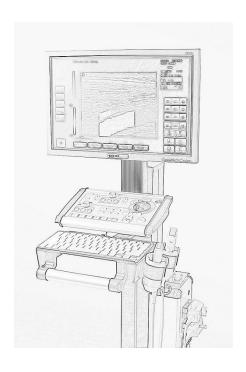


Ultrasound scanner **SPINEL**

(Touch Screen)

General Specifications



ver. S10.00.

CE₁₀₁₁

February, 2015

System overview

1. Display Modes

- B (2D) mode
- Multi-image: split(B/B); quad(4B) screen
- TM-mode, 2D+TM (real-time duplex)
- 2D+ PW (Pulsed Wave Doppler real-time duplex)
- 2D+CF (Colour Flow Doppler)
- 2D+ PD (Power Flow Doppler)
- double: 2D / (2D+CF); 2D / (2D+PD)
- 2D+CF+PW (triplex mode)
- 2D+PD+PW (triplex mode)
- ZOOM: 2D, 2D+CF, 2D+PD
- Cine view

2. Application

Linear probe:

- Vascular
- General
- Small Part
- Musculoskeletal
- Urology

Rectal probes

- Endorectal
- Endoanal

Transrectal Bi-Plane probe

- Rectal long
- Rectal cross

Endovaginal micro-convex probe

- Endovaginal
- Gyn/Fertility
- General

Convex probes

- General
- Abdominal
- Musculoskeletal
- OB/GYN
- First Trimester

3. Console Design

- Intuitive and simple user interface twofold truly unique system:
 - Touch Screen all functions accessible via Icon-based Graphical User Interface
 - Classic, functional Desktop plus Alphanumeric Keyboard on drawer system.
- Console providing left/right swivel adjustment
- Height adjustment of control panel

- Simultaneous connection of three electronic probes (optional -four probes: 3 electronic + 1 special)
- Trackball control
- System with one monitor (option the second patient monitor)
- Integrated HDD
- Two USB 3.0 ports
- One USB 2.0 port
- · Mini HDMI port
- Display port
- Ethernet LAN RJ45 connector
- DVD-R multi drive (optional)
- Integrated speakers (for Doppler mode)
- Probe and gel holders
- Footswitch (option)
- · Backlit operating keys

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4. LED monitor

• 21,5" High-Definition colour LED

• Touch Screen - capacitive, fingers and thin gloves operate,

- Monitor complies with latest the standards: ENERGY STAR® and EPEAT® Silver.
- Full HD resolution: 1920 x 1080
- Vertical and horizontal viewing angle 178°
- Bright regulator function incorporated
- DVI_D (HDCP), HDMI connectors
- · 16.77 million display colours
- Swivel to any viewing direction
- Adjustable

5. Trolley

- Console providing left/right swivel adjustment
- · Four swivel wheels with parking brake

6. Display Annotation

- Menu touch keys
- Function touch keys
- · Virtual on-screen keyboard for entering patient and user information
- Patient name (First and Last)
- Patient ID
- · Age, gender and date of birth.
- Date and Time
- User (Hospital) name
- Application type

- Freeze indication
- · Probe type and imaging frequency
- Frame rate
- Image orientation marker
- Dual and quad format orientation marker to indicate active window
- Depth scale marker
- Focus markers
- · Image depth
- · Gray and colour map
- Body markers: body- part icon with the marker relative probe position
- Cine image number/frame number
- Cine scrolling memory indication
- · Measurement results
- · Operation status message
- Text and arrows (places, moves, erases)
- Estimated Biopsy lines

B mode:

- Gain B
- Gray map
- · Post processing, filters, persistence
- Imaging depth
- Enlargement of an image (zoom) [in %]
- · Dual format orientation marker to indicate active window

M mode:

- Gain M
- Time scale

Doppler mode:

- · Gain PW and CF/PD
- · PRF PW and CF/PD
- · Angle SV
- · Sample Volume depth
- · Sample Volume width
- · Velocity scale
- · Speed sweep in PW
- Wall Filter
- Time scale
- · Colour map
- · Base line
- · TIS: Thermal Index Soft Tissue

7. System Setup

- User (Hospital) name
- Language selection
- Setting the Time and Date (two types selectable)
- Biopsy on/off
- Selecting Text size

- Selecting Cursor size
- User interface color customization possibility (4 sets and customize)
- Selecting a printer
- Colouring the B image
- Number of zone TGC
- Mode for special probe Bi-Plane 2PR
- Image FFT colour
- Auto switch AQ
- Doppler scale cm/kHz
- Storage destination (HDD,USB)
- Adjust the keyboard backlight brightness
- GA table set
- Programming shortcuts for alphanumeric keyboard
- Capture time (AVI)
- File format
- User settings (filters, post processing, persistence) for every application
- Internal database of patient data
- Customizable Anatomy Descriptions

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8. <u>Dimensions and Weight</u>

- 440 x 595 x 1230 mm
- Weight: ~25kg (with trolley and monitor)

9. Electrical Power

- Nominal input voltage: 100-240 VAC, 50/60 Hz
- Power consumption: ~120 VA

10. Environmental

- Operating temperature: 10°- 40 °C at 30% 85% relative humidity
- Liquid Ingress Protection :
 - Scanner: IPX0 (ordinary equipment without protection against ingress of water)
 - Probes: IPX1 dripping water (vertically falling drops) shall have no harmful effect

11. Electrical safety standards:

- Medical Device Directive 93/42 EEC
- EMC Directive 89/336/EEC
- Electromagnetic Compatibility EN 60601-1-2
- Electrical Safety IEC 601
- Medical device class IIa comply with Medical Device Directive 93/42 EEC
- Scanner complies with requirements for Class I devices of EN/IEC 60601-1

12. Acoustic safety standards:

Acoustic safety: EN 60601-2-37: 2007
 Declaration for ultrasound scanner SPINEL::
 In all modes Mechanical Index MI don't exceed the value 1.0

Imaging

13. Imaging - B mode

- 256 shades of Gray, 8 bits
- Adjustment of total gain value (touch screen or by knob)
- Gain adjustment for 5 or 8 individual zones (Time Gain Compensation)
- Single, dual, and quad image display capability
- ESR Enhanced Speckle Reduction
- Scanning angle: up to 360° (depends on the probe)
- Tissue harmonic imaging (THV)
- Multi-frequency ultrasound probes from 2 to 15 MHz
- Scanning depth range: from 1.5 to 31 cm (probe dependent)
- Controlling the number (1, 2, and 4) and position transmit focal zones.
- Digital dynamic receive focusing
- Frame rate in excess of 250 fps, depending on probe, settings and applications
- Image reverse L/R
- Image rotation of 90°,180°
- Colorized 2D-mode
- Automatic Optimization single keystroke optimizes automatically settings
- Normal key adjusted for the real time image
- Image filters (5 levels).
- Image digital filters in Freeze mode (10 levels)
- Image post processing (Exp;Lin; S)
- Correlation of images (Persist: P1...P4)
- Zoom the image (in/out adjustment from 40% to 800%; 19 levels)
- Negative of image (Inverse)
- · Background change
- Biopsy guide zone

14. <u>Imaging - M mode</u>

- Trackball steers M-mode line available with all imaging probes
- Adjustable gain M -mode
- Simultaneous real-time 2D- and M-mode
- · Top-bottom formats and time-motion only format
- Selectable scroll speed (sweeping rates): 4, 5, 8, 16 seconds

15. Imaging - PW mode

- Trackball steerable Doppler available with all imaging probes
- Doppler frequency: 3,125 or 6,250 MHz (probe dependent)
- Real-time duplex operation for all velocity settings and for all electronics probes
- Frame rate control for optimized use of acquisition power between spectrum and 2D
- Selectable horizontal scroll speed: 4,5, 8, 16 seconds across display
- · Adjustable spectral Doppler gain and power
- PRF settings from 0.75 to 9.0 kHz
- Wall Filter (5 level min 0,025 x PRF ...max 0,20 x PRF)
- Adjustable sample Volume (SV) size
- Spectral invert
- Automatic Doppler trace
- Adjustable velocity scale and baseline.
- Left/right steer on all linear transducers
- Angle correction with automatic adjustment of velocity scale (0..89°)
- Stereo speakers and volume of Doppler sound control
- Doppler colorization maps
- · PW image post processing
- Real-time display of Thermal Index (TI)
- Display annotations of frequency, SV setting, angle correction, acoustic power indices

16. <u>Imaging - CF/PD mode</u>

- Steerable colour Doppler available with all imaging electronics probes
- Simultaneous display of gray scale 2D and 2D with colour flow
- Doppler frequency: 3,125 or 6,250 MHz (probe dependent)
- True colour, 8bits for each RGB component
- Zoom the colour image (200%)
- Colour scale reversing
- Colour map
- Trackball-controlled ROI
- Variable ROI size in width and depth
- PRF settings from 0,5 to 9,0 KHz
- Adjustable colour Doppler gain and power
- Colour Doppler persistence
- Real-time display of Thermal Index (TI)
- Small flow filter
- Changing the priority and reject level
- Changing colour image resolution (line density)
- Display annotations of frequency, gain setting, acoustic power indices
- Left/right steer on all linear transducers

Measurement

17. Measurements - 2D-Mode

- Multiple cursor sets on frozen and cine playback images
- Distance measurement -: nine (9) independent pairs of cursor
- Angle (four measurements)
- Volume, area and circumference
 - ✓ Ellipse method
 - ✓ Trace (contour) method
 - √ 3 axis method

2D-Mode special measurements:

- · Thyroid gland volume with 3-axis method
- Bladder volume with 3-axis method
- · Differential of the volume Vm
- % Stenosis (diameter or area)
- %FS (LV Fractional Shortening)
- Predicted PSA (pPSA) and density PSDA (with ellipse and axial method)
- Thickness lateral abdominal muscles measurement

All measurements can be stored on the General REPORT page

Obstetrical measurements

- First Trimester assessment and measurements (Early Obstetrics) :
 - ✓ the Nuchal Translucency (NT),
 - ✓ the Nasal Bone (NB),✓ the Facial Angle (FA)

 - Ductus Venosus waveform (DV)
 - Fetal Tricuspid Valve flow (TV).
- Obstetrical generic measurements:
 - ✓ GA and EDD using BPD, CRL, FL, GS, AC, HC (factory preset and a user-modifiable table; the mean of three measurements)
 - ✓ HC/AC, FL/BPD and FL/AC relationships
 - ✓ Foetus weight EFBW (AC /BPD and AC/FL)
 - ✓ GA and EDD based on LMP
 - ✓ NT (Nuchal Translucency), NB (Nasal Bone), YS (Yolk Sac)
 - ✓ Determination of Amniotic Fluid Index AFI

All measurements can be stored on the REPORT pages: OB and First Trimester

18. **Measurement - M Mode**

- HR (Heart Rate) beats/min
- Distances, time, speed
- Dynamic parameters of left ventricle

- diastolic volume EDV
- o systolic volume ESV
- o ejection volume SV
- ejection fraction EF
- cardiac output CO
- Measuring single-dimension parameters
 - o AOD- aortic annulus
 - o LA left atrium
 - o IVS- interventricular septum
 - o RVEDD- right ventricle
 - o DEAmpl- mitral valve leaflets spreading amplitude

All measurements can be stored on the M- REPORT page

19. <u>Measurement – PW Mode</u>

- automatic measures (auto trace) :
 - o PSV (Peak Systolic Velocity)
 - o EDV (End Diastolic Velocity)
 - o TAM (Time Averaged Mean peak velocities)
 - o RI (Resistive Index)
 - o PI (Pulsatility Index)
 - S/D (Peak Systolic to end Diastolic)
 - o Area selection for automatic measurement
- two independent measurements of: velocity (v) and time (t), acceleration (A)
- distance measurement in 2D presentation
- Doppler gradient MaxPG (Maximum Pressure Gradient)
- Doppler gradient MeanPG (Mean Pressure Gradient)
- Mitral valve area MVA
- PI (Pulsatility Index)
- RI (Resistive Index)
- HR (Heart Rate) beats/minute
- A/B Ratio (Velocities Ratio)
- E/A Mitral valve coefficient
- S/D Ratio (Peak Systolic to end Diastolic)
- TV (Tricuspid value) and DV (Ductus venosus) for foetal measurements
- Doppler angle correction after measurement
- All measurements can be stored on the D- REPORT page

Memory

20. <u>Cine memory</u>

- Internal data storage in native format to facilitate review, measurement and manipulation of images recalled from memory
- In 2D and CF/PD mode last 1530 frames
- In M and PW mode up 80 sec (max time is scroll speed dependent)
- CINE review loop
- CINE gauge and cine image number display
- Measurements/calculations and annotations on cine playback
- Clip capture from cine review: the images stored in the cinema memory can be used to create a video file in the .avi format.
- Selectable Cine Sequence for AVI file create

21. <u>Image Storage</u>

- Internal hard drive image storage: ~128 GB -(optional 250 GB or more)
- · Internal storage of single and multi-frame images
- · Patients and study folders
- · Editable .txt file with a description of survey data
- Managing the stored files:
 - o Displaying
 - o Printing
 - o Deleting files
 - Exporting to external memory
 - Importing from external memory
- Thumbnails for archived images.
- · Storage formats:
 - o BMP (24bit) format (~5,9 MB one file).
 - JPG format (~0,2 MB one file).
 - AVI format
 - DCM DICOM format
- Storage devices:
 - Hard drive image storage: ~128 GB (optional 250 GB or more)
 - USB memory stick
 - DVD–R/RW and CD-R/RW drive (optional)

22. <u>DICOM Connectivity (option)</u>

 DICOM (Digital Imaging and Communications in Medicine) is an optional data-transfer feature that allows the SPINEL scanner to connect over a Local Area Network (LAN) to PACs archives, to remote printers and to Worklist servers

- Images in DICOM format can send from SPINEL ultrasound system to selected memory or, using an Ethernet or wirelessly connection, to PACs server or to DICOM printer.
- Service class offered by the interface SPINEL- DICOM (SCU):
 - Verify Communications to ensure that any particular device is properly connected before communication begins
 - Store the SPINEL SCU can send the images to a PACs (Picture Archiving and Communication System) server for review and archival
 - Print sending images to be printed on a DICOM printer
 - *Modality Worklist Management* using the work-list you can import patient data from Hospital Information System.
- The SPINEL scanner provides configuration pages (DICOM Setup) for setting up DICOM devices for network connectivity.

23. <u>Multifrequency probes</u>

- Multi-frequency ultrasound probes from 2 to 15 MHz:
- Scanning depth: 1.5 31 cm (depends on the probe)
- Scanning angle: up to 360° (depends on the probe)
- Linear **LA510** 40mm : 5 MHz to 12 MHz
- Convex CA255 (R60): 2 MHz to 5,0 MHz
- Micro-convex CA409 (R20):4 MHz to 9,5 MHz
- Convex CA305 (R20): 2,5 MHz to 6,0 MHz
- Micro-convex endovaginal CV-580 (R13): 5MHz to 10 MHz
- Anorectal R-510 (360°): 5MHz do 12MHz
- Endorectal bi-plane **2R-575** (90°/120°): 5 MHz to 10 MHz