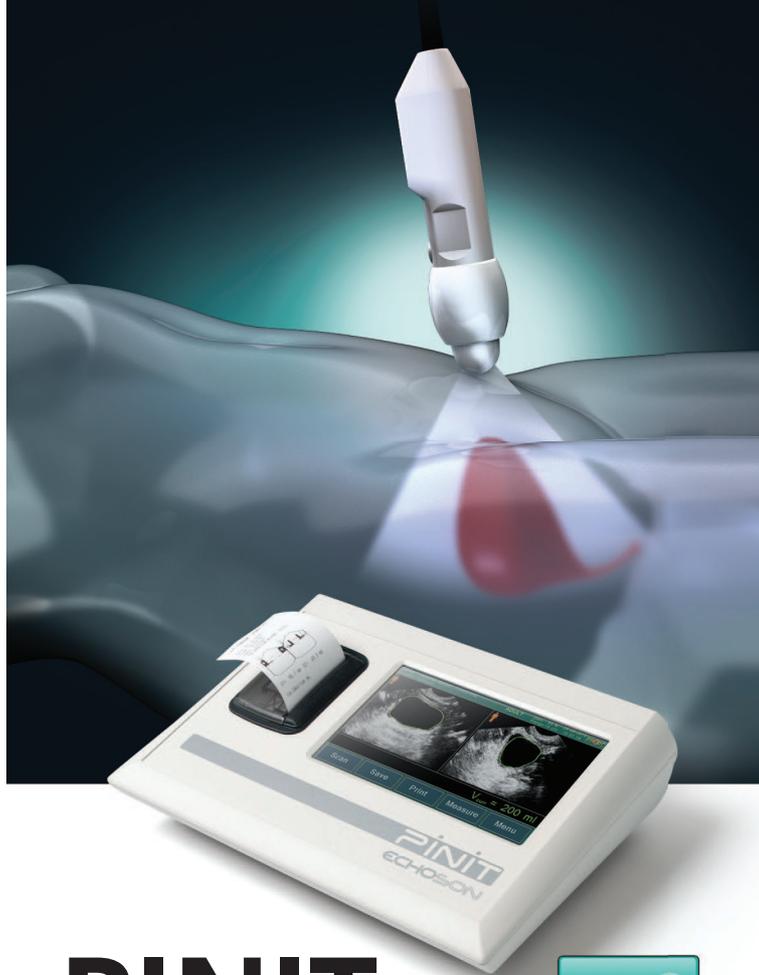SINCE 1993

ECHOSON
ULTRASOUND SCANNERS

PINIT
BLADDER SCANNER

TOUCH SCREEN

echoson.eu

The Bladder Scanner PINIT is portable ultrasonic device dedicated to quick and noninvasive urinary bladder volume measurement, very easy to operate by trained me...

Most common medical fields:
▶ Catheterization Management
▶ Urinary incontinence (PVR)
▶ Uroflowmetry (urodynamics) support
▶ Urinary Retention: Post Operative (POUR), Acute (AUR), Chronic (CUR)
▶ Urinary tract infections

Advantages:
▶ Minimizes needless catheterization
▶ Reduces incidence of urinary tract infection (UTI)
▶ Helps in caring and managing urinary incontinence
▶ Minimizes patients pain and discomfort
▶ Enables wide-range diagnose and anatomic measurements of urinary organs and tracts and prostate.

▶ Dimensions (with built-in printer): 290 x 205 x 85 mm
▶ Weight (with built-in printer): 1.4 kg

Volumetric Professional Tool (tool4vol):
▶ Easy and friendly user interface via 7" touch-screen
▶ Operating frequency: 2.5–5.0 MHz
▶ 3D Echo-Son technology
▶ Quick start-up (ca. 3 sec) and short scan time (ca. 2 sec.)
▶ Measurement range up 1499 ml, error <10%.
▶ Applications: male, female, children
▶ Three modes: Quick estimation, Automatic BV, Manual (3 algorithms) - for difficult cases

▶ Built-in thermal printer
▶ Battery and mains operations
▶ Internal memory/disk for save and retrieve measurement results
▶ Easy data transfers to the PC
▶ Ready for use in carrying case - optional trolley

Diagnostic B-mode (2D)
▶ B–mode visualization, scanning angle 120°, depth 13–23 cm
▶ Optimized probe operating frequency: 3.2 MHz
▶ Distances, volume and area measurement (ellipse method)
▶ Applications: visualization of urinary organs and prostate

More features and parameters: **www.echoson.eu**

ECHOSON

MADE IN POLAND

11.Komplektacija:

$C \epsilon$ 1011
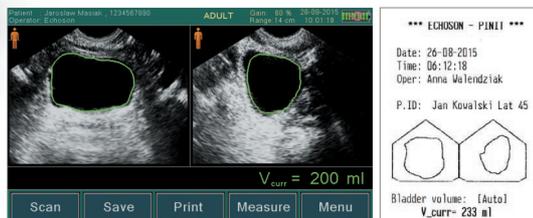
ECHOSON

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✉ **export@echoson.eu**

🖱 **www.echoson.eu**

European Funds
Smart Growth

Polska

European Union
European Regional
Development Fund

- 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)

- Entering patient's data (Name and ID) using on-screen alphanumeric keyboard

- Possibility of connecting an external alphanumeric keyboard

- Support for an external barcode reader

- 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);*   ←   **11.Komplektacija:**
  - *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

- Two automatic **BV** modes : **QUICK** for estimating volume and **AUTO** for measurement volume.

- Additional semi-automatic methods: multi-point, continuous outline, 3-axis method HWL

- 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

- Special algorithm switching off the automatic bladder edge detection in the absence of contact the probe with the body

- 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.. 23 cm (changing automatically)

6.Automatinis skenavimo gylio pasirinkimas

- 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 B 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 Echo-son Calibration Set 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)

- B-mode 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 (**tool4vol**) :
    - ✓ Automatic bladder volume measurement based on Echo-Son 3D technology (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
- Display maximum result of the volume measurement

9.Tūrio matavimo diapazonas

- 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

  7.Tyrimų rezultatų išsaugojimas

  - 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

  10.Daviklio parametrai:

- Automatic change of scanning plane without changing the position of the probe (based on Echo-Son 3D technology)
- 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 external 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 to PACS/RIS systems 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

  > 2.Maitinimo šaltiniai

- 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 Conditions :
- Temperature : +10°- +40 °C
- Relative humidity :   30% - 85% non condensing
- Atmospheric pressure range: 700 - 1060 hPa

Storage Conditions (limitations due to LI-Ion battery parameters):
- Temperature : 0°- +40 °C
- Relative Humidity :   10% - 90%

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*)
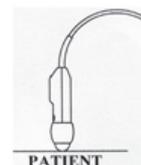
16. Liquid Ingress Protection

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

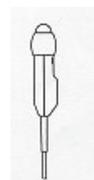 Position 1: Position of the probe during the patient's examination.

  IPX3 – *dripping water*

  10.Daviklio parametrai:

  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: