Ultrasound Bladder Volume Scanner

PINIT

General Specification

June 2017 ***Ver. 3.4.*** */2*

CE 1011

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Software version information

This System Specifications applies to PINIT scanner with software version ≥ ***01.66.***

Select ***Menu -> Info*** for details on what software version is installed on your PINIT scanner.

The Bladder Scanner ***PINIT*** is portable ultrasonic device dedicated for safe and comfortable non-invasive bladder volume contents measurement, as well as, for basic urinary organs and tracts exams and measurement.

1. General properties

- **Two modes** of operation, real-time imaging:
  - Automatic Bladder Volume (BV) measurement mode: - application **Bladder Volume** for ***Male,*** for ***Female,*** and for ***Children***.[1] ; additional BV-***Quick*** mode
  - Application for **2D** presentation mode (B-mode ultrasound)
- Fast and accurate measurements in real-time scanning – (live contour visualization)
- Large measurement range (up 1499 ml)
- Quick Start (about 3 sec) and quick measurement time of approximately 2 seconds
- Ergonomically and lightweight design: compact casing with Color LCD, Touch Screen and built-in Printer
- Friendly and easy-to-use, intuitive operation via **touch screen** – modern and intuitive user interface
- On-screen interface may also be quickly controlled by tapping the screen with the stylus.
- Colour LCD panoramic 16:9 screen, size 7", 800 x 480 pixels
- Monitor brightness adjustment
- Operating frequency: 2.5 - 5.0 MHz
- Internal clock - date and time
- Power Supply from the internal Battery or external Power Adapter
  - quick battery charging – even when device is in operation
  - monitoring the battery charging progress
- The Power Saving system:
  - Automatic shutdown of the scanner when the battery is max. discharged
  - In internal battery mode automatic shutdown of the scanner without using any key (after 3, 5, 10 or 15 minutes - selection in Setup)
  - In external power supply mode automatic shutdown of the scanner after 30 minutes without using any key (possibility turn off this function in Setup)

[1] BV-Child mode applies to children: growth up to 1.30 m; weight 7-30 kg

- Entering patient's data (Name and ID) using on-screen alphanumeric keyboard
- Internal patient's database: data exchange from *PINIT-PC* application (USB memory, USB connection or optional BT connection)
- Entering Operator (User) data using the touch screen keyboard
- Possibility to choose up to 10 different Operators (Users)
- Entering notes, comments, actions, abbreviations etc. after the measurement (optional)
- Possibility of printing the results of volume measurement on the **built-in** Thermal Printer
- Recording of measurement results and ultrasound images in Internal Memory for later review or transfer to PC.
- Possibility of printing on the supplied printer the measurement results of the images from the archive (Internal memory)
- Possibility to export (USB memory, USB connection) measurements and pictures to the PC computer, tablet, notebook etc. with special *PINIT-PC* image management software – (Patients Database and Exams Management)
- Support of multiple languages *(English, Polish, German, Swedish, Norwegian, French, Italian)*
- Trolley with locking wheels for easy mobility (optional):
  - *height : 87÷110 cm (adjust);*
  - *tray 20x28 cm;*
  - *bottom basked for accessories;*
  - *base diam. 52 cm;*
  - *weight 9.5 kg.*
- Easy software update via a USB port
- Possibility of introducing changes according to specific diagnosis requirements .

2. Application Bladder Volume

- Presentation B+ B (Double Scan) for the visualization of transverse and sagittal (longitudinal) bladder planes – in ***BV-Male*** mode, in ***BV-Female*** mode and in ***BV-Children*** mode
- Presentation B (Single Scan) for the visualization of transverse bladder plane – in estimated ***BV-Quick*** mode
- Real-Time Pre-scan (live B-mode visualization)
- High accuracy of Bladder wall recognition and contour technology during the scanning process
- Automatic displaying of the bladder contour on ***the live image*** both in sagittal and transverse bladder plane to reduce user error.
- Automatic displaying of the estimated bladder volume in real time during scanning.

- Dedicated sector probe with automatic change of scanning plane without changing the probe position
- Scanning angle: 120°
- Optimized probe frequency : ***2.7*** MHz (BV Male, BV Female and BV-Quick) / ***5.0*** MHz (BV Child)
- Scanning depth – 0 to 12.. 20 cm (changing automatically)
- Gain control
- Scanning surface selection and Run/Freeze function operated also by using on/off button located on the probe housing (one button operation)
- Graphical help in scan mode
- 4 methods for bladder's volume measurement
- Volume range in Automatic Mode : ***0 - 999*** ml
- Accuracy in Automatic Mode:
    - Absolute averaged error for experienced operator is less than +/- 10 %
    - Maximal measurement error is +/- 15 % , - 20ml, +10ml
- Volume range in Manual mode and Quick mode : ***0 - 1499*** ml
- Accuracy in manual mode and Quick mode:
    - In measuring range 0-999 ml just as in automatic mode
    - In measuring range over 1000 ml : +/- 25 %
- Over-range measuring indication: the sign ">" and changing the colour to red
- Cooperation with urodynamics systems (optional):
    - sending screenshot of measurements of bladder volume by composite video output (PAL B/W 625 lines/50 Hz)
    - sending full 2D- ultrasound images with examination of the urinary organs and tract through the composite video output (PAL B/W 625 lines/50 Hz)
- Two methods of calibration :
    1. ECS method - *the **E**cho-son **C**alibration **S**et model ECS 02 is needed.*
    2. SELF-TEST method - *don`t need any additional equipment (checks the probe, all electronic systems and software algorithms).*

    Note: Optional: Phantom method - the bladder volume phantom is needed: (e.g. Phantom Model 616 /www. fantom.dk / + special adapter ring by Echo-Son)
- Maintenance indicator - reminder of the calibration.(date of the last successful calibration)

  The manufacturer recommends to perform calibration process within 12 months.

3. Application B-mode (General)

- 2D presentation (Scanning angle : 120°)
- Optimized probe frequency : 3,2 MHz
- Scanning depth: 13,16,19, 23 cm
- Frame rate aver.: 15 fr/sec
- Digital Image processing
- Gain control
- Run/Freeze function operated also by the use of one button on the probe

4. Measurements

4.1. Measurement functions in application Bladder Volume:

- PINIT offer ***4 methods*** for bladder volume measurement (**tool4vo**l) :
  - ✓ Automatic bladder volume measurement (for Male/Female by *Double Area Method*; for Children by dedicated *3-axis method*, in Quick mode: *One-plane Area Method*)
  - ✓ Two semi-automatic measurement methods for adult :
    - Free-Hand-Trace of scanned organ
    - Multi-Point , polygon contouring by free hand set points on scanned organ.
  - ✓ Manual 3-axis method: for adult HWL (High-Width-Length) known and used for 35 years in ultrasound scanners; for children special WDH method
- Measuring volume: 0 .. 999 ml in automatic mode and 0 ..1499 ml in manual and quick modes
- Measurement method and selected application are displayed

4.2. Measurement functions in application 2D (General):

- Measuring the distance by two independent pairs of cursors.
- Measurement of the volume and area with ellipsoid method.

5. Displayed information

- Patient Name (i.e. name , surname , age , max. 22 characters)
- Patient ID (max. 22 characters)
- Date and Time
- Operator name
- Application mode

- Range of penetration
- Gain level
- Frequency of probe
- Processing
- Plane markers (transversal , sagittal)
- Battery level
- Measurements results
- Descriptions and comments entered by the operator (option)
- Selected measurement method
- Control menu buttons

6. System setup

- Selection of operator / user - operator name
- Date and time setting
- Brightness setting
- Application choice : BV Male / BV Children /BV Quick / 2D general application
- Selection of menu language
- Setting the auto shutdown in battery and external supply mode
- PINIT setup for urodynamics system output (option)
- Service mode: Info window - displays detailed information on the scanner and system
- Update mode: update procedure is performed trough USB port.

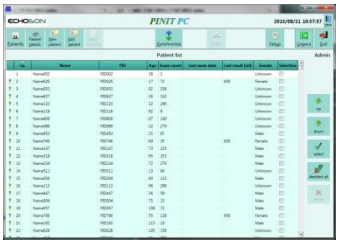
7. Archive

- Build- in thermal printer for printing measurement results in application Bladder Volume
- Printed values : results of measurements, contours of the bladder in two planes ,patient name, operator name, date and time
- Images and measurements can be stored in build-in Internal memory.
- Apart from the image itself archive file contains full information of the measurement, image parameters, patient data etc.
- Internal memory to save images and measurements in all applications
    - Image file : RGB 800 x 480 resolution (up to 8000 images)
    - Possibility to display images from internal memory
    - Possibility to delete selected image in internal memory
    - Possibility to export data from internal to external USB memory to display saved images on any PC computer
    - Possibility to upload images to the PC computer, tablet, notebook etc. with special *PINIT-PC* image management software – (Patients Database and Exams Management)
    - Possibility to print report from saved images on supplied thermal printer
    - Possibility to erase all internal memory

8. PINIT Ultrasound probe

- Dedicated ergonomic handheld sector Probe *S255B*
- Scanning angle: 120°
- Probe operating frequency: 2.5 ..5.0 MHz
- Automatic change of scanning plane without changing the position of the probe
- Probe button: choice of scanning plane and Run/Freeze function
- Displayed messages about probe: *Probe not connected* and *Probe malfunction*

9. *PINIT-PC* Software



- Special PC application under Windows system (compatible with Windows XP , Windows 7, Windows 8, Windows 10), for any PC computer, tablet, notebook etc - (scalable software)
- Simple, ergonomic menus, easy and quick to use.
- Database of patient's support (Name, PID) and measurement documentation (results of measurements, dates of exams, images)
- PINIT to PC synchronization - images and patient data (USB memory, directly USB connecting)
- Preparing special patient database for PINIT scanner
- Searching and managing patient study database
- Preparing and printing on any printer the special report of exams
- Optional - exporting images data via DICOM 3.0 (store, print, worklist)

10. Supply

- PINIT External AC/DC adaptor : input : 100 - 230 V AC /50-60hz/ 0.7A
  output : +12V DC / 2 A
- Internal long-lasting battery: 2600 mAh Lithium-Ion module:
  - recharging using PINIT External AC/DC adaptor
  - working time on batteries ca. 8 hours (typical exams and measurement procedures)
  - amount of a typical exams without printing, per one full battery charging cycle: ca 50; when printing each result - ca 30
  - typical frequency of charging: once per day
  - quick battery charging: fully charged in about 1.5 hour
  - battery charging is possible even when device is in operation
  - monitoring the battery status and charging progress
  - power consumption (battery supply) ~ 12 W

11. Dimensions and weight

- Dimensions (with built-in printer): 290 x 205 x 85 mm
- Weight (with built-in printer): 1.4 kg
- Overall weight (with transport suitcase) : ~ 2.6 kg

12. Environmental conditions:

- Operating Temperature : 10°- 40 °C
- Operating Relative Humidity : 30% - 85%

13. Electrical safety standards:

- Medical device **Class IIa** comply with Medical Device Directive 93/42 EEC
- Scanner complies with requirements for **Class II** devices of EN/IEC 60601-1
- Medical Device Directive 93/42 EEC
- EMC Directive 89/336/EEC
- Electromagnetic Compatibility EMC : EN 60601-1-2-2007; EN 55011_2009+A1:2010; EN61000--3-2-2014; EN61000-3-3-2013
- Electrical Safety EN 60601

14. Approvals :

- CE marking

15. Acoustic safety standards:

- Acoustic safety : EN 60601-2-37 : 2007

  Declaration for ultrasound scanner PINIT::

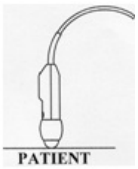
  *In all modes Thermal Index **TI** and Mechanical Index **MI** don't exceed the value 1,0*

- MI $_{maximum}$ = 0,3
- I_{SPTA} ≤ 0,8 mW / cm^2
- I_{SPPA} ≤ 72,7 W / cm^2

  (*by FDA /Track3/ : I_{SPTA} ≤ 720 mW/cm2 , I_{SPPA} ≤ 190 W/cm2 MI ≤ 1.9*)

16. Liquid Ingress Protection

- Scanner, printer, charger : **IPX0** - (ordinary equipment without protection against ingress of water)
- Probe S255B:

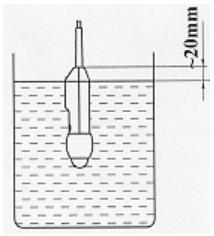


Position 1: Position of the probe during the patient's examination.

IPX3 – *dripping water*

Position 2: Position of the cleaning and disinfection of the probe.

IPX3 – *vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 60° from its normal (vertical) position*



Acceptable level of immersion of the probe in the liquid disinfection: