

Are Transmission Detectors a Necessary Tool for a Safe Patient Radiation Therapy Program?

Can you currently use direct documentation and measurement of delivered dose to ensure you did not underdose or overdose a patient for any delivered fraction?

If the answer is no, read on.

Over the last couple of decades, radiation therapy planning and delivery techniques have evolved substantially, leading to IMRT, IGRT, VMAT, and SBRT/SRS, to name a few. The development of these new techniques, however, has led to an increasing amount of complexity during the radiation therapy treatment planning and delivery process.

“What is common sense isn’t common practice.”

- Stephen Covey

When it comes to quality assurance for radiation therapy, the one aspect that matters above all else is the dose delivered to the patient. Equating time to dose (Co60) and MU (monitor units) to dose in the era of the Linac made sense, but since the advent of IMRT treatments, where the fluence is perturbed and modulated, there is no clear correlation between dose delivered with time and MUs. This means that there is no direct way of documenting the actual dose delivered to patients at every fraction. Moving to a hypofractionated treatment regime means the need for online dose verification becomes even more critical, yet we still cannot ensure accurate dose delivery by direct measurement for every fraction. Why? Because while progress was made in other areas of medical physics (namely delivery technology, imaging technology, etc.), the QA technology to measure actual dose in real-time did not keep pace, and was not available when these complex delivery techniques were introduced.

Q: I am doing a pretreatment patient specific QA, doesn’t that ensure correct delivery?

A: The pretreatment QA merely checks the machine’s deliverability, and ensures the physics of the planning system’s ability to model small field output. The pretreatment QA doesn’t tell what is happening during the actual treatment at every fraction, with every beam and for every field. What will happen on the 10th fraction of the 3rd arc, for example, is still unknown.

Q: I am doing weekly chart checks and making sure all the parameters are consistent & correct, doesn’t that ensure correct delivery?

A: The weekly chart checks ensure that all the delivery parameters on the machine are intact, but cannot guarantee the accuracy of the actual dose delivered during treatment. If you assume identical Linac behavior, it’s possible to correlate the dose delivered with pretreatment QA parameters and the dose delivered with at-treatment parameters. However, this is an assumption made without independent validation and is not an assurance of the actual dose delivered in real-time because a) there is no direct measurement of dose delivered, and b) the

behavior of the Linac during pretreatment and actual treatment cannot be determined solely with chart review.

Q: I have a rigorous machine QA program, doesn't the machine itself have interlocks?

A: Machine QA is preventive maintenance, and ensures output consistency on a daily, weekly, or monthly basis. It does not guarantee patient treatment delivery accuracy of the specific treatment plan itself, or the machine parameters.

Q: So, does that mean that our current treatments are not safe?

A: Currently, we use the combination of pretreatment patient specific QA, machine QA and chart review to determine that a treatment is safe, and to prevent errors in future treatments. While these lead to the logical and solid assumption that the treatment we are delivering is safe, they are merely tests of the parameters of the machine and the plan itself, and can't identify actual errors that might occur.

Q: What then, is the common-sense approach to dose delivery verification for every fraction of every treatment?

A: The common-sense approach to real-time dose delivery verification is to use a technology such as a transmission detector to measure the dose delivery error from the machine and combine it with set up errors and anatomy changes from IGRT. Combining these tools allows for the identification of the dosimetric impact of delivery set-up errors and independent assurance or validation with real-time direct dose measurement of the dose delivered to the patient.

Once the source of delivery errors is identified, clinicians can make real-time decisions and adjustments during the period of the treatment.

Q: Isn't the machine log file a viable option for in vivo dosimetry?

A: For in vivo dosimetry to truly be accurate, verification must be independent from the delivery system. Since the machine log information comes from the machine itself, it could report correct settings and results even if there are actual errors. If, for example, the dose rate is too low, the machine will make adjustments, but if the MU-chamber reading is inaccurate, the machine's control system will adjust the dose rate for that dose and the log will then report "correct data," even though the adjustment was made based on an incorrect measurement. Therefore, despite an "accurate" log file, the actual delivered dose could be inaccurate. This same situation can also happen with gantry and collimator angle settings. Since MLC miscalibration cannot be detected, incorrect MLC leaf-motion paths are possible and will not show up in the log file. Log file based in vivo dosimetry can give a false sense of accuracy.

Q: Isn't EPID based exit dosimetry an option?

A: The idea of EPID exit dosimetry has been around for more than 20 years, but has some issues.

Issue #1 The source of potential error (patient or machine) cannot be determined since there are several scenarios that would yield the same exit dose. Also, without knowing the incident fluence, it is not possible to predict dose errors and the location of the errors in the patient.

Issue #2 EPID is not primarily designed for dose measurement, although there have been several notable studies that have demonstrated its applicability for pretreatment QA. Additionally, in the presence of scatter, the behavior of the EPID will create false positives. While there are studies that have shown the effectiveness of machine log files [1] and EPID in detecting errors [2], *it is not acceptable to have false positives when designing a dose monitoring system to ensure dose delivery accuracy for patients. EPID based exit dosimetry is not a common-sense approach to dose delivery assurance for every fraction and every treatment. Errors should be measured separately and combined for dosimetric effect.*

Issue #3 Cost. A report from NKI, Amsterdam (who works closely with vendors in developing an EPID based in vivo solution and has used EPID frequently for the first three fractions of a treatment), reports that the average lifetime for the EPID in such use is 32 months [9]. Even under a service and maintenance agreement, this is an expensive replacement, which cannot be ignored, as such EPID use will result in image degradation [9], which is the main intended function of the EPID device.

Qualitative analysis of QA technique effectiveness in catching potential discrepancies

Table 1 shows different QA techniques and their effectiveness in catching errors. The first three columns are the extension of the table published in [5] for the purpose of this analysis. Highlighting has been added for clarity.

Data Transfer, Delivery Error, Point Dose, Planning Error Type	Transmission Detector + laser detection of pt position	EPID Exit Dosimetry + Dynalog	EPID Exit Dosimetry CT dose calc	DynaLog QA ^d	Point Dose Measurement ^a	Field-by-Field Planar Dose QA ^b	Composite Planar Dose QA ^c	Independent Dose Calculation QA ^e
Beam Parameters Discrepancy During Data Transfer or Machine Delivery								
Gantry Angle	1	1	2	1	3	5	4	5
Collimator Jaw Setting	1	1	3	1	3	3	3	5
Collimator Angle	1	1	3	1	3	3	3	5
MLC Positioning Error	1	1	3	1	4	3	3	5
MUs	1	3	3	5	1	1	3	5
Couch Angle Error	2	3	3	5	2	5	2	5
Machine Issues / Data Transfer Issues								
Dosimetry Characteristic – Energy Change, Symmetry, and Flatness Off	1	3	3	5	4	4	4	5
Absolute Dose Output Calibration	1	3	3	5	5	5	5	5
Relative Dose Output – Small Field Output Off	1	5	5	5	1	1	1	5
One Segment Dropped Out or Not Transferred Properly	1	1	4	1	4	3	4	5
One Field Not Transferred Correctly	1	1	2	1	4	2	3	5
Demanding MLC Sequence or MLC Positioning Issues – Beam Hold Off	1	1	3	1	4	4	4	5

TPS Beam Modeling Issues								
Small Field Out Prediction Issue	1	3	3	5	2	2	2	1
Heterogeneity Correction Issues	1	3	3	5	5	5	5	1
Wrong CT to ED	1	2	3	5	5	5	5	2
DVH Calculation Discrepancy	1	3	3	5	5	5	5	1
In vivo Changes								
Beam Data Modification After Pretreatment QA and Other Machine Issues During Each Fraction	1	3	3	5	5	5	5	5
IGRT Issues								
Anatomy Changes, localization Issues, Set-up Issues	5	3	3	5	5	5	5	5
Treatment Planning								
Isocenter Placement, Prescription, Wrong CT Voxel Size, Plan Quality	5	5	5	5	5	5	5	5
	28	46	60	67	70	71	71	80

Note: 1 is most effective, 4 is least effective, and 5 is not possible to find from QA test results.

- a Point dose measurement refers to ion chamber measurement with one or two points in a composite fashion (i.e., all beam delivered to a water equivalent phantom as it would be delivered to the patient).
- b Field-by-field planar dose measurement: all beams delivered from AP direction with gantry and could reset to default position.
- c Composite planar dose QA refers to measuring a plane using a 2D detector embedded in a phantom and the QA is performed with actual beam parameters as it will be delivered to the patients.
- d DynaLog QA: analysis of machine log file collected by delivering the actual plan to air or during composite point or planar dose measurement, as explained in a) and c).
- e Independent dose calculation is verifying the dose distribution of the planning system by recalculating in an independent dose calculation by exporting DICOM RT files (Plan, Dose, Images, Structure set) and any POIs.

Q: How safe is radiation therapy?

A: While radiation therapy is generally considered safe, over the last three decades, at least 3,000 patients have been affected by radiotherapy incidents, with medical radiation accidents accounting for more acute radiation deaths than any other source. In 2010, there was a series of *New York Times* articles that highlighted safety as a major weakness in our field [3]. Figure 1.1 from *Radiotherapy Risk Profile report* by the World Health Organization (2008) identifies commissioning, planning, treatment transfer and treatment delivery as the major contributors to errors in our field [4].

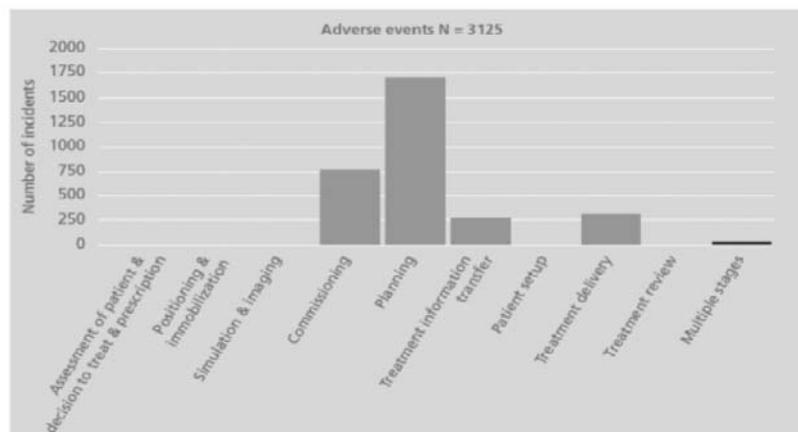


Figure 1.1: Radiotherapy incidents by stages of treatment process documented in *Radiotherapy Risk Profile* by World Health Organization.

Since radiation therapy errors are not adequately reported, it is hard to accurately predict the error rate, and there is currently no way to know if a patient is over dosed, under dosed or even treated correctly. We have a moral obligation to our patients to monitor their treatment quality. Medical errors are the third largest cause of death in the U.S., following heart disease and cancer [6]. While powerful in its ability to treat cancer, radiation therapy has not yet achieved the overall quality control found in other areas of healthcare, such as anesthesia, or in other industries, such as aviation. More safety research and development of robust tools to ensure accurate QA and dosimetry are needed for the continued growth of radiation oncology.

Delta⁴ Discover: Effectiveness and Efficiency

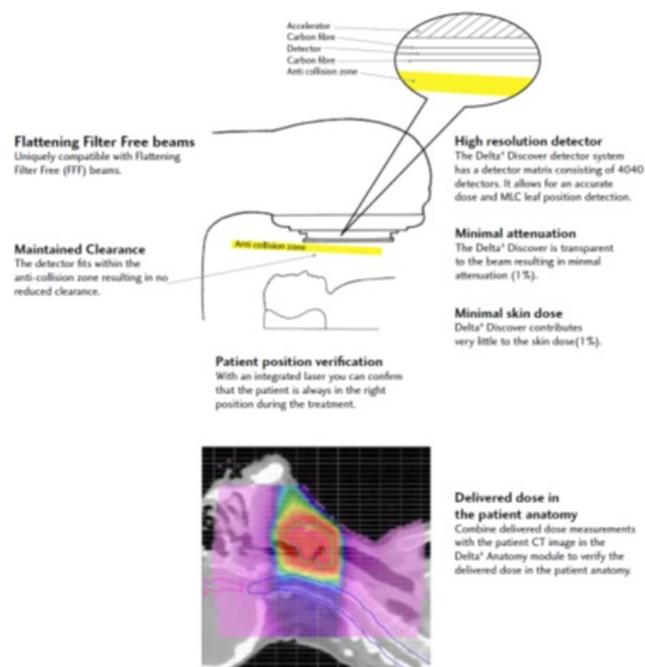
Delta⁴ Discover is an ultra-thin transmission detector, which enables accurate dose delivery verification at treatment, in the patient anatomy, and for every treatment fraction in real time. With Delta⁴ Discover, you can ensure that your patients are treated according to the dose prescription while immediately detecting dosing errors in critical structures.

Q: Is it FDA cleared?

A: Yes, the Delta⁴ Discover technology is FDA 510 (k) cleared.

Q: How does Delta⁴ Discover work?

A: The Delta⁴ Discover system measures the dose delivered by the accelerator, and automatically checks it against your user-defined pass-fail criteria. Combined with patient CT, you can see the dose that has been delivered to the patient.



Q: What information does Delta⁴ Discover provide?

A: Besides verification of the dose delivered to the patient, Discover's 4040 diodes can detect sub-mm errors in MLC position [7, 8] and collimator and gantry angle differences during delivery. A distance indicator provides an extra check of patient set-up.

Q: How easy is it to use Delta⁴ Discover?

A: The Discover workflow is completely automated. It is placed on the head of the Linac and interfaced with the R&V, then automatically analyzes the predicted and actual delivered dose to the patient, providing real-time feedback.

Q: Do I need to correct attenuation in the planning system?

A: Due to the ultra-thin design of the detector, attenuation and beam hardening are minimal. At 10cm, attenuation is 1.2% for 6 MV and 0.1% for 18MV. Beam hardening at 10 cm depth for 6MV is -0.7% and 18 MV is 0.6% [7].

Q: Does Delta⁴ Discover calculate CBCT dose?

A: The current version of Delta⁴ Discover calculates the dose delivered during the planning CT.

We recommend calibrating Delta⁴ Discover with a Delta⁴ Phantom+. After calibration, dose data can be viewed immediately in 3D with time resolution, control point by control point. After combining measurements with CT-data, the dose can be viewed in patient anatomy as dose distribution and DVH. For further analysis and to find causes of deviations, the time resolved measurements enable visualization of the 3D dose distribution per sub-arc or control points.

Q: What does Delta⁴ Discover mean to the patient and the overall therapy program?

A: Peace of mind. With independent verification, both you and your patient can now be confident of safe treatment and that the treatment dose is delivered as planned.

Safety is an Investment, Not a Cost!

A reliable organization will seek to utilize the latest technology in patient safety, and transmission detectors currently play a key role in this field. It is imperative that we continue to pursue the latest advancements in QA and develop programs that include the latest technology whenever possible. With the Delta⁴ Discover transmission detector, common sense can become common practice. Being able to document the delivery quality for every treatment fraction, beam and control point is a major step towards increasing patient safety throughout the entire treatment process.

References

- [1] D Rangaraj, et.al., "Catching errors with patient -specific pretreatment machine log file analysis," *Practical Rad.Onc.* 3(2), 80-90 (2013)
- [2] A Mans, et.al., "Catching errors with in vivo EPID dosimetry," *Med. Phys.*, 37, 2638 (2010)
- [3] Walt Bogdanich, "Radiation offers new ways to cure and ways to do harm" <http://www.nytimes.com/2010/01/24/health/24radiation.html>, Jan 2010
- [4] Radiotherapy Risk Profile report by the World Health Organization (2008)
- [5] Sun, Rangaraj, et al.: Independent dose calculation and DynaLog QA, *JACMP* Vol.13, No.5, 2012
- [6] Martin A Makary, Michael Daniel, "Medical error—the third leading cause of death in the US" *BMJ* 2016;353:i2139 doi: 10.1136/bmj.i2139 (Published 3 May 2016)
- [7] Saenz D, Gutierrez A, "Characterization of the Clinically Released ScandiDos Discover Diode Array for In-Vivo Dose Monitoring", *Med Phys*, Volume 43, (6) 2016
- [8] Taoran Li et al, "Diode-based transmission detector for IMRT delivery monitoring: a validation study." *JACMP*. 17 (5) 2016.
- [9] Ben J. Mijnheer PhD, Patrick González PhD, Igor Olaciregui-Ruiz MSc, Roel A. Rozendaal MSc, Marcel van Herk PhD, Anton Mans PhD , "Overview of 3-year experience with large-scale electronic portal imaging device–based 3-dimensional transit dosimetry Department of Radiation Oncology", *Practical Radiation Oncology*5, e679-e687 (2015)