

# 3D IMAGING C-ARM TABLE

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INSTRUCTIONS FOR USE

058-820

058-825



**BIODEX**  
Part of Mirion Technologies  
Biomedex Medical Systems, Inc.

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## 3D Imaging C-Arm Table

This instructions for use document covers safe operation of the 3D Imaging C-Arm Tables 058-820 and 058-825.

Additional information and resources are available upon request or directly from the Biodex website, [www.biodex.com](http://www.biodex.com)

If the desired information is not found, contact a local distributor or Biodex directly at [supportservices@biodex.com](mailto:supportservices@biodex.com)

Thank you,  
Biodex Medical Systems, Inc.



**Manufactured by:**

Biodex Medical Systems, Inc.



















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# Definition of Symbols

The following symbols and their associated definitions are used and implied throughout this manual.


Symbol	Definition
	Carefully read these instructions prior to use
	Operating Instructions
	Caution
	General Mandatory Action
	Dangerous Voltage
	"On" Power
	"Off" Power
	Pinch Point
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Non-Ionizing Electromagnetic Radiation
	Waste in Electrical Equipment
	Disposal Classification and Identification of Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part

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# Product Certifications and Classifications

<mailto:customerservice@biodex.com>

The 3D Imaging C-Arm Table has received the following certifications, and falls within the following classifications:

- IEC60601-1:2005 (Third Edition) + CORR1:2006+Corr 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint)
  - ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010
  - CAN/CSA C22.2 No: 60601-1:14
  - CE Class I Non-measuring
  - FDA Class II Equipment
  - IEC 60601-2-46 Edition 3.0
- 
- Type B Applied Part 



- Electromagnetic Compatibility: This equipment complies with the Medical Equipment IEC 60601-1-2:2014 EMC Standard.

## Authorized European Community Representative:



Emergo Europe  
Prinsessegracht 20  
2514 AP, The Hague  
The Netherlands

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## Before Proceeding



**NOTE:** The cautions and instructions provided in this manual must be read, followed, and kept available for consultation at all times. Observing the information, instructions and procedures presented throughout this manual is essential for using this product both properly and safely.



### SPECIFIC CAUTIONS

- Allow only qualified, trained personnel to operate or service this product.
- If the equipment is used in a manner other than specified in this operation manual, the protection provided by the equipment may be impaired and results could be compromised.
- Never leave patient unattended on device.



**CAUTION:** Unauthorized modifications to this product are not permitted and will void the manufacturer's warranty. Unauthorized modification of the product may result in a hazard to the user and/or patient. Do not modify this equipment without authorization from the manufacturer.



**CAUTION:** If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.



**NOTE:** Any serious incidents occurring with the use of this device should be reported to the manufacturer and appropriate local regulatory agency by end user, operator, or patient. Examples of local regulatory agency are EU competent authority, country specific Health Agency, or FDA.

## Training

This operation manual includes assembly and operating instructions. Operating/assembly questions can be directed to the Imaging Table Sales Department at [sales@biodex.com](mailto:sales@biodex.com).

## Operating Conditions

- Temperature: 10° C to 30° C (50° F to 86° F).
- Humidity Range: 30% to 70% (non-condensing).
- Atmospheric Pressure: 70kpa (10psi) to 106kpa (15psi).

## Transport and Storage Conditions

- Temperature: -20° C to 70° C (-4° F to 158° F).
- Humidity Range: 10% to 100%.
- Atmospheric Pressure: Sea Level 101kpa (14.7psi) to 10,000 feet, 69 kpa (10.1 psi).

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# Important Safety Information



CAUTION: Federal Law restricts this device to sale by or on the order of a physician, sonographer or other licensed professional.



Follow the unpacking and assembly instructions document.



Before using this equipment, read the entire operation manual carefully. Failure to read the manual may result in user error or injury. Be sure to save all provided documents for future reference.



Make certain to understand all caution labels as explained in the Before Proceeding section of this manual.



This product should be used only as specified in the operation manual.



CAUTION: Biodex devices are designed for use in a client environment.



For product specifications, refer to the Table of Contents.



This medical electrical equipment requires special precautions regarding EMC and must be assembled and placed into service according to EMC information provided in this manual.



CAUTION: Operation for 058-820: 115 VAC.



CAUTION: Operation for 058-825: 230 VAC.



CAUTION: Only use approved power supplies.



CAUTION: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.



CAUTION: The plug is considered the method of disconnecting the product from main power. Do not place the product in a position where the plug is not easily accessible.



CAUTION: This product is intended to remain in one location during operation. It is provided with wheels for relocation which should be used when moving.

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# 1. Introduction

## Intended Use

The 3D Imaging C-Arm Table 820 is designed for image-guided procedures where stability, access, and precise, quiet, vibration-free positioning are essential. It features motorized actuation of height, X-Y tabletop, lateral roll and Trendelenburg motions. Functional design provides complete access with reduced radiation exposure to clinicians. Patient comfort and stability are assured by table padding and an adjustable strap.

## Indications for Use

With the primary utility as a platform for positioning a patient for imaging during a medical procedure on a large radiolucent area, the C-Arm Table facilitates the end user, which could be urologists, brachytherapy specialists, and other clinicians.

## Contraindications

The 3D Imaging C-Arm Table 820 should not be used for bariatric patients who weigh more than 500 lb.

## Control Made Easy

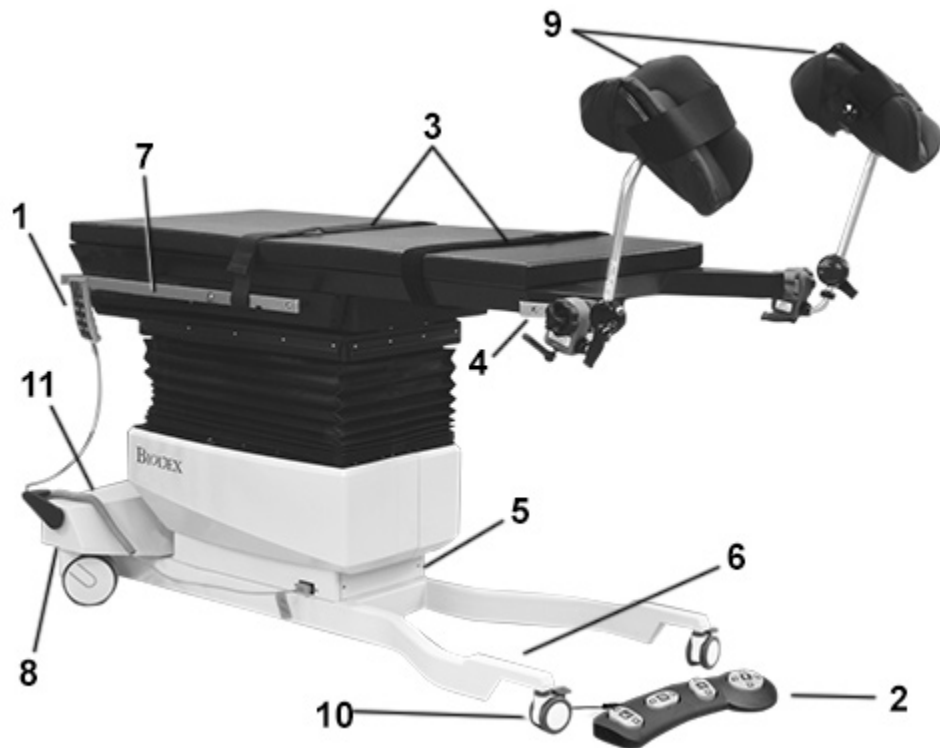
The portable hand-held and foot operated controllers ensure quick and safe tabletop positioning and can be positioned from any point around the table. Both the Hand and Foot Controllers operate table movements for X-Y tabletop motion, Trendelenburg motion, table height, and Lateral Roll (tilt). The hand-held controller provides the back to level function.

Both AC and battery power are standard. When operating on battery, the power cord can be stowed around the retaining clips at the rear end of the table. Battery charging occurs when the table is plugged into an AC outlet and the power switch is flipped to the ON position. When on batter power only and not in use, the power switch must be flipped to OFF to avoid draining the battery of power.



**IMPORTANT NOTE:** Remove battery if storing the table for a prolonged time.





*Figure 1.1. Parts and Adjustment Mechanisms*

**Standard Parts and Adjustments:**

1. Hand-Held Controller
2. Foot Controller
3. Body Restraining Straps
4. Accessory Rail
5. Low Profile Base
6. Open Leg Design
7. Accessory Rail
8. Head End Locking Brakes and Swivel Casters
9. Left and Right Knee Crutches (Optional Component)
10. Foot End Individual Locking Casters
11. Battery Pack

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## 2. Operating Instructions



**CAUTION:** Refer to instruction manual before operating or servicing system.



*This table can be operated with the power cord connected to an outlet or by using the battery. The battery recharges automatically while the table is plugged into an outlet even if the table is being used.*



**CAUTION:** Hospital grade plug to be plugged into a hospital grade receptacle only to achieve grounding reliability.



**CAUTION:** Before transferring a patient onto or off the table, ensure all four caster brakes are locked. Secure the restraining straps immediately after positioning the patient on the table.

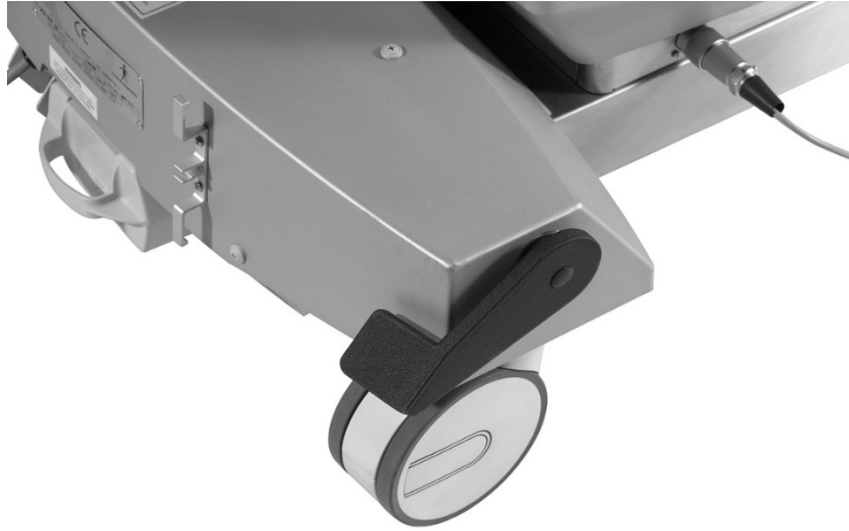


**CAUTION:** The restraining straps are not intended to restrain an uncontrolled patient.

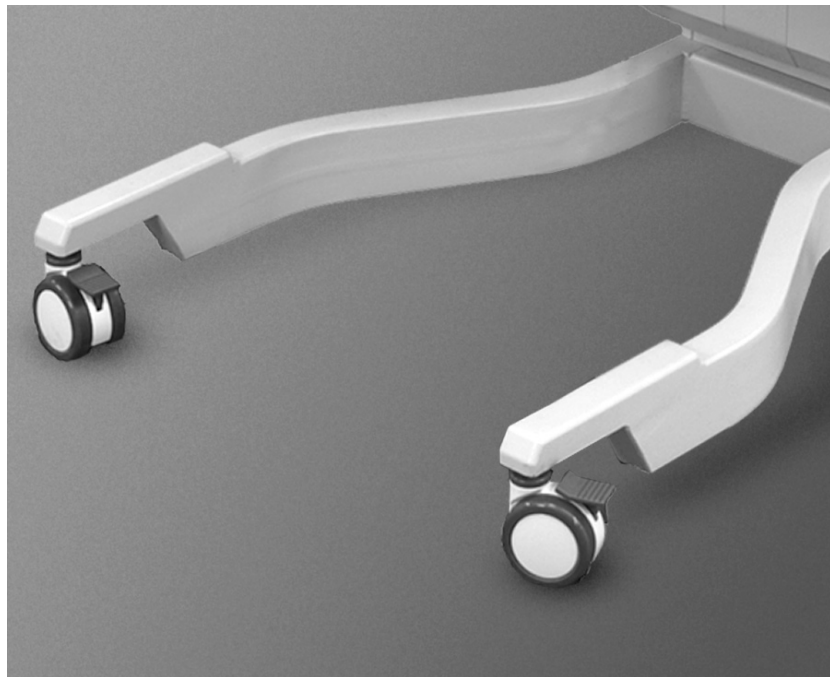
### The Locking Brakes and Swivel Casters

The locking brakes and swivel casters allow this table to glide effortlessly on hard surfaces. The foot end casters are locked from either side of the table while the head end casters are locked together using the Caster Brake Locking Bar.

1. To lock the foot end brakes and swivel casters, step down on the foot end caster brake locking lever on either side of the table.
2. To release the lock on the brakes and swivel casters at the foot end of the table, use a toe to lift up on the foot end caster brake locking lever on either side of the table.
3. To lock the brakes and swivel casters for the head end of the table, use a toe to press down on the center of the head end caster brake locking bar.
4. To release the head end brake and swivel casters, use a toe to lift up on either end of the head end caster brake locking bar.



*Figure 2.1. Locking Brakes and Swivel Casters.*



*Figure 2.2. Ergonomically designed leg supports to allow easy access and comfort.*

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## Using the Hand-Held Controller



**CAUTION:** Before adjusting the tabletop position, ensure the patient is secure to the tabletop with patient safety restraint straps.

The hand-held controller may be used to adjust table height, Trendelenburg/Reverse Trendelenburg, lateral roll and X-Y positioning. To adjust table position, press and hold the appropriate button and release to stop movement.



Figure 2.3. Hand-Held Controller

## Using the Foot Controller

The Foot Controller activates all motions for the table. Place the foot controller between the wide urologic access legs for proper representation. The four separate rocker style switches on the foot controller activate motions when pressed as follows: Trendelenburg, Lateral roll (tilt), Height Up/Down, and (Round switch) activates X-Y motion. Releasing the rocker switch at any time immediately stops the motion.

**NOTE:** When the table is used in a wet environment, it is recommended that the Foot Controller be covered with a plastic bag and sealed as watertight as possible.

### Note for Hand-Held and Foot Controllers:

**NOTE:** The table can perform only one motorized function (i.e. raising or lowering the tabletop, lateral roll, X-Y movement, Trendelenburg/Reverse Trendelenburg) at a time. If a second button on the Hand-Held Controller (or the Foot Controller) is pressed while the table is already performing a motorized function the tabletop movement will stop. At that point, all buttons must be released before the selected function can resume.



*Figure 2.4. Foot Controller*

### **Tabletop Extensions**

The Radiolucent Extension is used to extend the table when transferring a patient and can be used during imaging as it contains no metal cross members. The Head-End Extension is also used to extend the length of the table but is non-viewable and cannot be used for imaging.

The radiolucent leg extension inserts into access doors below the abdominal seat section. Pull on the extension to ensure it is secure.

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## **Disposable Skirt (Optional Component)**

The Biodex 3D Imaging C-Arm Table can be ordered with the optional Plastic Sanitary Skirts to protect the table bellows from patient blood and other liquids. The table has magnetic clips located immediately above the bellows. Secure the skirt to the clips as described below:

1. Slide the plastic skirt underneath the clip at the foot end of the table.
2. Close the magnetic clip.
3. Work around the table, tucking the top edge of the plastic skirt under each clip and lowering the clip to secure the plastic until the bellows are completely covered. Be sure to overlap the skirt across the entire length of the table's foot end.
4. Remove and replace the plastic skirt for each new patient.

**NOTE:** *Additional Bellows Skirts (part #056-802) can be ordered from Biodex.*

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## I.V. Pole (Optional Component)

The adjustable height I.V. pole should be installed onto the O.R. accessory rail. Loosen the I.V. pole locking knob at the base of the slide block and slide the block and pole onto the accessory rail until it is in the desired position. Tighten the locking knob to secure the pole. To adjust the height of the I.V. pole, loosen the height adjustment locking knob and raise or lower the top section of the pole to the appropriate height. Tighten the locking knob to secure.

## Charging the Battery

This table can be operated with the power cord connected to an outlet or by using the battery. The battery recharges automatically while the table is plugged into an outlet even if the table is being used. An optional wall-mounted battery charger is also available.

**NOTE:** *The table must remain plugged into an outlet when the battery is removed or reinstalled. If the battery is removed for any reason while the table is not plugged into a working outlet, the battery will discharge at a faster rate. Once the battery has been reinstalled, and it has been verified that the table is operating, the power cord plug can be removed from the outlet and operate on battery power.*



### Safety Guidelines:

1. Secure restraining straps immediately after placing the patient on the table. The restraining straps prevent the patient from rolling off the side of the table.

**NOTE:** *The restraining straps are not intended to restrain an uncontrolled patient.*

2. Always lock the casters before moving a patient onto or off the table.
3. This table supports patients weighing up to a maximum of 500 pounds.

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## 3. Maintenance and Cleaning

Follow the below instructions for the care and cleaning of your table and patient pads:

1. Clean the pad and exterior surfaces with a mild detergent solution, such as “Parker Laboratories Protex Disinfectant” or any disinfectant that *does not contain bleach*.
2. Do not pull the pad off the table. This may cause it to tear where the Velcro holds it in place. Reach underneath the pad and gently separate the Velcro to lift the pad off the table.
3. Do not place any arm boards, clamps, or other metal sharp objects on top of the pad.
4. Cover the pad before use with a standard patient care kit used in operating rooms.
5. Do not use the tabletop pad surface for transporting items when not in use.
6. Cover the pad when not in use with a standard patient care kit cover.
7. Keep wheel assemblies free of foreign materials and dirt accumulation.
8. Periodically inspect all welds.
9. Periodically check bolts on table, tighten if necessary.
10. Periodically inspect all strap holders. Any holder that feels loose should be removed and reattached after adding a spot of Loctite® Threadlocker (Blue #242) to the bolt threads. This should ensure that the bolt will not loosen.



**CAUTION:** *Disconnect power from source before removing panel or covers. Reliable grounding achieved only by connecting this unit to an equivalent marked hospital only or hospital grade receptacle.*

### Disposal

An appropriate waste disposal company is to be contacted (i.e., the local collection point for waste separation). Properly dispose of the device at the end of its service life:

- The device packaging is disposed of through resource recycling.
- The metal parts of the machine go to scrap metal disposal.
- Plastic parts are disposed of as hazardous waste.



***The disposal of equipment must be in accordance with the respective national regulations.***

***Wear parts are considered hazardous waste! After being replaced, wear parts must be disposed of according to country-specific waste laws.***



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## 4. Specifications

**Dimensions:** 103.75" l x 26" w (246 x 66 cm) with OR accessory rails

**Tabletop:** 103.75" l x 24" w (246 x 61 cm)

**Radiolucent Area:**

3D Imaging Area: 22.5" l x 24" w (57.1 x 61 cm)

**Other Tabletop Area:**

Radiolucent Extension: 29" l x 22.5" w (73.6 x 57.1 cm)

**Tabletop Material:** Carbon fiber

**Mattress:** Vinyl covered, seamless, 2" thick (5 cm)

**Attenuation:** 1.2 mm Aluminum equivalence

**Motions:**

**Height Adjustable:** 34" to 44" (86 to 112 cm)

**Tabletop X Motion (head-to-toe float):** 10" (25 cm)

**Tabletop Y Motion (side-to-side float):** 10" (25 cm)

**Trendelenburg:** 0° to 20°

**Reverse Trendelenburg:** 0° to 20°

**Lateral Roll:** 0° to 20°

**Controls:**

**Hand Control:** activates all motions

**Foot Control:** activates all motions

**Wheels:**

Head End - 3" (7.62 cm) swivel casters, integral locking system on base

Foot End - 5" (12.7 cm) swivel casters with central locking

**Accessory Rails:** Standard OR accessory rails, 1.12" x .375" (2.86 x .95 cm)

Head-End 30" l (75cm)

**Patient Restraints:** Body straps

**Finish:** Stainless Steel

**Patient Capacity:** 500 lb (227 kg)

**Weight:** 641 lb (291 kg)

**Shipping Weight:** 865 lb (392 kg)

**Power:** 115 VAC or 230 VAC and Battery. Battery automatically charges when table is plugged in.

An additional battery can be charged with optional wall-mounted charger.

**Warranty:** Two years parts and labor

**Certifications:** IEC60601-1:2005 (Third Edition) + CORR1:2006+Corr 2:2007 + A1:2012 (or IEC 60601- 1:2012 reprint), ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010 CAN/CSA C22.2 No: 60601-1:14, IEC 60601-2-46 Edition 3.0, CAN/CSA-C22.2 NO:60601-2-46 and CE Class I Non-measuring.



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## Optional Components

056-862	Battery and Charging Unit, 115 VAC
056-863	Battery and Charging Unit, 230 VAC
056-851	Drain Bag Frame
056-850	IV Pole, Rail Mounted
056-853	Crutch, Knee, Simplicity (pair)
058-862	Stirrups, PAL with boot pad (pair)
058-863	Arm Board, Dura Board with pad (pair)
058-865	Arm Board, Standard (pair)
058-866	Cassette Tray, 11" x 14"

## Replacement

056-802	Bellows Skirt, disposable plastic, 250/roll <i>Fits Surgical C-Arm Tables 840, 800, 810, and 820</i>
046-275	Dispenser, Disposable Protective Roll
056-857	Drain Bags
058-842-U503	Pad, 97.5" (247.65 cm) Rectangular tabletop
058-842-U501	Pad, 97.5" (247.65 cm) Contoured tabletop with face cutout

**NOTE:** To replace a part, contact our Service Department at 800-224-6339 and press 2, or email [SHR-ProductSupport@mirion.com](mailto:SHR-ProductSupport@mirion.com).

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