

Intraoperative radiation therapy using mobile electron linear accelerators: Report of AAPM Radiation Therapy Committee Task Group No. 72

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ABSTRACT

Intraoperative radiation therapy (IORT) has been customarily performed either in a shielded operating suite located in the operating room (OR) or in a shielded treatment room located within the Department of Radiation Oncology. In both cases, this cancer treatment modality uses stationary linear accelerators. With the development of new technology, mobile linear accelerators have recently become available for IORT. Mobility offers flexibility in treatment location and is leading to a renewed interest in IORT. These mobile accelerator units, which can be transported any day of use to almost any location within a hospital setting, are assembled in a nondedicated environment and used to deliver IORT. Numerous aspects of the design of these new units differ from that of conventional linear accelerators. The scope of this Task Group (TG-72) will focus on items that particularly apply to mobile IORT electron systems. More specifically, the charges to this Task Group are to: i) identify the key differences between stationary and mobile electron linear accelerators used for IORT, ii) describe and recommend the implementation of an IORT program within the OR environment, iii) present and discuss radiation protection issues and consequences of working within a non-dedicated radiotherapy environment, iv) describe and recommend the acceptance and machine commissioning of items that are specific to mobile electron linear accelerators, and v) design and recommend an efficient quality assurance program for mobile systems.

I. INTRODUCTION

Intraoperative radiation therapy (IORT) has had a long history in cancer management. The earliest concept of IORT as a cancer treatment modality was introduced in 1909, when Carl Beck attempted to treat patients with gastric and colon cancer.¹ Beck irradiated seven patients with inoperable gastric cancer and one patient with colon cancer by pulling the tumor into the abdominal wound and irradiating it. The treatments were unsuccessful due to low beam energies, low dose rates, and limited radiotherapy equipment, thus hindering these early efforts. It was not until 1984 in Japan,² that IORT treatment techniques using megavoltage radiation produced by a linear accelerator (linac) became successful. Therefore, modern IORT practice dates from the work of Abe et al in Japan^{3,4} published in the early 1970s and 1980s. The practice of IORT was started in the United States in the late 1970s by Goldson at Howard University,⁵ Gunderson et al at Massachusetts General Hospital,⁶ and Tepper and Sindelar⁷ and Fraas et al⁸ at the National Cancer Institute.

Initially, IORT flourished in both the academic and community hospital setting. In 1992, Coia and Hanks⁹ reported on a pattern-of-care study that indicated that of 1293 radiation oncology facilities in the United States, 108 reported doing IORT, and 29 of those had two or more residents. With approximately 90 residency training programs in existence at that time, that means that roughly one third were performing IORT. Fewer than 30 centers are now performing IORT. The reasons for this decline in interest are two fold. First, establishing the usefulness of IORT as adjunct therapy has been difficult. Single-institution experiences have suggested the usefulness of IORT for primary T4 and recurrent rectal cancer,¹⁰⁻¹³ retroperitoneal sarcoma,^{14,15} pancreatic cancer,¹⁶⁻¹⁸ and selected recurrent gynecologic¹⁹⁻²¹ and genitourinary malignancies.²²⁻²⁵ Because of the difficulty in accruing large numbers of patients for these disease sites, it is unlikely that phase III studies evaluating the utility of IORT as a definitive therapeutic modality could be performed unless this were done on an international basis. The exception could be in the area of breast cancer, where significant numbers of patients have already been treated in Europe. Secondly, the majority of centers use their conventional linacs to perform IORT. In this case, the anesthetized patient must be moved to a sanitized treatment room, accompanied by operating room (OR) personnel. This is technically difficult and relatively inefficient, with the linac often unavailable for conventional treatment for a considerable time for room preparation and waiting for the patient. The uphill battle faced by proponents of IORT is the high cost of a dedicated facility in the OR. A dedicated linac in an OR is no longer a cost-effective option for any hospital when the costs of the machine and radiation shielding are included.

The entry into the field of IORT of mobile linacs that can be used in existing ORs with reduced shielding requirements makes the cost and logistics of setting up an IORT program much easier and therefore provides a stimulus to the field. Two manufacturers of mobile linacs are Intraop Medical Incorporated of Santa Clara, California, which manufactures the Mobetron (Fig. 1), and Hitesys of Aprilia, Italy, which manufactures the Novac7 (Fig. 2). Currently, 26 mobile units are installed in the United States and Europe.²⁶ Thus, there has been a resurgence of interest in IORT in recent years.

By now, many of the new mobile units have been in operation for several years and we have gained important experience in mobile IORT technology. Although there are many similarities between IORT treatments via stationary units and mobile units, several important considerations are unique to mobile units. This installed base of mobile linacs and the degree of clinical activity that is currently being carried out motivates a review of all the physics procedures associated with operating these units in a clinical setting.

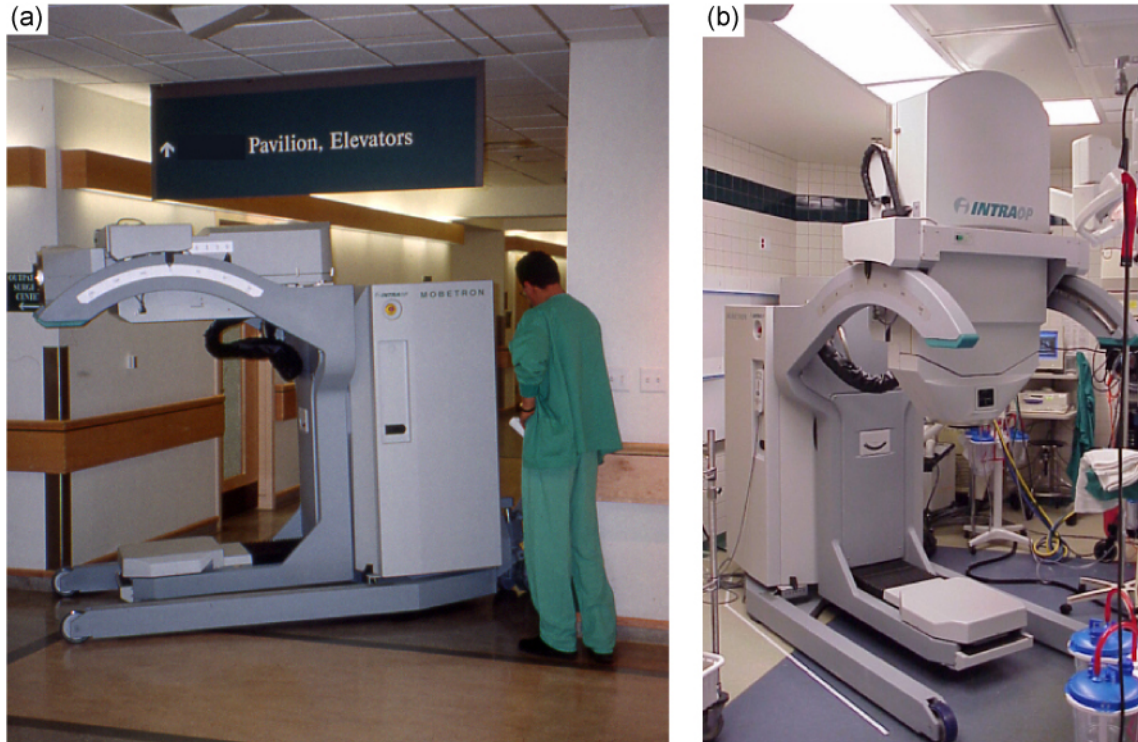


Fig. 1. (a) The Mobetron unit being moved to the operating room. The gantry is in the “transport mode” configuration. Note the height of the unit is comparable to the average height of a person. (b) The unit in its full upright position (“treatment mode” configuration), ready for treatment.

The purpose of this Task Group (TG-72) is to provide sufficient information for a physicist to contribute to the physical aspects of the planning process, such as room selection, estimation of required radiation shielding, and adequate selection of treatment equipment for the prospective IORT program, and to perform the required acceptance tests and commissioning to bring one of these units into clinical operation. There are significant differences between the two mobile systems in their mechanical design, acceleration methodology, dosimetry, and docking. Both the Mobetron and Novac7 are approved by the U.S. Food and Drug Administration (FDA), although there are no Novac7 units currently operating in the United States. The concepts and approaches discussed in this report should, in general, apply to the installation of new IORT programs using mobile linacs, regardless of manufacturer.



Fig. 2. The Novac7 in its normal mode for treatment.

The goal of this Task Group is to provide information on the physical aspects of clinical implementation of an IORT program with a mobile linac. This report complements the work of previous Task Groups on IORT²⁷ and electron-beam dosimetry.^{28,29} An overview of the differences in equipment and procedure for IORT done with a mobile linac is presented. This is followed by a discussion of IORT procedure in the OR, radiation shielding, acceptance testing and commissioning, and quality assurance (QA). The report concludes with a section on future considerations.

This Task Group has been careful to follow current AAPM practice in the use of prescriptive injunctions such as “*must*,” “*shall*,” and “*should*.” Imperatives such as “*must*” or “*shall*” apply to matters of compliance with law or regulation. “*Recommendations*” are applied to procedures that the Task Group deems important to follow, although a physicist may always choose alternatives after careful consideration. “*Should*” is used to identify suggested procedures to address significant QA issues for which a variety of approaches are reasonable. An abridged version of this report is published in *Medical Physics*.³⁰

Because the Mobetron is the only unit currently in use in the United States, this Task Group cannot refer to genuine experience with the Novac7. Therefore, this Task Group performed a survey of European Novac7 users. A questionnaire was formulated to gather information on physical differences between the Novac7 and other types of accelerator. This questionnaire was distributed to the physicists in charge of nine European installations. Three of the addressed institutions responded. Their answers and contributions are the basis for TG-72’s comments and recommendations specifically concerning the Novac7.

II. IORT USING MOBILE VERSUS STATIONARY LINEAR ACCELERATORS

Stationary and mobile linacs for electron beam IORT have many similarities. Both make use of shallow-penetrating radiation. Applicators are used to confine the beam to the volume of interest within the surgical area. Treatment is performed under sterile conditions with the patient anesthetized. Radiation is delivered in a large single fraction. Multiple fields may be used to treat different areas, treat larger fields, or conform better to the target volume. Beam modifiers include bolus, placed at the end of the applicator or on the patient surface, to increase surface dose (with reduced beam penetration), and absorbers such as lead, for shielding critical structures or field matching.³¹⁻³³ A typical IORT treatment using a mobile unit has been described by Domanovic et al³⁴ in detail in a case study in which IORT was used on a patient with sigmoid carcinoma.

In this report we concentrate on the differences in IORT delivery with mobile linacs. The logistics for treating patients in the OR differ from those when treating in a conventional linac vault and some of these differences apply to any linac (mobile or stationary) when used in a dedicated OR. Logistics for treating patients in the OR are different from those for treating patients in a radiation oncology suite. When a linac in a radiotherapy department is used, the patient must be transported, under anesthesia, from the OR to the treatment room, maintaining sterile conditions at all times. The linac will not be available for normal patient treatments for considerable time while the room is prepared for IORT and the patient is set up for treatment.

Mobile units and dedicated stationary units both permit treatment in a sterile OR. The anesthesia equipment is readily available, and the OR staff is well versed in sterile procedure. Special treatment accessories are required for both units, including a couch (surgical bed) to facilitate patient setup. A primary concern is radiation protection during treatment and daily QA. Mobile IORT units are designed primarily for use in an unshielded OR; therefore, exposure limits typically restrict their use to the treatment of a small number of patients per week plus the required daily QA and warm-up. To prevent excess exposure in adjacent rooms, especially on the floor below, the maximum beam energy is limited to 10-12 MeV, limiting target coverage to a depth of a few centimeters. A beam stop is incorporated in some designs, which may interfere with patient set-up. In addition to an unshielded OR, one must also plan for a facility for dosimetry and maintenance (which can be the storage room) providing sufficient structural shielding for commissioning, extended dosimetry (e.g., annual calibrations or experiments), and maintenance and adjustment contingencies. Some users have reduced this need by performing preadjustment and commissioning at the manufacturers' facilities.

The application-specific design of mobile units can lead to advantages over conventional units adapted to IORT. For example, electron beams could well have flatter beam profiles than conventional linacs, and the range of motion of the treatment head gives more flexibility in setting up the patient. On the other hand, limitations on these units are imposed by practical concerns of storage, transport, treatment setup and radiation protection.

Details that differ for mobile units in program implementation, including selection of the rooms required for the different procedures (commissioning, treatment, and storage), are dealt with in Section III. Radiation protection issues, arising from the higher leakage and scatter in an unshielded OR, are presented in Section IV. Differences in commissioning, including output calibration, are discussed in Section V.

III. IMPLEMENTATION OF AN IORT PROGRAM WITHIN AN OPERATING ROOM ENVIRONMENT

A successful IORT program within an OR environment requires careful planning, involving coordination of tasks with timely and efficient communication among several departments. These departments generally include operative services (usually referred to as the OR), radiation oncology, surgery, anesthesiology, and engineering. Depending on the institution, the engineering support personnel may be part of the radiation oncology department. The IORT team and the role of each member of this team have been clearly defined by Task Group 48²⁷ and therefore will not be dealt with in this report. Other support personnel,²⁷ such as housekeeping, security staff, transport personnel, and elevator operators, will not be needed because the unit will be in the OR where all IORT treatments will be delivered. Each department will have a significant role in the implementation of such a multi-disciplinary program. Consequently, a team approach should be embraced from the beginning.

Implementation of an IORT program using a mobile unit³⁵ in the OR includes staff preparation, documentation of specialized procedures, and selection of the OR(s) and surgical bed(s).

The following steps will facilitate smooth and efficient implementation of a mobile IORT program:

- a) Interdepartmental meetings early in the planning phase, involving all relevant departments.
- b) A site visit to an institution performing IORT using a mobile system.
- c) A written proposal for program implementation, tailored to the institution.
- d) Development of written procedures.
- e) Selection of the OR(s).
- f) Selection of the surgical bed(s).
- g) Education of staff involved in the IORT procedure and OR staff peripheral to the program.
- h) Scheduled training in the OR.
- i) One or more "dry runs" before the first IORT procedure.

At the beginning of such a program, we believe it is important to have all members of the IORT team involved in all of the initial procedures so they can go through the learning process rapidly, implement the improved methods efficiently, and reach optimum performance of IORT. The training of the rest of the OR staff should follow once the initial IORT team reaches an acceptable level of confidence.

A. Interdepartmental meetings

One of the first steps is to have an interdepartmental meeting involving all of the relevant departments. The primary purpose is to identify the needs and concerns of each department in all aspects of the program. These include the IORT procedure, adequacy of existing policies, equipment, space, storage, additional personnel, initial patient scheduling, notification of all departments involved, and other concerns. For instance, the notification of all departments of a potential IORT case is necessary to ensure that the radiation oncologist, medical physicist, radiation therapist, surgeons, nursing staff, and anesthesiologist will be available on the day of the surgery. One desired outcome of such a meeting would be to identify a member from each department to act as a contact person. This person would keep the rest of the department updated on the progress of the implementation of the program or on any issues that may rise during its course and therefore need to be attended to. Meetings would continue on a regular basis until the procedure becomes routine.

B. Site visit

A site visit to an established program would be useful to allow the staff to become acquainted firsthand with all aspects of mobile IORT, including program preparation and the dynamics and logistics involved in delivering IORT treatments, and to observe at least one IORT procedure. The multidisciplinary team making the site visit should include at least a surgeon, a radiation oncologist, a medical physicist, an anesthesiologist, and OR nurses for educational and perioperative services. This team would fulfill a previously drawn agenda, with members from each discipline meeting their counterpart to gain from their experience with challenges one may encounter and practicalities one should consider.

C. Program implementation proposal

The site visit should be followed by a written proposal containing recommendations for implementing the IORT program within the team's institution, adapted to their particular environment and policies. A sample of such recommendations can be found in a report by Beddar et al,³⁵ which includes an itemized list of recommendations, a discussion of each item, and a presentation of corresponding actions that need to be taken.

D. Development of written procedures

Written procedures specific to IORT in the OR should be developed in concert with all involved parties and finalized before scheduling the first IORT case. These procedures are likely to require updating during the early stages of an IORT program and should be reviewed on a regular basis. The mobile linac should be moved to the OR and the daily QA procedure should be done before the start of surgery. Furthermore, it has been found practical to schedule IORT early in the day, preferably as the first case of the day, to avoid keeping the multidisciplinary team in a waiting status until late hours, in case, for example, other surgical cases require longer operating times than expected.

E. Selection of various rooms including OR(s)

1. Operating rooms designated for IORT treatment

The primary criterion for the selection of an OR for IORT treatment is a room the accelerator can be easily moved into and out of and which meets radiation protection guidelines with minimal impact on the work conducted in adjacent rooms. Additional criteria are as follows:

- (a) A large room is preferable, to reduce the dose to adjacent areas.
- (b) The room should be large enough to house all the components of the mobile system, including the accelerator and the modulator, and to accommodate the full range of motion of the gantry.
- (c) A corner location or a location adjacent to sparsely occupied or unoccupied areas (including areas above and below the OR) is preferred to reduce radiation exposure and, hence, to permit higher workloads.
- (d) The structural strength must be sufficient to accommodate the weight of the mobile accelerator with all of its auxiliary components.
- (e) Electrical requirements to operate the mobile system should be adequate or easily installable.
- (f) Video monitoring of patients from outside the OR should be possible.
- (g) Anesthesia monitors and infusion hosing should be mobile enough to follow the patient easily and quickly when moved toward and underneath the mobile accelerator's gantry head.

2. Criteria for selection of the storage room

The closer the storage room to the designated OR, the better. This will minimize the time and effort needed to transport the system and all its components back and forth between storage and the OR. Other criteria are as follows:

- (a) Structural strength in the storage room and along the transportation routes (including elevators) must be sufficient.
- (b) Doors, hallways, corridors, and elevators must be wide enough to allow for safe passage of the mobile accelerator
- (c) The storage room must be equipped with electrical power, for example, to maintain a vacuum in the accelerator when it is not in use.

3. Criteria for selection of the dosimetry facility

An additional facility is highly recommended for maintenance and dose measurements, including commissioning, annual calibrations, and testing experiments. In the case where it is impossible for a given institution to afford such a facility, then all the above tasks can only be performed inside the OR (where the mobile unit is located) outside normal working hours, when access to all adjacent areas, including rooms above and below the OR, can be restricted. In such a situation, exposure limits for the physicists and other personnel would impose restrictions on how much beam-on time would be allowed during measurements. For instance, Mills et al³⁶ performed commissioning of a Mobetron linac in an unshielded area. Because of radiation safety concerns, they were limited to 30 minutes of beam-on time per week. This required use of film dosimetry rather than ionization chambers in water to obtain isodose curve data, as discussed in Section V.

The primary criteria for the dosimetry facility are that the accelerator can be easily moved into and out of the room and that radiation protection guidelines are met with minimal effects on the work conducted in adjacent rooms. Additional criteria are as follows:

- (a) The room should be adequately shielded for its intended use and equipped with the safety facilities required for a radiation vault, such as door interlocks and status indicators (signal lights).
- (b) The selected room should be large enough to house all the components of the mobile system, including the accelerator with the treatment head, the modulator, and the remote control console. Allowing for the full range of motion is not necessary; for example, the full range of gantry orientation is important, but full vertical motion is not necessary. An existing radiation treatment vault may serve, but consideration will need to be given to whether the room is large and high enough to permit the IORT unit to be set up.
- (c) A corner location or a location adjacent to sparsely occupied or unoccupied areas (including areas above and below the room) reduces the effect of radiation exposure and, hence, may permit higher workloads.
- (d) The structural strength must be sufficient to accommodate the mobile accelerator with all of its auxiliary components.
- (e) Power requirements should be adequate.
- (f) The structural strength along the transportation routes (including elevators) must be sufficient.
- (g) Doors, hallways, corridors and elevators must be wide enough to allow for safe passage of the mobile accelerator. If an existing vault is to be used, the possibility of transport through the treatment door and maze will need to be examined.

F. Criteria for the selection of an IORT surgical bed

The surgical bed is a major piece of equipment that needs to be carefully selected. The bed must be suitable for performing IORT using a mobile linear accelerator. The economical approach is to use a standard surgical bed with tilt capabilities and an extension that permits longitudinal repositioning of the patient. The surgical site is positioned on the surgical bed such that the bed support does not interfere with the accelerator legs or beam stopper when the patient is moved into treatment position (docking procedure).

The surgical bed should provide a wide range of motion to facilitate alignment of the applicator with the treatment head of the linac. This includes vertical travel, lateral and longitudinal travel, and tilt around both the lateral and longitudinal axes. The longitudinal travel of the top of the bed should extend far enough to move a tumor site, which will be over the column of the couch for surgery, to a position where the bed support stand does not interfere with the accelerator. The surgical bed would best provide fine adjustment to facilitate fine-tuning for either the soft or hard docking approach. Tabletop motions should be possible with the bed in an unlocked state so that they can be performed simultaneously with table rotation around the column.

G. Education

Another important phase of program implementation is staff education. This may be done using a combination of seminar series, grand rounds, in-service training, or other types of informative forums. All components of this multidisciplinary program should be dealt with, including radiation oncology, medical physics, radiation safety, perioperative nursing, and anesthesiology. Radiation safety is a critical subject that deserves special attention³⁷ because IORT is delivered in an OR and the personnel in that area may not be familiar with linacs. It is customary for most OR departments, at least in the United States, to schedule one hour once a week for educational conferences, with attendance mandatory for all OR personnel. No cases or other OR activities can be scheduled at that time. This would be an ideal time to schedule these educational sessions to allow almost all OR personnel to attend. Similarly, all radiation oncology staff that are to be involved in IORT need to be trained in OR procedures (e.g., scrubbing procedures and how to move around in an OR without violating the sterile field).

H. Training in the operating room

An important step in the preparation process is to schedule an all-day training session in the OR. The objective of the training session is to allow OR staff to become familiar with the specialized IORT equipment and auxiliary accessories. Figure 3 illustrates typical accessories used in IORT treatments.

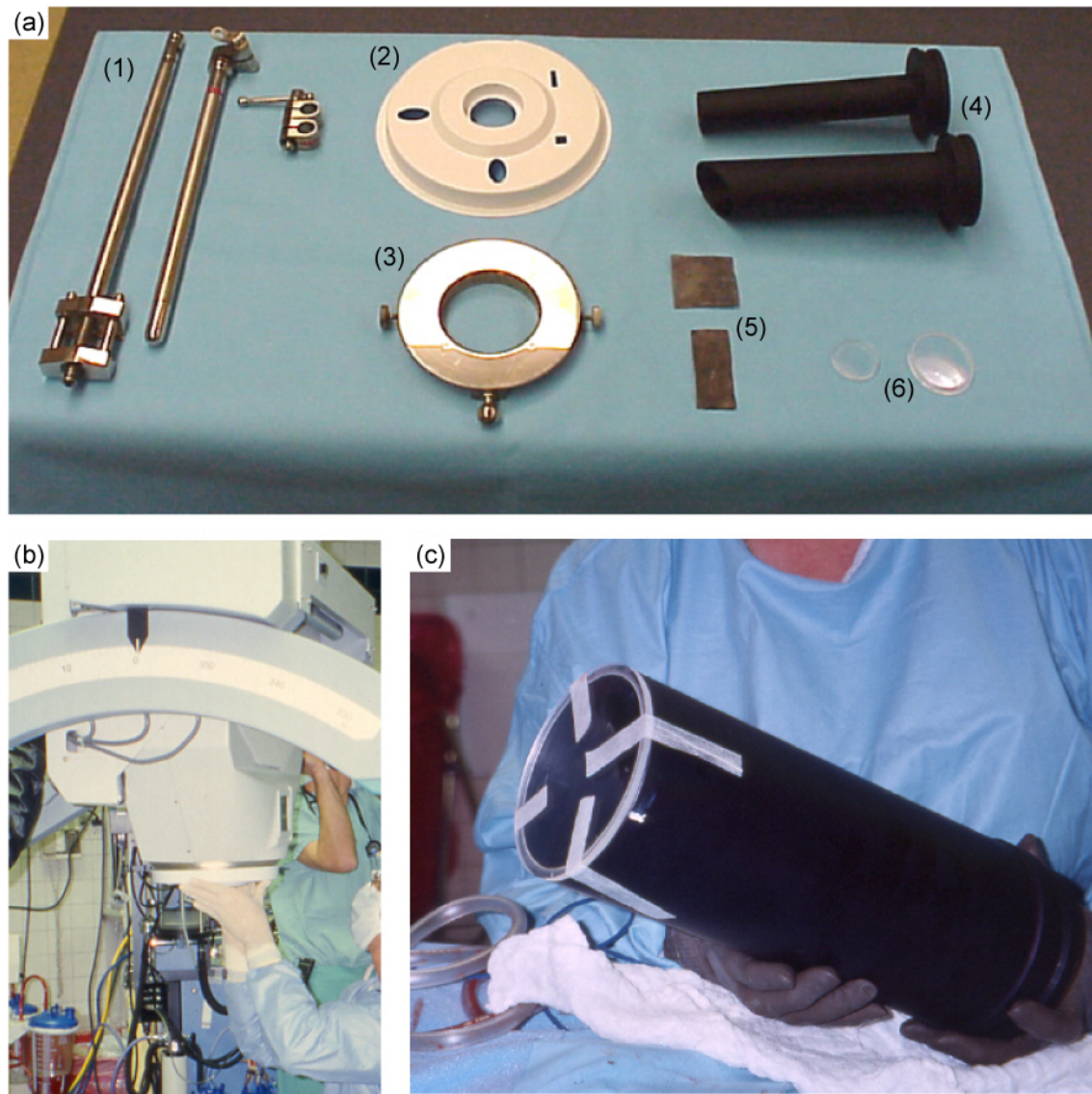


Fig. 3. (a) Example of accessories used by a mobile IORT unit, including (1) the components of a modified Bookwalter clamp, (2) sterile gantry cap, (3) mirror ring, (4) electron applicators, (5) lead shields, and (6) Lucite bolus. (b) The sterile cap being placed on the gantry for treatment. (c) The electron applicator, with a bolus attached to its end with Steri-Strips, ready for placement onto the tumor bed.

The following are topics covered in a typical session designed for the Mobetron linac:

- (a) Introduction to the use of the mobile linac.
- (b) The daily warm-up of the machine and QA.
- (c) Demonstration of the accessories necessary for the IORT procedure.
- (d) Attachment of an applicator to the surgical bed.
- (e) Preparation for treatment delivery and moving the surgical bed toward the docking area underneath the mobile accelerator gantry head.
- (f) Docking the gantry for treatment delivery.
- (g) Introduction to safety features and interlocks of the system.
- (h) Dose prescription and monitor-unit (MU) calculation.
- (i) Simulation of radiation treatment delivery.

(j) Post-treatment rearrangements to resume the surgery.

A similar format could be adopted for other mobile IORT units. The initial implementing members of the IORT team should be present at the session to address the questions and concerns from the staff and demonstrate the handling and use of the equipment to future users. Beddar and Krishnan²⁶ presented a typical clinical case (i.e. a retroperineal sarcoma) in which a mobile linac was used for IORT. The authors discussed the roles and coordination of multidisciplinary team members during IORT delivery.

I. The “dry run” sessions

Finally, it is very useful to have one or more "dry run" sessions³⁵ about a week before the first IORT procedure. During this session, a mock procedure approach is adopted, and the team should go through all the steps that would be involved in a real case, following their IORT checklist. A sample of such a checklist is presented in Appendix 1. A critical phase of this session is the attachment of the Bookwalter clamp or an equivalent accessory to the treatment applicator, moving the surgical bed toward the machines with all of the IV poles and other anesthesia equipment, and finishing with the docking of the gantry head onto the treatment applicator.³⁸ This approach is strongly suggested because the dry run will help to identify potential problems and will allow their resolution before the first IORT procedure is conducted. From our experience, centers that used this approach provided the opportunity for team members to collaborate more efficiently with each other and reach a comfortable level of interaction before that ultimate day when everyone would be behind a sterile mask.

Even though some of the tasks or steps undertaken during the IORT procedure may seem trivial, it is important to be sure everyone understands them. It is also important that the team members get a chance to discuss the dynamics of the procedure. These exercises will also help with team building— a crucial aspect of a successful IORT program.

A staff in-service session and review for IORT should be conducted yearly. This in-service session consists of training and reviewing the IORT treatment procedure and equipment used and should include the emergency procedures and safety features of the mobile linac. A team composed of a medical physicist, a radiation oncologist, and a certified OR nurse should conduct these reviews and training sessions. This is a good time to have a sign-up sheet to document the in-service session and training of hospital employees involved in special procedures. This documentation could be used to fulfill hospital and state regulations required for special procedures.

Training of personnel for in-house maintenance and QA of a mobile linac is an additional important consideration. In-house capabilities should include the ability to perform quick repairs in cases where the accelerator breaks down during an IORT treatment. Otherwise, the patient will not benefit from an IORT treatment because a second surgery would be unlikely. Therefore, special training should be considered.

IV. RADIATION PROTECTION

Mobile electron linacs are meant to be placed in existing OR suites that have been constructed with no special shielding requirements. These systems are designed with the

concept of being utilized to deliver radiation in non-shielded OR rooms and are provided with a beam stopper as illustrated in Figs. 4 and 5. The beam stopper for certain mobile IORT units is designed to track the movement of the gantry in all directions so that it will always intercept the primary beam, whereas other beam stoppers must be manually positioned. Radiation leakage results mostly from photon leakage, scatter, and x-ray contamination from the electron beams. The electron scatter produced in the OR has a limited range, and most conventional walls are sufficient to stop the electron scatter produced in the OR.³⁷ Therefore, radiation safety assessments for these mobile systems consist of performing radiation surveys around the ORs that are intended to be used for IORT and limiting the number of IORT cases that can be performed in any given OR so that the maximum exposure limits are not exceeded.

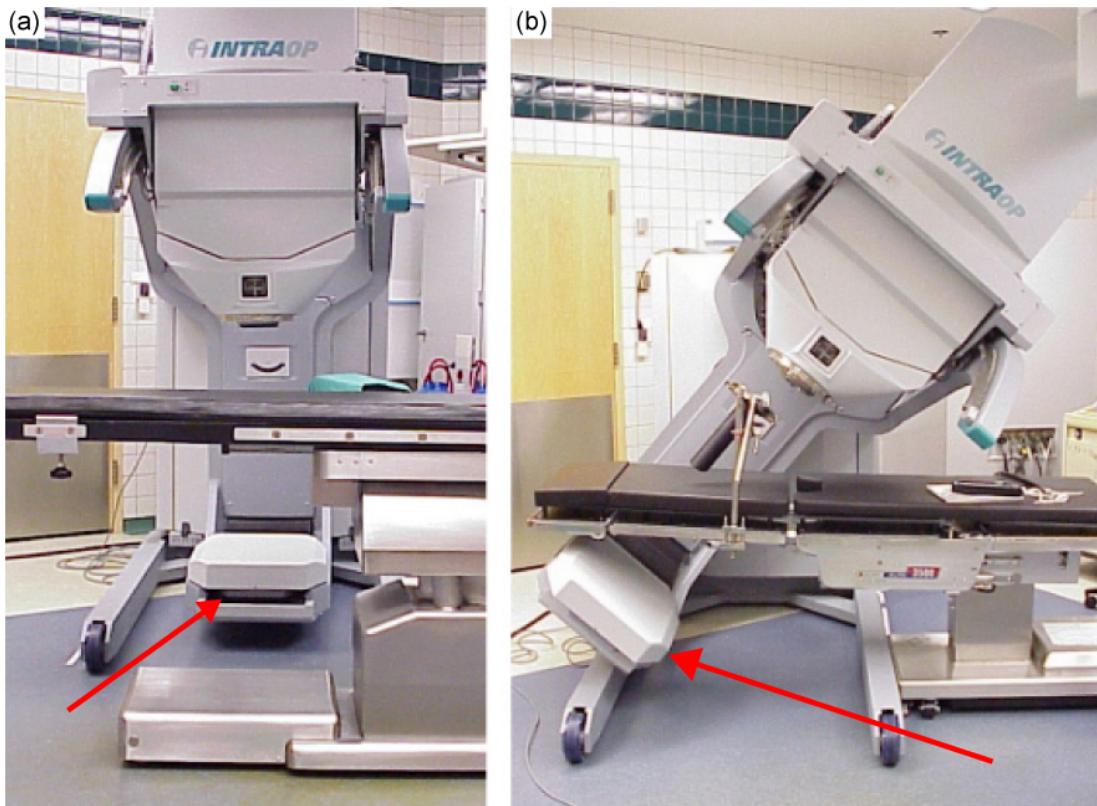


Fig. 4. Illustration of a beam stopper tracking the movement of the gantry for a Mobetron IORT unit. (a) Unit in the normal position at a gantry angle of zero. (b) Unit positioned at an arbitrary gantry angle, exhibiting the alignment of the beam stopper with the gantry. The beam stopper is marked with red arrows.

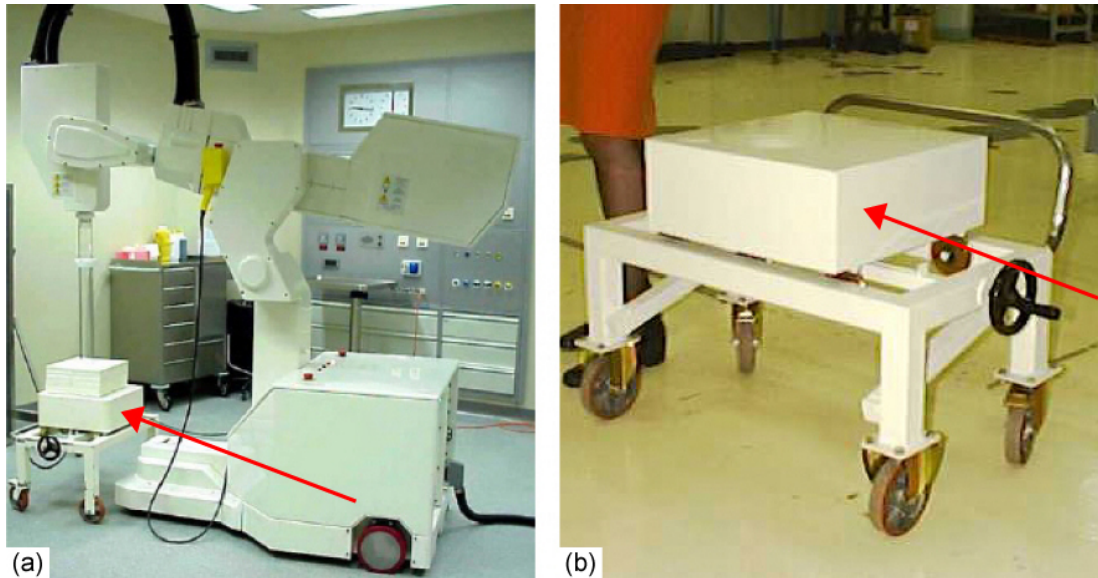


Fig. 5. A beam stopper for the Novac7 mobile IORT unit. (a) Unit in the normal position with the beam stopper placed directly below the gantry. Note that an electron applicator is attached the gantry and is docked on top of a phantom, illustrating a typical setup for quality assurance. (b) Close-up of the beam stopper in transit. The beam stopper is marked with red arrows.

A. Regulatory considerations

Limits for radiation exposure of personnel are usually regulated by national or state government agencies. In the United States, the National Council on Radiation Protection and Measurements³⁹ and the federal government promulgate standards.^{40,41} In addition, standards may vary between countries or states and may change with time. This Task Group (TG-72) believes the following to be absolute requirements:

- (a) The most current exposure levels applicable to the geographic location (country or state) of the mobile accelerator installation *shall* be adopted.
- (b) The site plan *must* be approved by the appropriate regulatory agency before delivery of the unit takes place.
- (c) A radiation survey *must* be performed for every OR where the unit will be used and for any other room where the unit could be used (e.g., the dosimetry room).
- (d) The survey *must* be performed for the highest electron energy, largest applicator, and for every anticipated and possible clinical configuration of the unit.
- (e) Electrical requirements *should* be evaluated for the ORs selected for IORT, the storage area, and any other room where the unit could be used.
- (f) Floor load capacities *should* be evaluated for the rooms selected for IORT, the storage area, any other room where the unit could be used and all possible transportation routes that could be used.
- (g) Exposures accrued by personnel *must* be evaluated according to a radiation safety Quality Management Program

B. Radiation site plan

1. Treatment operating rooms

The manufacturer will ordinarily provide a three-dimensional radiation leakage and scatter exposure profile for the IORT unit. If the unit is capable of a range of motion,

several profiles will be required to complete the site plan properly. The anticipated workload of each mode and energy will figure into the site plan. This workload, calculated for ORs, should include the MUs for machine warm-up and daily QA but should not include the workload for commissioning and annual QA measurements. (The workload for commissioning and annual QA is discussed in the following section.) Mills et al³⁶ calculated typical workload limits for existing ORs using the Mobetron system and found that it is possible to treat up to four patients per week in an existing, unshielded OR. Therefore, it may be necessary to consider more than one OR for IORT treatments if a higher patient load is anticipated.

The resulting site plan should specify anticipated operating restrictions and limit the time or number of MUs allowed for each mode and energy in a week. Anticipated radiation exposure levels per week are calculated for any area potentially occupied by personnel or members of the public.

It is desirable to declare all areas outside of the OR to be non-controlled. The OR *should* be considered non-controlled, except during the time the patient is irradiated with no personnel in the room. Usually, it is not practical to declare an OR to be a controlled area because a large number of physicians, nurses, and other personnel need access to the OR suite on a daily basis for procedures not related to IORT. During the time the patient is being irradiated, the access from ancillary doors other than the main OR door entrance *shall* not be allowed. This Task Group *recommends* that all ancillary doors *must* be provided with a locking mechanism and that such mechanism *shall* be used before initiating the irradiation. Temporary warning signs may also be posted on the doors. The purpose is to prevent any personnel accessing the room during the delivery of the treatment.

2. Commissioning and annual quality assurance location

The shielding of a mobile accelerator is designed for infrequent use for IORT, not for continuous use in an unshielded room.³⁶ Therefore, it is strongly preferred to establish a dedicated vault or location for commissioning and annual quality assurance activities. A separate site plan must be developed for the location chosen for commissioning and annual QA. Even an efficient commissioning will require several hundred thousand MUs.³⁶ An annual calibration will typically require less than 100 000 MUs. If occupied areas surround the intended location, the user needs to identify the type of occupied areas, the occupancy factor, the use factor, and the maximum exposure level allowed in each of the areas by state regulations. If the vendor provides the leakage data, the maximum workload during working hours can be estimated accordingly. If the maximum workload poses a problem in the acceptance testing and commissioning schedule, one solution is to conduct the procedures outside working hours and establish temporary controls on the surrounding areas. The actual exposure should be measured as soon as the mobile unit is able to generate a beam. The measured exposure values should be used for final workload limit calculations. The workload limit is determined by the maximum allowable weekly or hourly exposure, whichever is higher, in the adjoining area that receives the highest exposure. It is very important to get radiation safety personnel involved in the process early. If the location chosen is not sufficiently shielded and posted to be a controlled area,

then steps including temporary barriers and signs, are needed to make it a controlled area during the time of these measurements.

C. Radiation survey

According to current regulatory limits in most states in the United States, the allowable exposure level for uncontrolled areas is 1 mSv per year. This corresponds to a limit of approximately 0.02 mSv per week. In addition, in a non-controlled area, no more than 0.02 mSv is allowed during any one hour. The regulatory limits allow controlled areas an exposure of 50 mSv per year. This corresponds to a limit of approximately 1 mSv per week. Controlled areas *must* be labeled appropriately, and access by members of the public *must* be restricted. The occupancy factor is 1 for controlled areas in this environment. A radiation survey of the exposure level at various locations outside the OR for the IORT unit *must* be performed in every OR in which the unit will be used. Regulatory agencies require these surveys for any external beam radiotherapy unit. The survey *must* be performed for representative and anticipated worst-case situations of possible clinical configurations of the unit. The measured exposures are used to calculate the final operational limitations of the unit. A final operational plan must take into consideration the MUs generated during patient treatment, warm-up, output, energy check, and adjustment contingencies. Considering an OR with no added shielding, it is common for only a very limited number of patients to be accommodated per week without exceeding regulatory limitations. The doses necessary for QA and beam adjustments typically amount to many times the patient doses. The necessary restrictions on the availability of the OR and the surrounding rooms and possible organizational and staff issues should be planned. The site plan should be distributed to management and appropriate physicians so that patients are scheduled to follow the regulatory limitations on the use of the unit.

D. Exposure rate measurements

Daves and Mills³⁷ performed a detailed analysis of the shielding assessment on a Mobetron unit. Their method should, in principle, be applicable to the Novac7. Their investigation provided a resource to assess shielding and patient load restrictions for any facility performing IORT with units similar to the Mobetron. Their exposure rate measurements data indicated that the Mobetron may be operated in an area with no shielding under a nominal patient load expectation. Assuming standard building materials, their results demonstrated that a workload of three to four patients per week in a given OR, including warm-up, could be easily accommodated. Such workloads should be assessed for any facility used and will be specific only to that facility. If mobile IORT units are to be used without workload limitations, then they should only be used in shielded ORs.

E. Personnel monitoring

Hospital personnel who have a likelihood of accruing significant radiation exposure should be considered for personnel-monitoring devices. All personnel regularly exposed to radiation during IORT should be assigned badges and declared radiation workers. Regularly exposed personnel include radiation oncologists, physicists, dosimetrists, radiation therapists, equipment engineers, and radiation oncology nurses. Surgeons, anesthesiologists, surgical nurses, other OR personnel, and cleaning staff are usually not assigned badges for IORT. Exposures accrued by personnel *must* be evaluated according to a radiation safety quality management program, and any significant exposures must be reported to the institution's radiation safety committee for evaluation and follow-up. This Task Group does not recommend badging OR, surgery, or anesthesiology personnel. The necessary radiation safety precautions *should* be adopted such that none of this group of workers are exposed to more than 1 mSv per year, which corresponds to the annual exposure limit for the general public.

V. Acceptance testing and commissioning

This section provides guidance and practical recommendations on the acceptance testing and commissioning of mobile electron therapy units used for IORT. Published literature relevant to IORT with electron beams includes the Task Group 25²⁹ and Task Group 39⁴² reports on clinical electron beam dosimetry, the TG-48 report²⁷ on IORT using stationary linacs, Task Group 39⁴² protocol and the Task Group 51 protocol²⁸ for clinical reference dosimetry of high-energy electron beams. However, several important considerations in IORT accelerator acceptance testing and commissioning procedures are unique to mobile accelerator units. For instance, the lengthy testing procedures that are normally carried out in the dedicated and shielded treatment room vaults for stationary accelerators generally cannot be performed in the heavily scheduled ORs designated for IORT. The radiation exposure rates from these procedures to areas adjacent to the unshielded ORs would most likely exceed the acceptable exposure limits established for stationary accelerators.

A. Acceptance testing measurements

A mobile IORT unit must pass acceptance testing according to the manufacturer's specifications. The acceptance testing procedure for a mobile IORT unit includes the following:

- (a) Radiation survey.
- (b) Interlocks and safety features testing.
- (c) Mechanical testing.
- (d) Beam characteristics tuning.
- (e) Docking system test.
- (f) Options and accessories evaluation.

The radiation survey at the testing site is conducted as soon as the accelerator is able to produce a stable beam and after a preliminary output calibration. All surrounding areas, including rooms one floor above and below, should be characterized in terms of occupancy factor and radiation control classification (controlled area or non-controlled area) based on the 10CFR20 report.^{40,41} The exposure rates in each of the surrounding

areas should be measured under the same irradiation conditions to be used for the acceptance testing procedures, especially with respect to the location of the accelerator in the room. The workload limit for the acceptance and commissioning process can be calculated from the survey result and expressed in terms of MUs per hour. The effect of the workload limit on the anticipated measurements in the testing procedures should be analyzed ahead of time. The total MUs needed for the testing procedures can be estimated based on the type of commissioning dosimetry data to be taken and the measurement devices. For example, one can make the following estimate of the total MUs needed when a water scanner is used for beam profile and percentage depth ionization measurements. Assuming the average scanning speed to be used is 5 mm/sec and the average scan length is 15 cm (the maximum Mobetron applicator size is 10 cm), the beam-on time needed per scan, t^{scan} , should be less than 100 seconds (the actual time to scan 15 cm is 30 seconds). If one percentage depth ionization curve and one beam profile will be measured per electron applicator and there are N applicators, the total beam-on time for the ionization curve and profile scanning is $T^{\text{scan}} = 2N * t^{\text{scan}}$, which is 1600 seconds—less than 30 minutes. If the accelerator has a nominal MU rate of 1000 MU/min, then 30 minutes of beam-on time would require 30 000 MU per electron energy. The total beam-on time required for the entire acceptance testing and commissioning process can be estimated in units of T^{scan} . The beam-on time for the above measurements are estimated to be less than 10 units of T^{scan} . If the workload limit significantly hinders the commissioning process with the use of a water phantom, one can consider several options to shorten the procedure. These options include: (1) reducing the MU usage when appropriate in the testing procedures by using a low MU rate, (2) replacing the water phantom scans with film, and (3) conducting measurements outside normal working hours.

All interlocks and safety features should be tested following the manufacturer's acceptance testing procedures. One should make sure that these interlocks and safety features, including the emergency off switches, are operational during the normal mode of operation of the unit (e.g., the clinical mode). The mechanical testing includes verifying the full range of gantry motion, including rotational and translational movements. The mechanical movements and controls of mobile IORT units differ significantly in design and function from those of a conventional accelerator. The mechanical movements of the gantry and treatment couch for a conventional accelerator are designed to rotate and translate with respect to a fixed isocenter. In contrast, a mobile accelerator will have no isocenter *per se*, and the geometric accuracy of treatment delivery using a mobile unit will depend solely on the accuracy of the docking. Once the electron applicator is placed inside the patient and aligned to the intended treatment area, the operator should be able to control the gantry movement in all directions available to achieve docking. The proper operation of the beam stopper, if any, should also be verified.

Beam tuning includes adjustments of the beam energy, output rate, and flatness and symmetry of the reference applicator used for output calibration. The manufacturer's installation engineer usually performs the task of beam tuning. Relative output factors,

flatness, and symmetry of all other applicators should be measured afterward by clinical physicists.

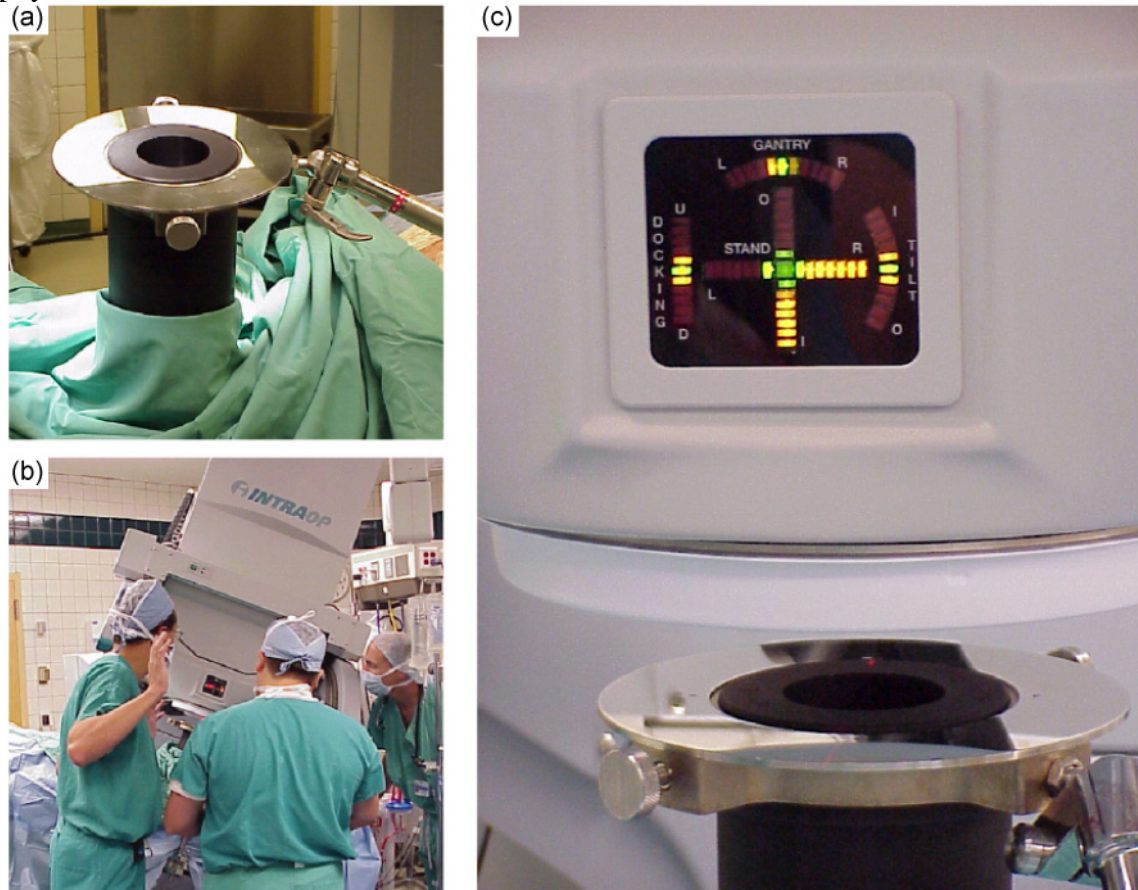


Fig. 6. The soft-docking system used by the Mobetron. (a) The electron applicator, in contact with the tumor bed, is rigidly clamped to the surgical bed using a modified Bookwalter clamp. (b) The gantry being moved for soft docking to the applicator. (c) The LED display and electron applicator. The green light in the center of the display indicates that proper alignment has occurred and the gantry is properly docked. Note the air gap ($4\text{ cm} \pm 1\text{ mm}$) between the end of the gantry and the top surface of the applicator.

Systems with soft docking, such as the Mobetron (Fig. 6), require acceptance testing of the docking system. The soft-docking system, also referred to as air-docking,^{27,43-46} is more flexible than the hard-docking system of the Novac7 (Fig. 7), in which the coupling of the electron applicator to the accelerator beam collimation system is direct and rigid.^{47,48} For the Mobetron unit, the optical docking system consists of a system of laser detecting devices mounted on the accelerator beam collimation system to assist the operator in performing the soft docking of the gantry with the electron applicator. The soft docking is achieved by adjusting the gantry's rotation angle, tilt angle, height, and two translational shifts (longitudinal and lateral) of the gantry in the horizontal plane. The status of each aspect of the alignment is shown on an LED display on the accelerator to guide the operator in the docking process.³⁸ During irradiation, the docking is interlocked for both alignments of the treatment head with the applicator and for treatment distance. Optical coupling can be very sensitive to the quality of the alignment, whereas the dosimetric quality of the treatment is likely less sensitive. We recommend that the clinical physicist evaluate the change in beam characteristics at clinically realistic

conditions when the soft-docking is not perfect in the commissioning process, when possible. Note that FDA regulations might prevent the use of a mobile IORT unit without the optical docking interlock. The TG-48 report²⁷ included a suggestion to make allowances for misalignment in soft docking because precise alignment can be time consuming and difficult to maintain in the presence of applicator motion due to patient breathing. Hogstrom *et al*⁴⁹ recommended that the user perform measurements of beam dosimetry sensitivity vs. optical docking accuracy to determine the docking tolerance for clinical use.

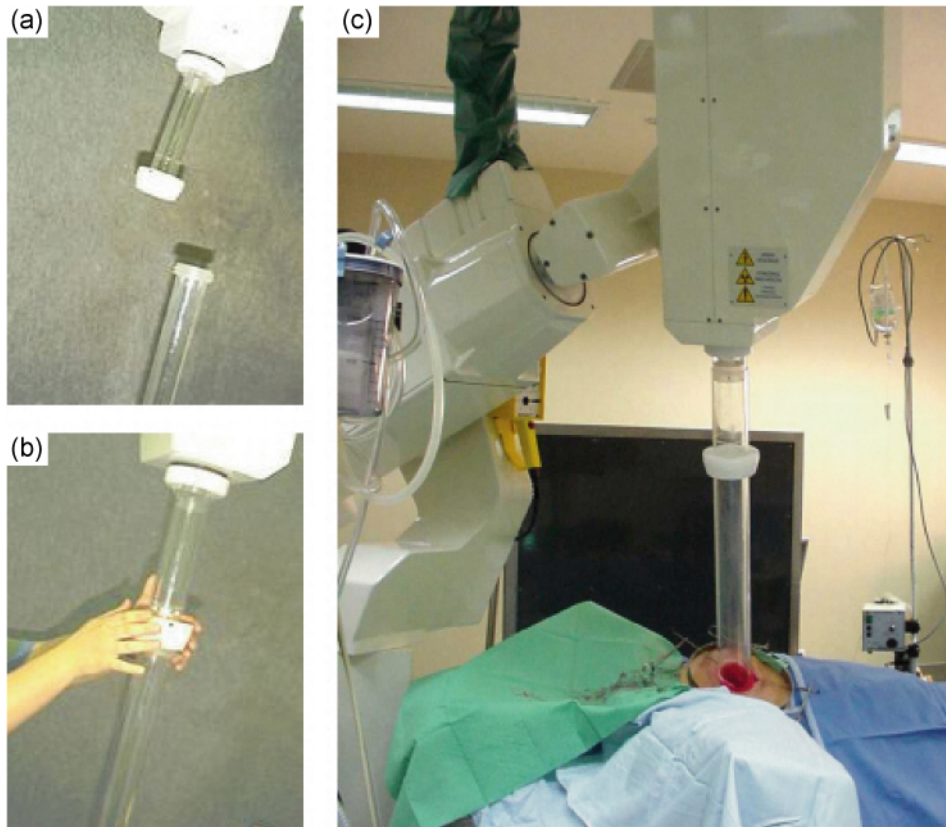


Fig. 7. The hard-docking system used by the Novac7. (a) The accelerator beam collimation system and electron applicator before docking. (b) The hard-docking mechanism. (c) The docked unit, with the electron applicator in contact with the tumor bed.

All accessories supplied with the unit should be individually examined in the acceptance testing process prior to use. The user *should* follow the manufacturer's specifications and tolerance in testing and examining the operation controls, docking system, interlocks, accessories, and any optional devices.

Details of the mobile electron IORT unit acceptance tests are specified in the acceptance test procedure document provided by the manufacturer. Table V.1, which lists the items included in the acceptance testing of Mobetron units, is shown as an example.

Table V.1: Typical procedures required for acceptance testing of a mobile IORT unit.

Procedure	Comment
Radiation Survey	Ensure no individual is exposed to radiation levels in violation of regulations, and verify the normal operation of emergency off switches.
Mechanical Inspection	Verify the movement range, speed, control, and accuracy of the gantry and beam stopper. Verify the physical sizes of all applicators.
Radiation Safety	Verify dose attenuation through the beam stopper.
Beam Characteristics	Verify beam energy, surface dose, dose rate, field flatness, symmetry, and X-ray contamination according to specifications. Verify beam energy constancy for all gantry angles.
Dosimetry System	Verify the precision of the backup MU chamber, the linearity and reproducibility of the MU chambers, and the dosimetry interlocks.
Control Console	Verify the normal function of each control on the control console.
Docking System	Verify the normal function of the optical docking system.
Options and Accessories	Verify normal function.
Safety Features	Examine all safety features (emergency off, rad-on light, and audible warning sounds.)

B. Commissioning and dose measurements

The methodology and equipment that should be used in the acceptance testing and commissioning of electron beams for IORT units *should* follow the general recommendations made in the TG-51 protocol for reference dosimetry on clinical electron beams.²⁸ This Task Group (TG-72) recommends the use of a water phantom for the beam calibration as described by TG-51. The methods for obtaining relative dosimetry measurements are at the discretion of the responsible clinical physicist, who must make the decision on the basis of multiple considerations, including radiation safety, the clinical accuracy needed for IORT treatment, commissioning time frame, resources available, and the limitations and availability of the measurement devices.

The beam characteristics commonly measured in the commissioning of a mobile IORT unit are listed in Table V.2.

Table V.2: Typical measurements used in mobile IORT unit commissioning.

Measurements	Comment
Beam profiles (depth dose and cross plane profiles)	Measurements are done for each applicator and beam energy and should extend to regions outside the treatment area.
Leakage profiles	Measurements are done for a limited sample of applicators and beam energies (including the highest beam energy) and should be made lateral to the applicator walls at various depths.
Applicator factors	Applicator factors are relative to a 10-cm circular cone, and the measurements are done at d_{max} for each applicator and beam energy.
Air gap factors	The air gap factor is the ratio of dose with an air gap to the dose without one at d_{max} . Air gap factors are measured at the appropriate depths of d_{max} for each combination of applicator and beam energy.
TG-51 output calibration	Output calibration is done at the TG-51 reference depth d_{ref} using the 10-cm circular applicator. From these measurements the dose/MU at d_{max} is determined.

This Task Group will not make any further recommendations as far as what type or model of ionization chamber or detector should be used for clinical reference dosimetry, because this has been covered elsewhere.^{27-29,42,50-52}

However, several unique aspects in the commissioning of a mobile IORT unit deserve the user's attention. Mobile IORT units have dose rate outputs several times higher than conventional accelerators so that they can deliver large doses (10 to 20 Gy) in a short time (1 to 2 minutes). The ion recombination correction factor, P_{ion} , depends on the dose per pulse in accelerator beams and thus will change if either the pulse rate for a fixed dose rate or the dose rate is changed.^{28,29,53} At the high dose rates used by mobile IORT units, cylindrical chambers can have large values of P_{ion} . For instance, the value of P_{ion} for a PTW cylindrical chamber (Model 30006, inner radius 3.05 mm) exposed to a dose rate of 10 Gy/min is greater than 1.05. However, P_{ion} did not exceed 1.03 for a Markus PTW parallel plate chamber (Model 23343, sensitive volume 0.055 cm³). This Task Group recommends that chambers with P_{ion} values outside the acceptable range specified by TG-51 *should not* be used for output calibration.

Furthermore, it is essential that the dose per pulse and hence the dose rate be kept fairly stable during data collection, because P_{ion} will no longer be constant and large fluctuations in the dose rate over time will therefore affect ionization measurements. For instance, when measuring applicator output factors, it has been observed that, as the dose rate changed from 10 Gy/min to 15 Gy/min over the course of one hour, the ion recombination P_{ion} also changed, and thus the output factors appeared to be changing. However, in normal operation where the beam is not used continuously for long time periods, the dose rate of a mobile linac is not expected to vary significantly. For instance,

Beddar⁵⁴ examined the stability of a Mobetron linac over twenty quality assurance trials and found variation within $\pm 2\%$. The author also found that hours of inactivity, with the unit powered on (in standby mode) either throughout the day or overnight, led to variations in output of about 1%.

Piermattei et al⁵⁵ found that, with high dose values of 30 to 60 mGy per pulse for the Novac7 (compared with 4 to 6 mGy per pulse for the Mobetron), the error in dose resulting from the use of a parallel plate chamber could be as high as 20% due to overestimation of P_{ion} . For different pulse rates, they measured P_{ion} from the ratio of the dose measured by radiochromic film to that measured by the parallel plate chamber uncorrected for ion recombination. Other users of the Novac7,⁵⁶ because of this ion recombination issue, have used chemical Fricke dosimeters, provided by the mailed dosimetry service at the Italian Primary Standard Dosimetry Laboratory in Rome, and radiochromic films for dosimetry. Di Martino et al.⁵⁷ have determined the relationship between P_{ion} and the dose per pulse based on generalized Boag theory. They found good agreement between percent depth dose (PDD) curves evaluated using Gafchromic films and parallel-plate ionization chambers with values of P_{ion} determined for doses of 30 to 130 mGy per pulse. This Task Group recommends determining P_{ion} using the standard two-voltage technique described in TG-51 for doses less than 10 mGy per pulse, and using an alternate method for higher doses per pulse as suggested by the Novac7 users.⁵⁵⁻⁵⁷

Another aspect of commissioning a mobile IORT unit is the lack of a gantry isocenter and a surgical bed with precise movement control. Additional time is needed to set up a water phantom. The beam stopper on a mobile IORT unit may also prevent the use of the water phantom support system (e.g., table support) that normally comes with most commercial phantom scanners. It may be necessary to build a special low table that straddles the beam stopper.

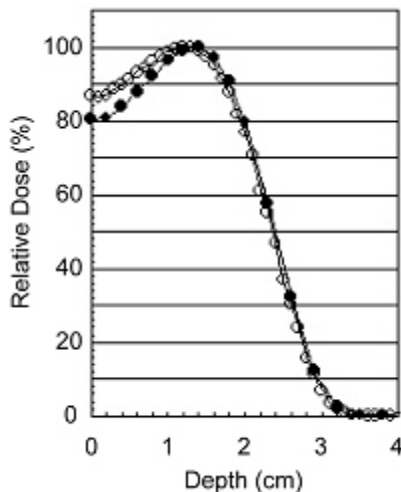


Fig. 8. The central axis percentage depth dose for a 10-cm circular applicator from a stationary linear accelerator (Siemens ME, filled circles) and a mobile linear accelerator (Mobetron, open circles) for a 6-MeV electron beam.

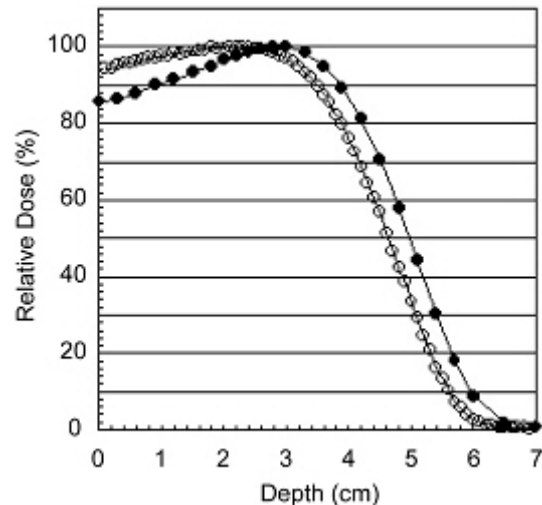


Fig. 9. The central axis percentage depth dose for a 10-cm circular applicator from a stationary linear accelerator (Siemens ME, filled circles) and a mobile linear accelerator (Mobetron, open circles) for a 12-MeV electron beam.

Figures 8 and 9 show the central axis depth dose curves for 6- and 12-MeV electron beams respectively from a stationary linac (Siemens) compared with those from a mobile linac (Mobetron) for a 10-cm electron applicator. All depth dose curves were measured using the method described by the TG-51 protocol.²⁸ The depth dose curves of the mobile unit have a higher surface dose, which can be attributed to a greater proportion of energy-degraded, scattered electrons in the beam. Figures 10 and 11 show beam profiles at the depth d_{\max} for 6 and 12 MeV electron beams obtained from a conventional accelerator (Siemens) and a mobile IORT unit (Mobetron). The difference between the flatness and symmetry curves shown in Figures 10 and 11 can be attributed to differences in the source-to-surface distance variation and the scattering foil design. The mobile units have smaller horns in their beam profiles, a desirable feature for delivery of a uniform dose within an IORT field. Typical isodose distributions for IORT mobile units are shown in Figs. 12 (Mobetron) and 13 (Novac7). Leakage beam profiles that extend beyond the applicator walls are needed to estimate the dose to normal tissue close to the applicator. This was discussed in the TG-48 report,²⁷ which also included typical scans measured lateral to the applicator walls.

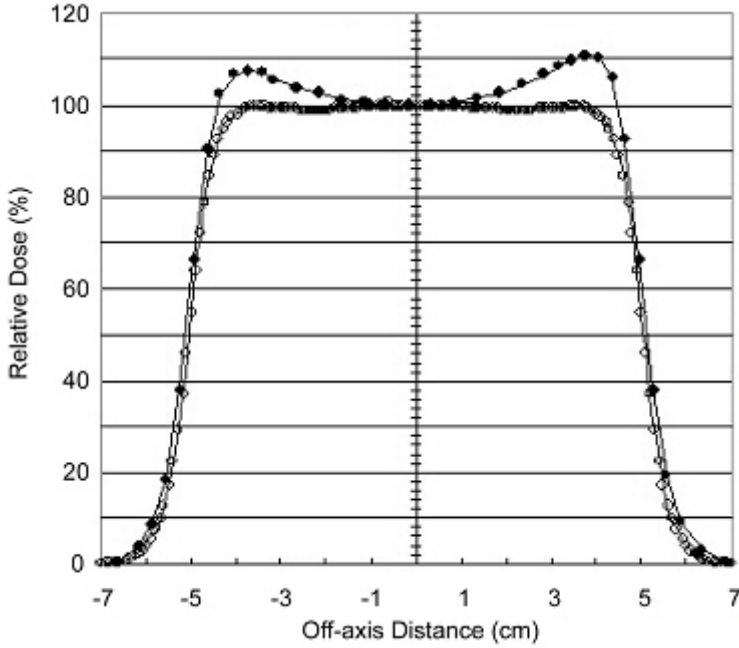


Fig. 10. A beam profile at the depth of d_{max} for a 6-MeV electron beam from a stationary linear accelerator (Siemens ME, filled circles) compared with beam profiles at the depth of d_{max} from a mobile linear accelerator (Mobetron, open circles) for a 10-cm electron applicator.

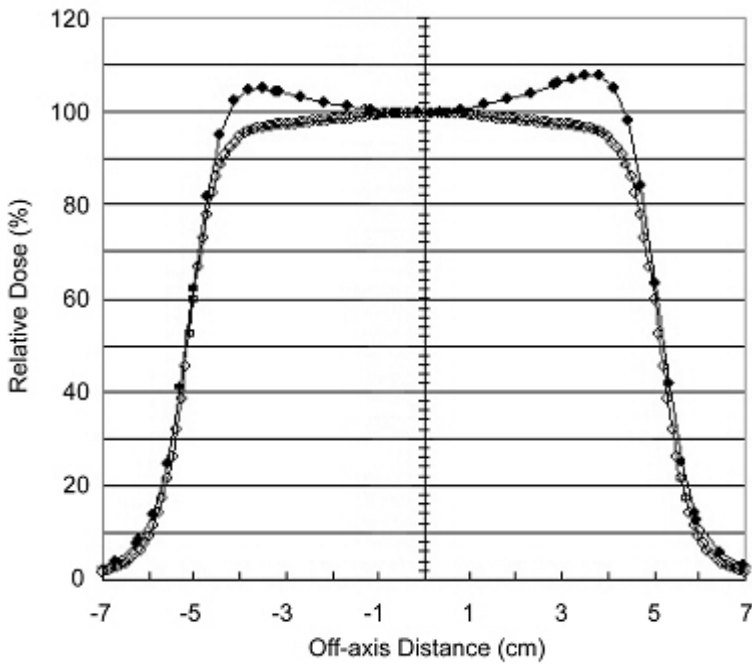


Fig. 11. A beam profile at the depth of d_{max} for a 12-MeV electron beam from a stationary linear accelerator (Siemens ME, filled circles) compared with beam profiles at the depth of d_{max} from a mobile linear accelerator (Mobetron, open circles) for a 10-cm electron applicator.

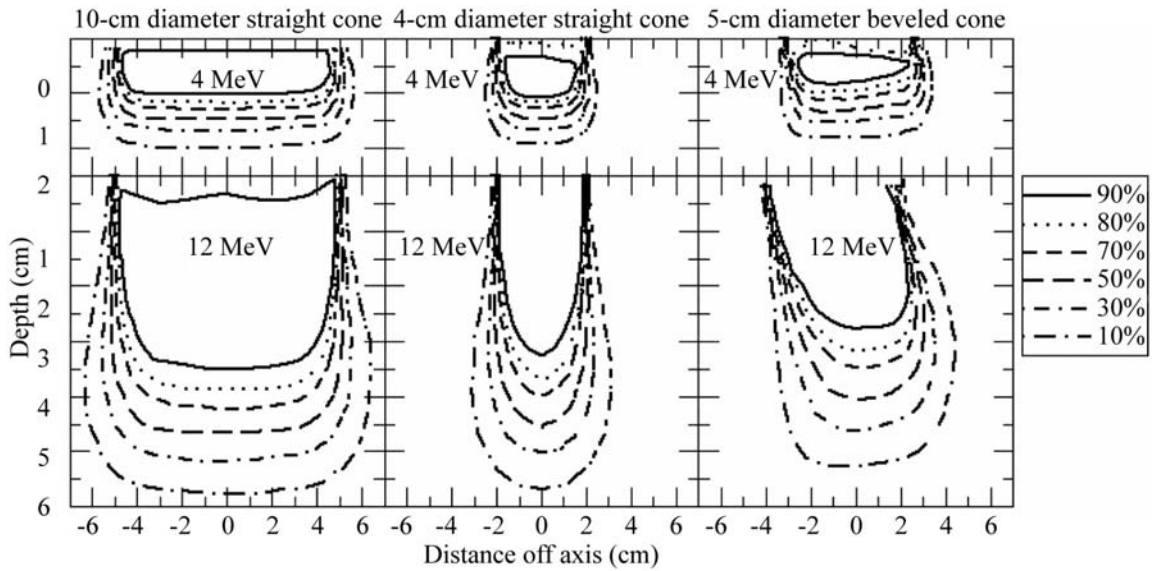


Fig. 12. Typical isodose distributions measured from the Mobetron for the 4- and 12-MeV beams using the largest applicator (10-cm diameter), a smaller applicator (4-cm diameter), and an applicator with a 30-degree bevel (5-cm diameter).

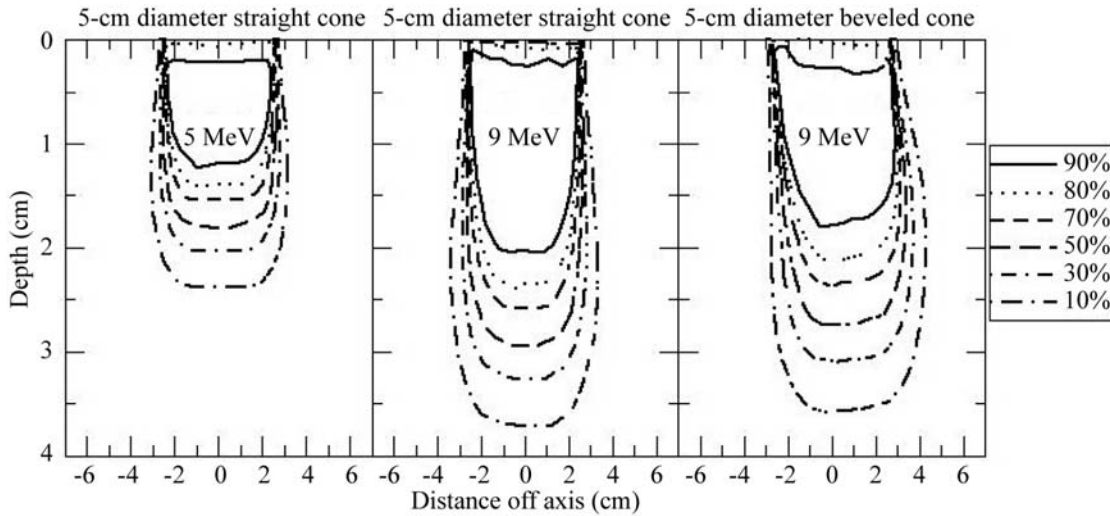


Fig. 13. Typical isodose distributions from the Novac7 for 5- and 9-MeV beams using an electron applicator with a straight cone of 5 cm diameter and for the 9-MeV beam using a 22.5-degree beveled applicator with a 5-cm diameter.

VI. RECOMMENDED QUALITY ASSURANCE

Individual state regulations require certain QA practices for medical linacs; these requirements differ from state to state, and some may not be well suited to these special-purpose devices. The physicist *must* ensure that the use of mobile IORT equipment complies with any relevant regulations and/or apply for exemptions where justified.

A. Previous quality assurance recommendations for medical linear accelerators

Any discussion of QA for mobile linacs used for IORT must acknowledge the recommendations published in the Task Group 40 report⁵⁸ regarding QA for medical linacs in general. In addition, the TG-48 report²⁷ discussed specific QA issues for linacs used for IORT. The following paragraphs summarize the pertinent recommendations of these previous, complementary reports regarding dosimetric and mechanical QA.

Output constancy

TG-40 recommended checking electron output constancy with a tolerance of 3% each day of use, with a tolerance of 2% monthly, and calibrating annually. TG-48 recommended day-of-use checks and monthly calibrations.

Depth dose

TG-40 recommended checking electron beam depth dose monthly and annually with a tolerance of 2 mm at the therapeutic depth. TG-48 recommended depth dose and isodose checks annually, although monthly checks are implied by the assertion “calibration of electron beams using standard departmental procedures.”

Flatness and symmetry

TG-40 recommended flatness and symmetry checks monthly with a tolerance of 3% and annually with a tolerance of 2%. TG-48 recommended annual checks. The monthly checks are implied in the phrase “calibration of electron beams using standard departmental procedures.”

Applicator output factors

TG-40 and TG-48 both recommended that the applicator output factors be checked annually with a tolerance of 2%. TG-48 specifically recommended checking all applicators and energies with a tolerance of 2-3% for a few years and then sampling²⁷ after that if results warrant.

Output versus gantry angle

TG-40 recommended checking the dependence of output on the gantry angle annually with a tolerance of 2%.

Monitor chamber linearity

TG-40 recommended checking monitor chamber linearity annually with a tolerance of 1%.

Docking mechanism

TG-48 recommended that the mechanical security of the system be checked each day of use.

B. Quality assurance for mobile electron accelerators

When adapting these recommendations to mobile accelerators, the clinical physicist needs to deal with some conflicting considerations. These units are partially disassembled and transported each day of use. They forgo adjustable collimator jaws and eliminate bending magnets to reduce weight and radiation leakage. These design elements simplify the system, but they make the electron beam energy more dependent on variations in RF power generation and coupling to the accelerator. Therefore, on one hand, there are reasons to perform more frequent beam measurements than with conventional installations. On the other hand, the equipment is used in ORs with little or no added shielding, so radiation safety considerations argue for limiting the beam time for QA as much as possible. These competing concerns can be partially resolved by developing an efficient QA process, but they do present an ongoing challenge.

Output and energy can be checked efficiently with the use of a dedicated solid phantom in which a dosimeter can be placed at two depths: near the depth of dose maximum and at a point on the depth dose curve in the 50-80% range. The output constancy is taken from the measurement near d_{\max} and the energy constancy from the ratio of the two readings. This Task Group *recommends* that for mobile accelerators, the electron output constancy be checked each day of use. The electron energy check *should* also be checked daily. If it proves to be sufficiently consistent, then the physicist may judge it reasonable to reduce the frequency to monthly after properly documenting the energy consistency. A typical arrangement for QA using a dedicated solid phantom for mobile IORT units is shown in Fig. 14.

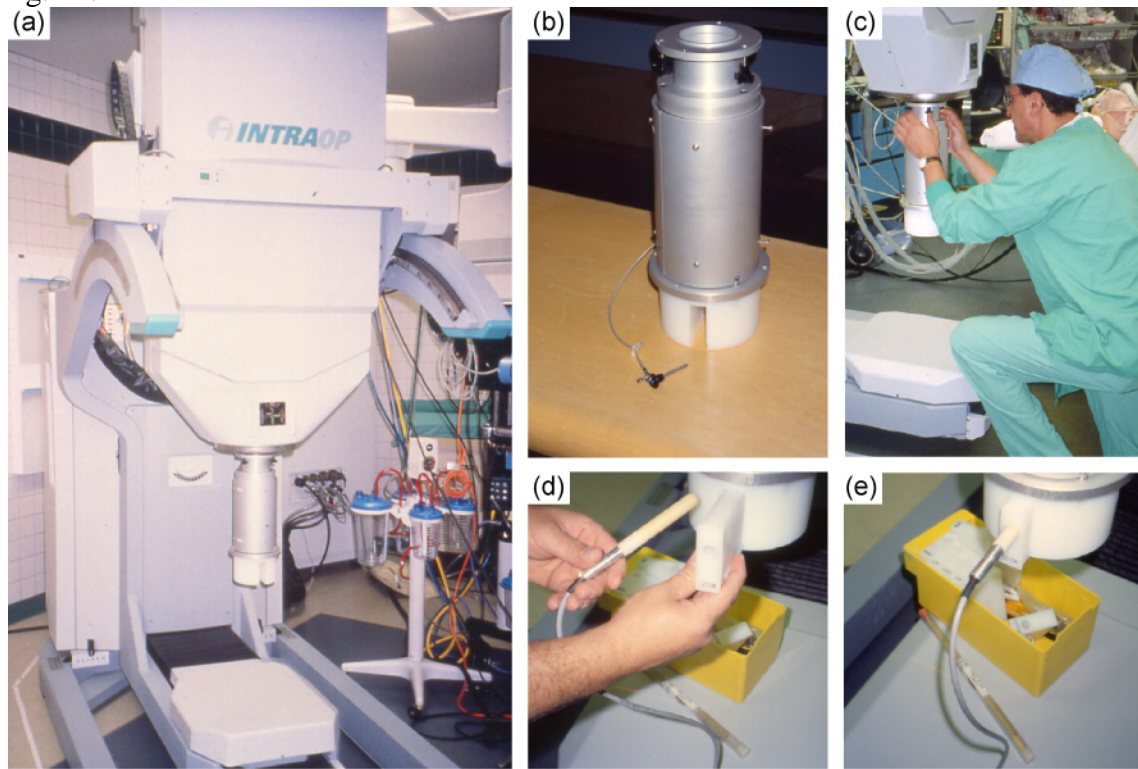


Fig. 14. Typical arrangement used for quality assurance for the Mobetron. (a) The mobile unit with the specialized quality assurance electron applicator attached to it. (b) Close-up of the specialized applicator. A dedicated plastic phantom, shown without inserts, is mounted at the bottom of the applicator. (c)

Attachment of the applicator to the gantry. (d) Placement of energy and depth-specific inserts into the dedicated phantom. (e) The applicator, ready for measurement. (The quality assurance electron applicator, phantom, and inserts are supplied with the unit.)

When judging how many MUs to apply to these measurements, the physicist needs to ensure that the beam runs long enough to enable all interlocks. (Some machines disable some dosimetry interlocks during an initial period.)

For a machine having four energies, a typical protocol is to warm up the machine and dosimeter with about 400 MU and then check the output and the electron energy for each energy with single 200-MU readings. The total number of MUs used for daily QA may exceed the number of MUs used for treatment. Given that the machine is prepared for use more often than it is actually used, more beam time (and ambient radiation) may be allocated to QA than to treatment. Hence, there is good reason to carefully assess which readings and how many MUs per reading are necessary for QA. Use of a dual channel dosimeter to simultaneously acquire readings at two depths would be advantageous.

Both the accelerator characteristics and the docking mechanism affect the flatness and symmetry of the treatment fields. This is especially true for machines using soft-docking mechanisms. This Task Group recommends that field flatness *should* be checked monthly, in accordance with TG-40. The docking apparatus *should* be checked for basic integrity each day of use, in accordance with TG-48. This Task Group (TG-72) further recommends that the alignment of soft-docking systems *should* be checked at least monthly. For systems that use special attachments for routine QA, this Task Group recommends that, at least annually, the flatness and symmetry of the beams *should* be checked in the soft-docked configuration used clinically.

For mobile systems, the practical question of when to set up the machine and do the QA checks takes on added significance. As with any multidisciplinary, single-dose procedure, the tolerance for machine downtime is very low, but the need to move and set up the machine adds complexity and the possibility of malfunctions. Consequently, there can be value to setting up and testing the basic operation of the machine on the day before its intended use. Recommended dosimetric QA can follow on the day of treatment, preferably early enough to permit some troubleshooting if needed. This is a labor-intensive process that can be simplified if experience with the machine demonstrates its reliability.

As for any radiation treatment equipment, annual QA checks *should* repeat critical elements of the initial acceptance testing and commissioning. The task is likely to be complicated by workload limitations, however, unless the unit can be moved into a shielded environment. For example, it may be necessary to use film instead of a scanning water phantom. If the initial commissioning and subsequent annual QA tests are to be done in different environments with different dosimeters, then appropriate baseline measurements should be done during the commissioning.

Table VI.1 summarizes the QA recommendations for mobile electron accelerators used for IORT. The term “constancy” refers to agreement with original commissioning data.

Table VI.1: Summary of the Quality Assurance Recommendations for Mobile Electron Accelerators used for IORT.

Parameter	Tolerance	Action level
Day of use		
Output constancy	3%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Door interlocks	Functional	Recommended
Mechanical motions	Functional	Recommended
Docking system	Functional	Recommended
Parameter	Tolerance	Action level
Monthly		
Output constancy	2%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Flatness and symmetry constancy	3%	Recommended
Docking system	Functional	Recommended
Emergency off	Functional	Recommended
Annually		
Output calibration for reference conditions	2%	Required
Percent depth dose for standard applicator	2 mm in depth over the range of clinical interest	Required
Percent depth dose for selected applicators	2 mm in depth over the range of clinical interest	Recommended
Flatness and symmetry for standard applicator	2%	Required
Flatness and symmetry for selected applicators	3%	Recommended
Applicator output factors	2-3%	Recommended
Monitor chamber linearity	1%	Recommended
Output, PDD, and profile constancy over the range of machine orientations	As above	Recommended
Inspection of all devices normally kept sterile	Functional	Recommended

In addition to these elements of dosimetric and mechanical machine QA, there are aspects of procedural QA that should be considered. In the OR environment, the attending radiation oncologist will usually be scrubbed and may verbally indicate the key elements of the prescription (applicator, energy, dose, etc.) to the person who will perform the MU calculation and program the machine. There are two likely sources of error in such a scenario. One is that the treatment planner may misunderstand the physician's verbal instructions. Another is that the planner may make a mistake in the calculation or in programming the treatment console. The team tasked with clinically implementing IORT will need to recognize this potential for error and design procedures accordingly. For example, the planner can use both manual and computerized calculation methods, thus double-checking the mechanics of the calculation. In addition, the calculation can be written out in such a way that the physician can check that the prescription has been properly understood. Finally, a second person, such as the physician or another physicist, can check that the energy and MUs have been properly programmed. Having more than one person check the critical elements in a single-shot procedure is crucial.

The Radiation Therapy Oncology Group continues to sponsor the Radiological Physics Center (RPC) QA program for inter-institutional clinical trials. TG-48 recommended in its report²⁷ that the RPC TLD service be used as part of an outside, independent check on an institution's dosimetry. This Task Group (TG-72) re-emphasizes that recommendation and strongly recommends institutions using mobile accelerators to use the services of RPC, before the initiation of treatments if possible.

As part of a comprehensive QA program, the annual review should include an assessment of clinical procedures and radiation safety procedures, maintenance history, and spare parts inventory.

VII. Clinical aspects of IORT treatment delivery

As discussed by TG-48, IORT treatments introduce additional responsibilities to all members of the team, and that requires additional education and information. The basic responsibilities of all personnel groups involved (surgeons, radiation oncologists, radiation physicists, anesthesiologists, nursing staff, pathologists, radiation therapy staff, engineering staff, and other support personnel) are described in the TG-48 report. Some more specialized clinical issues in IORT treatments (with both mobile and stationary units) may include the use of specialized instrumentation (e.g., the functions of the IORT surgical bed and its extensions). Special draping may be needed to maintain sterility during the placement of the ancillary accessories (Bookwalter clamp assembly) that fix the applicator to the surgical bed and during the docking phase. Patient positioning may be restricted by the limitations of beam positioning or the placement of the electron applicator, including the ancillary accessories.

A. Dose specification

Traditionally, IORT procedures performed under the Radiation Therapy Oncology Group protocol have specified that the 90% isodose line covers the target volume, whereas the International Commission on Radiation Units and Measurements Report 35⁵⁹ recommends that the dose be prescribed at d_{max} . Therefore, TG-48 recommended that

both the 90% dose and the maximum dose should be reported. Since the publication of the TG-48 report, neither the ICRU nor any other institution has achieved a formal agreement on dose specification for IORT. However most IORT groups follow the convention of prescribing to the 90% isodose level to ensure coverage of the target by the 90% isodose line. This Task Group recommends that the dose be prescribed at the 90% isodose level and then the dose be reported at both the 90% level and d_{\max} .

B. Treatment delivery parameters

As described in the TG-48 report, the IORT target is defined immediately before irradiation in a discussion among surgeon, radiation oncologist, and physicist on the basis of the direct view of the tumor or tumor bed after resection. The decision-making process will include consideration of intraoperative information by the pathologist concerning resection margins, tumor infiltration into surrounding tissues, histology, and other considerations such as risks to neighboring tissues and critical structures. For some tumors, additional surgical preparation may be necessary to render the target accessible to electron irradiation (e.g., the preparation of a flat target area for IORT for breast cancers).

Definition of target depth and lateral extensions of the tumor and selection of beam energy will depend mainly on these criteria. Intraoperative sonography to measure target depth or the distance of risk organs from the target has been suggested by TG-48 and other authors, however, only a few groups report its regular use.⁶⁰ Beam energy is usually selected to place the 90% isodose line of the dose distribution of the chosen applicator at the distal depth of the target. The argument for this strategy was outlined by TG-48. However, certain treatment situations containing gaps, inhomogeneities, or angulated beam incidences may require dosimetric studies to determine the correct energy to completely cover the target.⁶¹

Recommendations for target definition, selection of beam energy and applicator, field shaping, and dose reporting are discussed at length in the TG-48 report. This Task Group (TG-72) adopts the same general recommendations as TG-48 because they apply to IORT both with mobile systems and with stationary units.

VIII. RECOMMENDATIONS FOR FUTURE CONSIDERATIONS

Many aspects of IORT are still in an investigative and less standardized state than external beam radiation therapy. Therefore, in existing IORT programs, several centers have developed specialized applicators,^{4,8,43,46,48,62,63} alignment aids,⁶⁴ and other technical equipment to adapt to institutional methods or requirements, such as patient case selection and surgical techniques. For instance, the treatment of extended tumor sites (e.g., sarcomas located on extremities) may require the development of applicators and techniques for field abutment.⁸ Other design features of mobile IORT machines may limit the development of some specialized equipment. Adaptations of site-developed equipment, and possibly advice by the manufacturer, may be necessary to allow for the use of the soft-docking aids provided with the linacs.

The management of cancer using IORT is limited to the delivery of one single dose during surgery, which is an occasional modality that can hardly be postponed or repeated.

Therefore, machine interlocks, which exclude patient treatment, should be restricted to those that are necessary to warrant patient safety and to avoid machine damage. Interlocks of lower priority (e.g., those that are triggered by slight applicator misalignments or machine instability) should be well documented and their effect on the dose distribution well quantified so that, if necessary, an override can be considered at the time of treatment. Apart from few early phantom measurements on beam inclination and gaps,^{33,43,49} the effects of beam misalignment, gaps, bolus, changes of penumbra, and tissue inhomogeneities in realistic patient geometries are not well investigated. Further research is needed in these areas, and further development is necessary in the treatment planning of IORT for realistic patient geometries.

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Appendix 1: IORT checklist

Date _____

PREOPERATIVE CHECKLIST

_____ 1. Check status of equipment in OR

- Mobile accelerator
- Control console
- Modulator
- Sterile supply cart
- Physics QA supply cart
- OR surgical bed extender and accessories
- Foot extension and bed bits
- Ether screen and bed bits
- Camera and video/monitor cart

Physician _____

Procedure _____

Pre-op diagnosis _____

_____ 2. Validate availability and sterility of all supplies

- Applicator cones: 4 30-degree beveled: 3, 4, 5, 6 cm
8 flat: 3, 4, 5, 6, 7, 8, 9, 10 cm
- Gray surgical bed attachment clamping system
- Mirror attachment
- Sterile cap for collimator (disposable white plastic)
- All sizes of bolus inserts (12 inserts, 1 of each of the above sizes)
- Steri-Strips
- Sterile lead shields (peel-packed)
- Sterile plastic bags

_____ 3. Radiation safety room preparation

- Post "Caution-Radiation Area" and "Do Not Enter" signs
- Lock the doors to the core when indicated

INTRAOPERATIVE CHECKLIST

_____ 1. Notify radiation oncology team 1 hour before estimated treatment time

_____ 2. Hand up sterile supplies as requested by the radiation oncology team

_____ 3. Move sterile instrument tables to secure area of the OR

_____ 4. Assist with the application of the bed extender if required

_____ 5. Place a sterile drape around the operative site (MTC, DTC, or disposable drape)

_____ 6. Assist with patient transfer into the Mobetron unit

_____ 7. Reassess patient positioning after transfer

_____ 8. Lock doors to the core when indicated

_____ 10. Document staff involved from radiation oncology

_____ 11. Document delivery of radiation treatment in the operative record

_____ 12. Document times in appropriate QA fields

QA1 = setup time

QA2 = docking time

QA3 = 2nd docking time (if 2nd docking is done)

POSTOPERATIVE CHECKLIST

- ____ 1. Placed contaminated applicator(s), bed attachment and bolus in a clean-up pan
(Note: Do not place heavy pieces on top of fragile or bendable accessories)
- ____ 2. Notify radiation oncology team when patient is transferred to PACU
- ____ 3. Notify OR assistants when equipment can be disinfected
- ____ 4. Ensure that the equipment is returned to the proper storage location
- ____ 5. Place completed IORT checklist in the QA book on physics QA supply cart.

Nursing staff assigned to the case: _____

Procedure number _____

QA setup time Start _____ Stop _____

Docking procedure Start _____ Stop _____

2nd docking procedure Start _____ Stop _____

Comments:

IORT nurse _____