

Robotic magnetic navigation system with accessories for complex electrophysiology and catheter ablation procedures

	Subject of procurement	quantity (pcs)
	Complete equipment of the electrophysiological hall with a robotic magnetic navigation system with accessories, including a 3D electroanatomical mapping system, electrophysiological recording system, external stimulator, radio frequency generator and flushing pump.	3
Technical specification		
	Technical properties	Required item
1.	Robotic magnetic navigation system for electrophysiology	yes
	Robotic magnetic system with complete hardware and software equipment directly dedicated to electrophysiology and catheter ablation, including complex forgings	yes
	Ability to remotely control and navigate RMN (Remote Magnetic Navigation) catheters in both endocardial and epicardial anatomy of the heart with a high level of accuracy and safety and maintained high flexibility of controlled catheters	yes
	Control the procedure from the control room (mouse, joystick or keyboard)	yes
	Ability to control procedures remotely, from anywhere, using a computer network	yes
	Saving optional "one physician setup" settings for the ablation procedure to improve workflow and optimize and minimize human resources	yes
	Graphical integration and display of catheter position, mapping software and X-ray imaging to minimize X-ray exposure and maximize procedure success	yes
	Minimization of X-rays for the patient and the doctor	yes
	Semi-automatic RMN catheter navigation to improve workflow	yes
	Possibility to use automated functions, such as automatic mapping, moving the magnetic catheter to a specified position or moving the magnetic catheter along a specified trajectory using two-way communication with a 3D mapping system	yes
	Maximum possibility of integration and cooperation between the robotic magnetic navigation system and the 3D mapping system, including the transmission of information about the contact of the magnetic catheter with the tissue and the parameters of the ablation lesion	yes
	Possibility to use robotic magnetic navigation system for procedures with manual control of standard ablation and diagnostic catheters without robotic magnetic navigation	yes
	Monitors	
	2 pieces of QHD 58" monitors (1 pc in the operating room and 1 pc in the control room) with integrated and compatible display of video sources from the 3D electroanatomical mapping system and electrophysiological system without reducing the image quality	yes
	Integrated simultaneous display of min. 11 external video sources, including: X-ray, 3D electroanatomical mapping system, electrophysiological system, intracardiac ultrasound, hemodynamic monitoring and others.	yes
	Adjustable location and size of all application windows, including windows displaying connected third-party devices	yes
	Change and save window layout settings for individual users	yes
	Integrated control of all connectable devices (3D mapping system, RMN, RTG) on one terminal and monitor	yes
	Create and export large monitor desktop images and video files (screenshot)	yes
	Output of a digital video signal for the transmission of the image of a large-area monitor to the lecture room via an IP network	yes
	Open software interface for possible integration of additional mapping systems	yes
	Noise filter for Biosense Webster Carto mapping system	yes
	An operating room monitor with a ceiling mount that allows the monitor to be positioned in all directions, at least in range: left / right, down / up, closer / farther to ensure a good view of the monitor by the operator and allow it to be moved up or shifted longitudinally to free up space for manipulating the patient during movements in the operating room	yes
	Digital image processing system - post-processing	
	Acquisition matrix > 1548x1548px	yes
	Processing depth > 14 bit	yes
	Pulse sciascopy with a variable frequency in the range of at least 3.75 to 15 fps.	yes
	Image memory on HDD X-ray system without additional consoles, discs and external storage devices as well as CD / DVD ≥ 80,000 images	yes
	Possibility to import information from a 3D scan or 3D map and overlay it with an X-ray image in the integrated robotic navigation system	yes
	Zoom in, panning, flipping in post-processing	yes
	Digital system control panel in the control room	yes

	Implementation of digital system functions from the control panel in the control room	yes
	Image storage and recording on CD / DVD in the available DICOM 3.0 standard (Send, Inquiry / Get, Receive, Saving workbooks with browsing layering)	yes
	Operating table	
	Operating table length	min. 260 cm
	Operating table top width	min. 45 cm
	Longitudinal movement of the operating table	min. 120 cm
	Maximum load capacity of the patient's operating table	min. 200 kg
	Lateral movement of the operating table top	min. +/- 12 cm
	Patient table absorbance 1.0 mm Al	yes
	Mattress and pad for the patient's head	yes
	Integrated infusion bottle stand	yes
	Cable holder at the table	yes
	Imaging (registration) system	
	Ability to hold the last X-ray image (LIH) in the display	yes
	DICOM 3.0 interface (minimum Save, Send, Print, Inquiry / Received, Commitment, Workbook)	yes
	Saving images to CD / DVD / R / RW storage in DICOM 3.0 standard	yes
	Control console	
	Operators' workspace is equipped with a 58-inch QHD monitor to control the robotic navigation system and integrated third-party devices	yes
	Control panel for controlling the X-ray movement of the C-arm in the control console	yes
	Control interface for controlling the movement of the catheter tip	yes
	Emergency system switch	yes
	Accessories	yes
	Operating LED light installed on an adjustable articulated ceiling hinge	yes
	Medical tripod with articulated ceiling suspension with a load capacity of min. 300 kg, variably adjustable position and height, equipped with structured cabling and adapted to electrophysiological devices and accessories	yes
	Communication equipment, including a camera system with the possibility of video transmission to the lecture room	yes
	2. 3D electroanatomical mapping system	
	Electromagnetic sensor contact 3D mapping system including RF generator with flush pump and remote control	yes
	Possibility of full integration with a robotic magnetic navigation system using a magnetic ablation catheter and magnetic localization	yes
	Possibility to control the navigation of the magnetic ablation catheter directly in the application of the 3D anatomical mapping system	yes
	Possibility of creating electro-anatomical maps of individual anatomical structures of the heart and extracardiac structures (especially atria, ventricles, thoracic veins, aorta) using an ablation navigation catheter or navigation diagnostic catheter	yes
	Possibility of creating anatomical maps and reconstruction of individual anatomical structures of the heart and extracardiac structures (especially atria, ventricles, thoracic veins, aorta) using an intracardiac echo catheter	yes
	Possibility to determine the size of individual heart compartments	yes
	Possibility of displaying the time course of electrical activation, voltage information (unipolar and bipolar) or correlation of stimulation mapping of individual parts of cardiac compartments using color display	yes
	Possibility of detailed mapping of individual structures ("point by point"), fast anatomical mapping and automatic acquisition of points with automatic annotation using a catheter-heart contact filter using special multipolar diagnostic catheters and an ablation catheter	yes
	Ability to accurately locate and display ablation and multiple electrophysiological catheters in 3D reconstructed cardiac compartments in real time during exercise	yes
	Possibility of different way of displaying the magnitude of force / pressure and direction of action of the catheter on the tissue (graphically, numerically), using a fully integrated measurement system	yes
	Possibility of automatic acquisition of ablation points depending on power, pressure, stability and time	yes
	Possibility of integration of CT or MRI image into real 3D anatomy	yes
	Fast automatic mapping and sorting of ventricular extrasystoles and ventricular tachycardias	yes
	Possibility to use a controllable loader visible in the 3D map in real time	yes
	Support for catheters that allow the creation of maps with a high density of trigger points	yes
	Basic physical and technical requirements of the system:	yes
	System accuracy: less than 1mm in vivo	yes
	Sensor position detection in several directions and planes (min. 5)	yes
	Possibility to protect the system against shock from defibrillators	yes
	3. Electrophysiological recording system and stimulator	

Electrophysiological recording system designed for use in electrophysiological procedures with the possibility of monitoring and recording hemodynamic parameters and optional display of images on any monitors in the operating and control room.	yes
Compatibility with 3D mapping system and robotic magnetic system with the possibility of integrated control.	yes
Database with the possibility of storing results such as: patient demographic data associated with the time course of ECG waves, Intracardiac ECG, pressure and other measured parameters, as well as calculated indicators.	yes
Computer with at least two color TFT / LCD monitors with a diagonal of min. 20 "	yes
Transmission of images of the electrophysiological recording system to the monitor of the digital angiography system LDM (Large Display Monitor)	yes
Ergonomic set of amplifier connection modules (connection box) providing connection of at least 100 bipolar signals (minimum 200 individual inputs)	yes
Amplifier of electrical signals of the heart with at least:	
100 intrakardiálnymi kanálmi (minimálne 200 jednotlivých vstupov)	yes
12 ECG channels	yes
4 pressure channels	yes
4 inputs for external rhythm stimulator	yes
Communication between the amplifier and the control computer via an optical cable	yes
Frame rate: 1, 2 and 4 [kHz]	yes
Filter for frequency 50 [Hz] and 60 [Hz], designed and adjustable for individual intracardiac channels	yes
System requirements:	
Receiving signals	yes
Control of ablation parameters	yes
Storage of acquired data and their analysis	yes
Browsing the acquired data	yes
Real-time ECG display of intracardiac electrograms on the monitor	yes
Display of recorded ECG signals and intracardiac electrograms and their analysis on a "post processing" browser	yes
Interactive window - LOG enabling saving and editing of all events during the examination, as well as the possibility of complete editing of events and their entry	yes
Measurements and presentation of current (current) patient rhythm cycles from any two selected channels	yes
Possibility to set and change the ECG speed on the live monitor (real time) in the minimum range of 6 - 400 [mm / s], and on the viewing monitor in the range up to 1,600 [mm / s]	yes
Number of channels simultaneously displayed on the monitor at least 64 in real time	yes
Automatic data collection of ablation parameters and their presentation in digital graphic form	yes
Automatic data collection of cryoablation parameters and their presentation in digital graphic form	yes
The system must allow the user to freely set channels, including the independent setting of signal parameters for each intracardiac channel:	
magnification / amplification	yes
color	yes
frequencies for filter groups	yes
network filters	yes
Possibility to select any channel for direct stimulation from the live (real-time) monitor without the need to intervene via the system menu	yes
Ability to define the individual bipolar channels used as a stimulation channel and create an on-screen shortcut for them	yes
Possibility to create preferential settings of pages with preset composition and graphic location of individual channels.	yes
Possibility to set study protocols and assign individual events and intervals	yes
Possibility of free specification of a sample window with signals (both 12 ECG and intracardiac signals) for performing and comparing morphology with subsequence recorded signals implemented in real time	yes
User interface with functions for setting and visualization of electrophysiological signals with definition:	
regulation of intensity, ECG signal strength, intracardiac (IK) signal, invasive pressure	yes
horizontal and vertical adjustment of ECG signal pattern, IK, invasive pressure	yes
Automatic detection of RF applications with automatic recording of stimulation parameters and their presentation in the window - LOG for a subsequence of ablation steps with the most used RF generators available on the market	yes
Automatic recording of pacing pulses with automatic acquisition of pacing parameters and their presentation in the window - LOG for further pacing steps	yes
Ability to create comments for the collected data and their simple future analysis	yes
Possibility of analysis of ECG signals as well as intracardiac recordings	yes

	Manual and automatic measurement of intervals with analysis of ECG curves and intracardiac channels	yes
	Trigger and trigger mode (with the possibility of refreshing the screen)	yes
	Presentation and recording with the Holter system (Holter window)	yes
	Possibility to print ECG curves and intracardiac signals from the screen	yes
	Possibility of creating your own procedural reports	yes
	Automatic recording of total ablation time and cryoablation time information in reports	yes
	Save browsing screens and images in BMP and JPG format	yes
	Creating presentations in MS Power Point software, including exported data in Excel	yes
	Ability to export "RAW data" in binary or xls format	yes
	Software integration of electrophysiological recording system with electro-anatomical 3D mapping system	yes
	Emergency pacing-function to bypass the amplifier (directly from the stimulator)	yes
	Possibility of later modernization of the device for measuring hemodynamic parameters such as calculation of cardiac output, invasive and non-invasive pressure on one platform	yes
	Other parameters	
	Possibility of Barcode scanner used for registration of consumables used during procedures	yes
	Archiving of measured data on DVD or SD card, or on a network disk at the level of electrophysiological software	yes
	Fast storage of patient data on disk, including patient identification data	yes
	HL7 data export for hospital system	yes
	DICOM MWL import patient data via communication user interface	yes
	Sharing monitors, workstation and keyboard in case of expansion by hemodynamic module	yes
	UPS for electrophysiological station	yes
	Programmable stimulator	yes
	Programmable stimulator with at least two channels, based on a computer platform with its own keyboard, LCD touch monitor and control stimulator located in the control room	yes
	Programmable stimulator with programmable parameters:	yes
	amplitude of the stimulation pulse in the range of at least 0.5 - 20 [mA] adjustable in 0.1 [mA] steps	yes
	pulse length 0.5 [ms] and in the range 1 - 2.9 [ms] with adjustable rise 1 [ms]	yes
	Burst stimulation with a pulse length of at least 30 - 3000 [ms]	yes
4.	Other requirements	
	New, unrefined, unused goods	yes
	Free service during the warranty period of 24 months	yes
	Commissioning of the device	yes
	Training min. 3 employees at the place of delivery	yes
	Service available within 24 hours	yes
	Transport to the place of performance	yes
	Assembly and installation of equipment into operation	yes
	Submission of documents necessary for its collection and use (delivery note, or acceptance protocol, invoice, operating manual in Slovak or Czech language)	yes
	Testing the functionality and operability of the delivered equipment	yes
	Educational program for employees	yes