VARIAN
medical systems

GAMMAMED*PLUS* iX, 3/24 iX AFTERLOADERS FEATURE SHEET

The GammaMed*plus*™ iX HDR/PDR afterloader with its iX control software offers compatibility with hospital networks and enhances the high dose rate (HDR) and pulse dose rate (PDR) brachytherapy experience. Commercially available for over 50 years, the GammaMed*plus* iX is the fifth generation in a reliable and respected line of afterloaders.

Intelligent | Integrated | Intuitive

KEY FEATURES OF GAMMAMED*PLUS* iX:

- Fixed length treatment distance aims to help reduce errors associated with applicator-to-afterloader connection
- Unique applicator end test to verify applicator connection integrity and treatment length
- Distal-to-proximal source movement
- Fully integrated with BrachyVision™ treatment planning system* and ARIA® oncology information system* network.
- 3/24 iX unit (3 channel)** allows easy and cost-effective entry into HDR for typical treatments with minimal capital expenditure.
- Upgradeable to 24 channels with little downtime to expand usage to all body sites
- Wide range of treatment accessories suitable for CT imaging

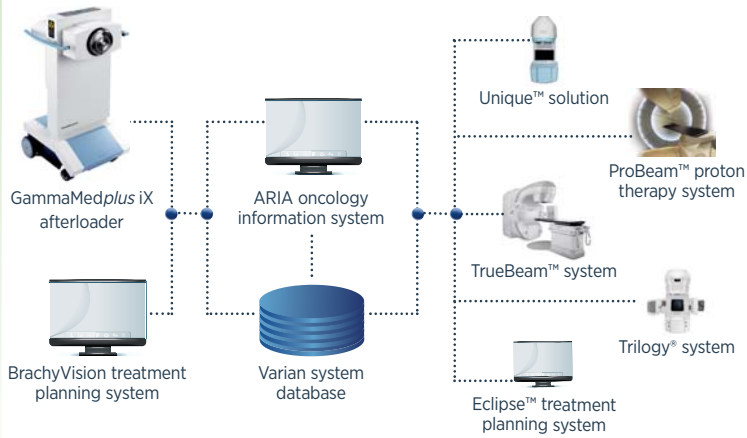
Contact your Varian BrachyTherapy representative to discuss these and other key features of GammaMed*plus* iX.

* *Version 11 and above*

** *PDR is not available for the GammaMedplus 3/24 model.*

BRACHYTHERAPY INTEGRATION

1. Patient scheduled in ARIA
2. Treatment plan created in BrachyVision and scheduled in ARIA
3. Afterloader console pulls treatment plan from ARIA
4. After patient treatment, afterloader console returns the treatment record to ARIA
5. Afterloader console updates the appointment status
6. RT Summary and Patient Summary display the treatment record and dose in ARIA



COMPREHENSIVE BRACHYTHERAPY TREATMENT

FEATURES

3.5 mm long active source encapsulated into the tip of a braided cable*

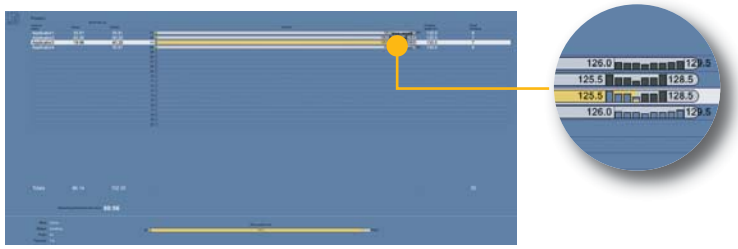
- Source can be installed at an activity of up to 15Ci.**
- Certified for up to 5,000 transfers meeting requirements, even for heavy users.
- Solid core-designed source cable permits movement in a distal to proximal direction during treatment delivery ensuring accuracy and potentially reducing errors caused by cable bunching.
- Distal 200 mm of the cable is a highly-flexible braided design that facilitates movement through tight catheter turns.

Flexibility in plan delivery

- Connects to up to 24 channels.
- Programmable up to 60 dwell positions per channel and variable step sizes ranging from 1 mm up to 10 mm in 1 mm increments.
- 0.1 second dwell time resolution with 0.0-999.9 seconds variable dwell time range for flexibility and precision in dwell time delivery.
- Source transit speed of up to 60 cm/second.
- Adjustable indexer head enables a level source treatment path from indexer to patient, whether laying down or in a seated position optimizing the path to the treatment site.

iX control software creates intuitive, streamlined, user-friendly experience

- Presents information in a controlled and logical manner with the aim of ensuring no detail is overlooked or misinterpreted.
- Logical screen layout, intuitive icons, and clear graphics provide the pertinent information when and where it is needed.
- Icons at the foot of the screen indicate the system status, source calibration information, and prior to treatment initiation, the status of all critical interlocks.
- Treatment delivery steps include: selecting the patient, confirming the demographic data, selecting the fraction, and checking the treatment parameters. Once reviewed, the treatment report may be printed or stored.
- For added patient safety, a unique treatment code is entered to begin treatment delivery.
- Imports patient data from the treatment planning system using a wizard-style, field-matching process to reduce the risk of selecting the incorrect patient for treatment. When a patient is recognized, users can create a new course or add the treatment to the existing course as a new fraction.
- View dwell times in a bar graph format to identify discrepancies.
- During treatment delivery, observe the radiation status, source position, remaining channel time (in minutes and seconds) and a graphical representation of real-time source position.
- Integration with the BrachyVision treatment planning system and ARIA oncology information system allows for the direct download of treatment plans with the aim of achieving accurate and reliable transfer of plan data, both to and from the database.



Treatment display streamlines workflows and shows pertinent information relating to the treatment in progress. The unique channel display facilitates clear indication of both dwell times and positions.

* *HDR. PDR source is 0.5 mm.*

** *Typical source installation activity may not be 15Ci for regulatory and/or logistic reasons.*

Fixed length treatment distance

- Combined length of the applicator and correct source guide tube is always 1300 mm.
- Potentially reduces errors caused by incorrect treatment length entry since the length is always the same.

Unique applicator end test

- Sends the inactive source to the end of the channel and then further extends to ensure that it detects a closed-end catheter.
- Verifies an unobstructed source path and a total channel length with the aim of ensuring uninterrupted treatment delivery and applicator connection integrity.
- Optional end test for intraluminal catheters where having the dummy push against the end is undesirable. Channels that do not perform the applicator end test include the last five channels on a 24-channel device and two channels on the 3/24 model.

Remote text displays at the console area and on the afterloader itself provide information on the source position and status.

Hardware and software safety

- Access to treatment delivery secured through two hardware keys and password protection.
- Mechanical verification of secure connection of catheters/applicators prior to treatment delivery.
- Inactive source cable extends to the end of the channel to verify that no obstructions or kinks in the guide tubes, applicator or catheter exist.
- Immediate cable retraction occurs when console communication failure is detected.
- Mechanical switch indicates when the cable is in the home position and the source is returned to the safe.
- Automatic detection of catheter/applicator blockages with position reporting.
- Checks performed by internal radiation detector during and after treatment delivery.

Emergency retraction

- Backup battery for emergency source retract.
- Independently powered Geiger Muller radiation detector alerts users if radiation is not detected during treatment or is detected after the source cable has retracted.
- Automatic source retraction on power failure or hardware error.
- Easily operated manual retract handle.

Varian BrachyTherapy Suite

The Varian BrachyTherapy Suite stems from the collaboration between Varian and Siemens successfully pairing imaging and treatment technologies to facilitate in-room brachytherapy procedures. The Varian BrachyTherapy Suite features the Siemens CT sliding gantry (CTSG) with either the VariSource™ or GammaMed*plus* afterloader and BrachyVision treatment planning. The Siemens CTSG can be configured with a dedicated full featured operating table, facilitating the most complex brachytherapy procedures.

TECHNICAL SPECIFICATIONS

Radioactive source -GammaMed*plus* iX

- Iridium-192, metallic
- Cylindrical configuration
- Iridium-192 pellet- HDR: 0.6 mm diameter, 3.5 mm active length; PDR: 0.6 mm diameter, 0.5 mm active length
- Capsule- HDR: 0.9 mm diameter, 4.52 mm length; PDR: 0.9 mm diameter, 2.97 mm length
- Nominal activity- HDR: 370 GBq (10 Ci)*; PDR: 37 GBq (1 Ci)
- Air Kerma Rate (HDR): 0.063 Gy/h (±5%) for 555 GBq at 1 m

** Currently, systems in the USA are subject to regulatory restrictions of use at or below 10 Ci only. The unit has been qualified to 15 Ci, and higher activity sources may be installed and used outside the USA.*

Source cable

- Iridium-192 source encapsulated in stainless steel
- Capsule welded to a flexible stainless steel cable
- Distance from distal cable tip to the beginning of the active pellet- HDR: 0.67 mm; PDR: 2.07 mm (To ensure consistent "cable tip to source center" distance for HDR and PDR sources)
- Cable diameter: 0.9 mm
- Maximum extension length: 130 cm
- The most distal 200 mm section of the cable is an ultra-flexible cable.
- Source manufactured according to ISO1677, ISO2919, ISO/TR4826, ISO9978 resulting in ISO source classification: C63333

Transportable options

The GammaMed*plus* iX HDR/PDR system has been qualified as a Type A shipping container. Every GammaMed*plus* iX HDR/PDR afterloader can be converted to a transportable system for use in multiple locations. In order to best meet our customer's transportation needs, Varian has developed a partnership with PHS West of Minneapolis, MN, USA. Depending on the transportation requirement, PHS West is able to provide solutions to include motorized carts and customized vans.

Afterloader

Meets the recommitments of the following standards:

- Electrical safety of medical devices standard IEC 60601-1
- Collateral standards of IEC 60601-1 specific to afterloaders IEC 60601-2-17
- IAEA and US DOT-7A.

Cable and drive parameters

- Nominal cable speed zero slip: approximately 60 cm/s
- Source positioning accuracy: ±1 mm relative to the indexer

Source placement

- 24 treatment channels
- 60 dwells per channel
- Step size: default 5 mm, programmable from 1-10 mm, in 1 mm increments
- Minimum radius of curvature at the distal end of the catheter: 1.3 cm in a ring probe of diameter 2.6 cm and in a 5 Fr bronchial catheter
- Method of source movement: commences at most distal dwell positions and steps back

Afterloader shielding

- Safe material: Tungsten
- Maximum storage capacity of safe: 555 GBq (15 Ci)
- Maximum Air Kerma Rate 1 m from afterloader: does not exceed 3 μGy/h for maximal load
- Radiation shielding: Conforms to International Electrotechnical Commission requirements (IEC 60601-2-17) ICRP codes and applicable NRC standards in the USA

Room shielding

- Controlled by local codes and conditions of operation
- Approximately 4 cm of lead or 35 cm of concrete is generally required

Electrical power requirements

- System power rating: 115 VAC / 60 Hz or 220V / 50 Hz models available; 100 VA
- In the event of a power failure, the afterloader is powered through the internal batteries to allow the source to retract to the safe.

Environmental requirements

- Operating temperature range: +15 to +35°C
- Humidity range: 30% to 75% (non-condensing)
- Air pressure: 70 kPa - 110 kPa

Weight & dimensions

- 130 kg
- 105 cm H x 51 cm W x 57.5 cm D

Equipment classification

- Type of protection against electric shock: CLASS 1
- Degree of protection against electric shock: TYPE B
- Degree of protection against harmful ingress of water: IP 40
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
- Class of operation: CONTINUOUS

Safety equipment (emergency container)

- Emergency source container is designed to hold most applicators directly
- Minimum shielding: 26 mm lead
- Minimum diameter (inner plastic container): approximately 60 mm
- Container height (internal): 270 mm

GammaMed*plus* 3/24

The GammaMed*plus* 3/24 has all of the safety features of the 24-channel GammaMed*plus*. Using the same source and flexible cable, it has the same precision and flexibility, except for the reduced number of channels.

Specifications subject to change without notice.

Intended Use Summary

Varian Medical Systems' software, afterloaders, and applicators are intended to provide radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects varying with the part of the body being treated. This may include, but not be limited to irritation to the mouth, respiratory system, digestive system, genitourinary system, fatigue, nausea, skin irritation, and hair loss. In a minority of patients, side effects can be severe. Typically, the side effects are temporary. Radiation treatment is not appropriate for all cancers. Treatment sessions may vary in complexity and time. Patients should discuss the treatment and side effects with their physicians before starting. Side effects of applicator placement and/or implantation may occur. These side effects may include, but are not be limited to, localized discomfort, bleeding, and infection or other localized side effects based on the location the applicator is placed. Patients should discuss the treatment and side effects with their physicians before starting.

Medical Advice Disclaimer

Varian as a medical device manufacturer cannot and does not recommend specific treatment approaches. Individual treatment results may vary.

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