

GammaMed*plus* iX, 3/24 iX HDR Afterloader



The GammaMed legacy



Proven performer moves to the next level

Excellence and innovation are the hallmarks of the GammaMed™ name in high dose rate (HDR) brachytherapy. For more than 40 years, GammaMed products have long forged a legacy of firsts, driving technology forward to provide cancer centers worldwide with the most advanced tools for planning and administering brachytherapy treatments. The GammaMed*plus* iX is the fifth generation in a long and respected line of GammaMed afterloaders.

The GammaMed*plus* iX introduces a new level of digital technology, with a new console computer system that is compatible with today's hospital networks; enhancing the brachytherapy experience today and providing a platform for future development.

Applying the principles of integration and openness, the GammaMed*plus* iX system has evolved to include multiple options and flexibility for the end user: GammaMed*plus* iX and GammaMed*plus* 3/24 iX remote afterloaders, BrachyVision™ treatment planning software, and Varian and third-party applicators.

To meet the needs of a broader range of customers, Varian BrachyTherapy includes the GammaMed*plus* 3/24 iX model in its family of brachytherapy solutions. Based upon the proven GammaMed*plus* platform, the 3/24 model can handle typical brachytherapy procedures requiring three treatment channels, and can be upgraded to a 24 channel afterloader on site, at any time, by a Varian service engineer.



A complete treatment solution

Precision-engineered and equipped with such critical features as an on-board radiation detector (a practice pioneered by GammaMed), an emergency source retraction system and a back-up power source, the GammaMed*plus* iX is safe, precise and flexible—a complete treatment solution.

Safety, precision, and flexibility combined

Safety you can trust

GammaMed*plus* iX complies with and has been validated against IEC 601-2-17 and meets major international standards for product performance and safety. In addition, the system comes complete with a built-in Geiger Muller radiation detector and features distal-to-proximal source movement, and a unique applicator length test for utmost safety and quality assurance.

Fixed length treatment distance

To eliminate errors due to incorrect treatment length entry, the GammaMed*plus* offers a fixed length treatment distance. The combined length of the applicator and source guide tube is always 1300 mm. You will always know where the source will deliver radiation, without worrying about treating the wrong area.

Unique applicator end test

Only the GammaMed*plus* offers the unique applicator end test capability, which sends its dummy source to the end of the channel and then presses another 5 mm to ensure that it detects a closed-end catheter. This test also verifies an unobstructed source path and a total channel length. The last five channels in the device, and two of the five usable channels on the GammaMed*plus* 3/24 model, however, do not perform this applicator end test. These channels are used for intraluminal cases where it is not desirable for the dummy to push against the end of a flexible catheter.

Distal-to-proximal source movement

By sending the source to the furthest point and pulling it back towards the safe, the device maintains wire integrity, accuracy in positioning, and again verification of clear source passage.

Simple source data entry

After source exchange calibration, the source strength is entered one time into the control software. The decay factor is maintained on the non-volatile memory of the control computer.

Uniquely bases treatment times on nominal 10 Ci source activity

Treatment plans are accepted with a fixed 10 Ci activity, so you develop a knowledge base of typical dwell times for similar cases. It is the device that tracks the decay of the source and then modifies the treatment time to accommodate this decay.

Direct transfer of patient information

Treatment data can be transferred between networked computers to remove the possibility of data entry error. Data can also be transferred via USB memory stick between non-networked computers.

Additional features

- 0.1 second dwell time resolution
- 0.0-999.9 seconds variable dwell time range
- Selectable treatment step size, 1-10 mm, in 1 mm increments



Additional safety features

GammaMed*plus* iX safety features also include a safe key-lock, a dummy source positioning control, a radiation warning light, an emergency source-retract button, and an emergency source hand crank.

Precision and flexibility

Source

- 0.9 mm capsule diameter, 4.52 mm capsule length.

Cable

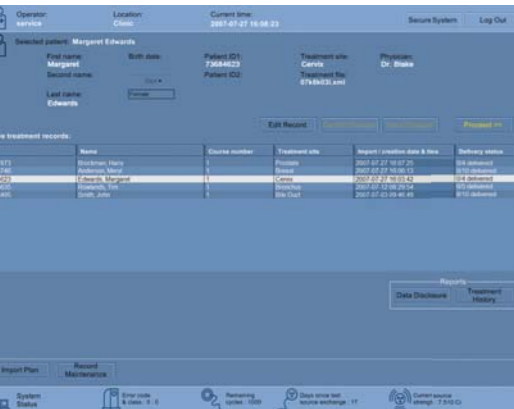
- 200 mm ultra-flexible final braided section. This section at the end of the cable allows for the ultimate flexibility in negotiating tight catheter turns.
- Tested for up to 5000 transfers. The durability of the cable will exceed typical or extended use.
- 13 mm minimum bending radius. This exceptionally flexible source cable can easily navigate even the tight bends in an ERCP bile duct treatment.

Adjustable Afterloader Height

The indexer head can be raised to enable a level source treatment path from device to patient. This optimizes the path to the treatment site and provides for patient comfort in seated or prone positions.



HDR brachytherapy with the latest digital technology



Streamlined workflows presents information in clear and logical layout.

Network capability

Able to be connected to the BrachyVision Treatment Planning system over a network it is possible to directly download treatment plans to insure accurate and reliable transfer of plan data.

Dedicated, intuitive control software

Varian recognizes the unique challenges of delivering HDR treatments. Time pressure is high and patients are anxious, while the importance of getting it right is paramount. That is why Varian has worked with customers, human interface engineers, and software developers to produce an after-loader control interface that is both intuitive and simple to use.

The best way to travel the information highway is step by step

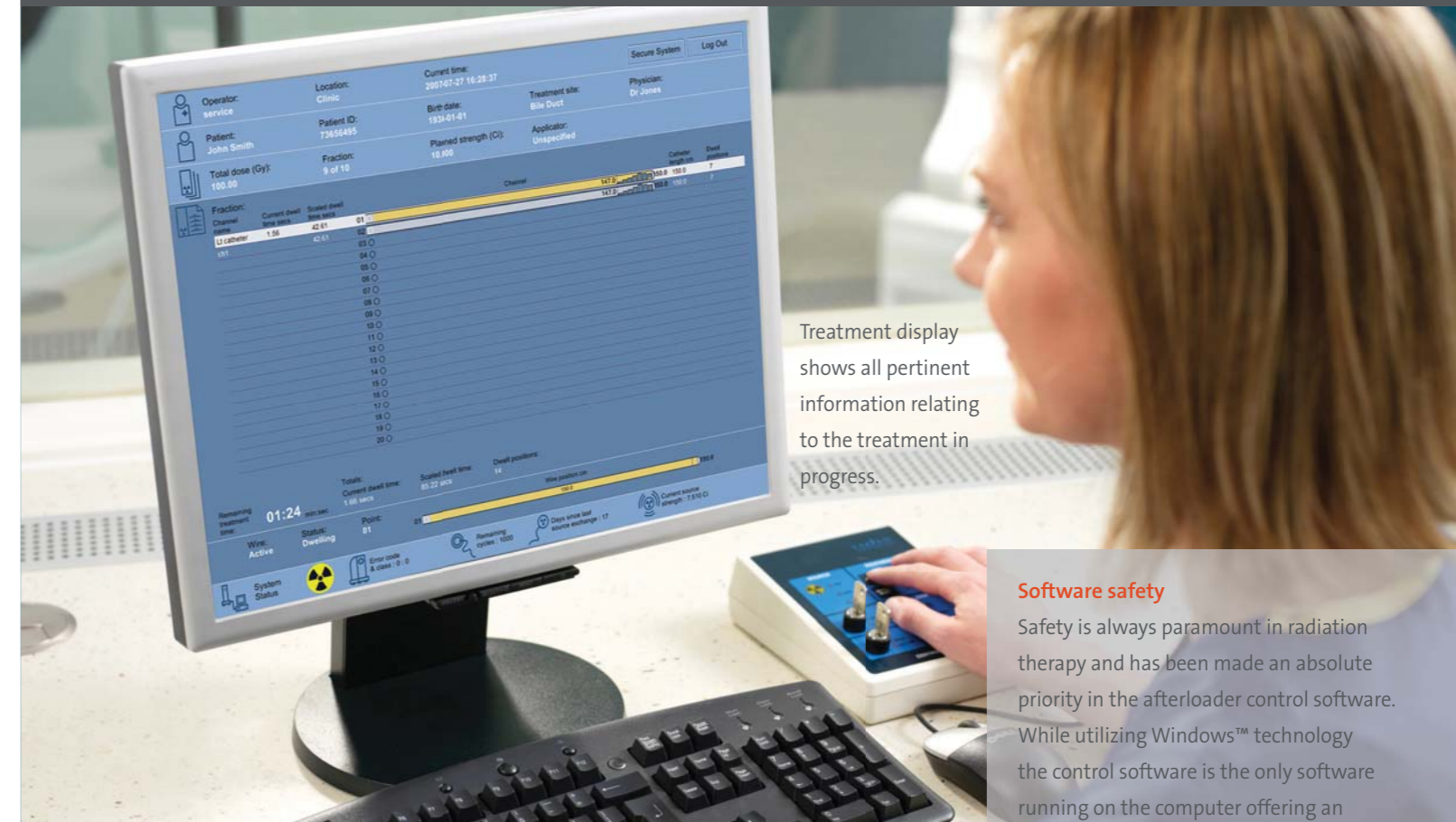
From logging on to the system, to treatment delivery, the new console software walks you through the process one step at a time. At each stage, you are presented with information in a controlled and stepwise manner in order to ensure no detail is overlooked.

After logging on, you have a simple choice of workflows – deliver a treatment, or create a treatment. Then, in the case of treatment delivery, the software steps through selecting the patient, confirming the demographic data, selecting the fraction, checking the treatment parameters and then helps you monitor and control the treatment delivery process.

Data is only useful when you can understand it

With the logical screen layout, intuitive icons, and clear graphics the control software gives you everything you need where, and when, you need it. 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.

In order to reduce the risk of selecting the incorrect patient for treatment the iX software uses a “wizard” style process for importing patient data from the treatment planning system. The user is stepped through the patient demographic data to ensure that all fields match. The software will also recognize if the patient file already exists on the system and offer to create a new file or add the treatment to the existing course as a new fraction.



Treatment display shows all pertinent information relating to the treatment in progress.

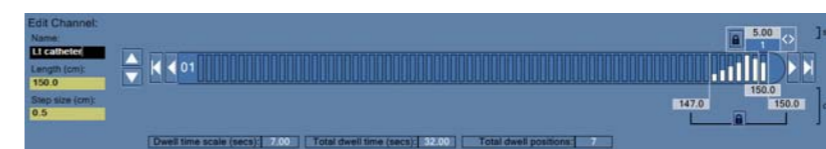
Software safety

Safety is always paramount in radiation therapy and has been made an absolute priority in the afterloader control software. While utilizing Windows™ technology the control software is the only software running on the computer offering an “appliance” look rather than the conventional Windows look and feel. This unique Varian feature offers you the security of knowing that the control PC is dedicated totally to the task at hand and not prone to interference by any other programs.

The software is also fully protected through a system of user rights and passwords. These are managed by the system administrator and gives the clinic all the control and flexibility it needs in assigning access levels and rights. Any number of groups can be set up and a different set of rights assigned to each group.

In addition treatment initiation is also controlled through the use of a password to ensure all pre-treatment checks are performed.

Another unique feature of the software is the way plan data is presented. Rather than present a mass of figures that are easily misinterpreted, the software represents dwell times in a bar graph format making it straightforward to spot a discrepancy. Furthermore, prior to treatment delivery the console displays a full treatment report that can be printed or stored.



The unique channel display facilitates clear indication of both dwell times and positions.

When it comes to treatment delivery knowing exactly what is going on during a treatment is essential. With the iX software this can be determined at a glance – radiation status, wire position, remaining channel time (in minutes and seconds), all can be easily seen on the screen. The display even contains a graphical representation of real-time wire position.

Easy entry into HDR brachytherapy



The right tools

Applicators and accessories for every brachytherapy need

Precision treatment requires precision applicators, accessories and quality assurance tools. Varian BrachyTherapy offers a wide selection of applicators and accessories for your HDR intracavitary, interstitial, intraluminal, intraoperative and surface treatments. We are especially proud of our titanium range of CT and MR compatible applicators. These products are a major step forward from plastic products. They are robust, and the tubing used is very thin—thin enough that the tandems can be used with Smit sleeves for rapid and easy tandem placement for each fraction, without the need for anesthetic. And, these products are steam sterilizable.



Fletcher-Suit-Delclos-type applicator set



CT/MR Ring & Tandem applicator



Segmented cylinder applicator set

The GammaMedplus 3/24 iX

Precise and flexible brachytherapy system

Nearly 80% of all HDR brachytherapy procedures are performed with up to three channels. A modified version of the 24 channel GammaMedplus iX, the 3/24 is the easiest way to initiate a brachytherapy program. As your HDR brachytherapy program grows, the 3/24 can be upgraded on site at any time by a Varian service engineer.

The 3/24 has all of the safety features, precision and flexibility of the GammaMedplus iX, with five channels rather than the standard 24. Channels 1-3 are typically used for intracavitary treatments and allow for GammaMed's unique applicator end test. Channels 23 and 24 are used for intraluminal or other treatments where an end test check is not desired. A maximum of three channels can be used in one treatment delivery session.

Transition to HDR brachytherapy

The 3/24 offers facilities the most efficient way to begin a brachytherapy program. As the HDR brachytherapy program grows, the 3/24 can be upgraded on site at any time by a Varian service engineer to the full GammaMedplus iX 24 channel afterloader.



The latest technology

Varian is committed to providing you with the latest technology in applicators and accessories, and proud to offer the most comprehensive line of applicators and accessories available.

Quality that speaks for itself

Technical specifications

Radioactive source - GammaMedplus iX

- Iridium-192, metallic
- Cylindrical configuration
- Iridium-192 pellet: 0.6 mm diameter, 3.5 mm active length
- Capsule: 0.9 mm diameter, 4.52 mm length
- Nominal activity: 370 GBq (10 Ci)*
- Air Kerma Rate: 0.063 Gy/h ($\pm 5\%$) 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 wire

- Iridium-192 source encapsulated in stainless steel
- Capsule welded to a flexible stainless steel cable
- Distance from distal wire tip to the beginning of the active pellet-HDR: 0.67 mm; PDR: 2.07 mm
- Wire diameter: 0.9 mm
- Maximum extension length: 130 cm
- The most distal 200 mm section of the wire is an ultra-flexible wire
- Source manufactured according to ISO1677, ISO2919, ISO/TR4826, ISO9978

Tested to the following standards:

Impact

ANSI level 3 impact test (same as ISO 2919 Class 3) and ANSI/HPS 43.6-1997 section A.2.2.6 and A.2.2.7 liquid nitrogen bubble test and helium leak test.

External pressure

ANSI level 3 external pressure test ANSI N43.6-1997 section 7.3 (same as ISO 2919 for Class 3) and then ANSI/HPS 43.6-1997 section A.2.2.6 and A.2.2.7 liquid nitrogen bubble test and helium leak test.

Temperature

ANSI heating and cooling and thermal shock test ANSI/HPS N43.6-1997, paragraphs 7.2.1, 7.2.2. and 7.2.3. (more severe than ISO 2919 section 8.2 [8.2.1-8.2.3, Class 6]) and then ANSI/HPS 43.6-1997 section A.2.2.6 and A.2.2.7 liquid nitrogen bubble test and helium leak test.

Vibration

ANSI level 2 vibration test ANSI N43.6-1997 section 7.5 and then ANSI/HPS 43.6-1997 section A.2.2.6 and A.2.2.7 liquid nitrogen bubble test and helium leak test.

Puncture

ANSI level 2 puncture test ANSI N43.6-1997 section 7.6 ANSI/HPS 43.6-1997 section A.2.2.6 and A.2.2.7 liquid nitrogen bubble test and helium leak test.

Resulting ISO Source Classification: C63333

Transportable options

The GammaMed HDR system has been qualified as a Type A shipping container. Every GammaMed HDR 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.

For more information on Varian's transportable solutions, see the brochure, Varian BrachyTherapy Transportable Afterloader Solutions, RAD #9601.

Afterloader

Manufactured according to IEC 601-1, IEC 601-1-1, IEC 601-2-17, IAEA and US DOT-7A, Type A. GammaMedplus is certified as a Type A container for transport of GammaMedplus sources.

Wire and drive parameters

- Nominal wire speed-0 slip: approximately 60 cm/s
- Wire 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 μ Gy/h for maximal load
- Radiation shielding: Conforms to International Electrotechnical Commission requirements (EN 601-2-17) 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

Safety listings

- EN60601-2-17

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

GammaMedplus 3/24

The GammaMedplus 3/24 has all of the safety features of the 24 channel GammaMedplus. It uses the same source and flexible cable, and it has the same precision and flexibility, except for the reduced number of channels.

Specifications subject to change without notice.



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For more information on the GammaMed*plus* iX and 3/24 iX HDR afterloaders, visit <http://www.varian.com/brachytherapy>.

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