

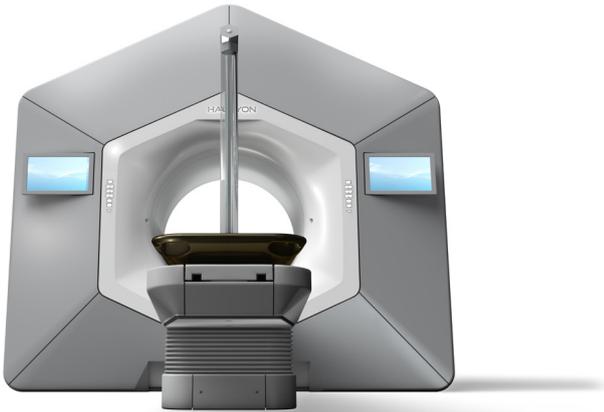
HALCYON RADIOTHERAPY SYSTEM

OPERATIONAL EXCELLENCE:

Optimized, Simplified, Expedited Quality Care

Operational Excellence

Halcyon™ is Varian’s newest cancer treatment system, engineered to simplify and enhance virtually every aspect of image-guided volumetric IMRT. Halcyon was designed to set a new standard in operating efficiency and patient care while enabling high quality treatments that are delivered quickly, safely, and accurately. This document describes the contributions of the device’s component systems, which are tightly integrated to add up to much more than the sum of the parts.



This level of efficiency is enabled by several coordinated technologies:

- The flattening filter free (FFF) beam, which maintains a high dose rate of around 800MU/min throughout a treatment.
- A new gantry design with brushless motors that enable fast rotation (4 revolutions per minute).
- The dual-layer multileaf collimator, with leaves that travel at a speed of five centimeters per second, allowing the MLC to keep pace with the gantry speed and high dose delivery rate.
- The Maestro control system—an electronic controller that dynamically directs, synchronizes, and monitors each of Halcyon’s fully integrated subsystems—which generates instructions and checks system performance every ten milliseconds.

Safety

Efficiency is balanced with safety. A built in six-point safety system includes an automated daily machine performance check that fully tests the system every day, automatically, consistently, and quickly, in about five minutes. This amounts to less time invested in testing.

Operating Efficiency

Speed of Halcyon Treatments

Halcyon treatments are 100% image guided. The system enables imaging and treatment with unprecedented speed:

- Sharp cone-beam CT images can be acquired in about 15 seconds; 2-D orthogonal image pairs in seven seconds or less.
- Multiple RapidArc® radiotherapy trajectories and complex multi-field IMRT treatments can be completed in about two minutes (beam-on time).
- Image-guided IMRT or RapidArc treatments are typically completed in just nine steps.
- Standardized workflows that are easy to master so clinicians can spend more time concentrating on their patients.



Optimizing Value of Ownership

Halcyon was designed to maximize the value of ownership across the lifecycle of the system.

Fast Path from Acquisition to Clinical Use

A Halcyon system offers accelerated installation timeframes and expedited commissioning, for a fast path from acquisition to clinical use. Many factors contribute to a speedy clinical deployment:

- The system's small footprint and self-shielding reduces the amount of primary shielding needed.
- Two-crate shipments make for easy transportation through normal-sized freight elevators.
- The gantry frame bolts to the floor and the couch connects directly to the gantry frame, making a base frame unnecessary. Consequently, concrete work is minimized.
- Integrated components, including the intercom, camera, lasers, solid state modulator, and shielding, are installed as one unit. Installations can be completed in less than two weeks.
- Beam parameters are pre-configured in the Eclipse™ treatment planning software, which means that Halcyon reduces the amount of effort needed for commissioning.
- Simple workflow lends itself to fast mastery by the clinical team. Training is delivered onsite, and through a multi-media eBook manual (installable on a tablet), including animations, videos, and step-by-step instructions.

Capital and Operational Efficiency

Many factors contribute to making Halcyon a revolutionary new system with the potential to impact the overall economics of cancer care. In addition to the factors mentioned above as

contributing to expedited treatments, Halcyon also offers:

- Consistent simplified workflow. Standard image-guided IMRT or RapidArc treatments are completed in nine intuitive steps guided by a "follow the light" methodology that was first developed for Varian's TrueBeam® platform, making the therapists' job easier and freeing them to focus more on the patient.



Therapist uses a "follow the light" methodology for managing treatment

- Reduced physics QA. The TG142 test requirements for Halcyon are about half that of a standard C-arm linac. This frees physicists up to focus on complex patient cases, research, or other priorities.
- Halcyon requires less energy to run, which contributes to cost savings.
- A water cooled system that offers efficient heat removal for reliable operation. It also contributes to patient comfort in that it operates quietly and allows for a comfortable room temperature.
- SmartConnect™ remote servicing. Every Halcyon system is SmartConnect enabled, so that Varian personnel can perform diagnostic and support services remotely, via network connection.
- IT security. Halcyon ships with security-hardened versions of Eclipse™ treatment planning and the ARIA® oncology information system.

Intended Use Summary

Varian Medical Systems' linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

DISCLAIMERS

This product brief is not for use in the United States, as the Halcyon Radiotherapy System is 510(k) pending and not yet cleared for sale by the U.S. FDA. Not available for sale in all markets. Devices or features presented in this brochure may not be available for sale in all markets. Specifications and features subject to change without notice.

VARIAN
medical systems

A partner for **life**

USA Headquarters, California

Varian Medical Systems
Palo Alto, CA
Tel: 650.424.5700
800.544.4636
Fax: 650.493.5637
varian.com

Headquarters Europe, Eastern
Europe, Africa, Middle & Near East

Varian medical Systems
International AG
Zug, Switzerland
Tel: 41.41.749.8844
Fax: 41.41.740.3340
email: info.europe@varian.com

Asia Pacific Headquarters
Hong Kong

Varian Medical Systems
Pacific, Inc.
Kowloon, Hong Kong
Tel: 852.2724.2836

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