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Simplicit^{90}Y™ Personalized Dosimetry Software | TECHNICAL SPECIFICATIONS

Simplicit^{90}Y is a customized, easy-to-use dosimetry software developed as an accessory to TheraSphere™ Y-90 Glass Microspheres. Simplicit^{90}Y can help accelerate treatment planning and improve Y-90 SIRT workflow. Simplicit^{90}Y enables physicians to quickly embrace TheraSphere personalized dosimetry and effectively advance clinical practices with dedicated tools and features.

HARDWARE SPECIFICATIONS

WORKSTATION/LAPTOP		
Item	Minimum Specification	Recommended Specification
Processor	Intel Core i5 or quivalent	Intel Core i7 or equivalent
Memory	8 GB RAM	16 GB RAM
Disk	250 GB. 10 GB available, 7200 RPM	500 GB SSD. 10 GB available
Graphics	128 MB graphics card, DVI	512 MB graphics card, DisplayPort
Display Resolution	1920 x 1080	1920 x 1080, 2560 x 2048 or similar
Mouse	2-button + wheel	2-button + wheel
Operating System	Windows 7 Windows 10 Server 2012, 2016, 2019	Windows 7 Windows 10 Server 2012, 2016, 2019

THIN CLIENT SERVER		
Item	Minimum Specification	Recommended Specification
Processor	Quad Core Xeon or equivalent E5420 2.50 GHz	Three cores/2.5 GHz per concurrent user
Memory	16 GB RAM	16 GB RAM per concurrent user
Disk	250 GB. 10 GB available, 7200 RPM	750 GB. 20 GB available for system 10k or 15k RPM
Graphics	128 MB integrated graphics	128 MB dedicated graphics card
Operating System	Windows Server 2012 R2 *Both physical servers and virtual machines are supported*	Windows Server 2012 R2 Windows Server 2016 *Both physical servers and virtual machines are supported*
Network	1 GB connection to client machines	1 GB connection to client machines
Network Card		Dual teamed cards for four or more concurrent users

Recommendations will be individually made for server specifications to ensure suitability based on environment and number of concurrent users. This table is for guidance only. Client machines should be reasonably modern but do not require a high specification and must run Windows 7 (SP1 recommended) or Windows 10.

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ARCHITECTURE OVERVIEW

Environment & Application/Storage Management

Simplicit^{90}Y runs as a clinical application embedded in the DBx patient selector. DBx and Simplicit^{90}Y require the execution of two separate installation files. The software supports unlimited concurrent users and includes administrative interface which provides troubleshooting and debug tools.

The DBx browser and Simplicit^{90}Y solution are intended for short term storage only and are proposed as a single production environment. DBx requires access to PACS for an optimum workflow management.

Our solution adheres to all DICOM standards and DICOM datasets are stored in a derby database, internal to the application.

Server & Desktop

Simplicit^{90}Y application software, packaged as an ".MSI", supports server virtualization and is compatible with windows 64-bit server and client systems. Simplicit^{90}Y is also a tested, verified and trusted Citrix-compatible solution, and is compatible with Microsoft RDS system.

Customer Support

While product installation and maintenance can be run with local administrator rights, access to hospital network is required to provide remote support and can be done through various applications like "GoToAssist".

Cyber Security

Simplicit^{90}Y is designed to use data sent to it in DICOM format only from sources within a hospital network as configured by users. Simplicit^{90}Y does not include any firewall or anti-virus protection and is not specifically designed to protect against malicious attack. Users are strongly advised to ensure that appropriate measures are in place in the infrastructure around Simplicit^{90}Y to protect against malicious attack as well as to comply with data protection regulations. Such measures may include, but are not limited to, secure local area networks (LANs), appropriate firewall provision, network directory permissions and anti-virus protection.

Please refer to the user manual for full warning, labelling and regulatory information.

For more information, please contact your BSC TheraSphere™ Sales Team representative or send an email to **SimplicitySupport@bsci.com**

Intended Use (US Only)

Simplicit^{90}Y™ is intended to be used by trained medical professionals for TheraSphere™ pre-treatment dosimetry planning and post-treatment dosimetry evaluation following Y90 treatment. Simplicit^{90}Y is a medical image and information management system that is intended to receive, transmit, store, retrieve, display and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, SPECT and PET. Simplicit90Y provides the user with the means to display, register and fuse medical images from multiple modalities. Simplicit90Y provides tools to create, transform, and modify contours for the user to define objects in medical image volumes for use in TheraSphere pre-treatment dosimetry planning and for post-treatment dosimetry. The objects include, but are not limited to, tumors and normal tissues. For post-Yttrium-90 (Y90) treatment, Simplicit^{90}Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y90 microspheres.

Indication for Use (US Only)

Simplicit^{90}Y is a standalone software device that is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. Simplicit^{90}Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicit^{90}Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files. Simplicit^{90}Y is indicated, as an accessory to TheraSphere, to provide pre-treatment dosimetry planning support including Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRD schema dosimetry, in accordance with TheraSphere labelling. Simplicit90Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit90Y includes features to aid in TheraSphere dose vial selection, dose vial ordering and creation of customizable reports. Simplicit^{90}Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit90Y provides tools to create, transform, and modify contours/Regions of Interest for the user to define objects in medical image volumes to support TheraSphere post-Y-90 treatment calculation and evaluation. The objects include, but are not limited to, tumors and normal tissues, and liver volumes. Simplicit^{90}Y is indicated for registration, fusion display and review of medical images allowing medical professionals to incorporate images, such as CT, MRI, PET, CBCT and SPECT in TheraSphere Yttrium-90 (Y-90) microspheres pre-treatment planning and post-Y-90 treatment evaluation For post-Yttrium-90 (Y-90) treatment, Simplicit90Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres. PI-994110-AA

TheraSphere™ Yttrium-90 Glass Microspheres

INDICATION FOR USE: TheraSphere is indicated for use as selective internal radiation therapy (SIRT) for local tumor control of solitary tumors (1-8 cm in diameter), in patients with unresectable hepatocellular carcinoma (HCC), Child- Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status. **CONTRAINDICATIONS:** TheraSphere is contraindicated in patients: whose Tc-99m macroaggregated albumin (MAA) hepatic arterial perfusion scintigraphy shows any deposition to the gastrointestinal tract that may not be corrected by angiographic techniques • who show shunting of blood to the lungs that could result in delivery of greater than 16.5 mCi (0.61 GBq) of Y-90 to the lungs. Radiation pneumonitis has been seen rarely in patients receiving doses to the lungs greater than 30 Gy in a single treatment. • in whom hepatic artery catheterization is contraindicated, such as patients with vascular abnormalities or bleeding diathesis • who have pulmonary insufficiency (conventionally defined by an arterial oxygen pressure (Pa,O2) of < 60 mmHg, or oxygen saturation (Sa,O2) of < 90%) or severe liver dysfunction, including hepatic encephalopathy, clinically evident ascites or treatment with diuretics for ascites • with portal vein thrombosis (PVT) Type 4 involvement and lack of Tc-99m MAA deposition on the PVT seen on the Tc-99m MAA imaging with >70% tumor replacement in the liver • with comorbidities or poor overall health (e.g., ECOG performance status rating > 2) which may make the patient a poor candidate for locoregional radiation treatment. • who are pregnant. **WARNINGS:** The following pre-treatment, high-risk factors (disease characteristics) have been associated with serious adverse events deemed possibly related to use of the device: infiltrative tumor type • tumor nodules too numerous to count • AST or ALT > 5 times ULN • bilirubin > 2 mg/dL • tumor volume > 50% combined with albumin < 3 g/dL. Keep the TheraSphere dose vial upright and stored in its lead pot before and during patient treatment, except as required for radiation measurement. Do not open the dose vial acrylic shield prior to patient treatment. Post-treatment, waste materials require caution to prevent contamination and beta shielding due to residual glass microspheres. **PRECAUTIONS:** GENERAL PRECAUTIONS: As in any intra-arterial procedure, aseptic technique should be practiced, and care should be taken to ensure minimum patient anesthesia exposure extraneous to therapeutic objective. • Consideration of patient comorbidities should be used when determining the type and volume of fluid to infuse via catheter to avoid electrolyte imbalance, fluid shift, and hyperglycemia. • It is important to avoid any aggressive arterial procedure that may lead to arterial spasm that impairs TheraSphere distribution into the perfused liver target volume which may lead to underdosing or non- target deposition of TheraSphere. PRECAUTION IN PATIENTS WITH IMPAIRED LIVER FUNCTION: No efficacy or safety data from the LEGACY study are available to support the use of the device in patients with Child-Pugh score B or C cirrhosis. PRECAUTION IN VULNERABLE PATIENTS: No effectiveness or safety data are available to support the use of the device in children or breast- feeding women. ENDOCRINE DISRUPTION, CARCINOGENICITY, MUTAGENICITY, TOXICITY TO REPRODUCTION: Ideally the use of this radioactive device in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. RADIATION SAFETY: Radioactive products should be used only by healthcare professionals who are qualified by specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides. • As in the use of any radioactive material, ensure minimum radiation exposure to the patient extraneous to the therapeutic objective, and to minimize radiation exposure to workers and others in contact with the patient. RELEASE AND POST-TREATMENT PRECAUTIONS: Post treatment patient care: use universal precautions for body fluid contact. Trace Y-90 may be detectible in blood and urine; handle with gloves and dispose as normal body fluids. The radiation field is expected to be less than 1 mrem/h (10 µSv/h) at 3 ft (1 m) from the patient's abdomen. Supplemental shielding and segregation of the patient are not required to maintain exposure to others below regulated limits. • Release instructions: The patient should follow good hygiene (e.g., proper hand washing). Caregivers, family, and others do not require restrictions on patient contact; however, they can minimize their radiation exposure by avoiding prolonged time (>12 hours per day) within 1 ft (0.3 m) of the patient's abdomen for the first week post therapy. Patients should be advised that radiation emitted from the patient may be detectible at security screening (e.g., international travel). • Special precautions post-administration: If the patient requires hospitalization, surgery, medical assessment or treatment regarding any part of their thorax or abdomen within first 2 weeks of treatment, the patient should advise the hospital and treating physician of the Y-90 TheraSphere implant. The physician should consult their radiation safety staff for handling and disposal of liver tissue. • Special liver tissue handling: Special liver tissue handling may be required for post-treatment surgery, explant, or transplant since the glass microspheres remain permanently implanted in the liver tissue. Disclosure of the treatment will be required if cremation is considered. **POTENTIAL ADVERSE EVENTS:** The use of this product leads to irradiation of both tumorous and normal liver tissue. As a result, patients with compromised liver function may be at greater risk of liver function impairment and hence could experience complications. Clinical side effects usually occur within the first 4 to 6 weeks after treatment. Based on clinical trial data, literature reviews and post market surveillance, adverse events potentially associated with treatment using Y-90 microspheres, including TheraSphere, may include the following: Allergic reaction • Altered liver function, acute or chronic • Anorexia • Anxiety • Ascites • Bile Duct injury • Bleeding/hemorrhage • Chills / rigors • Cholecystitis (inflammatory or infectious) • Colitis • Death • Dehydration • Diarrhea • Dizziness • Dyspnea • Edema (any location) • Electrolyte abnormalities • Elevated BUN/creatinine • Fall • Fatigue • Fever • Gastrointestinal bleeding / hemorrhage • Gastrointestinal ulcer or ulceration • Hepatic encephalopathy • Hepatorenal failure • Hiccups • Hypertension • Hypotension • Infection (any location) • Liver failure, acute or chronic • Lymphopenia • Malaise • Mood alteration • Muscle weakness • Nausea • Neutropenia • Pain (any location) • Pancreatitis • Platelet count abnormalities • Pleural effusion • Portal hypertension • Pre-existing chronic liver disease decompensation • Pulmonary edema • Pulmonary fibrosis • Radiation hepatitis • Radiation induced disease, acute • Radio Embolization Induced Liver Disease (REILD) • Sepsis • Supraventricular arrhythmia • Thrombosis (arterial or venous) • Tumor inflammation (including tumor edema) • Tumor-lysis syndrome • Vomiting • Weight loss. Complications related to the administration procedure itself may include: Allergic reaction: Arterial injury including vessel dissection • Aspiration pneumonia • Bruising/bleeding/hematoma at site • Constipation/abdominal distension • Fatigue • Flushing • Infection • Nausea • Nerve damage. **CAUTION:** Federal (USA) law restricts this device to sale by or on order of a physician. PI-992004-AA

Note: Dose to the liver does not exceed 150 Gy. The physician should always take the above-noted Pre-treatment High Risk Factors into consideration for each patient when making decisions regarding the use of TheraSphere for treatment.

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