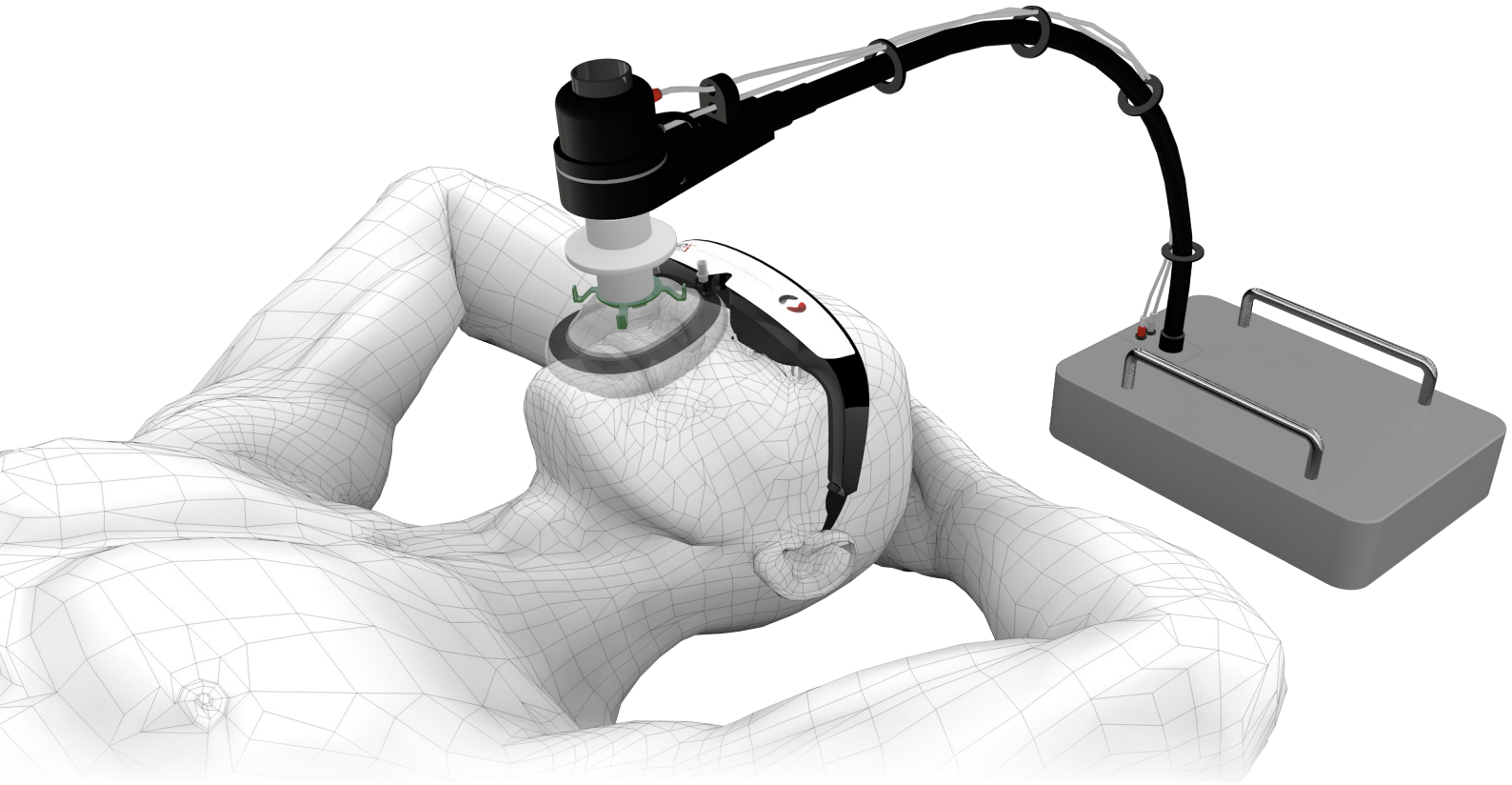
positioning
patients for life.®

NEW

SDX®

RESPIRATORY
GATING SYSTEM

3.0



Manufactured by

DYN'R®
MEDICAL SYSTEMS

NEW

SDX

RESPIRATORY GATING SYSTEM

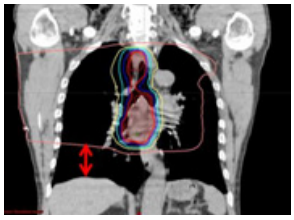
The SDX® System's unique ability to pair a patient's inspiration rate and lung volume measurement with clear visual biofeedback makes it possible to maximize the stability of internal organs and the tumor treatment zone. This allows for an increased dose to the tumor with decreased toxicity to vital organs. SDX® is a spirometry based system for managing thoracic and abdominal tumor motion during imaging and radiotherapy.

SDX® enables both voluntary breath hold and free breathing techniques for :

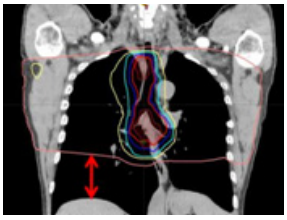
- Reducing tumor motion during imaging and treatment [1-3]
- Enhancing tumor imaging and visualization [4]
- Reducing treatment margins [6-8]
- Increasing dose while decreasing toxicity to vital organs [8-10]
- Repositioning vital organs out of the high dose region [6,8,10]

Lung Patient

Decrease Toxicity



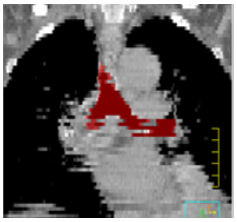
With respiratory motion



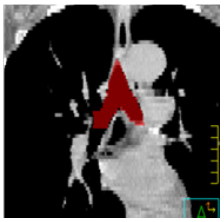
Using SDX® with DIBH expands healthy lung tissue out of the high dose region

SDX® with DIBH allows dose escalation while reducing both lung and cardiac toxicity. [6,8,10]

Image Improvement



With respiratory motion

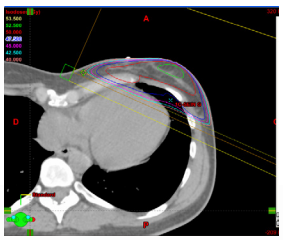


Using SDX® with DIBH Enhances tumor imaging

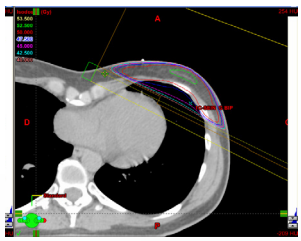
SDX® with DIBH manages organ movement within the thoracic cavity allowing for enhanced imaging and visualization.[4]

Left Breast Patient

Decrease Toxicity

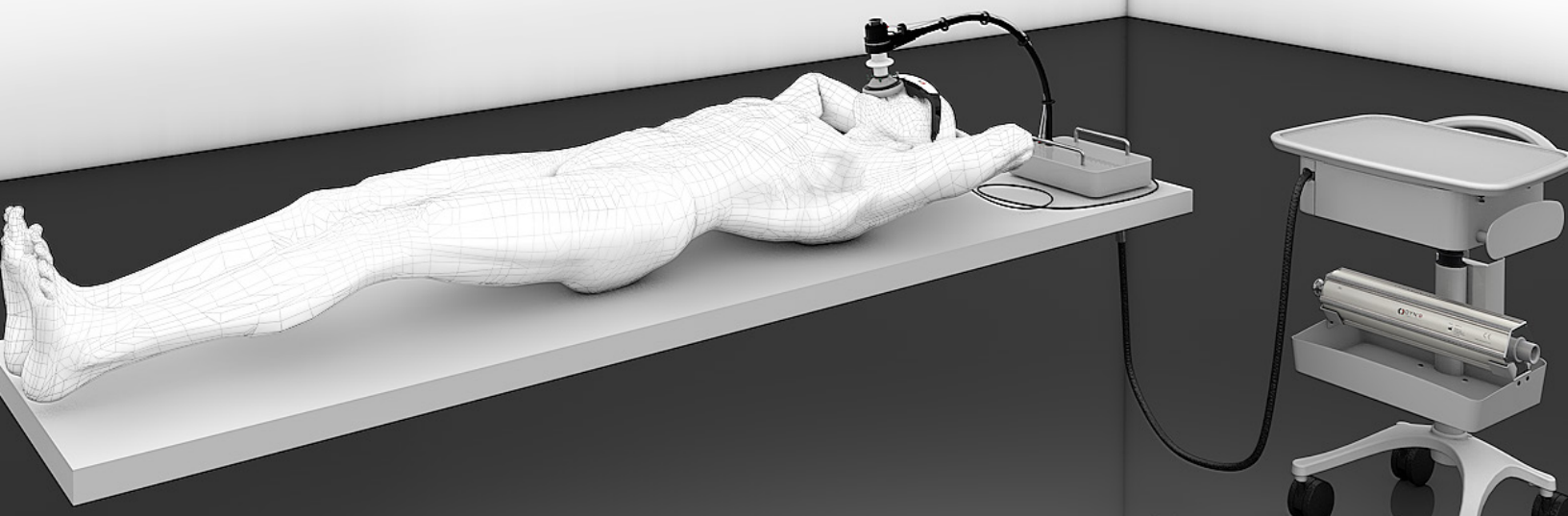


With respiratory motion

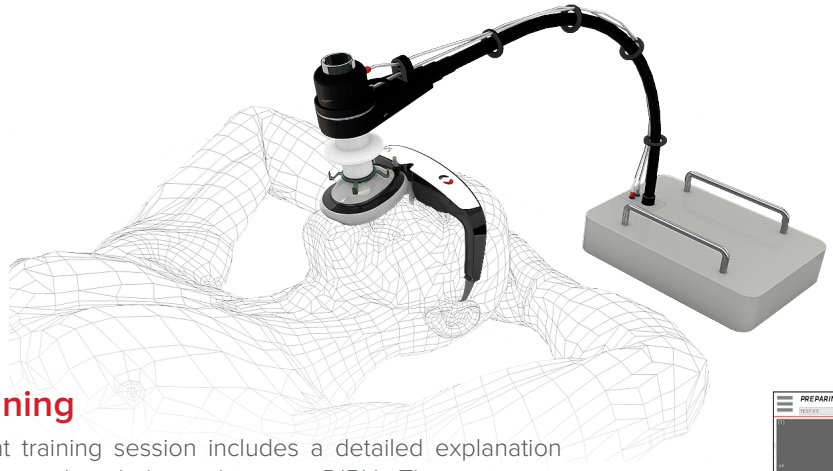


Using SDX® with DIBH repositions the heart out of the high dose region

SDX® with DIBH is a highly effective cardiac sparing technique to treat left-sided breast cancer. DIBH allows for the displacement of the heart during the isocenter planning process, thus allowing greater reduction in dose to the heart. With the use of this technique tangent radiation beams can effectively treat tumors while reducing dose to the heart. The liver can also be spared to a larger extent with DIBH for right sided breast cancer.[11]



SDX® Voluntary Breath Hold Technique



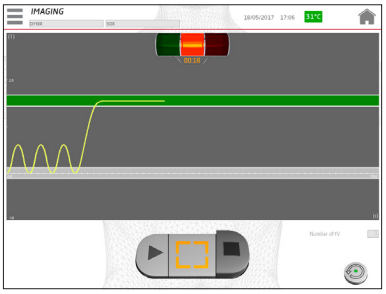
Patient Training

The initial patient training session includes a detailed explanation of the procedure and verbal coaching on DIBH. The patient is then introduced to the SDX® System and breathes freely through the spirometer until instructed to take a full inspiration. The SDX® calculates a target inspiration zone, which is a percentage of the patient's maximum inspiration capacity. This ensures the patient can comfortably maintain repeated breath holds of 20-25 seconds. The result is a repeatable breath hold, taken with the same inspiration volume every time.

Patient breathes normally until instructed to take a full inspiration and then exhales.

CT Scanning & Treatment Planning

After training, the patient proceeds to the CT scanner for imaging. With the use of the video goggles, the patient is able to visualize the target inspiration zone. CT images are taken while the patient performs the breath hold, thereby reducing artfacts. SDX® with DIBH decreases the movement of organs within the thoracic cavity, allowing for enhanced tumor imaging and visualization.[5] The acquired CT images are used to develop the treatment plan.

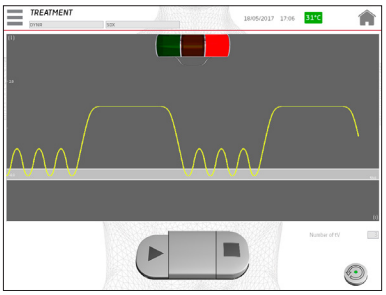


Patient voluntarily performs a breath hold in the target inspiration zone during CT imaging.

Patient Treatment

The process for treatment is the same as CT Scanning. With the SDX® System, the patient remains in control by voluntarily repeating breath holds during the course of treatment. The clinician monitors the breathing pattern to determine the optimal moment for delivering the radiation.

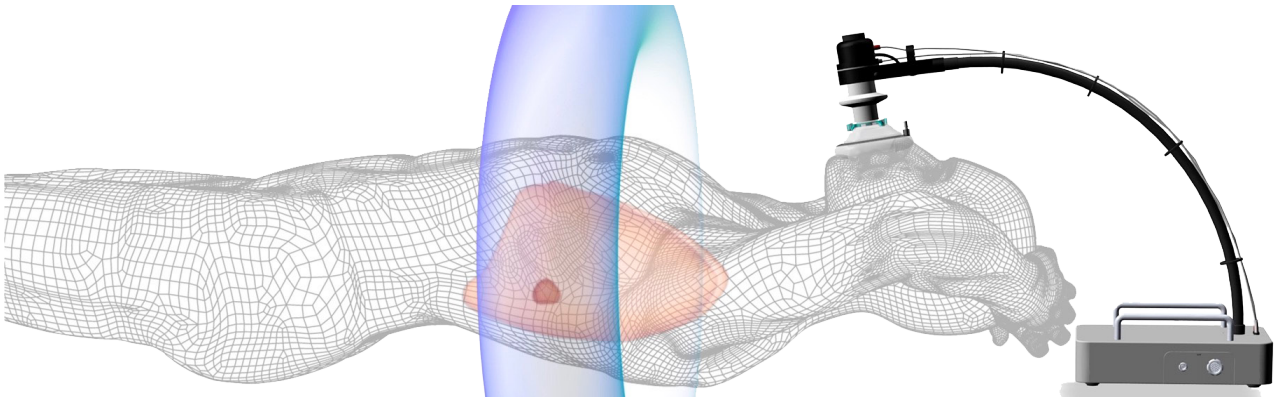
Optional Gating Modules (Varian® C-Series, Varian® ProBeam®, IBA™ Proteus®PLUS) pauses the beam if the patient cannot maintain his breath hold until the end of the radiation treatment.



The patient voluntarily performs multiple breath holds in the target inspiration zone, allowing the full treatment dose to be delivered.

SDX® Gating

Free Breathing Technique



Gating Modules (Optional)

The SDX® System can be used in manual or synchronized mode with the use of optional Gating Modules.

Imaging  **Treatment**

4D-CT reconstructions are often degraded due to poor abdominal motion. Compared with external systems, the respiratory signal obtained with the SDX® spirometer provides a high quality volumetric amplitude that is ideal for managing Free Breathing 4D-CT.
The Gating Module links the SDX® to the scanner, driving 4D-CT acquisition. The Gating Module receives the two signals, X-Ray on and X-Ray off, defining the acquisition period. The resulting high quality respiratory data allows for superior 4D-CT reconstructions.

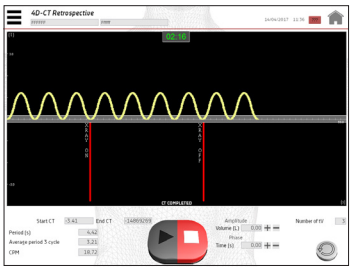
Gating Modules available for :
Siemens®

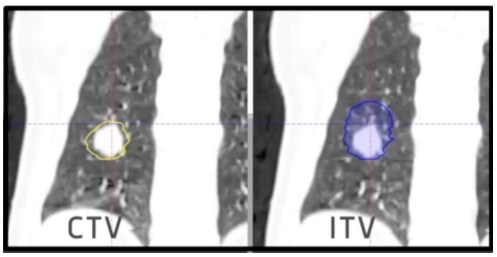
The Gating Module continuously monitors the patient's breathing and adjusts for motion in real time, delivering the dose only when the patient is in the breath hold zone. If the patient's breath hold moves beyond the defined breath hold zone, the Gating Module signals the equipment to immediately pause the radiation beam; when the patient moves back into the breath hold zone, the equipment is triggered to resume the radiation. The Gating Module allows the patient to return to the defined breath hold zone as many times as required to complete the daily radiation plan.

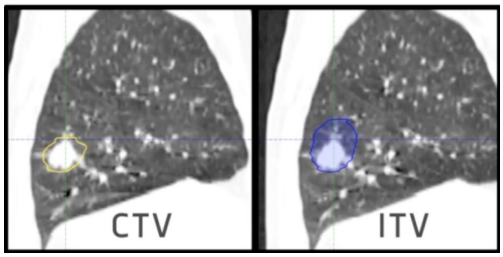
Gating Modules available for :
Varian® C-Series, Varian® ProBeam®, IBA™ Proteus®PLUS

4D-CT

The optional Gating Module for Siemens® enables free breathing techniques for specific treatments. The patient is positioned for treatment and breathes freely without seeing the breathing curve in the video goggles. When the software identifies that the patient is breathing normaly, it starts the process of image acquisition. The CT is configured based on the respiratory cycles. The image acquisition takes place between X-Ray on and X-Ray off. A specific .vxp file is produced for treatment planning and can be used with the image reconstruction software (CT or TPS).







SDX® System

New SDX® 3.0 Module

Features reinforced cable connections and integrated video goggle connection for improved workflow efficiency.

New Video Goggles

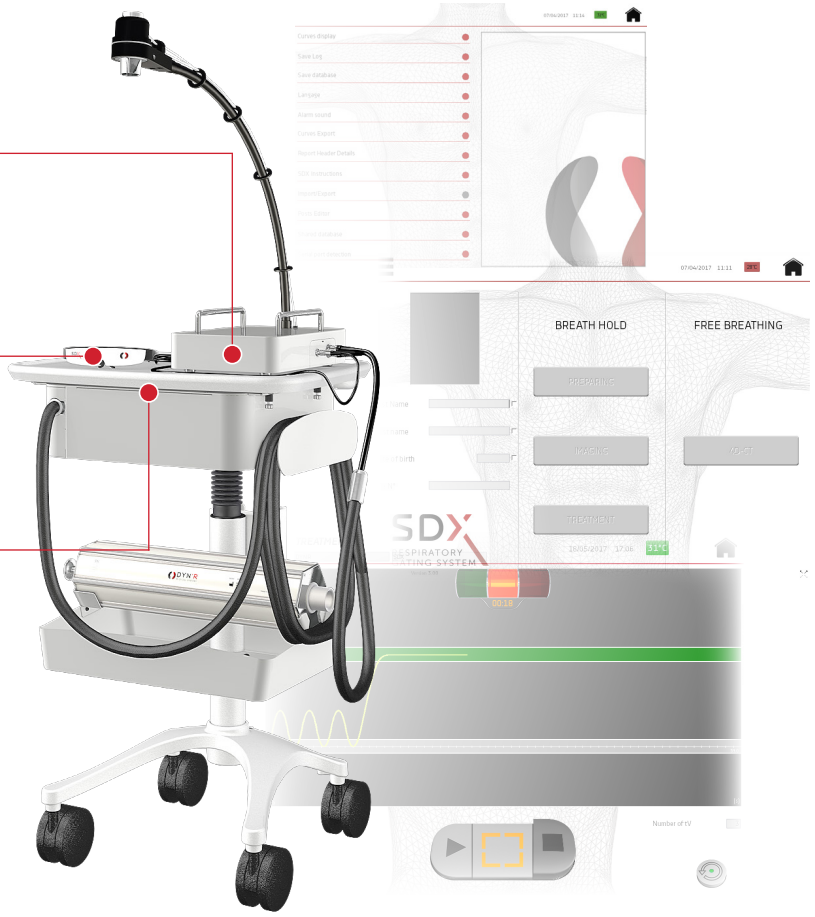
Connect directly to the SDX® 3.0 module and main power source for improved ease of use.

New SDX® 3.0 Custom Trolley

The new trolley design features a single connect combined power and data cable to enhance workflow efficiences between multiple simulation and treatment modalities.

New SDX® 3.0 Software

New user friendly interface with touch screen design for enhanced usability.



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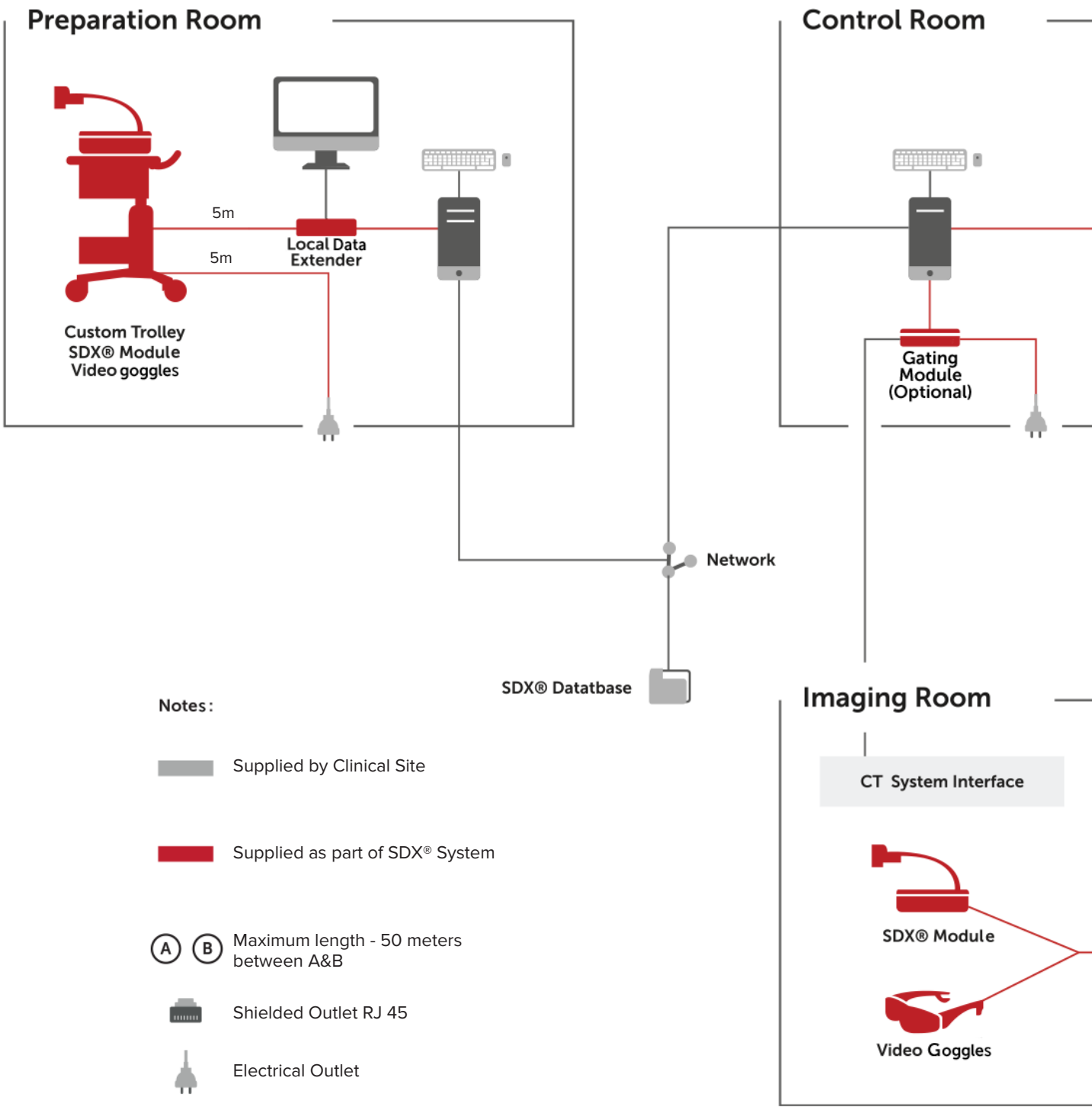
*1. Bortfeld, Th., Schmidt-Ullrich, R., De Neve, W., et al. (Eds.) Image-Guided IMRT. Springer; 1 edition 2005. 276. 2. Hanley J, Debois MM, Mah D, et al. Deep inspiration breath-hold technique for lung tumors; the potential value of target immobilization and reduced lung density in dose escalation. Int J Radiat Oncol Biol Phys. 1999 Oct 1;45(3):603-11. 3. Mah D, Hanley J, Rosenzweig KE, et al. Tracking lung tissue motion and expansion/compression with inverse consistent image registration and spirometry. Med Phys. 2007 Jun;34(6):2155-63. 4. Nehmeh SA, Erdi YE, Meirelles GS, et al. Deep-inspiration breath-hold PET/CT of the thorax. Nucl Med. 2007 Jan;48(1):22-6. 5. Kubas A, Chapet O, Merle P, et al. [Dosimetric impact of breath-hold in the treatment of hepatocellular carcinoma by conformal radiation therapy]. Cancer Radiotherapy. 2009. 6. Keall PJ, Mageras GS, Balter JM, et al. "The management of respiratory motion in radiation oncology; AAPM Report No. 91, Task Group 76." Med Phys. 2006;33. 7. Christensen GE, Song JH, Lu W, et al. Low DA Tracking lung tissue motion and expansion/compression with inverse consistent image registration and Spirometry. Med Phys. 2007 Jun;34(6):2155-63. 8. Rosenzweig KE, Hanley J, Mah D, Mageras G, et al. The deep inspiration breath-hold technique in the treatment of inoperable non-small-cell lung cancer.Int J Radiat Oncol Biol Phys. 2000 Aug 1;48(1):81-7. 9. Garcia R, Oozeer R, Le Thanh H, et al. [Radiotherapy of lung cancer: the inspiration breath hold with spirometric monitoring], Cancer Radiother. 2002 Feb;6(1):30-8. 10. Ramachandran P, Ganesh T, Pramod K, et al. Impact of different breathing conditions on the dose to surrounding normal structures in tangential field breast radiotherapy. J Med Phys. 2007 Jan-Mar;32(1):24-28. 11. Prabhaka, Ramachandran, et al. "Impact of different breathing conditions on the dose to surrounding structures in tangential field breast radiotherapy." J Med Phys. 2007 Jan-Mar; 32(1): 24-28. 12. Yang W, McKenzie EM, Burnison M, Shiao S, Mirhadi A, Hakimian B, et al. Clinical experience using a video-guided spirometry system for deep inhalation breath-hold radiotherapy of left-sided breast cancer. Journal of Applied Clinical Medical Physics. 2015;16(2):251 60. 13. Paumier A, Ghalibafian M, Gilmore J, Beaudre A, Blanchard P, el Nemr M, et al. Dosimetric Benefits of Intensity-Modulated Radiotherapy Combined With the Deep-Inspiration Breath-Hold Technique in Patients With Mediastinal Hodgkin's Lymphoma. International Journal of Radiation Oncology*Biology*Physics. 2012;82(4):1522 7. 14. Giraud P. Contribution of respiratory gating techniques for optimization of breast cancer radiotherapy. Cancer investigation. 2012;30(4):323 30. 15. Paumier A, Ghalibafian M, Beaudre A, Ferreira I, Pichenot C, Messai T, et al. Involved-Node Radiotherapy and Modern Radiation Treatment Techniques in Patients With Hodgkin Lymphoma. International Journal of Radiation Oncology*Biology*Physics. 2011;80(1):199 205. 16. Giraud P. Respiratory gating techniques for optimization of lung cancer radiotherapy. Journal of Thoracic Oncology. 2011;6(12):2058 68. 17. Lorchel F, Dumas J-L, Noel, A, Wolf D, Bosset, J-F, Aletti, P. DosimetricConsequencesofBreathHold Respiration in Conformal Radiotherapy of EsophagealCancer. Physica Medica. 2006;22(4):119 26. 18. Simon L, Giraud P, Servois V, Rosenwald J-C. Lung volume assessment*

SDX® Clinical Workflow Setup

PREPARATION PHASE

IMAGING PHASE



Notes:

Supplied by Clinical Site

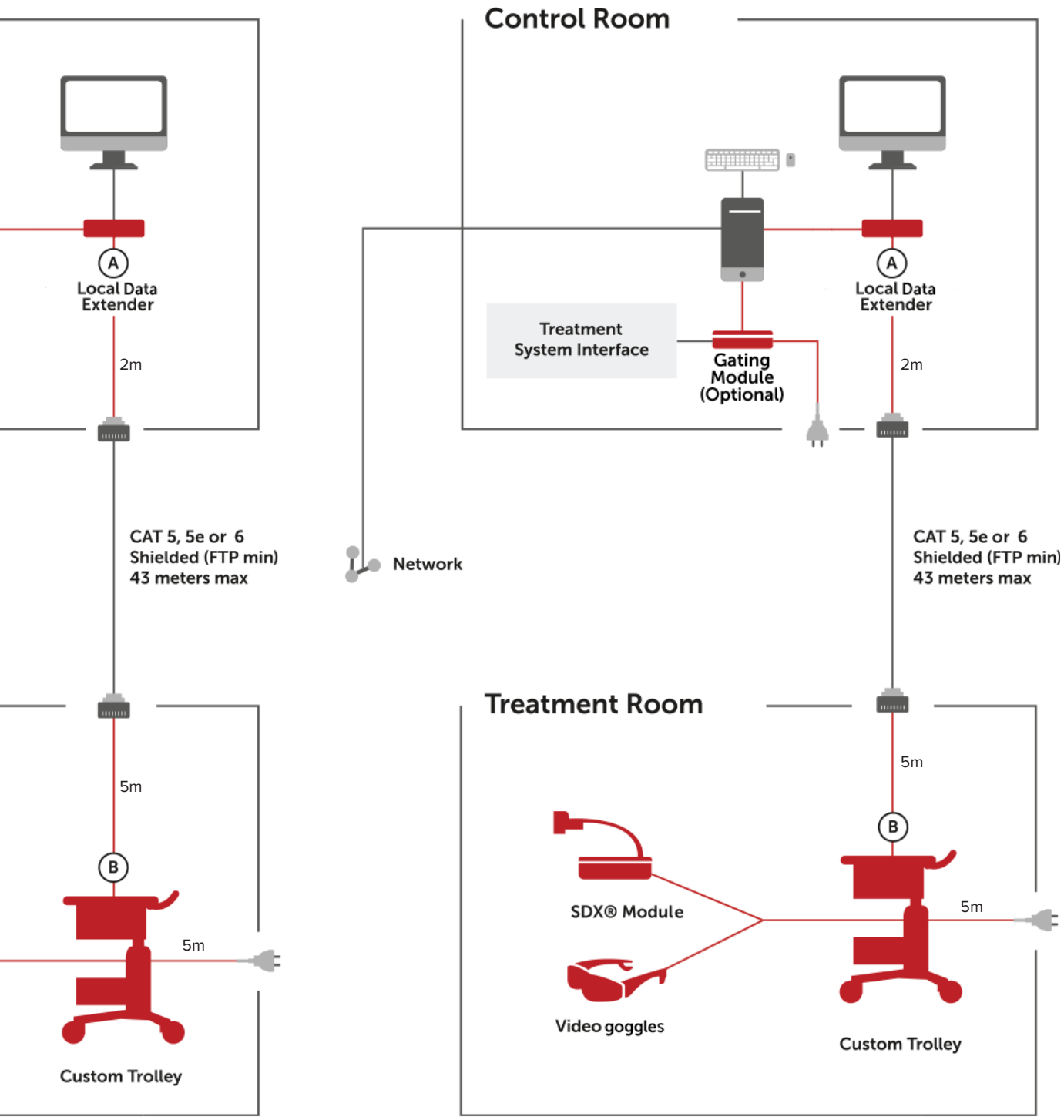
Supplied as part of SDX® System

A B Maximum length - 50 meters between A&B

Shielded Outlet RJ 45

Electrical Outlet

TREATMENT PHASE



Overview of the SDX® System

SDX RESPIRATORY GATING SYSTEM

NEW

SDX® 3.0 - Trolley Package

Includes:

- SDX® 3.0 Module
- SDX® Custom Trolley
- Video Goggles (HDMI)
- Calibration Syringe
- Software Version 3.0

SDX System :

RT-4410-SDX-05	SDX® 3.0 - Trolley Package
RT-4410-SAV-03	Annual Maintenance of the SDX® Module (includes 1 year warranty extension – US)
RT-4410-SAV-04	Annual Maintenance of the SDX® Module (includes 1 year warranty extension – EU)

Consumables* :

RT-4410-FLTR-01	Bacterial Filter - Qty of 100
RT-4410-MP-01	Mouthpiece - Qty of 100
RT-4410-NC-01	Nose Clip - Qty of 100

* Pictures shown may vary from actual product

Bacterial Filter

Mouthpiece

Nose Clip

SDX Gating Modules Optional** :

RT-4410-SNC-01	SDX Gating Module - IBA™ **
RT-4410-SNC-02	SDX Gating Module - Varian® C-Series**
RT-4410-SNC-03	SDX Gating Module - Varian® ProBeam®**
RT-4410-CT-01	SDX Gating Module - 4D-CT Siemens®**

**Please contact Qfix® for assistance in determining the prerequisites required to install the Gating Module with Varian®'s MMI for SDX®, or IBA™, Varian® ProBeam® and Siemens® interfaces.

Desktop Computers :

RT-4410-01	Desktop Computer
RT-4410-02	Desktop Computer Monitor
RT-4410-03	Desktop Computer Speakers

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