Personalized confidence in radiation oncology



The increased complexity of high-tech radiotherapy techniques, such as stereotactic radiosurgery, proton therapy, MR-guided radiotherapy, revealed an emerging need for equally sophisticated technology in machine validation and patient treatment verification.

RTsafe as a medical technology innovator meets the challenge for integrated Machine and Patient QA solutions. By utilizing cutting-edge 3D printing technology and real 3D dosimetry, introduces truly end-to-end QA procedures and patient-centered processes.

Our team of experts specializes in the sectors of medical physics, engineering, software development, and quality management combining both clinical and research experience. A team fully committed to quality, striving through continuous R&D for optimal and innovative products and services aiming to meet radiotherapy professionals' expectations. Providing the opportunity for individualized care: physicians gain total control of the process, medical physicists reduce uncertainties, clinics build stronger brand name and patients get a better quality of living.

Machine QA

Customized Phantom Service

Remote Dosimetry Services

 $succeS^RS$

PseudoPatient®

Machine QA

Prime

Broadening the spectrum of quality assurance

Complexity of contemporary radiotherapy demands a novel approach in quality assurance. **Prime** is a 3D-printed head phantom that broadens the spectrum of quality assurance through an integrated solution.

It offers comprehensive dosimetry in a true-to life human anatomy phantom for End-to-End evaluation of advanced radiotherapy applications, focusing on stereotactic radiosurgery.

Prime can be combined with RTsafe's Remote Dosimetry Services.

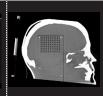






















Key Features

Confidence through 3D dosimetry

Prime phantom enables 3D gel dosimetry measurements for the evaluation of the spatial accuracy in complex treatments, in combination with the Remote 3D Dosimetry service, RTsafe provides multi-level comparison with TPS calculations incorporated in a detailed 3D dosimetry report.

True-to-life human anatomy

Based on an actual patient's CT scan, Prime utilizes bone and soft tissue-equivalent materials providing realistic contrast in MR and CT imaging.

End-to-End QA in stereotactic radiosurgery

All the links of the radiotherapy chain are evaluated in a holistic way by simulating patient's treatment processes from imaging to setup and dose delivery. Comprehensive Point/2D/3D dosimetry and imaging assessment form the ultimate QA solution in SRS.

Imaging and dosimetry inserts available

- Ion Chamber/diode/diamond detector
 Fixed Position Dosimetry kit
- Ion Chamber/diode/diamond detector
 Variable Position Dosimetry kit
- Film Dosimetry kit (2D dosimetry)
- Gel Dosimetry kit (3D dosimetry)
- MR-related geometric distortion evaluation insert
- Winston-Lutz insert with central and offset targets
- Multiple-OSL dosimetry kit
- Multiple-TLD dosimetry kit
- SGRT Positioning check insert
- Human-like anatomy and skin tone

- End-to-End QA in SRS Applications
- Commissioning and Benchmarking
- Periodic Quality Assurance
- Confidence Building & Training
- Remote or Internal Audit Tests
- Clinical or Academic Research
- Comprehensive QA in SGRT Techniques
- End to End QA in Proton Therapy
- Suitable for End-to-End testing of SGRT systems



Encephalon 3D

Limitless SRS QA

Current QA equipment is inadequate for the commissioning of cutting-edge technology for multiple brain metastases treatments.

Encephalon 3D is a single-use head phantom constructed from bone equivalent material. The brain area is filled with 3D polymer gel dosimeter, as a tissue equivalent material, giving to the end-user the ability to gain a real-3D map of the delivered dose.

Encephalon 3D is the absolute solution for the validation of the overall hardware and software performance. Explore the limits of your SRS treatment procedures in an End-to-End manner through 3D dosimetry in a unique patient derived phantom.



Key features

3D dosimetry

Encephalon 3D head phantom enables high spatial resolution real-3D dosimetry, in a patient-derived anatomy. The 3D evaluation of the spatial accuracy reveals any minor uncertainties even in the most demanding plans, such as peripheral multiple metastases cases, making the Encephalon 3D an excellent margin-strategy decision tool.

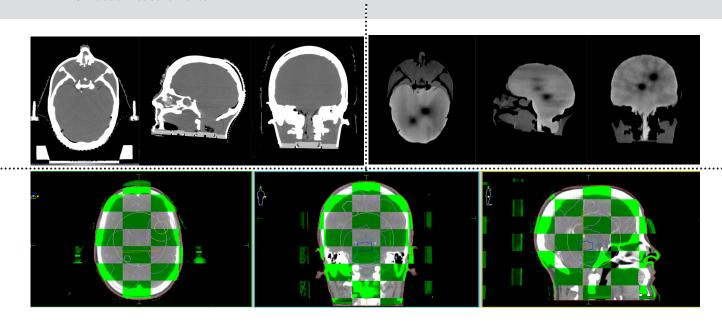
End-to-End QA

Encephalon 3D is treated as if it is the real patient, checking the whole SRS process, from imaging and planning to positioning, IGRT and treatment delivery. Commissioning and periodic QA of the SRS platform is achieved through an in-depth multi-level validation.

SRS confidence

A unique solution for boosting the SRS program at your clinic by adapting cutting-edge technology. Full exploitation of the system capabilities through data-driven decisions.

- Advanced End-to-End QA
- Commissioning of SRS equipment and software
- Evaluation of multiple metastases SRS applications
- 3D dose measurements



SBRT phantom

Ensure target localization and patient repositioning

SBRT requires precise target localization, patient immobilization, and frequent positioning checks to avoid significant dose deposition in critical organs at risk. Given that challenge, SBRT phantom by offering dosimetry options within the lung area and vertebrae/bone is an ideal End-to-End QA tool for radiosurgical body treatments.

SBRT phantom is an anthropomorphic 3D-printed phantom that simulates the anatomy of an abdominal case, with bone and tissue-equivalent materials. The unique advantage of having realistic bone and soft-tissue contrast in both CT and MR imaging makes SBRT phantom an excellent tool for online adaptation of advanced SBRT techniques.

SBRT phantom is set up and treated just like a real patient. Through target localization as in the clinical workflow, it provides confidence in advanced and challenging SBRT techniques.



Key Features

END-TO-END QA

- Direct measurements in spinal cord/vertebrae and lung
- Validation of a clinical treatment plan
- · Positioning as a patient

TRUE-TO-LIFE HUMAN ANATOMY

- Based on patient's CT data of abdomen case
- Realistic bone and soft tissue contrast in CT/MR imaging
- Bone and soft tissue equivalent materials

ACCURATE LOCALIZATION

- Treated like a real patient
- Target localization as in the clinical workflow



Inserts

- Ion Chamber/diode/diamond detector Fixed Position Dosimetry kit
- Ion Chamber/diode/diamond detector Variable Position Dosimetry kit
- Film Dosimetry kit (2D dosimetry)
- Gel Dosimetry kit (3D dosimetry)
- MR-related geometric distortion evaluation insert
- Exchangeable lung insert
- Winston-Lutz insert with central and offset targets
- Multiple-OSL dosimetry kit
- Multiple-TLD dosimetry kit
- SGRT Positioning Check insert

- End-to-End QA in SBRT Applications
- Comprehensive QA in SGRT Techniques
- Commissioning and Benchmarking
- Periodic Quality Assurance
- Confidence Building & Training
- Remote or Internal Audit Tests
- Clinical or Academic Research

Spine

More accurate spine radiosurgery

RTsafe's 3D printed **Spine** phantom is an accurate replica of a real patient's spine anatomy for SBRT quality assurance test. Spine phantom is manufactured to meet the need of a patient specific End-to-End solution in SBRT field. It is an ideal choice for building confidence and ensuring safety in treatment delivery for patients treated with hypofractionated SBRT schemes.

Key Features

Bone equivalent material

3D printed bone anatomy with density corresponding to bone equivalent material.

Realistic anatomy-treat as the real patient

Evaluates all steps of treatment chain: planning-CT, TPS, set-up, image guidance, treatment delivery.

Flexibility to accommodate different types of point dosimeters

Properly machined to accommodate point dosimeters such as ion chambers, diodes or diamond detectors into the spinal cord and the spinal bone.

- End-to-End QA in SBRT Applications
- · Commissioning and Benchmarking
- Periodic Quality Assurance
- · Confidence Building & Training
- · Remote or Internal Audit Tests
- · Clinical or Academic Research







CUSTOMIZED PHANTOM SERVICE

Build your own phantom

5 Levels of Customization - 5 Degrees of Freedom Body Part Dosimetry Options Dosimetry Inserts Extra Features

Customized Phantom Service

Meeting specific radiotherapy needs via a user guided service

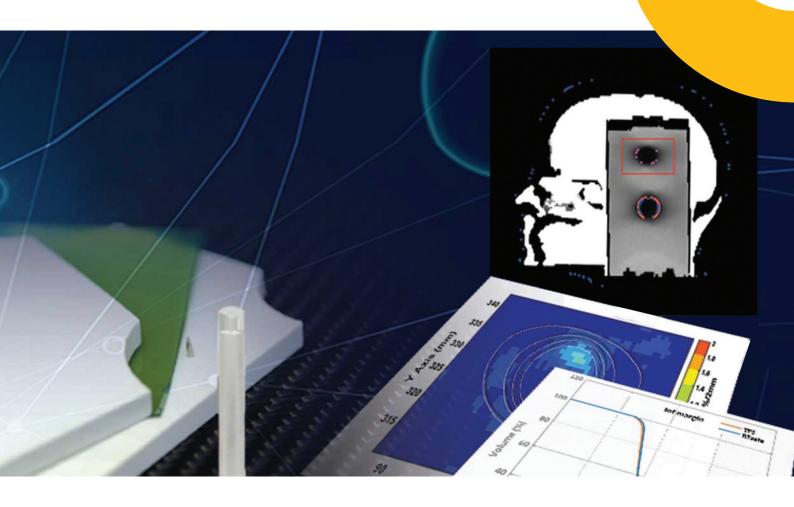
Modern Radiotherapy is a complex and constantly changing technological environment consisted of many parts. Even minor changes in isolated points of this chain can upset the balance of the system. QA tools need to always adjust and be able to control all variables and parameters, however commercially available phantoms are mass production products that often fail to meet specific needs.

Customized Phantom Service is a totally customer-centric phantom construction service, where the end-user becomes part of a multi-level design process defining the desired features, and in harmonization with the know-how of a specialized team, creates custom phantoms perfectly tailored to designated specific needs.



Remote Dosimetry Services

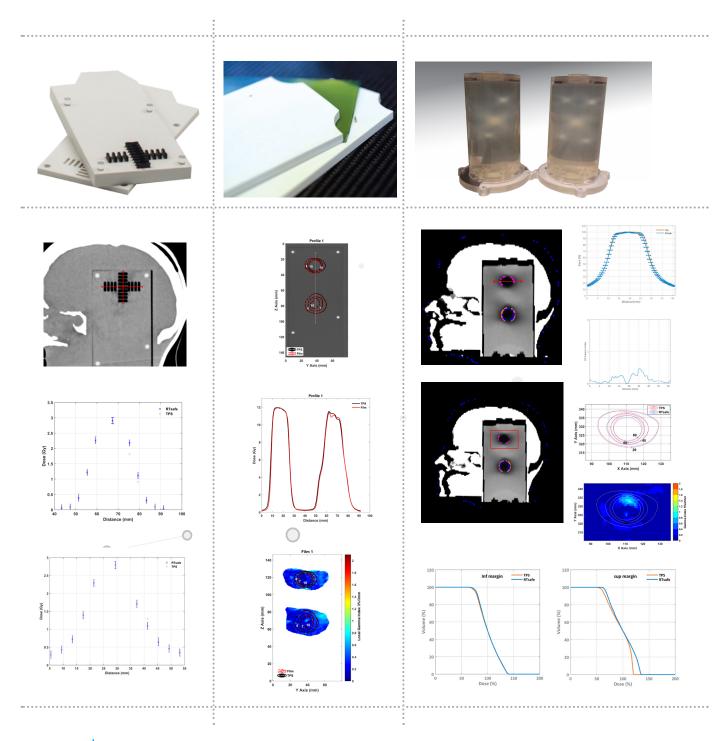
Advanced dosimetry. Simple implementation.



Remote Dosimetry Services

Advanced dosimetry. Simple implementation.

The complex nature of advanced radiotherapy treatment process demands a commitment to the highest levels of accuracy and precision. The RTsafe **Remote Dosimetry Services** package forms a powerful tool for quality improvement. Promote the best practice and assure high quality treatments, by outsourcing the routine quality control program of your radiation oncology QMS using a cost and time effective solution.



Remote Dosimetry Services

Advanced dosimetry. Simple implementation.

Key Features

High quality treatments

Point, 2D & 3D dosimetric and geometric accuracy is verified through independent measurements, traceable to SSDL, empowering treatment's efficiency.

Effortless high-end QA

All RTsafe remote dosimetry processes are based on existing standards and protocols from international organizations. QA solutions tailored to the department's specific needs assist radiotherapy professionals to evaluate the whole treatment chain.

Cost & time effective solution

All dosimeters provided are ready-to-use requiring the minimum effort for machine and patient QA. An advanced solution that supports the implementation of novel and complex techniques.

Offered services

Point dosimetry

Calibrated OSL (*myOSLchip $^{\text{TM}}$) dosimeters for absolute dosimetry.

2D dosimetry

Calibrated EBT3 and EBT-XD **GAFchromic films for relative and absolute dosimetry based on single/triple channel protocols.

3D dosimetry

Polymer gel formulation for relative dosimetry.

*myOSLchip™ is a trademark of RadPro International GmbH, Germany

**Gafchromic™ is a trademark of Ashland Inc. (Wayne, NJ)

RTsafe performs combined with Prime phantom the dose read-out and analysis of the results providing a comprehensive dosimetric report including multi-level comparison between dose measurements and TPS calculations.

Depending on the provided service, results include:

- Dose profiles
- 2D isolines
- 3D gamma evaluation
- DVHs
- Plan quality metrics
- Geometric offsets



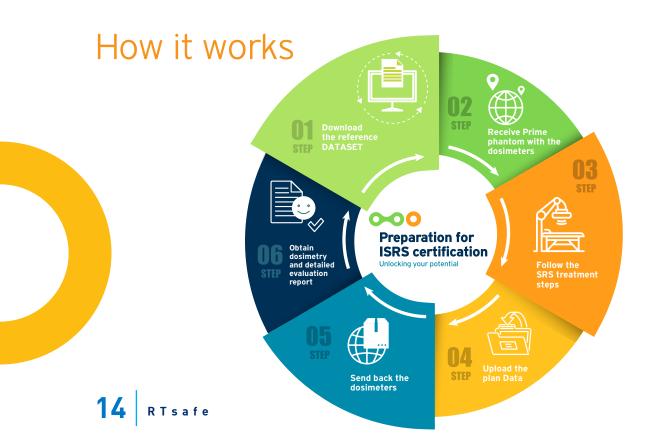
Preparation for ISRS certification

Unlocking your potential

The **ISRS Certification Service** requires radiosurgery departments to demonstrate proficiency in quality assurance and patient safety through a thorough review and documentation of their processes and procedures. To prepare for a successful dosimetry audit, centers have the opportunity to enlist the consulting services of RTsafe, which specializes in End-to-End Stereotactic Radiosurgery external dosimetry evaluation, using the same equipment and methodology as ISRS auditors.

RTsafe provides expert guidance and support to identify areas for improvement and develop strategies to meet the standards set forth by ISRS. The proposed package includes a Prime phantom bundled with Remote Dosimetry Services, where the user is supported step by step to achieve a particular level of accuracy for required treatment objectives. Results are reported using selected gamma passing rates suitable for SRS plan analysis and the tolerance limits proposed by ISRS.

Collaborating with RTsafe will help prepare the department for the ISRS Certification Service and demonstrate a commitment to the highest quality patient care.







SRS & SBRT remote dosimetry audit services

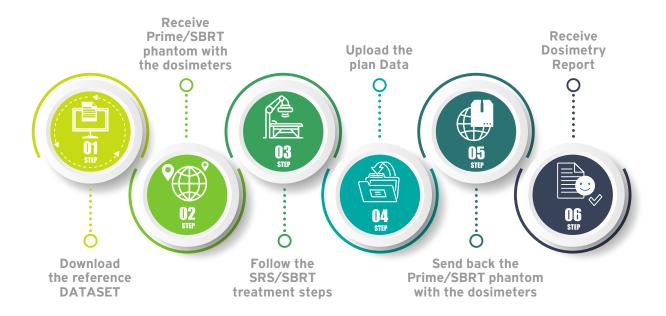
Ensuring the indispensable precision and accuracy of the inherently intricate stereotactic treatment process is paramount.

succeS^R**S** emerges as a formidable tool, elevating the standard of intracranial and body stereotactic radiotherapy through its comprehensive remote dosimetry audit services.

Conducted with the advanced RTsafe Prime and SBRT phantoms for intracranial and body stereotactic radiotherapy applications respectively, these audit services employ tailored inserts accommodating Gafchromic EBT3 or EBT-XD film, OSL, and polymer gel dosimeters. Dosimeters' calibration at the Greek Atomic Energy Commission's Secondary Standard Dosimetry Laboratory ensures traceability to BIPM-France, assuring the required dosimetric accuracy.

Facilitate best practices and ensure the excellence of SRS and SBRT treatments by seamlessly integrating a dedicated credentialing program into your radiation oncology Quality Management System. Transform your clinic's SRS and SBRT programs with state-of-the-art technology, unlocking the full potential of the treatment delivery platforms through informed, data-driven decision-making.

This unique solution not only promotes quality but also propels your clinic to the forefront of cutting-edge radiotherapy advancements.



PseudoPatient®



Reassurance before Radiotherapy

An entirely new and technology driven way to treat patients, rooted in over 20 years of research and development.

PseudoPatient®

Patient Treatment Verification Redefined. Safety Personalized.





For the first time, ensuring optimal results before the actual treatment in a personalized way.

Every medical practice is associated with some degree of uncertainty. With RTsafe's technology driven and personalized PreTreatment service, this uncertainty is minimized to the lowest level, leading to a near zero risk radiotherapy.

PseudoPatient® is an FDA cleared device intended for personalized pre-treatment verification, constructed by patient's planning CT data using highly accurate 3D printing technology.

It is an anatomically accurate replica of patient's head, manufactured by bone and tissue equivalent materials, providing physicians and medical physicists highly accurate dose measurements, either:

- Point (PseudoPatient ® IC)
- or full visualized 3D projected on patient's treatment imaging (MR/CT), ideal for verification of demanding SRS cases (PseudoPatient ® 3D).

PseudoPatient® IC

The PseudoPatient® IC, is a precise model of a patient's CT-scan. Bone structure and external contour are 3D printed using bone equivalent material. The PseudoPatient® is a pre-treatment end-to-end verification device. The device verifies the TPS dose calculations as well as the following parts of the treatment chain: patient set-up, patient immobilization, image guidance, and treatment delivery. The 3D printed, PseudoPatient® accommodates this type of dosimeters: ion chamber (IC) insert (or any kind of insert for point dosimetry).

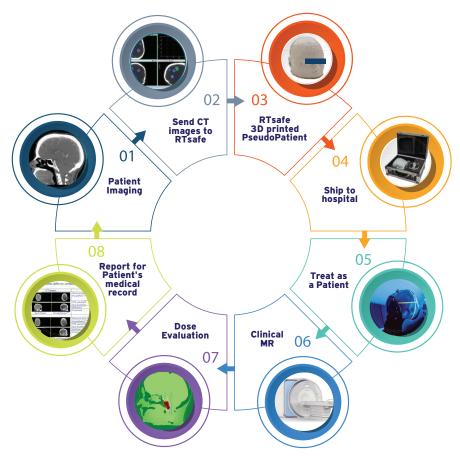
The insert can be relocated depending on demands of treatment. The ion chamber inserts are specifically designed for the detector type indicated by the end user and constructed of Poly(methyl methacrylate) (PMMA).

The PseudoPatient® is intended for the quality assurance of patient specific brain treatments done prior to and/or inter-fractionally to delivery by external beam radiotherapy, including SRS, IMRT and VMAT.

Evidence-based confidence

- Direct measurements on anatomic regions of high interest (PTV, OAR).
- End-to-end data-driven medical evaluation of all treatment processes.
- Unique & personalized approach optimizes treatment outcomes and minimizes the risk of side-effects.





PseudoPatient ®3D

The PseudoPatient® 3D is used to verify third party treatment planning as well as radiation treatment chain for brain lesion radiation through the visualization of the 3D Dose pattern. First, the CT scan of the patient is obtained and used to construct the exact replica of patient's head. The final product is constructed from bone equivalent material and polymer gel as tissue mimicking material. Second, the CT-scan of the PseudoPatient® 3D is co-registered with the patient's CT images using any third-party treatment planning system (TPS). The physician and physicist shall create an irradiation plan, using department guidelines, and treat the phantom as the real patient in order to simulate the whole treatment chain. After irradiation the phantom has to be MR scanned using a clinical T2 weighted sequence (or a T2 parametric map). These MR images depict the high dose areas of the dosimetric gel as darker than the low dose ones. After coregistering the TPS calculations and the MR images the user can qualitatively verify the geometric accuracy of the dose delivered to the phantom.

The PseudoPatient® 3D is intended for the quality assurance of patient specific brain treatments done prior to and/or inter-fractionally to delivery by external beam radiotherapy, including SRS, IMRT and VMAT.

Data-driven practices

- Designed to provide 3D-dose visualization through a real-to-life treatment simulation.
- Allows the physician to fully control and evaluate the treatment. Check that what is planned
 is accurately delivered.
- Medical record evidence of true treatment results under realistic conditions.

Patient Treatment Verification Redefined. Safety Personalized.

- Evidence based confidence
- Data-driven practices
- Efficiency & Safety



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