INTRAOP

IORT

Mobetron® 2000 Product Specification

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(Intraop reserves the right to modify the design and change the specifications contained herein)

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Mobetron®

The Mobetron is a mobile electron beam accelerator designed for Intraoperative Radiation Therapy (IORT). 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. 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. Compared with conventional IORT, IORT treatment in standard operating rooms is significantly simpler and less expensive. The Mobetron can also augment the capacity of conventional electron beam treatment facilities.

1.0 Physical Description

When not in use, the Mobetron can be put into a transport configuration for moving or storing the unit. The treatment head can lie horizontally, which reduces the overall height of the gantry structure. This enables access through doorways and into many elevators. The main gantry transport mechanism consists of a motorized jack, wheels, and a steering handle. The operator console is mounted on lockable casters.

When in use, the Mobetron operator console and Treatment Module assembly are linked with cables. The Mobetron incorporates five variable-speed motor drives that align the radiation output head with the patient and applicator. The operator console houses most of the system's beam control and dosimetry adjustment electronic circuitry. The operator console incorporates a touch screen display and keypad for remote set up and treatment delivery from a location offering sufficient radiation protection. The Treatment Module houses the Accelerator Head, High Voltage Unit, Magnetron, RF system, Gun Control, cooling system and misc. monitoring and power control. Before treatment, the operator pre-positions the radiation field defining applicators and affixes them to the operating table before using the patented laser alignment system to orient the treatment head.

2.0 Electron Beam Characteristics

2.0 Beam Energies

Nominal Energy	80% Depth Dose (D80)	30% Depth Dose (D30)
6 MeV	2.0 ± 0.2 cm	< 2.9 cm
9 MeV	3.0 ± 0.2 cm	< 4.2 cm
12 MeV	4.0 ± 0.2 cm	< 5.6 cm

Notes:

i. The energy specification is defined with a 10 cm diameter applicator at 50 cm SSD.
ii. The Depth Dose is defined as per NACP protocols.
iii. The user must commission each energy and field size combination before commencing treatments.

2.2 X Ray Contamination

The central axis intensity measured in water at a depth of 10 cm beyond the 10% isodose line is ≤ 1% of the maximum intensity for all field sizes.

2.3 Dose Rate

The nominal dose rate in each energy is 1000 cGy/minute measured using a 10 cm applicator at Dmax and 50 cm SSD. The dose rate is not servo-controlled.

2.4 Field Flatness (homogenity)

The difference in intensities between minimum and maximum intensity points is ≤ 10% within the flattened region. The flattened region is defined as 1 cm inside the 90% isodose contour edges as measured at the Dmax depth and 50 cm SSD.

2.5 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 circular field sizes of > 5 cm. Measurements should be averaged over an area of 1 cm^2.

2.6 Field Size and Angle

The available field sizes are 3 cm to 10 cm in diameter, as defined by cylindrically shaped electron applicators with 0° bevel angle. The Mobetron also provides optional applicators with end bevels that produce nominal radiation field angles of 15° and 30°.

2.7 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 Dmax and 50 cm SSD with 0° bevel applicators.

2.8 Duty Cycle

The Mobetron is designed for a 40% beam on duty cycle. This allows for 24 minutes of beam on in any one hour. Since most applications require beam on for less than 3 minutes, the duty cycle will not affect any end user requirement.

3.0 Dosimetry System

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

3.1 Dose Reproducibility (repeatability)

Delivered dose variations are ≤ 1% for the primary dose channel and ≤ 2% for the backup dose channel with the gantry in the vertical position. Set dose values are reproducible between 250 and 2500 MU in the high dose rate mode. This specification applies for barometric pressures over the range of 29-31inHg (736-787 mmHg) and room ambient temperatures of 60-95°F (15-35°C).

3.2 Dose Proportionality (linearity)

Delivered dose variations due to changes in set dose shall not vary by more than +/-1%. This applies for set dose values of 250 to 2500 MU and for dose rate variations from 800 - 1200 MU/min.

3.3 Dose Variation with Gantry Angle

Dose variation for non-vertical gantry angles will be < 1% from calibrated dose at zero degree gantry angle.

3.4 Dose Variation with Field Size

The depth of maximum ionization and dose output factor both vary with field size. During commissioning, the user (or agents of the user) must measure the actual values. Typical data is available upon request.

3.5 Backup Dose Counters

Independent dual battery-powered backup dose counters retain primary and secondary dose count values if power is interrupted during a treatment. They are viewable from the front of the console.

3.6 Dosimetry Interlocks

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

- Time Complete (backup time termination)
- Dose Difference Interlock (MU 1 vs. MU 2 count values)
- Beam Asymmetry Interlock (inplane or crossplace beam asymmetry)
- Excess Dose Rate Interlock
- Excess Dose/Pulse Interlock
- Under Dose Rate Interlock
- Dose Chamber Voltage Interlock (loss of ion chamber bias voltage)
- Applicator misalignment (Soft Docking Interlock)
- Energy / Dose Rate Control Interlocks (RF Power / Gun Controller)

4.0 Mechanical Specification

4.1 Transport System

The Mobetron Treatment Module's Motorized jack is located at the rear of the gantry stand. The module also has swiveling lockable wheels attached to the front of the transportation support legs. The Operator Console comes equipped with locking casters.

4.2 Motions and Controls for Setup

- **SSD**: Nominal electron source-to-treatment distance (SSD) is 50 cm. (SSD is defined as the distance on the beam axis from the electron field flattening filter to the end of the treatment applicator.)
- **Motion Control**: A lightweight hand held pendant provides control over all motor-driven motion. Single axis controls and slow motion drives ensure the patient safety during the treatment setup process.
- **Gantry Rotation**: The gantry can rotate over the range +/- 45° with variable speed.
- **Gantry Lateral (left-right)**: The gantry is capable of +/- 5 cm lateral movement with variable speed control.
- **Gantry Longitudinal (fore-aft)**: The gantry is capable of +/- 5 cm longitudinal movement with a variable speed control.
- **Head Tilt**: The head assembly can tilt +10°/- 30° with a variable speed.
- **Head Vertical**: The head assembly is capable of 30 cm vertical movement (docking) with variable speed.
- **Position Readouts**: Positioning readouts are for reference only.
- ***Ranges of travel are approximate

5.0 Safety Features

5.1 Emergency Off

The Mobetron provides three conveniently located Emergency Off switches for removing power in emergencies.

5.2 Audible Warnings

An audible signal warns of impending radiation five seconds before the beam turns on. While the beam is on, short audible tones (beeps) occur every 10 MU in order to indicate that radiation is being produced.

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.

5.4 Keys and Passwords

Key protection ensures only authorized persons can activate the beam. *The machine requires a separate key to operate in Service Mode. The user is provided with a visual warning whenever the service mode is selected.*

5.5 Customer Interlocks

The Mobetron provides connection for one independent customer-supplies external interlock circuit (e.g. door switch) in order to inhibit the radiation beam when activated.

5.6 System Interlocks

Numerous system interlocks protect that machine against transient events or failures that could damage or compromise machine performance or reliability. The user can clear most system interlocks.

5.7 Soft Docking

The Mobetron employs a patented laser alignment soft docking system that maintains alignment of the electron applicator to the beam axis. The alignment system also provides a 4 cm gap between the sterile applicator and the non-sterile machine surfaces.

5.8 Beamshield

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

5.9 Stray Radiation Shielding

Internal self-shielding limits stray x-ray radiation to less than 6 uGy at a distance of 3 m from the patient for a delivered 10 Gy electron beam dose.

- All measurements are made with an IntraOp QA Applicator or a 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 and Class I medical devices.

Reference: FDA -21 CFR 820 QRS; ISO 13485; FDA - 21 CFR, Chapter 1 Subchapter J, Part 1040; FCC, Part 18; MDD 93/42/EEC; EN 60601-1; EN 60601-1-2; EN 60601-1-4; EN 60601-2-1; EN 550; EN 55011- Class A; EN 980; IEC 60976; IEC 977; IEC 60417-1; ISO 10993; JIS T 1001; JIS T 1002.

6.0 Accessories and Options

6.1 Surgical Table

IntraOp can recommend specialized IORT surgical table manufacturers and models that work well with the Mobetron. IntraOp can also provide specifications for the customer to provide their own.

6.2 Applicator Clamps

Two sets of applicator clamps for attaching and positioning the applicator to the table rails are supplied (standard).

6.3 Treatment Applicators

Electron applicators with field sizes of 3 to 10 cm in size increments of 5 mm and with 0° and 30° bevel tips are available. Applicators with bevel tips of 15° are available and custom design applicators can be developed for specialized uses (optional).

6.4 Bolus Caps

5 mm and 10 mm thick acrylic bolus caps are available for each applicator.

6.5 Quality Assurance System

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

6.6 Sterilizable Cap

A cap provides a sterilizable, electrical barrier between the machine and patient. Two sterilizable caps are supplied (standard). Additional sets can be purchased as needed.

6.7 Physics Accessories

A set of physics accessories is available to aid in daily checks, calibrations and commissioning. (Optional)

7.0 Facility Requirements

7.1 Operating Room Electrical:

- Power rating: 2 KVA
- Voltage Input: 208/240 VAC 50/60 Hz.
- Current: 17 amperes maximum
- Wiring: 3 wire (2 line plus separate safety ground) , 20 Ampere Service (minimum)
- AC power receptacle for machine power cord

7.2 Operating Room Temperature and Humidity:

- Temperature: 60° F (16° C) to 80° F (27° C)
- Humidity: Maximum 75%
- Room Heat Load: 2 KW added by the Mobetron

7.3 Temporary Storage Conditions:

- Temperature 34° F (1° C) to +110° F (43° C)
- Humidity: Maximum 70% non-condensing
- Single phase 115/230 VAC, 50/60 Hz, 10 amp 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 AC power receptacle is not available) - requires regular battery changing/charging.

7.5 Host Facility Layout and Space Requirements:

- **Door Opening** should be 45" (114 cm) wide by 79" (201 cm) high.

- **Ceiling Height** in the operating room should be 109.5" (278 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. Minimum ceiling height is 9'2" (279 cm).
- **Gantry Side Clearance** next to the Treatment Module while in the operating room should be 6' (160 cm) to allow full Gantry rotation. Additional space on one side is required to facilitate free patient table positioning.
- **Control Console Location** must be no more than the 45 ft (13.7 meters) cable length from the Modulator Cabinet. Typically the console is placed in the corridor or scrub room during patient treatment.
- **Temporary Storage Location** of 39 sq ft (3.7 sq meters) is required to stow the machine between treatments. Additional space may be needed for storing accessories.

7.6 Mobetron Physical Dimensions and Weights

COMPONENT	HEIGHT	WIDTH	LENGTH	WEIGHT
Treatment Module (Transport Configuration) Includes motorized jack	78 in (198 cm)	42.7 in at front casters 40.6 in main machine 103 cm	95 in ** 241cm	2937 lbs (1335 Kg)
Treatment Module (Treatment Configuration) Includes motorized jack	97 to 109 in 246-276 cm At 0 degrees	42.7 in at front casters 40.6 in main machine 103 cm	95 in 241 cm	2937 lbs (1335 Kg)
Operator Console	48 in 122cm	28in 71cm	26 in 66cm	145 lbs 66 Kg
Motorized Jack	-	-	13 in	230 lbs 104.5 Kg

** Treatment Module length with transport jack removed is 82" (212 cm).