# **Bravos Feature Sheet**

Bravos™ HDR afterloader system for radiation oncology

# Intuitive interface designed for optimal precision

- Touchscreen controls on the back of the afterloader allow you to perform treatment preparation in the patient room
- The length and dummy checks can be completed while with the patient for optimal treatment experience
- Afterloader displays interlock status and treatment preparation progress
- Intuitive applicator connection detection via LED display
- Solid green for channels that are "good to go"
- Flashing green for connections not yet completed
- Red for incorrect connection
- Source position verification test using external CamScale™ system
- Simple, fast and precise position verification method
- Recordable and reproducible

# Integrated safety and security

- Built-in, customizable checklists can be required before each procedure, including electronic signature verification
- Transfers data from treatment planning systems (supports BrachyVision™ brachytherapy treatment planning system, Vitesse™ real-time planning for HDR brachytherapy and imports in DICOM RT format).
- Integrated with the ARIA® oncology information system, including full integration with ARIA v11 and higher.
- Records delivered dose upon treatment completion.
- Records partial dose for interrupted treatments.
- Tracks dose against prescription, including treatment parameters and treatment details.
- Fully supports DICOM worklists, including transfer of plan and updated treatment appointment and status indicators in ARIA.
- MICAP firewall (by Juniper Networks, Inc.) provides additional layer of security to help protect the afterloader and patient data from viruses, malware and malicious attacks.



# SmartConnect Remote Service Monitoring

- The SmartConnect™ remote monitoring system allows Varian's service engineers to quickly identify, diagnose, and respond to issues.
- SmartConnect, as part of Varian's PremierAssurance™ program, complies with privacy standards and regulations:
- Health Insurance Portability and Accountability Act (HIPAA) compliant
- Encrypted, using 128-bit Secure Sockets Layer (SSL) and Advanced Encryption Standard (AES)
- Federal Information Processing Standard (FIPS) 140-2 compliant and VeriSign certified
- Uses multifactor authentications, such as Active Directory and the Hardware Against Software Piracy (HASP) key
- Firewall compatible, allowing connections to be made without special firewall rules

## Key features at a glance

#### Interoperability

 Varian interoperability means the Bravos afterloader system works seamlessly with ARIA and the Eclipse™ treatment planning system to manage the patient's entire journey—from initial diagnosis through posttreatment follow-up.

#### Connectivity

· Connects with the ARIA oncology information system.

#### Customizable

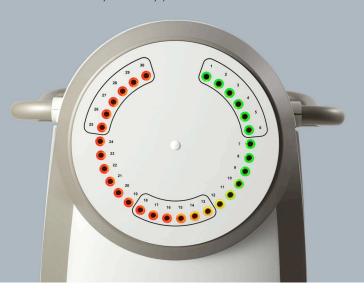
 Customizable pre-treatment checklist, similar to surgical procedures, can be set to require checklist review and an electronic signature before proceeding, for greater confidence and accountability.

#### Seamless recalibration

 Recalibration of source position by the clinic can optimize uptime. The Bravos afterloader system with the CamScale provide tools to visualize and recalibrate both source and dummy positions between source exchanges, minimizing the need for a service call.

#### Instinctive LED lights

• Instinctive LED lights in green, yellow, and red guide you through the correct connection of the transfer guide tubes and alert you to any potential errors.



## **Specifications**

#### Weight & Dimensions

- 143 kg
- 113.8 cm H x 53.8 cm W x 68.8 cm D

#### Radioactive Source

- · Iridium-192, metallic
- Cylindrical configuration
- Iridium-192 pellet: HDR: 0.6 mm diameter, 3.5 mm active length
- Capsule: 0.9 mm diameter, 4.52 mm length
- Distance from distal cable tip to the beginning of the active pellet: 0.67 mm
- Nominal activity: 370 GBq (10 Ci)
- Maximum installable activity: 555 GBq (15 Ci)
- Iridium-192 source encapsulated in stainless steel
- Capsule welded to a flexible stainless-steel cable

#### 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 1uSv/h for maximal load
- Maximum air Kerma rate 5 cm: Does not exceed 10uSv/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.

#### **Enhanced Cable and Drive Parameters**

- Nominal wire speed-0 slip: Approximately 100 cm/s
- Wire positioning accuracy: ±1 mm relative to the indexer

#### Source Placement

- 30 treatment channels
- 100 dwells per channel
- Step size: programmable from 1-99 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.

#### **Electrical Power Requirements**

- System power rating: 100 240 VAC | 50 60 Hz | 110V/60 Hz or 240 V | 50 Hz models available
- Power consumption: 100 VA maximum
- Afterloader system is powered through an uninterruptible power supply (UPS). If all power is lost, retract is powered by emergency back-up batteries situated in the afterloader system.

### **Environmental Requirements**

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

### Regulatory Standards

- $\bullet$  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 anesthetic 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: 2.6 cm lead
- Minimum diameter (inner plastic container): approximately 5 cm
- · Container height (internal): 27 cm

Specifications are subject to change without notice. Not all features, products or options are available in all markets.

#### Intended Use Summary

The Bravos afterloader system is intended for use in the treatment of both benign and malignant disease or other conditions, for both curative and palliative intent, in the delivery of remote-controlled high dose rate (HDR) brachytherapy.

#### Important Safety Information

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.

Side effects of applicator placement and/or implantation may occur. These side effects may include, but are not limited to, localized discomfort, bleeding, and infection or other localized side effects based on the location the applicator is placed. Side effects may also occur as a result of procedural anesthesia, and may include, but are not limited to, hypotension, bradycardia, respiratory suppression, airway obstruction, bronchospasm, or decreased oxygen saturation. Patients should discuss the treatment and side effects with their physicians before starting treatment sessions.

#### 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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