

# SpotLight™ and SpotLight Duo

Product Data Sheet (For US use)

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## INTRODUCTION

SpotLight™ is the first dedicated cardiovascular and thoracic CT designed to provide comprehensive clinical information useful for diagnosis and therapy planning. SpotLight is optimized for imaging the entire heart, cardiovascular and thoracic system with 140 mm coverage at a rotation speed of 0.24 sec per rotation.

The system is designed so you can image the heart using less radiation dose than whole-body CT scanners. Further, the fast speed of the scan may allow you to reduce contrast volumes and refrain from administering beta blockers.

SpotLight has three configurations: 25cm FOV, Extended FOV (25cm with extended 45cm FOV) and Duo (full high resolution 45cm FOV).

Key technology enablers include:

- **Unique Stereo CT® technology.** Two overlapping x-ray beams rotate about the patient in parallel trajectories, allowing you to obtain excellent image quality and wide z-axis coverage without the need for two detectors.
- **Focused field-of-view (FOV).** SpotLight's focused FOV of 250mm generates high-resolution images of the area of interest, while highly reducing dose to peripheral anatomy, allowing you to lower doses and eliminating physician over reads for peripheral anatomy versus whole-body systems.
- **Ultra-fast gantry rotation.** By using the 0.24 second rotation speed and partial scan mode you can achieve true uniform<sup>1</sup> temporal resolution of 120 msec for excellent cardiac imaging.
- **Dedicated image processing technologies.** Proprietary DLIR (Deep Learning Image Reconstruction), MBAF2 (Advanced Model-Based Adaptive Filter) and ASiR-CV<sup>2</sup> technologies, designed to reduce noise levels while maintaining low-contrast detectability, even at low signal levels

<sup>1</sup> The entire heart volume is imaged within the same narrow time window, unlike step-and-shoot or spiral scanning where different parts of the heart are imaged in different times.

- **Ultra-short gantry geometry & small footprint.** The ultra-short geometry means you'll always be making efficient use of the x-ray sources while benefiting from the small footprint gantry for your installation, even in small rooms.

## INDICATIONS FOR USE

The SpotLight / SpotLight Duo is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission projection data taken at different angles. The system has the capability to image cardiovascular and thoracic anatomies, including the heart, in a single rotation. The system may acquire data using Axial, Cine and Cardiac scan techniques from patients of all ages (DLIR is limited for patient use above the age of 2 years). These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes.

The system is indicated for x-ray Computed Tomography imaging of cardiovascular and thoracic anatomies that fit in the scan field-of-view.

The Low Dose CT Lung Cancer Screening Option for SpotLight Duo is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body or a professional medical society. Information from professional societies related to lung cancer screening can be found but is not limited to: American College of Radiology® (ACR) – resources and technical specification; accreditation American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

<sup>2</sup> ASiR-CV is an option

The DLIR and ASIR-CV algorithms are not compatible with the Low Dose Lung Cancer Screening option.

The device output is useful for diagnosis of disease or abnormality and for planning of therapy procedures.

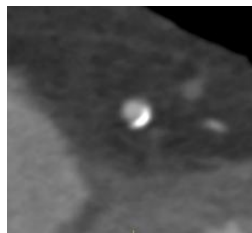
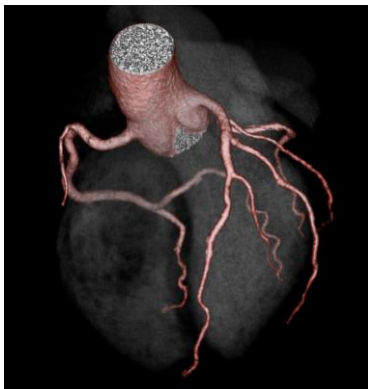
## CLINICAL HIGHLIGHTS

### *Making Advanced Imaging Routine and Routine Imaging Advanced*

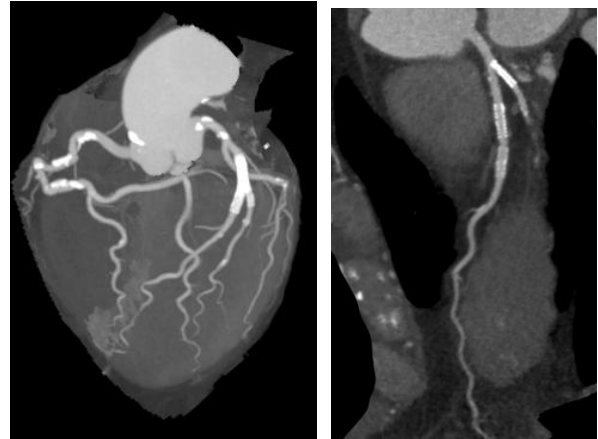
#### Cardiac and cardiovascular

**One-beat, high-definition, motion-free coronary imaging** at any heart rate is enabled by a prospectively ECG-gated whole heart cardiac axial acquisition protocol that utilizes 140mm of high-definition coverage with 0.16 seconds scan time<sup>3</sup> and real-time control to complete the scan in a single beat. This ensures robust, low-dose and high-definition cardiac imaging for all heart rates, with or without beta-blockers.

- For cardiac scan modes, SpotLight provides best-in-class spatial resolution of 0.24mm with 20.5 lp/cm in the (x,y) plane at cutoff frequency. This spatial resolution provides clear images to help you with tasks such as accurately quantifying stenosis in coronary arteries and other vascular structures.
- One-beat scanning technique ensures IV contrast and temporal uniformity across the whole volume within a single beat.



**Diagnostic quality results for any patient** - thin slice imaging, high spatial and temporal resolution, and advanced noise reduction algorithms (DLIR, MBAF2, ASIR-CV), provide you with exquisite images even for hard-to-do cases such as patients with high coronary calcium, post stenting and bypass grafting, unstable heart rate or high obesity.



Left: Low noise 0.5mm axial slice from a scan of highly obese patient (BMI 48) at temporal resolution of 120 msec; Right: Clear imaging of the lumen post stenting

**Comprehensive cardiac assessment** allows for acquiring motion-free coronaries and functional data in a single beat, giving you a comprehensive assessment and potentially reducing the need for additional imaging tests.

#### Dynamic acquisition mode

SpotLight enables whole heart dynamic acquisition with up to 140 mm of coverage. This ensures acquisitions with uniform contrast. The scanner allows adaptable aperture size and sampling rate, for enhanced anatomical localization. This is enabled by selecting collimations between 50 mm and 140 mm, and 10 mm option for bolus tracking).

The scanner is capable of 4D imaging to capture both morphology and functional information in a single acquisition. This aids in the assessment of conditions like congenital heart disease and provides clear visualization of blood flow within vascular structures.

<sup>3</sup> Partial Scan at 0.24sec rotation time. The temporal resolution is 120msec.

## Scanning for TAVR/TAVI planning

Dedicated TAVR/TAVI protocols allow you to mix ECG-gated axial acquisition of the heart with non-ECG-gated modes covering 700 mm in less than 14 seconds. 140mm coverage ensures no boundary locations at the valve plane.



## Calcium scoring

The system allows single-beat acquisition for cardiac calcium scoring with or without ECG gating.

## Triple-rule-out

The system allows robust triple-rule-out studies, with motion-free coronaries, pulmonary emboli and aorta evaluation in a single acquisition. The system can cover the entire thorax in under 4 seconds to provide contrast uniformity at low dose<sup>4</sup>.

## Adaptive ECG gating scans

The system has been designed to improve the robustness of cardiac exams for patients with high or irregular heart rates and in situations involving irregular heartbeats, arrhythmia, PVC's, etc. ECG gating methods include phase-based, timed or R-to-R acquisitions.

## Peripheral Vascular imaging

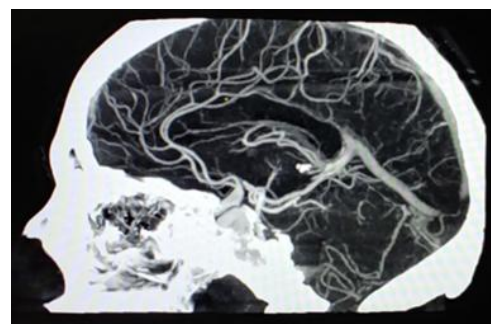
The scanner offers dedicated protocols for runoff, carotids, aorta, pre-surgical TAVR planning and other CTAs.



## Whole-organ diagnosis & follow-up

You can achieve low-dose, whole-heart and lungs coverage for diagnosis and follow-up<sup>5</sup>.

Fast scanning enabled by multi-volume 140mm acquisition with excellent image quality allows for reduced breath-hold times and shallow breathing techniques. Dose exposure is minimized through the ability to personalize collimations, ranging from 50mm and 140mm, tailored to each patient's unique requirements.



<sup>4</sup> When the Focused FOV of 25cm is used, only main and second branch pulmonary arteries are viewed in PE study.

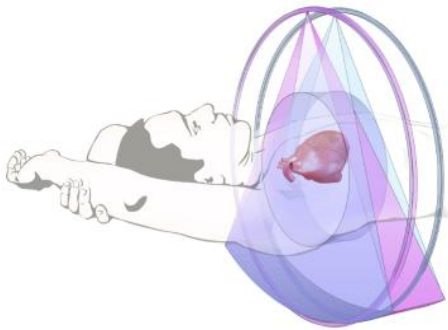
<sup>5</sup> Whole organ imaging limited to organs that fit 250 mm FOV (450 mm FOV with Extended FOV and Duo options)

## STEREO CT TECHNOLOGY

Unlike conventional single and dual-source CT scanners, SpotLight uses dual overlapping cone beams to achieve 140 mm coverage. Stereoscopic imaging provides a more complete data set than mono-beam CT, allowing for better artifact free images. Stereoscopic imaging also improves the dose utilization of the scanner.

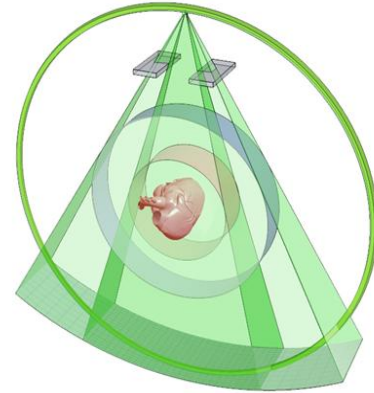
Key elements of the technology are:

- Dual MCS-2093 Gemini x-ray tubes.
- High voltage generator capable of ultra-fast x-ray beam switching between the two sources
- SpotLight detector capable of low-noise, high-rate acquisition
- Unique Stereo CT reconstruction algorithm for optimal integration of data from the two sources into a single image set



## FOCUSED FIELD OF VIEW

SpotLight uses Focused Field-of-View technology to allow high quality imaging of an area-of-interest, while reducing radiation dose in peripheral anatomy outside the area-of-interest (shown for a single x-ray source).



Radiation outside the 250 mm field-of-view of interest is attenuated by a factor of 10 to 20 (depending on kVp) so you can lower the dose to the patient<sup>6</sup>.

## CONFIGURATIONS AND OPTIONS

### SpotLight Duo Configuration

SpotLight Duo provides selectable field of view of 450mm for whole thorax imaging with high resolution detectors. The Focused 250mm FOV for cardiac imaging is still available.

### Extended Field of View (EFOV) <sup>7</sup>

Optional Extended Field of view provides selectable coverage of 450mm for whole thorax imaging. The Focused 250mm FOV for cardiac imaging is still available. The Extended FOV data is with reduced resolution.

### Extended Coverage Option (ECOV)

Extended coverage option enables longer scan range (up to 1370mm) to cover mediastinum to toe scanning for runoff CTA. The feature includes leg extender.

<sup>6</sup> Actual dose saving depends on kV, selected FOV and patient size.

<sup>7</sup> Available for SpotLight configuration

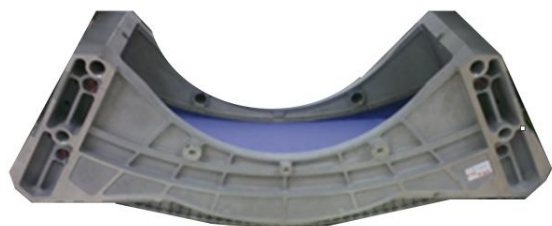
## Low Dose Lung Cancer Screening Option<sup>8</sup>

Low-Dose Lung Protocols designed in compliance with AAPM Guidelines for Lung Cancer Screening

### FOCUSED FOV DETECTOR

The scanner features the next generation, dual resolution SpotLight detector with ground-breaking technology. The focused field-of-view up to 250 mm in SpotLight or 450 mm in SpotLight Duo, is imaged by a high-density, high-definition detector array whereas the peripheral parts of the patient, outside the area of interest, are imaged with attenuated beam by high-sensitivity detector elements.

The SpotLight detector features a unique focally aligned layout of the detector sub-modules and high-precision grid to minimize scatter artifacts, ensure HU uniformity and reduce beam hardening artifacts associated with some wide coverage systems. Combined with the Stereo CT reconstruction technology, the system delivers excellent image quality at 140 mm coverage for whole organ imaging.



The SpotLight detector uses high-speed ceramic scintillator arrays, ultra-low capacitance photo diode arrays and new ASIC technology for conversion of the detector currents to digital signals. The detector includes electronics that allow acquisition of up to 12,900 views per second for high-definition dual tube imaging of full 140 mm coverage.

The detector system also features 32 reference channels on the source-side that allow you to leverage the bore fully while ensuring that neither the patient nor any patient-attached equipment blocks the detector's x-ray reference channels.

### Detector Specifications

|                             |                                                                                                                      |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------|
| Z coverage / rotation       | Up to 140 mm                                                                                                         |
| Number of slices / rotation | Up to 560 Slices with 0.25 mm spacing.                                                                               |
| Number of detector rows     | 384 (with dual tubes)                                                                                                |
| Number of detector elements | SpotLight: 74,528<br>SpotLight Duo: 103,328<br>All cells with individual DAS electronics for excellent data fidelity |
| Number of views             | Up to 12,900 views per second                                                                                        |
| Effective ADC dynamic range | 1:4,000,000                                                                                                          |

### Data Acquisition Subsystem

The SpotLight data acquisition subsystem (DAS) features trigger rates capable of supporting features such as high-definition imaging up to 3,096 views per rotation at a 0.24 second rotation speed. DAS gain is dynamically optimized for each detection module in each scan for minimal electronic noise.

### TUBE & GENERATOR

#### MCS2093 Gemini X-Ray Tube

MCS2093 Gemini is a next generation anode-grounded metal-ceramic x-ray tube adapted to allow two tubes to be placed back-to-back, thus enabling overlapping coverage. Electrostatic gate electrodes allow switching between the tubes at high rates. The tube enables improved spatial resolution via dynamic, in-plane focal spot deflection plus control of the focal spot width in the x-axis which optimizes the focal spot to deliver consistent beam quality across the full 140 mm z-axis coverage. This unique design makes MCS2093 Gemini one of the most innovative CT

<sup>8</sup> Available for SpotLight Duo configurations

### Tubes and Generator specifications

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Maximum peak power          | Nominal 72 kW<br>Effective 139 kW <sup>9</sup>                                                                                                                                                                                                                                                                                                                                                                                                              |
| Tube current range          | Nominal mA: 50 to 600,<br>Effective mA: 100 - 1,160 <sup>9</sup>                                                                                                                                                                                                                                                                                                                                                                                            |
| Tube Voltage                | kVp: 80, 100, 120, 140                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Thermal Rating              | <ul style="list-style-type: none"> <li>Efficient anode heat transfer and casing design eliminates inter-patient delays</li> <li>Max anode heat content (dual tubes):<br/>Nominal 2.00 MJ (2.8 MHU)<br/>Effective 5.4 MHU</li> <li>Max anode input power:<br/>Nominal 72 kW<br/>Effective 139 kW</li> <li>anode heat dissipation (dual tubes): 7.2 kW (10.08KHU/sec)</li> <li>Max continuous heat dissipation (dual tubes): 5.2 kW (7.28 KHU/sec)</li> </ul> |
| X-Ray Tube Housing Assembly | <ul style="list-style-type: none"> <li>Anode-Grounded Technology</li> <li>Nominal tube voltage: 140kVp</li> <li>Leakage technique factor: 140 kV, 14 mA</li> <li>Quality equivalent filtration: Min 3.0 mm Al equivalent at 120 kV</li> </ul>                                                                                                                                                                                                               |
| Large Focal Spot            | Large 1.1 mm x 1.6 mm                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Small Focal Spot            | Small 0.7 mm x 1.6 mm                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Target Angle                | 13.0 degrees                                                                                                                                                                                                                                                                                                                                                                                                                                                |

tubes offered today. The design is optimized for cardiovascular exams requiring high power for sequences of short exposures.

Mounted on the ultra-short geometry SpotLight

gantry, the MCS2093 Gemini provides x-ray flux equivalent to a 139kW scanner with a wider source-to-detector distance<sup>9</sup>.

The two MCS2093 Gemini x-ray tubes are powered by an onboard high frequency generator capable of ultra-fast beam switching between the two tubes. Proprietary technology is used to monitor the health of the x-ray tubes.

With the unique Stereo CT architecture, wide coverage and ultrashort geometry, the SpotLight tubes provide effective heat capacity of 20.7 MHU<sup>10</sup>. The tubes cooling rate allows practically unlimited number of CCTA studies per hour without overloading the tubes.



### MCS2093 Gemini Tube License

The MCS2093 Gemini tube includes a standard license that automatically enables the use of tube dependent advanced applications. The use of a third-party x-ray tube will require an additional license for the activation of these features.

## GANTRY

SpotLight's gantry platform has been designed from the ground up and tested to support rotation speeds as fast as 0.24 seconds per rotation.

<sup>9</sup> Calculated for source axis distance of 450 mm for SpotLight versus 626 mm for conventional whole-body scanner.

<sup>10</sup> Calculated for SpotLight with source axis distance 450mm and coverage of 140mm versus conventional scanner with source axis distance of 626mm and coverage of 40mm.



To ensure safe & reliable performance at these fast rotation speeds, the gantry platform features the following state of the art technologies:

### SpotLight high-speed bearing

Dual-raceway, high-speed, preloaded bearing with embedded elastomer support for excellent rotation precision and lower audible noise.

### SpotLight drive system

Digitally controlled, brushless DC motor coupled to the main bearing by a low-noise, multi-V belt system for smooth accurate rotation.

### High-speed slipring

Data transfer from the rotating frame to computer by a capacitive coupling contactless slipring for high-reliability, error-free data transmission. Power and control communication transfer to the rotating frame by high-speed carbon-silver contact brushes.

### Fail-safe mounts

The gantry frame features a redundant mounting design for all major components designed and tested to stringent standards to ensure safe and reliable operation at 0.24 second rotation speed.

### Laser alignment lights

Axial, sagittal and coronal laser alignment lights external to the bore are provided for convenient patient alignment with  $\pm 1$  mm accuracy. "Go-to-Scan" and "Go-to-Landmark" controls shuttle the patient between the alignment lights and scan position. The alignment lights may be activated any time during exam without stopping rotation.

### Easy access displays and controls

The gantry features LCD display monitors and control panels on the front and back sides of the gantry. The display includes the following information:

- Table vertical, horizontal and lateral position, including indication of landmark
- ECG waveform from the integrated ECG (if connected) including marking of R-wave triggers
- Selected ECG lead
- Heart rate
- Patient name and ID



The gantry control panels feature intuitive patient-orientation-based design and include the following controls and indications:

- Vertical, horizontal and lateral table movements
- Alignment lights on/off
- Horizontal shuttle from external lights position to scan position and back
- Setting landmark
- Selection of ECG lead for optimal ECG waveform
- Demo function for practicing the breathing instructions with the patient
- X-ray on indication

### Patient intercom

The gantry includes a high-fidelity intercom system for patient-operator communication during the exam and transmission of recorded messages in a language of choice (Auto Voice).

### Breathing Lights

A visual display facing the patient includes illustrative faces and time bar, used as additional mean to instruct the patient to hold and resume breathing.

### Gantry Specifications

|                                   |                                      |
|-----------------------------------|--------------------------------------|
| Source to isocenter distance      | 450 mm                               |
| Source to detector distance       | 854 mm                               |
| Aperture                          | 600 mm                               |
| Scan FOV                          | 250 mm in high definition            |
| Extended FOV (EFOV configuration) | 450 mm with limited resolution       |
| Wide FOV (Duo configuration)      | 450 mm in high definition            |
| Rotation time                     | 360° in 0.24, 0.27, 0.33, 0.5, 1 sec |
| Fan beam angle                    | 60°                                  |
| Temporal resolution <sup>11</sup> | 120 msec @ 0.24 sec/rot              |

## TABLE

SpotLight includes a high-stiffness table to reduce deflection and provide the best possible images even under heavy load conditions. The table is shorter than typical CTs which helps reduce the system footprint and needed suite size. The scanner is configured to image from the femoral to head with the patient positioned supine for patient comfort.

Table features include:

- Lateral motion for optimal centering of the scanned organ in the field of view
- Foot pedals controls on both sides of table for fast loading and unloading.
- Cradle position control from the operator console for prescribed scans
- Alternative manual horizontal motion using ergonomic handle at back side of cradle.
- Integrated ECG module with waveform display and lead selection through the gantry control

panels

### Table Specifications

|                            |                                                 |
|----------------------------|-------------------------------------------------|
| Vertical range             | 45 cm to 82.5 cm<br>50 cm to 87.5 cm w/ lateral |
| Vertical scannable range   | 68 cm to 82.5/87.5 cm                           |
| Elevation speed            | 30 mm/sec to 100 mm/sec                         |
| Horizontal range           | 150 cm                                          |
| Horizontal scannable range | 100 cm<br>137 cm with Extended Coverage option  |
| Horizontal speed           | Slow 30 mm/sec<br>Fast 300 mm/sec               |
| Lateral range              | ± 50 mm                                         |
| Load capacity              | 227 kg (500 lb) max allowed                     |

## OPERATOR CONSOLE

The SpotLight operator workstation allows simultaneous scanning, image reconstruction, display, processing, analysis, networking and archiving.

The operator workstation features the new SpotLight Operator Environment designed with your everyday needs in mind. The environment allows for more real-time adaptive capabilities like TAVR protocol with automatic transitioning from ECG gated cardiac scan to non-gated aorta scan with a single contrast injection. The benefits provided by the new interface include:

- Seamless multi-tasking through ability to have multiple patient sessions open with one active patient for acquisition and another for post-acquisition tasks.
- Improved protocol consistency by controlling access to changes and simplifying the inputs required .
- Better dose awareness through a clearly visible,

<sup>11</sup> Temporal resolution is defined as the full width at half maximum (fwhm) in time space of the projection data used to generate a given image.

real-time projected dose indicator for the selected protocol

### Operator workstation

|                         |                                                                                                                                                                            |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Host computer           | CPU: Intel XEON W-2123 3.6 GHz<br>RAM 32GB DDR4 ECC<br>NVIDIA QUADRO P620 / T600<br>930 GB SSD for images data                                                             |
| Reconstruction computer | CPU: Intel XEON W-2235 3.8 GHz 6-Core<br>RAM 64GB DDR4 ECC<br>NVIDIA RTX-3070 GPU or RTX-4000<br>SpotLight PCI express acquisition card<br>930 GB SSD for raw data storage |
| System storage          | up to 1.8 million 512 <sup>2</sup> matrix images using 930GB SSD for scan data (raw)                                                                                       |
| Additional storage      | USB 2.0 Port for External Hard Disk Drive Connectivity                                                                                                                     |

### Peripheral components

- Dell 23-in monitor with full HD 1920 x 1080 resolution and ultra-wide 178°/178° viewing angle<sup>12</sup>
- 104-key USB 2.0 keyboard
- 3-Button USB 2.0 mouse
- Scan control interface

### Image networking

- Transfer rate of 16 images per second on a dedicated 1 Gbit connection
- Standard auto-configuring Ethernet (UTP connection) - 1000/100/10 BaseT
- Direct network connection: multi-suite Ethernet card not required for gateway out of suite
- Protocols supported: DICOM network send.

<sup>12</sup> Alternative DIN 6868-157 compliant monitor provided in certain regions.

## PRODUCTIVITY & WORKFLOW FEATURES

Simplified, automated scan prescriptions, personalized to the patient and easy-to-use reference or site-specific protocols make SpotLight fast and efficient in-patient set-up, prescription & scanning. The following features further help you streamline your workflow.

### Protocols Collection and Timeline

Pre-programming and operation by a single button press of several chained protocols with different scan parameters is supported, where the relationship between protocols may be by time delay or trigger event.

A graphical timeline assists in the programming of the protocols collection.

### Contrast Bolus Tracking

Software for monitoring of contrast enhancement at a prescribed location and determination of optimal scan delay for the CTA scan. You can choose a separate test bolus sequence or monitor the contrast flow and perform the CTA in one sequence.

**Test bolus:** series of scans to monitor the contrast flow, and plan the clinical scan timing based on a graph.

### Automatic Bolus Tracking with Manual Transition

The contrast flow is monitored by low dose scans until the contrast enhancement reaches the preferred point and then the user initiates the prescribed scan.

### Automatic Bolus Tracking with Dynamic Transition

Dynamic Transition allows the scan phase to start automatically when the HU of the monitor ROI reaches the desired enhancement threshold.

**ROI setting on Scout data:** Uniquely in SpotLight, the ROI location may be set on the Scout data, eliminating the need for a baseline scan.

## Volume Viewer

SpotLight is a volumetric scanner and scan results are displayed in any of axial, coronal or sagittal modes in a main viewport with the other two axes displayed in adjacent mini viewports. The viewer includes pan, zoom, customary graphical tools and adjustment of the displayed slice thickness.

Further, double oblique multiplanar reformatting (MPR) and maximum intensity projection (MIP) are supported for fast viewing of clinical results on the scanner.

## Breath Control

Means are provided to manage the breathing of the patients during the scan:

- Demo function used to train the patient before scanning.
- Auto Voice automatically transmits to the patient recorded breathing instructions in a language of choice. Alternatively, intercom may be used.
- Graphical breathing light facing the patient provides the patient with visual indications.

## Reconstruction and Preview Images

Reconstruction speed is up to 80 images per second. The time to first Image is: 2.9 sec.

Quick View images are displayed to the operator within seconds and replaced by final images shortly thereafter.

## Retrospective image reconstruction

You have the option to retrospectively request additional reconstructions with different thickness, reconstruction kernels or cardiac phases.

Graphical user interface allows the user to easily plan the reconstructed volume.

## Trauma patient entry

You can scan patients and complete image display/analysis without entering patient data by selecting anonymous patient details.

# SCAN MODES

## Axial

- Up to 140 mm of contiguous axial coverage

acquired simultaneously with each 360° rotation, (240° rotation in partial scan mode) with the time between scans set by the user-selected interscan delay (ISD)

- Coronary CTA's acquired at a single heartbeat with temporal resolution of 120 msec<sup>6</sup>. Whole heart scanning in a single shot eliminates stair artifacts in the whole heart volume and provides uniform temporal resolution for the entire vessels length.
- Minimum scan-to-scan cycle time of 2 seconds with table moves of up to 130 mm (any scan time) and 1 second without table move.
- Flexible detector coverage with collimations from 50 mm to 140 mm (10mm for bolus tracking)

## Cine

Up to 140 mm of contiguous axial coverage acquired continuously for up to two heart cycles and reconstructed at multiple user selected phases.

## 3D Scout

A unique simultaneous acquisition of AP and lateral scout images with presentation of axial images at the ends of the range and easy graphical prescription of scan location.

## Scan parameters

SpotLight acquires 140 mm of axial coverage in one 360° rotation or in a partial scan (240° rotation). There are a variety of acquisition and reconstruction modes available for creating images from the multi-slice scan data.

### Scan Parameters

|                                                        |                                                                                                   |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Scan time                                              | 0.24 to 4 sec ( $\geq 360^\circ$ )<br>0.16, 0.18, 0.22 sec (partial scan in Cardiac Scan setting) |
| kVp                                                    | 80 to 140 kV in steps of 20 kVp                                                                   |
| mA                                                     | 50 to 600 mA<br>(Effective mA 100 - 1,160 <sup>8</sup> )                                          |
| Focal spot selection                                   | Small<br>Large                                                                                    |
| Resolution                                             | Selectable: STD or High                                                                           |
| Scan Gating                                            | ECG gating: Prospective, Retrospective or None                                                    |
| Scan position                                          | Horizontal increment 0.1mm<br>Vertical increment 1mm<br>Lateral increment 1mm                     |
| Aperture                                               | 10mm single tube mode<br>50 to 140mm dual tubes mode                                              |
| Inter scan Delay (ISD)                                 | Minimum of 1 second with no table movement. 1.7 seconds with up to 130 mm table move              |
| Scan to scan cycle                                     | Minimum scan to scan cycle with different protocol of 2.1 second                                  |
| Scan FOV - SpotLight                                   | 250 mm                                                                                            |
| Scan FOV with Duo configuration or Extended FOV option | Selectable 250mm or 450 mm                                                                        |

### Image reconstruction

A variety of reconstruction kernels such as Standard, HD Standard, HD Detail are available.

### Reconstruction Parameters

|                             |                                                               |
|-----------------------------|---------------------------------------------------------------|
| Number reconstructed slices | Up to 560 slices at 0.25 mm spacing                           |
| Reconstruction matrix       | 512 x 512                                                     |
| Reconstruction FOV          | 50 mm up to Scan FOV<br>Up to 450 mm in Scout                 |
| CT number scale             | -1024 to 3072                                                 |
| Reconstruction slice width  | 0.5, 1, 1.5, 2, 2.5, 3, 5, 10 mm                              |
| Multiple reconstruction     | Up to 20 reconstructions at different phases can be requested |

## IMAGE QUALITY

SpotLight is a sub-millimeter isotropic CT scanner making it possible to leverage coronal and sagittal reformats.

The optimized x-ray sources (focal spot shape and dynamics as well as reduced off-focal radiation) allow for improved measurement methods to fully characterize the limiting resolution of the SpotLight system design.

### Spatial Resolution<sup>13</sup> (scan plane)

| MTF | lp/cm |
|-----|-------|
| 50% | 7.2   |
| 10% | 13.3  |
| 4%  | 16.0  |

<sup>13</sup> High-contrast spatial resolution

## Stereo CT high-definition volume reconstruction

SpotLight includes state-of-the-art Stereo CT image reconstruction technology designed to mitigate cone beam artifacts associated with wide coverage systems. In addition, the algorithm preserves temporal uniformity and provides excellent image quality at full 140 mm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 140 mm z-axis coverage, typically caused due to heel effects.

## Noise reduction technologies

SpotLight's image comprises several noise reduction technologies advanced gating technologies that can be used to receive clear and sharp images even for large patients at fast scans. These include:

**DLIR Deep Learning Noise Reduction** is an artificial intelligence (AI) algorithm based on convolutional neural network technology that reduces image noise.

**MBAF2** Advanced Model Based Adaptive Filter for reduction of directional noise in large patient's low dose scans, combined with non-local mean volumetric filtering of the raw data for further reduction in image noise while preserving clinical details.

**ASiR-CV** Integrated advanced iterative reconstruction technology reduces noise, even at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable a reduction in dose<sup>2</sup> for all clinical applications<sup>14</sup>.

**ECG Gating:** Advanced gating algorithms that enable acquiring data in part of the heart cycle, according to the requested diagnostical test and patient's physiology.

## High-contrast resolution

The SpotLight detector provides high contrast spatial resolution.

In-plane MTF is demonstrated on a 0.05 mm tungsten wire. In-plane spatial resolution performance for full or partial scan (HD-Sharp kernel):

Spatial resolution calculated cutoff is 20.5 lp/cm in cardiac mode.

$0.24 \pm 0.05$  mm voxel size is seen in the scan plane.

Resolution in the axial direction is demonstrated on the Catphan High Contrast Resolution Insert Module CTP528:  $0.42 \pm 0.05$  mm voxel size is seen in the reformatted plane.

## Low-contrast resolution

LCD is measured on an 8-inch (20 cm) CATPHAN phantom low contrast module CPT515, 10 mm slice thickness, 0.30% (3HU) contrast using axial scan.

### Low Contrast Resolution

|                           |                                      |
|---------------------------|--------------------------------------|
| Object size               | 4 mm                                 |
| Contrast                  | 0.3%                                 |
| Scan parameters           | 120 kVp 250 mAs                      |
| Reconstruction parameters | 10 mm slice width<br>Standard kernel |
| CTDI                      | 22.6 mGy                             |

## Image noise<sup>15</sup>

Image average noise for the axial range (140 mm) is demonstrated on a 20 cm water phantom.

### Image Noise

|                           |                                  |
|---------------------------|----------------------------------|
| Noise                     | 3.5 HU                           |
| ROI size                  | 500 mm <sup>2</sup>              |
| Scan parameters           | 120 kVp, 250 mAs                 |
| Reconstruction parameters | 10 mm slice width<br>Soft kernel |
| CTDI                      | 22.6 mGy                         |

<sup>14</sup> In clinical practice, the use of ASiR-CV may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a physician and

a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task

<sup>15</sup> Pixel-wise noise magnitude

## DOSE REDUCTION AND OPTIMIZATION

### Focused FOV

Focused FOV technology is designed for optimal imaging of the organs of interest in 250 mm FOV while significantly minimizing the radiation outside of the 250 mm, thus, eliminating the need for physician over reads of peripheral anatomy.

### MBAF2

Complimentary raw data noise reduction and Model Based Adaptive Filter for reduction of directional noise for further noise reduction in low dose scans.

### Stereo CT geometry

The dual-tube volumetric coverage minimizes the irradiated patient volume that cannot be reconstructed into images at full image quality, thus improving dose utility further.

### SmartBeam™

The scanner features bow-tie filter and additional beam filtering at the x-ray source for further improvement of dose utility.

### 80 kV scanning

80 kVp scan mode to enable low dose pediatric and small patient scans while improving contrast.

### Prospective ECG gating

For cardiac applications, prospective ECG gating adjusts the scan time to the minimum necessary to achieve images at the requested phase and minimize the patient's exposure to X-rays.

## DOSE REPORTING

### Dose computation and display

CTDI volume (CTDIvol), dose length product (DLP), and dose efficiency computation and display during scan prescription provide you with dose information.

### Dose reporting

Dose reporting saves the CTDIvol, DLP, and phantom type in a DICOM Radiation Dose Structured

Report (RDSR) and a secondary screen capture. Series and cumulative exam values are saved. Saved values can be networked and archived.

### Dose Check

Provides you with tools to help you manage dose in your clinical practice and is based on the standard XR-25-2019 published by the National Electrical Manufacturers Association (NEMA).

Dose Check provides the following:

- Checking against a Notification Value if the estimated dose for the prescribed scan is above your site established value
- Checking against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value
- The ability to define Alert Values with a threshold
- Audit logging and review capabilities
- Protocol change control capabilities

## DICOM CONFORMANCE

### DICOM interchange

The following DICOM services are supported:

- DICOM Storage Service Class
- Service Class User (SCU) for image send
- DICOM Modality Worklist
- DICOM secondary capture
- DICOM Structured report

For detailed information, please refer to the SpotLight DICOM conformance statement.

The software allows the saving of any image from the database to a USB device for later reading.

### Image Networking

You can select and move exams from SpotLight to any imaging system supporting the DICOM protocol for network receive and pull/query.

Image transfer time using DICOM protocols is at least 16 images per second on a 1000BASE-T network.

## SITING REQUIREMENTS

Easy, convenient siting of SpotLight allows for installation in a scan room as small as 15 m<sup>2</sup> (162 square feet).

### Siting Requirements

|                       |                             |           |
|-----------------------|-----------------------------|-----------|
| Scan room size        | 4.4 m X 3.4 m               | Minimum   |
|                       | 6.0 m X 5.0m                | Suggested |
| Power Supply          | Three phases                |           |
|                       | 380/400/420/440/460/480 VAC |           |
|                       | 50/60 Hz                    |           |
|                       | 115 KVA                     | Maximum   |
| Scan room temperature | 20°C – 24°C (68°F – 75°F)   |           |
|                       |                             |           |
| Scan room HVAC        | 21,700 BTU/Hr               |           |

## BASE SYSTEM & SOFTWARE

One Beat cardiac  
 0.5mm slice thickness  
 Partial scan  
 80/100/120/140 kVp scan mode  
 High resolution mode  
 MBAF2  
 Data Export to USB device  
 Integrated Trigger ECG  
 Image Recon (80 images per second)  
 Patient table pad  
 Leg Support  
 Head and Hands Support  
 Tube License

## COMPATIBLE OPTIONS

The following options are available on the SpotLight scanner and operator console.

### Included options

0.24s rotation speed  
 72kW Generator  
 Lateral table  
 Bolus Tracking with Timing Bolus, Manual and Automatic Transition  
 Auto-Voice  
 DLIR  
 connection to HIS/RIS Modality Worklist – Scanner Side  
 Recon 560 slices/scan  
 Patient table pad with slicker  
 ECG Cables with Carbon Fiber leads

### Selectable options / accessories

EFOV (Extended FOV)<sup>16</sup>  
 Low Dose Lungs Cancer (LDLC)  
 ECOV (Extended Coverage)  
 ASiR-CV  
 Bar code reader  
 USB storage device  
 Uninterruptible power supply - Console  
 Uninterruptible power supply – System - Partial  
 Operator console table  
 Operator chair  
 Main Disconnect Panel  
 Service Cabinet  
 Seismic Kit

### Standard, Selectable Items

- Keyboard: English

## WARRANTY

The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

## REGULATORY COMPLIANCE

SpotLight complies with a wide variety of industry

<sup>16</sup> Some options are available in all countries.

standards to facilitate safe error-free scanning as well as more rapid adoption of features and performance improvements as the computing and medical imaging industry evolves.

The product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968.

This product complies with the performance standards of 21 CFR, sub-chapter J, and the applicable IEC 60601-1 series. Laser alignment devices contained within this product are appropriately labeled according to the requirements of the Center for Devices and Radiological Health.

This product complies with NEMA XR-25, XR-26, XR-28 and XR29



This product is eligible to bear the CSA Mark (CSA certificate 70124237). The device satisfies regulations regarding Electro-Magnetic Compatibility (EMC) and Electro-Magnetic Interference (EMI), pursuant to IEC-60601-1-2

SpotLight is not available in all markets.

SpotLight, DLIR and Stereo CT are registered marks of Arineta Ltd.

## MANUFACTURER:

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