Astrasono

A3Pro

Product Manual

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Contact Information

To obtain additional information regarding Astrasono
A3Pro Bladder Scanner, contact Astrasono technology co., ltd..

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Information in this manual may change at any time without notice.

Product Summary Description

A3Pro is a portable bladder scanner produced by Astrasono technology co., ltd. (hereinafter called "Astrasono"), which is used for medical clinical non-invasive measurement of bladder volume of the patients (not applicable to pediatric patients). It is the B-mode pulse echo ultrasound equipment. A three-dimensional mechanical sector scanning probe was used to scan the bladder, and follow the principle of ultrasound imaging to measure bladder volume from the abdomen surface. This device can only be used by trained professional medical staff.

This device consists of a console(including a rechargeable Li-ion battery pack and built-in printer), a probe, and a medical switching power supply.

The console showcases critical information such as ultrasonic images, bladder volume values, and offers the majority of the control. The lithium-ion battery pack is accountable for the power supply and can be charged via the console when a supply mains is connected using a medical switching power supply. The built-in printer can print bladder scan reports and self-test reports. The probe is utilized to scan the patient bladder.

tatement of Intended Use

A3Pro is used for medical clinical non-invasive measurement of bladder volume of the patients (not applicable to pediatric patients).

Notice to All Users

A3Pro can only be used by trained professional medical staff. Users should read this entire manual before using the device. Do not attempt to operate the device until you thoroughly understand all instructions and procedures in this manual.

Environmental Condition

1. Environments of intended use

Use	Professional medical environments
Ambient temperature	10°C to 40°C (50°F to 104°F)
Humidity	20%RH to 75%RH
Atmospheric pressure	700hPa to 1060hPa

2. Environments of storage and transportation

Ambient temperature	-20°C to 55°C (-4°F to 131°F)
Humidity	15%RH to 85%RH
Atmospheric pressure	600hPa to 1060hPa

The packaging box of this device is equipped with simple shock absorption measures, suitable for aviation, railway, highway, and ship transportation.
Avoid rain and snow splashing, inversion, and mechanical collision. It should not be mixed with corrosive substances for loading or transportation.
When the storage period of the equipment is more than 6 months, the equipment should be taken out of the packaging box, and after 4 hours of charging, the equipment is packed into the box according to the direction shown on the package and placed in the warehouse.
Equipment should not be placed close to the ground, walls, or roof. Indoor ventilation should be good, avoiding strong sunlight and corrosive gas erosion.

Applicable Scope

Patients who require bladder volume measurement.

Contraindications

A3Pro is not intended for fetal use or for use on fetal patients, pediatric patients, pregnant patients, patients with open skin or wounds in the suprapubic region, or patients with ascites.It is not advisable to measure when inserting a catheter into the patient's bladder.

FCC Regulatory Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.
This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

Ultrasound Energy Safety

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used prudently, and total patient exposure should be kept as low as

reasonably achievable (ALARA). Following the ALARA principle, ultrasound should only be used by medical professionals when clinically indicated, using the lowest possible exposure times necessary to obtain clinically useful information. For more information on ALARA, refer to the American Institute of Ultrasound in Medicine publication, Medical Ultrasound Safety.
The ultrasound output power of A3Pro is not user adjustable and is limited to the minimum level necessary for effective performance.

HIPAA Privacy

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) regulations require our customers to monitor and limit the ways in which patients’ confidential information is accessed, used, stored, transmitted, and disposed of. Our customers are ultimately responsible for ensuring all electronic health information contained within A3Pro is protected. In the course of providing services to customers, Astrasono will remove any electronic protected health information from A3Pro, if such information is still present.

Technical Specifications

Power supply:	Medical Switching Power Supply Model: LXCP62(11)-143 Input: AC 100-240V,50/60Hz.1.5A Max Output: DC 14.3V.4.2A DC 10.95V,6800mAh Rechargeable Li-ion Battery Pack
Operation Frequency:	2402MHz to 2480 MHz
Bluetooth Version:	V 5.1
Modulation Type:	GFSK
Number of Channels:	40
Channel Spacing:	2MHz
Antenna Type:	Chip Antenna
Antenna Gain:	1.72dBi
Sample Type:	Portable device
Hardware Version:	X1
software version:	V1.0
Wireless function:	Transmission the device data from transmission terminal equipment to receiving terminal equipment, as well as ensuring integrity and security of data during transmission.
Wireless QoS:	Latency<2s, Packet Error Rate<2%, Throughput<800bps
Test Software:	HLK-B40
Test Software version:	V1.1.8

Battery	Lithium battery10.95V,6800mAh
Battery Life	6 years
Waterproof Rating	IPX3
Classification	Type BF equipment, Continuous operation
The applied parts	Probe
Communication:	Wireless 2.4GHz (BLE mode)
Transmission Range:	Up to 10 meters
Data Save:	sd in Device

Measure Bladder Volume

Place the Probe on Patient

1. Have the patient lie down flat. Stand or sit at the patient's right side. 2. Place an ample quantity of gel on the probe; Make sure the probe button is facing the patient's head directly.3. Place the probe onto patient's abdomen, approximately 1.2 inches above his pubic bone. 4. Position the probe at the center of the patient, using left and right as reference directions.

Finding the best bladder position in Empower Mode.

5. Press the scanning button to start searching for the optimal bladder position.
6. Observe the position projected on the screen and make small adjustments to the probe's position until the projection is centered on the crosshair.
7. When the projection is centered on the crosshair, firmly press the probe against the patient's abdomen. Getting ready for the 3D scanning for the bladder.
8. Press the scanning button again; meanwhile, hold the probe steady until it completes scanning the 12 slices (total 5 seconds).

Accuracy Check

After scanning, check if the final projection position is centered on the crosshair. If it's significantly off-center, scan again. Take the maximum value from multiple scans.

Clearning

Use the following procedure to clean the probe front casing of A3Pro. Ensure that the power is turned off for cleaning.

1. Put on new gloves.
2. After every exam, using a dry lint-free soft cloth, wipe any ultrasound gel completely off the probe front casing. Wipe 3 to 5 times, each time with a new lint-free soft cloth.
3. Use a lint-free soft cloth dipped in purified water to wipe off any residual particles or liquids on

the probe front casing. Wipe 3 to 5 times, each time with a new lint-free soft cloth.

4. Visually inspect the probe front casing for contamination, paying particular attention to the outer surface and seams. If the probe front casing is visually contaminated, repeat the above steps until no contamination remains.
5. Allow the probe front casing to air dry or towel dry with a clean dry lint-free soft cloth before disinfection.
6. Continue to the following section, ***Disinfecting***. Intermediate-level disinfection of the probe front casing is required between uses.

Disinfecting

Intermediate-level disinfection of the probe front casing is required between uses. Only use disinfectants prior to their expiration date.

1. Remove the gloves used in the ***cleaning*** procedure, and then put on new gloves.
2. Use a lint-free soft cloth dipped in 70%~75% alcohol disinfectant to wipe the surface of the probe front casing, keeping it moist for no less than 5 minutes. If using alcohol disinfectant wipes, follow the manufacturer's instructions.
3. Use a lint-free soft cloth dipped in purified water to wipe off any residual disinfectant on the probe front casing. Wipe 1 to 3 times, each time with a new lint-free soft cloth.
4. Allow the probe front casing to air dry or towel dry with a clean dry lint-free soft cloth.

Warranty

1. From the date of purchase, A3Pro is entitled to a 2-year free warranty service with the invoice.
2. Our company will not provide free warranty services for malfunctions caused by personal reasons of the users, including but not limited to:

(1) Failures arising from unauthorized disassembly or modification of the product;

(2) Failures due to accidental drops during usage and handling;

(3) Failures stemming from inadequate maintenance;

(4) Failures caused by improper operation contrary to the instructions provided in the user manual;

(5) Failures resulting from repairs conducted at non-authorized repair stations by Astrasono, among others.

3. Maintenance services that fall outside the warranty coverage are subject to fees.
4. For any inquiries regarding warranty service, please contact your supplier.

5. During warranty service, if necessary, we may request qualified technical personnel designated by our company to provide circuit diagrams and information on repairable components for the product.

6. We guarantee that replacement parts will be available for seven years following discontinuation of the product.

7. To find out the production date, please refer to either the device itself or its packaging.

8. If needed, you can reach out via Astrasono's after-sales service call.

Appendix A Electromagnetic Compatibility

A3Pro was tested according to the recommendations of lEC 60601-1-2: 2014 /AMD1: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
A3Pro was tested according to the recommendations of lEC TS 60601-4-2: 2024 Medical electrical equipment - Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

 **warning**	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 **warning**	Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) may not be used within 30 cm (12 inches) of any part of A3Pro, including cables provided by Astrasono. If this distance is not maintained, performance of the system may be degraded and image display may be compromised.

 **warning**	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The essential performance of A3Pro is to produce ultrasonic output energy, display ultrasonic images, and display numerical values for bladder volume.

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1

RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz

Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m
Immunity to proximity magnetic fields in the frequency range IEC 61000-4-39	Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56	See table 11 of standard Any one of its nominal input voltages and frequencies

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Table 5

EMC Standards for Accessories

No.	Accessory	Length(m)	Shielded	Remarks
1	Probe cable	2	Yes	Console to paitent
2	Power cord	1.5	No	Supply mains to medical switching power supply
3	Medical switching power supply cable	1.5	No	Medical switching power supply to console

Appendix B Acoustic Output Reporting

The data in each column corresponds to the highest measured global maximum value* for each of the parameters in the column title (MI, $I_{spta.3}$, $I_{sppa.3}$), measured for three probes.

Table 1

TRACK 3 SUMMARY					
System: A3Pro					
Transducer Model	$I_{SPTA.3}$ (mW/cm^2)	TI Type	TI Value	MI	$I_{PA.3}@MI_{max}$ (W/cm^2)
S9	7.19-7.96	TIS	0.0127-0.0128	0.309-0.333	16.78-18.67
		TIB	0.0127-0.0128		

*MI and TI values are both below 1.0.