FREQUENTLY ASKED QUESTIONS

Patient-Specific Quality Assurance

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Identifying Risks to Patient Safety

Q: What are the most common sources of error during treatment?

A: Most clinicians agree that the patient is the largest source of uncertainty in any treatment delivery. One study confirmed that patient set-up, anatomy changes, and isocenter placement were the most common sources of error.[1] The same study showed in-vivo EPID analysis to be an efficient and effective method for detecting these patient-related errors.

Q: Can rigorous machine QA negate the need for patient-specific measurement QA?

A: Rush University demonstrated that even when linacs pass stringent TG-142 monthly QA, there can still be large dose errors (greater than 10%) in patient specific QA.[2] The study suggests patient-specific QA is still necessary, and that, "Unacceptably large changes in dose delivered are possible… despite the machine passing routine QA." Their conclusion stated, "The cumulative effect of many small errors can, in worst case scenarios, produce large ones. This amalgam should be considered as part of the QA process."

Q: Is a "similarity index" comparison between CBCT and CT a suitable method for detecting patient set-up errors or anatomy changes?

A: A similarity index can be used to make the user aware that there is potential for an issue due to differences in the patient set-up and/or anatomy. However, the dosimetric impact of these issues is not known unless the dose computation is performed using the CBCT. Relying on a CBCT image to detect patient issues will also not detect issues related to patient movement during treatment. Additionally, in cases where a CBCT is not performed, there is no ability to detect potential patient issues unless an EPID is used.

Log File-Based QA

Q: Does PerFRACTION™ use log files?

A: When configured for EPIDs, PerFRACTION uses machine log files for some information, but primarily in conjunction with EPID measurements. Specifically, monitor chamber dose rate and output data (via log files) are used with independent MLC leaf position measurements acquired using the EPID.

Only in cases when the EPID is not deployable for specific patient treatment beam(s), the imaging technique for EPID transit dosimetry is not compatible with 3D reconstruction, or EPID data collection has not been configured will PerFRACTION perform log-based 3D dose reconstruction (if enabled).

Q: Can PerFRACTION be configured to use only log files?


WHAT LOG FILES MISS

A: Yes. PerFRACTION can be configured to use only log files for 3D dose reconstruction, but users should be aware of the limitations of using only log files and consider this in terms of clinical use and interpretation of results. For more information on the limitations of log file QA, see Sun Nuclear's Patient QA: What Log Files Miss document

Q: Are log files measurements?

A: Not exactly. Log files contain data reported by motor encoders and onboard systems. The MU/output data in a log file is a measurement from the monitor chamber. However the MLC leaf position information in a log file is not a physical measurement; it is merely the feedback from an electrostatic motor.

The log file-based approach relies on machine information as the foundation for "self-reporting" of errors. But, the accuracy of machine information for the detection of errors remains firmly in question.[7,8,17]

Q: Can log files be considered independent?

A: No. Log files cannot be considered independent. They accumulate machine interlock encoder data defined and recorded by the linac, and they do not measure the radiation fluence distribution.

Log files provide great precision (different from accuracy) and support automation[4,5]. However, log files remain a reflection of what the machine "thinks" happened during treatment, and have been shown to be unreliable as the sole source for patient QA, missing many common errors that can be detected by measurement using EPIDs. In addition, log files cannot detect patient related issues.[4,6,7,17]

It is important to understand that log file data is a direct extension of the machine interlocks, and therefore provides no ability to identify critical errors above and beyond the early warnings and shut-offs already provided by the interlock system of the treatment unit.

Relying solely on data obtained from the linac control system or treatment planning system cannot be considered independent QA.[17]

Q: Can log files detect MLC or dose errors?

A: It has been demonstrated that log files can detect severe MLC errors, but routinely miss critical MLC positioning errors and drift due to a variety of issues, including T-nut or motor failure, encoder error, or mis-calibration.[6,7,17] A 2014 linac manufacturer field safety notice underscored this point, announcing dose rate errors up to 5% had been missed by the recorded monitor chamber units. This error was detected by a measurement device[8]

Q: But, aren't log files easy to analyze?

A: Log files are easy to access and work with. Recognizing this appeal, and in response to customer feedback, PerFRACTION can be configured as a calculation (i.e.log file) only-based option. However, ease of use for log file-based analysis should be understood in the context of the inherent limitations and risks of relying on it alone for pre-treatment and in-vivo patient QA. It is important to know EPIDs are easy to work with as well, and include the benefit of providing independent information. This is why an increasing number of QA products have focused on using the EPID to its full potential.

EPID-Based PerFRACTION

Q: Does PerFRACTION include both 2D and 3D functionality?

A: Yes, when using EPID data.

Q: What is the difference between 2D and 3D analysis functionality in PerFRACTION?

A: Both functions are included with PerFRACTION. PerFRACTION 2D (only available when using EPID data) provides the following:

1. Automatic Fraction 0 pre-treatment IMRT QA using absolute dose (Included in optional Dosimetry Package)
2. Automatic capture and 2D comparison of daily treatment EPID images.
3. Automatic detection of failures related to patient setup, patient movement, and anatomical issues including weight loss and tumor growth/shrinkage, via transit image analysis.
4. Automatic email of failed results.

PerFRACTION 3D adds the following:

1. Automatic reconstruction of 3D dose on the patient CT (or on daily CBCT with optional Dosimetry Package).
2. Automatic dose/volume analysis, including Clinical Goals and 3D gamma results for the total volume and structure by structure.
3. Automatic Point Dose analysis for composite dose to Points of Interest and per-beam calculation points.
4. Automatic email notification summarizing pass/fail verification of clinical objectives.

Q: What planning data is needed by PerFRACTION?

A: For 2D Planar Analysis: DICOM RT Plan

For 3D Dose Reconstruction: DICOM RT Plan, RT Dose, RT Structure Set, and CT Image (Planning CT or CBCT).

EPID-Based PerFRACTION *Continued*

Q: Does PerFRACTION calculate absolute or relative dose?

A: Both. 2D Absolute Dose for Fraction 0 is a powerful option for pre- treatment IMRT/ VMAT QA. 3D dose reconstruction is always absolute. 2D transit measurements for Fraction n are (currently) relative.

Q: Is PerFRACTION a true in vivo dosimetry solution?

A: Yes. PerFRACTION provides a true in-vivo dosimetry solution by harnessing the power of simultaneous 2D transit measurement and 3D absolute dose reconstruction and analysis. When the additional power of CBCT-based dose reconstruction is added, all potential sources of error are accounted for.

This is consistent with the accepted definition in the literature as presented in a comprehensive review by van Elmpt, et al, 2008:[18]

"in-vivo dosimetry: measurement or determination of the dose inside the patient. Measurements performed during treatment can be performed invasively, i.e. inside the patient, or non-invasively, i.e. on or at some distance from the patient, whereby the in vivo dose at the point of interest is obtained by extrapolation."

An in-vivo solution that utilizes back-projected EPID data is simply using different inputs to provide the representation of the delivered patient dose. It is noteworthy that such solutions actually make it harder to discern sources of potential error since all sources — linac output, MLC leaves, jaws, and patient — are combined in the EPID signal. Interested readers are referred to the SNC white paper On the Matter of Forward Versus Back Projection for further details.

Further considerations for the use of EPIDs for in-vivo dosimetry is presented in the AAPM vision 20/20 paper.

Q: A recent publication found that a high percentage of errors can be detected during the first fraction. How can PerFRACTION detect these errors if the comparison baseline is the first fraction?

A: An absolute dose functionality for Fraction n, which generates a predicted planar dose based on the patient's plan and CT, is currently under development.

Q: Does PerFRACTION recalculate onto CBCT?

A: Yes, PerFRACTION has the option to retrieve and recalculate dose onto the CBCT instead of the treatment planning CT. This is an automated process and easy to set up in the system preferences. The system will default to the most recent acquired CBCT for dose reconstruction and analysis when this feature is active.

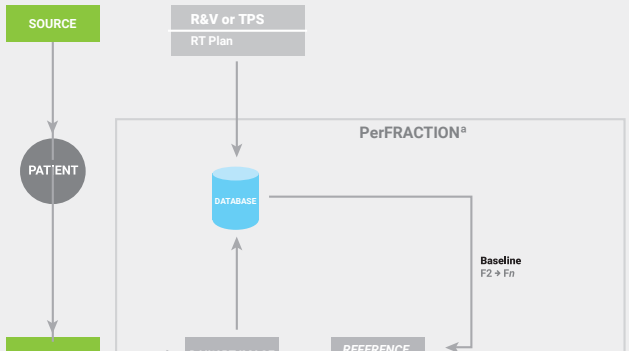
Q: Is the use of PerFRACTION a good way to spend my limited QA time?

A: Yes. A 2015 study from University of Washington reviewed 30 months of failure mode data. From the analysis, 343 incidents were rated as "potentially severe" or "critical."1 Of these incidents:

- 6% were detected by EPID-based pre-treatment QA
- 74% were detected by EPID-based in-vivo QA for the first fraction
- 20% were detected through EPID-based in-vivo QA following the first fraction

Clearly, routine measurement-based patient QA using the EPID can improve your ability to discover and reduce the impact of the 94% of potentially severe common treatment errors not detected by pre-treatment QA alone, thus improving patient safety.

Furthermore, PerFRACTION's automated processing provides these benefits with minimal footprint on your daily workflow (see below).



For a detailed overview of process flows for PerFRACTION 2D and 3D modes, please see the inside back cover of this document.

Workflow Efficiency

Q: Do I have to use PerFRACTION for every fraction?

A: It's up to you. PerFRACTION has been designed to handle automated pre-treatment phantom-less IMRT QA and automated in-vivo QA for every fraction, but actual frequency can be selected to suit departmental needs. As described earlier in this document, a 2015 study from the University of Washington found 74% of errors rated as "potentially severe" or "critical" were detected when a first-fraction in-vivo QA was added to the pre-treatment QA,[1] and a further 20% when used for later fractions.

Q: 2D image to image comparison for pre-treatment QA can be done with my Varian linac with Portal Dosimetry. How is PerFRACTION different?

A: In addition to full independence, PerFRACTION offers several important advantages in efficiency and clinical value:

Automated. Portal Dosimetry requires manual initiation of the calculation/comparison. With PerFRACTION, the analysis and alerts happen automatically.

Flexible. Point dose, 2D, and 3D analysis tasks can be simultaneously performed using different methods and settings. This streamlined, automated workflow makes it more likely that analysis can and will be performed daily for all patients.

Comprehensive. PerFRACTION is part of an integrated patient QA workflow and user interface that provides quality and clinical goals tracking from secondary calculations (DoseCHECK™) to pre-treatment QA (PerFRACTION Fraction 0) through in-vivo monitoring (PerFRACTION Fraction n) and exists within the larger integrated environment of the SunCHECK Quality Assurance platform

Practical Concerns

Q: What about fields that are larger than the EPID, fields that require an EPID shift, or a field (i.e. vertex) where the EPID cannot be deployed?

A: PerFRACTION's dose reconstruction algorithms are capable of handling fields where part of the field is outside the EPID sensitive area. Panel shifts and sag are managed using the Auto-Align functionality within 2D analysis. For Fraction 0, the EPID can be deployed at a closer SDD to better fit the field sizes.

In cases where the EPID is not used, is impractical, or images are missing, PerFRACTION can use the log files to reconstruct dose.

Q: What linac/R&V configurations are currently supported by PerFRACTION?

A: The following configurations are supported by PerFRACTION:

- Varian configurations:
  - TrueBeam™ / ARIA®, TrueBeam / MOSAIQ®, C-Series / ARIA, C-Series / MOSAIQ®
- Elekta configurations*:
  - Elekta digital accelerators (includes Versa) with iViewGT 3.4 or 3.4.1 / MOSAIQ

*Mosaiq 2.5+ and XVi 5.0+ are required for CBCT functionality.

Practical Concerns *Continued*

Q: With phantom-less pre-treatment QA, is there any need for arrays like MapCHECK® 2 and ArcCHECK®?

A: Patient QA arrays remain the gold standard for fully independent AND rigorous QA. Arrays offer a variety of benefits in combination with phantom-less QA:

1. **Audit QA** – Arrays should be used for periodic audit QA (every nth patient) to ensure issues are not present which the EPID or log file may miss (gantry rotation, sag, etc). Periodic array measurements test the system in more than one manner. Array audit frequency can be a function of the complexity or clinical familiarity with the QA case type. There are many examples of audit QA in use at clinics. For instance, a daily device (e.g. Daily QA™ 3) is used for morning output checks, but a different device (e.g. PROFILER™ 2, MapCHECK™2) is used for monthly output checks, and yet another device (e.g. 1D SCANNER™, PC ELECTROMETER™, IC PROFILER™) is used for annual output checks. These devices check the same QA parameters in different ways and serve as an overall audit of other QA devices.
2. **Commissioning** – Arrays are essential tools for efficient and stringent commissioning of new accelerators and treatment modalities. Arrays can collect data on a wide range of parameters that EPIDs and machine log files cannot. Medical Physics Practice Guideline 5, created by AAPM Task Group 244, recommends the use of arrays with volumetric capabilities (such as MapCHECK or ArcCHECK® with 3DVH®) as a step in a rigorous test of TPS commissioning16.
3. **Troubleshooting** – Arrays are uniquely valuable for troubleshooting unusual machine behavior and inconclusive results. Their physical independence from other systems offers flexibility and stringency to test the system end to end. Arrays are credited with discovering systematic and systemic errors that phantom-less methods will not see.
4. **Post-Service / Upgrade Verification** – Arrays enable completely independent verification (and base comparison) following any machine or TPS service or upgrade.
5. **Backup** – Arrays offer an invaluable backup for occasions where a phantom-less method may be off- line or unavailable.

IT & Setup Considerations

Q: Is SunCHECK (including PerFRACTION, DoseCHECK, SNC Machine, and SNC Routine) a Cloud application?

A: SunCHECK applications are 'cloud enabled' because they are accessed from anywhere on your clinical network via the web browser. By running locally, these applications provide more automation and faster processing performance than a purely Cloud application. A remote Cloud data storage service will likely be available in the future.

Q: How do I access PerFRACTION in my clinic?

A: Simply direct a supported web browser to the network location where PerFRACTION is installed.

Q: I am a consulting medical physicist; how will I use these applications at my client sites?

A: For optimal performance, SunCHECK applications such as PerFRACTION, DoseCHECK, and SNC Machine are designed to run on a local network.

This is also required for proper function of the automation architecture. Consulting physicists may access these applications by connecting to the network hosting them.

Q: Can I install PerFRACTION on a server that I provide?

A: Yes. Documentation is available upon request to help ensure user provided servers meets the required specifications.

Q: How does PerFRACTION's automation function?

A: PerFRACTION utilizes the information contained in DICOM headers to enable automated data retrieval and processing. When a DICOM RT Plan is first received by the system (usually via DICOM export from the Treatment Planning System, or TPS) patient information such as name and medical record number, as well as plan details such as plan name and number of fractions, are read from the DICOM header. The patient record is automatically created within the system and it begins monitoring for any further incoming information related to that patient and plan.

Q: How does PerFRACTION communicate with ARIA?

A: PerFRACTION communicates with ARIA through the system's DICOM Query/Retrieve service to automatically find and process new PerFRACTION data.

Q: How does PerFRACTION communicate with MOSAIQ?

A: PerFRACTION monitors the MOSAIQ import folder and automatically retrieves relevant data once it is found. CBCT data is retrieved using a SQL database query.

Q: What is the process for installation and training? What is required from Elekta and Varian?

A: Upon receipt of your order, Sun Nuclear Installation and Support will contact you to schedule a date for installation and training. Sun Nuclear will collect information about your facility and guide you through the process of understanding what will be required from Elekta and/or Varian for your specific configuration. Sun Nuclear will work with you to ensure that all the pre-requisites are configured prior to coordinating PerFRACTION specific installation and training.

Q: What kind of involvement from our center's IT department does PerFRACTION require?

A: During the pre-installation process, Sun Nuclear will work closely with your IT department to ensure that the server(s), linac(s), TPS and R&V are configured correctly prior to PerFRACTION installation and training.

Technical Considerations

Q: What method does PerFRACTION use to analyze 2D results?

A: Analysis methods for available for 2D (relative and absolute dose) include gamma, percent difference, composite evaluation (DTA), gradient compensation, and Diff-to-DTA (Sun Nuclear exclusive based on ICRU 83 Appendix A).

Q: What algorithm does PerFRACTION use to calculate & evaluate 3D results?

A: GPU-accelerated collapsed cone convolution/ superposition exclusively licensed from Johns Hopkins University. 3D dose is evaluated using Point Doses, 3D Gamma, Clinical Goals, Dose Volume Histogram (DVH), and isodose images.

Q: How is the EPID calibrated for absolute dose?

A: PerFRACTION generates a calibration RT Plan that is specific to the linac, MLC, EPID panel, energy, and SID. This plan can be exported directly to the Record & Verify system for delivery. Once images are collected, PerFRACTION automatically retrieves them and compiles the calibration.

Q: What accuracy studies exist on PerFRACTION?

A: There have been several accuracy studies performed on both PerFRACTION 2D[10, 12, 13] and 3D results[14], 15. These papers have found that PerFRACTION 2D is "sensitive enough

to detect small positional, angular, and dosimetric errors within 0.5mm, 0.2 degrees, and 0.2% respectively,"[13] and that PerFRACTION's dose calculations are accurate to within 1% of other treatment planning systems.[14]

Q: How does PerFRACTION handle electron density corrections?

A: PerFRACTION provides the ability to enter CT-to-electron (CT-to-ED) density values for CT scanners used for treatment planning. These CT-to-ED values are

automatically applied using information from the DICOM header in the CT image during 3D dose calculation. Default tables based on published literature are also available.

Q: How does PerFRACTION handle beam modeling?

A: PerFRACTION uses a standard library of beam models covering most commercial linear accelerator energy/ MLC configurations. The PerFRACTION beam model library uses beam data that is more specific and accurate than universal/golden beam data provided by linac manufacturers.

Q: Can the beam model be customized for my machine?

A: Sun Nuclear can provide a custom beam model in situations where this is determined necessary.

Q: Is EPID drift a concern?

A: PerFRACTION 3D dose reconstruction is immune to EPID drift or changes in the EPID because the proprietary leaf-edge detection algorithm does not rely on absolute values from the EPID image. When using the EPID for absolute dose analysis in 2D-mode, the EPID requires calibration, the process for which is included in PerFRACTION.

Q: By using PerFRACTION frequently, will the lifetime of my EPID be reduced significantly?

A: Not likely. The shift toward EPID dosimetry over the last decade has fueled innovation in the design of EPIDs, so with newer EPIDs radiation lifetime has been improved.

One OEM notified customers that the dose tolerance of their EPID is 5M cGy (or 50 kGy) in one year. In order to exceed that number, 195 patients per day would have to be treated with the EPID extended for every field for the entire year on one linac. PerFRACTION also allows the use of log files and/or intermittent EPID measurements for transit/in-vivo dose monitoring as a way to manage EPID life expectancy.

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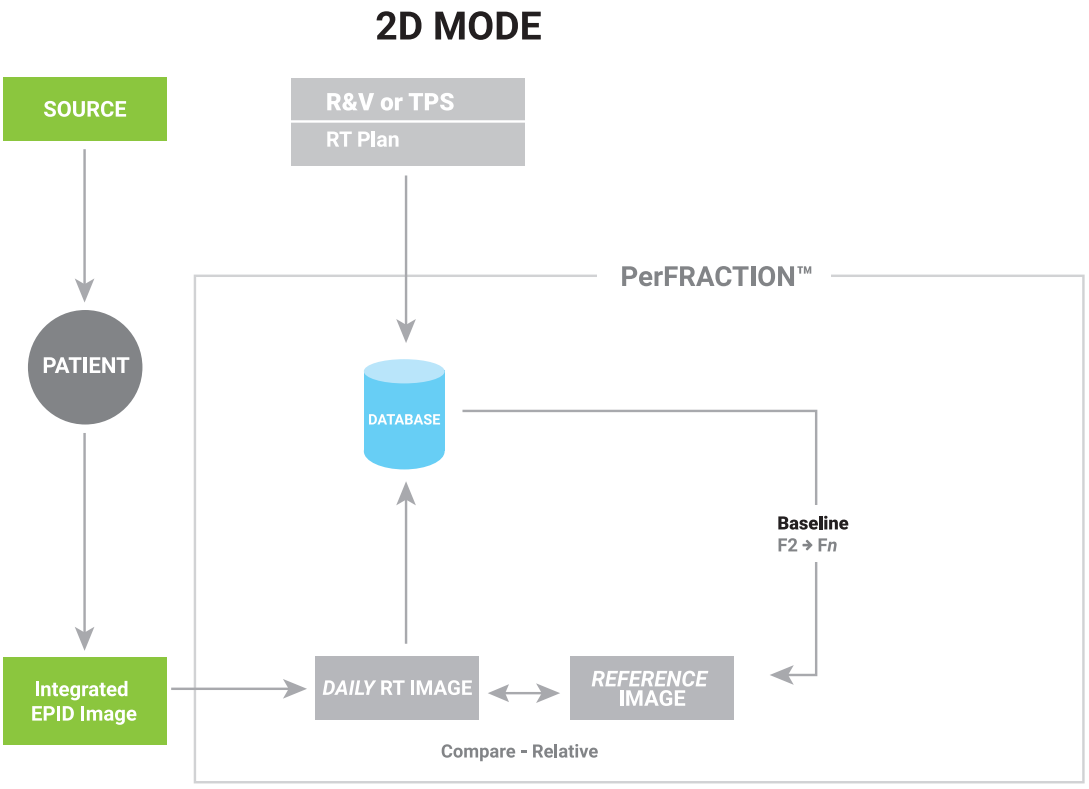
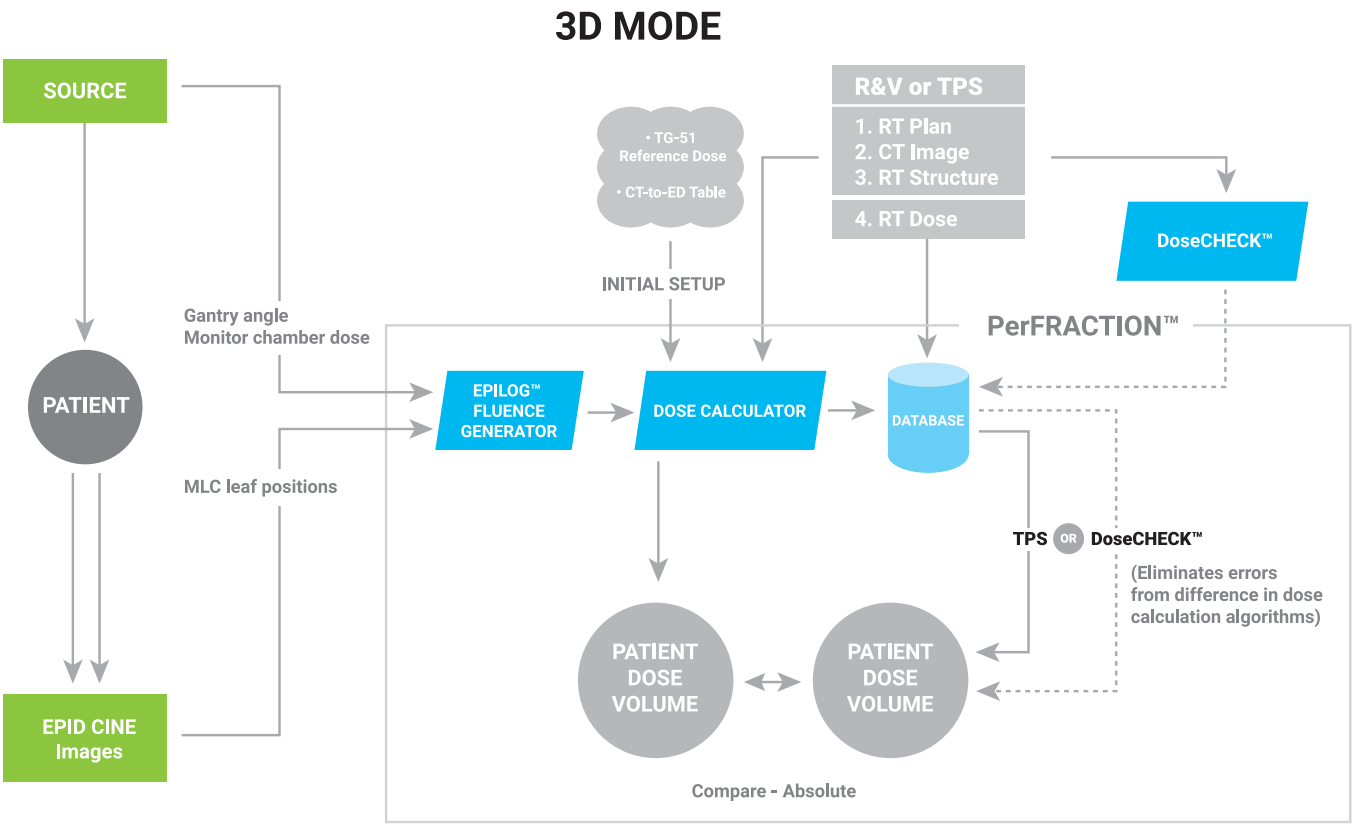
Process Flows: Per**FRACTION**™ Fraction *n*™





Fraction n 3D mode includes the option of using DoseCHECK calculated dose as a reference dose (dashed line). DoseCHECK as a pre-treatment secondary check sold separately.

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