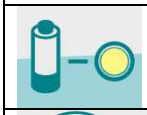
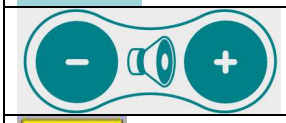
Microflow-S

User's Documentation

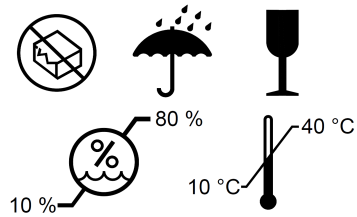
This document contains all information on the **Atys MICROFLOW S** devices manufactured by Atys.
Information in this document is subject to change without notice and does not represent a commitment on the part of Atys.
Atys does not assume liability for damages that may occur because of the use of the information in this manual.

1 Symbols

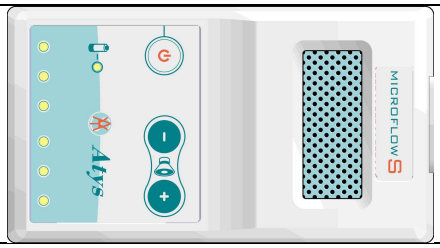
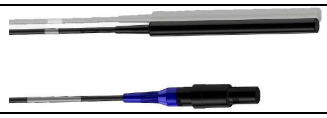
1.1 Device

	DEEE Directive 2012/19/UE General medical device Directive 93/42/EEC	Separate collection for Electrical Electronic Equipment CE mark with number of the Notified body
	ISO7000-434 IEC60417-5077	Consult accompanying documents. HEADPHONES
	IEC60417-5333 IEC60417-5134 IEC60417-5109	Applied part type BF ESD sensible Not for home use
	ISO7000-2498 ISO7000-2493 EN980	Serial number Catalogue reference number Manufacturer
	ISO 7000-2497 ISO7010-M002	Follow operating instructions With manufacturing year
	IEC60417-5009	Stand by
	Battery level. Blink when low.	
	Sound volume adjust	
	IEC60417-5134	Electrostatic sensitive device

1.2 Packaging

	ISO7000-626 ISO7000-2606 ISO7000-621 ISO7000-2620 ISO7000-632	Keep dry Do not use if package is damaged Fragile Limitation of relative humidity Limitation of temperature

2 Models & accessories

08 540 Module MICROFLOW S	
Detachable component and applied part: **13 496 CWD 4MHz non preamplied probe L1.0m Medisnap6**	
Detachable component and applied part: **13 503 CWD 8MHz non preamplied probe L1.0m Medisnap6**	

3 Application specification

3.1 Intended medical indication

The MICROFLOW S is intended for detection of blood flow in veins and arteries and as an aid for the diagnosis of peripheral arterial disease and venous insufficiency.

3.2 Intended patient population

Adult only.

3.3 Intended part of the body or type of tissue applied to or interacted with.

The detachable parts of the MICROFLOW S are applied on the patient's skin mainly of the limbs, fingers, toes and neck.

3.4 Intended user profile

The device must be used by or on the order of physician

3.5 Intended conditions of use

The device shall be used in the specified environmental operating conditions

3.6 Expected service life

½ hour per day
200 days/year during 5 years
½ year for probes

3.7 Contact duration on applied parts and accessible parts

Probe's active surface.
Contact time on the applied part on the same body place: less than 1mn.

3.8 Contraindication

Never use the probe on skin surfaces with recent wounds/operative cuts.
Never allow the transducer to come in contact with body fluid
It is not intended for foetal use
It not intended for use around eyes

3.9 Essential performance

Main performances are:

- Doppler sound
- Detection of flow/backflow for peripheral arteries using LED's.

Loss or alteration of performance for these 2 items cannot result in injury.
Then there is no essential performance for this device documentation

4 CAUTION

4.1 Operator

	The **MICROFLOW S** must be used by or on the order of physician.
	Cleaning and disinfection procedure must be applied between patients.
	The **MICROFLOW S** shall be used by trained people.
	**MICROFLOW S** is not intended to replace other means of evaluating vital patient physiological processes.

4.2 Storage environment

	**Climatic environment**: storage: 10-40°C, 10-80% Hr.700-1060 Hpa For transport and storage, the device must be placed in its original packing. Cautions to be applied for the transport and the storage are labeled on the box.
	If you do not have the original packing materials, please contact your Atys dealer. Do not use the **MICROFLOW S** if the packing of the device or of the probe is damaged.
	The **MICROFLOW S** must be stored and moved in its box. The complementary protective packing must be used in the case of a dispatch.

4.3 Operating environment

	**Climatic environment**: operating: 15-25°C, 10-80% Hr, 700-1060 Hpa Do not use the device outside the specified environment. To prevent fire and electrical hazards, keep the **MICROFLOW S** out of rain, water and humidity. If the system does come in contact with liquid, shut the system down and contact your Atys service representative.
	The **MICROFLOW S** shall not be used at home environment
	The **MICROFLOW S** must not be used outside the specified environment.

4.4 Electrical safety

	Before use, control the sensor and its cable for visible damages. Never use the sensor if cracks or other damages are visible.
	Use only the battery supplied by Atys. To change the battery, follow instructions delivered into user documentation. In case of no use of the device for some time, remove the battery to prevent battery leakage.
	Do not use after fulid insertion
	Use only the probes supplied by Atys

4.5 Maintenance and service

⚠	In case of breakdown of the **MICROFLOW S**, please contact your Atys dealer.
⚠	The **MICROFLOW S** performs properly only when operated and maintained as specified in this manual. It is the responsibility of the operator to use the MICROFLOW S in accordance with the user's documentation, the warnings and the labels.

⚠	If the **MICROFLOW S** is found defective, it should not be used. The MICROFLOW S should not be used if any parts are missing or are damaged. Parts that are visibly broken, worn out, warped or contaminated must be replaced.
⚠	No components should be replaced with parts from any other manufacturer. If the customer suspects a part may be defective, it is the customer's responsibility to contact Atys or Atys representative. The **MICROFLOW S** should only be repaired by technicians authorized by Atys.
⚠	No modification of this equipment is allowed

4.6 Ultrasound field

⚠	**Contraindication**: to be used by trained people, not use on ophthalmic, fetal application and fetal monitoring.
⚠	The operator should limit the length of the Doppler tests to the time required for diagnostic purpose to minimize his/her exposure to ultrasound and as well the patient's.

4.7 Environmental protection

⚠	Do not dispose the **MICROFLOW S** and its accessories in rubbish bins. They can be partially recovered and re-used.

4.8 Electromagnetic compatibility

⚠	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.
⚠	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 device shall not be used in home environment **NOTE** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
⚠	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **Microflow-S**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
⚠	The **Microflow-S** emits electromagnetic perturbations in ultrasound probe working frequencies, fundamental and third harmonics. The effects result from the high voltage and high frequency emission pulses. These perturbations do not allow to be compliant to the B class in every configuration

5 Standard and regulation

5.1 Quality management

The product is designed produced and serviced in compliance with ISO13485 requirements.

5.2 Regulation

EC: Class IIa
CE 0459

The package must be wasted according the national regulations.
The device must be wasted according the national regulations.

⚠ Do not waste the MICROFLOW-S and its accessories. They can be partially recover and re-used.

5.3 Safety and performance

The device is compliant with IEC60601-1 2005/A1:2012 international standard of safety.
Safety class:

- Class Internally powered
- Applied parts: Doppler probes are BF type.

Mechanical protection index: IP20.
Water leak tightness height of the Doppler probes: 20 mm.

5.4 Ultrasound

Devices are compliant with IEC60601-2-37.
Ultrasound data on probes, TIB and TIS not require to be displayed. (Below the limit)

5.5 Usability

The usability is processed in compliance with IEC60601-1-6

5.6 Risk management

The risk management is processed in compliance with ISO14971

5.7 Electromagnetic compatibility

The **Microflow-S** has been designed to work normally in conditions specified by the international standard IEC60601-1-2: 2014
Information 1
Refer to the essential performance on this document.

Information relative to the A class limitation
The **MICROFLOW S** emits electro-magnetic perturbations in ultrasound probe working frequencies, fundamental and third harmonics.
The effects result from the high voltage and high frequency emission pulses.
These perturbations do not allow to be compliant to the B class in every configuration

Table 1

Manufacturer's Declaration – Electromagnetic Emissions (IEC60601-1-2)		
The **Microflow-S** is suitable for use in the specified electromagnetic environment. The customer and/or user should assure that it is used in an electromagnetic environment as described below;		
Emission Test	**Compliance**	**Compliance Electromagnetic Environment**
RF emission CISPR 11	Group 1	The **Microflow-S** must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

Emissions RF CISPR 11	Class A	The emissions characteristics of **Microflow-S** make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential **Microflow-S** might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting this equipment.

Table 2

Manufacturer's Declaration **–** Electromagnetic Immunity (IEC60601-1-2)			
The **Microflow-S** is suitable for use in the specified electromagnetic environment. The customer and/or user should assure that it is used in an electromagnetic environment as described below;			
Immunity Test	**Test Level IEC 60601-1-2**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV ± 4 kV ± 8 kV ± 15kV air	± 8 kV contact ± 2 kV ± 4 kV ± 8 kV ± 15kV air	Floor should be antistatic, wool. If floor are covered with synthetic materials, the relative humidity should be minimum at least 35%.

Table 3

Manufacturer's Declaration - Electromagnetic immunity			
The **Microflow-S** is suitable for use in the specified electromagnetic environment. The customer and/or user should assure that it is used in an electromagnetic environment as described below;			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.5 GHz	3 V/m 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Microflow-S** including cables, than the recommended separation distance of 30cm or 12 inches.
Note 1: 80 MHz to 2.7GHz, the higher frequency range applies. Note2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Microflow-S** is used exceeds the applicable RF compliance level above, the **Microflow-S** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Microflow-S**. Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m			

6 Environmental data

6.1 Battery

Battery type: 9 V alkaline - 6LR61 or PP3 not rechargeable
Battery life: 5h charge.

6.2 Physical specifications

Casing Width = 80 mm
Depth = 150 mm
Height = 40 mm
Weight 200 g to 300g with battery and probe

6.3 Doppler sound output

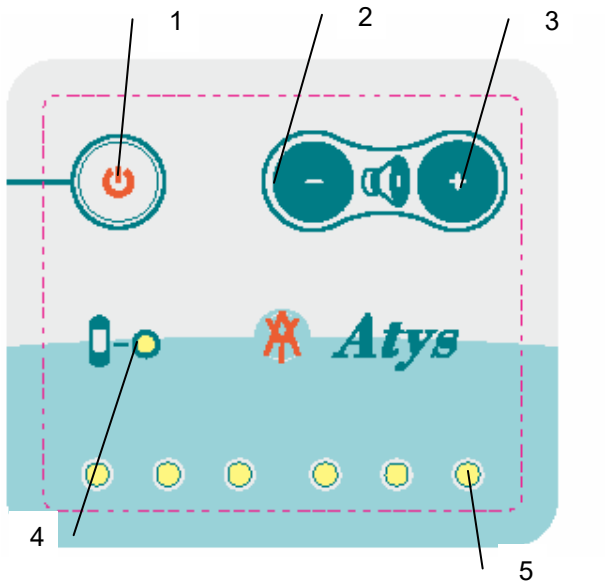
Outpour power: 500mW RMS

7 Operating

7.1 Theory of operation

The 4 MHz and 8 MHz transducers are used to examine the arteries and veins of the upper and lower limbs as well as to examine the vessels supplying the brain, enabling vascular disease to be evaluated quickly and easily.
The Doppler principle is used routinely to transcutaneously detect the motion of red blood cells. The probe is placed against the skin nearest to the target vessel.
One crystal emits 4 or 8 MHz frequency. When sound waves strike the moving blood cells, parts of them are reflected towards the transducer. The reflected signal has a different frequency than the emitted signal. This frequency difference is known as the Doppler shift. It is proportional to the blood velocity.
The equipment amplifies the frequency change and channels it to the speaker.
It also calculates the frequency shift and displays it on 6 LEDs, 3 red l LEDs for the flow and 3 blue LEDs for the backflow.

7.2 Device description



1: Power on/off button. Auto power off after 5mn without signal
2: Volume down button
3: Volume up button
4: Yellow LED.
- Lights continuously when the battery is operational
- Flashes if the battery is low.

5: Three red LEDs indicate flow towards the transducer and three blue LEDs flow away from it.
The number of lightning LEDs is related to the flow intensity.

Since the device is bi-directional, the red and blue LEDs might light simultaneously. This would indicate that an artery and a vein have been located at the same time.
The seven LEDs light up during 1 second when the device is switched on.

The probe is used with a gel for ultrasound.

7.3 CLEANING

Casing cleaning: The panels of the device can be cleaned with a soft cloth dampened with alcohol.

⚠	Always turn off the system before cleaning the machine. Otherwise, electric chock may result. Do not place fluid on or near the system. Make sure that the cloth is damp but not saturated, as you should avoid introducing fluids into areas of electrical components

Probe cleaning: The probes must be cleaned after each use with a usual mild disinfectant solution.
As the probe comes in contact only with intact skin, the risk of infection is low; so the probe and the probe casing need only to be cleaned and low-level disinfected between patients.

⚠	Never place the probe over open wounds or allow it to encounter body fluid.
⚠	Be very careful for the cleaning of the probe. It must be handled carefully. Never bend or pull the cable.
⚠	Use only hospital approved cleaning agents (for example 70-90% isopropyl alcohol) to clean the probe and probe casing after each use and wipe dry immediately.

	Do not immerse the probe casing. Do not clean the probe with acetone, ethyl alcohol or sodium hypochlorite (bleach) as this will damage the surface Avoid any cleaner that may scratch or dissolve plastic surface

High level disinfection using liquid agent.
The probes can be sterilised with peracetic acid solution (for example Anioxyde).
Soaking duration: 20 min
Leak tight length of the probes: 20 mm

After cleaning
The proper state of the probe must be checked after sterilisation: a visual checking of the extremity of the probe must be performed. There must not be any cracks or upheaval.

7.4 BATTERY REPLACEMENT

The battery should be replaced as soon as the yellow LED flashes
Respect the battery type: 9 V alkaline - 6LR61 or PP3
Be careful about the polarity when replacing the battery.

8 Service

8.1 Microflow S spare parts

Order number	designation
04 739	Loud speaker
04 753	Microflow grid
08 470	Casing
08 512	Electronic board

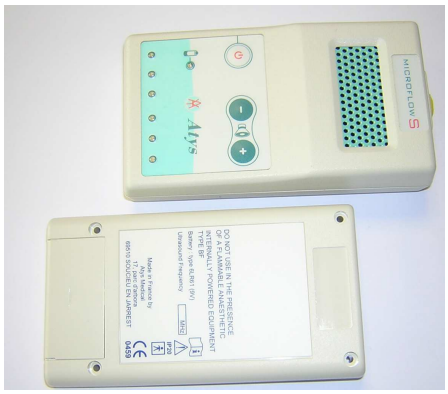
Order number	designation
11 830	Microflow S: keyboard
11 837	Labels
04 746	Plastic box

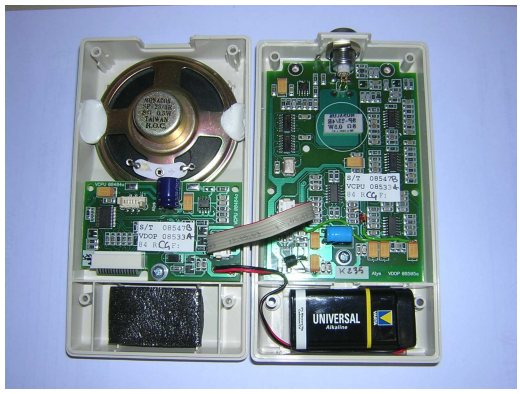
8.2 Probe warranty

The pencil probes are warranted for six (6) months against manufacturing defect.

Limitation of the duration of the probe warranty in the case of liquid sterilisation
The warranty of the pencil probes is limited to 50 sterilisation periods of 20 min each.

8.3 Assembly

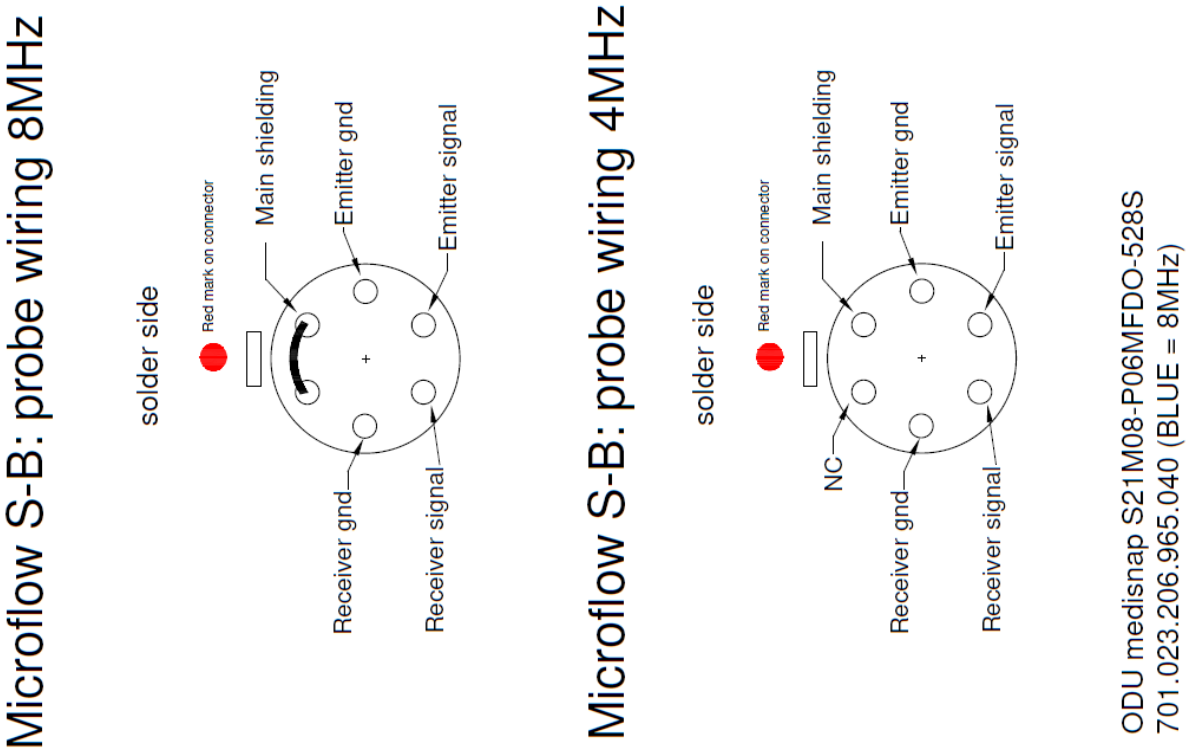




8.4 Test

- Connect a new battery.
- Switch on the unit: all the leds must switch on and then off.
- Activate the probe: a clear sound should be eared.
- Keyboard: does the sound volume control work?
- Switch off the unit.

8.5 Probe connector wiring



9 Document revision history

Reference: 20 174 C MICROFLOW S User's documentation
March, 2017

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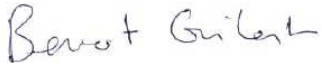
Change #	R.	date	Description
04 272	A	March 16, 2012	Initial release
05 371	B	January, 2017	Phase 401 revision
05 518	C	March, 2017	Accessories reference update
Issued by	Benoît Guibert		
Approval	Christine Turlat		

DECLARATION OF CONFORMITY / *DECLARATION DE CONFORMITE*
Directive 93/42/EEC / *Directive 93/42/CEE*

Manufacturer's Name: *Nom du fabricant :*	**Atys**
Manufacturer address: *Adresse du fabricant :*	**17 Parc d'Arbora** **69510 SOUCIEU EN JARREST, FRANCE**
Product name: *Nom du produit :*	**Microflow-S**
Model name: *Nom du modèle :*	**Microflow-S**
Product category: *Catégorie du produit :*	**Electromedical devices** **Doppler non-imaging ultrasound systems for blood flow measurement, associated probes** *Dispositifs électro médicaux* *Systèmes Doppler à ultrasons sans imagerie pour la mesure des flux sanguins, sondes associées associés*
Classification (per Annex IX): *Classification (Annexe IX) :*	**Class IIa**
Conformity Route: *Annexe :*	**Annex II section 3** *Annexe II point 3*

We herewith declare that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for the Medical devices. All supporting documentation is retained under the premises of Atys, 69510 Soucieu en Jarrest, FRANCE.
Nous certifions que le produit mentionné ci-dessus est conforme aux exigences de l'annexe II point 3 de la Directive 93/42/CEE pour les dispositifs médicaux. Atys tient un dossier technique à la disposition des Autorités compétentes.

Notified Body: *Organisme notifié* :	**LNE** **1, rue Gaston Boissier** **75724 PARIS cedex 15, FRANCE** **ID#0459**
EC certificate: *Certificat CE :*	**7761**
Date:	
Signature:	_____ **Benoît Guibert** **Quality Manager** / *Responsable qualité*