

TCD-X

Ambulatory monitoring transcranial Doppler

User manual



This document contains safety information on the **Atys TCD-X** device 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 as a result of the use of the information in this manual.

No part of this manual may be reproduced or transmitted in any form for any purpose other than the use of the purchaser of **Atys TCD-X** system.

Reference:

18 319 TCD-X: User manual

Date: 19/06/2015

Atys

17 Parc d'Arbora

F69510 SOUCIEU EN JARREST

France

Tel: 33 4 78 05 69 69

Fax: 33 4 78 05 69 60

Content

1	Abbreviation.....	5
2	Icons	5
3	TCD-X description	6
3.1	Unpacking.....	6
3.2	Main components	6
4	Installation of the software.....	7
4.1	Requested equipment	7
4.2	Software description	7
4.3	Installation.....	7
4.3.1	Installation of the USB driver	8
4.3.2	Installation of ADMS	9
5	TCD-X module.....	12
5.1	Description.....	12
5.2	Battery	12
6	Headset description.....	13
6.1	Probe casing.....	13
6.2	Counter piece	14
6.3	Elastic band	14
6.4	Head band	14
7	Preparation of the headset	15
7.1	Selection of the size of the spectacle frame.....	15
7.2	Search of the acoustic window and marking.....	15
7.3	Installation of the counter piece.....	15
7.4	Installation of the probe on the spectacle frame.....	16
7.5	Installation of the whole set on the patient's head.....	17
7.5.1	Installation of the headset.....	17
7.5.2	Tightening of the bands	17
7.6	Finding the acoustic window.....	17
7.6.1	Finding the acoustic window before the installation of the whole head set on the patient.....	17
7.6.2	Finding the acoustic directly with the robotized probe.....	17
8	ADMS	18
8.1	Welcome screen.....	18
8.2	Patient file	20
8.2.1	Identification.....	20
8.2.2	Symptom.....	21
8.2.3	History.....	22
8.3	User file.....	22
8.4	Archive database.....	23
8.5	Configuration menu	25
8.5.1	Archive Menu.....	25
8.5.2	Configuration menu	26
8.5.3	Printer configuration	26
8.6	TCD-X protocols	26
8.7	Preview	27
9	Adjustment and start of the monitoring.....	29
9.1	Preparing the SD card for recording of TCD-X data.....	29
9.1.1	Generalities.....	29
9.1.2	Writing patient name or identification number	29
9.1.3	Formatting a SD card	30
9.2	Inserting SD card in the TCD-X module	31
9.3	Connections.....	31
9.4	Switch on the TCD-X module	31
9.5	Start the TCDX setup software.....	31
9.5.1	Connection problem	32
9.5.2	Connection is well established	33
9.6	TCD-X setup software generalities.....	33
9.7	Adjustment of the Doppler parameters and of the sound volume	34
9.8	Options for online operations.....	35

9.9	Probe Control Software	36
9.9.1	Description	36
9.9.2	Interpretation of the position of sample volume.....	36
9.9.2.1	Posterior – anterior tilt angle.....	36
9.9.2.2	Superior - inferior tilt angle	37
9.9.3	Scan for the Doppler signal	37
9.9.3.1	Global scan	37
9.9.3.2	Doppler parameters adjustment	37
9.9.3.3	Local search	38
9.9.3.4	Manual scan	38
9.9.3.5	Final Doppler parameter adjustment	38
9.9.4	Recording	38
9.9.5	Disconnection of the TCD-X module from the PC.....	39
10	Stop of the recording and transfer of the Data from SD-card to the PC	40
10.1	Stopping the recording	40
10.2	Transferring of the Data from SD-card to the PC	40
11	Monitoring software (tcdX4) – Emboli detection and trend analysis	41
11.1	Principle of emboli detection.....	41
11.2	Load a DOPX or TCDX file.....	42
11.3	Main screen	42
11.4	Header	43
11.5	Configuration menu	44
11.5.1	Doppler settings.....	44
11.5.2	Display settings.....	45
11.5.3	Index settings.....	45
11.5.4	Trend settings & adjustment of the averaging time	46
11.5.5	Emboli settings	46
11.5.6	Print settings	47
11.6	Doppler zone	49
11.6.1	Indices	50
11.6.2	Scrolling bar.....	50
11.7	Emboli detection zone	51
11.7.1	Before emboli detection.....	51
11.7.2	After emboli detection	52
11.7.3	Emboli table	52
11.7.3.1	Description	53
11.7.3.2	Configuration	54
11.7.3.3	Definition of the data displayed in the table.....	54
11.7.4	Audiogram	55
11.7.5	Histogram	55
11.7.6	Emboli play back.....	56
11.8	Trend zone.....	57
11.8.1	Before computing trends	57
11.8.2	After computing trends	57
11.9	Toolbar.....	58
11.9.1	Sweep.....	58
11.9.2	0-line	58
11.10	Examination report printing.....	59
12	Alarms and warning lights	60
13	Cleaning.....	61
13.1	Probe	61
13.2	TCD-X module.....	61
14	Maintenance and after sales service	61
15	Specifications.....	61

1 Abbreviation

TCD: Transcranial Doppler

MCA: Middle Cerebral Artery

Vm: mean velocity

Vs: systolic velocity







Vd: diastolic velocity

HITS: High Intensity Transient Signal. It can be an emboli or an artifact.

ERD: Embolic Relative Duration. It is calculated as HITS velocity multiplied by HITS time duration divided by sample volume length

EBR: Embolus-Blood Ratio» (dB)

2 Icons

	ADMS (Atys Data Management Software): main software for welcome screen and Atys data management
	tcdX4: Trend analysis and emboli detection software. It is also named monitoring software
	AtysDB2: Database Management software
	tcdx : set up software
	PatientX : software for patient identification
	SDManager: Memory card manager software

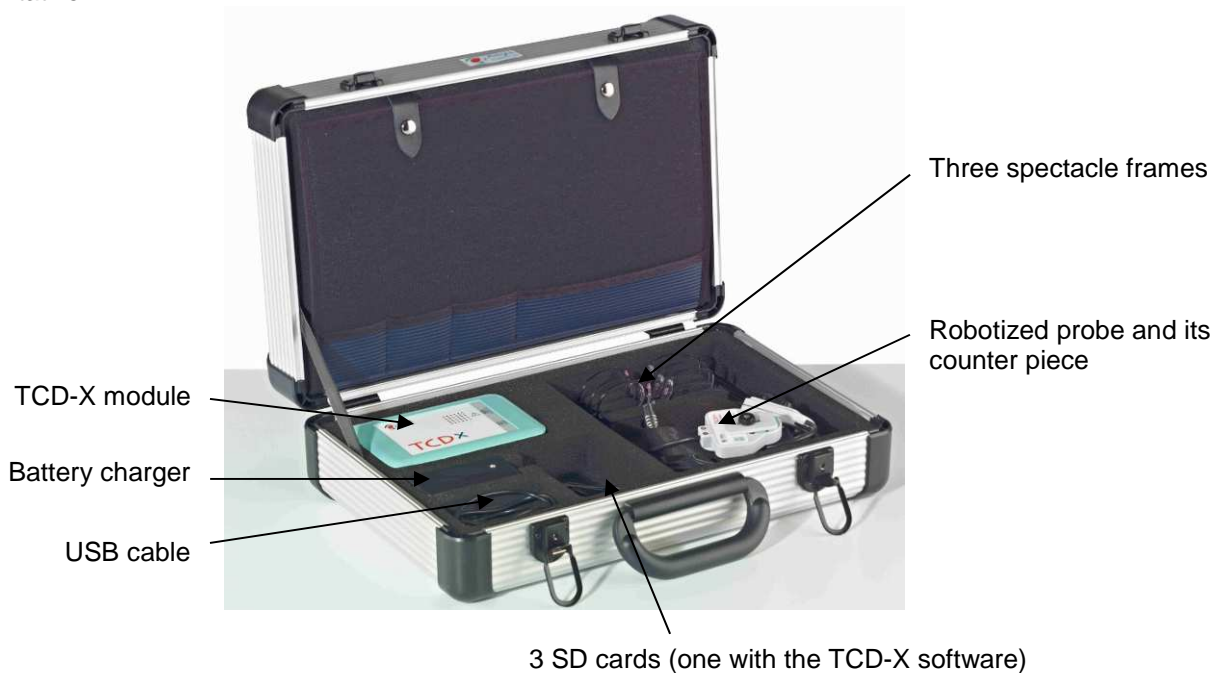
3 TCD-X description

3.1 Unpacking

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

3.2 Main components

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



The following elements are also supplied but are not seen on the above picture:

- Cross body carry bag
- Instructions for use
- A pencil handheld 2 MHz probe

The hardware consists of:

- A Doppler electronics unit, fitted with a SD card slot, a rechargeable battery and a USB interface. It is named TCD-X module.
- A probe headset that comprises a spectacle frame, a robotized probe, a counter piece, a cable and a headband.
- A pencil handheld 2 MHz probe

4 Installation of the software

4.1 Requested equipment


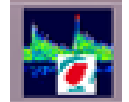

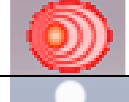

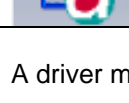
The PC dedicated to TCD-X application should have the following requirements:

- Operating system = Windows
- Memory card reader
- One USB port
- Integrated loud-speakers,
- Processor >= 2GHz.
- Memory >= 2 Go
- Hard disk >= 200 Go
- Minimal screen resolution = 1360 x 768
- Good battery autonomy (to work close to patient for setup settings)

It is advised to use a PC dedicated only to this application. Indeed, when other software programs are present on the PC, there may be conflicts with the TCD-X programs and that prevents their proper running.

4.2 Software description

TCD-X software is composed of several software units:

	« ADMS » : main software for welcome screen and Atys data management
	« tcdX4 » : monitoring software (post-treatment) for trend analysis and emboli detection
	« AtysDB » : Database Management software
	« tcdx » : setup software for Doppler settings, adjustments and recording start
	« patientX » : software for patient identification
	« SDmanager » : memory card manager software

A driver must also be installed for the USB communication between the PC and the TCD-X module.

4.3 Installation

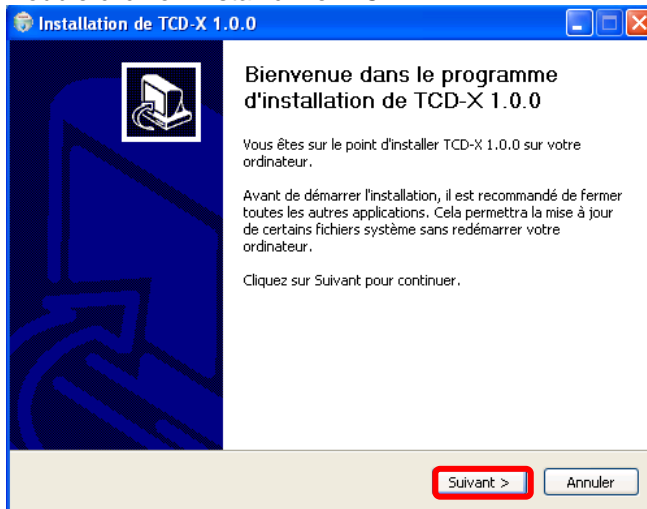
- Insert the installation SD card in the PC SD slot.
- Or insert the memory stick in a PC USB port.

Display the content of the SD card or memory stick.



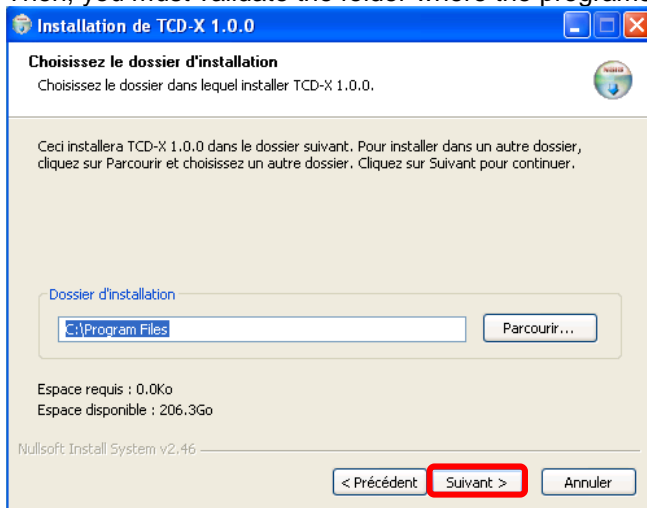
4.3.1 Installation of the USB driver

Double click on Install driver TCD-X.

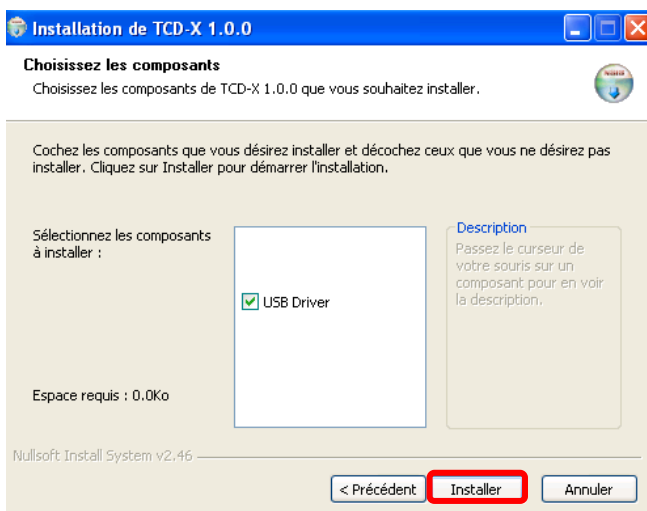


Click on Next.

Then, you must validate the folder where the programs will be copied automatically in.



Click on Next

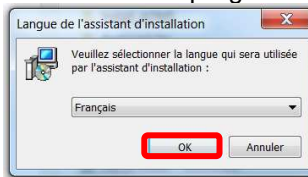


Click on Install.

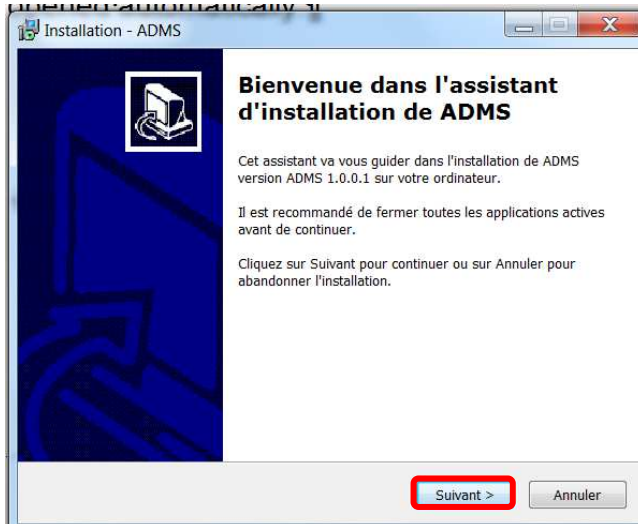
4.3.2 Installation of ADMS

Double click on Install on Adms Install.

The installation program is opened automatically.

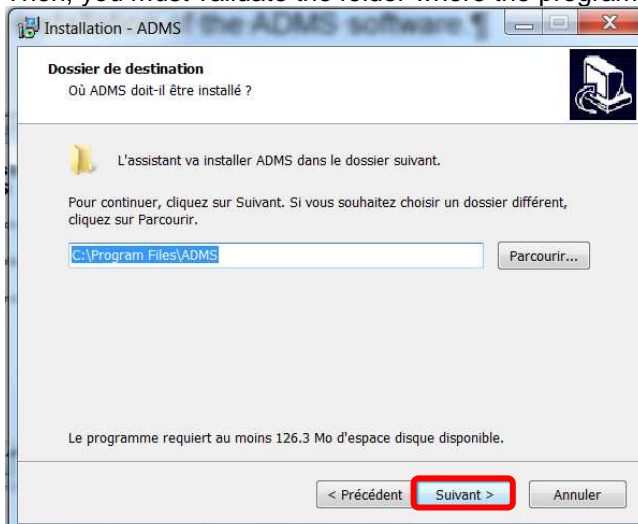


Select the language for the installation of the ADMS software.
Click on OK.



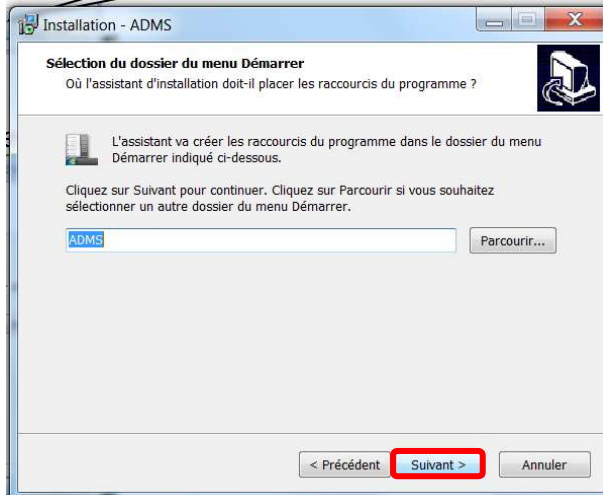
Click on Next.

Then, you must validate the folder where the programs will be copied automatically in.



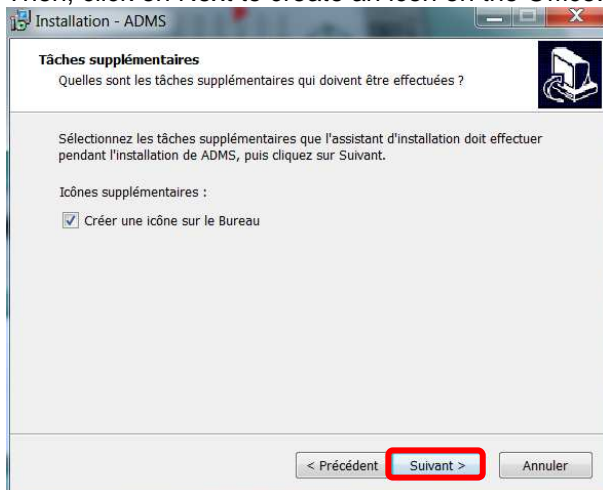
Click on Next.

Then you must select where the shortcut will be installed.

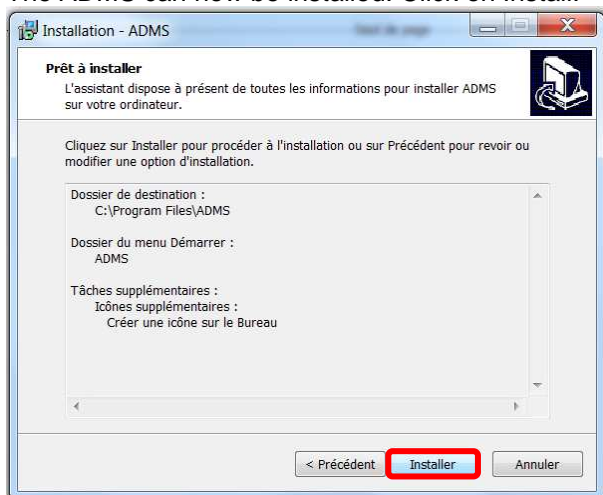


Click on Next.

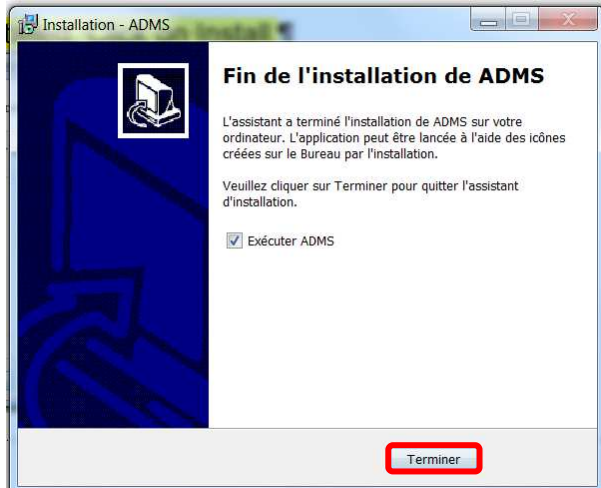
Then, click on Next to create an icon on the Office.



The ADMS can now be installed. Click on Install.



When the installation is completed, click on the icon with the red border.



5 TCD-X module

5.1 Description

Loud speaker



SD card slot

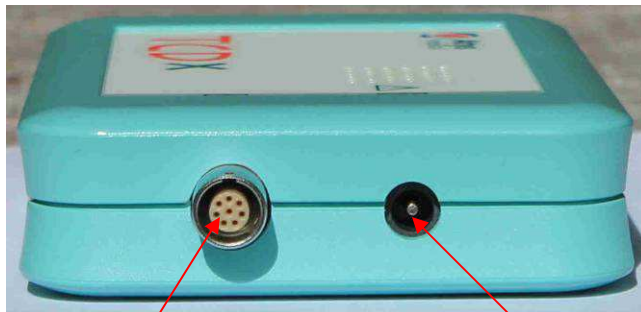
LED 2
orange

Analog datat

USB connector

LED 1
green

ON/OFF push button



Probe connector

Battery charger connector

To switch off the device, the push button must be pushed during 8 s.

The LED 2 flashes during the recording.

The LED 1 provides information on the power supply.

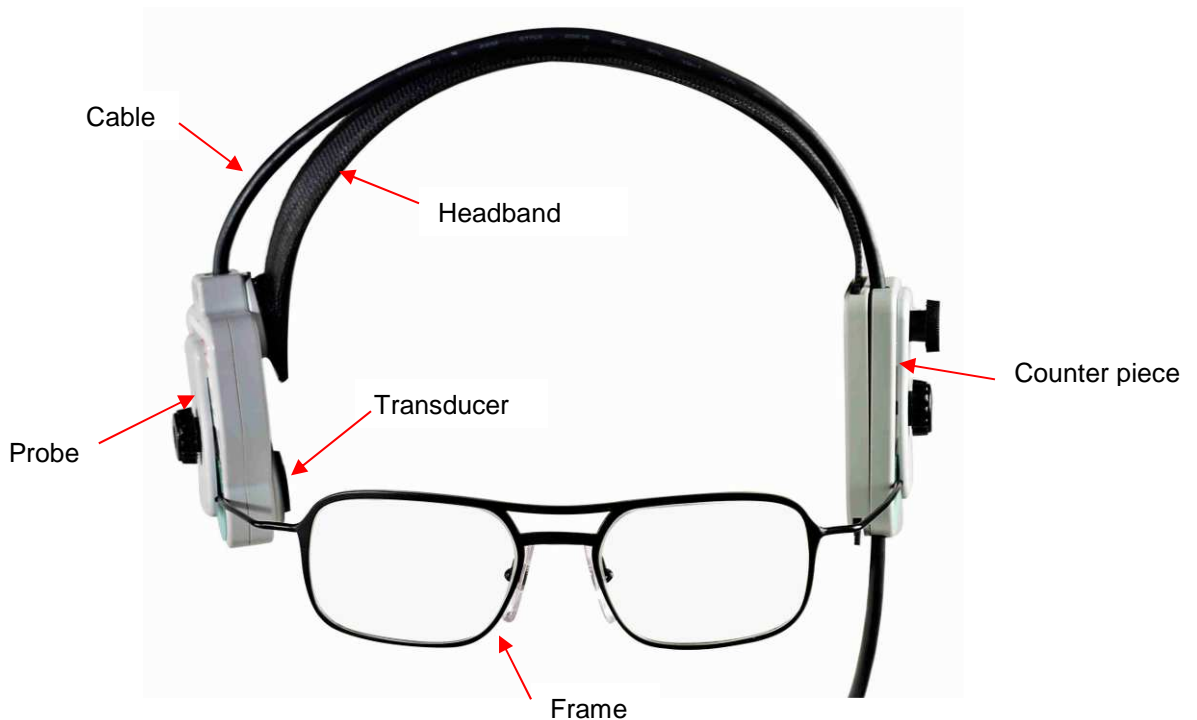
Loudspeaker function: output of the Doppler signal during the monitoring and output of the alarms.

5.2 Battery

7.4V LI-ION 2200mAH.

External charger (charge duration: 3.5 h).

6 Headset description



Three sizes of frames are provided.

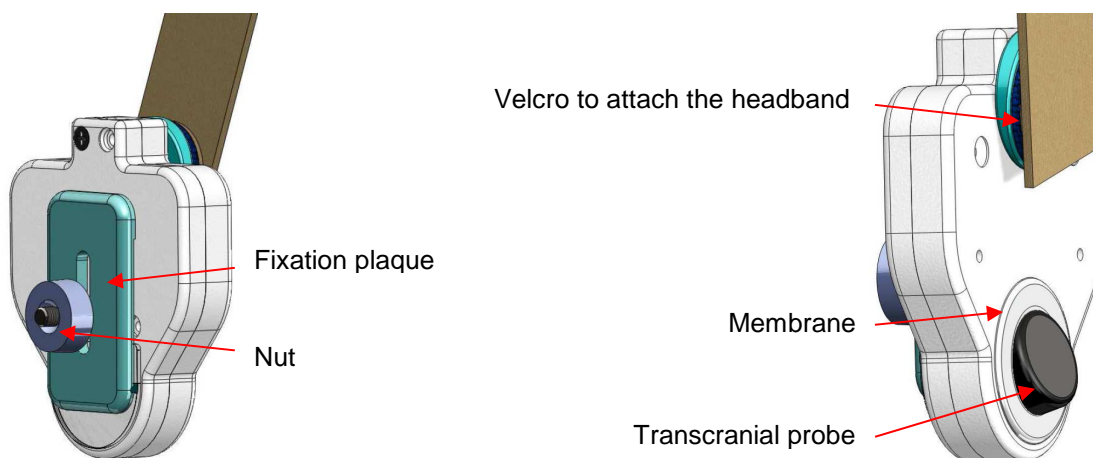
On the opposite side of the probe, a counter-piece (without any electronics) is used to balance the headset.

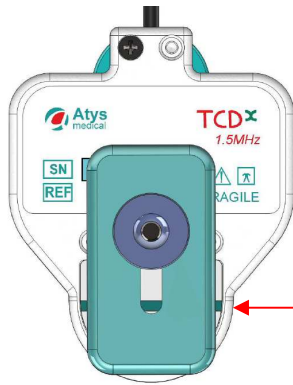
On the back of the headset (not shown on the above picture), the elastic band, allows the user to just tighten the headset enough with the Velcro to keep the headset stable and the transducer in contact with the temporal skin.

6.1 Probe casing

The probe casing includes the transcranial probe and the engines that allow the adjustment of the probe orientation.

The probe is coupled to the casing through a silicone membrane.



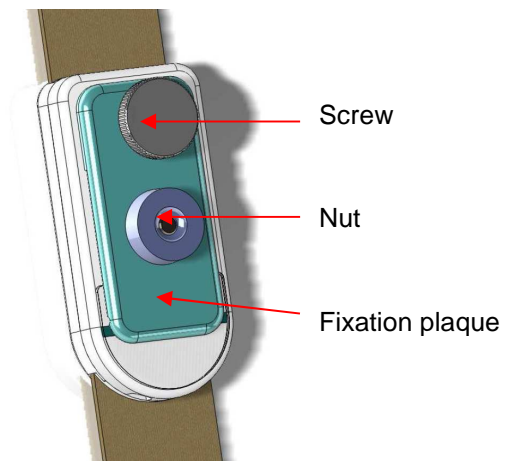


Horizontal black line on the outside of the probe casing

6.2 Counter piece

It ensures

- The balance the spectacle frame,
- The positioning of the balance on one arm of the frame,
- The tension of the headband,
- The passage of the cable.



6.3 Elastic band

The elastic headband is composed of two parts.

Each part is fitted with a slot to insert the small metal part that is perpendicular to the frame arm.



This part must be inserted in the slot of the elastic band. Then turn the elastic band through 90° so that the slot is perpendicular to the metal part of the frame arm.

Slot of the elastic headband

6.4 Head band

The headband links the probe to the counter piece. It is attached to the probe casing with a Velcro pad. It can slide into the counter piece for the adjustment of its length when the counter piece screw is unscrewed.

The headband must rest on the patient head in order to transmit a part of the weight of the headset to the upper part of the patient's head. The weight of the headset is shared between the nose, the ears and the upper part of the head.

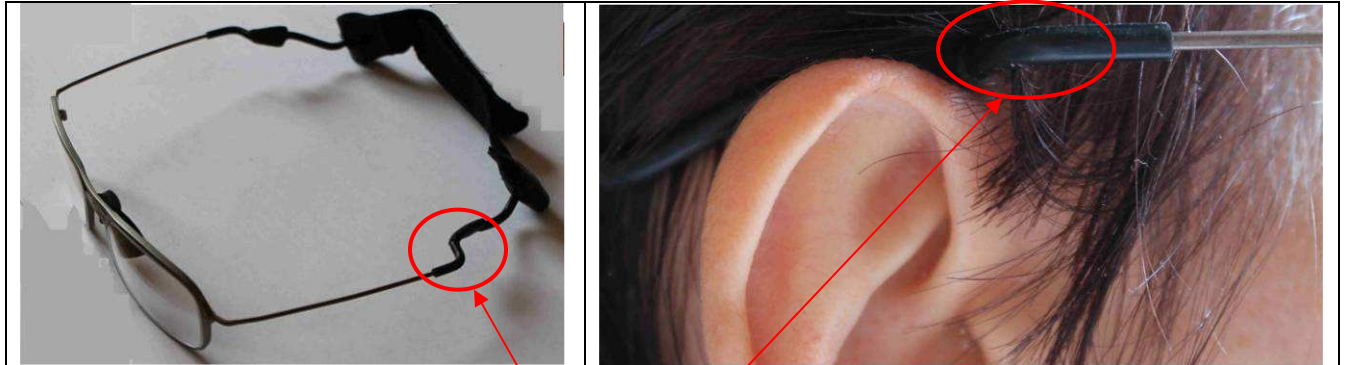
The headband can be easily changed by the users.

7 Preparation of the headset

7.1 Selection of the size of the spectacle frame

The TCD-X is delivered with three frames of three different sizes. Select the frame that fits well the patient.

First of all, the patient has to try each spectacle frame. Select the frame for which the angle of the arm is just above the ear as shown hereafter.



This angle must be just above the ear

Then, the gap between the frame arm and the patient's temple must be large enough to accommodate the probe but it must not be too large.

Select the spectacle frame for which the distance between the frame arm and the patient's temple is one thumb thickness but not more (roughly 1.5 cm).

7.2 Search of the acoustic window and marking

Before installing the headset on the patient, it is advised to:

- Search the patient's acoustic window with the hand held probe.
- Draw a mark on the found acoustic window.

Note the position of the acoustic window with regards to frame arm.

7.3 Installation of the counter piece

Unscrew the nut to loosen the fixation plaque.

Insert the frame arm between the counter piece casing and the fixation plaque. Place it in the groove of the fixation plaque.

Laterally, this piece should be positioned just in front of the ear. It is advised to place it at the extremity of the spectacle arm (just before the angle on the frame arm).



The counter piece should stand vertically

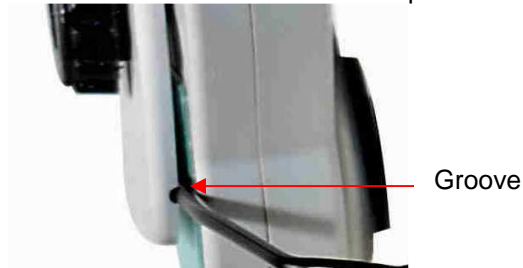
The counter piece can be slide backwards up to the angle of the spectacle arm.

Once the counter piece is positioned, screw the nut.

7.4 Installation of the probe on the spectacle frame

Unscrew the nut to loosen the fixation plaque

Insert the frame arm between the probe casing and the fixation plaque. Place it in the groove of the plaque.



The position of the transducer relative to the spectacle frame can be adjusted to cover the ultrasonic window by loosening and tightening the nut.

To adjust the probe position laterally, have the probe slide along the frame arm.



The probe position can be adjusted vertically by moving up and down the fixation place.



Put the headset on the patient.

Adjust the position of the probe on the frame according to the position of the patient's acoustic window.

- If the acoustic window is just in front of the arm of the spectacle frame, this arm must be placed on the horizontal black line that is drawn on the probe casing.
- If the acoustic window is above the arm of the frame, this arm must be placed below the horizontal black line that is drawn on the probe casing.
- If the acoustic window is below the arm of the frame, this arm must be placed above the horizontal black line that is drawn on the probe casing.



The acoustic window is above the frame arm.



The acoustic window is below the frame arm



The acoustic window is in front of the frame arm

Once the probe is well placed on the spectacle frame, screw the nut.

7.5 Installation of the whole set on the patient's head

7.5.1 Installation of the headset

Put gel on the probe and on the patient's temple window.

Put the spectacle frame on the patient.

Remove the hair from under the probe.

Adjust the probe casing position in order to place the probe on the patient's acoustic window.

The probe casing can be moved laterally, vertically and can rotate a little along the vertical axis.

7.5.2 Tightening of the bands

Tighten the band at the back of the head. It must be just tightened enough with the Velcro to keep the headset stable and the transducer in contact with the temporal skin. Do not over-tighten the Velcro, it may be uncomfortable and cause pain to the patient.

Unscrew the counter piece screw. Adjust the head band over the head. Pull on the part of the band that can slide in the counter piece and that is under the counter piece. The head band adjustment should be treated carefully. Indeed when the headband is well adjusted, one part of the weight of the headset is supported by the upper part of the head. This improves the comfort of the patient.

The head band must rest on the head to provide a support to the whole system.



7.6 Finding the acoustic window

Two strategies can be considered.

7.6.1 Finding the acoustic window before the installation of the whole head set on the patient

Just before the installation of the headset, it is advised:

- To find the patient's acoustic window with the hand held probe.
- To remove the gel and write a cross on the patient's acoustic window.

The robotized probe will be placed on this cross.

7.6.2 Finding the acoustic directly with the robotized probe

Installed the head set with the robotized probe on the patient's head.

Place the robotized probe on the presumed acoustic window.

Run the TCDX-setup protocol of ADMS.

Adjust the Doppler parameters as explain in § 9.7, § 9.9.3.2 and § 9.9.3.5.

Perform a SCAN.

If no signal is found or if the quality of the signal is poor, move a little the robotized probe and redo a Scan.

8 ADMS

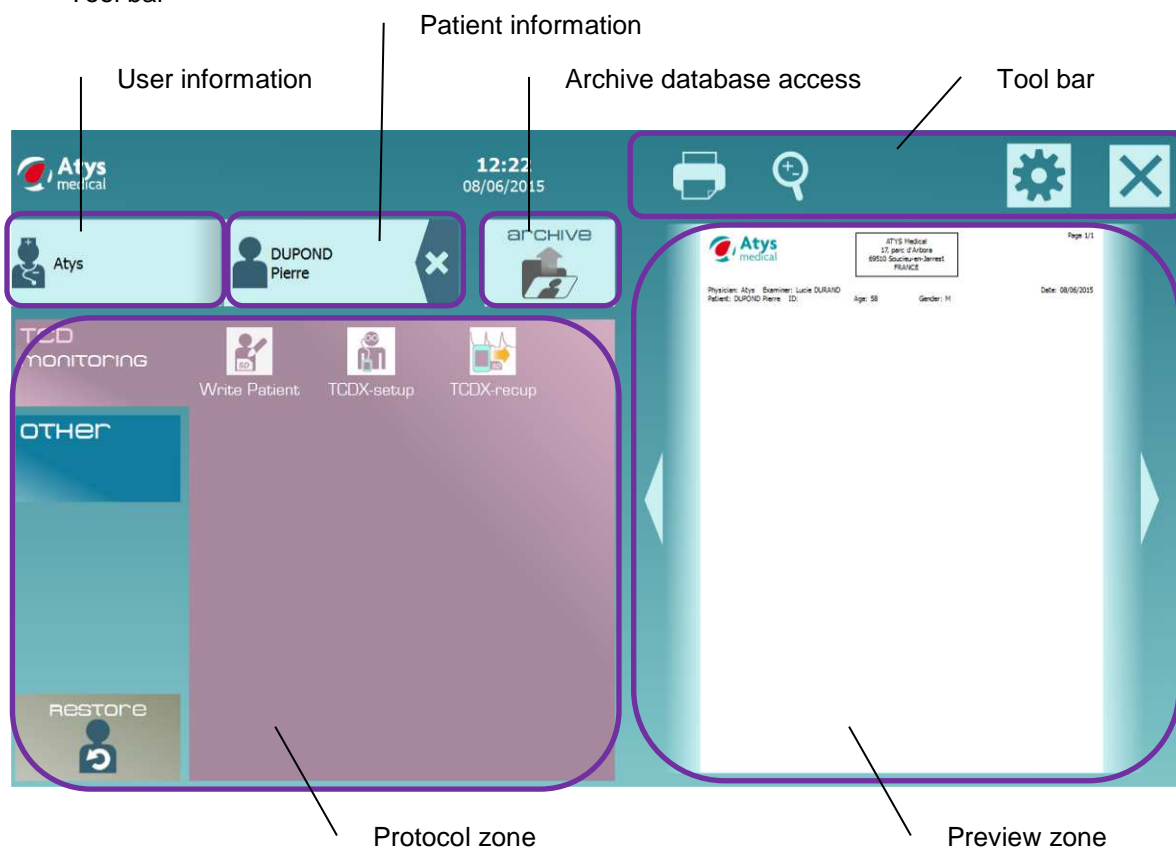
8.1 Welcome screen




Click on the following icon to reach main ADMS screen.

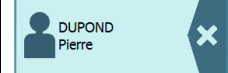



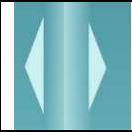









The main ADMS screen is composed of several elements:

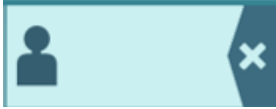
- User information
- Patient information
- Protocol zone
- Archive database access
- Preview zone
- Tool bar



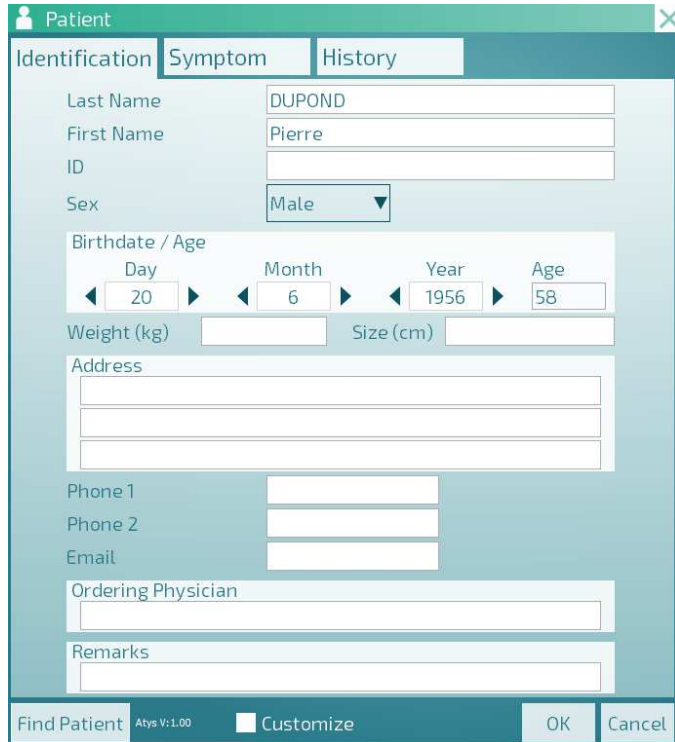
Icon	Name	Function
	User	Click on user information to access user file to add or edit current user.
	Patient	Click on patient information to access patient file to add a new patient.
	Patient	Click on patient information to edit the current patient file.

	Patient	<p>Click on the cross to close current patient session or archive. No new patient can be input, no new archive can be displayed until the current patient session or archive is not closed.</p>
	Archive	Click on archive button to open archive database
	Protocol list	Select suitable protocol to perform examination
	Restore	Use Restore button in case last examination has been unexpectedly lost
	Page up / Page next	Use left/Right arrows to go to previous or next page in preview
	Print	Click on print icon to print out all pages displayed in preview
	Zoom +/-	Click on zoom icon to adjust zoom level
	Configuration menu	Click on configuration icon to access configuration menu
	Close	Click on close button to exit ADMS application
		<p>Click on this button to add to the current examination report:</p> <ul style="list-style-type: none"> • a comment • pictures
		To add pictures in the current examination report
		To add a comment in the current examination report

8.2 Patient file

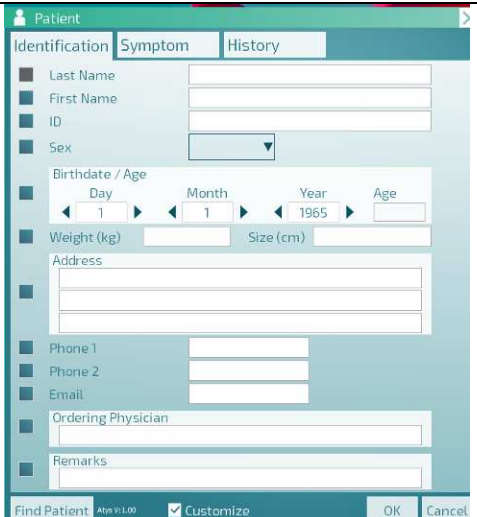

	Patient	Click on patient information to access patient file to add or edit current patient
		Click on the cross to close current patient session or archive

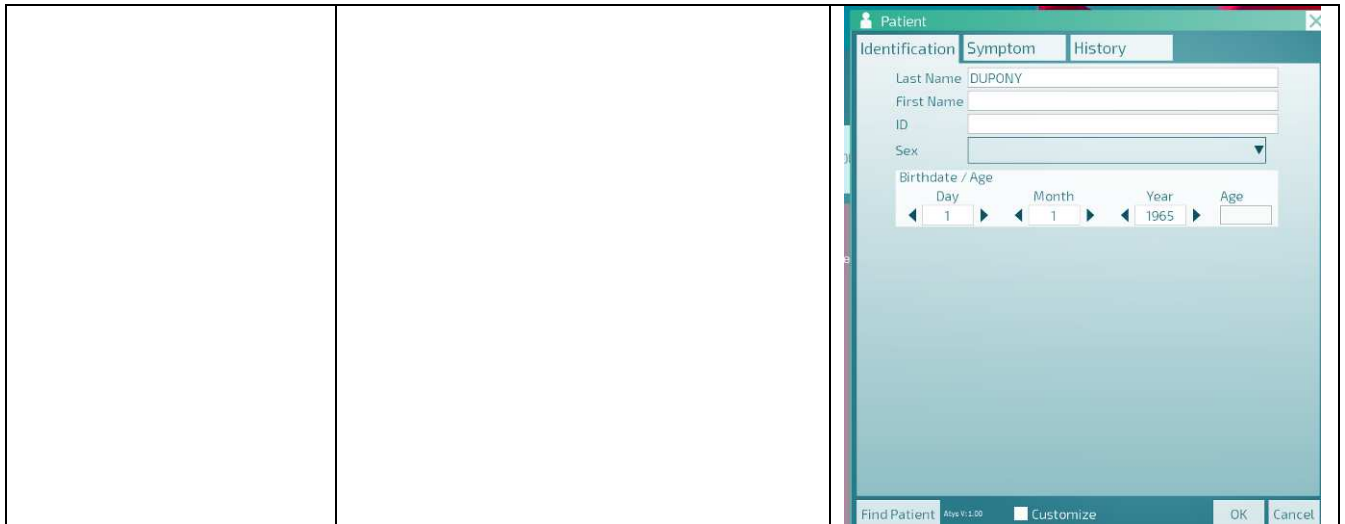
8.2.1 Identification



Please note that for TCD-X application, one of the following fields is requested.

- Last name (up to 30 characters)
- ID (Identification number)

Find Patient	Find the patient information in the Archives
<input type="checkbox"/> Customize	
	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;">  <p>The field is displayed: <input checked="" type="checkbox"/></p> <p>The field is not displayed: <input type="checkbox"/></p> </div> <div style="width: 48%;">  </div> </div>

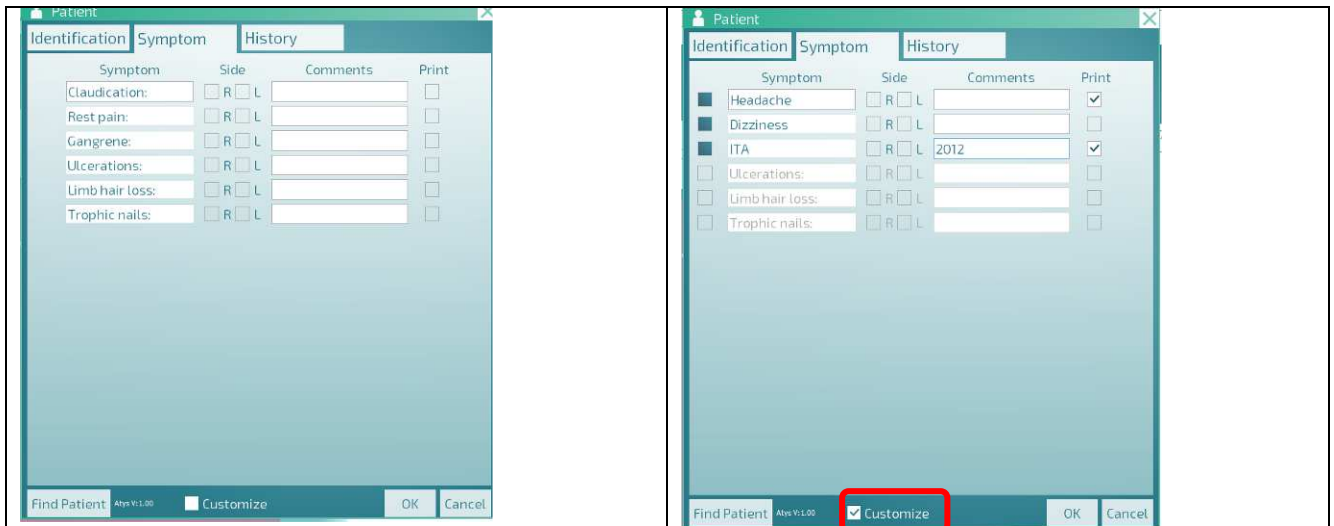


The patient file will be associated to the examination when examination is saved in archive database.

It is possible to create new patients files without any associated examination/monitoring files. In the Archives, the patient files are identified with the following type: PATIENT EDIT.

Lastname	Firstname	Birthdate	Sex	User Name	Examinati Date	Type	Protocol Name	File Name
jkjk		1/1/65		Atys	6/20/15 3:	PATIENT EDIT		jkjk_20062015_150912.adms
54353		1/1/65		Atys	6/20/15 3:	PATIENT EDIT		54353_20062015_150834.adms
jkjk		1/1/65		Atys	6/20/15 3:	PATIENT EDIT		jkjk_20062015_150757.adms
		1/1/65		Atys	6/20/15 3:	PATIENT EDIT		_20062015_150735.adms

8.2.2 Symptom



Customize the symptoms for the current patient. The symptom is selected and customizable: ■.

The symptom is not selected: □.

Print Determine whether the symptom shall be printed out on the examination report.

Print

8.2.3 History

<p>Customize History for the current patient. The corresponding history item is selected and customizable: <input checked="" type="checkbox"/> .</p> <p>The history item is not selected: <input type="checkbox"/> .</p> <p>Print <input checked="" type="checkbox"/> Determine whether the history item shall be printed out on the examination report.</p>	


8.3 User file

	<p>User information on the examination report</p>
--	---

Both user information and examiner information can be set. User information corresponds to major reference physician or service. Can be common for all examiners. An examiner list can be set if several examiners are supposed to perform examinations.

	<p>Display the list (users or examiners) Click on a name for its selection</p>
--	--








8.4 Archive database

	Click on archive button to open archive database
---	--



Lastname	Firstname	Birthdate	Sex	User Name	Examination Date	Type	Protocol Name	File Name
TURLAT	Christine A		M	Atys	6/21/15 8:...	TCDX		TURLAT_Christine A_21062015_094338.adms
test	summer	1/1/65		Atys	6/21/15 8:...	PATIENT EDIT		test_summer_21062015_094043.adms
test	summer		F	Atys	6/21/15 8:...	DOPX		test_summer_2015621_9356.dop
yuyu		1/1/65		Atys	6/21/15 8:...	PATIENT EDIT		yuyu_21062015_093147.adms
trabit		1/1/65		Atys	6/21/15 8:...	PATIENT EDIT		trabit_21062015_085629.adms
turlat	christine		M	Atys	6/21/15 8:...	TCDX		turlat_christine_21062015_084408.adms
turlat	christine	1/1/00	M		10/14/14 1:...	DOPX		turlat_christine_20141014_124726.dop
TEST chr	1102014-1	3/18/61	F		10/1/14 10:...	DOPX		TEST chr_1102014-1_20141001_104618.dop
DUPONT	Pierre	1/1/00	M		6/3/14 10:...	DOPX		DUPONT_Pierre_20140603_103058.dop
turlat	christine	3/18/61	F		4/29/14 5:...	DOPX		turlat_christine_20140429_170110.dop
TURLAT	Christine A	3/18/25	M		3/31/14 11:...	DOPX		TURLAT_Christine A_20140331_112458.dop

Archive database allows user to access all available archives in a given directory. Several fields are displayed in the archive database. Sorting can be performed for each one of these fields.

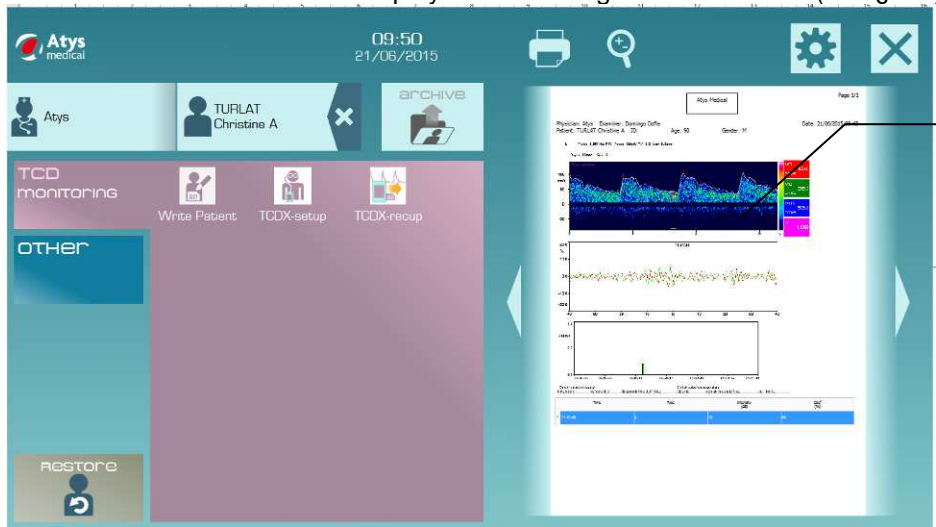
Icon	Function
	Selection of archive directory; this directory will be used for TCD-X data recuperation. All the monitoring files will be placed automatically in this directory.
	Restore current archive database.
	View examination. By clicking on this icon (same as double-click on examination), the corresponding archive is opened.
	Display selected patient data file.
	Give access to sorting menu.
	Move selected examination(s) to another folder.
	Copy selected examination(s) to another folder.

	Delete selected examination(s).
---	---------------------------------

The following files can be found in the archive database:

TYPE	Description
PATIENT EDIT	Patient file only
DOPX	Raw Doppler signal from TCD-X recording. It is advised to store safely the DOPX files.
TCDX	Doppler signal with saved analysis results. This file generated is generated by ADMS after results have been saved in monitoring software.
TCDM	Extract of a DOPX or TCDX file

A double click on a TCDX file displays the following screen: Preview (see § 8.7)

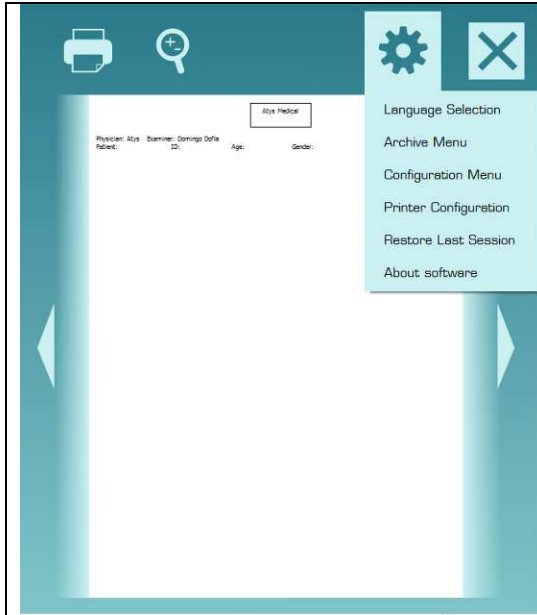


Single or Double click
(according to Device
Configuration) on a
curve, a spectrum or a
graph to display

A double click on a DOPX file displays directly the monitoring software screen.



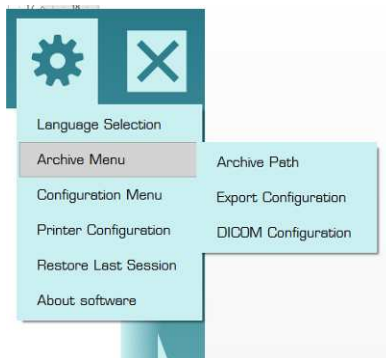
8.5 Configuration menu




This configuration menu allows the user to:

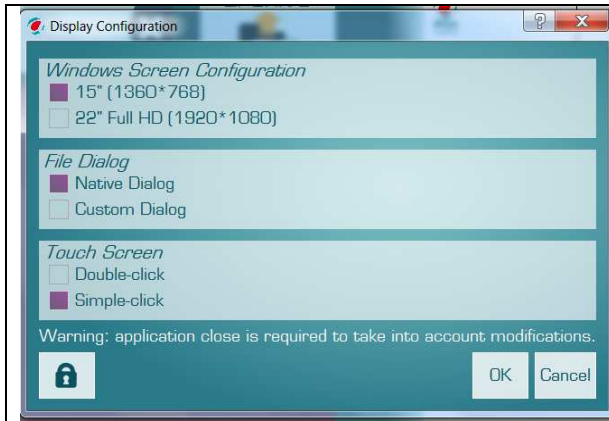
- Select language
- Set archive folder path
- Save/load user's protocol configuration
- Set printing parameters
- Restore Last session
- View current software version

8.5.1 Archive Menu



Archive Path	Selection of the folder where the archives (DOPX, TCDM, TCDX and PATIENT EDIT files) are stored
Export Configuration	 <p>Determine whether and where the examination reports in ODT or PDF format are stored.</p> <p>The corresponding examination report is stored in the input folder: <input checked="" type="checkbox"/></p> <p>The corresponding examination report is not stored: <input type="checkbox"/></p> <p>The examination report is exported when ADMS software is closed or when the patient session is closed.</p>

8.5.2 Configuration menu



Selection of the size & resolution of the screen

For browsing in your folders, you can chose to use the native Explorer or customized Explorer. Please note that for touch screen interface (without keyboard), it is advised to select Custom Dialog.

You can choose a Single-click or a Double click to open a protocol or to display the monitoring software screen. This is choice is only applicable on protocol zone and preview of the ADMS welcome screen. Elsewhere, unless otherwise specified, it is the single click that is effective.

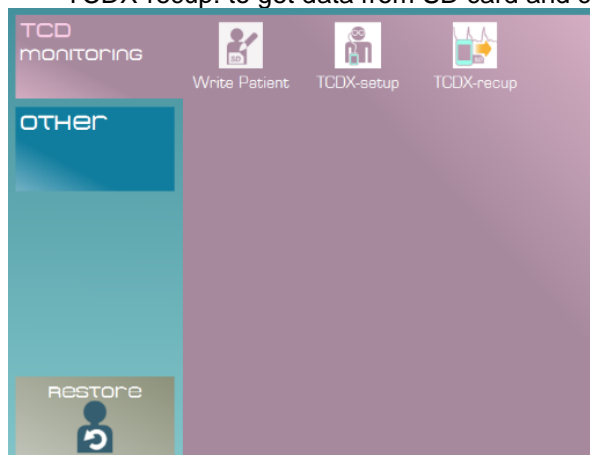
8.5.3 Printer configuration



8.6 TCD-X protocols

3 protocols are needed to use TCD-X device:

- Write Patient: to write patient information on SD card and prepare SD card for use in TCD-X.
- TCDX-setup: to set Doppler parameters, adjust Doppler signal and start recording.
- TCDX-recup: to get data from SD card and create an archive in current database folder.



To launch a protocol, click (or double click see § 8.5.2) on the corresponding icon.

8.7 Preview

Preview displays a preview of the examination report.

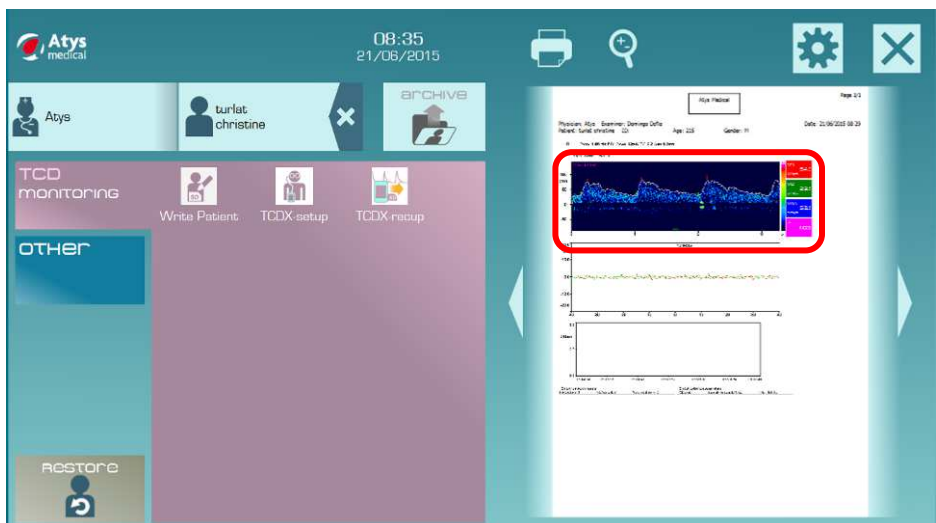
After saving the analysis results in the monitoring software (tcdX4), the report preview is displayed in ADMS welcome screen.



Preview of the examination report

Icon	Function
	Use left/Right arrows to go to previous or next page in preview
	Click on print icon to print the examination report as displayed in preview. Examination can be printed out and exported in ODT and/or PDF (see file export configuration in the main configuration menu).
	Click on zoom icon to adjust zoom level

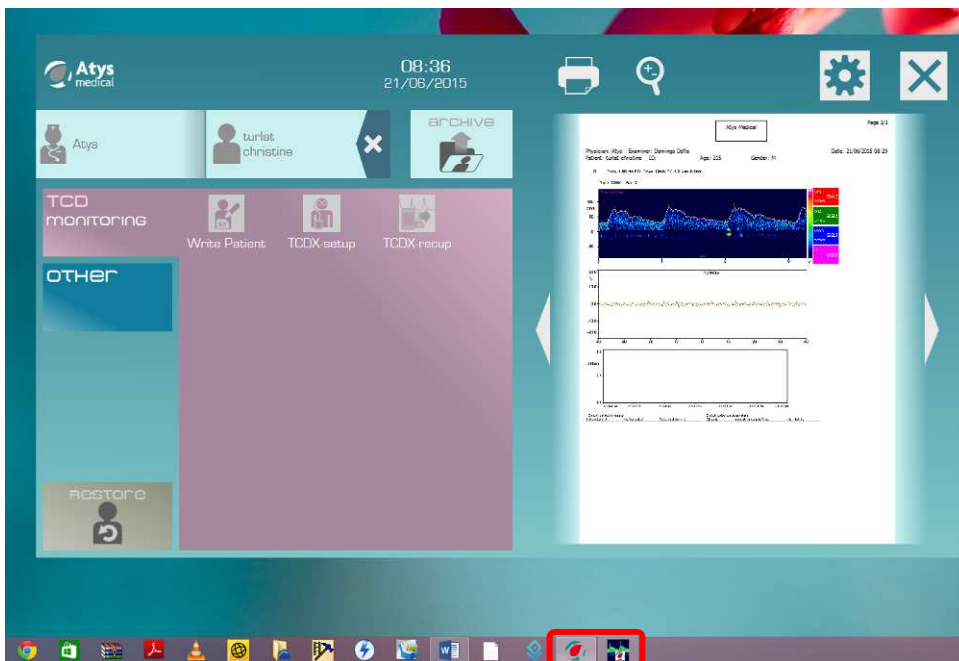
By clicking (or double clicking see § 8.5.2) on an image in the preview, the corresponding monitoring software is automatically opened for archive visualization or edition.



The following screen is then displayed.



Be careful! If a double-click is done instead of a simple clic, the monitoring software screen might be hidden. Only ADMS remains, but no action is available.



	<p>Click on this icon to display the monitoring software (tcdX4)</p>
--	--

Monitoring software shall be closed to retrieve the ADMS welcome screen functions.

9 Adjustment and start of the monitoring

Click on the following icon to reach main ADMS screen.



9.1 Preparing the SD card for recording of TCD-X data

9.1.1 Generalities

The TCD-X module uses specially prepared SD cards for recording the Doppler data.

Besides the installation SD card, two SD cards are delivered with the TCD-X, both pre-formatted, ready to be used in TCD-X device.

Do not write or delete anything on formatted cards (this would corrupt the special formatting required for use in TCD-X module).


Should you need new SD card please contact atys at atys@atysmedical.com.

The TCD-X unit cannot create files by itself, it can only write on a SD card in a specially prepared file named TCD_01.DOP. The content of this file is overwritten every time a new recording is started after a power down/up of the unit and a new initialization of the SD card (see § 9.1.2).

Before the recording of any monitoring session on an already formatted SD card, patient data must be written (see § 9.1.2).

9.1.2 Writing patient name or identification number

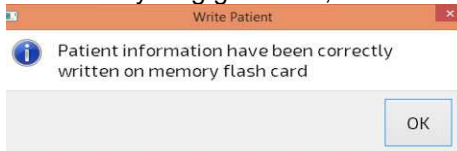
Insert provided Atys TCD-X card in PC reader.

	<p>Click on the patient icon to input the patient data. One of the following data is requested:</p> <ul style="list-style-type: none"> • Name • ID
---	--

Once the patient data are input, click on the following icon to write patient information on TCD-X card, and prepare card for use in TCD-X device.



When everything goes well, the following message is displayed.



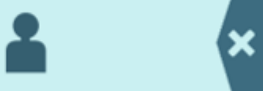
NB: this action is mandatory!!! If not, data recorded on TCD-X device might be lost...

9.1.3 Formatting a SD card

This formatting has not to be performed at each use of the TCD-X.
It has to be performed on a new SD card or when the SD card has been corrupted.

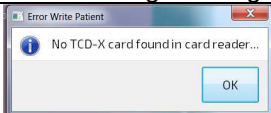
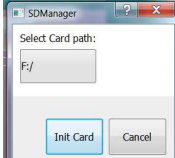
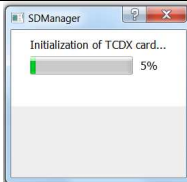
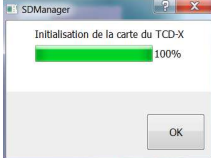

Insert the SD card in PC reader.

The SD card must be emptied.
If there is a TCD_01.dop file, it must be deleted.

	<p>On ADMS welcome screen, click on the patient icon to input the patient data. One of the following data is requested:</p> <ul style="list-style-type: none"> • Name • Or ID
---	---

Once the patient data are input, click on the following icon to write patient information on TCD-X card, and prepare card for use in TCD-X device.



The following messages are displayed	Click on
	OK
	Init Card
	
	OK
	OK

9.2 Inserting SD card in the TCD-X module

Once the patient data are written on the SD card, get the SD card out of the PC.
Insert the SD card in the TCD-X module taking care of the proper orientation of the SD card.



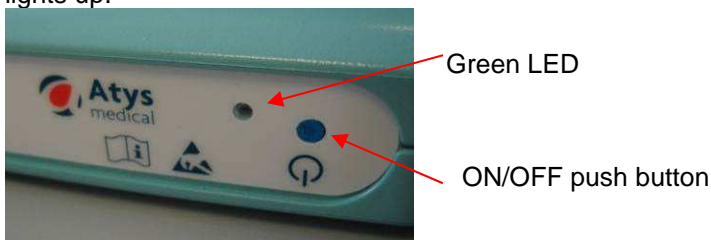
9.3 Connections



Connect the TCD-X module to the PC with the USB cable.
Connect the probe on the TCD-X.

9.4 Switch on the TCD-X module

Press on the ON/OFF push button of the TCD-X module with a thin point for roughly 2 s. When the green LED comes on, release the pressure on the push button. The TCD-X is properly switched on when the green LED lights up.



9.5 Start the TCDX setup software

The SD card is in the TCD-X, the TCD-X is connected to the OC and switched on.

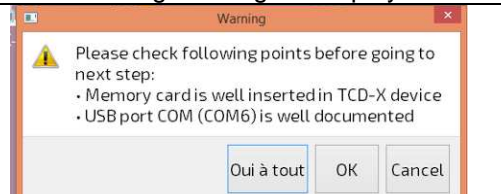
On ADMS welcome screen, click on



to start the TCD-X software (Doppler software)

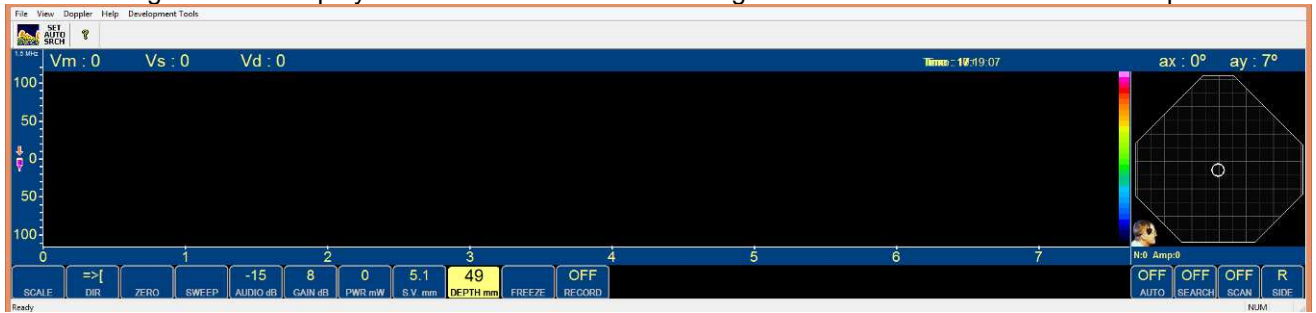
The setup software is then displayed.

The following message is displayed:

	<ul style="list-style-type: none"> • Check that the SD is well inserted into the TCD-X. • Note the number of the USB port COM (here it is 6). It will be needed. • Click on OK <p>Then refer to §9.5.1 or 9.5.2.</p>
---	---

9.5.1 Connection problem

The following screen is displayed. This screen is fixed. Nothing moves on it. There is a connection problem.



Check that the number of the USB port COM is the one indicated in the previous Warning box (here 6). Click on Doppler and on Options

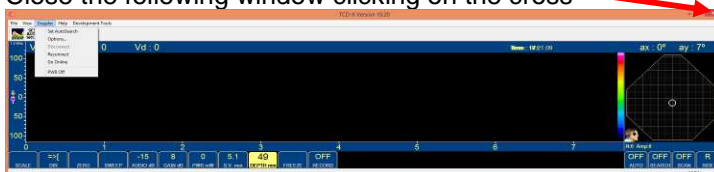


The following dialog box is displayed.

Change the number of the USB port COM as indicated here

Click on OK

Close the following window clicking on the cross

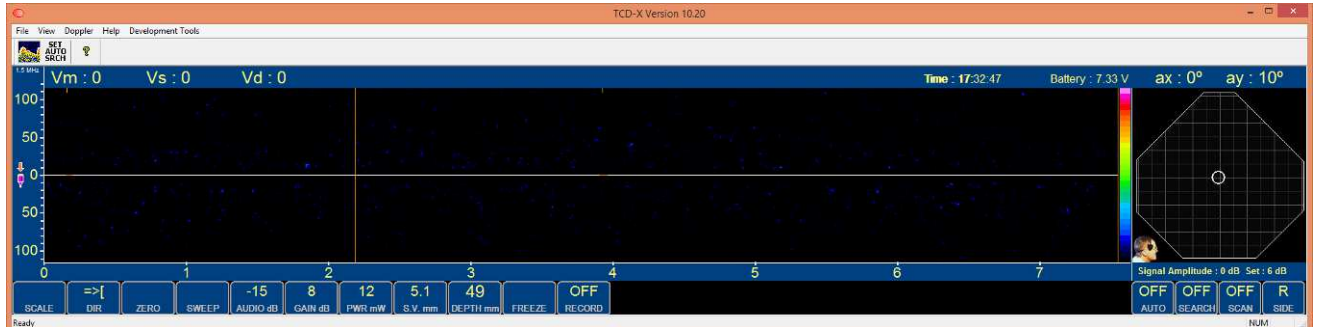


On ADMS welcome screen, click on



9.5.2 Connection is well established

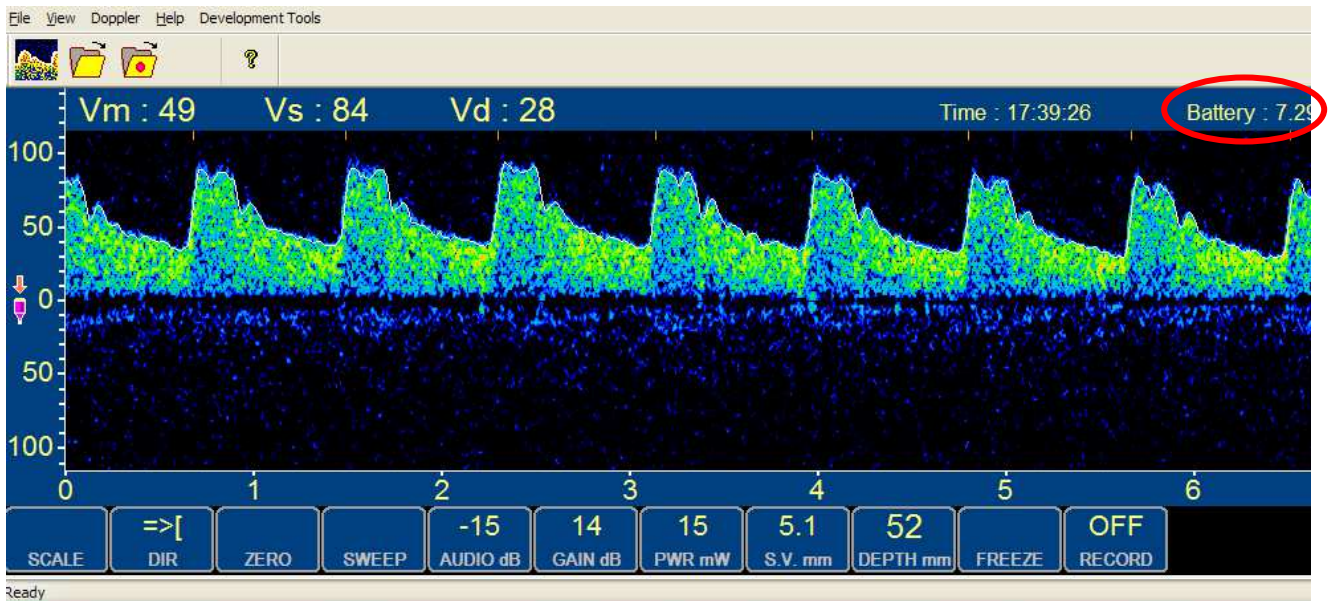
The following screen is displayed. The yellow vertical cursor moves. The screen is swept.



The Doppler module is functional.

9.6 TCD-X setup software generalities

The TCD-X program is the Doppler control software. It is used to set up the system for monitoring. It is assumed that the operator has some experience with Transcranial Doppler (TCD) instruments and their operation (a TCD teaching program can be downloaded from www.transcranial.com).



The above figure shows the spectral display and controls.

For the Doppler parameters, changes are made by clicking on the upper (higher setting) or lower (reduced setting) half of the buttons.



The buttons with a toggle function (DIR, FREEZE and RECORD) respond equally to clicks in both halves.

Alternatively to mouse clicking, the right/left arrows of the keyboard can select the desired button and the up/down arrows will increment/decrement/toggle the function.

Note that in the Online mode, the AUDIO button controls the audio volume of the miniature loudspeaker on the TCD-X module; therefore use Windows audio volume controls (found in the tray lower right) to set the audio volume of the PC audio system.

The PWR control selects the power supplied to the ultrasonic burst transmitter. It is calibrated in mW transducer input power. The actual output power is lower due to losses in the conversion from electrical to acoustic power. The voltage to the burst transmitter amplifier is limited to 30 Volts. It is recommended to use less than 75mW input power for extended monitoring (see § 9.7 for recommendations for emboli monitoring).

9.7 Adjustment of the Doppler parameters and of the sound volume

The TCD-X software can automatically search the signal from the middle cerebral artery. It automatically changes the probe orientation.

Before starting this scan it is advised to adjust the Doppler parameters as follows:

- Increase the power (PWR) ($\geq 50\text{mW}$)
- Increase the size of the sample volume (SV) ($\geq 9\text{ mm}$)
- Adjust the depth to 49 mm or 52 mm.

These parameters make easier the first scan.

For the emboli detection monitoring, these parameters will have to be set to the following values when the signal is found and before starting the recording of the signal.

- Decrease the power (PWR) ($<30\text{mW}$).
In clinical practice, we advise investigators to minimize the background signal by using a low power and low gain to allow the strong embolic signal to be completely displayed within the dynamic range of the instrument.
- Decrease the sample volume (SV) ($=5.1\text{mm}$)

The following table summarizes these different adjustments.

Parameter	Description	Default value when the software is started	Advised value for SCAN (signal research)	Advised value for emboli detection (§ Erreur ! Source du renvoi introuvable., Erreur ! Source du renvoi introuvable.)
SCALE	Velocity scale (cm/s)	100 cm/s	150 cm/s	150 cm/s
DIR	Flow direction	+	+ (ACM)	+ (ACM)
ZERO	Zero line	In the middle of the spectrum window	In the middle of the spectrum window	In the middle of the spectrum window
SWEEP	Sweep velocity	6s	6s	6s
AUDIO	Sound volume on the TCD-X module	-15dB	0dB	0dB
GAIN	Spectrum gain	Last selected value	14dB	14dB
PWR	Power	25mW	$>50\text{mW}$	25mW
S.V.	Sample volume (gate)	5.1mm	9 mm	5.1mm A short S.V. enhances the EBR
DEPTH	Exploration depth	49mm	49 →51 mm	49mm →51 mm (depends on the patient)

DEPTH

Try different Depth settings to get the cleanest signal. Figure in § 9.6 is an example of a clean signal where the intensity is higher in the upper part of the Doppler spectrum than in the lower part. This is ideal. Avoid recording in or very near to where the ICA bifurcates into the MCA/ACA.

SCALE

It should be set so that the systolic velocities are about 2/3 of full scale (see Figure in § 9.6).

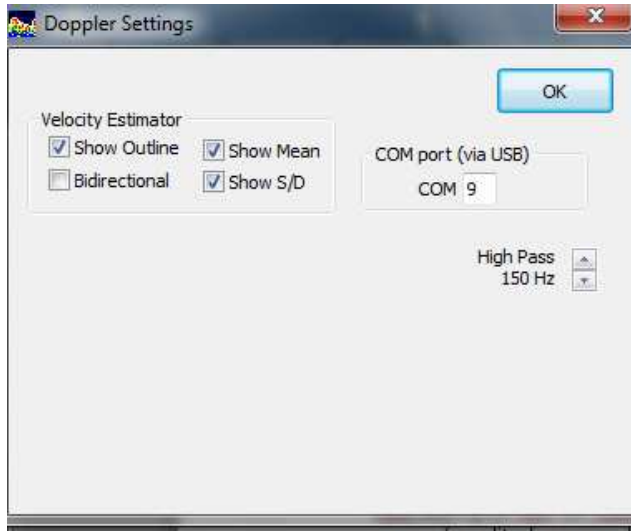
SOUND

Do not confuse the sound volume on the PC and the sound volume on the TCD-X module. The sound volume on the PC is switched OFF by right-clicking outside the TCD-X software window. The sound on the PC is switched ON by right-clicking on the software window. Do not left-click on the spectrum window otherwise the acquisition is frozen. When the acquisition is frozen, a sound can be heard. It is the previous recorded sound that is continuously played back.

The sound volume on the PC is adjusted as for any other applications.

9.8 Options for online operations

Some Doppler settings for Online operations (the TCD-X module is connected to the PC) can be selected using the **Doppler | Options** menu item.



The check-boxes as shown are set up for normal TCD use.

Not recommended is the **Bidirectional** mode.

Show outline	Display of the spectrum envelop
Show Mean	Display of the mean velocity index
Show S/D	Display of Vs/Vd index
Bidirectional	Display of bidirectional spectrum
High pass	Value of the high pass filter

9.9 Probe Control Software

9.9.1 Description



The transducer is controlled in two axes: **ax** is the posterior — anterior tilt angle and **ay** the superior — inferior tilt angle, (see the figure). The area inside the octagonal is the possible combination of angles that can be reached with the current servos and geometry. The white circle indicates the sample volume. The probe is tilted and the sample volume moved by clicking inside the octagonal.

The **SIDE** button toggles between right and left temporal insonation.

A **SCAN** of the region is started by the appropriately named button. The scan grid is chosen to give a rapid overview of possible signals, and the dots on the map indicate signal strength, using the same scale as for the spectral display (blue for weak signal, green, yellow, orange, red for strong signal).

The scan is typically followed by a search in the region where the best signal is found. Further searches around the current sample volume position can be started by clicking the button **SEARCH**. This may be done repeatedly.


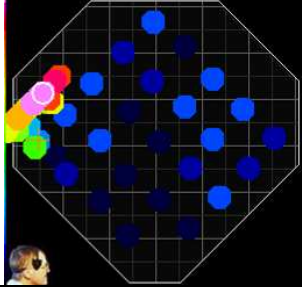

9.9.2 Interpretation of the position of sample volume

9.9.2.1 Posterior – anterior tilt angle

For this explanation, it is consider that the probe is on the right side.

For a probe on the left side:

- Posteriorly should be read Anteriorly and vice versa.
- Eye should be read ear and vice versa.

<p>The sample volume is on the right side boundary of the octagonal. The probe is tilted anteriorly, it is oriented towards the eye.</p>	<p>The sample volume is on the left side boundary of the octagonal. The probe is tilted posteriorly, it is oriented towards the ear.</p>	<p>The sample volume is nearly in the centre of the octagonal. The probe angles are small. The probe position is optimal.</p>
		
<p>If you want to try to get a sample volume in the centre of the octagonal, slide the probe casing a little (few millimetres only) along the frame arm in the groove of the fixation plaque: towards the eye towards the ear.</p>		



9.9.2.2 Superior - inferior tilt angle

The sample volume is on the lower boundary of the octagonal. The probe is tilted downward	The sample volume is on the upper boundary of the octagonal. The probe is tilted upwards	The sample volume is in the centre of the octagonal
If you want to try to get a sample volume in the centre of the octagonal, move a little the probe casing (few millimetres only) vertically:		
downwards	upwards	



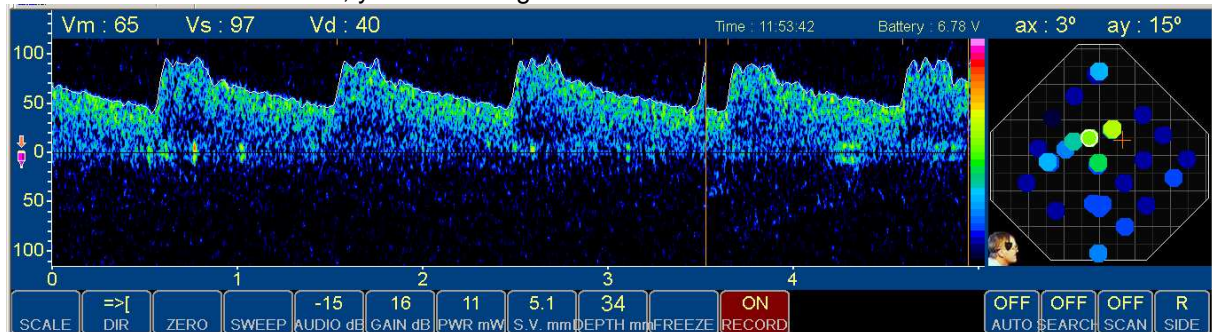
9.9.3 Scan for the Doppler signal

9.9.3.1 Global scan



Press on this button to start the SCAN

When the scan is successful, you should get screen as follows.



When the scan fails to find a signal, there is no displayed spectrum and all the dots on the octagonal are blue. In this case, the probe position must be changed before starting a new SCAN.

If available, a conventional handheld Doppler probe can be used to determine the position of the **'ultrasonic windows'** in the individual patient. This may facilitate the positioning of the probe casing on the spectacle frame. If not available, try positioning the probe casing at various locations (posterior, middle and anterior window) just above the zygomatic arch, and perform a SCAN at each location.

9.9.3.2 Doppler parameters adjustment

After a successful global scan, change slightly the depth value (increase and decrease it by one or two mm in order to determine the proper depth for optimal signal).

9.9.3.3 Local search



When the SCAN is successful, press on this button to start the **SEARCH** that is a search only in the region where the best signal is found

9.9.3.4 Manual scan

It is possible to perform a manual scan or some manual adjustments by clicking with the mouse inside the octagonal: the probe tilts with the new requested orientation.

9.9.3.5 Final Doppler parameter adjustment

For emboli detection only.

Once the Doppler signal has been found, it is advised to:

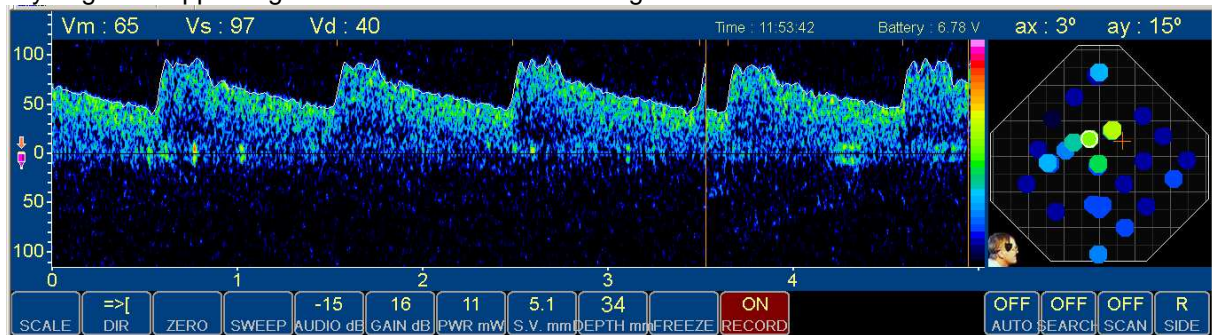
- Decrease the sample volume to 5 mm
- Decrease the power

However, the quality of the signal must remain good enough to allow recording over several hours.

So a compromise must be found. If a decrease of the sample volume results in a poor Doppler signal, then the sample volume must not be decreased.

It is the same for the power.

Try to get a Doppler signal that looks like the following one.

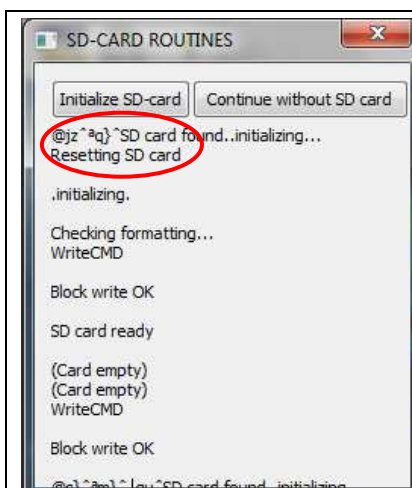


9.9.4 Recording

When an adequate signal has been found, and the Doppler parameters have been set according to § 9.7 and § 9.9.3.5, click on the following button.



A window with messages is open and closed automatically. The RECORD button becomes red

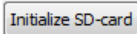


Example of the window that is opened automatically.

If the window is not closed automatically, do not close it clicking on



Click on



If the windows does not close: click on Initialize SD-card again.

After two unsuccessful attempts to close this window, close it clicking on the

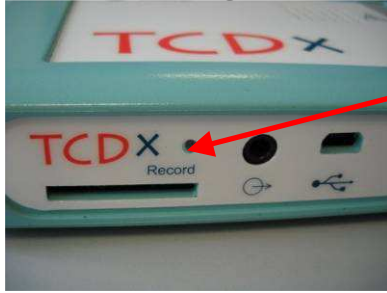


Rewrite the patient data on the SD card as explained in § 9.1.2

If the RECORD button is not red, click again on the RECORD button.

If the RECORD button has not turned red, the recording does not work. Nothing is recorded on the SD card.

When the recording runs, the orange LED 2 flashes.



Orange LED

9.9.5 Disconnection of the TCD-X module from the PC

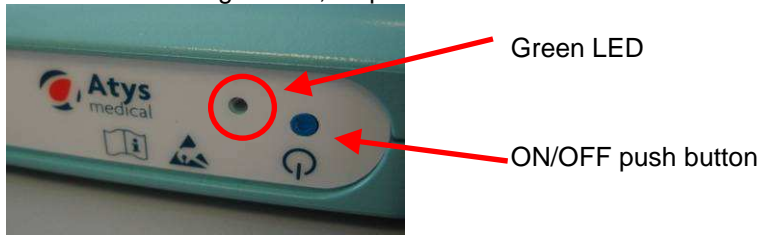
Once the recording has well started, disconnect the TCD-X module from the PC (USB cable).
The TCD-X module can be placed in the cross body carry bag.



10 Stop of the recording and transfer of the Data from SD-card to the PC

10.1 Stopping the recording

Once the recording is over, stop the TCD-X module with the ON/OFF push button.



Push on the ON/OFF button during 8/10s until the LED is switched off.

10.2 Transferring of the Data from SD-card to the PC

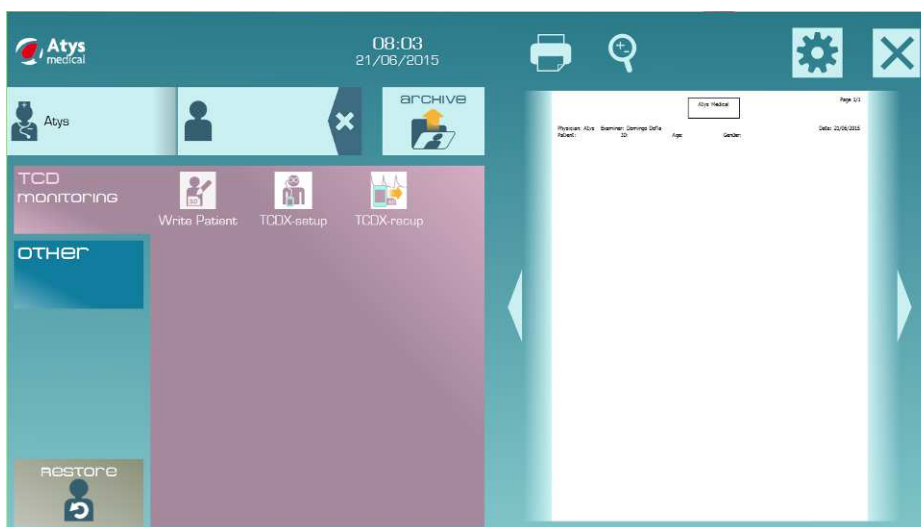
Once the TCD-X module is switched off, remove the SD card from the TCD-X module by pressing on the card.



Insert the SD card in the PC drive.

Windows displays a box about the analysis of the SD card. Click on « Continue without analyzing »

On the PC, click on the following icon to reach main ADMS screen.



Click on



to copy the Doppler file to the Archive folder (see § **Erreur ! Source du renvoi introuvable.** et 8.5.1)

The monitoring file (DOPX) is placed in the archive folder.
The analysis software (tcdX4) is automatically opened.

11 Monitoring software (tcdX4) – Emboli detection and trend analysis

TcdX4 allows analysis of transcranial Doppler data coming from TCD-X. This software gives the user the opportunity to perform spectrum/audiogram analysis, trend analysis and emboli detection. Data analysis results can be exported in several formats.

11.1 Principle of emboli detection

Emboli are particles of platelets, fibrinogen, cholesterol, fat, particles of disrupted plaque (thrombus) or gas bubbles that travel through circulation.

Emboli signals (ES) are usually high intensity and with short time duration (HITS). But some artefacts also may have similar properties.

Artifacts can be caused by patient moving the head, coughing, chewing or any movement that causes displacement of the probe (or displacement of the skin below the probe). The artifacts also cause intensity increase of Doppler spectrum which can produce similar signals as emboli.

Therefore the HITS can consist of emboli or artifact.

The EBR (Embolus to Blood Ratio) method is used to discriminate of HITS from background (normal signal).

The definition of EBR used here is the power (in dB) of spectral peak in the embolic signal above the median spectral power for the period before and after the embolus. This median is calculated from the maxima in the upper half of the spectra below the spectral envelope. The threshold can be adjusted depending on how weak signals are emboli as differing from normal spectral speckle.




The algorithm is basically built upon the recommendations published some time ago by the HITS expert group in Stroke:

Consensus on Microembolus Detection by TCD, International Consensus Group on Microembolus Detection

E. Bernd Ringelstein, MD (Chairman); Dirk W. Droste, MD; Viken L. Babikian, MD;
David H. Evans, PhD; Donald G. Grosset, MD; Manfred Kaps, MD; Hugh S. Markus, MD;
David Russell, MD; Mario Siebler, MD. Stroke. 1998; 29:725-729.

The algorithm monitors and calculates the EBR. If some signal exceeds the threshold, the algorithm checks if the signal has approximately the expected time duration (the ERD, based on sample volume length and the velocity of the embolic signal). This eliminates most voice artifacts because they are much longer. The algorithm also checks if the signal has asymmetrical increase in amplitude below the zero-line – which eliminates most probe movement and voice artifacts. It also checks if the signal has a relatively narrow peak in the spectrum – this also very useful to eliminate probe movement artifacts.

11.2 Load a DOPX or TCDX file





	Click on this icon to reach main ADMS screen.
	Click on archive button to open archive database
	Double click on the selected file to open the tcdX4 software Or click on the file and click on the opposite icon

If a DOPX file is loaded, the tcdX4 main screen is displayed.
Otherwise (TCDX, TCDM files), it is the ADMS welcome screen (with a preview of the report) that is displayed.
Click on a picture of the preview to display the tcdX4 main screen.


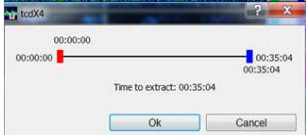







11.3 Main screen

After archive load, Doppler spectrum is displayed from beginning of monitoring. Only spectrum and audiogram can be displayed. Display of index trend requires **“trend update”** action. Display of emboli detection results requires **“emboli detection”** action.




	Header
	Doppler zone
	Scrolling bar
	On the bottom zone, can be displayed as required, by selecting corresponding tab: Trend, Emboli histogram and result table, Toolbar

11.4 Header

	<p>Menu:</p> <ul style="list-style-type: none"> • Save: save the current monitoring with the result of the analysis in a TCDX file. • Print: print out the examination report • Export: in a txt file that can be opened with Excel <ul style="list-style-type: none"> – Emboli Table: export the result table of emboli detection – Envelop Data: export of max velocity envelop and spatial mean velocity envelop. All displayed envelops are exported every 5ms, using a TAB separator. – Trend: export of the trends that are displayed in the trend window. The trend curves are exported every 1s in a text file, using TAB separator. • Export: <ul style="list-style-type: none"> – Wave Format: export a wave file in a folder specified by the user. – Extract Archive: extract a part of the monitoring file and place it in the Archives. <div style="text-align: center;">   </div> <p>The file name includes ExtractArchiveMonit1</p> <ul style="list-style-type: none"> • Help <ul style="list-style-type: none"> – ?: User manual display – About: versions of the software, firmware • Exit: close tcdX4
	<p>To display the preview of the examination report</p>
	<p>Patient name</p>
 25/10/2012 09:26:29	<p>Date and time of the monitoring</p>
 00:18:42	<p>Duration of the monitoring session</p>
<p>ARCHIVE TCD-X/test_52.dop</p>	<p>Archive pathname is displayed; if the whole path do not fit in header, use “...” before the archive name</p>
	<p>Close tcdX4</p>
	<p>Configuration menu</p>

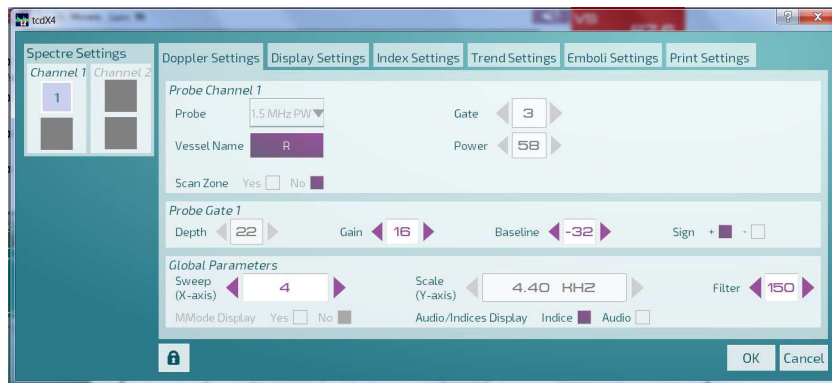
11.5 Configuration menu

	Click on this icon to reach configuration menu.
---	---

The configuration menu allows the user to adjust the following settings:

- Doppler
- Display
- Index
- Trend
- Emboli
- Print

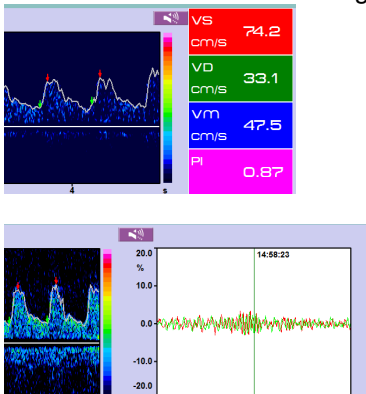
11.5.1 Doppler settings



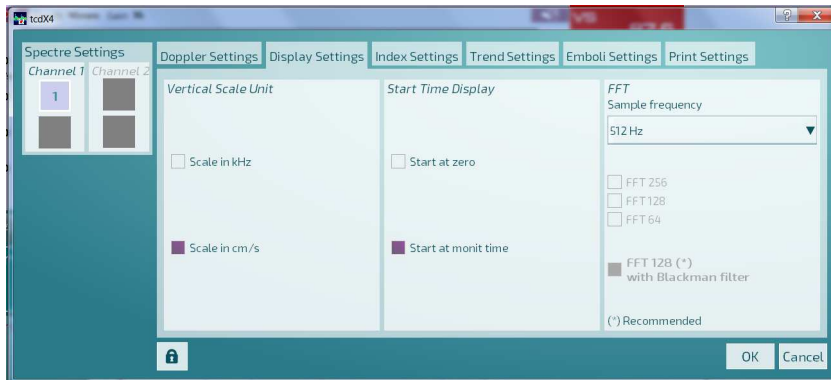
The Doppler parameters that can be adjusted are indicated by the purple colour.

For the TCD-X, the Doppler settings can be performed directly on the Doppler zone and with the Toolbar.

Most of the labels are explicit enough not to require any further explanations.

<p>Audio/Indices Display Indices <input checked="" type="checkbox"/> Audio <input type="checkbox"/></p>	<p>To specify what should be displayed beside the spectrum, either the indices or the audiogram.</p> 
---	---

11.5.2 Display settings



It is possible to choose:

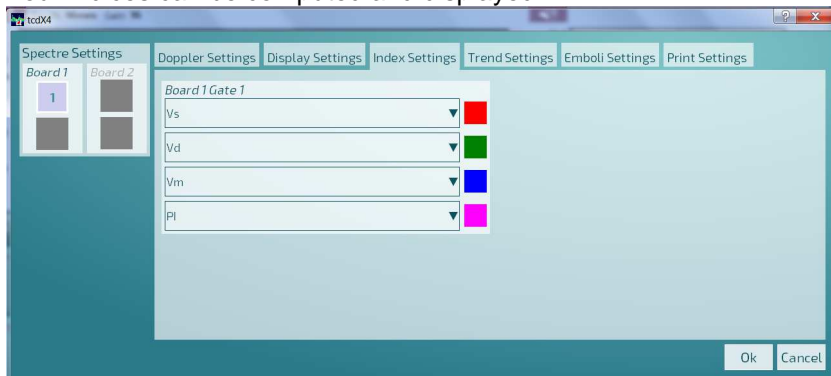
- The vertical scale unit: cm/s (velocity scale) or kHz (frequency scale).
- The start time:
 - Selecting *Start Time at 0* makes start time scale starts at 0 (ex: 00:00:00).
 - ➔ Useful if analysis is based on duration
 - Selecting Time start at begin monit allows time scale to start at the real time corresponding to the beginning of examination (ex: 15:54:28)
 - ➔ Useful if analysis is based on real time events, along day

For emboli detection with the TCD-X, the FFT adjustments must be as follows:

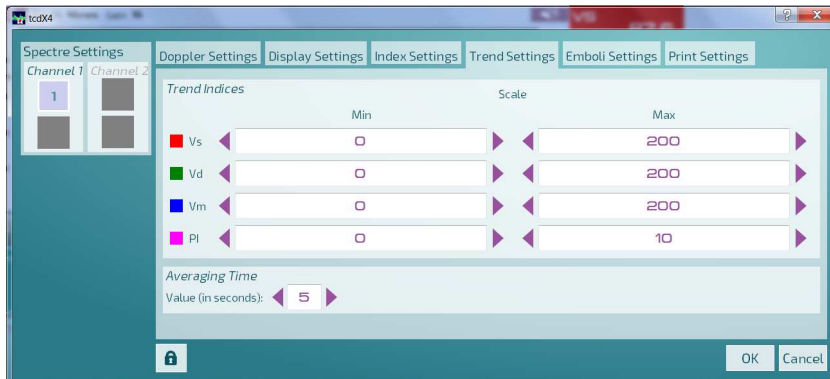
- FFT sample frequency: 512 Hz
- FFT number of point: FFT 128 with Blackman filter

11.5.3 Index settings

Selection of the indices that are displayed beside the spectrum.
Four indices can be computed and displayed.



11.5.4 Trend settings & adjustment of the averaging time

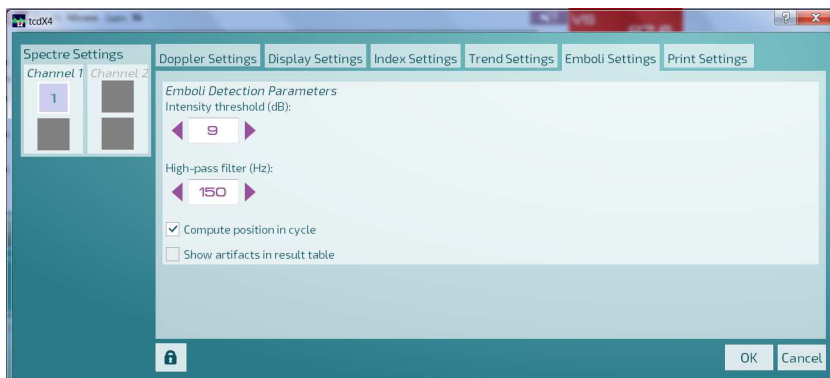


Min	Min scale value
Max	Max scale value

Four indices can be computed and drawn in trend zone at the same time.

- Adjust first numeric value to set minimum trend scale in trend zone
- Adjust second numeric value to set maximum trend scale in trend zone
- Adjust averaging time value to set suitable filter parameter on trend curves: the trend of an index represents the time evolution of the averaged value of this index. The average is calculated over the last “Averaging time” seconds.

11.5.5 Emboli settings



It is advised to adjust the emboli settings as follows:

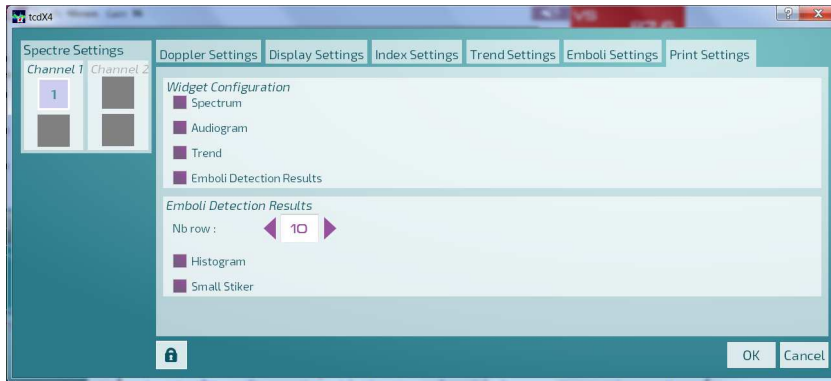
- Intensity threshold: 9 dB
- High-pass filter: 150 Hz.

The **High Pass filter** is applied to the raw Doppler signal. Its purpose is to reduce distortion due to “knock” and movement artifacts. The filter is a 4th order digital Butterworth with adjustable cutoff frequency (defined by 3dB attenuation). The cut-off frequency can be set using the “spin” control. A setting of 140-200 Hz is recommended for emboli detection. Initial setting is 150 Hz.

<input checked="" type="checkbox"/> Compute position in cycle	<p>To display the position of each emboli in the heart cycle. Pos is for position. Each heart cycle is divided in 4 sectors (see § 11.7.3.3)</p>	<table border="1"> <thead> <tr> <th>Time</th> <th>Type</th> <th>Intensity (dB)</th> <th>Pos</th> <th>Coef (%)</th> </tr> </thead> <tbody> <tr> <td>14:49:54</td> <td>E</td> <td>24</td> <td>2</td> <td>77</td> </tr> <tr> <td>14:37:01</td> <td>E</td> <td>11</td> <td>1</td> <td>74</td> </tr> <tr> <td>14:40:52</td> <td>E</td> <td>09</td> <td>1</td> <td>72</td> </tr> <tr> <td>14:49:28</td> <td>E</td> <td>09</td> <td>3</td> <td>72</td> </tr> </tbody> </table>	Time	Type	Intensity (dB)	Pos	Coef (%)	14:49:54	E	24	2	77	14:37:01	E	11	1	74	14:40:52	E	09	1	72	14:49:28	E	09	3	72
Time	Type	Intensity (dB)	Pos	Coef (%)																							
14:49:54	E	24	2	77																							
14:37:01	E	11	1	74																							
14:40:52	E	09	1	72																							
14:49:28	E	09	3	72																							

Time to perform emboli detection might be slightly longer if this option is checked...

11.5.6 Print settings



To define which elements should be printed out in the examination report.

<input checked="" type="checkbox"/>	Selected
<input type="checkbox"/>	Unselected
Nb row	Number of rows of the detected emboli table that is printed in the examination report.
Small Sticker	Pictures of emboli can be included in the report. They are selected by the user on the tcdX4 screen.

Widget configuration

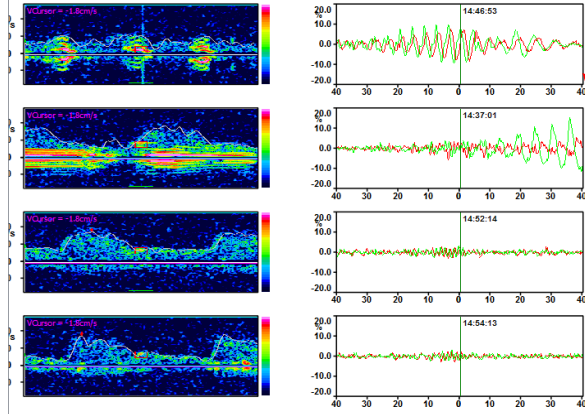
- Spectrum
- Audiogram
- Trend
- Emboli detection results

Emboli detection results

Nb row :

- Histogram
- Small Sticker

14:48:54	E	24	2	77
14:37:01	E	11	1	74
14:40:52	E	09	1	72
14:49:26	E	09	3	72
14:52:15	E	11	3	72
14:54:14	E	09	3	72
14:58:23	E	10	3	72
14:47:10	E	09	2	86
14:45:51	E	14	4	55
14:38:07	E	12	4	57



The spectrum displayed on the top of the report is the spectrum relative to the emboli with the blue marker on.

Emboli detection results

Nb row : ◀ 10 ▶

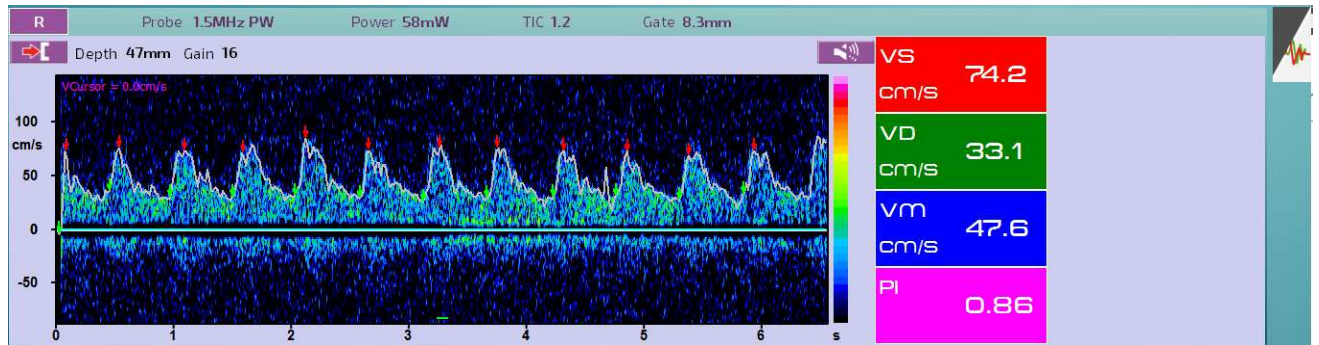
- Histogram
- Small Stiker

Number of rows of the emboli detection table printed on the examination report.

Time	Type	Intensity (dB)	Pos	Coef (%)	Print
14:48:54	E	24	2	77	✓
14:37:01	E	11	1	74	✓
14:40:52	E	09	1	72	✗
14:49:26	E	09	3	72	✗
14:52:15	E	11	3	72	✓
14:54:14	E	09	3	72	✓
14:58:23	E	10	3	72	✗

The small stickers are selected on the tcdX4 screen

11.6 Doppler zone

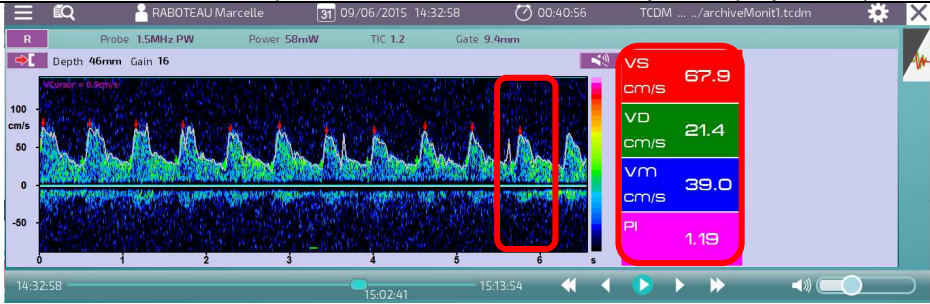
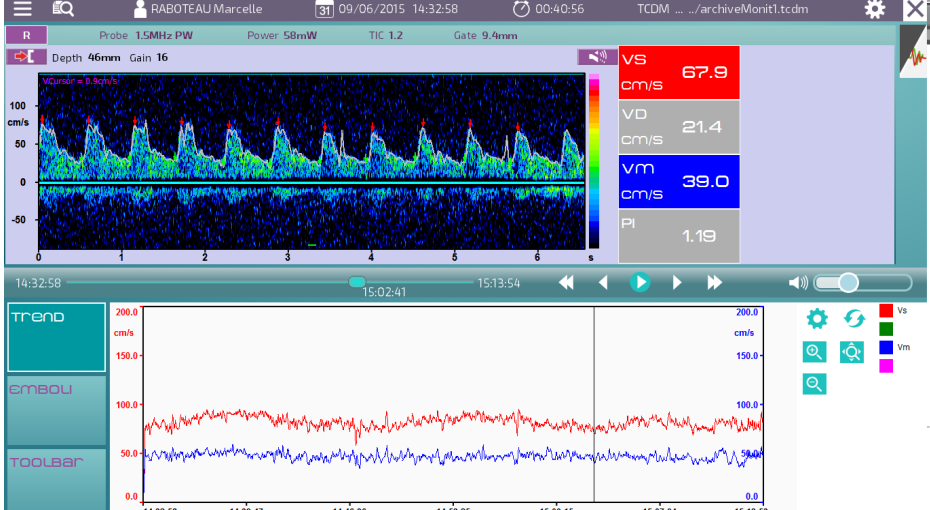


The Doppler zone is composed of several elements:

- Spectrum zone
- Index or audiogram zone

	Functionality	Description
	Vessel name	Click on this key to input the vessel name.
	Probe	Display probe data
	Power/TIC	Probe power value during the recording
		Thermal cranial index value
	Gate	Gate or sample volume value during recording
		Click on this key to invert spectrum display with regards to zero line. Indicate the flow direction of the blood flow corresponding to the spectrum displayed above the zero line: The blood flows towards to the probe The blood flows away from the probe
	Value of depth during monitoring	
	Gain value. Can be adjusted with Toolbar	
	velocity-cursor can be moved using trackball or Up/down keys to indicate velocity (cm/s or kHz)	
	Click on this key to display the audiogram beside the spectrum. Audiogram is useful for emboli detection.	
	Click on this key to display the indices beside the spectrum.	

11.6.1 Indices

Functionality	Description
Index value	<p>The index value corresponds to the last valid cardiac cycle displayed in spectrum zone.</p>  <p>The systolic peak is marked with a red arrow, whereas the diastolic position is marked with a green arrow. These 2 arrows should be well positioned to get reliable indices.</p>
Trend	<p>When an index is displayed on a colour background, it means that its trend is drawn in the trend window.</p> <p>Click on the index to switch ON/OFF the colour background.</p> <p>On the below example two indices are displayed on a colour back ground. Their trends are drawn in the trend window.</p> 

11.6.2 Scrolling bar



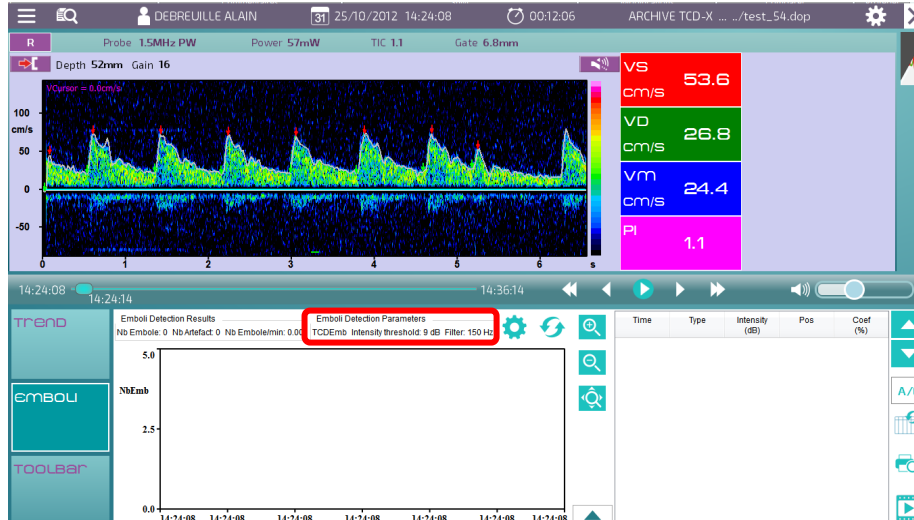
	Time of the beginning of the monitoring
	Time relative to the displayed spectrum
	Time of the end of the monitoring
	Fast scrolling of the buffer content of the spectrum
	Scrolling of the buffer content of the spectrum
	Start play back of the recorded signal
	Stop play back
	Sound volume adjustment

11.7 Emboli detection zone





Click on this key to display the emboli detection screen

11.7.1 Before emboli detection



Check and adjust if necessary the emboli detections parameters.
The emboli detection parameters are displayed on the top of the emboli detection window.
It is advised to adjust the emboli detection parameters as follows (see § 11.5.5):

- Intensity threshold: 9 dB
- High-pass filter: 150 Hz.

	To adjust the emboli detection parameters
	To run or update emboli detection

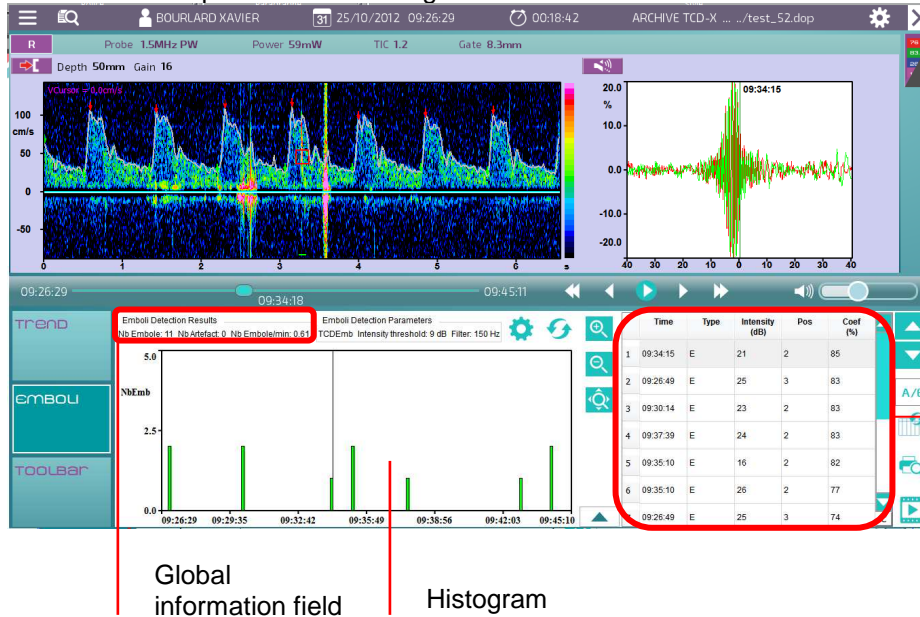
11.7.2 After emboli detection

At the end of emboli detection algorithm, the results are presented in:

- Global information field
- Emboli detection table
- Histogram

The tcdX4 screen shows also:

- On the spectrum window: the HITS with the focus on. It is surrounded with a red square. The spectrum is displayed cantered on the HITS.
- Beside the spectrum: the audiogram of the HITS with the focus on.



Emboli detection table able showing all the detected emboli

Global information on emboli detection results are listed below:

Emboli Detection Results
 Nb Embole: 11 Nb Artefact: 0 Nb Embole/min: 0.61

- Nb emboli = only events classified as emboli by the algorithm and/or the user
- Nb artifact = only events classified as artifacts by the algorithm and/or the user
- Nb emboli/min = number of emboli detected per minute

11.7.3 Emboli table

The emboli table shows the list of all the events suspicious of being embolic signals.

Unfortunately, no embolus detection algorithm is perfect, and we do not claim that for ours either.

The suspicious events shall be inspected by an expert. (It is not difficult acquire the skill to differentiate between artifact and emboli when the data are judged with sound, high-resolution FFT display and audiogram).

During the evaluation, about 2 seconds of the signal is played back with full quadrature sound. If the event is deemed to be a false positive (not an embolus) the **Change Status** button (A/E) is clicked, an **A** will appear and the event will be considered as an artifact.

11.7.3.1 Description

	Time	Type	Intensity (dB)	Pos	Coef (%)
1	09:34:15	E	21	2	85
2	09:26:49	E	25	3	83
3	09:30:14	E	23	2	83
4	09:37:39	E	24	2	83
5	09:35:10	E	16	2	82
6	09:35:10	E	26	2	77
7	09:26:49	E	25	3	74

By default the focus (blue cursor) is given to the first emboli in the list. Emboli focus can be changed by clicking on any of the emboli in the list or clicking on the vertical arrows beside the emboli detection table. The display is automatically updated in the Doppler zone. It is the spectrum of the emboli with the focus on that is displayed.

Default order in the table is based on confidence coefficient: events that are more likely to be emboli are displayed on top of the list (coef > 80%), events that are less supposed to be emboli are displayed at the bottom of the list (coef < 50%).

To change the classification, double-click on the top cell indicating the name of criterion based on which the sorting needs to be performed (for example Time).

Time	Type	Intensity (dB)	Coef (%)
------	------	----------------	----------

The default classification can be adjusted by the user (see §11.7.3.2)



	Emboli table configuration
	To move the cursor up in the emboli detection table
	To move the cursor down in the emboli detection table
	To change the status of an emboli to an artefact and vice versa. Emboli (E) → Artefact (A*) Artefact (A) → Emboli (E*) The symbol "*" is automatically added at the end of the type to specify that a manual change has been made in comparison with initial automatic detection. Thus, an embolus reclassified in artifact will appear as "A*", an artifact reclassified as an embolus will appear as "E*".
	To update the emboli detection table after a change of status. The artifacts will be placed at the end of the table.
	To select the emboli that shall be printed in the examination report.

Time	Type	Intensity (dB)	Pos	Coef (%)	Print	
1	09:44:14	E	10	4	50	✗
2	09:44:14	E	22	4	60	✗
3	09:42:55	E	09	2	73	✗
4	09:26:49	E	25	3	74	✗
5	09:30:14	E	16	2	74	✗
6	09:35:10	E	26	2	77	✗
7	09:35:10	E	16	2	82	✗


Time	Type	Intensity (dB)	Pos	Coef (%)	Print	
1	09:44:14	E	10	4	50	✗
2	09:44:14	E	22	4	60	✓
3	09:42:55	E	09	2	73	✓
4	09:26:49	E	25	3	74	✓
5	09:30:14	E	16	2	74	✗
6	09:35:10	E	26	2	77	✓
7	09:35:10	E	16	2	82	✗

✗ Not printed in the examination report


✓ Printed in the examination report

	To generate a video file (avi) of the selected emboli
	To scroll the content of the emboli detection table

11.7.3.2 Configuration

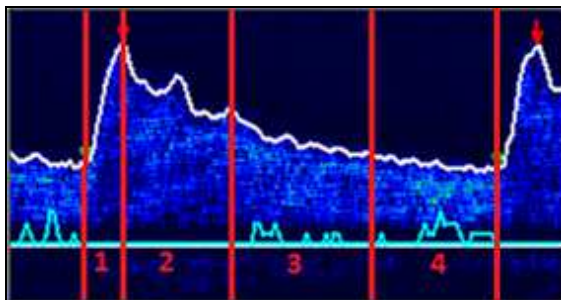
	Click on this key to define the emboli detection table
---	--

The following dialog box is displayed.

	<p>Select the data that shall be displayed in the emboli detection table.</p> <p>The emboli shown in the table can be sorted versus any of these data:</p> <p>Click on the key below Sort Selection in order to select the default presentation order of the emboli in the table.</p> <p>Default classification is based on confidence coefficient: events that are more likely to be emboli are displayed on top of the list (coef > 80%), events that are less supposed to be emboli are displayed at the bottom of the list (coef < 50%).</p>
---	---

11.7.3.3 Definition of the data displayed in the table

- Time (s): time at which the HITS have been detected; can be displayed from 0 or from real time start depending on the value of start time display parameter (described in §3.2.1)
- Type: Embolus(E)/Artefact(A); can be manually changed (double-click on cell)
- Intensity (dB)
- Energy (dB*ms)
- Velocity (cm/s): velocity of the detected HITS in cm/s
- Time duration (ms): duration of the HITS (depends on selected FFT): It is calculated as HITS velocity multiplied by HITS time duration divided by sample volume length. Ideally this ratio should be 1, but some variations are to be expected depending on emboli trajectory and insonation angle.
- Position in cardiac cycle (1, 2, 3, or 4)



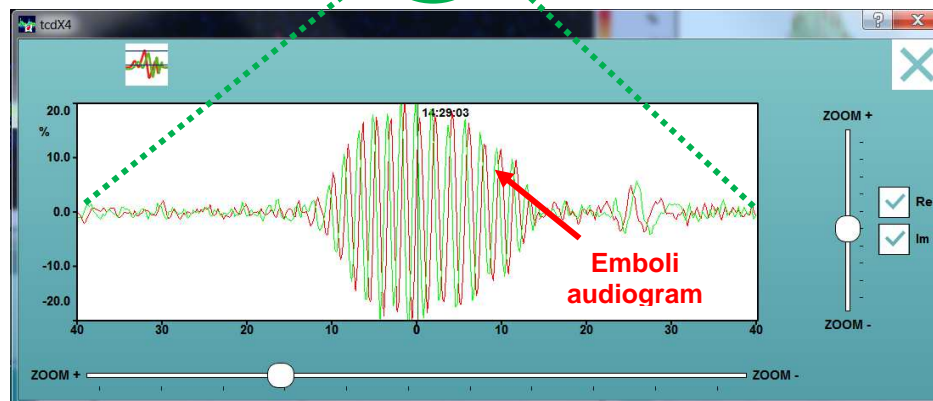
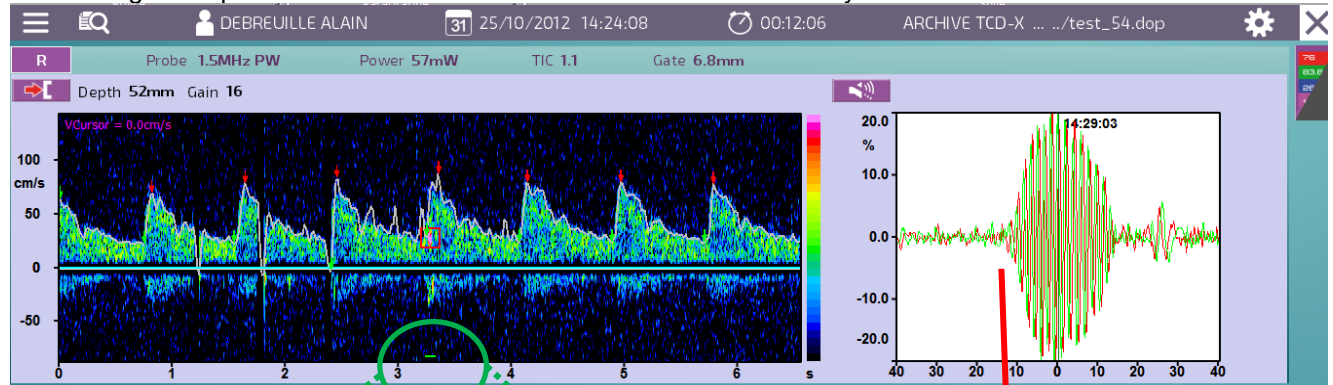
Position 1: proto-systole
Position 2: télé-systole
Position 3: proto-diastole
Position 4: télé-diastole

- Confidence coefficient (%): criterion of global reliability on emboli detection based on statistical information on all previous criterions.

11.7.4 Audiogram

The Audiogram is displayed on the Doppler zone. However, it is relative to emboli detection. It is why it is presented in this section.

The audiogram represents the time evolution of the normalized intensity.



Click on the audiogram to enlarge its window

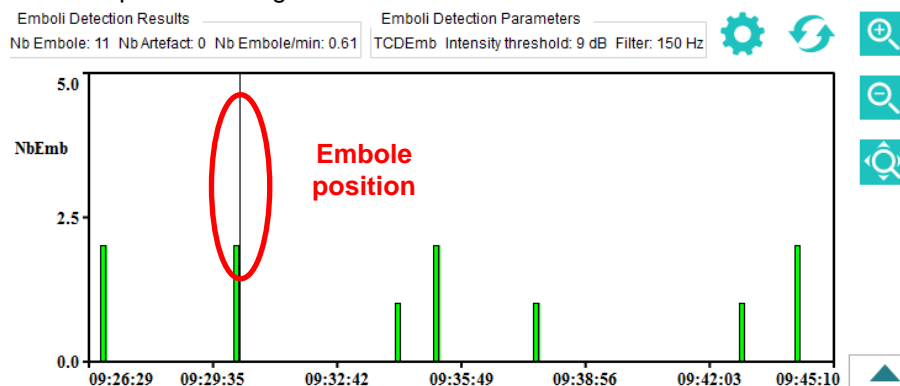
Audiogram extent can be adjusted with horizontal zoom; audiogram vertical scale can be adjusted with vertical zoom (indicated in % of maximum possible value).

NB: the playback must be stopped before adjusting zoom parameters on audiogram...




Re	Real part
Im	Imaginary part

11.7.5 Histogram

As soon as the emboli detection has been performed, the emboli histogram is updated. This histogram shows emboli repartition along exam duration.



Zoom +

	Zoom -
	No zoom
	Selection of the histogram type: Number of emboli versus: Intensity, Energy, Velocity, Length, Position, Confidence coefficient, Time (mm), Time (hh:mm:ss)


A vertical black cursor indicates current position in monitoring.

A single click in the histogram allows the user to go from one embolus to the next one (closer detected emboli being automatically detected). The associated spectrum/audiogram is simultaneously displayed on the screen.


11.7.6 Emboli play back

To play back on emboli, select (single click) it on the emboli detection table (the blue focus is on the selected emboli) or on the histogram.

Then click on:

	Start play back of the recorded signal
---	--

NB: playback remains automatically when an event is selected; a white vertical cursor goes from beginning of page to end of page; at the end of page, after 1s, the playback starts again on event from the beginning. Be careful!! Don't forget to stop playback when you want to access function keys... (Except change of event in the emboli table result which is authorized).

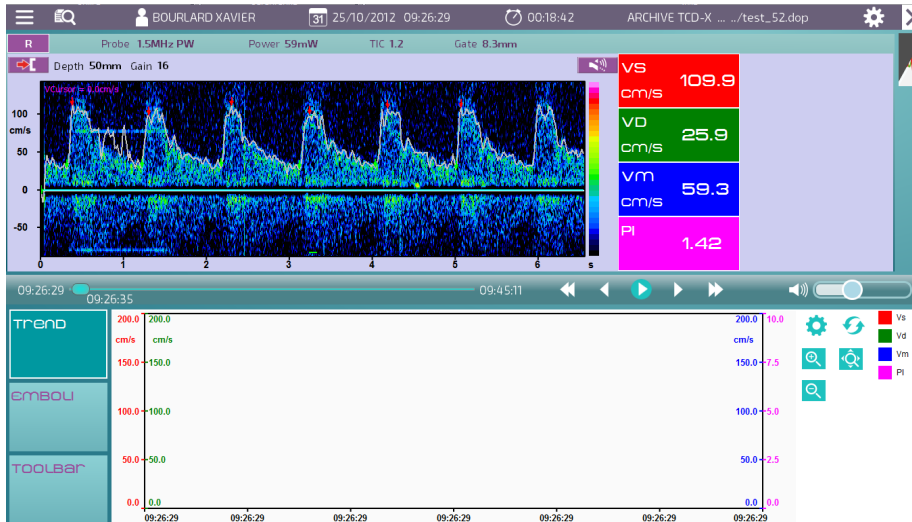
	Stop play back
---	----------------

11.8 Trend zone



Click on this key to display the trend screen

11.8.1 Before computing trends



The trends of Vs, Vd, Vm and PI will be drawn.

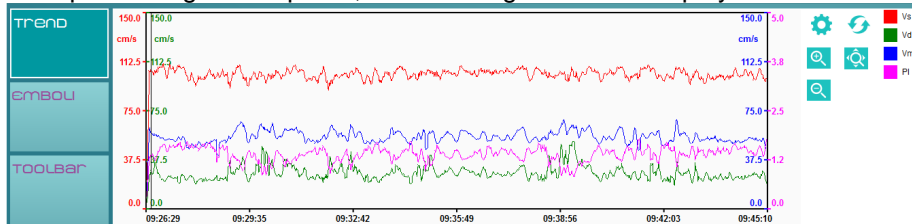
NB: By default, all four indices are selected for trend display

Check and adjust if necessary the trends parameters (§ 11.5.3 and 11.5.4.).

	To adjust the trend parameters (Index Settings and Trend settings)
	To run or update trend display NB 1: if a new index is selected in the list, a trend update is automatically performed. NB 2: If a change of gain has been made on spectrum display, it is strongly advised to perform a new trend update.

11.8.2 After computing trends

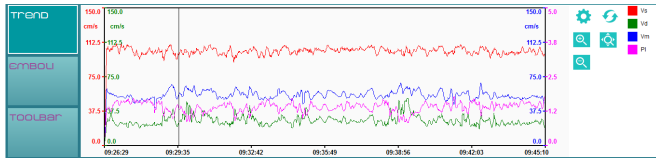
After performing trend update, the following window is displayed in the trend tab.



Four vertical scales are displayed corresponding to the 4 monitored indices.

	Zoom +: zoom in on trend (can be accessed with double-click)
	Zoom -: zoom out on trend
	No zoom. Trend display on the whole duration of monitoring

Scrolling: The **vertical black cursor** indicates time position in monitoring. A simple click allows the user to change time position in monitoring and display corresponding spectrum in spectrum zone.



11.9 Toolbar



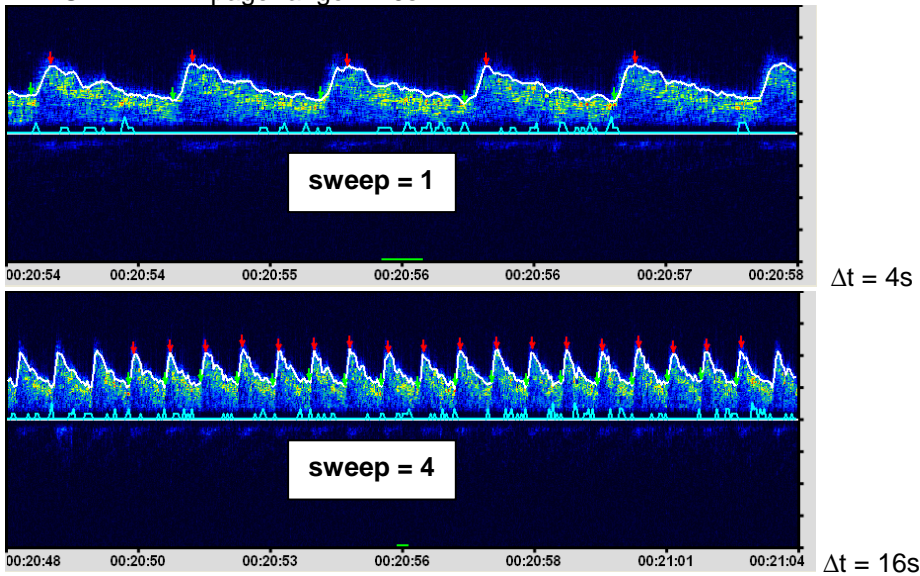
This is to adjust the following parameters:

- Gain
- Baseline
- Sweep
- Filter

11.9.1 Sweep

4 sweep values can be selected:

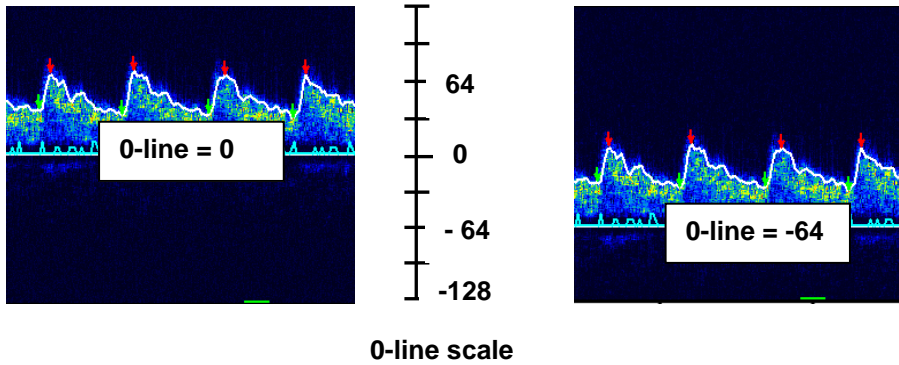
- SWEEP =1: page range = 4s
- SWEEP =2: page range = 8s → default value
- SWEEP =3: page range = 12s
- SWEEP =4: page range = 16s



11.9.2 0-line

4 values are available to move the 0-line among the 256 points of the spectrum zone:

- 0-LINE=-64: 0-line at 1/4 of the spectrum zone
- 0-LINE=0: 0-line at the middle of the spectrum zone → default value
- 0-LINE=64: 0-line at 3/4 of the spectrum zone



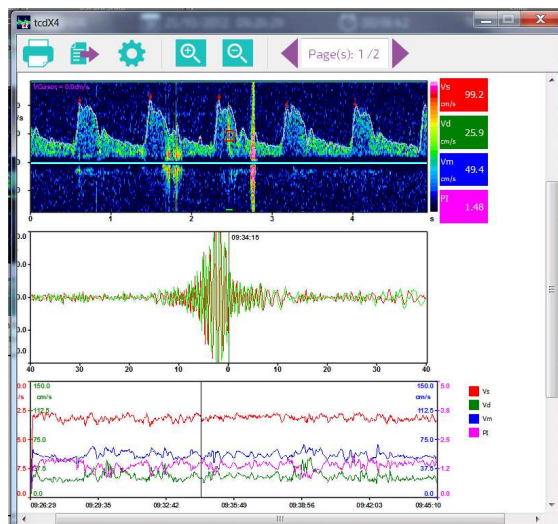
11.10 Examination report printing

The examination can be printed out from the monitoring software (tcdX4) or from the preview on the ADMS welcome screen.

If pictures and/or comments (conclusions) have to be added on the examination report, then the examination report has to be printed out from the ADMS welcome screen.

	To view, configure and print out the examination report
--	---

The following preview is displayed



	To print out
	To export in PDF or PNG
	Print settings (see §11.5.6)
	Zoom +
	Zoom -
	To display the different pages of the report

12 Alarms and warning lights

A sound alarm and a warning light (orange LED) provide information about the status of the SD card, the communication between the TCD-X module and the PC, and the battery level.

Communication of the TCD-X module with the PC (the TCD-X module is still connected to the PC):

- TCD-X does not communicate with the PC → fast flashing of the orange LED (examples of such cases: the window for the initialization of the SD card is opening, the Setup program is not launched yet, the USB port is not properly configured, etc...)

SD card detection when the TCD-X communicates with the PC:

- The SD card is properly detected when inserted in the TCD-X module → the orange LED is continuously lighted on.
- There is an error with the card detection as the card is properly inserted in the TCD-X slot, or there is no card in the TCD-X SD card drive → fast flashing of the orange LED.

NB: if the card is properly inserted in the SD card drive of the TCD-X and if the orange LED flashes quickly, it is advised to format the SD card (see § 9.1.3).

Start of the recording (the TCD-X module is still connected to the PC):

- The recording starts normally → the orange LED flashes slowly and the RECORD ON button (on the PC display) is red.
- The recording does not start → the orange LED flashes quickly, the RECORD button on the PC display does not become red, a sound alarm is triggered (one BIP).

NB: if the recording stopped abnormally during the previous monitoring session → format the SD card; if the recording was stopped normally during the previous monitoring session → rewrite the patient data on the SD card (the software will tell you if it is necessary to format or initialize the card) or reboot the TCD-X module.

- The recording seems to be normally under progress, but a discontinued alarm can be heard → stop the recording, format the SD card and restart a new recording.

During the recording (the TCD-X module is no longer connected to the PC):

- The SD card is removed from the SD card drive → isolated BIP alarm and end of the recording. The SD card should be formatted once the recorded file is transferred to the PC.
- $V_{batt} < 7V$ → discontinued BIP: the battery is low, the recording has to be stopped quickly (the TCD-X module can work until $V_{batt} = 6.5V$)
- The ON/OFF button is pushed → discontinued BIP

End of the recording (the TCD-X module is connected to the PC again):

- Stop of the recording with the TCD-X setup program (TCDX.exe) clicking on **Doppler/PWR off** → isolated BIP indicating the end of the recording. When everything goes well, the RECORD ON button becomes grey.
- Stop of the recording by pushing the ON/OFF button → discontinued BIP during 6s, then the Record LED is switched off.

NB: If the stop of the recording of the **TCD-X setup** program does not work → stop the recording with the ON/OFF push button on the TCD-X module.

13 Cleaning

13.1 Probe



Never place it over open wounds or allow them to come in contact with body fluid.

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.



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.

Damages may occur if gamma sterilization, autoclave and ethylene oxide sterilization is used on any part of the TCD-X.

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

13.2 TCD-X module



Always turn off the system and disconnect it from the power outlet before cleaning the machine.
Otherwise, electric shock 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 Maintenance and after sales service

All maintenance must be done by an Atys authorized service technician.

15 Specifications

See the Read Me First

Unilateral transcranial Doppler

Doppler frequency: 1.5 MHz

Pulsed Doppler

One monitoring probe

One hand held probe

Internal battery

Universal external charger

Recording of the transcranial signal on a memory card

Maximum recording duration: 6h

USB port.

Analog data output

Recorder dimensions (mm): 150 X 92 X 28

Recorder weight: 0.35 kg