# 14168 G SysToe, user's manual

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CE
0459

# SysToe

## User's manual

## April 27, 2012

14 168 *Rev.G*

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**Contents**

# 1 Read first

## 1.1 Operator

The SysToe performs properly only when operated and maintained as specified in this manual.
It is the responsibility of the operator to use the SysToe in accordance with the user's manual, the warnings and the labels.

The SysToe must be used by or on the order of physician.

## 1.2 Storage environment

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.
Storage: 10-40°C, 10-80% Hr.

If you do not have the original packing materials, please contact your Atys' dealer.
Do not use the SysToe if the packing is damaged

## 1.3 Operating environment

Climatic environment

Do not use the device outside the specified environment.
To prevent fire and electrical hazards, keep the SysToe 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.
Operating: 15-25°C, 10-80% Hr.

Power supply
Universal medical grade AC-DC converter, class II, 9Vdc.

Use only the power supply supplied by Atys.

Electro-magnetic compatibility (EMC)

For best product performance and measurement accuracy, use only accessories supplied by Atys. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the SysToe.

The SysToe shall not be used in home environment

## 1.4 Maintenance and service

The SysToe performs properly only when operated and maintained as specified in this manual.
It is the responsibility of the operator to use the SysToe in accordance with the user's manual, the warnings and the labels.

If the SysToe is found defective, it should not be used. The SysToe 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 SysToe should only be repaired by technicians authorized by Atys.

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 SysToe should only be repaired by technicians authorized by Atys.

No modification of this equipment is allowed

## 1.5 Safety requirements for PC-USB connection

Commercial associated computer shall be in compliance with IEC60601-1 or with the standards applicable to the PC.
In the case where it is not in compliance with IEC60601-1,
the computer:
-- shall be placed outside the patient area,
- leakage current must be verified for the whole system following IEC 60601-1 standard.

To be outside the patient area, minimum distances of 1.5 m to the side, 2.5 m above (IEC countries) or 1.83 m to the side and 2.29 m above (UL countries) are required.

## 1.6 Sensor and cuffs

Never use the sensor or the cuffs on skin surfaces with recent wounds/operative cuts. Never allow the transducer to come in contact with body fluid.

The sensor and cuffs must be disinfected between patients in order to prevent cross contamination.
Use all cleaning and disinfection procedures applicable to your institution.

The sensor and cuffs are fragile.
Be very careful during their use and cleaning.

## 1.7 Electrical safety

To avoid the risk of electrical shock, do not remove the covers of the charger.

To avoid the risk of electrical shock, contact a qualified service representative for service.

Before use, control the sensor and its cable for visible damages. Never use the sensor if cracks or other damages are visible.

Disconnection from the main supply: disconnect the 2 poles simultaneously: unplug the charger.
Do not position device so that it is difficult to disconnect from the mains.

In case of breakdown of the SysToe, please contact your Atys dealer.

## 1.8 Environmental protection

Do not wasp the SysToe and its accessories. They can be partially recovered and re-used.
The wasting of the package and the SysToe must be performed according the national regulations.

# 2 Intended use

The **SysToe** is designed to measure the toe or the digit systolic pressure in a non-invasively way in order to assess peripheral vascular disease. The **SysToe** must be used in hospitals, physician office or medical facilities.

# 3 Principle of operation

## 3.1 Introduction

The **SysToe** inflates the occlusion cuff up to the preset occlusion pressure. Then, it deflates the occlusion cuff slowly until the pressure in the cuff reaches 10 mmHg.
The pressure in the cuff and the PPG (Photo PlethysmoGraphy) signal are recorded during deflation. The pressure at the time of resumption of arterial inflow is the systolic pressure.
Resumption of arterial inflow is detected by the PPG sensor.

## 3.2 Photo plethysmography (PPG) sensor

The PPG sensor is composed of an emitter and a photodetector (Infrared).

The interaction of light with biological tissue is complex and includes the optical processes of multiple scattering, absorption, reflection, transmission and fluorescence.
Light received by the photodetector is affected by the blood volume, blood vessel wall movement and the orientation of red blood cells (RBC).

The pulsatile component of the PPG waveform ('AC' component) has its fundamental frequency depending on heart rate.
This AC component is superimposed onto a large quasi-continuous component ('DC' component) that relates to the tissues and to the average blood volume. This DC component varies slowly due to respiration, vasomotor activity and vasoconstrictor waves, Traube Hering Mayer (THM) waves and thermoregulation.

# 4 Main features

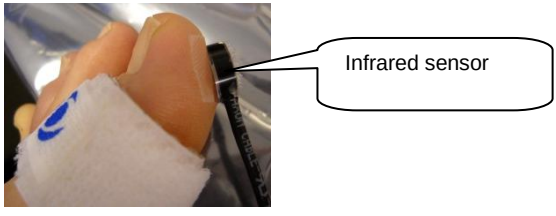
The **SysToe** is a portable, lightweight instrument which measures the systolic pressure in the digit in a non-invasive way.

The principal features of the **SysToe** are the followings:

- Automatic inflation and deflation the cuffs.
- Display the PPG sensor signal and the systolic pressure (SYS) in the toe or digit.
- Display the TBI (Toe Brachial Index or Finger Brachial Index) once the user inputs the systolic brachial pressure.
- Can store up to 32 examinations.
- Enables data to be transmitted to a computer via the USB port for their storage and the printout of examination reports.

# 5 Applied parts

Infrared sensor.



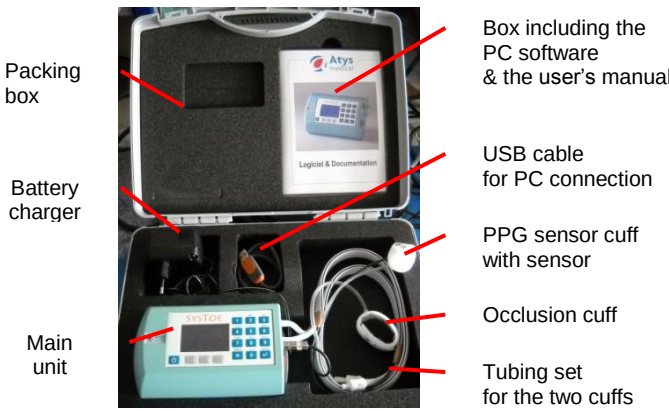
# 6 Component set-up

## 6.1 Unpacking

Atys ships the system in a box specially designed for the **SysToe**. It is essential to ship the equipment using the original packing materials.

## 6.2 Main components

Confirm all components below are present. If any component is missing or damaged, contact Atys or its representative.



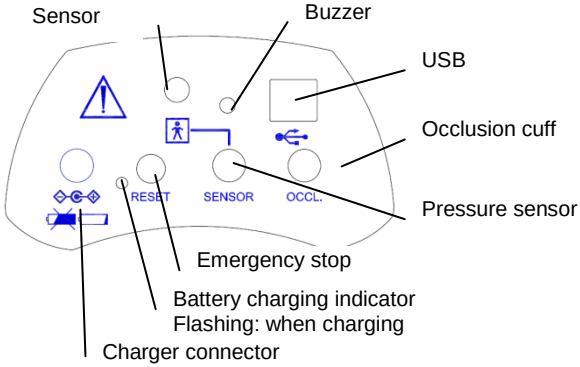

## 6.3 Preparation for use

The device is shipped ready for use. All the elements (the cuffs and the sensor) are connected to the SysToe.

To use the PC software, you will have to connect the USB cable.

For packing or moving of the device, you can place the device with the connected sensor and cuffs in the packing box.

## 6.4 Side panel

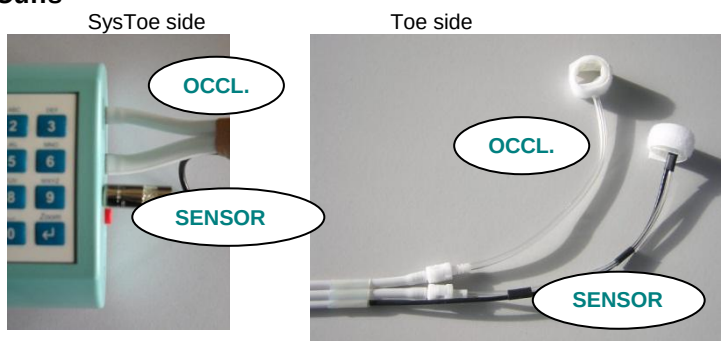



**RESET**: To stop the system in case of emergency.
Could damage the system: do not use to stop the system.

## 6.5 Tubing set

The tubing set is composed of 2 linked tubes that make the connection between the cuffs and the **SysToe** and one half-tube for the sensor cable.

## 6.6 Cuffs




### 6.6.1 Sensor cuff

The sensor cuff includes a tube that is fitted with a female connector.
This female connector is connected through the tubing set to the device.

### 6.6.2 Occlusion cuff

The occlusion cuff includes a tube that is fitted with a male connector.
This male connector is connected through the tubing set to the device.

## 6.7 Safety Symbols


ROHS
Do not wasp. To be partially recover and re-used.


USB input/output signal


IEC60417-5333
Sensor protection type is BF.


IEC60417-5031
DC charger input


IEC60417-5109
Do not use in a private home environment


ISO7000-1641
Consult operating instructions


CE MARK


IEC60417-5134
Electrostatic sensitive connector

ISO7000-2498
Serial number.


IEC60417-5448
Data Input and Output


IEC60417-5546
Battery load indicator

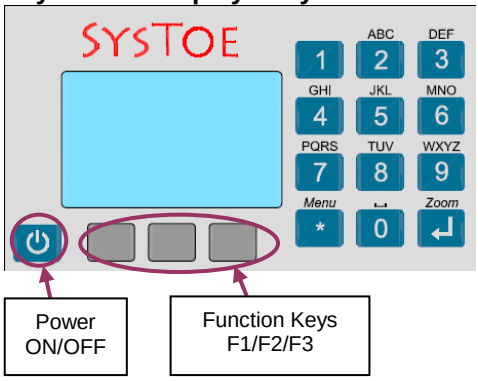

ISO7000-434
Consult accompanying documents.

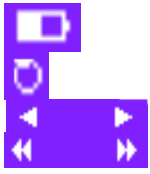

IEC60417-5009
standby

## 6.8 Device labels

| | |
|---|---|
| **RESET** | Halts the system in case of emergency.<br>Can damage the system: do not use to stop the system. |
| **MENU** | Access to menu |
| **ZOOM** | Zoom curves after acquisition |
| **SYS** | Systolic pressure in the toe or finger |
| **TBI** | Toe (or Finger) brachial index = Toe (or Finger) systolic pressure/ brachial systolic pressure or |
| **SENSOR** | Air flow connector to sensor cuff |
| **OCCL.** | Air flow connector to occlusion cuff |

## 6.9 Layout and displayed symbols



Battery power indicator

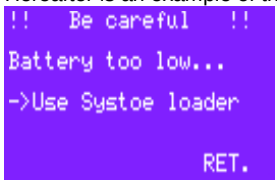
Occlusion pressure

Slow scrolling

Fast scrolling

# 7 Management of the battery

Replace the battery pack annually or when its capacity is noticeably diminished.
The battery has been designed for a certain number of charge/discharge cycles.
The battery must be charged only when a specific message is displayed.
Hereafter is an example of this kind of messages.




When the **SysToe** is switched off or on, a message is displayed in order to let you know if you have to connect the charger or not.

If the battery is low and if you have to do a measurement you can work with the **SysToe** connected to the charger.
Once the **SysToe** is connected to the charger, it must remain connected to the charger for 5 hours in order to charge fully the battery.

To charge the battery, plug the charger to the charger connector on the side of the **SysToe**.

The yellow CHARGING indicator flashes during charging.

The **SysToe** uses a Nickel Medal Hydride (NiMH) battery pack. The system charges a fully depleted battery in 5 hours.

Do not always use the SysToe connected to the charger.

# 8 A measurement step by step

## 8.1 Patient preparation

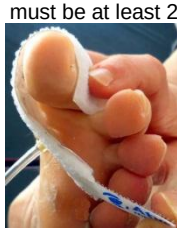
Position the patient appropriately on his/her back on the examination table. You may elevate the patient's head (the head only not the back) with pillows for greater comfort. The patient's feet should be resting comfortably on the examination table.

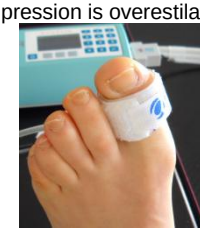
For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25 °C. If the patient's toes are cold, it is advised to warm them up. The skin temperature of the toe for low toes blood flow volume must be higher than 27°C.

The patient must remain relaxed throughout the exam. The user should remind him/her to remain still and refrain from talking.

## 8.2 Occlusion cuff

Wrap the occlusion cuff at the base of the toe so that the pipe goes downwards. For the big toe, studies have shown that the width of the cuff must be at least 25 mm otherwise the measured pression is overestilated.





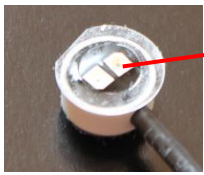
## 8.3 Double-sided ring tape

For a better contact of the sensor with the skin during the measurement, stick a two-sided ring adhesive on the sensor before positioning the sensor on the toe. It is compulsory to stick the sensor otherwise the quality of the measurement is not warrantied.
The double sided tape has been designed by Atys especially for the SysToe. It must be supplied only by Atys.

Remove one double sided tape from its support pulling the tongue.
Apply the sticky part of the ring tape on the sensor.

Press firmly all over the ring to make sure it is well stuck on the sensor

Remove the protective layer pulling the tongue off



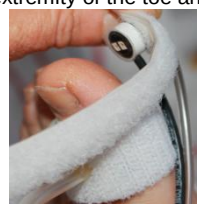
The adhesive ring must not cover the infrared cells

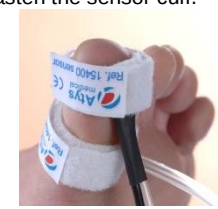
## 8.4 Sensor and its cuff

Then, there are two cases according to the length of the toe: Normal toe (§8.4.1) and Short toe (§ 8.4.2)

### 8.4.1 Normal toe

Stick the sensor on the extremity of the toe and fasten the sensor cuff.

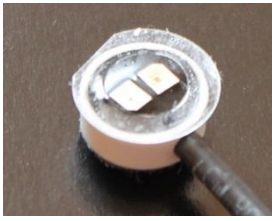


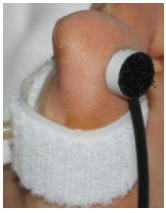


The whole surface of the sensor must be well in contact with the toe.
The sensor must be placed on the back of the toe and not on the nail.
The sensor and its cuff must be positioned so that the sensor wire and the cuff tube go downwards (as shown on the picture below).
Both cuffs must fit the toe but they must not be too tight. They must not induce any residual pressure on the blood vessels.

### 8.4.2 Short toe

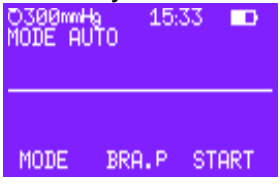
The toe is too short to accommodate both cuffs. The sensor cuff is not placed on the toe. Remove the sensor from its cuff.
Stick a two-sided adhesive on the sensor and stick the sensor on the toe.





## 8.5 Acquisition screen

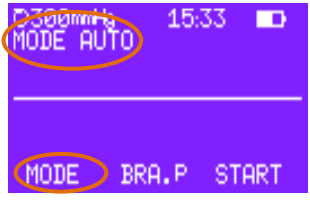
Once the **SysToe** is switched on, the acquisition screen is displayed.




MODE: Selection of AUTO (normal toe) or SEMI-AUTO (short toe)
BRA.P: Input of the brachial pressure (only if TBI is needed).
START: START the measurement
✶ : Access main menu

### 8.5.1 MODE: selection of automatic or semi-automatic mode

When the toe is long enough to accommodate both cuffs (occlusion and sensor cuffs), press on MODE to select MODE AUTO.
When the toe is too short to accommodate both cuffs, remove the sensor from its cuff (see § 8.4.2) and press on MODE to select MODE SEMI-AUTO.





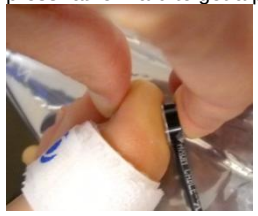
### 8.5.2 BRA.P: brachial pressure input

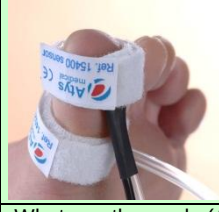
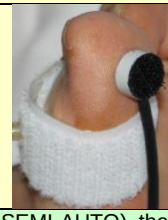
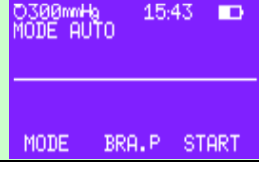

Input the value with the numeric pad.
The arm pressure is not measured by the **SysToe**.
DEFLT: Load last programmed value
CLEAR: Erase value
RET.: Save & return to the acquisition screen

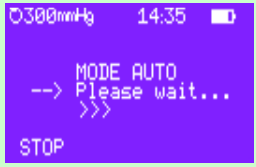
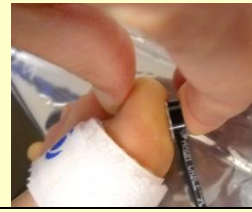
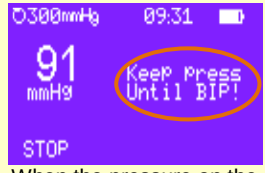
## 8.6 START: start the measurement

From the acquisition screen, press on START to start an examination.

- If current mode is AUTO (regular toe), cuffs are automatically inflated once the user has pressed on START.
- If current mode is SEMI-AUTO (short toe), the user needs to press on the sensor to start the examination. The pressure on the sensor should be kept as long as the message “Keep press until bip” is displayed (see hereafter description table with illustrations). The user needs to
press rather hard to get a proper emptying of the toe pulp.

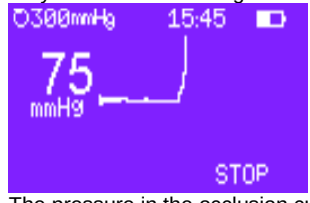


| Toe length | REGULAR TOE | SHORT TOE |
|---|---|---|
| Examination mode | AUTO (see §8.3) | SEMI-AUTO (see §8.4.2) |
| Occlusion cuff positioning | YES | YES |
| Sensor cuff positioning | YES | NO<br>(Remove the cuff) |
| Sensor positioning | YES, with double-sided tape | YES, with double-sided tape |
| Before START |  |  |
| Before START | Whatever the mode (AUTO or SEMI-AUTO), the display of the **SysToe** looks like one of these two displays.<br>  <br>  | |

| START | Press on START to start the measurement | |
|---|---|---|
| After START | AUTOMATIC PUMPING<br>  | Press quite strongly on the sensor as shown below to start the inflation of the cuffs.<br>  <br>  |
| | | Keep pressing on the sensor until the following message is no longer displayed “Keep press until BIP”.<br>  <br>When the pressure on the sensor must be released, the **SysToe** emits a sequence of beeps. |

Once the occlusion pressure is reached, then the pressure in the occlusion cuff decreases slowly. The display of the SysToe is the following ones.


The pressure in the occlusion cuff is higher than the systolic pressure



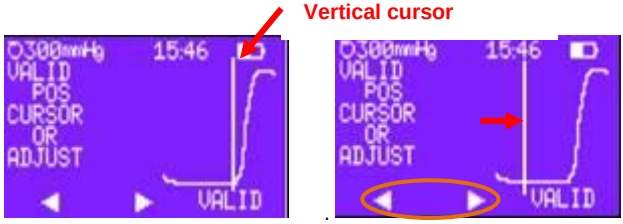

The pressure in the occlusion cuff is lower than the systolic pressure

The examination automatically stops when the pressure reaches 10 mmHg. But, if the backflow is clear, it is possible to stop the exam before. The return of the blood flow takes place when the pressure in the cuff is lower than the systolic pressure. This is shown on the SysToe by a clear and confirmed increase of the sensor signal.


STOP: Manual STOP of the examination procedure.
Use this function to stop the examination procedure before the occlusion cuff is fully deflated if you have noticed the backflow return or if you are under the impression that something is wrong.

## 8.7 Display of the systolic pressure and TBI

Once the examination is over, the following screen is displayed.
The **SysToe** places automatically the vertical cursor. It must be placed at the foot of the increase of the sensor signal (as on the left hand display).
If it is the case, the user has to press on VALID.
If it is not the case, the user has to move the vertical cursor to its proper position with the horizontal arrows and then press on VALID




VALID: validation of the vertical cursor position and go to the result page.


: Displacement of the vertical cursor.
✶: Change the displacement speed for cursor scrolling


: Fast scrolling


: Zoom IN/OUT

Once the user has validated the cursor position the following results screen is displayed.


TOE: Toe or finger systolic pressure
BRA.: Brachial systolic pressure
TBI: Toe or finger Brachial Index

BACK: To go to the previous screen
NEW: To go to the acquisition screen to perform a new measurement
VALID: To save the measurement in the internal memory
✶ To input the brachial pressure

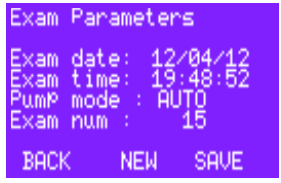
## 8.8 Input of the patient data

Before saving the measurement in the internal memory of the SysToe, it is advised to input some patient data in order to:

- Make easy the identification of the measurement
- Take advantage of the report generator

It is advised to input the patient name, the type and the side of the digit (toe or finger)
The VALID key on the results screen allows the saving of the measurement in the **SysToe** memory. But before, the three following screens are displayed one after the other to give the opportunity to the user to input some specific data about the patient.
When there is a figure or a symbol in front of a line of a menu, it means that if you press on the alphanumeric pad on the same figure or symbol, you will adjust or display the corresponding field.


BACK : To go to the previous display
NEW: To go to the acquisition screen in order to perform a new measurement
VALID: To validate the input data


SAVE: To save the current measurement and go to the acquisition screen in order toperform a new measurement.

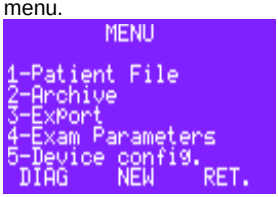
# 9 Configuration menus

When there is a figure or a symbol in front of a line of a menu, it means that if you press on the alphanumeric pad on the same figure or symbol, you will adjust or display the corresponding field.

## 9.1 Main menu

From the acquisition screen, press on 

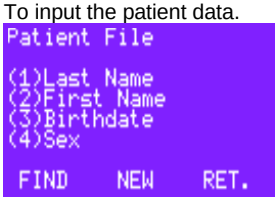
to go to the main configuration menu.




DIAG: DIAGNOSTIC (see §**Erreur ! Source du renvoi introuvable.**)
NEW: Go back to acquisition for a new measurement
RET.: Go back to acquisition for a new examination

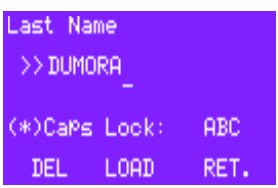
## 9.2 Patient File

To input the patient data.




FIND: To load the name of the patient from the archives. Then scroll the archives with the vertical arrows in order to find the proper name.
NEW: Toe return to the acquisition screen to perform a new measurement
RET.: To return to the main menu
✶: Display the help screen about the Different fields of the patient file.
0: Re-initialization of the current patient file.
The default parameters are displayed.

### 9.2.1 Name




Enter patient name with the alphanumeric pad

✶: Change mode caps lock (ABC→abc→123)

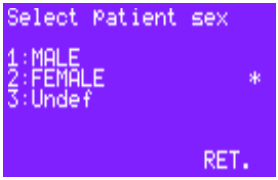
DEL: Delete last character
LOAD: Load current patient last name
RET.: Save and go back to patient file

### 9.2.2 Birth date


Enter patient birth date (DD/MM/YYYY) with the numeric pad

 Selection of the figure that must be modified
RET.: Save and go back to patient file

### 9.2.3 Sex




Select the patient sex with the Alphanumeric pad

RET.: Save and go back to patient file

## 9.3 Archive

To review the saved measurements and select the Export mode.
From the main configuration menu, select “Archive” (2).

### 9.3.1 Display the archive list and open an archive

This is the number of the archive.


: List scrolling up
: List scrolling down
RET.: Go back to previous menu

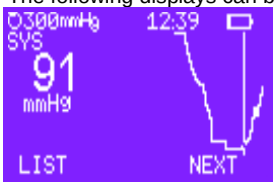
 : Open an archive for re-visualization (see §9.3.2)
0: Delete current examination
0+0: Delete all examinations

The **SysToe** can store up to 32 examinations.
The archive number is from 1 to 32.
For each archive position, the backup status is displayed:

- If no examination is saved at current archive position, the label “NONE” is displayed.
- If an examination is saved at current archive position, the name of the patient is displayed.
- If the current examination has been deleted:
  - when the selected export mode is “export not needed”, the examination is not fully deleted →the label “DELETED” is displayed but the current examination cannot be replaced.
  - when the selected export mode is “export needed”: the examination is fully deleted → the label “NONE” is displayed, current archive location can be used.

### 9.3.2 Review the content of an archive

When an archive is under re-visualization, all information specified in §8.7 and §8.8 can be reviewed, but no new value can be input.
The following displays can be reviewed





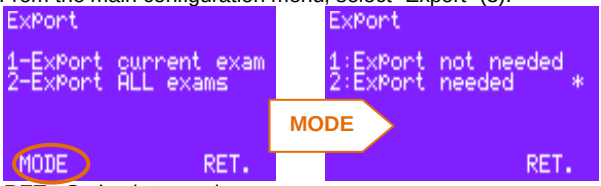


LIST: To go back to the archive list
NEXT: To display the next screen of the archive

BACK: To go back to the previous screen
NEW: To go to the acquisition to perform a new measurement

## 9.4 Configuration of the export mode

From the main configuration menu, select “Export” (3).



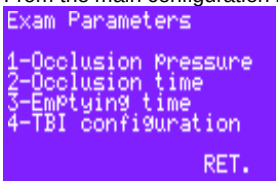

RET.: Go back to previous menu
MODE: To display the export configuration screen
Use the numeric pad. The selected mode is marked with a star.

- Export not needed: once the internal memory is full (32 examinations), the next examination that will be saved will erase automatically the archive n°1 and so on.
- Export needed: once the memory is full, no more examination can be recorded until examinations are deleted or exported to a PC. A message will be displayed at the START of a new examination to let the user know that the memory is full.

NB: The **SysToe** archives can be deleted either from the PC (« clear flash »), or from the archive screen (see §9.3)

## 9.5 Exam parameters

From the main configuration menu, select “Exam Parameters” (4).




RET.: Go back to the main menu

### 9.5.1 Occlusion pressure


Input the value with the numeric pad.

DEFLT: Load default value (300 mmHg)
CLEAR: Erase value
RET.: Return to configuration menu

### 9.5.2 Occlusion time

This is the time the occlusion pressure is applied.


Input the value with the numeric pad.

DEFLT: Load default value (5s)
CLEAR: Erase value
RET.: Return to configuration menu

### 9.5.3 Emptying time

This is the time the sensor cuff pressure is applied.


Input the value with the numeric pad.
The default value is 3 s.

DEFLT: Load default value
CLEAR: Erase value
RET.: Return to configuration menu

### 9.5.4 TBI configuration

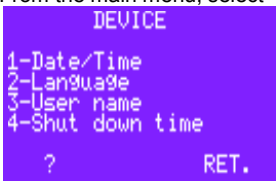

1: Display TBI index calculation
2: Do not display TBI index

RET.: Return to configuration menu

The selected mode is marked with a star

## 9.6 Device parameters

From the main menu, select “Device parameters” (5)




1: Go to date and time adjustment
2: Go to language adjustment
3: Go to default user adjustment
4: Go to the shut down time adjustment

?: Device information
RET.: Return to main menu

### 9.6.1 Date and time


Input the value with the numeric pad.

1: Go to date adjustment
2: Go to time adjustment

RET.: Return to configuration menu

See §9.2.2 for explanations on how to input a date.

### 9.6.2 Language

The current language is marked with a star.

### 9.6.3 User

To input the user name.
Press on LOAD to load the last input user name.

### 9.6.4 Shut down time

The **SysToe** is shut down if it is not used during X min. X min is the shut down time.


Input the value with the alphanumeric pad.

DEFLT: Load default value
CLEAR: Erase value
RET.: Return to configuration menu

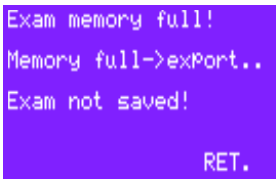
### 9.6.5 Device information

Display device information like the unit serial number or the software version.

# 10 Error messages

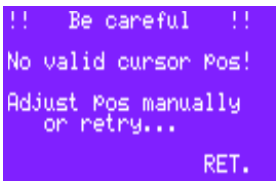

If no sensor is detected when the user presses on START, a message indicates that no examination can be performed…

RET.: Return to acquisition screen



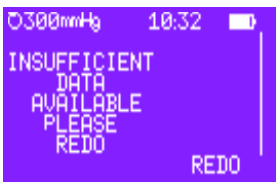

If 32 examinations have been recorded on the **SysToe** and
if the selected export mode is “export needed”,
a message indicates to the user that the memory is full and that he/she should export the examinations on the PC.

RET.: Return to acquisition screen




If no position of the systolic pressure can be detected automatically, a message indicates to the user that he/she should manually adjust cursor position or retry the measurement…

RET.: Go to examination curve review

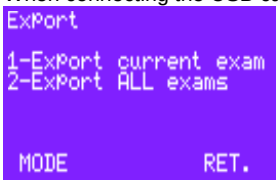



The measurement process was stopped too early or signal level is not sufficient.

The measurement must be redone after verification of sensor and cuffs positioning.

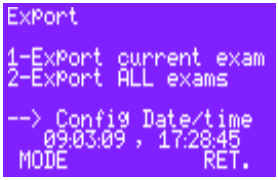
# 11 Examination export via USB

Connection between the **SysToe** and the PC-Windows is allowed in order to down load the measurements stored into the **SysToe** to a PC.
The software delivered with the **SysToe** must be installed on the PC.
When connecting the USB cable, the **SysToe** directly goes to this menu.



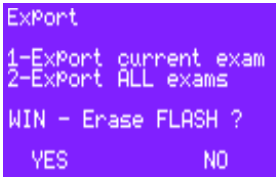

1: Export current examination to the PC
2: Export all examinations to the PC

MODE: Go to export mode configuration
RET.: Go to main menu




If the user select adjust Time/Date on **SysToe** from the PC, the following screen is displayed.

MODE: Go to export mode configuration
RET.: Go to main menu

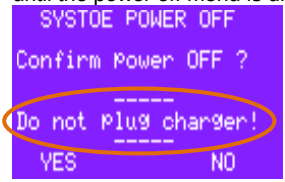



If the user select “erase all exams” on the PC, a message is displayed on the **SysToe** to allow the user to validate or not the complete deletion.

YES: Erase all exams
NO: Do NOT erase all exams

# 12 Powering off the device

The **SysToe** be switched from any screen.
To switch off the **SysToe**, press the power ON/OFF key for a few seconds until the power off menu is displayed.




YES: To confirm the switch off
NO: To cancel the switch off

Here, it is advised not to plug the **SysToe** to the charger.

# 13 Cleaning

## 13.1 Sensor and cuff

As the cuffs and the sensor come in contact only with intact skin, the risk of infection is low; so the cuffs and the sensor need only to be cleaned and low-level disinfected between patients.

Use only hospital approved cleaning agents (for USA: FDA cleared) to clean the cuffs and the sensor after each use and wipe dry immediately.

Be very careful for the cleaning of the cuffs and the sensor.
They must be handled carefully.
Never bend or pull the cable.
Never place it over open wounds or allow them to come in contact with body fluid.

Do not use the following methods for sterilization and disinfection.
They would induce damages on the cuffs and the sensor.
Sterilization:

- Autoclave and Ultrasound

Disinfection:

- Chlorine at 100 %
- Glutaraldehide at 100 %
- Hydrogen peroxyde at 100 %
- Iodine at 100 %

## 13.2 Console

Always turn off the system and disconnect it from the power outlet before cleaning the machine. Otherwise, electric chock may result.
Do not place fluid on or near the system.
Clean the external surface (casing) with soft cloth soaked with alcohol.
Make sure that the cloth is damp but not saturated, as you should avoid introducing fluids into areas of electrical components.

Allow the unit to dry before returning it to operation.

# 14 Service

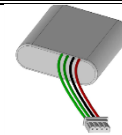
## 14.1 After sales service

To obtain additional information contact your Atys representative.

Inspect the cuffs and the sensor regularly for visible cracks and leaks. If such damage is found do not use the cuffs and the sensor.

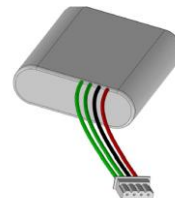
## 14.2 Spare parts and accessories

| Reference | Description | |
|---|---|---|
| 14 112 | **SysToe** module |  |
| 14 133 | **SysToe** occlusion cuff set<br>25 mm X 120 mm |  |
| 14 525 | **SysToe** occlusion cuff set<br>15 mm X 90 mm FOR 2nd or 3rd TOE |  |
| 14 154 | **SysToe** carrying box |  |
| 14 504 | **SysToe** Software to transfer the data to a PC under Windows | |
| 16 954 | Charger<br>Atys power supply, universal input, 9Vdc, 8W |  |
| 15 393 | Cuff for sensor |  |
| 18 844 | Sensor |  |

| | | |
|---|---|---|
| | Battery pack SysToe |  |
| 14 140 | Double sided ring tape |  |

## 14.3 Replacing the battery

Must be performed by a qualified service technician.
Tool required: screwdriver
To replace the battery, use a PZ head screwdriver to remove the four battery compartment screws. Unplug the old battery.
Plug in the new battery and close the battery door. Tighten the screw firmly but do not over tighten.

**CAUTION**: The battery pack contains a temperature measurement component that is matched to the cell type and to the product requirements. Use only replacement battery packs as specified by Atys medical.
**CAUTION**: Unauthorized battery substitutions will void the warranty and may cause overheating.
**CAUTION**: Used NiMH batteries must be recycled or disposed of properly. Do not incinerate.

## 14.4 Troubleshooting

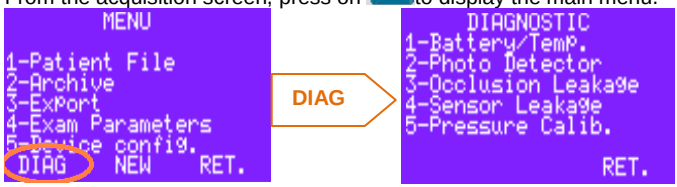
In case of trouble and at least once a year,

- Verify the unit integrity and the sensor/cuff connections
- Operate the following software assisted tests from the diagnostic module.

### 14.4.1 Main menu

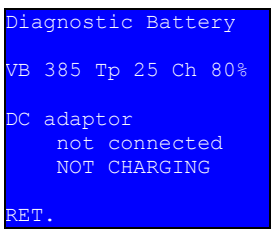
From the acquisition screen, press on 

to display the main menu.




Press on DIAG to display the diagnostic menu.

### 14.4.2 Control of the battery charge and temperature

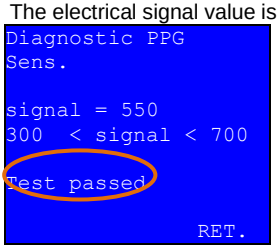



VB: Current battery level.
VBatt > 450mV at end of charge
Tp: Internal device temperature in °C < 60°C
Ch: Actual charge level.

RET.: Return to diagnostic main menu

### 14.4.3 Control of the sensor (photo detector)

Press on INFO. Apply the sensor on a digit. Press on RESET.
The electrical signal value is displayed.



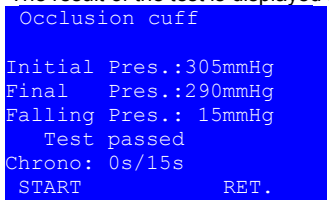

The result of the test is displayed:

- Test passed
- Test failed

RET.: Return to diagnostic main menu

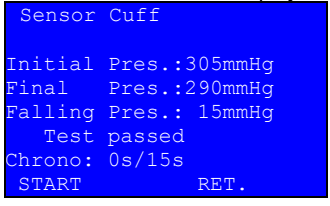
### 14.4.4 Control of the occlusion cuff leakage

Install the occlusion cuff on a tube of 10-20mm diameter.
Press on START
The device will inflate the occlusion cuff and test for leakage during 15s.
The final leakage value is displayed.
The result of the test is displayed as “test passed” or “test failed”.



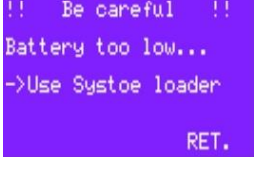

### 14.4.5 Control of the sensor cuff leakage

Install the sensor cuff on a tube of 10-20mm diameter as above.
Press on START
The device will inflate the sensor cuff and test for leakage during 15s.
The final leakage value is displayed.
The result of the test is displayed as “test passed” or “test failed”.



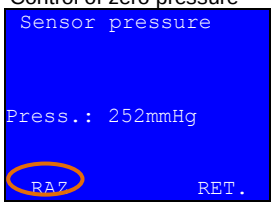

### 14.4.6 Control of the pressure sensor calibration

The control of the pressure sensor calibration can be performed by any qualified technician.
It is advised to perform this control once a year.
The calibration of the pressure sensor must be performed by Atys.
Required equipment: sphygmomanometer that must be calibrated by an accredited laboratory.
The battery of the SysToe must be charged. The following message should not be displayed.




Connect a sphygnomanometer on the occlusion cuff output.


Control of zero pressure




RAZ

Press on RAZ

The value on the manometer should be 0 mmHg
Control of the 100 mmHg pressure
With the bladder of the sphygnomanometer, input a pressure equal to 100 mmHg on the manometer. Read the value displayed on the SysToe.
The SysToe passes the test when the displayed pressure on the SysToe is equal to 100 mmHg ± 3 mmHg.

If the SysToe fails the tests, it should be calibrated by Atys.

### 14.4.7 Calibration

The following calibrations can be performed:

- Calibration of the pressure sensor.
- Calibration of the deflation of the occlusion cuff.

The calibration must be performed by Atys.

# 15 Regulations

EC: Class IIa device
Canada: Class 2 device

# 16 Technical data

## 16.1 Electrical characteristics

Internally powered equipment with a NiMH battery.
Type: 18 522 Systoe battery pack 2500mAh

Replacement interval: 1 year
Charge time: 5h
Discharge time standby: 3h
Discharge time operating: 150 examination cycles.

## 16.2 Physical specifications

Dimensions: 15 cm x 10 cm, height: 5.5 cm
Weight: 0.5 kg

## 16.3 Pressure sensor

Measurement and display range: 0-330 mmHg
Accuracy: +/- 3%, above 70mmHg and +/- 2mmHg below 70mmHg

## 16.4 PPG Sensor

Infrared type sensor.

# 17 Standard compliance

## 17.1 Safety

**SysToe** is compliant with IEC60601-1 international code of safety.

Safety Class:
Type internally power appliance when operating or class II when battery in charge.
Applied parts: BF type.
Mechanical protection index: IP20.

**SysToe** is compliant with CE and Canada regulations.

## 17.2 Quality management

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

## 17.3 Software development

The software is compliant with IEC60601-1:2005

## 17.4 Usability

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

## 17.5 Risk management

The risk management is processed in compliance with ISO14971

## 17.6 Electro Magnetic Compatibility

The SysToe has been designed to work normally in conditions specified by the international standard IEC60601-1-2.
**Essential performance for immunity tests.**
A Criteria:
Start and stop image display, image visible and allowing diagnosis.
B Criteria:
Image is affected, but no diagnosis error is possible.
**Information relative to the A class limitation.**
The SysToe emits electromagnetic radiations.
These radiations do not allow the compliance to the B class in every configuration.

Table 1

| Manufacturer's Declaration **–** Electromagnetic Emissions (IEC60601-1-2) | | |
|---|---|---|
| The **SysToe** 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<br>CISPR 11 | Group 1 | The **SysToe** must emit electromagnetic energy in order to perform its intended function.<br>Nearby electronic equipment may be affected. |
| Emissions RF<br>CISPR 11 | Class A | The **SysToe** is suitable for use in all establishments other than residential.<br>It can be used in residential establishment with the respect of the following advising:<br>Advising: This device is designated to be used exclusively by professional medicine people.<br>The **SysToe** can provide radio electrical perturbations or can affect the operation of nearby electronic equipment.<br>It could be necessary to use reduction measures like reorienting, displacing, installation in other place or shielding place. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emission<br>IEC 61000-3-3 | Complies | |

Table 2

| Manufacturer's Declaration **–** Electromagnetic Immunity (IEC60601-1-2) | | | |
|---|---|---|---|
| The **SysToe** 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 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electric fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for Input/output lines | ± 2 kV for power supply lines<br>± 1 kV for Input/output lines | Mains power quality should be that of a typical commercial and/or hospital environment |
| Surge IEC 61000-4-5 | ±1 kV differential mode<br>±2 kV common mode | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial and/or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply. IEC 61000-4-11 | <5 % U T (>95 % dip in UT) for 0.5 cycle<br>40 % U T (60 % dip in UT) for 5 cycles<br>70 % U T (30 % dip in UT) for 25 cycles<br><5 % U T (95 % dip in UT) for 5 sec. | <5 % U T (>95 % dip in UT) for 0.5 cycle<br>40 % U T (60 % dip in UT) for 5 cycles<br>70 % U T (30 % dip in UT) for 25 cycles<br><5 % U T (95 % dip in UT) for 5 sec. | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the **SysToe** requires continued operation during power mains interruption, it is recommended that the **SysToe** powered from an uninterruptible power supply or battery. |
| Power frequency(50/ 60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | It may be necessary to position the **SysToe** further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low. |
| Note: UT is the AC mains voltage prior to application of the test level.<br>Table 38. Electromagnetic Immunity (IEC60601-1-2) | | | |

Table 3

| Manufacturer's Declaration - Electromagnetic immunity | | | |
|---|---|---|---|
| The **SysToe** 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** |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz<br><br>3 V/m 80 MHz to 800 MHz<br>3 V/m 800 MHz to 2.5 GHz | **V1 =** 3 Vrms<br><br>3 V/m<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the **SysToe** including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.<br><br>Recommend separation distance<br>$d = [\frac{3,5}{V_1}]\sqrt{P}$<br>$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz à 800 MHz<br>$d = [\frac{7}{E_1}]\sqrt{P}$ de 800 MHz à 2,5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and<br>d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 **SysToe** is used exceeds the applicable RF compliance level above, the **SysToe** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **SysToe**.<br>b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m | | | |

Table 4

| Recommended separation distance between portable and mobile RF communications equipment and the **SysToe.** | | | |
|---|---|---|---|
| The **SysToe** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **SysToe** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **SysToe** as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated Maximum Output Power of Transmitter in watt | Separation distance according to frequency of transmitter in meter | | |
| | 150 kHz à 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.7 | 3.7 | 7.4 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br>Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.<br>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |

Table 5

| Cables | Maximum Length |
|---|---|
| USB Cable | 2 m |