Use of the VALIDATOR Dosimetry System for Quality Assurance and Quality Control of Blood Irradiators

1- Introduction

The VALIDATOR, model TN-ID-60, is a compact, and stand-alone dosimetry system for measuring and recording absorbed dose in blood irradiators. The system, manufactured by Best Medical Canada (BMC), enables technicians to immediately verify the absorbed dose delivered inside a canister and check the constancy of the irradiation process. The system is intended as a Quality Assurance (QA) tool of irradiators to ensure constancy of the output radiation, for medical and research applications. The system is not intended for calibrating or measuring absolute dose rates of blood irradiators.

The VALIDATOR system, which uses electronic MOSFET dosimeters, is versatile and allows real-time dose readout and verification for radioisotope, X-Ray or linear accelerator based irradiators, used in hospitals, blood banks and clinical research laboratories.

The system has undergone extensive testing in the field and was found reliable; it satisfies all regulatory requirements as a QA instrument for blood irradiators (CE, FDA class I, Health Canada).

2- System Operation

The system consists of a compact Reader, a MOSFET dosimeter held within a Dosimeter Module, and a verification module. All dosimetry data are stored in internal memory for future display (LCD screen) or transfer to a PC via a USB connection using the **VALIDATOR Connect** software.

The radiation dosimeter technology is based on a semiconductor device known as the MOSFET (Metal Oxide Semiconductor Field Effect Transistor). This device is characterized by its threshold voltage V_T, which is altered by radiation; the resulting change in mV is converted to absorbed dose delivered by the irradiator, using appropriate calibration factors (CF).

Two MOSFET dosimeters with two different sensitivities (TN-502P and TN-252P) are used, with a maximum measured signal of 20000 mV (~ 200 Gy or 20.0 kRAD).

To perform absorbed dose verification the Module containing the MOSFET dosimeter is connected to the Reader for initialization (INITIALIZE button), and then placed in the irradiation container. After irradiation at a target dose, the Module is removed and connected to the reader for a direct readout (READ button) of the delivered dose.

Using the **VALIDATOR Connect** software, dose data can be transferred to a computer for further processing in Excel format or for printout in customised reports.

The system has two modes of operation: Calibration and Normal modes.

For regular QA operations the Normal Mode is used, allowing a user to enter manually a sensor calibration factor for a given energy modality, and select their desired dose units.

For advanced research activities and other radiation sources, it may be required to determine the sensor calibration factor; the user is advised to set the Reader in the Calibration Mode, and perform a new sensor calibration (see sec 3-3).

3- Quality Assurance (QA) of Blood Irradiators

The VALIDATOR system is intended as a QA tool for periodic dosimetric constancy measurements between the annual dose distribution measurements of blood irradiators. The MOSFET dosimeters provide relative dose measurements, and enable the user to assess the constancy check of the blood irradiator output within an acceptable set limit (5-10 %) during routine use. The system provides records of proper operation and monitoring of the irradiators.

Blood irradiators may show a sporadic variability in output radiation due to hardware failure or operator misuse. This variability can be detected if the output of the irradiator is checked daily using quantitative dosimeters such as the MOSFETs, before starting the process of blood irradiation.

The VALIDATOR system is suitable for Gamma or X-ray based irradiators used for blood irradiation or for research specimens. Depending on the application, the dosimeter module can be placed at the bottom of the container (zone of minimum dose for typical Gamma irradiators), or at the middle of a customized plastic phantom to assess the central dose. Specific calibration factors are delivered by the manufacturer for different types of dosimeters (TN-502P and TN-252P) and for different energy modalities (see Appendix A-1).

Note 1: The MOSFET measured dose **should not be used** to determine the dose delivered to the blood; the user is advised to use the machine absolute dose rate provided by the manufacturer or calibration data obtained during irradiator dose validation.

The VALIDATOR dose measurements are meant as a Statistical Process Control (SPC) tool to check the irradiator output constancy from day to day use; absolute dose values are not important but the dose variation range from the day of the last maintenance and calibration is a good parameter to assess the output stability of the irradiator and to detect any system premature failure. The SPC control methodology is discussed in Appendix A-2.

The advantage of using the VALIDATOR system for daily QA, in comparison to TLD or Alanine dosimeters, is that it offers real-time dose readout, immediately after the irradiation and with no temperature or humidity dependence. System reproducibility compares well with Alanine dosimeters in controlled settings.

Note 2: The VALIDATOR system is not meant to replace the annual dose validation and verification required by FDA for checking blood irradiators. Dose mapping kits should still be used to assess the dose inside the canister at several locations in the 3-D distributed volume.

3-1 Quality Assurance of Gamma Irradiators

Gamma irradiators, when used correctly, are highly reliable and produce a constant radiation output as they are based on an isotope of known decay activity (Cesium or Cobalt irradiators).

It is however possible for an operator to inadvertently change the timer settings to values which do not produce the intended dose. Timer corrections to account for radiation decay may be wrongly implemented by a user, and canister placement may not be at the right setting. These possible shortcomings may result in deviations of the dose delivered at the center of the canister (2500 cGy) and of the minimum required dose at the bottom.

To perform QA verifications of Gamma beam based irradiators, the user proceeds as follows:

- The MOSFET dosimetry Module is connected to the Reader, set in Normal Mode of operation, for initialization (INITIALIZE button), and then placed in the irradiation container.

- After irradiation at a normal cycle, the Module is removed and connected to the reader for readout (READ button) of the minimum delivered dose.

Note: Use the TN-502P type sensor for these measurements and ensure that the applicable CF has been applied as discussed in Appendix A-1.

Examples of QA measurement data obtained for a Gammacell 3000 machine are provided in Table A2 of the Appendix. The dosimeter module was positioned at the bottom center of the canister for an irradiation time of 7 min 20s for all irradiations. In addition, saline water bags of 400 cc were placed on top of the module. Using a calibration factor of 0.91mV/cGy, the average dose measured was 2721.4 cGy, with 4% standard deviation for 21 measurements.

3-2 Quality Assurance of X-ray Based Irradiators

Low energy X-ray based irradiators show more variability in comparison to Gamma based ones, as their output is affected by the electronic power supplies of the X-ray tube, which may have limited reliability after aging. Indeed, an X-ray tube in a typical irradiator configuration may have its power supply characteristics altered, resulting in a change of its X-ray radiation output and possibly in a latent failure in between machine maintenance schedules. It is also possible to inadvertently change the timer settings to values which do not produce the intended dose at the center of the canister. These deficiencies may result in deviations of the dose delivered at the canister from the nominal value (2500 cGy).

To perform QA verifications of X-ray based irradiators, the VALIDATOR dosimetry module is inserted at the bottom of the canister at a fixed location. For dose measurements at the center of the canister, customized phantoms can be used. A specific calibration factor delivered by the manufacturer for the TN-252P type sensor, and determined for the Raycell machine (160 kVp), is used for these measurements (see Appendix A-1).

Examples of QA measurement data obtained for a Raycell CE machine are provided in Table A3 of the Appendix. The dosimeter module was positioned at the bottom center of the canister for an irradiation time of 4.7 min for all irradiations, and with no saline water bags used. Using a calibration factor of 0.68 mV/cGy, the average dose measured was 2765.4 cGy, with 4.8% standard deviation for 9 measurements.

3-3 Quality Assurance of Research Irradiators

Research irradiators are used to irradiate various scientific specimens such as live animals (mice), live tissue (bone marrow), and other materials, which require knowledge of the dose delivered for a given set-up and machine configuration. The irradiator timer settings can be changed by the user and no requirements are followed with regard to absolute machine calibration, as done with blood irradiators.

Knowledge of the dose for a given set-up and location inside the canister is important to quantify or produce the intended change on the specimen. For most applications using Gamma beam irradiation, e.g. ^{60}Co, the BMC supplied CF on the MOSFET sensor tube is sufficient to determine the absorbed dose delivered to the irradiated specimen (see section A1). For other irradiators, the user is advised to perform a proper calibration of the sensors, taking into account the energy modality and the beam filtration, using a reference ion chamber; he can then use his calibration factors to determine the radiation dose delivered.

To perform a new calibration the user should set the Reader in the Calibration Mode, where the MOSFET readings are in mV absolute units only, and no calibration factors are applied. Before irradiation the "INITIALIZE" button is pressed to measure the "TOTAL" accumulated voltage of the attached MOSFET. After delivering radiation of known dose, the sensor is read using the "READ" button. The new total accumulated voltage of the attached MOSFET as well as the difference in mV between the new total voltage reading and the previous one are displayed.

Using the difference in mV, which is proportional to the dose in cGy delivered to the dosimeter, a calibration factor CF in mV/cGy can be determined for a given sensor. This operation may be repeated 3 to 5 times until a satisfactory CF average is reached, with a lower standard deviation.

4- System Maintenance Requirements

The VALIDATOR system has been shown to be reliable for regular use during dosimetry sessions for blood irradiators. No specific maintenance is required on the reader other than occasionally cleaning its faceplate by wiping it with a soft cloth.

Periodically, to ensure good performance of the electronic system components, the user is required to perform verification checks using the "Instrument check system" tool as described in the user's manual.

As the sensor life is limited, it may need replacement after several uses and when dose accumulated reaches 20000 mV (~200 Gy or 20.0 kRAD). The internal batteries of the Dosimeter Module might need replacement after several years of operation. Sensor and battery replacement procedure is described in the user's manual.

Appendix A

A-1 System Specifications and Sensitivity Data

Case of Gamma beam (^{60}Co) based irradiators

The VALIDATOR system was tested in ^{60}Co radiation beam conditions, similar to those used for blood irradiation, at the National Research Council of Canada, Ottawa (Institute of Ionizing Radiation Standards). The dosimeter module was placed under tissue equivalent build-up material.

Reproducibility: The system dose-to-dose reproducibility at 1σ is less than 0.3 % for all sensor types (TN-502P and TN-252P) at high doses (1500 cGy). At low dose values (200 cGy), the reproducibility for TN-502P sensors was found to be less than 3 %.

Sensitivity: The average sensitivity (CF value) for the whole dose range from 0 to 20000 mV was found to be 0.91 mV/cGy for the TN-502P sensor, with CF variation within 3 %, 1σ throughout the dosimeter life.

Accuracy: Using the determined sensitivity value CF, the dosimeter accuracy over its dose life (0-20000 mV) was found to be within ±5% in controlled ^{60}Co beam testing conditions.

Fade: Less than 1 % for 1500 cGy, rad, or mV after 15 min.

Case of X-ray based irradiators

The VALIDATOR system using the TN-252P type dosimeter was tested in a low energy X-ray based blood irradiator (Raycell CE, Best Theratronics Ltd) to determine its sensitivity. The dosimeter was sandwiched in the middle of a Polystyrene phantom, placed in the blood container.

The Raycell CE irradiator operates under 160 kVp X-ray tube voltage. The TN-252P detector sensitivity was determined using the dose rate at the middle of a Polystyrene phantom, obtained using 3-D dosimetry mapping data of TLD dose measurements. Sensitivity variations are expected for different machine energies or filtrations.

Sensitivity: From the dose rate at the middle of the phantom, and for 1-minute time setting of the irradiator, an average sensitivity (CF) of 0.68 mV/cGy was estimated for the TN-252P sensor, with 8 % , 1σ variation throughout the dosimeter life.

Note: The above sensitivity value (CF) should be used for relative dose determination only, and **not** for absolute dose measurements or calibration of the X-ray irradiator. The user is advised to use the irradiator manufacturer supplied dose rate data and follow their recommendations for their absolute dose checks of the irradiator. .

A-2 Statistical Process Control Methodology Using the VALIDATOR

The QA of the blood irradiator methodology is based on SPC control. The user determines the base dose average response for given settings of the irradiator (time, location in container or phantom) by performing several irradiations (3 to 5), then they calculate the standard deviation (1σ) of the response and deduce the maximum allowable limits of dose variability during irradiation (average dose $\pm$ 3σ)

Note: This methodology is provided for illustration only; the user should ensure that his control method is consistent with other implemented procedures and regulatory requirements.

Important: Dosimeters should be connected to their module for at least 1 hour before use. Waiting times of 3~5 minutes between consecutive exposures is advised for better reproducibility. Electrostatic Discharge (ESD) handling procedures should be followed when handling dosimeters (avoid touching dosimeters lids with hands).

Blood irradiation conditions

Measurements should be done using the TN-502P sensor for Gamma beams and TN-252P for X-ray based irradiators (Raycell). Machine type, timer settings and delivered doses at the dosimeter location should be specified on the test sheet (see Tables A2 & A3). Target doses similar to blood irradiation conditions (2500 cGy at the center) should be used for these QA tests. The dosimeter module is placed at the bottom of the container or at the middle if customized phantoms are used. No real blood specimen is to be used during these tests.

Dosimeter response and estimation of dose limits

- Manually enter the sensitivity CF for the sensor (printed on the tube label), set dose units to cGy, and set the VALIDATOR to Normal Mode of operation.

- Perform at least 3 consecutive irradiations and dose measurements as discussed in section 2, and fill Table A1.

- Calculate the average dose response and estimate the standard deviation (1σ). Determine the maximum allowable limits of dose variability (average dose $\pm$ 3 σ).

Date :		Machine Type :	
Dose Rate (Gy/min):		Dosimeter Location :	
Timer (min):		CF (mV/cGy) :	
	Dose Reading (cGy)	Expected Dose (cGy)	
Test 1			
Test 2			
Test 3			
Average dose (cGy):		Dose Max (cGy):	
STD (1σ) :		Dose Min (cGy) :	

Table A1. Determination of average response and limits of variation for dosimeters

Note: This step is performed only at the time of the VALIDATOR installation and use for a given irradiator and for a new batch of dosimeters; same limits can be used for sensors of a same batch.

Daily dose measurements and quality control

- Perform the daily monitoring and the constancy check of the irradiator and record measured dose data as shown in Table A2 for the Gammacell irradiator and Table A3 for the Raycell irradiator. This sequence is performed before starting the blood irradiation.

- For each measurement, determine the dose deviation from the average dose value and check if it is within acceptable limits.

- After a period of time (weekly or monthly), perform statistical analysis on data: Calculate the average of all measurements and determine their standard deviation and ensure that it is low (low variability) and that measurements do not show abnormal trends. Investigate any abnormal increase or decrease from accepted dose limits, which may warrant premature irradiator maintenance or repairs.

- Print the reports and archive them as part of the QA records of the irradiator for future review.

Machine Type	Gammacell 3000		
CF (mV/cGy)	0.91	Timer	7min20s
Location	Bottom center	Sensor	TN-502P
Date	**Measured Dose (cGy)**	**Expected dose (cGy)**	**Deviation (%)**
Day 1	2809.3	2800	-0.33
Day 2	2776.9	2800	0.82
Day 3	2912.6	2800	-4.02
Day 4	2900.6	2800	-3.59
Day 5	2897.2	2800	-3.47
Day 6	2582	2800	7.79
Day 7	2630.7	2800	6.05
Day 8	2797.4	2800	0.09
Day 9	2766.9	2800	1.18
Day 10	2714.2	2800	3.06
Day 11	2756.8	2800	1.54
Day 12	2630.9	2800	6.04
Day 13	2602.9	2800	7.04
Day 14	2757.8	2800	1.51
Day 15	2662.2	2800	4.92
Day 16	2779.9	2800	0.72
Day 17	2529.5	2800	9.66
Day 18	2609.8	2800	6.79
Day 19	2653.3	2800	5.24
Day 20	2713.3	2800	3.10
Day 21	2665.2	2800	4.81
Average	**2721.4**	**2800**	**2.81**
STD (%)	**4.0**		

Table A2- Daily dose measurements -TN-502P in a Gammacell

Machine Type	Raycell CE		
CF (mV/cGy)	0.68	Timer	4.7 min
Location	Bottom center	Sensor	TN-252P
Date	**Measured Dose (cGy)**	**Expected dose (cGy)**	**Deviation (%)**
Day 1	2892.6	2760.4	-4.79
Day 2	2844.8	2760.4	-3.06
Day 3	2898.8	2760.4	-5.02
Day 4	2874.5	2760.4	-4.13
Day 5	2810.2	2760.4	-1.81
Day 6	2730.5	2760.4	1.08
Day 7	2692.1	2760.4	2.47
Day 8	2622.6	2760.4	4.99
Day 9	2522.8	2760.4	8.61
Average	**2765.4**	**2760.4**	**-0.18**
STD (%)	**4.8**		

Table A3- Daily dose measurements -TN-252P in a Raycell