IntraOp® Mobetron®

Product Specification

CE 2797

U.S. FDA Class II, FDA 501(K) Cleared
FDA Registration #2953704

ISO13485:2016
MDSAP
Intertek

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The Mobetron is a compact electron beam accelerator designed for Intraoperative Radiation Therapy (IORT) and External Beam Radiotherapy (EBRT). The e-beam accelerator system incorporates standing wave X-band technology that results in significant size and weight reduction over more conventional S-band accelerator designs.

1.0 Physical Description

The Mobetron Treatment Console and Treatment Module assembly are linked with cables. The Treatment Console houses most of the system's electronic circuitry for beam control and dosimetry adjustment. The Treatment Console incorporates a touch screen display and keypad for remote set up and treatment delivery from a location offering sufficient radiation protection. The Treatment Console is mounted on lockable casters. The Treatment Module houses the accelerator head, high voltage unit, magnetron, RF system, gun control, cooling system monitoring and power control.

The Mobetron has the following configurations:

- There are two Gantry configurations:
  - Standard Gantry
  - Extended Gantry

- There are two Treatment Alignment configurations:
  - Auto Soft Docking System
  - Quick-Connect 360 Applicator System

1.1 Gantry Configurations

1.1.1 Standard Gantry Configuration

- The Standard Gantry configuration is a mobile unit. The in-line compact accelerator configuration and integrated beam shield serve to minimize stray radiation and leakage and facilitate IORT treatments in operating rooms without specialized shielding.
- The Mobetron can be put into a transport configuration for moving and storing the unit. In this position the treatment head lays horizontally, reducing the overall height of the gantry structure enabling access through doorways and elevators.
- The main gantry transport system is battery-powered and consists of self-locking motorized wheels and front casters operated with a hand pendant.
- This configuration is typically used for IORT with Auto Soft Docking.

1.1.2 Extended Gantry Configuration

- The Extended Gantry configuration utilizes a floor mounted frame.
- Has extended travel in the lateral, longitudinal and gantry rotation movements.
- Does not have a Beamstopper and will need to be used in a shielded room.
- This configuration is typically used for either IORT with Auto Soft Docking or EBRT with Quick-Connect 360 Applicator System.

1.2 Treatment Alignment Configurations

1.2.1 Auto Soft Docking System

- Maintains alignment of the electron applicator to the beam axis. The alignment system provides approximately a 4 cm gap between the applicator and the machine surface to ensure precise alignment and maximize patient safety.

- Functionality to automatically assist in the alignment of the treatment head in all five axes simultaneously to reduce treatment set up time.
- This alignment process is typically achieved within 2 minutes once the machine is placed in a dockable position.

1.2.2 Quick-Connect 360 Applicator System

- Connects the Applicator directly to the Treatment Head while allowing an approximately 5 cm gap between the accessories and the patient.
- Utilizes laser cross-hairs, a light field and range finder / optical distance indicator for treatment alignment.
- 360-degree rotation of the applicator about the beam axis.
- Touch Guard Sensor safety feature. See section 5.8.

2.0 Mechanical Specification

2.1 Transport System

The Treatment Console comes equipped with locking casters and may be easily moved and positioned. For the Treatment Module, there are separate modes of transportation depending on the gantry configuration.

2.1.1 Standard Gantry Configuration

The Standard Gantry Configuration transportation system is self-propelled with a battery-powered differential steering system consisting of two mechanically self-locking drive motors (Worm Gear), front casters and is controlled with a hand pendant.

2.1.2 Extended Gantry Configuration

The Extended Gantry Configuration has a mechanism for transporting the unit for manufacturing and installation. The transport mechanism is removed after installation is complete.

2.2 Motions and Controls for Setup

The Mobetron system includes motorized movement with six degrees of freedom in the Standard Gantry configuration and five degrees of freedom with the Extended Gantry configuration. The motion type and range can be seen in the table below. Each type of movement includes variable speed control.

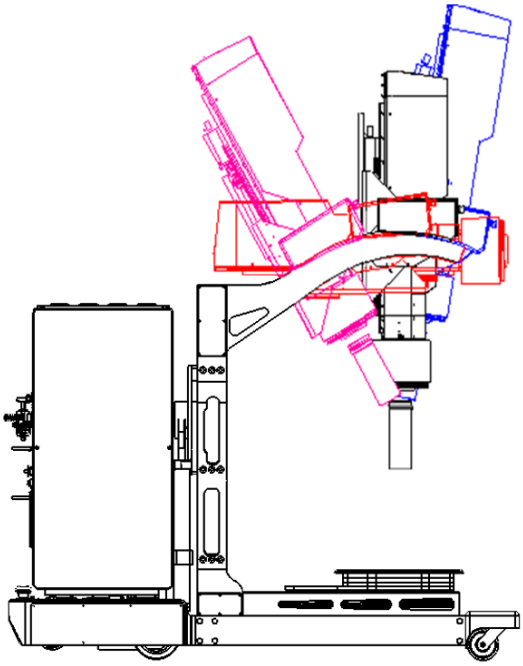
Motion Type	Standard Gantry Configuration	Extended Gantry Configuration
Gantry Rotation *	± 45° from vertical	± 80° from vertical (IORT) ± 90° from vertical (EBRT)
Gantry Lateral (left-right):	± 5 cm	± 10 cm
Gantry Longitude (in-out):	± 5 cm	± 10 cm
Head Tilt:	-10°/+30° from vertical	-10°/+30° from vertical
Head Vertical:	± 15 cm	± 15 cm
System Revolution	360° about the center axis of the rear wheels	N/A

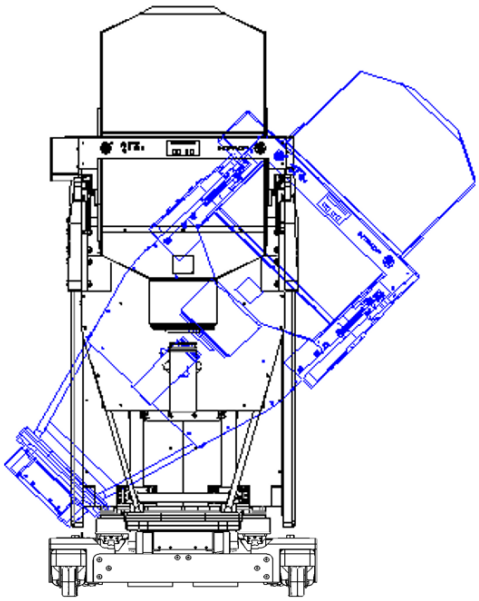
* The Extended Gantry Configuration with Soft Auto Docking has a maximum gantry rotation of 80° and when equipped with the Quick-Connect 360 Applicator System, the gantry rotation maximum is 90°.

2.3 Mobetron Physical Dimensions and Weights

2.3.1 Standard Gantry Configuration

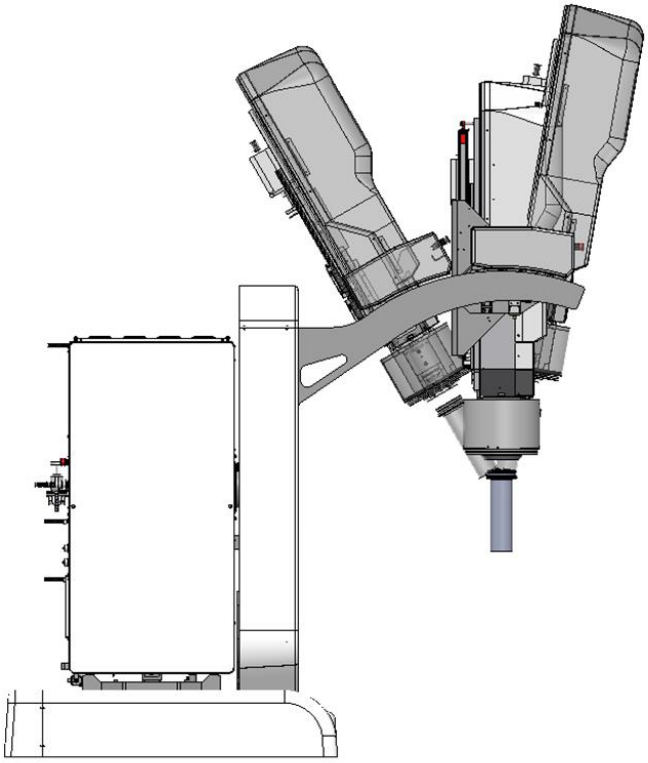
COMPONENT	HEIGHT	WIDTH	LENGTH	WEIGHT
Treatment Module Transport Configuration	78 in (198.1 cm)	42.8 in (108.7 cm)	88 in (223.5 cm)	2978 lbs. (1350.8 Kg)
Treatment Module Treatment Configuration	100 to 112 in (254 to 284.5 cm) At 0 degrees	42.8 in (108.7 cm)	88 in (223.5 cm)	2978 lbs. (1350.8 Kg)
Treatment Console	48 in (121.9 cm)	28 in (71.1 cm)	26 in (66 cm)	145 lbs. (65.8 Kg)

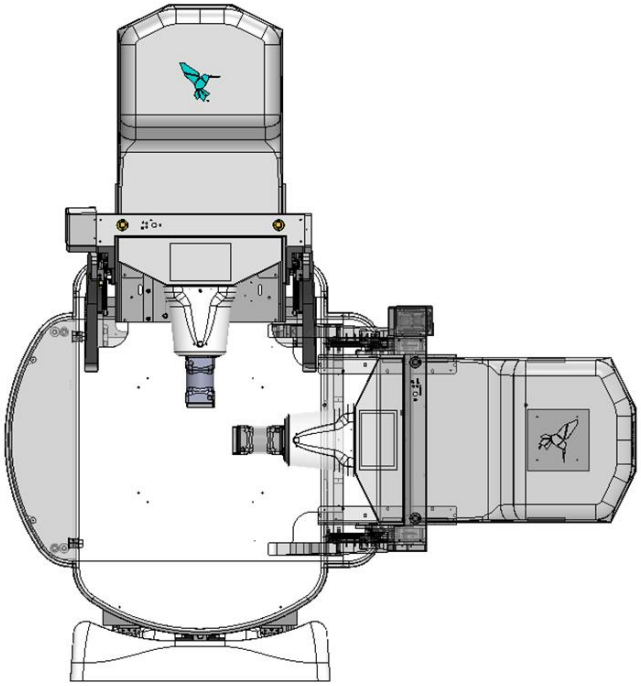




2.3.2 Extended Gantry Configuration

COMPONENT	HEIGHT	WIDTH	LENGTH	WEIGHT
Treatment Module Treatment Configuration	100 to 112 in (254 to 284.5 cm) At 0 degrees	42.8 in (108.7 cm)	88 in (223.5 cm)	3931 lbs. (1783 Kg)
Treatment Console	48 in (121.9 cm)	28 in (71.1 cm)	26 in (66 cm)	145 lbs. (65.7 Kg)





3.0 Electron Beam Characteristics

3.1 Beam Specifications

All beam and dosimetry specifications are defined in water at **D_{max}** and **50 cm SSD**. Beam Profiles are measured inside the flattened region, defined as 1 cm inside the 90% isodose contour edges.

- IORT: 10 cm circular 0° bevel tip applicator
- EBRT: 10 cm diameter with open insert

3.2 Beam Energies

Nominal Energy	90% Depth Dose (D90)	80% Depth Dose (D80)	30% Depth Dose (D30)
6 MeV	1.7 ± 0.2 cm	2.0 ± 0.2 cm	< 3.0 cm
9 MeV	2.6 ± 0.2 cm	3.0 ± 0.2 cm	< 4.3 cm
12 MeV	3.4 ± 0.2 cm	4.0 ± 0.2 cm	< 5.7 cm

- The user must commission each energy and field size combination before commencing treatments.
- One, two or three energy can be activated.

3.3 X-Ray Contamination

The central axis intensity measured in water as the dose of the intersection point of calculation of Practical Range - Rp is ≤ 0.5% of the maximum intensity for all field sizes.

3.4 Dose Rate

The nominal dose rate for each energy can be factory set to either 300 cGy/min or 1000 cGy/min, measured as defined in 3.1. The dose rate is not servo controlled.

3.5 Field Flatness (Homogeneity)

The difference in intensities between minimum and maximum intensity points is ≤ 6% within the flattened region. The flattened region is defined as 1 cm inside the 90% isodose contour edges. The flatness is within the specified tolerance for all energies, gantry angles and for all field sizes. In IORT, this only applies to 0° bevel tip applicator.

3.6 Field Symmetry

The difference in ratio of absorbed dose between any two points equidistant from the beam centerline within the flattened region is ≤ 2%. The symmetry is within the specified tolerance for all energies, gantry angles and for all field sizes. In IORT, this only applies to 0° bevel tip applicator. Measurements should be averaged over an area of 1 cm^2.

3.7 Field Size

3.7.1 IORT

- Available field sizes are 3 cm to 10 cm in diameter, as defined by cylindrically shaped electron applicators with various bevel angles.
- Three rectangular applicators with various bevels are also available.
- Full lists of applicator bevels and sizes are described in Sec. 6.2.

3.7.2 EBRT

- Two applicators are available; 6 cm and 10 cm diameter with many customizable inserts to define the field shapes and sizes. More details are provided in Sec. 6.2.

3.8 Field Penumbra

The maximum width of the penumbra region between the 20% and 80% intensity points is ≤ 2 cm for all field sizes and energies when measured at D_{max} and 50 cm SSD with 0° bevel applicators.

3.9 Duty Cycle

The Mobetron is designed with a restricted beam on duty cycle. The system requires 10 minutes of beam off for every 40 minutes of beam on. This restriction is most commonly reached during physics activities. Treatment exposures typically require beam on for less than 3 minutes. QA exposures are less than one minute each.

4.0 Dosimetry System

The Mobetron incorporates a dual (primary and backup) dosimetry system for measuring radiation output. The dosimetry system includes automatic pressure compensation for the vented ion chamber output current.

4.1 Dosimetry Performance

Delivered dose variations in the Standard Field will not exceed ±1% for the primary dose channel and ±2% for the backup dose channel due to:

- Proportionality (Linearity) i.e., length of an exposure
- Reproducibility (Repeatability) i.e., repeated exposures
- Variation due to treatment head angle

This specification applies for delivered doses between 250 and 2500 MU with the Mobetron's internal system of temperature and pressure compensation values of less than ± 4%.

4.2 Backup Dose Counters

Power independent backup dose counters retain primary and secondary dose count values if power is interrupted during a treatment. The two counters are viewable from the front of the console with system power off.

4.3 Dosimetry Interlocks

The following dosimetry events and interlocks can terminate the beam during treatment. Continuing treatment after a dosimetry interlock requires entering a password.

- Treatment Complete
- Dose Difference Interlock
- Flatness / Symmetry Interlock
- Overload Dose Rate 1&2 Interlock
- Under Dose Rate Interlock
- Dosimetry PS Interlock
- Energy Control Interlocks (RF Power / Gun HV)

5.0 Safety Features

5.1 Emergency Off

Two (2) emergency off buttons are located on the front of the Treatment Head, one (1) on the back of the Treatment Module and one (1) on the Treatment Console.
The Transport system is also equipped with an emergency stop button on the back of the machine on the transport frame. This button will cut power to only the transport system.

5.2 Audible Warnings

To indicate that radiation is present, the following audible signals are produced:

- Console: Warning tone for approx. 6 seconds before the beam is turned on
- Console: Short tone (beep) every 10 MU during treatment
- Treatment module: Steady tone during treatment

5.3 Warning Lights

Local warning lights flash at the user console when the beam is on. The customer may use the Mobetron's auxiliary external warning light connections to provide additional radiation indication. (Ref. Sec. 7.1)

5.4 Keys and Passwords

Key protection ensures only authorized persons can activate the beam. The machine requires a separate key to open the door to operate in Service Mode. The user is provided with a visual warning whenever the service mode is selected. A password is required to override dosimetry level interlocks.

5.5 Customer Interlocks

The Mobetron provides connection for one independent customer-supplied external interlock circuit (e.g., door switch) to inhibit the radiation if activated. In the same electrical connector is a 24 VDC signal to operate a warning light relay. (Ref. Sec. 7.1)

5.6 System Interlocks

Numerous interlocks protect the machine against transient events or failures that could damage or compromise machine performance or reliability. The user can clear most system interlocks. An interlock that does not clear indicates a failure.

5.7 Beamstopper (Standard Gantry Configuration Only)

A gantry-mounted lead beamstopper attenuates the forward bremsstrahlung radiation to < 50 µSv (approximately), measured directly behind the beam shield, for a delivered dose of 10 Gy. The beamstopper is servo-controlled to automatically track the treatment head movement. Interlocks inhibit the radiation beam if the beam shield is out of position.

5.8 Touch Guard Sensor (EBRT Only)

The Touch Guard Sensor is a safety feature that terminates all Mobetron movements when a collision is detected along the Applicator or Insert. If using a Mobetron compatible treatment table, motions of the table will also be disabled.

5.9 Stray Radiation Shielding

Internal self-shielding limits stray x-ray radiation. For calculation purposes, the expected value of 3 uSv averaged over all energies at a distance of 3 m from the patient for a delivered 10 Gy electron beam dose should be used. Measuring point shall be 3 m from beam centerline, outside of the OR and 1 m above the floor.
All measurements are made with an IntraOp QA Applicator or a 6 cm 0 deg IntraOp treatment applicator and water phantom.

5.10 Regulatory Compliance

Mobetron meets or exceeds applicable international FDA/MDD/IEC/JIS/SFDA product performance and safety standards. IntraOp Medical Inc. is FDA, ISO 13485 and CE registered for design and manufacture of Class IIb medical devices, Class IIa and Class I accessories.

Reference: FDA -21 CFR 820 QRS; ISO 13485; FDA - 21 CFR, Chapter 1 Subchapter J, Part 1040; FCC, Part 18; MDD 93/42/EEC and 2007/47/EC; IEC 529; EN 5011; ISO 10993; EN 55011- Class A; EN ISO 14971; EN ISO 15223-1; IEC 60417 /ISO7000; EN/IEC 60601-1; EN/IEC 60601-1-2; EN/IEC 60601-1-4; EN/IEC 60601-2-1; IEC 60976; IEC 60977; IEC 60417-1; EN IEC 62304; EN IEC 62366, JIS T 1001; JIS T 1002; AAPM TG72

6.0 Accessories and Options

6.1 Table Clamp Assembly (IORT Only)

Clamping assemblies for attaching and positioning the applicator to the table rails are available. Two sets are recommended. (Optional)

6.2 Treatment Applicators

Custom design applicators are available for specialized uses (Optional).

6.2.1 IORT

- Cylindrical applicators with field sizes of 3 to 10 cm in size increments of 5 mm and with 0°, 15°, 30° and 45° bevel tips.
- Rectangular 7 cm X 12 Cm, 8 cm X 15 cm and 8 cm X 20 cm with 0° and 20° bevel tips.

6.2.2 EBRT

- 6 cm and 10 cm diameter

6.3 Inserts (EBRT Only)

Placed at the end of the applicator, with sizes ranging from 3 cm – 11 cm. Custom shapes also available.

6.4 Bolus (IORT Only)

5 mm and 10 mm thick acrylic bolus caps are available for each applicator size and bevel. Only 5 mm bolus available for rectangular applicators.

6.5 Radiation Shield with Plastic Cover

Stainless Steel disk with a removable plastic cover designed to protect critical structures.

6.6 Docking Target Assembly

Attaches to the top of the applicator facilitating the auto soft docking alignment process.

6.7 Quality Assurance System (IORT Only)

The quality assurance system aids in daily checks of the alignment soft docking system and the electron beam output. Sets of constancy blocks are provided to check energies (standard).

6.8 Sterilizable Cap (IORT Only)

A cap provides a sterilizable barrier between the machine and patient. Two long life (approx. 25 uses) sterilizable caps are supplied (standard). Additional sets can be purchased as needed.

6.9 Radiation Treatment Planning Connectivity

The Mobetron employs an interface to communicate with a Mobetron compatible radiation treatment planning system. This radiation treatment planning system can send treatment parameters to the Mobetron. After the treatment finishes, the Mobetron will send treatment results to radiation treatment planning system.

7.0 Facility Requirements

7.1 Treatment Room Electrical:

- Power rating: 2 KVA
- Voltage Input: 200-240 VAC 50-60 Hz.
- Voltage Variation: ± 5% from machine setup voltage
- Current: 10 amperes maximum
- Wiring: 3 wire (2 line plus separate safety ground), 20 Ampere Service
- AC power plug and receptacle for machine power cord
- Door Switch and Warning Light Control connection (Ref. Sec. 5.3, 5.5)

7.2 Treatment Room Temperature and Humidity:

- Temperature: 60° F (16° C) to 80° F (27° C) with max variation of +/- 6°F (+/- 3.3° C)
- Relative Humidity: Maximum 75% non-condensing
- Room Heat Load: 2 KW added by the Mobetron

7.3 Temporary Storage Conditions:

- Temperature 34° F (1° C) to +110° F (43° C)
- Relative Humidity: Maximum 70% non-condensing
- Single phase 100 - 240 VAC, 50/60 Hz, 10amp power receptacle (for vacuum pump power supply)
- Battery operated vacuum pump power supply requires regular battery changing/charging.

7.4 Long Term Storage and Shipment Conditions:

- Temperature 34° F (1° C) to +122° F (50° C)
- Humidity: Maximum 70% non-condensing
- Battery operated vacuum pump power supply (where a permanent AC power receptacle is not available) - requires regular battery changing/charging.

7.5 Altitude and Atmospheric Pressure at specified Altitude

- Max Altitude above sea level: 9000 feet (2743.2 meters)
- Min Atmospheric Pressure: 543 mmHg (72.40 KPa)

7.6 Laser Specification

7.6.1 Class I Laser Product - Keyence

- Class I Laser Product (FDA CDRH Part 1040.10 Laser Product)
- 60825-1 (2014) compliant
- Wavelength 655 nm
- Output 560µW

7.6.2 Class I Laser Product – Quarton

- Class I Laser Product (FDA CDRH 21 CFR Chapter 1. Subchapter J.)
- FDA Accession # 0820048-104
- Wavelength 520 nm
- Output < 2mW

7.7 IEC 60601-1 CLASSIFICATION OF ME EQUIPMENT

- Class I ME equipment, externally powered
- Internally powered ME equipment
- Mobetron has no applied parts (based on IEC 60601-1)
- Not ME System (Mobetron is a stand-alone device)

7.8 Host Facility Layout and Space Requirements:

7.8.1 Standard Configuration

- **Door Opening** should be no less than 43 in (109.2 cm) wide by 78 in (198.1 cm) high.
- **Ceiling Height** for full Mobetron use in the treatment room should be no less than 111 in (281.9 cm) for full vertical travel of the treatment head. Limits on vertical travel can be set for ceilings that do not meet the full vertical height requirement.
- **Gantry Side Clearance** next to the Treatment Module while in the operating room should be no less than 63 in (160 cm) to allow full Gantry rotation.
- **Treatment Console Location** Typically the console is placed in the corridor or scrub room during patient treatment at a distance less than 70 ft (21.3 meters). Longer cable lengths are available (Optional).
- **Temporary Storage Location** of 32 sq. ft. (3.0 sq. meters) is required to stow the machine and console between treatments. Wall outlet power is required, single Phase 100 - 240 VAC, 50 - 60 Hz 10 Amp. Additional space may be needed for storing accessories.

7.8.2 Extended Configuration:

- **Door Opening** should be no less than 42 in (106.7 cm) wide by 78 in (198.1 cm) high.
- **Ceiling Height** for full Mobetron use should be no less than 110 in (279.4 cm).
- **Gantry Side Clearance** The center line of the Mobetron should not be located less than 78 in (198.1 cm) from the left or right wall and 74 in (188 cm) center to back wall. However, radiation protection requirements may increase this distance.
- **Treatment Console Location** must be in a location, less than 70 ft (21.3 meters), that is shielded from stray electron radiation during the Mobetron treatment. Longer cable lengths are available (Optional).
- **Storage Location** of 32 sq. ft. (3.0 sq. meters) is required to stow the machine and console. Wall outlet power is required, single Phase 100 - 240 VAC, 50 - 60 Hz 10 Amp. Additional space may be needed for storing accessories.

Appendix A **Warnings and Cautions**

Warnings and informational labels are affixed to the machine as reminders.
Operators and service personnel must familiarize themselves with all items described in this section before using the Mobetron.

Information Label Descriptions

Figure A-1

Located on the back of the treatment head, this placard explains how to manually move the treatment head away from the patient in the event of motor problems.

Figure A-2

Users should only connect or disconnect power cables when system power is off.

Figure A-3

Warns about placing body parts and equipment between the beamstopper and floor frame.

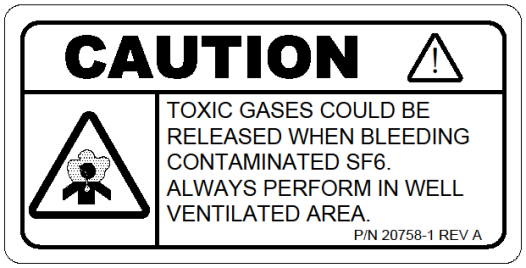


Figure A-4

Warns about the danger of toxic gas by-products in the RF system. While SF_6 gas is non-toxic, electrical arcing can cause SF_6 to react and form toxic and corrosive by-products. If a pungent smell is detected when venting SF_6, remove all personnel to an area with fresh air.

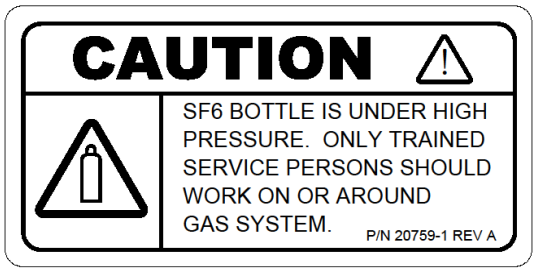


Figure A-5

The contents of the steel SF_6 gas cylinder are under pressure. Any puncture in the cylinder or damage to the regulator can create high-speed projectiles. For this reason, only trained personnel should work on or around the gas system.

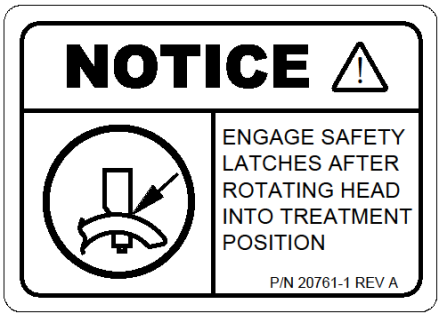


Figure A-6

Reminds the user to engage the safety latches after the treatment head is rotated into position.

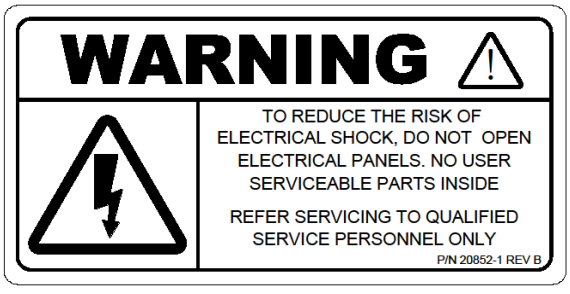


Figure A-7

Warns the user not to open the Mobetron's electrical panels.

Figure A-8

Warns that the user of the Mobetron must take steps to minimize their radiation exposure and reduce the risk of accidental exposure.

Figure A-9

Warns the user that the alignment lasers can cause eye damage. Users must take care to protect their eyes and the eyes of the patient.

Figure A-10

Figure A-11

Read the Book.

Warning and Caution Instructions

 WARNING: Crushing Hazard During Treatment Head Motion

The treatment head is top-heavy. To avoid injury, always maintain control of the treatment head when configuring for transport.

 CAUTION: Tilting the Treatment Head

If the tilting motion is difficult, do not proceed to tilt the treatment head. Doing so could damage the Mobetron. Check that there are no trapped cables or other obstructions preventing the movement of the treatment head.

 CAUTION: Lowering the Treatment Head

Use extreme caution when lowering the treatment head to avoid damage to equipment.
Do not allow the treatment head to strike the gantry sharply, as damage to internal components can result. Always lower the treatment head into position gently.

 WARNING: Hazards During Transportation

Transporting the Mobetron can involve numerous hazards:

- Crushing Danger: Do not allow any personnel to come between the Mobetron and a wall or other rigid object. Do not place feet, hands, or other body parts underneath the Mobetron when it is supported by the transportation system.
- Elevator Carrying Capacity: Do not place the Mobetron on an elevator with a carrying capacity of less than 3000 lbs. (1360.8 kg) for Standard Gantry Configuration and 4000 lbs. (1814.4 kg) for Extended Gantry Configuration. Be sure to account for the weight of any accompanying personnel and the Treatment Console 145 lbs. (65.8Kg).

 CAUTION: Equipment Damage during Transportation

During transportation, push and pull only on the gantry frame elements and mobility legs. Do not push or pull on the treatment head or collimator.

Do not allow the Treatment Module to collide with obstructions.

Take due care when moving the Mobetron on a path that includes a ramp or inclined surface. The Mobetron is very difficult to control on an inclined surface. If possible, find a different path.

 CAUTION: Depleted Batteries

Should the depleted battery condition arise, report it to IntraOp or Authorized Service Provider. Connect power to TM Rear Panel J9 to move the system with depleted batteries.

 CAUTION: Loss of Ion Pump Power

The transport power cable must be connected while the Mobetron is in storage. Failure to supply power to the ion pump can result in partial loss of internal vacuum and lead to equipment damage.
When the Mobetron is in storage, check the transport power cable connection on a weekly basis. See “Performing Weekly Maintenance” for a weekly maintenance checklist.

 WARNING: Electrical Hazard

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

 WARNING: Electrical Hazard: Abraded or Damaged Cables

Abraded or cut cables can cause damage to equipment and serious injury or death to personnel. Never operate the system with faulty or damaged cables.

 WARNING: Laser Light Hazard
Do not stare into the laser beam. Provide the patient with adequate eye protection when necessary.

 WARNING: Radiation Hazard
When the Mobetron is producing radiation, all personnel should be at least 10 feet (3 meters) from the treatment head, either outside the room or in a shielded area inside the room.

 WARNING: Disabled Safety Interlocks in Service Mode
Many interlocks are or may be bypassed in service mode. Due care must be taken to avoid injury. Consult a qualified Mobetron service engineer.

 WARNING: Stray Radiation in Service Mode
Service mode inhibits most radiation monitoring related interlocks. Due care must be taken to avoid accidental exposures. Only IntraOp trained and authorized persons my use service mode.
