1. INTRODUCTION
IORT (Intra-Operative Radiation Therapy) is a radiotherapy treatment technique consisting in the administration, during a surgical intervention, of a single and high radiation dose (up to 30 Gy) to the tumour bed/environment, after the surgical removal. The main objective of IORT is to increase both the probability of local control of the tumour and the therapeutic ratio between local control of the tumour and tolerance of the adjacent healthy tissues and organs; this goal can be achieved through a better definition of the target volume and the displacement and/or screening of the “organs and tissues at risk” during the surgical intervention. IORT is not a new treatment technique: it had been proposed in 1909 at the beginning of radiotherapy, when only X-ray orthovoltage therapy equipment (120 – 250 kV) were available, and the results obtained did not justify the development and a widespread use of this technique. The main reason for this situation lied in the unfavourable depth dose distribution of the X-ray beams. When, in the years after 1970, the new linear accelerators (linacs), able to produce electron beams with energies > 4 MeV were introduced in the clinical use, IORT was again taken into serious considerations by radiotherapists and surgeons. Abe et al. demonstrated that IORT could offer great advantages over conventional radiotherapy with external beams, not only for tumours located nearby critical organs and tissues, but also for locally advanced tumours, difficult to be controlled by surgery or external radiotherapy alone, thanks to its possibility of delivering high radiation doses to the regions of possible macroscopic local diffusion of tumour cells. This possibility is offered by an appropriate choice of the energy, and consequently of the range in the tissues, of the electron beams. As a simple mnemonic rule, we remember that the maximum range in water (and therefore in the soft tissues) of the electron beams, if expressed in cm, is approximately equal to half of the electron beam energy, expressed in MeV, and that the “useful range”, or “therapeutical range” (corresponding to a DPP of 80%), always expressed in cm, is approximately equal to 1/3 of the electron beam energy, always expressed in MeV. From this considerations, it is clear that the availability of electron beams with initial energy in the range between 4 and 15 MeV allows to treat with IORT any “target”, up to a thickness of approximately 5 cm. The main reason why IORT with “conventional” linacs did not have a great diffusion, despite of its theoretical advantages, was the need of one of these two radical choices: the installation of an operating room inside the bunker of a linac or the transport of the patient, under anaesthesia, from the operating room to the bunker of the linac and back to the operating room after the irradiation: it is clear that both these two choice create a lot of problems and difficulties. These difficulties have been solved a few years ago with the development and the introduction in the clinical use of mobile linacs producing only electron beams, that can easily be transported and employed directly in the operating room. It is clear that the use of such linacs in a space not specially designed sets important problems of radiation protection, that must be analysed and solved specifically for each situation.

At the beginning of 1999 a mobile Linac (Novac 7, manufactured by Hitesys, Aprilia, Italy) able to produce electron beams in the energy range 4.5 – 9 MeV became available at the European Institute of Oncology, Milano, for being employed in “traditional” operating rooms, especially for the IORT of early breast cancer patients.

2. MATERIALS AND METHODS
Physical and mechanical characteristics of the mobile linac Novac 7 – Novac 7 is a mobile linac, specifically designed for being employed in a “normal” operating room (s. Fig. 1). It is mounted in a motorised structure that can be easily displaced inside the operating room thanks to a caster installed in the base, and pushed very slowly towards the operating table and the patient, so as to be easily positioned with great accuracy in the treatment position. For this purpose, 4 degrees of freedom are foreseen:
- Azimuth, with a possibility of rotation between – 45° and + 45° around a vertical axis (s. Fig. 2)
- Elevation in a vertical plane (s. fig. 3)
- Inclination (± 45°) of the radiating head (s. Fig. 4)
- Rotation (± 45°) of the radiating head (s. Fig. 5)
Fig. 1. The mobile linac Novac 7 with an applicator mounted on the radiating head

Fig. 2. – Azimuthal rotation around the vertical axis

Fig. 3. – Elevation of the whole structure in the vertical plane

Fig. 4. – Inclination of the radiating head

Fig. 5. – Rotation of the radiating head
Novac 7 is equipped with three sets of four plexiglas circular applicators each, plane (0°) and bevelled (22.5° and 45°), whose characteristics are shown in Table 1 and Figure 6.

<table>
<thead>
<tr>
<th>Applicator’s diameter (cm)</th>
<th>SSD (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>6</td>
<td>80</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>10</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1. Available applicators

According to the manufacturer, Novac 7 can deliver electron beams of 4 nominal energies: 3, 5, 7 and 9 MeV; the emission of electrons is pulsed, with a frequency of 5 Hz, a pulse duration very short (4 µs) and a very high dose/pulse. In order to reduce the production of Bremsstrahlung, and consequently to reduce the radiation protection problems, no scattering foil is present along the path of the electrons from the exit window to the patient; the enlargement of the beam’s section is due only to the geometrical divergence and to the rather large SSD (80 cm for the applicators with a diameter ≤ 8 cm and 100 cm for the applicators with a diameter = 10 cm). However, Bremsstrahlung is produced as a consequence of the interaction of the electron beams with the patient’s tissues. Before using Novac 7 in the operating rooms (placed at the second floor of the building) a very rigorous acceptance test was planned; for safety reason, all the evaluations and measurements were performed at the ground level of the building, inside a bunker where a 25 MeV conventional linac was installed and operating. The main parameters checked during the acceptance test were the following:

- User’s interface
- Stability (constancy of the emission)
- **Actual energy of the beams**
- Beams profiles (symmetry and flatness)
- Isodose curves in water
- Dose (Monitor Units – number of pulses / Gy) and dose rate
- **Stray radiation** (leakage radiation from the radiating head – Bremsstrahlung – scattered radiation)
- Mechanical characteristics and reliability, connection to the earth, warnings, etc.

The evaluation of the actual energy $E_{p,0}$ of the beams was based on the measurement in a water phantom and using small diodes (s. Fig. 7) of the depth dose curves along the beam’s central axis, the determination of the practical range $R_p$ and the use of the following range-energy relationship:

$$E_{p,0} = C_1 + C_2 R_p + C_3 R_p^2$$

where:

$C_1 = 0.22 \text{ MeV}$

$C_2 = 1.98 \text{ MeV cm}^{-1}$

$C_3 = 0.0025 \text{ MeV cm}^{-2}$

The actual energies of the beams are lower than those declared by the manufacturer, as shown in Table 2.

<table>
<thead>
<tr>
<th>Energy declared by the manufacturer</th>
<th>Actual energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 MeV</td>
<td>3.9 MeV</td>
</tr>
<tr>
<td>5 MeV</td>
<td>4.7 MeV</td>
</tr>
<tr>
<td>7 MeV</td>
<td>5.7 MeV</td>
</tr>
<tr>
<td>9 MeV</td>
<td>6.9 MeV</td>
</tr>
</tbody>
</table>

Table 2. Nominal and actual energies of the electron beams
Figure 6. Experimental set-up for the determination of the percentage depth dose curves (PDD), of the practical range \( (R_p) \) and of the actual energy of the electron beams.

Figure 7. Depth dose curves in water. From links to right, nominal energies of 3, 5, 7 and 9 MeV. In abscissa: depth in mm; in ordinate: percentage depth dose, normalised to the maximum.

The dose-rate of the beams, expressed in cGy/pulse, was measured for every nominal energy and every applicator. The values found for the plane applicators are listed in Table 3.

<table>
<thead>
<tr>
<th>( \Phi ) of the applicator (mm)</th>
<th>3 MeV</th>
<th>5 MeV</th>
<th>7 MeV</th>
<th>9 MeV</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>3.2</td>
<td>4.7</td>
<td>6.8</td>
<td>8.5</td>
</tr>
<tr>
<td>60</td>
<td>3.5</td>
<td>4.7</td>
<td>6.2</td>
<td>7.5</td>
</tr>
<tr>
<td>80</td>
<td>3.2</td>
<td>4.2</td>
<td>5.4</td>
<td>6.4</td>
</tr>
<tr>
<td>100</td>
<td>1.9</td>
<td>2.5</td>
<td>3.2</td>
<td>3.9</td>
</tr>
</tbody>
</table>

Table 3. Dose-rate of the electron beams for the plane applicators.
The stray radiation generated during the functioning of Novac 7 is made up by four different components (s. Fig. 8):
1. low energy radiation, scattered into the environment by the patient or by any object present along the beam’s path
2. leakage from the radiating head
3. electrons emerging from the applicator’s walls (PMMA, 5 mm thick) and scattered at various angles
4. Bremsstrahlung generated by the interaction of the electron beam with the patient or any other object present along its path.

In order to evaluate both the intensity and the “quality” of such environmental radiation, some different detectors have been employed, namely:
- a ionization chamber Victoreen mod. 450 P
- a radiation GM monitor Rados RDS-120 Universal Survey Meter, equipped also with a beta-ray probe
- a radiation monitor (proportional counter) FAG Contamat FHT 111M.

3. RESULTS
The measurements were made at the maximum nominal energy of the linac (9 MeV), and irradiating a PMMA phantom (30 cm × 30 cm × 10 cm) using the plane applicator having a diameter of 10 cm and working therefore at a SSD = 100 cm. Two main conclusion could immediately be drawn:
- the components 1. and 3. (low energy radiation and electrons emerging from the applicator’s walls) can be completely absorbed by 5 mm Pb
- the intensity of the Bremsstrahlung strongly depends on the angle, being maximum in the direction of the beam (angle = 0°) and minimum in the opposite direction (angle = 180°), according to the second column of Table 3
- also the energy, evaluated through the measurement of the attenuation in lead depends on the angle, as can be seen in the third column of Table 3., where the TVL (Tenth Value Layers) are listed

<table>
<thead>
<tr>
<th>Angle</th>
<th>% intensity</th>
<th>TVL (mm Pb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>30°</td>
<td>14</td>
<td>45</td>
</tr>
<tr>
<td>45°</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td>60°</td>
<td>3</td>
<td>35</td>
</tr>
<tr>
<td>90°</td>
<td>1.3</td>
<td>32</td>
</tr>
<tr>
<td>135°</td>
<td>0.2</td>
<td>30</td>
</tr>
<tr>
<td>180°</td>
<td>0.04</td>
<td>30</td>
</tr>
</tbody>
</table>

Table 3: Angular dependence of the intensity of the Bremsstrahlung

Moreover, in order to evaluate the attenuation produced by the floor and of the ceiling of the operating rooms (25 cm concrete), the attenuation properties of concrete were evaluated, and TVL of 26 cm at 0° and of 20 cm at 180° were found.
In order to design the mobile shields to be used during the functioning of the linac, measurements of dose-rate in air at various distances and with different thickness of lead were performed. The results, expressed in µGy/100 pulses are reported in Table 4.

<table>
<thead>
<tr>
<th>Angle</th>
<th>0°</th>
<th>30°</th>
<th>45°</th>
<th>60°</th>
<th>90°</th>
<th>135°</th>
<th>180°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance (cm)</td>
<td>130</td>
<td>140</td>
<td>150</td>
<td>150</td>
<td>130</td>
<td>165</td>
<td>300</td>
</tr>
<tr>
<td>mm Pb</td>
<td>0</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>µGy/100 pulses</td>
<td>160</td>
<td>95.5</td>
<td>70.2</td>
<td>59.2</td>
<td>43.1</td>
<td>34.5</td>
<td>28.2</td>
</tr>
</tbody>
</table>

The following working load was estimated:
- 400 treatments/operating room/year
- 30 Gy (corresponding approximately to 500 pulses – s. Table 3) / treatment

A dose constraint of 1 mSv/year/operator (surgeons, anaesthetist, radiotherapist, medical physicist, etc.) was taken into account; the same dose constraint was established for the people living in the underlying and overlaying spaces.

On the basis of the above mentioned evaluations, 4 mobile barriers mounted on casters and having the following characteristics were designed and built:
- height : 150 cm
- width : 120 cm
- thickness : 15 mm Pb from the floor to an height of 50 cm
  - 10 mm Pb from 50 cm to 100 cm
  - 5 mm Pb from 100 cm to 150 cm
- cover : 10 mm PMMA on the face of the barrier oriented towards the patient
- total weight : 230 kg

In order to absorb the Bremsstrahlung emerging from the patient during the treatment, moreover, a shield mounted on casters and having the following characteristics was designed and built:
- width : 45 cm
- length : 60 cm
- thickness : 150 mm Pb
- weight : 330 kg

This shield is interlocked with the linac, so as to make the emission of radiation impossible if the shield itself is not placed under the operating table during the emission of the beam.

A schematic layout of the operating room and of the control room, where the control panel (CP) of the linac is installed is shown in Fig. 9.
4. PROCEDURE
After the surgeon has removed the tumour, a technician, assisted by a medical physicist, brings the linac nearby the operating table and helps the radiotherapist and the surgeon to put the applicator (that is hard-docked to the radiating head of the linac) in the treatment position. In the meantime, a series of light- and acoustic warnings is activated; immediately after, the technician places the mobile barriers in the right positions around the operating table and all the personnel (surgeon, anaesthetist, radiotherapist, medical physicist, technician, nurses of the operating room, etc.) leaves the operating room and remains in the control room, from which the patient can constantly be controlled via the window of the door of the operating room. The radiotherapist prescribes the energy and the dose and the medical physicist starts the irradiation. The personnel classified as exposed worker due to its usual activities (radiotherapist, technician, medical physicist) wears its usual personal dosimeters. The other personnel, classified as not exposed (surgeon, anaesthetist, nurse, etc.) was monitored with a personal dosimeter only for the first three months, in order to check the adequacy of the classification. All the dosimeters indicated a value of the effective dose < 50 µSv, thus confirming the adequacy both of the classification and of the barriers.

5. CONCLUSIONS
During the first month of activity, and afterwards with a quarterly frequency, environmental film and TLD-dosimeters have been placed inside the adjacent, underlying and overlaying spaces; all the results were always very near to the natural background; even dosimeters placed on the inner face of the walls of the operating rooms revealed doses very low, < 6 mSv/y. This results allow to conclude that the radiation protection measures taken are adequate and effective and that the whole procedure can be considered as completely safe from the point of view of radiation protection.

6. REFERENCES