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4 Detector for monitoring potential bleeding during electron

5 intraoperative radiotherapy

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17 Abstract

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19 Purpose: The aim of this work is to develop a bleeding detector integrated into the 20 acrylic circular applicators for specific mobile linacs. Thus, a bleeding detector has been 21 developed based on a capacitive sensor to be used with plastic applicators, as in the case 22 of LIAC HWL from Sordina IORT Technologies SpA. According to the clinical impact,

23 we have selected 0.5 cm as the minimum depth of fluid that should be dete*cted*.

Methods: An experiment was developed using water-simulating blood. Two setups were considered: non-beveled applicators with 7 cm and 10 cm diameter. Measurements were done for applicators 0° and 45° tilted, both with respect to the horizontal surface, in order to mimic the worst clinical scenario according to the irradiation gantry and applicator bevel angle. The behavior of the detector under irradiation was analyzed and the impact of the stray radiation on the detector was also evaluated.

- 30 *Results:* The detector was able to distinguish the presence of liquid at a minimum height 31 of 0.5 cm. A linear behavior was obtained for both setups. We have also verified that the
- 32 LIAC HWL radiation does not affect the measurements nor does the detector interfere
- with the stray radiation. The bleeding detector is a quasi-digital capacitive sensor withlow-cost, high linearity, and easy to install.
- 35 *Conclusions:* With this detector it is possible to perform a continuous monitoring of the 36 liquid measurements even during the irradiation phase. Thus, it can operate not only as 37 a pre-treatment detector but also as a continuous one.
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- 39 Keywords: Intraoperative radiotherapy, bleeding, electrons, capacitive sensors

40 I. INTRODUCTION

Intraoperative radiotherapy is an extended technique being applied to a wide range of specific diseases in exclusive mode or combined with external radiotherapy. For example, it is suitable for the treatment of several malignances [1], such as: the central nervous system, head and neck, breast, lung, gastric, pancreas, bile duct, gallbladder, colorectal, retroperitoneal, extremity and trunk soft-tissue, bone, gynecologic, genitourinary and pediatrics. Intraoperative radiotherapy with mobile linear accelerators is a well-established modality that is gaining popularity because, thanks to the significant improvement in technology, it can be used in a conventional surgery room without specific shielding conditions. Task Group 72 (TG-72) from the American Association of Physicists in Medicine [2] provides enough information for the physical aspects of the planning process, such as room selection, potential shielding, acceptance, commissioning and quality assurance.

54 One of the potential uncertainties or misadministration events in this technique is the 55 fluid instability in the post-resected surface [3]. It can be especially critical in surgery 56 beds with high-vascularized scenarios. Electron energy for treatment is selected 57 according to the specific depth of the target. Due to the high dose gradient after the therapeutic range of electrons, if bleeding exists at the time of irradiation then a non-58 59 desired target underdose can be produced. The adequate coverage of the target volume 60 plays a crucial role in a successful treatment. According to [1], 0.5 cm height of fluid 61 has been identified as the threshold for fluid detection.

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64 II. MATHERIAL AND METHODS

65 66 II.1 Mobile linac

LIAC HWL (SIT, Sordina IORT Technologies, Vicenza, Italy) is an intraoperatory tool
for radiotherapy (IOERT) dedicated mobile linac specifically designed for executing
IOERT treatment inside a conventional operating room (OR).

LIAC HWL is available in two models, the 10 MeV model, with energy of 4, 6,
8 and 10 MeV, and 12 MeV model, with energy of 6, 8, 10 and 12 MeV; its dimensions
and weight allows its use without any modification and reinforcement of the OR floor.

The LIAC HWL commissioning process is very similar to LIAC, widely discussed both for the experimental part [4–7] and for the Monte Carlo modelization [7,8].

The equipment has been designed in order to reduce the stray radiation (SR) to a minimum. This specific achievement has been pursued by reducing the interaction between the accelerated electron beam and any metallic element, by means of the development of a beam optic system. Such design has allowed to minimize the overall SR: in the patient plane it results lower than 0.2 μ Sv/Gy at a distance of 3 m from the target [9]. Therefore, according to NCRP 151 approach [10], the weekly workload is higher than 100 Gy/week.

The choice of PMMA for the applicators allows both the possibility of implementing hard docking and the direct visualization of the target to be irradiated (Fig. 1). Two different applicator sets are available, with the same overall length but different lengths of the terminals (lower applicator).

Applicators have diameters ranging from 3 to 12 cm with terminal bevel angles ranging from 0° to 45°. Dose rate with reference applicator (10 cm diameter, bevel 0°) can be adjusted in the range 10–30 Gy/min. The radiation treatment for typical doses up to 20 Gy is completed in less than two minutes.



Fig. 1. LIAC HWL applicator.

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95 *II.2 Bleeding detector*

97 The bleeding detector is based on a capacitive sensor. The main advantages of these 98 capacitive sensors being their low cost, low power consumption and linearity [11,12]. 99 The bleeding detector is implemented by using two metallic strips made of copper 100 surrounding the bottom part of the applicator as shown in Fig. 2. The strips are placed 101 as close to the bottom surface as possible in order to provide a signal with the minimal 102 possible blood quantity. These strips act as a capacitor that enables changes in the 103 presence of liquid in the applicators.

104 The measurement process is based on repetitive charge-discharge cycles of the 105 capacitor through a resistor, performing a quasi-digital sensor. The discharging time is 106 measured through a microprocessor working in free-running mode. The chosen resistor 107 value of 20 M Ω is a satisfactory compromise between obtaining a good time resolution 108 and having enough statistics. Because each charge-discharge process is fast, it is 109 possible to continuously monitor the bleeding inside the applicator. In order to have 110 statistically significant measurements we monitorize the detector signal continuously at 111 a rate of 10 Hz.

Fig. 3 shows the test bench that comprises the sensor, cabling, the microprocessor for data acquisition and a computer.

The tests carried out so far have allowed the dimensions of the sensor to be established in order to obtain a detectable signal while maintaining visibility through the walls of the applicator. Specifically, the sensor is 0.02 cm thick, 2.0 cm high; the length being dependent on each applicator and covering the entire perimeter with a gap of 0.5 cm at each end of the strip. Two tilting angles for the applicator 0° and 45° have been considered. In both cases, the two strips surround the applicator perimeter and are located at the end of the applicator.

For the connection between the sensor and the microprocessor a coax cable 70 cm long has been chosen. This length was chosen because it fits the distance between the bottom part of the lower applicator and the LIAC's HWL head where a microprocessor is installed. As the system measures time differences, the added capacity due to the coax cable introduces a bias that is not relevant for the measurements.

126 Measurements during intraoperatory sessions will be done using a port of this 127 microprocessor connected through a RS-485 standard port to a computer located outside 128 the operating room. Thus, the system would operate as follows: once the applicator is 129 configured, the absence of blood is verified and the time reference as "zero condition" t_0 130 is acquired, showing its value on the computer. Later, after the preparation (fixation and 131 coupling), either the computer or the microprocessor processes the sensor signal 132 continuously and indicates the presence or absence of blood in the applicator. It is 133 possible for the system to operate in a yes/no decision mode or in a linear mode.

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Figure 2: Capacitive sensor located at the bottom part of the applicator.

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Figure 3: Block diagram of the test bench.

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141 II.3. Detector sensitivity

To evaluate the detector sensitivity an experiment was developed using water simulating blood at room temperature. In order to simulate the patient's breathing, we have installed the detector on top of the Quasar Respiratory Motion Phantom from Modus QA [13], which has been programmed at 16 bps to represent a worst scenario baseline condition during the intraoperative intervention.

Taking into account that during clinical treatment both the LIAC HWL gantry angle and the applicator bevel are selected according to the specific treatment site and the patient anatomy, if bleeding exists it will accumulate partially in the field due to gravity. Therefore, for testing, two setups employing the most typical applicator sizes used in clinical procedures have been considered:

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- 1. 7 cm diameter applicator with no bevel: 0° tilted, where the liquid has the same height along the entire surface, and 45° tilted (highest bevel angle in practice), where the liquid is accumulated in a corner.
- 157 2. 10 cm diameter applicator with no bevel: again, 0° tilted and 45° tilted.
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159 *II.4 Detector performance under radiation*

161 One of the most important features of the mobile electron linacs is the low SR 162 component, which facilitates its use in conventional surgery rooms. In fact, this feature has the greatest effect on the maximum workload in a specific room. The main 163 164 contamination component is the x-rays produced by electron bremsstrahlung. As 165 mentioned before, in case of the LIAC HWL this value is significantly low (0.2 µSv per administrated Gy at 3 m distance in patient plane), so it is necessary to evaluate whether 166 167 the bleeding detector modifies this value or not. Consequently, the SR was evaluated 168 with or without the bleeding detector for the worst-case energy (12 MeV) and for the 10 169 cm diameter applicator.

The set-up used is shown in Fig. 4. The main reason that led us to define such set-up was to establish a minimum standard for the wall of any OR. It is also a thickness capable of shielding the low energy electrons escaping from the applicator as typically done in these types of measurements [14].

The SR was measured using two different survey meters: Fluke INOVION 451 B and 451 P [15]. In this specific experiment, the aim was to evaluate whether extra SR is produced due to the strips of the fluid detector or not. Then, relative measurements were performed with the 10 cm diameter applicator with or without strips. The measurements were performed in integration mode delivering 500 monitor units (15 s) per each irradiation, repeating the irradiation three times in both setups. The statistical uncertainty of the resulting ratios was estimated as less than 5%.

181 On the other hand, the performance of the sensor was evaluated under radiation 182 in order to classify it as either a pretreatment or permanent sensor. For this purpose, we 183 used the LIAC HWL at the Sordina installations. Measurements were taken for different 184 electron energies: the minimum (6 MeV) and maximum (12 MeV) for both setups. It 185 has been checked for a liquid volume equivalent to a height of 1 cm for both setups. 186



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Figure 4: SR measurement set-up: SR is measured behind a 5 cm drywall layer at a distance of 3 m from the target.

197 **III. RESULTS**

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199 III.1 Detector sensitivity

201 Fig. 5 (setup 1) and Fig. 6 (setup 2) show the percentage variations of the 202 discharging time Δt with respect to the zero condition t₀ as a function of the depth of 203 liquid, measured with respect to the horizontal surface. The maximun value of liquid depth shown in Fig. 5 and Fig. 6 is the one that, measured with respect to the horizontal 204 205 surface, equals the height of the sensor strip (i.e. 2 cm for the bevel 0° applicator and 206 1.4 cm for bevel 45°).

207 Fig. 5 shows the experimental results for setup 1, with the response of the 208 detector against the depth of liquid present in the 7 cm applicator, both for bevel 0° (blue) and bevel 45° (red). Sensitivity is about 1.74 (%)/cm for the 7 cm diameter 209 210 applicator, bevel 0°, and about 0.73 (%)/cm for bevel 45°. The statistically expanded 211 uncertainty is 0.32%, coverage factor k= 2.

212 Fig. 6 shows the experimental results for setup 2, with the response of the 213 detector against the height of liquid present in the 10 cm applicator, both for bevel 0° 214 (blue) and bevel 45° (red). Sensitivity is about 2.55 (%)/cm for the 10 cm diameter applicator, bevel 0°, and about 1.64 (%)/cm for the same diameter applicator but bevel 215 216 45°. The statistically expanded uncertainty is 0.36%, coverage factor k=2.



the depth of liquid for setup 1 (7 cm applicator diameter).

Blue: bevel 0°. Red: bevel 45°. Error bars represent one standard deviation.



Figure 6. Percentage variations of the time discharging ∆t with respect to the zero condition t∂ vs the depth of liquid for setup 2 (10 cm applicator diameter). Blue: bevel 0°. Red: bevel 45°. Error bars represent one standard deviation.

230 III.2 Detector performance under radiation

On the one hand, no variation of the SR was found in the measurements performed with or without the detector. On the other hand, with respect to the performance of the detector with or without radiation, the results obtained have shown invariability (in the range of 0.4%).

The very minimal effect of the radiation over the detector is due to some peaks observed during data taking due to the LIAC's HWL electromagnetic radiation (i.e. mainly power supply switching). These peaks can easily be suppressed by software, thus eliminating the effect.

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241 IV DISCUSSION

There are specific clinical scenarios (i.e. rectum, breast, prostate, gynaecological recurrence, sarcomas, retroperitoneal, etc.) where the resulting bed to be irradiated can be composed of highly vascular tissue with potential bleeding [1,16–20]. Although a full sucked is done, the bleeding probability is not negligible. If bleeding occurs, the thickness to be irradiated changes and, consequently, also changes the therapeutic range of selected electrons energy, resulting in underdose of the deeper target layers.

Until now, the bleeding is controlled by looking through the transparent wall of the applicator so there is no control when the applicator is partially covered with tissue. When bleeding happens, typically the surgeon realizes it once the applicator is removed after finishing the irradiation with no chance for correction. With the help of the proposed detector this nondesired effect is permanently controlled allowing for an adjusted therapeutic range with the selected electron energy. To the best of our knowledge, no other bleeding detector exists nor in the market nor in the literature.

In our opinion, the results are quite promising for liquid detection even in the worst clinical scenario, i.e. minimum diameter applicator 45° tilt. As seen in Figs. 5 and 6, it is possible for both setups to clearly detect a depth of 0.5 cm of liquid accumulated in the applicator, as required. We observed a dependence on the detector sensitivity with the applicator diameter (i.e. the bigger the diameter of the applicator the greater the sensitivity). Because of this, the uncertainty associated with the 0.5 cm depth value for setup 1 (0.2 cm) is bigger than for setup 2 (0.1 cm). The response of the detector is linear throughout the range of measurements for both setups.

The detector proposed and studied in this work is characterized by its low cost and linear behavior between the amount of liquid present in the applicator and the percentual deviation in the discharge time measured with respect to the so called zero condition. The linearity observed in the behavior of the detector enables new measurements to be used to determine, not only whether or not there is liquid present in the applicator, but the amount of liquid present. This would offer advantages over the single liquid detection option (yes/no) in any clinical scenario.

In a second phase of the study we will optimize the behavior of the sensor, i.e.
study of materials, dimensions and geometry.

274 V CONCLUSIONS

276 A bleeding detector system has been developed that can be used from the 277 treatment preparation to the irradiation phase, which benefits it as a pre-treatment and 278 also a continuous detector, allowing to survey the bleeding along the whole clinical 279 procedure. The bleeding detector is performed using a quasi-digital capacitive sensor 280 with low-cost, low-power consumption, high linearity that is easy to install. The detector is able to reveal the presence of a volume of liquid in the applicator 281 corresponding to a depth of water of 0.5 cm measured in the applicator, even in the 282 283 worst-case situation, i.e. 7 cm diameter applicator tilted 45°.

The detector can be used directly with plastic applicators, as is the case of LIAC HWL, making it highly suitable for industrialization, as there is no need for additional electronics in this specific linac. Given this, any future work would consist of the integration of the sensor into the applicator body. Eventually, if needed, the coax cable connecting the sensor to the microprocessor could be easily replaced by a standard wireless communication.

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295 **Disclosure**

Giuseppe Felici, is an employee and shareholder of S.I.T. – Sordina IORT Technologies
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