Špecifikácia nového prístroja PET.CT v zmysle čl. V. ods. 6 zmluvy

Príloha č.2: Technická špecifikácia Biograph Vision 600 č. CPQ-403842-2

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Product Name: Biograph Vision 600

Item Nr: 1

Biograph Vision 600 consists of the following.

Scanning Unit (Integrated PET•CT Gantry):

The fully integrated PET•CT gantry incorporates CT and PET detector assemblies and electronics in an efficient, compact design. The large gantry opening, continuous patient port and short tunnel length provide ease of positioning for up to 500 lb (227 kg) patients and help to minimize patient claustrophobia. Quad operator controls are featured on the gantry for positioning from either side of patient and from either the front or rear. Dual gantry displays (front and rear) provide system status.

PET/CT Quality Control Phantoms:

- CT Quality Assurance Phantom (20 cm)
- PET Cylindrical Water Phantom (20 cm)
- PET Gantry Offset Phantom

Note sources offered separately

CT System:

The CT imaging capability of the Biograph Vision 600 consists of a 64-slice CT featuring a full range of spiral CT clinical applications with high performance.

Gantry:

Aperture: 78 cm; power supplied via low-voltage slipring.

Rotational speed of the gantry: 182 rpm with a rotation time of 330 ms.

Scanning system:

Adaptive Array Detector (AAD) system based on UFC™ (ultrafast ceramics) with up to 23,552 elements depending on configuration, and 1472 measuring channels per slice (the measuring system can contain replacement components).

STRATON tube high-performance X-ray system:

The STRATON tube provides direct oil cooling of the anode with the ball bearings located outside the vacuum. The direct anode cooling and the small and compact design of the anode eliminates the need for heat storage capacity (equivalent of 50 MHU) and enables an unprecedented cooling rate of 7.3 MHU/min. Therefore cooling delays between multiple long range scans are eliminated, even for large patients. Tube current range: 20-800 mA. Focal spot size according to IEC 60336: 0.7 x 0.7mm/7°, 0.9 x 1.1mm/7°. Computer controlled monitoring of anode temperature, multifan principle with flying focal spot.

Z-Sharp technology:

The unique STRATON X-ray tube utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in the z-direction, known as Double Z-Sampling. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary, high-speed Ultra Fast Ceramic (UFC) detector enables a virtually simultaneous readout of two projections for each detector element - 2 x 32 slices for every viewing angle - resulting in a full 64-slice acquisition.

80 kW X-ray generator:

Microprocessor-controlled, low-noise high-frequency generator with integrated, automatic self-testing system for continuous monitoring of operation. Settings: High-voltage range 70, 80,100, 120 and 140 kV; power max. 80 kW, adjustable in fine steps (100 kW optional).

PET System:

The PET imaging capability of the Biograph Vision 600 is supported by a multi-ring LSO/SiPM (lutetium oxyorthosilicate silicon photomultiplier) PET detector system with 3D acquisition and reconstruction, featuring 159 image planes comprising a 26 cm axial field of view.

The Vision detection system provides:

- High spatial slice resolution in trans-axial and axial dimensions.
- Slice spacing (1.65 mm) optimized for speed and resolution.
- LSO crystal for fast response and high light output.
- High-performance SiPM-based detectors.
- High-bandwidth electronics for low deadtime and high signal-to-noise.
- MARS combined acquisition and reconstruction computer system for high count rate capability and fast reconstruction of PET data.
- Three-dimensional display of organs with a large axial view.
- Excellent volume sensitivity.
- Fast acquisition and reconstruction at any available PET matrix size.
- Simultaneous data acquisition and image reconstruction for high patient throughput.
- Simultaneous reconstruction of two images in parallel (e.g. AC and NAC)
- Static and whole body acquisition capability.
- 820 mm detector ring diameter.
- 78 cm gantry aperture.
- 70 cm transverse field of view.
- Dedicated PET/CT Patient Handling System.
- TrueC advanced scatter correction technique

Patient Handling System:

The Biograph Vision 600 patient handling system (PHS) has a unique reinforced cantilever design that provides reliable patient support with high weight capacity and minimal pallet deflection. As one of the pillars of SMART (Siemens Molecular & Anatomical Registration Technologies), the PHS provides:

- Reinforced cantilever design for maximum patient support and absolute positioning between PET and CT scan.
- Integrated patient table design for easy patient positioning.
- Low attenuation carbon fiber pallet.
- 43 cm vertical motion range.
- Maximum 2 m PET•CT co-scan range.
- Low attenuation head holder, table extensions, head-arm support, knee-leg support.
- Maximum patient weight of 227 kg (500 lbs.).

Control and evaluation unit:

CT control box with intercom system with user-programmable patient instruction system. Dual monitors (19 inch (48 cm) LCD flat panel displays), keyboard and mouse for *syngo* Acquisition Workplace.

Computer system:

The computer system of the Biograph Vision 600 consists of three components.

- syngo Acquisition Workplace console for the planning and execution of the PET/CT examination, including evaluation and management of the PET/CT images.

- Reconstruction computer for the preprocessing and reconstruction of the CT data.

- PET acquisition and reconstruction system (MARS) with supported image reconstruction of 128x128, 220x220, 256x256, 440x440, 512x512, and 880x880.

The syngo Acquisition Workplace console consists of a high performance Windows based computer with 8 core Xeon processor, 16 GB RAM, 300 GB storage capacity, and DVD DICOM with 4.7 GB storage. External USB 2.0/3.0 devices for data storage are supported.

The CT reconstruction computer contains a cluster of high performance processors performing the preprocessing and reconstruction of the CT data at up to 40 images/sec (512x512). Raw data memory is 900 GB.

The PET acquisition and reconstruction system (MARS) provides high performance 3D acquisition and reconstruction. It contains dual Xeon 10 core processors with a total of 256 GB RAM. Disk storage of 3 TB for PET raw data and images is provided.

syngo User Software:

syngo features an intuitive and easy-to-learn user interface. *syngo* visualizes the examination in individual process steps on so-called *task cards*, such as patient registration or examination card. A large number of functions and input parameters as well as the language used can be selected according to individual requirements. Frequently repeated processes can be automated and saved.

Patient registration - The system can accept patient data in different ways. These include entering the data via keyboard or transfer of a worklist via network.

DICOM Worklist - Software module for accepting lists of patient data and exam requirements from a Radiology Information Systems (RIS) via DICOM "Get Worklist" functionality. The module enables efficient workflow and helps ensure consistent patient data.

Examination card - The scanner is supplied with a large number of predefined CT and fully integrated PET•CT examination protocols, making examination planning a fast and efficient procedure.

Viewing card - On the viewing card it is possible to move interactively with the mouse through the image volume of the ongoing examination. The images of different examinations can be displayed in parallel for comparison. A large number of functions are available for evaluation, documentation and archiving.

Filming card - A virtual film sheet shows a 1:1 display of the film sheets to be printed out, thus permitting an effective preview of the filming job and re-windowing the images, as well as providing a large number of evaluation functions. Layout changes are possible interactively with up to 64 images. The printout parameters for the ongoing auto-filming running parallel to acquisition or reconstruction are also defined with the filming card.

3D card - The 3D task card contains the User Interface for the operation of the MIP (Maximum Intensity Projection), SSD (Surface Shaded Display), and MPR (Multi-planar Reconstruction) three-dimensional post-processing. The 3D card also features an intuitive and fast bone removal function for CTA post processing and presentation.

3D VRT - Advanced 3D functionality as an extension to the basic 3D viewer, containing volume rendering technique (VRT) and advanced editing functions. Advanced 3D application package for the optimal display and differentiation of different organs through independent control of color, opacity, and shading in up to 4 tissue classes.

CT Angio - Software for the reconstruction of angular projections from the images of a spiral data record for the display and diagnosis, e.g. of aneurysms, plaques, stenoses, vascular anomalies or vascular origins. MIP: Maximum Intensity Projection, MinIP: Minimum Intensity Projection, and Thin MIP are available. Interfering or irrelevant parts of the image can be eliminated with the integrated volume editor. The angular projections are reconstructed around a definable axis, whereby the maximum CT values in this direction are selected for each angular projection. The resulting images can be viewed with the CINE function as a series of images with a 3D image effect.

Workstream - Planning and reconstruction of diagnostic CT coronal, sagittal, oblique and MIP images can take place directly after scanning.

DynEva card - Software for dynamic evaluation of the contrast enhancement in organs and types of tissues, enabling the reconstruction of

- Time-density curves (up to 5 ROIs)

- Peak-enhancement images

- Time-to-peak images.

Video Capture and Editing Tool - Integrated solution for imaging and visualization of 4D information, allowing the generation and editing of video files for improved diagnoses, recording and teaching. A wide range of multimedia formats is supported, e.g. AVI, Flash (SWF), GIF, QuickTime (MOV), streaming video.

HD FoV Pro - Extended Field of View option which allows visualization of objects with a CT FOV up to 78 cm, and improved CT image quality beyond the traditional 50 cm CT FOV for improved PET attenuation correction. HD FoV Pro can show reconstructed CT attenuation values outside the conventional FoV with an accuracy of +/- 50 HU within a 65 cm FoV.

TrueD Basic - Single-mode, single timepoint layout for displaying the PET and CT either fused or side-by-side comparison with viewer formats and color map tables. Support for 3D spherical regions-of-interest with units of Bq/ml or Standard Uptake Value (SUV). Allows re-registration of PET to CT data for correction of misregistration as a result of patient motion.

Media Viewer - Provides basic viewing capabilities in a portable Windows-based application that can be burned to media (CD, DVD) along with patient images. Not intended for diagnostic use.

- Review volume datasets from CT and PET

- Supports viewing single-modality or fused images

- View linked axial, coronal, and sagittal views

- Navigate in three dimensions

- View MIP images correlated to axial, coronal, and sagittal views

- Blend fused images

- Quantify Hounsfield units, SUV

CARE Solutions:

UFC Detector - Up to 30% dose reduction compared to conventional CT detectors. High efficiency for low mAs requirements enable best possible image quality with low patient dose.

CARE Filter - Specially designed X-ray exposure filter installed at the tube collimator. Up to 25% dose reduction with increased image quality.

CARE kV - Automated, organ-sensitive voltage setting to optimize contrast-to-noise-ratio and reduce dose by up to 60%.

CARE Profile - Visualization of the dose distribution along the topogram prior to the scan.

CARE Dashboard - Visualization of activated dose reduction features and technologies for each scan range of an examination.

CARE Child - Pediatric protocols, special examination protocols with 70 or 80 kV and a large range of adjustable mAs values for optimum adaptation of the radiation exposure to the age and weight of the child to be examined.

CARE Topo - Real-time topogram, Manual interruption possible once desired anatomy has been imaged.

CARE Bolus - Operating mode for CM-enhancement triggered data acquisition. The objective is optimum utilization of the contrast medium bolus in its "plateau" phase in the target organ. This option has been especially adapted to the increased speed and timing requirements resulting from the multirow capability and faster rotation. The CM enhancement is observed via monitoring scans in a user-defined ROI with a trigger threshold. As soon as the

enhancement reaches its predefined threshold, the spiral scan is triggered as quickly as possible. License for software use on one modality.

CARE Dose4D - This software feature provides automatic, real-time x-ray dose management for all scan modes. The minimal x-ray dose level needed to obtain optimal image quality is determined from extensive computer analysis of the topogram image and also from the data collected during every slice scanned, on a real time basis. This automatic approach ensures optimal image quality at the lowest possible x-ray dose. CARE Dose4D uses at first a automated adjustment of the dose level depending on patient size based on the attenuation values obtained from the standard topogram along the patient axis. In addition CARE Dose4D uses a real-time adaptation of the tube current during the scan based on the actual attenuation of the X-ray beam measured around the patient. Up to 2,320 projections are evaluated per second to optimize the mA level instantaneously. In combination with the extreme adjustment speed of the tube current, CARE Dose4D ensures consistent high quality images in every anatomical position. And that's at anytime with the minimal possible X-ray dose.

Several clinical benefits are achieved with CARE Dose4D:

- Significant x-ray dose reduction (up to 68 %) possible for all body regions scanned compared with standard sequence or spiral scanning;

- Consistent, optimal image quality with the x-ray dose level unique for every patient and for every anatomical region;

- Thinner axial slices and/or longer scan ranges possible because of reduced tube loading;

- Ultra-low dose examinations for pediatric patients.

CARE Dose Configurator - Enhancement of Siemens' renowned realtime dose modulation CARE Dose4D, introducing new reference curves for each body region and for each body habitus allowing to adjust the configuration even more precisely to the patient's anatomy.

Dose Notification - The Biograph Vision provides the ability to set dose reference values (CTDIvol, DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user.

Dose Alert - The Biograph Vision automatically adds up CTDIvol and DLP depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.

Adaptive Dose Shield - eliminates clinically irrelevant radiation in every spiral scan, adding to the lowest possible dose that CARE Solutions provide.

Ultra-low CT dose protocols for PET attenuation correction - non-diagnostic CT imaging protocols enabling sub 1 mSv CT acquisitions for PET attenuation correction

FAST CARE:

With Siemens' unique FAST CARE platform, the Biograph Vision is set to raise the standard of patient-centric productivity. Utilizing FAST – Fully Assisting Scanner Technologies, typically time-consuming and complex procedures during the scan process are extremely simplified and automated, not only improving workflow efficiency, but optimizing the overall clinical outcome by facilitating reproducible results, making diagnosis more reliable and reducing patient burden through streamlined examinations.

FAST Scan Assistant - An intuitive user interface for solving conflicts by changing the scan time, resp. the pitch and/or the maximum tube current manually.

FAST Adjust - assists the user to handle system settings in a fast and easy way by automatically solving of conflicts within user defined limits by one single click on the FAST Adjust button. The limits for scan time and tube current per scan are defined via the Scan Protocol Assistant. FAST Adjust offers an undo functionality to return to previously set values.

Examination and Evaluation Functions:

Topogram - Scanning perspectives: a.p., p.a., lat.; length of scan field: 128 - 2200 mm, width of scan field: 512 mm, 1.5 - 20s. The topogram can be switched off manually when the desired examination length is reached.

Tomogram - Scan field size: 50 cm. Standard scan times: 0.33, 0.5, and 1 seconds. Slice thickness in sequence: 0.6, 0.75, 1, 1.2, 1.5, 2.0, 2.4, 3, 4.0, 4.8, 5, 6, 7, 7.2, 8, 10, 12, 14.4, and 15 mm. Slice thickness in spiral: 0.4**, 0.5**, 0.6, 0.75, 1.0, 1.5, 2, 3, 4, 5, 6, 7, 8, and 10 mm (**optional with z-UHR).

Real-time image display - Immediate image reconstruction and display without time delay simultaneously to data acquisition in 512x512 matrix size.

Spiral - Scanning technique for continuous volume scans with continuous table feed in multirotation mode. Max. scan time 100 seconds and up to 2M scan length with full low-contrast resolution. Selection of the pitch factor between 0.35 and 1.5 depending on scan mode. Selection of up to 33 separately parameterizable examination ranges in a patient protocol. In addition individual anatomic sections can be successively combined and then scanned automatically. Storage of up to 10,000 examination protocols. Rotation times/cycle: 0.33 sec, 0.5 sec, and 1 sec.

Dynamic - Program for functional dynamic examinations. Serial scanning technique in one slice position with variable scan cycle times.

Serio-sequential examination without table feed - Up to 100 scans in uninterrupted, continuous sequence without table feed. Scan cycle time: 0.75 - 60 seconds.

Multiscan spiral examination without table feed – Continuous multirotational data acquisition in one slice position. Quantitative evaluation and graphical display of time-density curves.

WorkStream4D with Asynchronous Recon - 4D workflow with direct generation of axial, sagittal, coronal, or double-oblique images from standard scanning protocols. Elimination of manual reconstruction steps. Asynchronous Recon allows for multiple image reconstructions and reformats, parallel to scanning. With this feature, up to eight reconstruction job requests can be loaded into a scan protocol. Immediately upon completion of the scan acquisition, these reconstruction jobs are automatically executed in the background without delaying the start of next patient examination.

CT Image reconstruction and storage - Image reconstruction in full resolution (512x512 matrix) takes place during the examination with up to 40 images per second, with full cone beam reconstruction, z-Sharp Technology and full image quality. Reconstruction fields of 5 cm to 50 cm through raw data zoom with the possibility of freely selecting the image center either prospectively before each scan or retrospectively. Reconstructions of different slice thicknesses from a single raw data record, e.g. lung soft tissue and lung high-contrast with CombiScan, with simultaneous suppression of partial volume artifacts. Up to 8 reconstructions per scan range can be predefined with the examination protocol. Patient-related storage of the image and raw data.

Image display - 1024x1024 display matrix; screen splitting configurable up to 64 image segments; CT value scale from -1024 to +3071 HU. For very dense objects, the CT value scale can be extended from -10240 to +30710 HU (extended CT scale) e.g. for suppressing metal artifacts.

Image evaluation - Complete software-controlled image evaluation program for all diagnostic requirements.

CINE Display - Dynamic display technique for the visualization of time or volume series. A series of up to 1024 images can be displayed at a frame rate of at least 30 f/s. Automatic or interactive mouse-operated control.

Multitasking functions - Simultaneous processing during operation of the scanner.

Real-time Display - Image reconstruction in pace with the examination in full image quality (512x512 matrix) with up to 40 images/second (with full cone beam reconstruction and z-Sharp Technology).

Metro Display - Simultaneous display, processing and evaluation of images from other patients while the current patient is being scanned.

Metro Documentation - Simultaneous documentation of images from any previously examined patient while the current patient is being scanned.

Metro Copy - Automatic transfer of image data to the syngo CT Workplace (optional) or a DICOM network node.

Networking and Documentation:

For the connection to a local Ethernet (10, 100 Mbit or 1-Gigabit) in order to communicate with networked printers, diagnostic and therapy workstations, RIS or HIS systems and teleradiology routers.

Scope of functions:

- Configurable network stations.

- Unlimited selection of stations.

- DICOM Standard (Digital Imaging and Communications in Medicine) for the transfer of information between DICOM-compatible units from different manufacturers. The scope of functions is described in detail in the DICOM Conformance Statement, and the standard version comprises the functions Send/Receive, Query/Retrieve and BasicPrint, Worklist, Storage Commitment, and MPPS (Modality Performed Procedure Step).

System Documentation (1 set)

Smart Remote Services:

Smart Remote Services (SRS) offers a wide range of medical equipment-related remote services resulting in increased system availability and efficiency. SRS employs sophisticated authentication and authorization procedures, state-of-the-art encryption technologies and logging routines together with strictly enforced organizational measures that provide optimal patient data security and access protection. The following SRS services are included for all service agreement customers and during warranty period:

Remote Diagnosis & Repair: In case of an unforeseen system malfunction, Siemens competent experts may directly connect with the PET/CT system in order to identify the problem quickly. Moreover the remote repair function enables Siemens to often correct software errors immediately. Should an engineer on site be required, Remote Diagnosis & Repair allows Siemens to identify defective parts efficiently and accelerate their delivery, thereby keeping repair times to a minimum.

Event Monitoring: Event Monitoring screens the performance of the system. If a parameter deviates from a predefined value, a status message is automatically sent to the Siemens UPTIME Service Center. Service Engineers may evaluate the status message at periodic intervals and may initiate appropriate action within the scope of the service agreement.

Product Name: AIDAN

Item Nr: 2

Product Name: PET Gantry/MARS UPS

Item Nr: 3

Product Name: Keyboard, English

Item Nr: 4

Product Name: ultraHD-PET Option (AWP)

Item Nr: 5

HD•PET Package provides improved PET image quality compared to conventionally reconstructed images. HD•PET Package contains TrueX, an innovative image processing technique and 3D iterative reconstruction.

TrueX is an innovative image processing technology that is the key to achieving HD•PET performance levels. Conventional PET does not take into account the detector geometry and incorrect positioning of the LORs. HD•PET incorporates measured point spread functions (PSF) into the iterative reconstruction algorithm. Through modeling of the PSF, HD•PET more precisely accounts for the positioning of the LOR yielding visually sharper clinical images, visual improvements in contrast and in resolution.

3D Iterative reconstruction (OSEM) provides improved image quality in the most demanding low statistics acquisitions.

Product Name: CT SAFIRE (AWP)

Item Nr: 6

Dose reduction with CT has been limited by the currently used filtered back projection (FBP) reconstruction algorithm. When using this conventional reconstruction of acquired raw data into image data, a trade-off between spatial resolution and image noise has to be considered. Higher spatial resolution increases the ability to see the smallest detail; however, it is directly correlated with increased image noise in standard filtered back projection reconstructions as they are used in CT scanners today.

Iterative reconstruction approaches allow decoupling of spatial resolution and image noise. With the Sinogram Affirmed Iterative Reconstruction (SAFIRE), correction loops are introduced into the image generation process. These iteration loops utilize raw-data information to significantly improve image quality. Additionally, image noise is removed in the iterative corrections the without degrading image sharpness. The noise texture of the images is comparable to standard well-established convolution kernels. The new technique results in a significantly superior image quality with reduced noise and increased image sharpness that can be translated to dose savings for a wide range of clinical applications.

In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

Product Name: iMAR (AWP)

Item Nr: 7

The iMAR CT metal artifact reduction algorithm combines three successful approaches to reduce metal artifacts: beam hardening correction (in sinogram regions of less severe metal attenuation),
normalized sinogram inpainting (in sinogram regions of high metal attenuation), and frequency split (to mix back noise texture and sharp details that are potentially lost during inpainting).

The correction process is then iteratively refined by repeating the normalized sinogram inpainting and the mixing steps thanks to the Adaptive Sinogram Mixing.

Along with the new algorithm comes the simple user interface of iMAR. Besides the typical reconstruction parameters it only requires to select the desired protocol from a drop down menu which contains the following type of implants: dental fillings, neuro coil, thoracic coil, hip implants, extremity implants, pacemakers, spine implants and shoulder implants.

Product Name: Water Cabinet Kit - Vision

Item Nr: 8

Product Name: Install Kit w/PDU - Vision

Item Nr: 9