PAIN MANAGEMENT C-ARM TABLE™

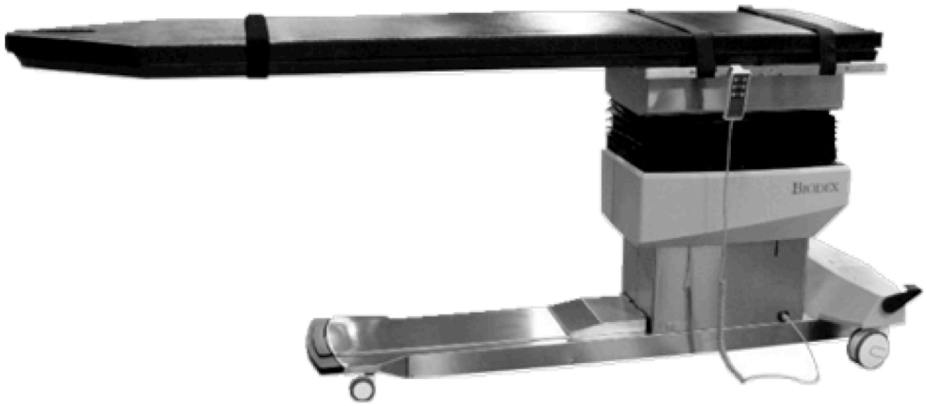
INSTRUCTIONS FOR USE

058-870

058-875

058-870-10

058-875-10



BIODEX

Biodex Medical Systems, Inc.

FN: 20-323-CLR 11/20

Pain Management C-Arm Table™

This instructions for use document covers safe operation of the Surgical C-Arm Tables 058-870, 058-875, 058-870-10, and 058-875-10.

Additional information and resources are available upon request or directly from the Biodex website, www.biodex.com/tables870.

If the desired information is not found, contact a local distributor or Biodex directly at supportservices@biodex.com

Thank you,

Biodex Medical Systems, Inc.

Contact information

Manufactured by:

Biodex Medical Systems, Inc.

Table of Contents

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 Warning
	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

Product Certifications and Classifications

The Surgical 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 

CE

SGS
C US
800350

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

Authorized European Community Representative:

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Before Proceeding

NOTE: *The warnings, 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.

WARNING: 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.

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

Training

This operation manual includes assembly and operating instructions. Operating/assembly questions can be directed to the service department during business hours.

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).

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 warning and caution labels as explained in the Before Proceeding section of this manual.

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

WARNING: 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 058-870 and 058-870-10: 115 VAC.

CAUTION: Operation for 058-875 and 058-875-10: 230 VAC.

WARNING: 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.

1. Introduction

Intended Use

The Pain Management C-Arm Table 870 is designed for image-guided procedures where stability, access, and precise, quiet, vibration-free positioning are essential. A cantilevered low attenuation carbon fiber tabletop, with choice of contoured or rectangular design, accommodates portable or ceiling-suspended C-Arms.

The contoured top provides ample workspace for anesthesiologists, yet the narrowness required for cervical procedures. The rectangular top offers additional space to allow for superior image quality for long-leg runoff studies. Select the top that best suits the requirements to achieve optimum image resolution.

Indications for Use

The large radiolucent area is free of cross members allowing full fluoroscopic visualization and unobstructed C-Arm positioning. Functional design provides complete access with reduced radiation exposure to clinicians. Patient comfort and stability are assured by two-inch thick table padding and three adjustable straps with hook and loop fastening. The contoured tabletop features a face cutout for prone positioning.

Contraindications

The Pain Management C-Arm Table 870 should not be used for bariatric patients who weigh more than 500 lb.

Automatic Positioning

The portable Hand-Held and optional foot-operated controllers can be positioned for convenient access from any point around the table. Both controllers offer the freedom to adjust height, lateral roll, and Trendelenburg motions. The foot-operated controller can be used when hands are busy with other functions.

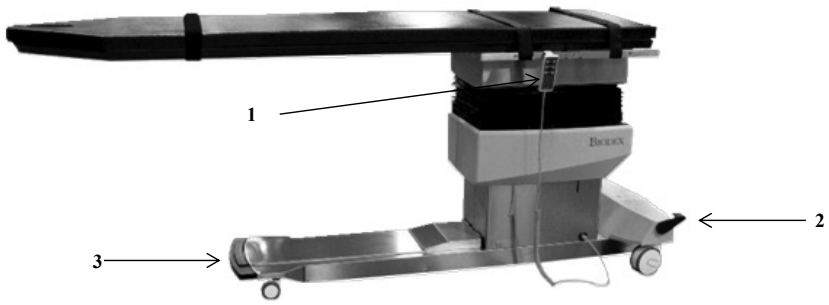


Figure 1.1. Parts and Adjustment Mechanisms

Standard Parts and Adjustments:
1. Hand-Held Controller
2. Foot End Locking Brakes and Swivel Casters
3. Front End Caster Brake Locking Bar

Optional Parts:
4. Foot Controller (not illustrated)

NOTE: *The Pain Management C-Arm Table tabletop is manufactured of carbon fiber. This material, as used in this product, is certified to meet all the requirements of radiation performance standards of 21 CFR Subchapter J.*

2. Operating Instructions

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 and across firm rugs. 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.

NOTE: *The head-end caster brake locking bar, when pressed down in the lock position, raises the head-end casters slightly off the ground. The amount that casters are raised can be adjusted by simply using a 5/8" open-end wrench to adjust up or down the support foot located under the head end caster brake locking bar.*

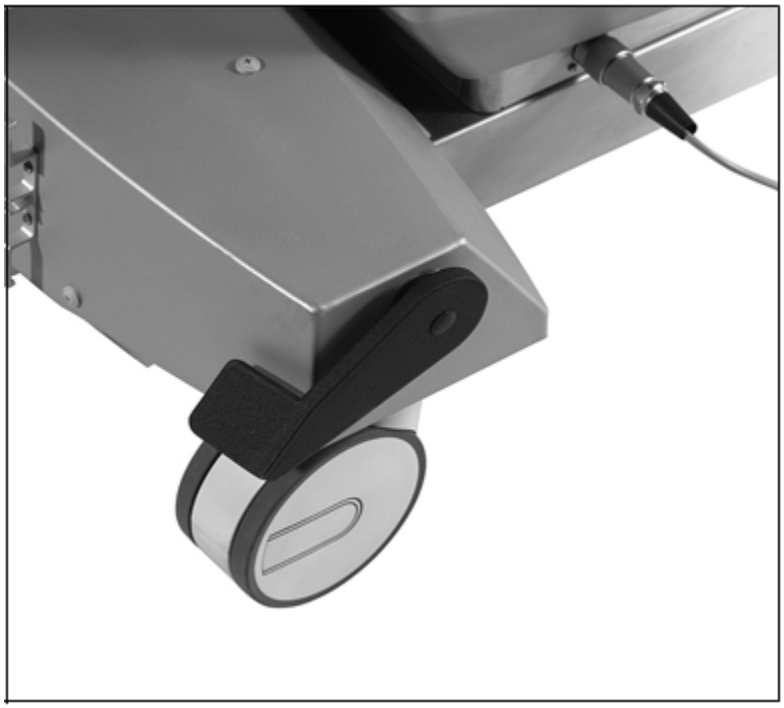


Figure 2.1. Locking Brakes and Swivel Casters

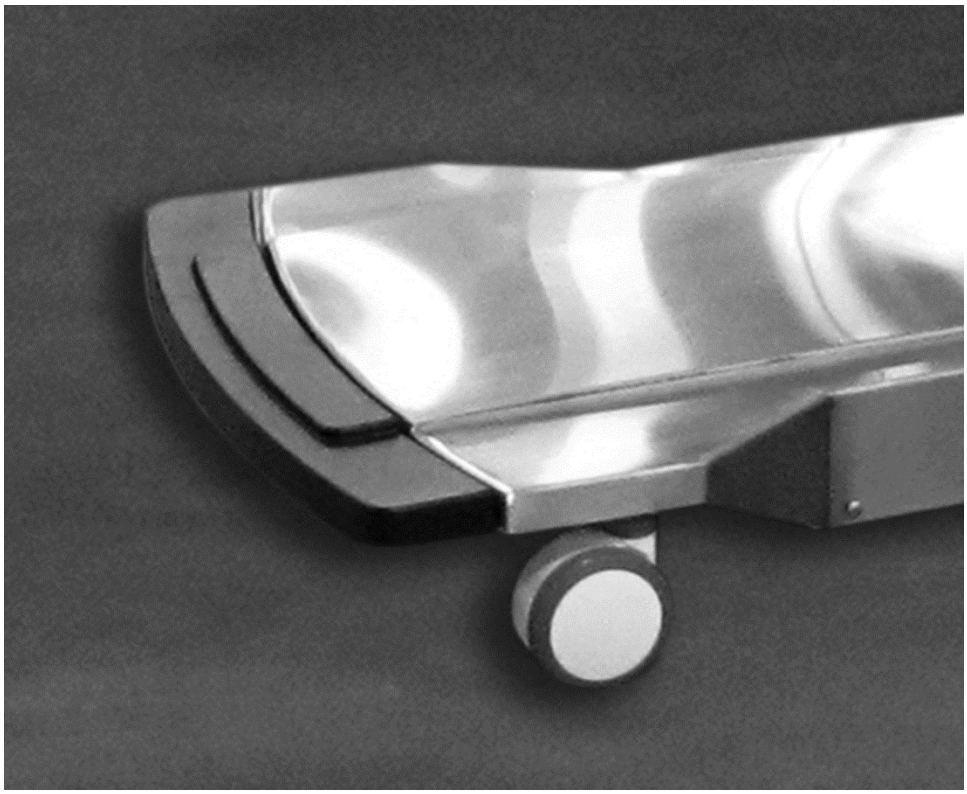


Figure 2.2. Head End Lock Bar

Using the Hand-Held Controller

The Hand-Held controller may be used to adjust table height, Trendelenburg/Reverse Trendelenburg, lateral roll and X-Y positioning. When not in use, the Hand-Held Controller can be hooked onto the metal loop on the restraining strap, or on the accessory rail.

CAUTION: *Before moving the tabletop, be sure that all I.V. lines, attachments and restraining straps, and such, are out of the way. Ensure that the patient is fully secured to the tabletop by the restraining straps.*

To adjust the table position, press and hold the appropriate switch on the Hand-Held controller. The tabletop will move or rotate in the direction indicated by the switch. Release the switch when the tabletop achieves the desired position.

Figure 2.3. Hand-Held Controller

Using the Foot-Operated Controller (Optional)

The Foot Controller activates all motions. The three separate rocker style pedals control two movements each. From left to right on the Foot Control, press and hold down the appropriate rocker switch to adjust Trendelenburg/Reverse Trendelenburg positioning, lateral roll, and tabletop height. 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-Operated Controllers*:*

NOTE: *The table can perform only one motorized function (i.e. raising or lowering the tabletop, lateral roll, 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

I.V. Pole (Optional)

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.

3. Maintenance and Cleaning

The Biodex Surgical C-Arm Table is virtually maintenance free. By following the instructions below at suggested time intervals, or as often as necessary, the table will remain in "like new" condition.

1. As required, cleanse all exterior surfaces and tabletop pads with a mild detergent solution, such as Parker Laboratories Protex Disinfectant or any one-step disinfectant that does not contain bleach.
2. Keep wheel assemblies free of foreign materials and dirt accumulation.
3. Periodically inspect all welds.
4. Periodically check bolts on table, tighten if necessary.
5. 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

NOTE: *When cleaning the pads, do not pull them off the c-arm table forcefully. The industrial strength Velcro will hold the pads in place, causing them to rip. Instead, reach underneath the pads and gently pull the Velcro apart.*

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.

4. Specifications

Dimensions: 97" l x 26" w (246 x 66 cm) with OR accessory rails
Tabletop: 97" l x 24" w (246 x 61 cm) – choice of classic contoured or rectangular design. Tested and complies with IPx4.
Radiolucent Area: 70" l x 24" w (178 x 61 cm)
Tabletop Material: Carbon fiber with integral head section (contoured or rectangular end)
Mattress: Seamless, 2" thick (5 cm)
Attenuation: 1.2 mm Aluminum equivalence
Motions:
Height Adjustable: 29.5" to 39.5" (75 to 100 cm)
Trendelenburg: 0˚ to 20˚
Reverse Trendelenburg: 0˚ to 20˚
Isocentric Lateral Roll: ±15˚ clockwise or counterclockwise
Controls:
Hand Control: activates height, isocentric lateral roll, and Trendelenburg motions
Foot Control (optional): activates height, isocentric lateral roll, and Trendelenburg motions. Tested to and complies with IPx6.
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
30" x 1.12" x .375" (75 x 2.86 x .95 cm) mounted near foot end of table
Patient Restraints: Three body straps
Finish: Stainless Steel
Patient Capacity: 500 lb (227 kg); weight tested to IEC 60601-2-46.
Lift Capacity: May vary between 460 lb - 500 lb (209 - 227 kg) based on line voltage
Shipping Weight: 749 lb (340 kg)
Power: 115 VAC or 230 VAC
Warranty: Two years
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
CE Class I Non-measuring
FDA Class II Equipment
IEC 60601-2-46 Edition 3.0

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