

VariSource iX, iX(t) HDR Afterloader



Uniquely VariSource



Superior HDR brachytherapy

The VariSource™ iX and iX(t) afterloaders advance high dose rate (HDR) brachytherapy with a new level of digital technology. Their new control software is compatible with today's hospital networks, enhancing the brachytherapy experience today and providing a platform for future development.

Utilizing the latest technology, the VariSource iX offers several unique features along with superior specifications to meet all of your brachytherapy needs:

- Smallest diameter source wire for lower trauma in new interstitial techniques, and the most kink-resistant bronchial catheter in the business
- Intelligent Drive™ with force feedback
- Electronic turret for easy, positive, and accurate transfer tube engagement
- CamScale™ automated position verification system for fast, efficient daily QA checks
- Full UPS and battery back-up for safe treatment completion in a power failure, and automated wire recovery
- Broad and growing range of treatment accessories, including new patient- and user-friendly titanium CT- and MR-compatible applicators
- Backed by the international service and support network of the world's leading radiation oncology equipment supplier



Smallest diameter source wire

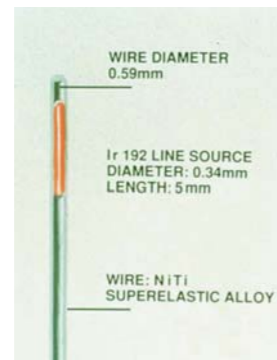
When it comes to choosing an afterloader, sometimes the race comes down to the wire, and that is the case with VariSource. Unique among HDR systems, VariSource uses a solid nitinol wire to convey the source rather than a stranded cable. The result is a thin wire which does not compress along its length when pushed through a catheter or treatment channel.

Thinnest source wire available for clinical use

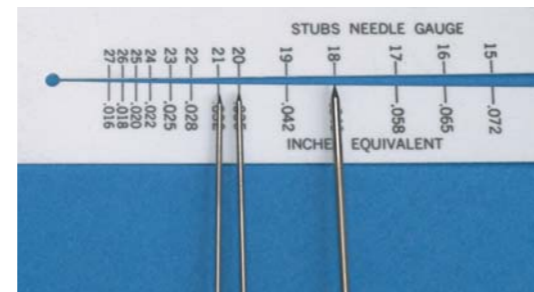
Down to the wire

Fine needles for faster healing

The VariSource iX has the thinnest source wire available for HDR procedures, permitting the use of needles as fine as 20 gauge (0.9 mm diameter), offering treatment options which would not be possible with other systems. Even for transperineal use, 18 gauge needles (1.27 mm) are standard. Smaller needles mean less trauma and promote faster wound healing. The source itself conveniently measures 5 mm in length and is embedded directly into the tip of the wire, leaving no crimps or joints which may produce weak spots. Loaded with enriched iridium, and annealed at the tip for greatly improved trackability, the source wire can be installed at an activity of up to 11Ci.



The 5mm long active source is embedded into the ϕ 0.59mm wire.



The thin source on the VariSource allows needles as thin as 20 gauge (0.9mm), much smaller than the 15 gauge (1.83mm) that is typically used with other afterloaders.

Kink-resistant catheters for uninterrupted treatment

In addition, the thin source profile permits the wall of the VariSource standard catheter to be thick with respect to its outer diameter (4.7 Fr. gauge, 1.57 mm), making it extremely robust and kink resistant. Therefore, not only is the catheter one of the thinnest standard catheters for use with an HDR afterloader, it also has the thickest wall, meaning fewer treatment failures due to catheter kinking. The VariSource advantage is a higher treatment delivery success ratio. The annealed tip of the source wire gives it just the right amount of flexibility to navigate the tightest catheter bends that are encountered clinically.

Smart navigation

Unique force feedback device for navigating constrictions

The VariSource iX uses a solid wire rather than a cable to position the radioactive source. This has the advantage that as the source is driven to the treatment position and forces are exerted upon it, there is no change in the length of the wire.

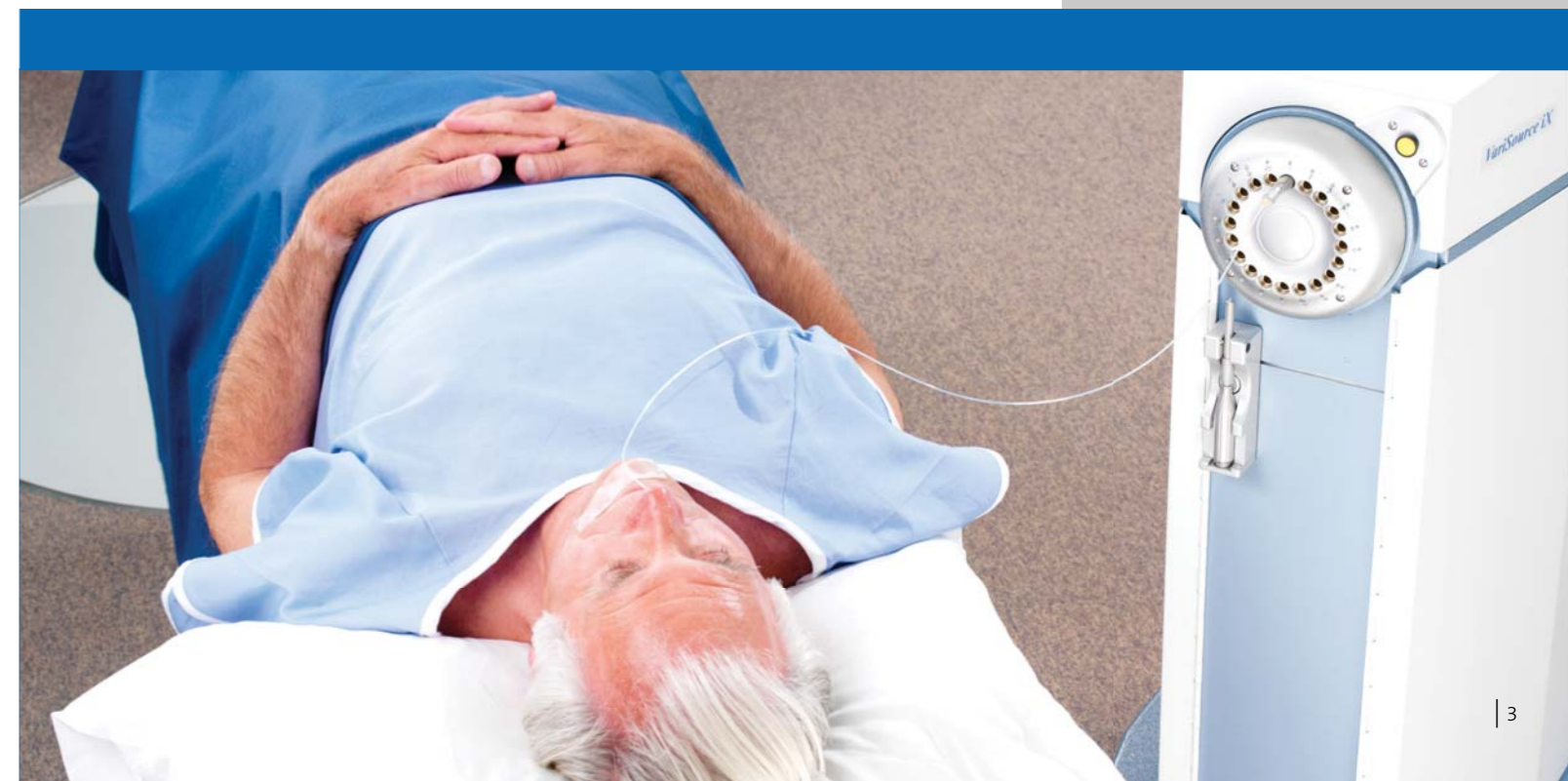
The solid wire allows for accurate transmission of the forces on the wire back to the afterloader. Here they are constantly measured by the unique Intelligent Drive System, and decisions are made to determine if they are consistent with normal operation. In cases where the force measured indicates a tight bend in the catheter, the system will attempt to step around it. If an obstruction is detected, the system will retract the wire. This compares with other systems which simply use a go/no-go slip clutch mechanism.

With the possibility of connection to 20 channels, the source wire can be positioned at any distance from the afterloader turret up to 150 cm, with a transit speed of up to 60 cm/second. The system also permits the user to program up to 60 dwell positions and select a large range of step sizes, from 2 mm up to 99 mm, in 1 mm increments. Use of the default step size of 5 mm gives the system the unique ability to match step size with source length in order to produce a uniform line.



Intelligent Drive System

The VariSource Intelligent Drive System includes a unique force feedback device which constantly and accurately monitors the force on the wire, allowing the drive to easily distinguish obstructions and constrictions. Constrictions are easily navigated as VariSource slows the wire and traverses the area stepwise, rather than giving up.



HDR brachytherapy with the latest digital technology



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 afterloader control interface that is both intuitive and simple to use.

Streamlined workflows presents information in clear and logical layout.

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.

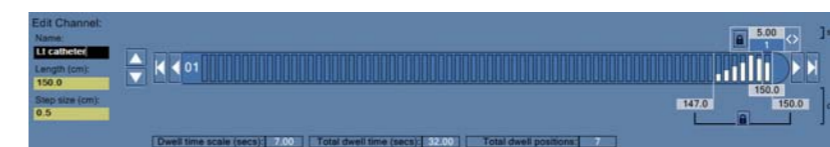
After logging on, you have a simple choice of workflows – deliver a treatment, or create a treatment. Then, in the case of treatment delivery, the software steps through selecting the patient, confirming the demographic data, selecting the fraction, checking the treatment parameters and then helps you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

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.



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.

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

More software features

Enhanced capability

In addition to delivering patient treatments the control software is also capable of managing source calibration calculations, producing customized QA check lists and wire positional calibration (CamScale) reports.

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.

Precision and safety at the same time



Precision at its best

The perfect connection

The connectors themselves are not only simple to operate but are designed to ensure a perfect connection every time, almost eliminating misconnection errors. The electronic lock precisely aligns the connectors to the reference plane, and a sensor sweeps the channels checking the connections, then provides a visual indication (red or green) of which channels are ready for treatment. This saves the embarrassment and inconvenience of having to re-enter the treatment room to check catheter connections.

Staying informed

Remote text displays at the console area, treatment room door and on the Afterloader itself, give important information on the wire position and status, and any error messages which may be present.

Exceptional accuracy

Another unique feature of the VariSource iX is its built in CamScale system. This device consists of an internal video camera focused on a scale upon which the wires can be positioned, allowing the user to check the positional accuracy of both the dummy and active wires at distances of 80 cm and 140 cm. The images are displayed on the control console and can be printed on plain paper. This feature allows extreme accuracy and avoids repeat trips into the room. The need to develop and file film is eliminated, saving physicists time on each and every treatment day.



Safety

In a system where a radioactive source is utilized, safety is obviously a prime concern, and is an area where the VariSource iX excels. The VariSource iX offers the following extensive safety features:

Hardware and software safety

- Control console access provided through two hardware keys and password protection.
- Mechanical/electrical verification that all programmed treatment channels have properly connected and locked catheters.
- Inactive wire executes programmed treatment to test for proper guide tube routing, programming, and to ensure there are no obstructions or kinks in the guide tubes.
- Wire always moves in a distal-to-proximal direction during treatment, ensuring accuracy and eliminating errors due to wire bunching or sticking.
- Automatic detection of console communication failure followed by immediate wire retraction.
- Uninterruptible Power Supply isolates the system and provides enough power to complete a treatment in the case of a power failure.

Wire tracking

- Wire position tracked by a combination of discrete position sensors and a precision encoder.

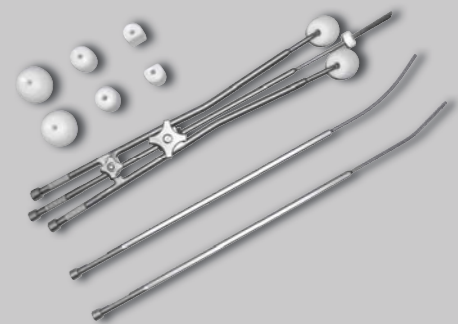
- Mechanical switch to accurately indicate when wire is in the parked position at the center of the safe.
- Back-up mechanical switch to prevent wire over-extending from machine.
- Wire length checked at treatment completion utilizing position sensors and precision encoder.
- Unique wire force sensing system.
- Automatic detection of catheter/ applicator blockages with accurate position reporting.

Emergency retraction

- Independent emergency retract drive assembly.
- DC emergency retract motor with backup battery.
- Independently powered Geiger Müller radiation detector alerts users if radiation is not detected during treatment or is detected after the source has retracted.
- Automatic source retraction on UPS power failure or hardware error.
- Easily operated manual retract handle.

A complete selection of applicators and accessories

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.



Quality you can count on

Technical specifications

Radioactive source - Model VS2000

- Iridium-192, annealed
- Cylindrical configuration
- Two sources, 2.5 mm active length each, 0.34 mm diameter
- Initial nominal activity: 370 GBq (10 Ci) maximum; (maximum activity: 407 GBq (11 Ci))

Source wire

- Iridium-192 source integrally encapsulated in a super-elastic annealed nitinol (nickel-titanium) wire with plugged and welded end
- Distance from distal wire tip to active source: 1 mm
- Wire diameter: 0.59 mm
- Usable wire length: 150 cm

Tested to the following standards:

Impact

ISO 2919 section 8.4 (8.4.1-8.4.3) Class 2 and ISO/TR 4826 section 2.1.1 Wipe (smear) test

External Pressure

ISO 2919 section 8.3 (8.3.1-8.3.3) Class 3 and ISO/TR 4826, section 2.1.1 Wipe (smear) test

Temperature

Heating and cooling: ISO 2919 section 8.2 (8.2.1-8.2.3) Class 5 and ISO/TR 4826, section 2.1.1 Wipe (smear) test

Thermal shock: ISO 2919 section 8.2 (8.2.1-8.2.3) Class 5 and ISOTR 4826, section 2.1.1 Wipe (smear) test

Wire and drive parameters

- Nominal wire speed (0 slip): 50-60 cm/s (mean 55 cm/s)
- Wire positioning accuracy: ± 1 mm relative to the turret

Afterloader

Manufactured according to EN60601-1, EN60601-1-1, EN60601-2-17, IAEA SS6 and US DOT-7A, Type A. VariSource is certified as a Type A container for transport of VariSource sources.

Source placement

- 20 treatment channels
- 60 dwells per channel
- Step size: Default 5mm, programmable from 2-99 mm, in 1 mm increments
- Minimum radius of curvature: 1.7 cm in a supported catheter at 120 cm from the afterloader turret in the 4.7 Fr. standard catheter
- Method of source movement: Commences at most distal dwell positions and steps back

Afterloader shielding

- Safe material: Tungsten
- Maximum storage capacity of safe: 407 GBq (11 Ci)
- Maximum Air Kerma Rate 1m from afterloader: Does not exceed 10 μ Gy/h for maximal load
- Radiation shielding: conforms to International Electrotechnical Commission requirements (EN 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: Isolated from local power grid by a combined power conditioner and un-interruptible power supply (UPS)
- In the event of a power failure, the control console and afterloader are powered through the UPS for up to 40 minutes
- System power rating: 90-275 VAC, 48-62 Hz, 500 VA continuous

Environmental requirements

- Operating temperature range: +15° to +35°
- Humidity range: 30-75% (non-condensing)

Weight

- Console (PC, Display, Monitor): 29kg (approximately)
- Afterloader: 144 kg

Dimensions

- Console (PC, Display, Monitor): 63cm H x 45 cm W x 45 cm D (approximately)
- Afterloader: 112 cm H x 53 cm W x 71cm D

Safety listings

- BS 5724-2.17 / 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

CamScale

- Scale increment: 1 mm nominal
- Scale increment accuracy: ± 0.12 mm
- Scale line width: 0.2mm for 10 & 5 mm increments; 0.15 mm for others
- Measurement area channel 1*: 79 - 81 cm
- Measurement area channel 2*: 139 - 141 cm

*Lengths are measured with the proximal end of a normal treatment catheter as the reference point.

Dosimetry requirements

- Optional: Standard Imaging HDR 1000 Plus well chamber
- Optional: Standard Imaging CDX-2000B electrometer

Safety equipment

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



Transportable options

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

Specifications subject to change without notice.

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For more information on the VariSource iX HDR afterloaders, visit <http://www.varian.com/brachytherapy>.

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