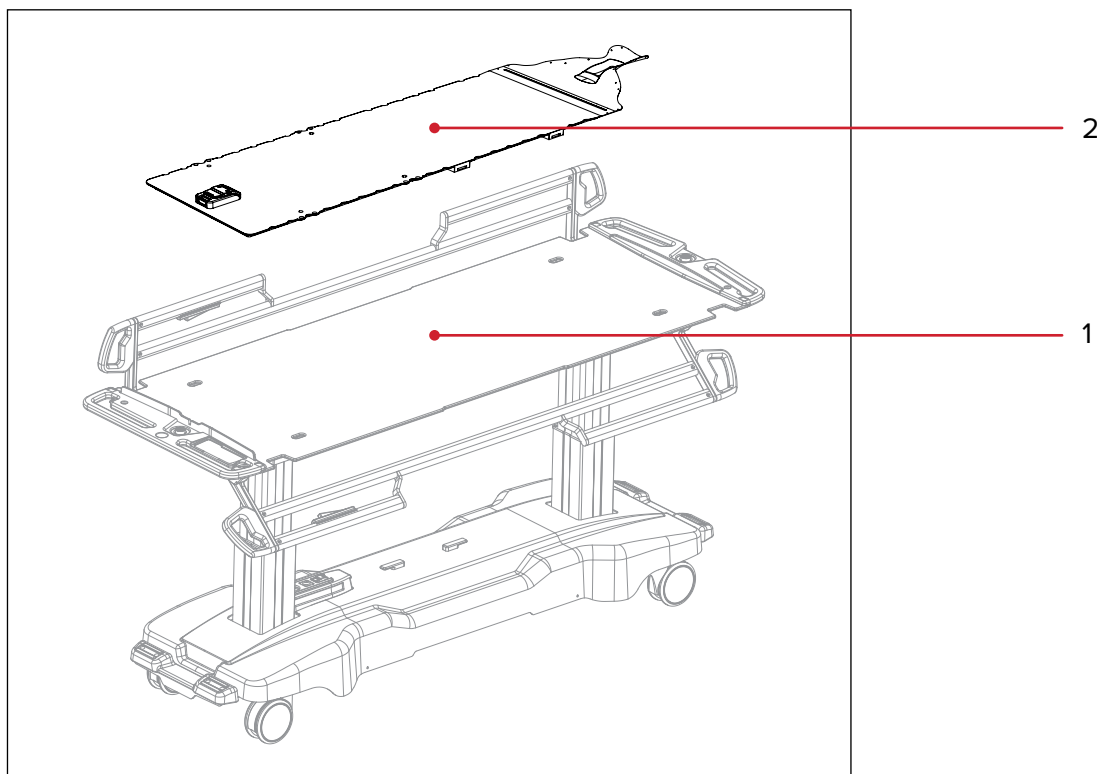


Fig. 1

1. The Symphony Patient Trolley

The self contained Symphony Patient Trolley consists of an integrated air source, two batteries, and electronic height adjustable pillars. The unique design promotes safety of the patient and user during patient transfer.

2. Symphony Transfer Devices

The Symphony Patient Trolley is designed to work with a variety of Symphony Transfer Devices. Consult the Product Guide and User Manual for the transfer device you intend to use. The Symphony BoS Transfer Device is depicted above.

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

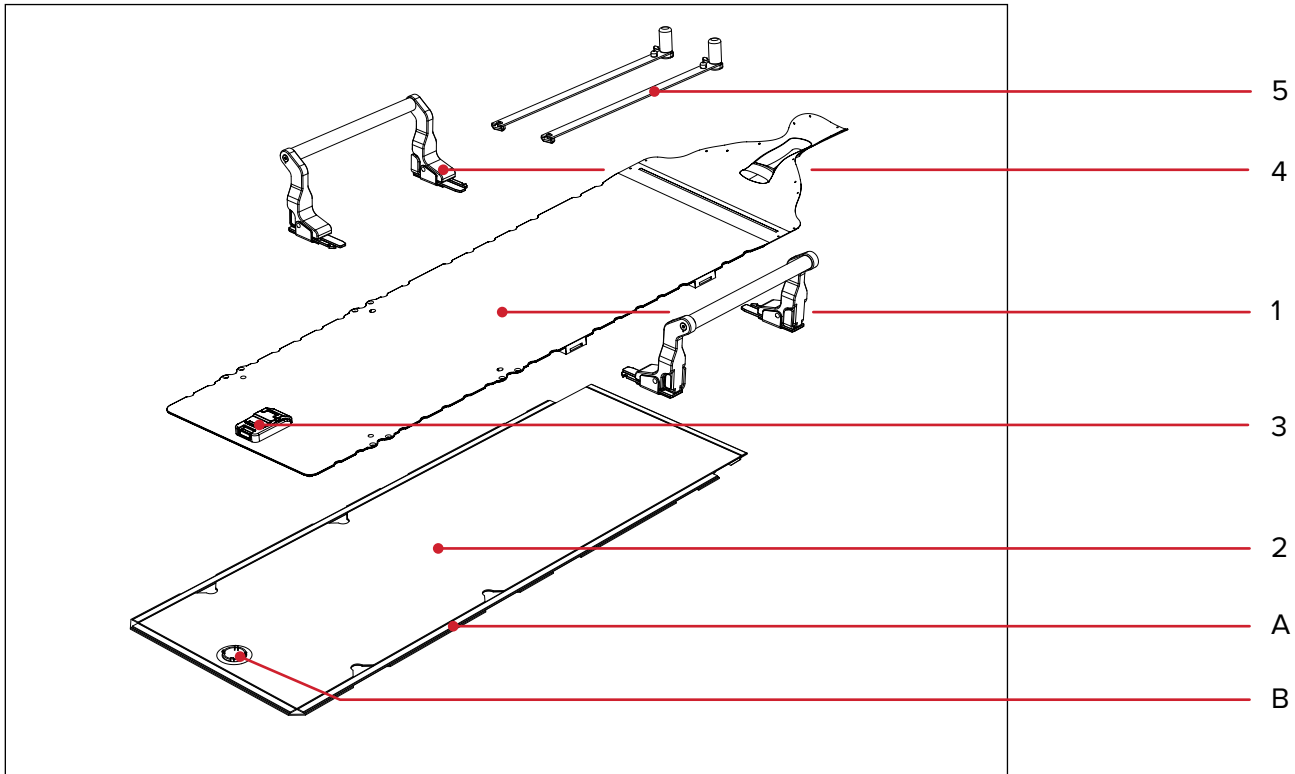


Fig. 2

1. Symphony BoS Transfer Device

2. Air Bearing

- (A) Hook and loop attachment
- (B) Transfer Device Connection

3. Air Inlet

4. Symphony Transfer Handle (accessory)

5. Symphony Locating Bar (accessory)

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

SYMPHONY® TRANSFER DEVICE

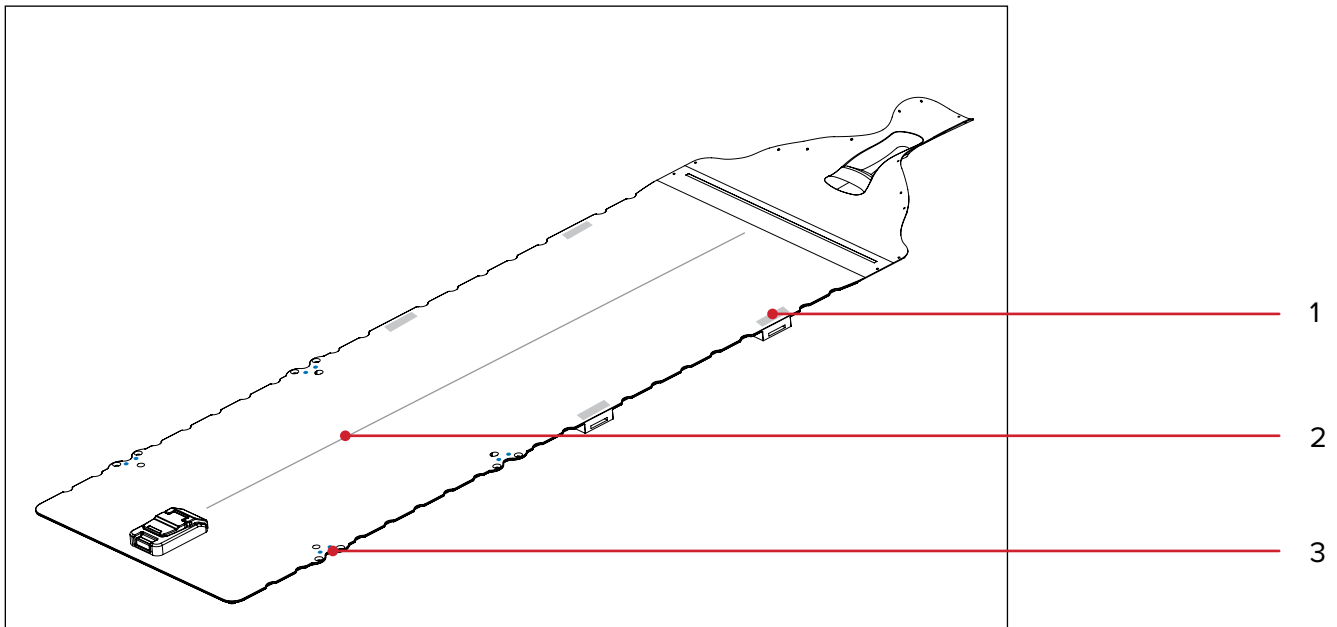


Fig. 3

1. Transfer Handle Locations

These pockets are receivers for the Symphony Transfer Handle when attached to the device.

2. Laser Alignment Guides

These markings on the surface of the transfer device can be used with room lasers to help align the patient during setup.

3. Symphony 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 Symphony Locating Bar. (Fig. 4)

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

SYMPHONY® TRANSFER DEVICE

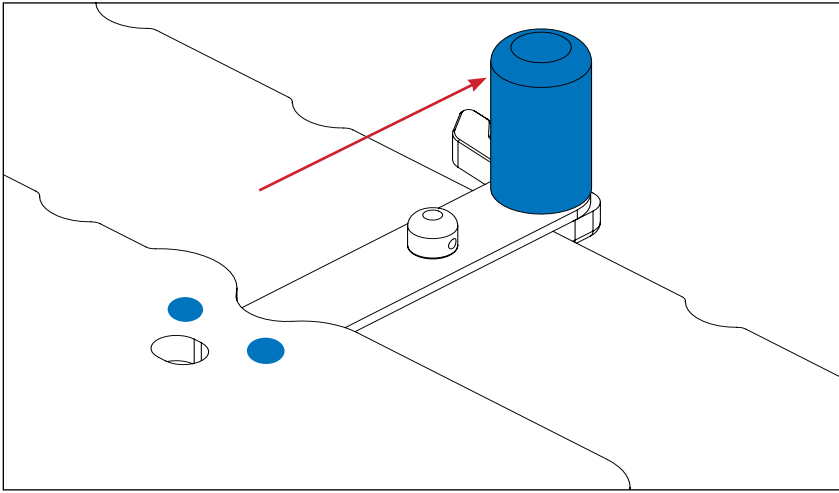


Fig. 4

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

AIR INLET

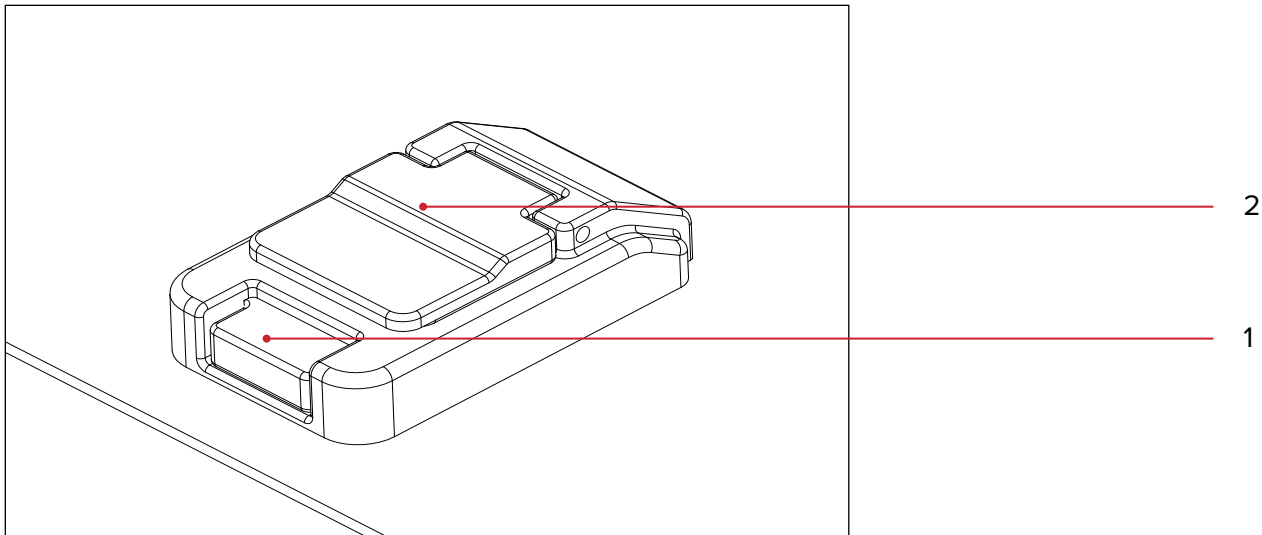


Fig. 5

1. Release

The release is used to disengage the Transfer Device Hose from the air inlet on the device. Press the release and pull up on the Transfer Device Hose to remove. (Fig. 6)

2. Cover

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

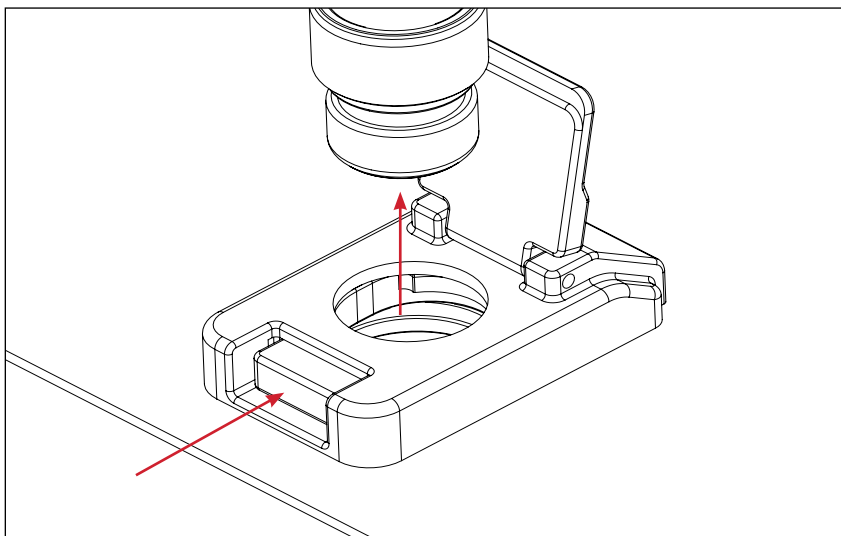


Fig. 6

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

SYMPHONY® TRANSFER HANDLE

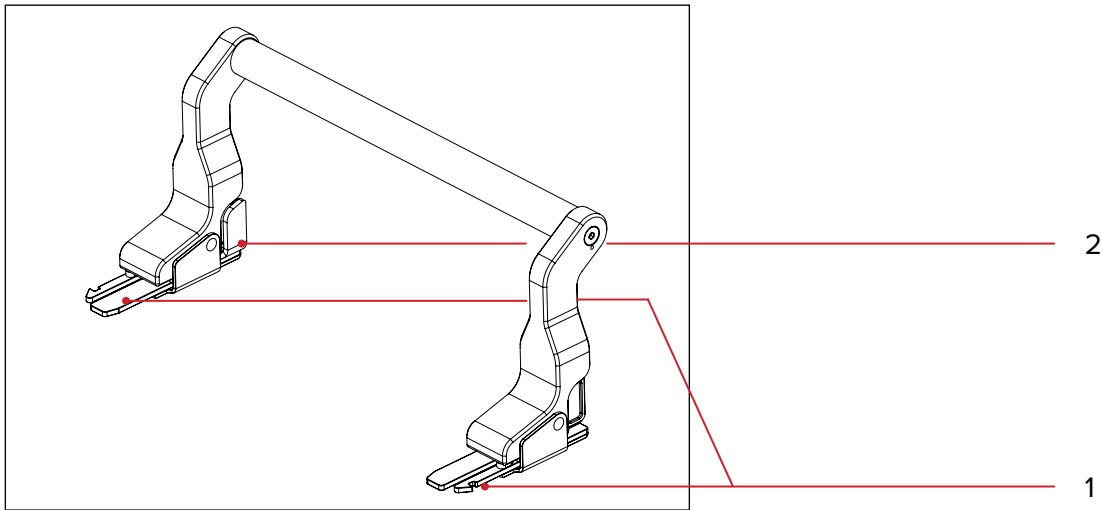


Fig. 7

1. Symphony Transfer Handle Locks

The Symphony Transfer Handle uses two locks to attach to the Symphony Transfer Device.

2. Releases

The releases are used to detach the Symphony Transfer Handle from the Symphony Transfer Device after use.

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

SYMPHONY® TRANSFER HANDLE

To Attach

Line up the Symphony Transfer Handle locks with the receivers on the device and slide in until a click is heard. Always be sure that both locks on each transfer handle are secure before transferring a patient. (Fig. 8)

To Detach

While squeezing the bottom portion of both red releases, pull the transfer handle away from the transfer device. (Fig. 9)

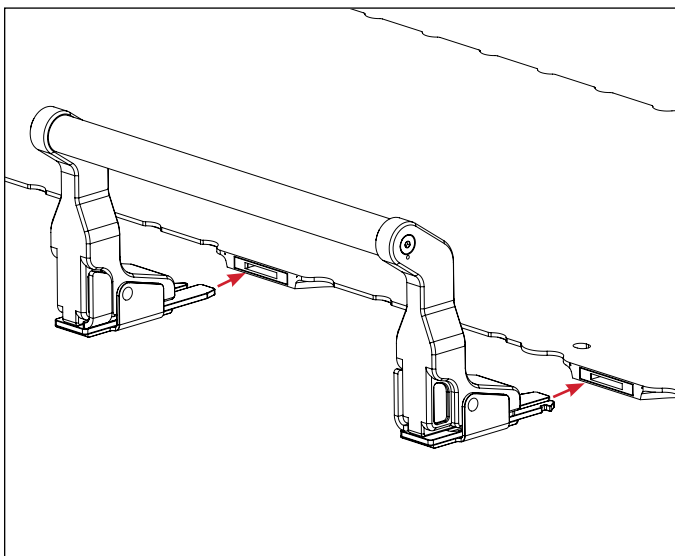


Fig. 8 – Attach

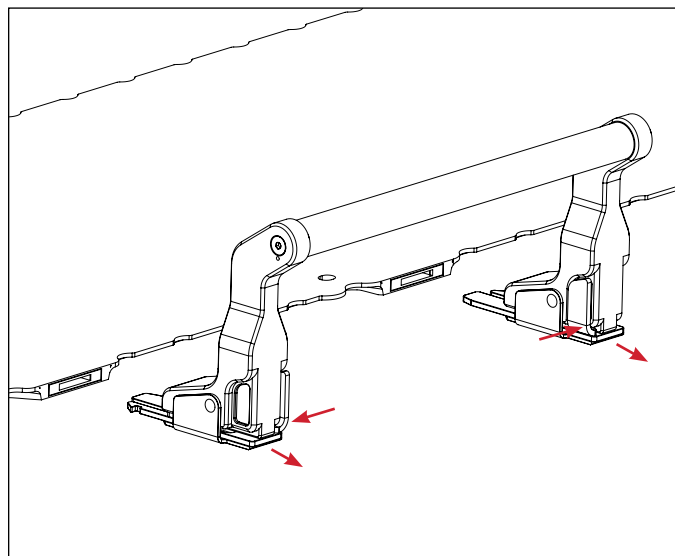


Fig. 9 – Detach

GETTING TO KNOW YOUR SYMPHONY® TRANSFER DEVICE

SYMPHONY® LOCATING BAR

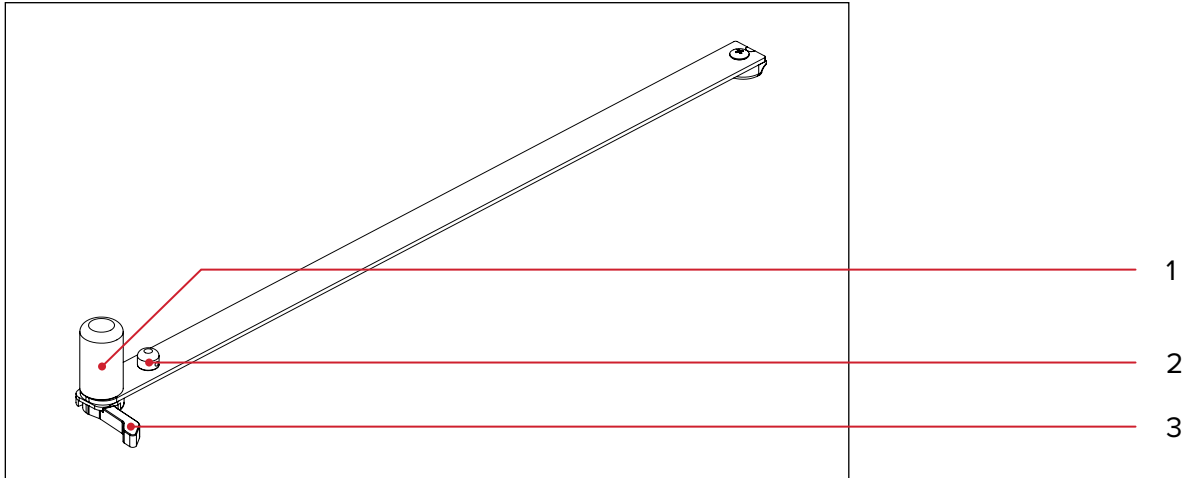


Fig. 10

1. Alignment Stop

The alignment stops are used to stop the Symphony Transfer Device at the end of the transfer as well as align the transfer device for indexing.

2. Indexing Pin

The indexing pins are designed to index the Symphony Transfer Device to the Receiving System after the transfer is complete.

3. Locking Lever

The locking lever is used to lock the Symphony Locating Bar to the Receiving System.

To Attach

Place the Symphony Locating Bars in the appropriate notches on the Receiving System, then tighten the locking lever by rotating the handle clockwise to lock the locating bar in place.

To Detach

Loosen the locking lever by rotating the handle counter-clockwise and remove the Symphony Locating Bar from the Receiving System.

SYMPHONY® BOS™ HEADFRAME TRANSFER DEVICE

PREPARING THE TRANSFER DEVICE FOR USE

Inspect the transfer device, including the air bearing, for damage prior to use. Place the Symphony Transfer Device on the Symphony Patient Trolley.

Verify the Symphony Transfer Handles are attached to the transfer device.

⚠ ! WARNING ! TRANSFER HANDLES ARE MR CONDITIONAL. ONLY USE IN A STATIC MAGNETIC FIELD OF 3T OR LESS AND DO NOT PLACE IN THE BORE OF AN MR SYSTEM. REFER TO MRI SAFETY INFORMATION SECTION.

LOADING & POSITIONING THE PATIENT

Attach Transfer Device Hose to the Symphony Transfer Device.

Remove transfer handle on the loading side; this will make it easier to load the patient.

Place the BoS foam head/neck support onto the neck area of the device.

- MOLDCARE® may be used instead of the foam head/neck support. Qfix recommends RT-4492U for use with the BoS Headframe (refer to the MOLDCARE® Instructions for Use).
- A foam shim (RT-4485) may be used to increase patient comfort.

Lower the trolley, if necessary, to an appropriate height. Sit the patient approximately centered on the transfer device.

Lift and rotate the patient's legs onto the transfer device, then lay the patient gently backwards until the patient's head and neck are comfortably resting on the foam cushion or MOLDCARE®. Set up the patient as needed for particular treatment; record relevant positioning data on supplied patient set up sheet located at the end of this Product Guide and User Manual.

Prior to simulation, mold an Aquaplast RT™ or Fibreplast® mask on patient.

! NOTE ! Refer to the Product Guide and User Manual for the Aquaplast RT™ & Fibreplast® Thermoplastics & IntegraBite™ (P/N 2002890) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of Aquaplast RT & Fibreplast Thermoplastics.

For treatment, place the pre-made mask on the patient and attach to BoS.

Reattach the Symphony Transfer Handle and raise the siderail.

SYMPHONY® BOS™ HEADFRAME TRANSFER DEVICE

MOVING & TRANSFERRING WITH THE SYMPHONY SYSTEM

For Instructions for Use on moving and transferring patients please refer to the Symphony Patient Transport System Product Guide and User Manual (P/N 2005112).

UNLOADING THE PATIENT

Remove the thermoplastic mask.

! NOTE ! Refer to the Product Guide and User Manual for the Aquaplast RT™ & Fibreplast® Thermoplastics & IntegraBite™ (P/N 200890) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of Aquaplast RT & Fibreplast Thermoplastics.

Remove the Symphony Transfer Handles from the transfer device.

Lower the trolley, if necessary, to an appropriate height. Assist the patient in getting off of the Symphony Patient Trolley.

END OF DAY INSTRUCTIONS

Ensure Symphony Transfer Handles are installed and all other accessories are removed from the transfer device.

MAINTENANCE

BOS™ PIN REPLACEMENT

1. Place (1) M3 PHS through the hole with the head of the screw on the inside surface. Hold the head of the screw in place with the pad of your finger. (Fig. 11).
2. Screw (1) BoS Pin onto the protruding tip of the screw several turns. (Fig. 12).

! NOTE ! DO NOT TIGHTEN. The pin assembly should be loose in the hole. (Fig 13).

3. Using the flat-jaw Pliers, grasp the Bos Pin on the flat sides. (Fig. 14).
4. Carefully align the assembly to the hole and force the pin neck into the hole (Fig. 15).

! NOTE ! Excessive force or misalignment can damage the pin neck, preventing the pin from sitting flush.

5. Tighten the screw using ⅛" flat blade screwdriver until snug. (Fig. 16).

⚠ ! CAUTION ! DO NOT OVER-TIGHTEN AS OVER-TIGHTENING CAN MAKE PIN REPLACEMENT DIFFICULT.

To remove the pin, do the previous steps in reverse.

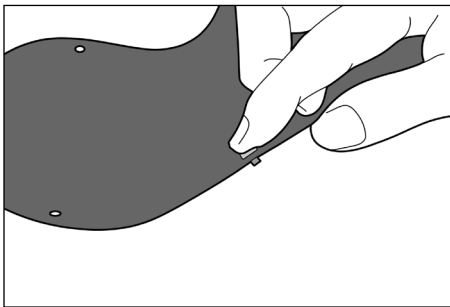


Fig. 11

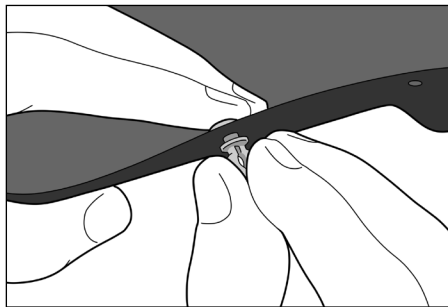


Fig. 12

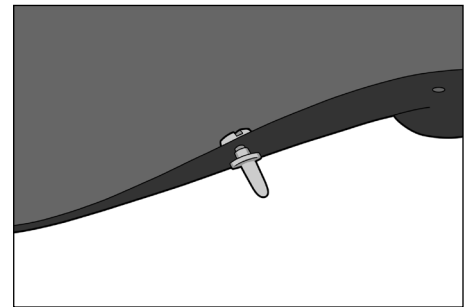


Fig. 13

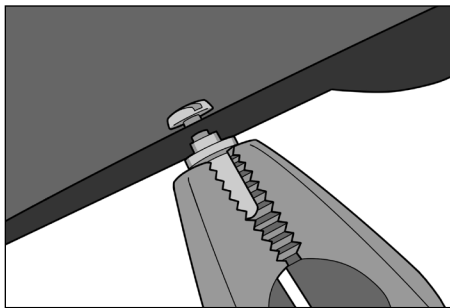


Fig. 14

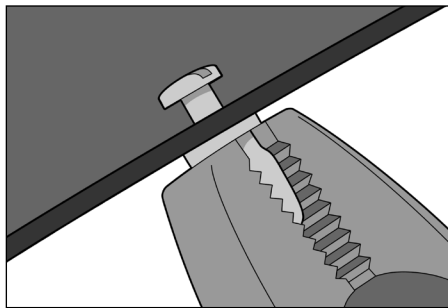


Fig. 15

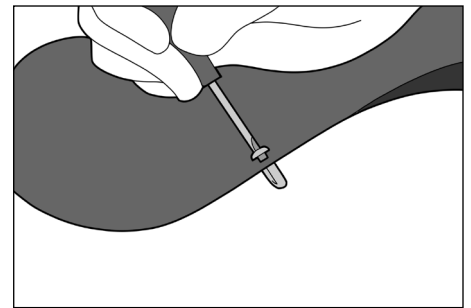


Fig. 16

MAINTENANCE

CLEANING THE SYSTEM

The Symphony® Patient Trolley, Transfer Devices, and accessories can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to a clean cloth and wipe external surfaces.

DISINFECTING THE SYSTEM

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

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

To disinfect the Symphony Patient Transport System, refer to the specific instructions from the cleaning agent manufacturer. Qfix recommends spraying the cleaning solution onto a clean cloth, then using the cloth to wipe the device clean.

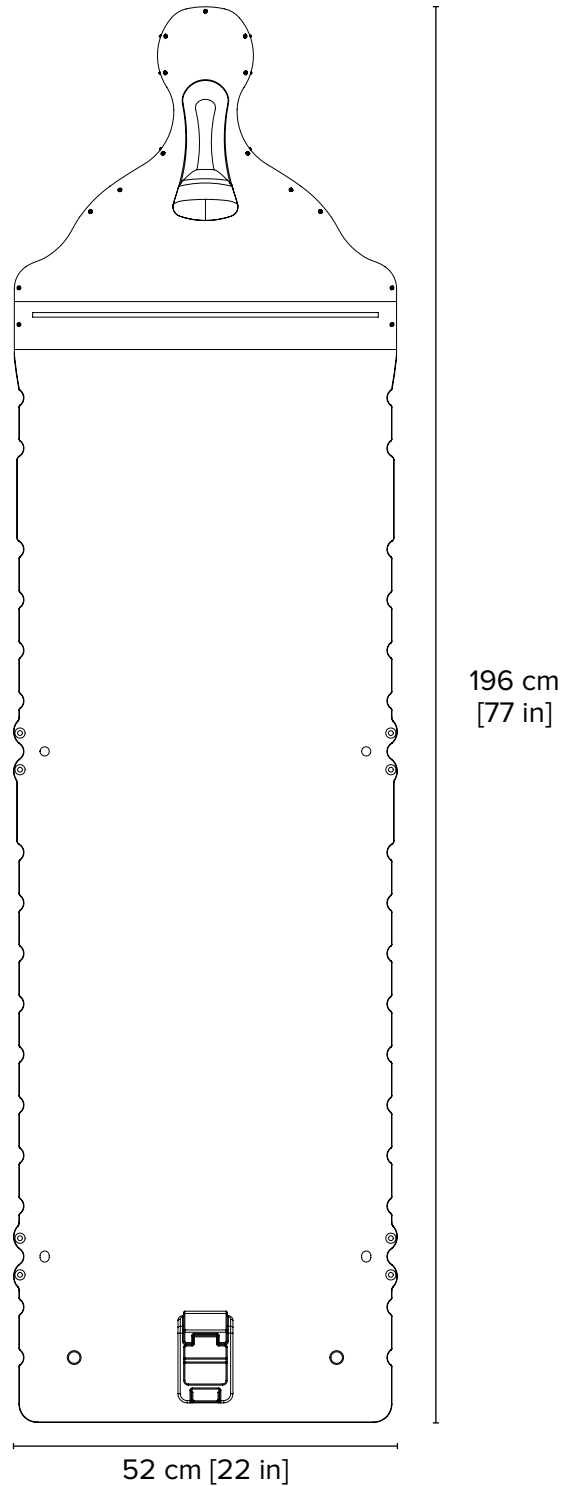
For proper operation of the air bearing, ensure no residue remains after cleaning. Perform final cleaning step with water, if necessary. Wait for air bearing to dry prior to next use.

⚠ ! CAUTION ! FLUIDS THAT ENTER THE SYMPHONY PATIENT TROLLEY, ESPECIALLY THE TROLLEY BASE OR SYMPHONY TRANSFER DEVICES, MAY CAUSE DEVICE MALFUNCTION. DO NOT SPRAY DIRECTLY ONTO THE SYMPHONY PATIENT TROLLEY OR TRANSFER DEVICES OR ALLOW LIQUIDS TO FLOW INTO THE TROLLEY BASE.

SPECIFICATIONS

WEIGHT

6 kg (12.5 lb)



SETUP SHEET

RT-5100-04 SYMPHONY® BOS™ HEADFRAME TRANSFER DEVICE

Patient Name:

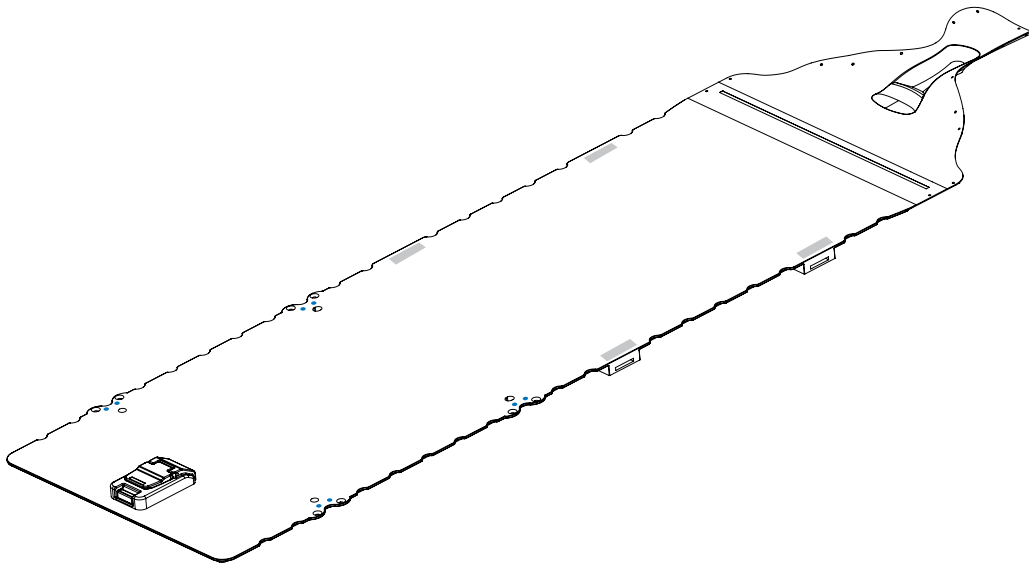
Patient ID #:

Setup by:

Physician:

Date:


Comments:




Notes:



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