M'Ath-M'Ath PACS® Software User Guide

The software M'Ath® is a quantification tool of normal and pathological vascular structures, in semi-automatic or manual mode from sonographic or radiological images, and a tool for managing patients' data, images and measurements (archiving, report print out, appointments list).M'Ath©PACS can communicate with a PACS and has no database.

Do not forget to read the warnings indicated by *on pages 18, 28, and 32.*

CONTACTS

Intelligence in Medical Technologies

15 Bis Rue Marignan 75008

Support : support@iimt.fr

Phone : +33 1 45 78 11 11

Web site : www.iimt.fr

TABLE OF CONTENTS

INTENDED USE STATEMENT

This software enables to perform the measurements of the intima media thickness of carotid and superficial arteries of a patient. It also allows storing clinical data and images in order to follow the evolution of the disease, and to print a synthetic report of the images selected during the ultrasound examination.

Biometry is applied to normal and pathological images collected through B-mode ultrasound examination of carotid arteries. The aim of this software is to perform measurements, archiving and printing of ultrasound images.

M'Ath® software is dedicated to physicians specialized in vascular pathology. (Cardiologists, Neurologists, Angiologists, Vascular Surgeons, Radiologists, Sonographers...)

> **Caution: United States Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner)**

It is dedicated to quantification of normal and pathological arteries visualized by ultrasound techniques (i.e. atherosclerotic or inflammatory diseases).

This medical device has been proven to give reliable measurements with a high number of samples in a precise, fast and reproducible way. But it does not perform in any way a direct diagnosis. The most that it could provide is a contribution to the diagnosis. Only the physician can take the decision regarding the patient management, in accordance to all the data he has. The results obtained from this medical device must be considered as a part of the overall data. With this medical device, the physician can carry out a complete organized data acquisition as all the data regarding the patient are put together in a database. These data are the images and the video acquired during each examination, the measurements performed at each visit, and also the patient file identification. Patient data, health information will be protected and not revealed in any manner, any time to a third party according to rules and regulations in United States.

FOREWORD

5

The author, editor and distributors of the software cannot be held responsible for the diagnosis made from the measurements carried out and generally for decisions made by the practitioner. The editor of the software and its distributors cannot also be held liable for damages resulting from the use or the impossibility of using this software or the medium supporting it: loss of data, bodily injury and financial loss of any kind whatsoever. The editor guarantees that the software conforms to the written documents accompanying it. The medium has been guaranteed and tested as working correctly at the time of dispatch. The editor does not accept any liability in case of wrong operation related to the installation of other software without his approval. Information contained in this manual may be subject to modification without notice. Any reproduction of this manual or software is strictly prohibited and may be subject to legal proceedings. Training adapted to using this product will be proposed to you systematically when you purchase it.

PRODUCT DESCRIPTION

B-mode imaging has particularly evolved during these last years improving spatial and densitometry resolution. Vascular ultrasonography brings a lot of interest by its non traumatic characteristic and the quality of the information obtained from the vascular structures. The quantification of the parameters characterizing these structures appeared to be fundamental in order to quantify precisely the data obtained from the ultrasound examination of the arteries.

Using the dedicated software M'Ath®, the sonographer, the physician, and his/her patient will get a reproducible and quantified information from ultrasound examination. This software is user-friendly, and results can be obtained immediately. The simultaneous storage of the results allows a good security and is time effective. The training is short (half a day) and easy for physicians and technicians.

Additional information and training can be obtained through the hotline: support@iimt.fr or by phone at + 33 1 45 78 11 11.

M'Ath® Std includes the measurement, editing and storage of the data and images of the patients.

M'Ath® SR is more dedicated to research as it provides a reproducibility tool (see page 45).

This software enables the user to take essential measurements of the atherosclerotic lesions of the patient. The database contains all the information concerning the measures and medical information. It also allows the user to compare images in order to follow the evolution of the disease, and to print a synthetic report of the selected images, with all the necessary clinical data of the patient and corresponding measurements.

M'AthPACS is dedicated to measurements done on images received from PACS . M'Ath PACS can be installed on a virtual PC to receive DICOM images from pre specified PACS , and send back images and DICOM pdf reports to this or another PACS.

USER LICENSE

Warning: You need to accept the IMT license agreement before using the product.

AGREEMENT:

Between the end-user

And

Intelligence in Medical Technologies Company

As soon as you use this software by installing, copying or running it, you recognize being bound by the terms of this contract. This software is protected by the regulation and the international treaties as regards to royalties and intellectual property.

Conditions of use:

The software is not sold but is conceded under license with annual renewal. You are authorized to install and to use a specimen of the software on your computer. The operating systems chosen by the editor are Windows Seven , Windows 8 Windows 10 and Windows server 2008. You will be able to use the software only under these operating systems, the editor declining any responsibility if you use it on other systems. You are not authorized to rebuild the logic of the product, to uncompile or to disassemble it. The software is conceded under license as a single product. You are not authorized to dissociate the components from it to use them on several computers. In the event of update of the product, the update is regarded as component of the product and cannot thus be dissociated or separately used. You are not authorized to lend or rent the software. IMT reserves the right to modify the terms of this contract and to terminate it if you do not observe if you don't observe these conditions.

MINIMUM CONFIGURATION

IMT disclaims any liability on software dysfunction if the PC used does not comply with the minimal characteristics below. Access runtime or Office 2010 has to be installed before launching the software. The link below allows a free download of Runtime Access 2010.

Minimum Required Configuration	
Processor	Intel P4 or Higher
RAM Memory	4 Giga bytes or more
Graphic Card	8 Megabytes
Operating System	**For M'Ath** Windows 64bits: Seven/8/10/Server 2008 Windows Seven 32 Bits **For M'AthPACS** Windows Seven 32 Bits
Frame Grabber *	Osprey 100 or Dazzle
Run-Time Access office 2010 Or Office 2010 with access	http://www.microsoft.com/en-us/download/details.aspx?id=10910

*

Consult us if different

I. Installation & Start up

1. HARDWARE INSTALLATION

1 For the desktop option, we recommended the ViewCast Osprey 100 for video acquisition. The capture size of the image or video is 768 x 576 pixels.

2 For the laptop option, it is the analog-digital converter (Dazzle 100) connected on one side to the USB port of the laptop and on the other to the video output of the ultrasound device. The capture size of the image or video is 640 x 480 pixels.

3 For the device connection, RCA/BNC or Y/C connectors can be needed.

4 Adapters: RCA/RCA video cable for the connection of the ultrasound output to the dazzle input.

2. SOFTWARE INSTALLATION

Step 1: Run Setup.exe

1. In the File M'Ath_xxx uploaded on your desktop , double click on Setup.exe
   Then click on "Next" to start the Installation.
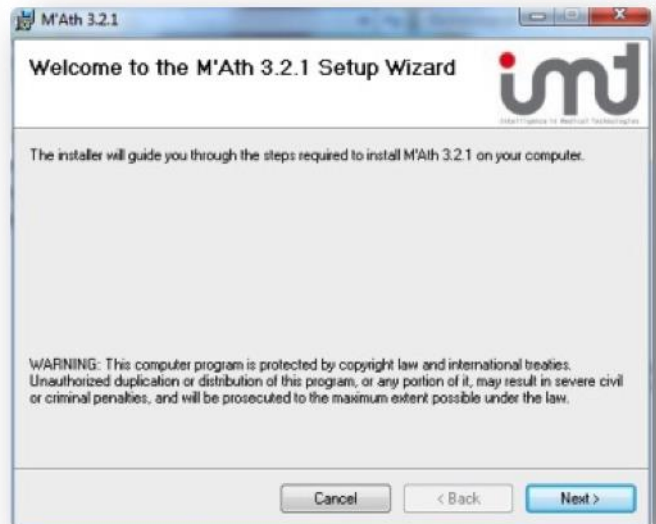
Step 2: License Agreement

2.Read the License agreement and

click "I agree" to start the software

installation, and then click on "Next".

2. SOFTWARE INSTALLATION

Step 3: M'Ath Installation
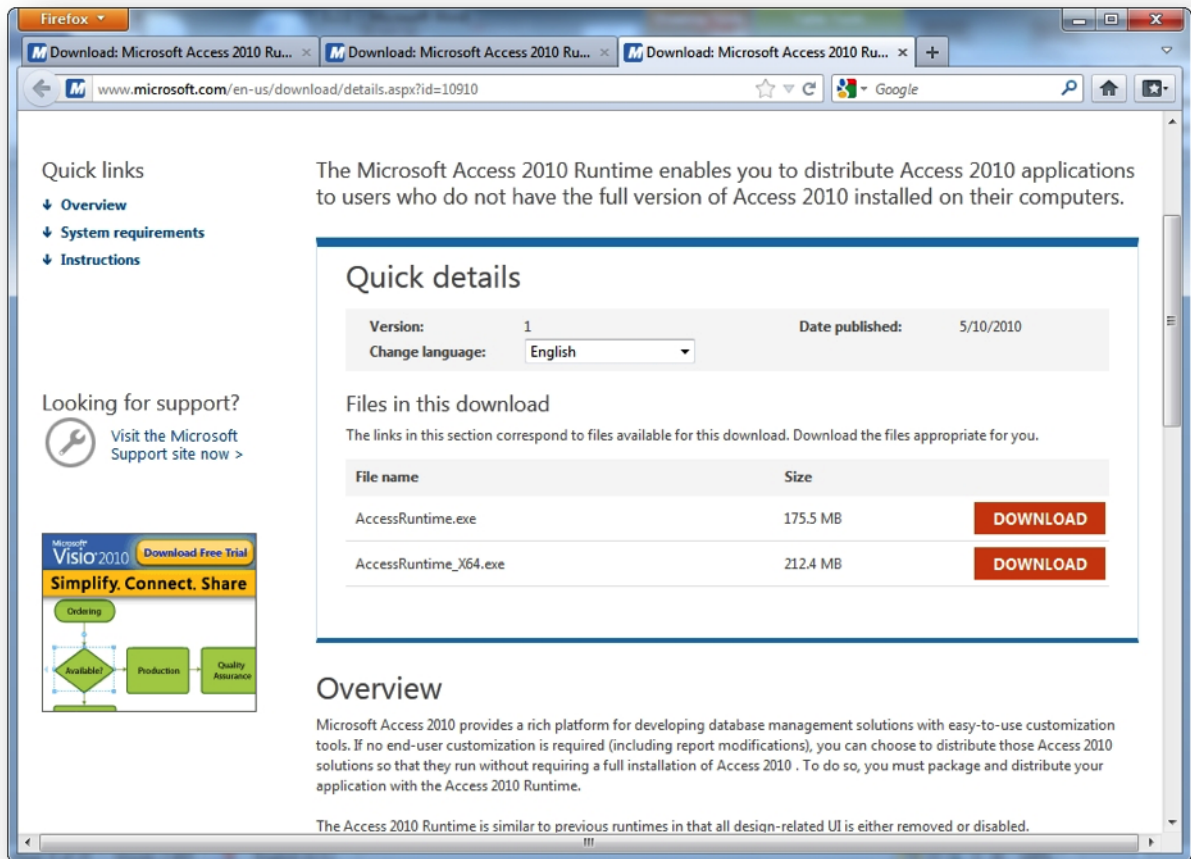
3.Click "Next" after the

license agreement to

confirm the installation.

2. RUNTIME ACCESS INSTALLATION

You have to download the Runtime at the link :

http://www.microsoft.com/en-us/download/details.aspx?id=10910

Then select the preferred language in the menu and download and run access2010 runtime.

3. FIRST LAUNCH and REGISTRATION

1. Once M'Ath ® has been completely installed, double click on the shortcut displayed on the desktop. The two series of digits should be sent to support@iimt.fr in order to get the 20-digit record key of your license.
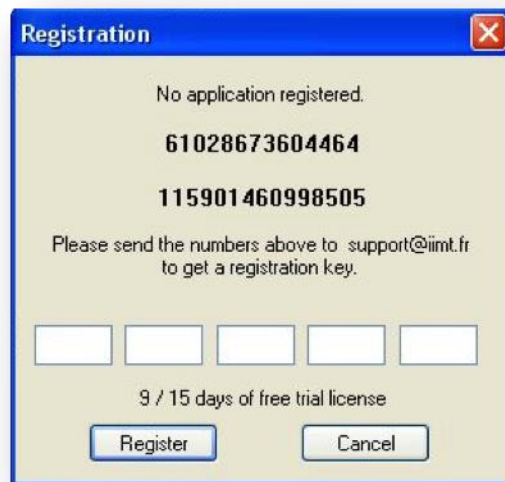
2. After having entered your license key number , this windows will warn you to create the first calibration as mentioned below for your first frame capture.

4. IMAGE and VIDEO SETTINGS

1 Source and Format

To set these parameters, go to the menu "Display" and click on "Video Settings".

A .For a laptop installation with a **Dazzle Pinnacle** type converter, check:

1. The video source: Display / Video Settings / Source

   choose: Video Composite or SVideo according to your connection

   Select the corresponding Video Standard: PAL or NTSC for US

2. The image format: Display / Video Settings / Format

   choose: 640 x 480,

B. For a desktop installation with Osprey 100 frame grabber

1. The video source: Display / Video Settings / Source

   Choose: Video Composite or SVideo according to your connection

   Select the corresponding Video Standard: PAL or NTSC for US

2. The image format: Display / Video Settings / Format

   choose: 768 x 576.

2 Video Settings

By default, the capture rate is 24 images per second. The recording time is automatically

limited to 5 seconds.

5. SCALES

1. DICOM format: the DICOM scale name is automatically displayed in the scale list box. DICOM Multi Image Format is not supported in this version

2. Other formats: It is necessary to create a calibration.

   Any use of the software requires a one-time calibration of the image. You have to check the Scale name to confirm that it corresponds to the image or video you are measuring .The number of scales is not limited.

3. Calibration Procedure :

   ➢ Click on the "Freeze" button ![Freeze button icon] (or press the space bar)

   ➢ In the "Measure" menu click on "Scale/New".(Fig.1)

   ➢ Fill the scale items and validate by a click on button "OK".

      o Brand of the sonographic device: **Ultrasound**

      o Frequency of the probe: **5-8Mhz**

      o Depth of exploration in mm: **40**

      o Any zoom and its value (x2, x3, etc.) : **2**

   Thus, the name of the corresponding scale will be: **Ultrasound-5-8Mhz-40-Z2**

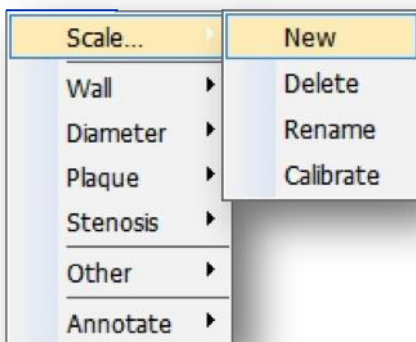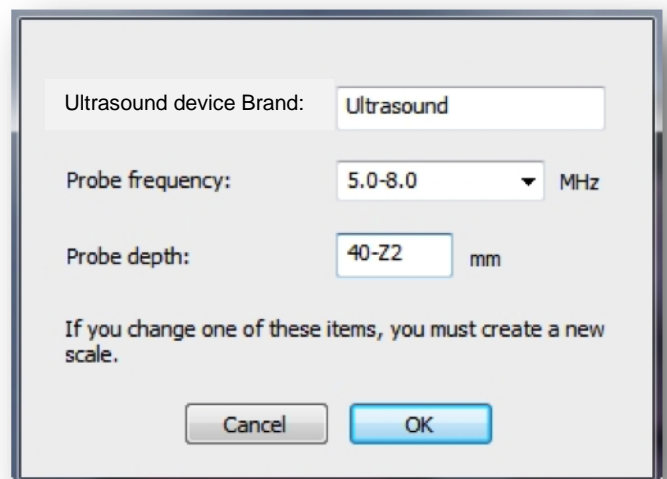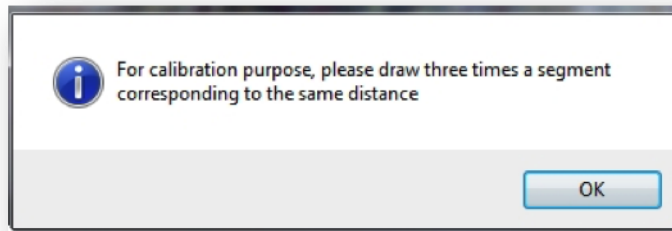Fig. 1   Fig. 2

5. SCALES

➢ Draw and validate successively three **vertical lines** of the same length using the reference landmarks seen on the image.

➢ Left mouse click and release on the starting point (landmark) , move down the cursor vertically to the last landmark and click again. After each drawing, a segment validation window is displayed. The distance in mm corresponding to the 3 traced segments must me entered.
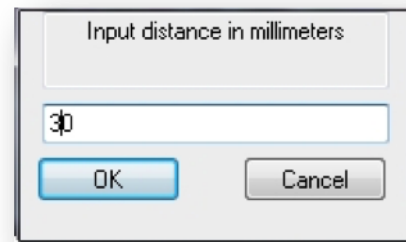
➢ Click on "OK" to validate the calibration.

If the 3 traced segments differ by more 1% from their average value the procedure has to be repeated.

1. **To delete a scale**, first select it, then go to the menu "Measure», «Scale /Delete".

   To validate click on "OK", or "N0" to keep the scale.

2. **To rename a scale**, select "Measure" , "Scale / Rename" in the menu, then input the new name.

3. **To calibrate the scale** (recalibration). select "*Measure», «Scale/Calibrate*"

   The name of the scale is displayed in the menu bar.

NB: **Non-calibrated scales appear in red in the toolbar. After any measurement done on the image, the scale is automatically recorded when it is stored. Conversely every retrieved image comes with its scale, and appears in the scale list box.**

6. CALIBRATION CONTROL PROCEDURE

To be compliant with quality procedures requirements, the user must check calibration periodically (each month) in order to validate the whole system of acquisition, capture, calibration and measurement.

A message box is displayed at first launch of M'Ath® and periodically to warn the user to check calibration and follow this procedure.

- Create a patient file dedicated to validation,

- Create a visit date,

- Freeze an image on the ultrasound device

- Capture the image on M'Ath®

- Calibrate the image,

- Measure a reference distance with M'Ath® then the same distance on the ultrasound device.

- Compare the two results.

- If the measurements are not comparable, recalibrate, and then revalidate the scale.

Only the user decides whether or not to conduct the calibration test.

This process protects the system from any error resulting from a geometric deformation of the:

- Video signal output from the ultrasound device.

- Video signal processed by the acquisition card on a PC.

- Unit Display

II. Use

1. PATIENT CARD

DESCRIPTION


1. This Card manages all the patient's clinical and sonographic data, archiving the images and video sequences and editing the report of the examination conducted.

2. Situation: It appears on the left side of the screen. It can be moved by clicking on the upper left corner and by holding the left-click.

When this window is restored under the tool bar, the upper part of the window disappears. The window is then "docked" to the screen. To hide this card uncheck "Patient information" in the main menu "Display".
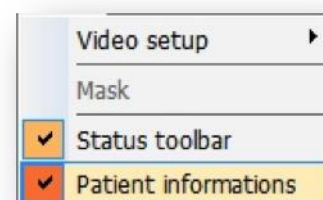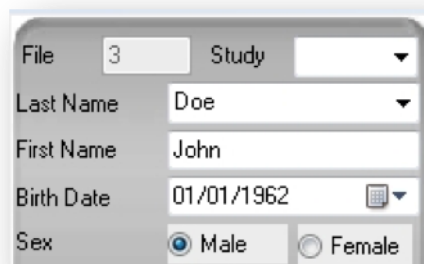
3. Color: The patient card color can be changed by pressing F6 key. Colors are successively grey, beige, blue, yellow and violet.
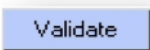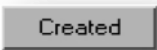
NEW PATIENT FILE

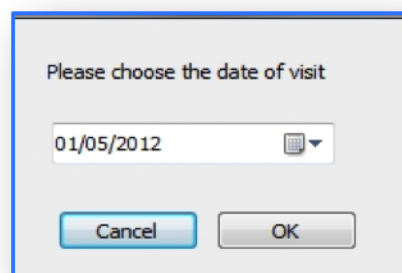Select "*New*" in the "*Patient*" menu
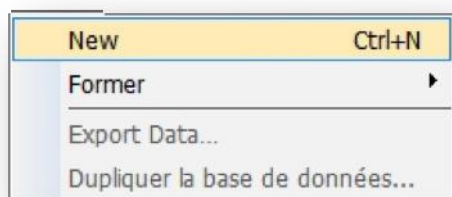
The fields *Last Name, First Name, Date of Birth and Sex* of the patient, are mandatory to validate this new file. A file number is automatically given to each patient.

To confirm this new record click on which will change in to end this new patient file creation

CREATE A NEW VISIT

+ The current date is automatically recorded when you click on   in the visit space.

+ A message box then appears with the current date.

+ If you wish to delete the current visit, click on this button

Note: Data connected to this visit will be automatically erased.

SELECT A VISIT

In the section Visit of the patient card, click on the list box button. The list of all the appointment dates are displayed. N° and Dte indicate the order and the date of the current visit. All images recorded during this visit can be displayed and measurements reassessed, if required.

21

RETRIEVE A PATIENT FILE

In the Menu "Patient", select "Former" and then "Seek".
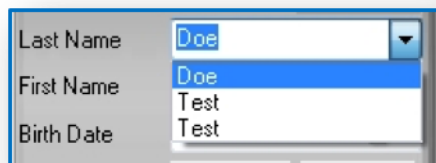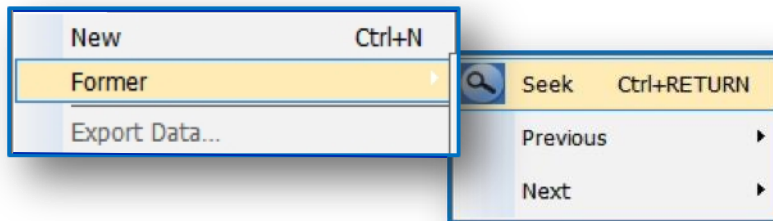
You can choose the former patient in the Last Name list box or type the first letters of the last name

2. PATIENT EXAMINATION

PATIENT HISTORY

➢ Click on display to visualize the following tabs

| Patient File | Display |

➢ By clicking on the "History" tab you will get the following card which includes:

1 The heading Atherosclerosis Risk Factors which allows recording their presence and duration

2 The heading Personal History of cardio-vascular events

3 The heading Clinical Examination

PATIENT DIAGNOSTICS

➢ By clicking on the "Diagnostics" tab you will get the following card which includes:

    1 The headings Diagnosis and Other to record vascular events history

    2 The heading Biology, Radiology and MRI for the results of these examinations

User Guide M'Ath-M'AthPACS® EN 05 2016 V3.2.x e   Author P-J Touboul 1997-2018

MEASUREMENTS TABLE

➢ This table (read-only) displays all the measurements done : IMT , Diameter , Plaque ,

Measures/Arteries	CBif - CS		CCA - LV	
I.M.T. (mm)	R	L	R	L
Distance				
QI(> 50%)				
Minimal				
Mean				
Maximal				
Sd				
Diameter (mm)	R	L	R	L
Distance				
Adventitia-Adventitia				
Intima-Intima				
Distensibility %	R	L	R	L
Distance				
Adventitia/Adventitia Dmax				
Adventitia-Adventitia Dmin				
Adventitia-Adventitia Dmean				
Distensibility (1-Dmin/Dmax) %				
Intima-Intima Mean				
Plaque thickness (mm)	R	L	R	L
Mesure type	Auto.			
Maximale De.	3,56			
Mean De.	2,55			
Distance	17,14			
Mean Density	53			
Area	42,28			
Stenosis degree (CT)	R	L	R	L
Degree in %				
Total Area (mm²)				
Lumen Area (mm²)				
Mean Density				
Stenosis Degree (CL)	R	L	R	L
Lumen diameter			3,946	

Stenosis degree and Distensibility according to the M'Ath® application.

➢ To print this table , Click on File / Preview / Print

PATIENT DRUGS

| History | Diagnostics | Measurements | Medications |

Anti-Hypertensive

Hypolipidemic

Anti-Diabetics

Anti-Thrombotics

Others
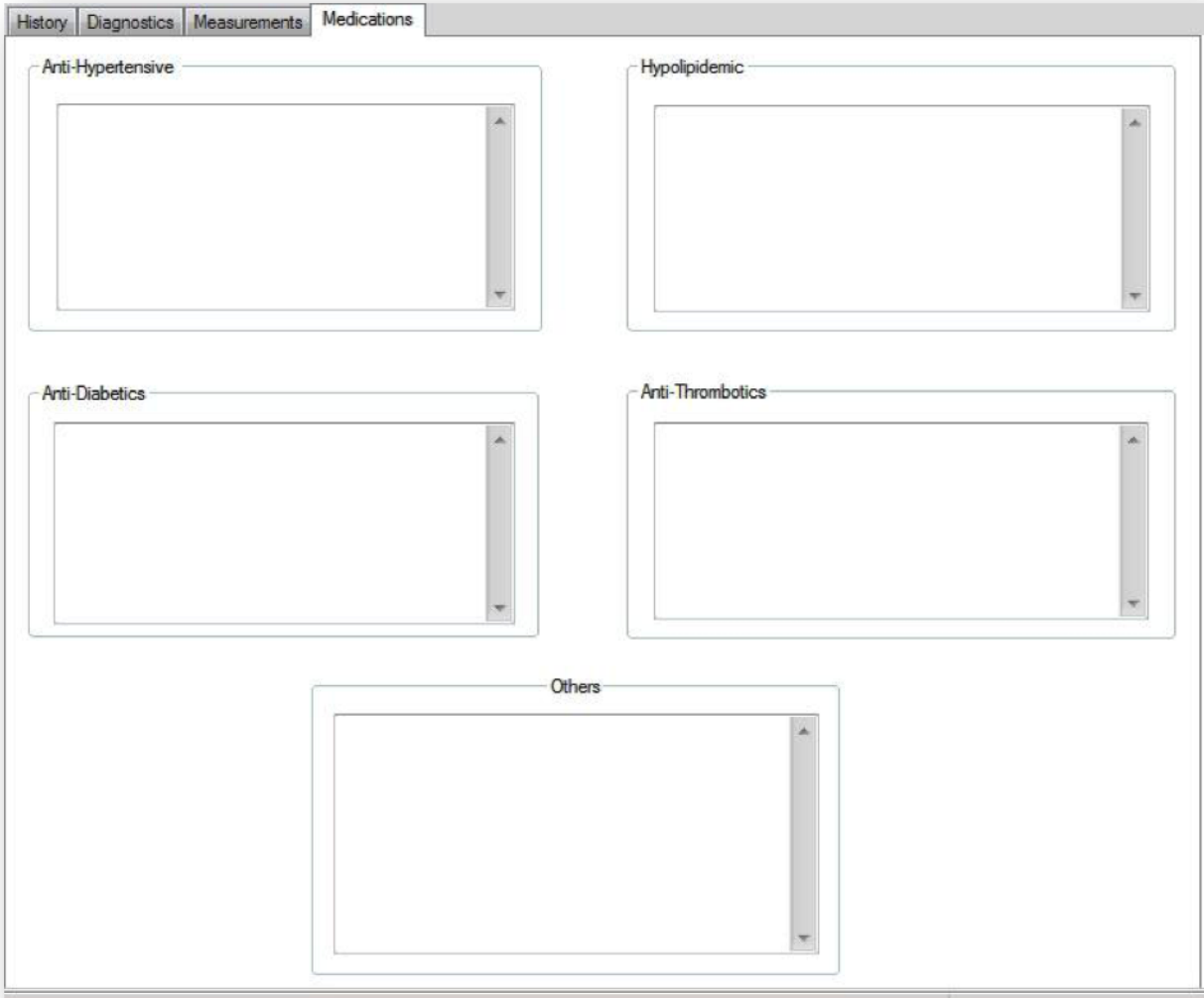
3. EXPORT and DATA BASE BACKUP

In the Menu "Patient", select "Former" and then "Seek".
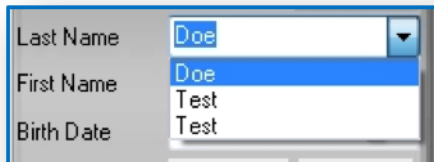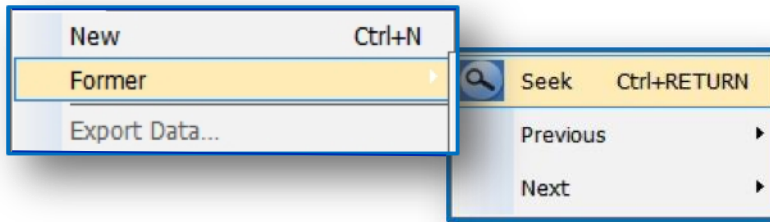
 You can choose the former patient in the Last Name list box or type the first letters of the last name.

EXPORT DATA

Export function allows transfer of an entire patient file on a storage device to be defined (hard disk, USB key). The data can be burned on a CD from the hard disk copy but not directly from M'Ath.

In the "*Patient*" menu, click on "*Export data*", then choose the destination drive to transfer your file. A list of recorded patients appears on the screen. You can select those you wish to export by left-clicking on the mouse (keep the Ctrl key pressed if you wish to export several patients). Then press "OK"

User Guide M'Ath-M'AthPACS® EN 05 2016 V3.2.x e   Author P-J Touboul 1997-2018
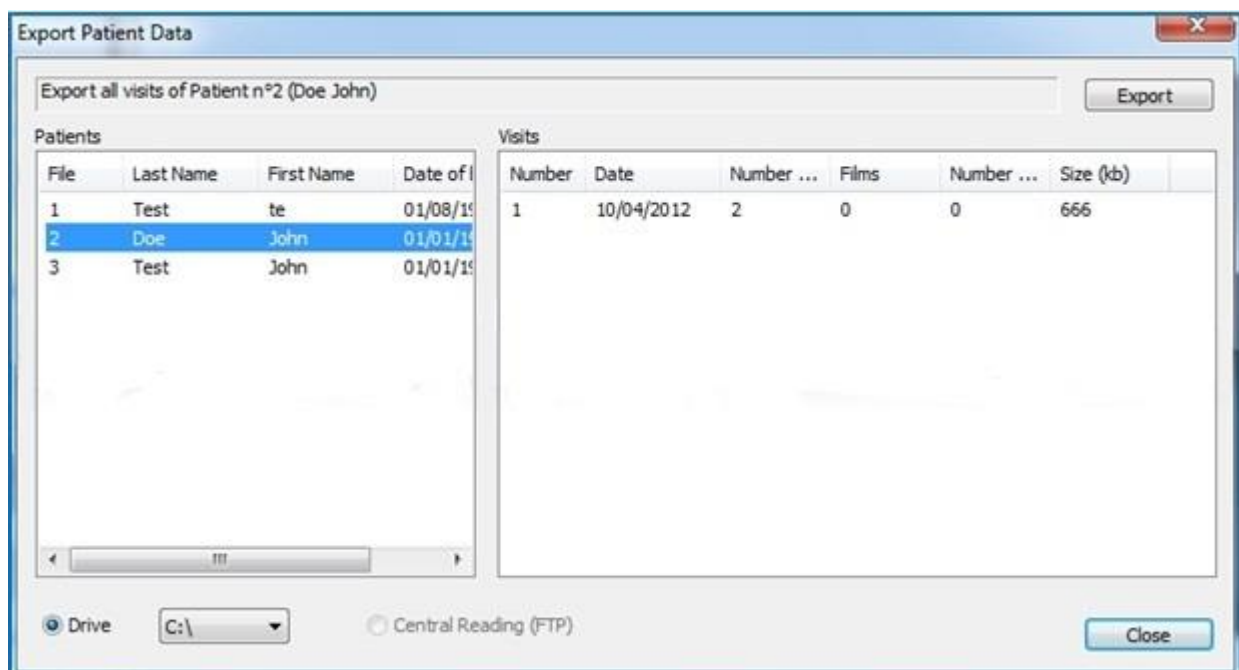
DATABASE DUPLICATE

1 To duplicate the Database you can choose in the Patient Menu, Duplicate Database.
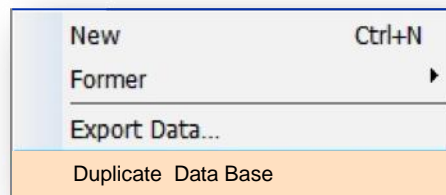
2 For Windows XP and Seven, the copy is stored in the file C: / with the format:

MAthDataBaseYYYY_DD_MM_hh_mn.mdb

On windows Seven, the Data are automatically transferred to the directory

C:\Users\"UserName"\AppData\Local\VirtualStore

3 In order to secure your data and database, you must do a weekly or monthly backup of data

directory (images) and the associated database.

    1. Images : C:\Documents and Settings\All Users\Application Data\IMT\Data

    2. Data : C:\Documents and Settings\All Users\ApplicationData\IMT\Data\MAth.mdb

These data can be exported on your hard disk, USB key, or on CD Rom and DVD from your

 hard disk.

4. IMAGES and VIDEOS RECORDINGS

1. Online storage:

Storage is done by clicking on the button [+] of images or video. It includes image, associated measurements and scale.

2. Offline storage:

An image can be imported and measurements made offline. A patient file must be created and during the image storage, a dialog box will ask the side and the situation of the corresponding artery. Once this information given, the image will be automatically stored in the database by a left mouse click on the [.+] button.

3. Offline measures on stored images:

Some sonographers prefer to perform the measurements at the end of the vascular examination.

- ▪ Click on display to visualize images or videos
- ▪ Select the thumbnail to be measured by a double click.
- ▪ Calibrate the system
- ▪ Make the measurements
- ▪ Store the measures.
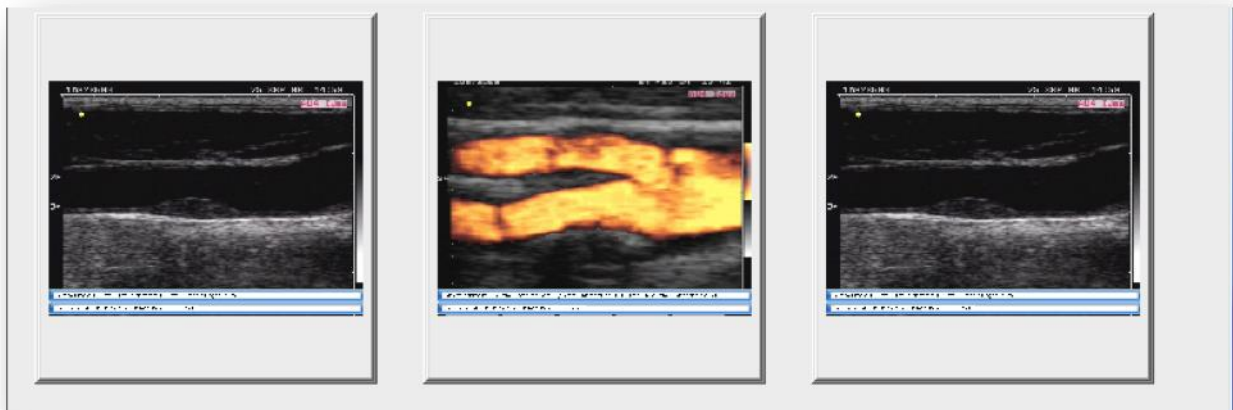
To view images (bmp, jpg , tiff, targa, pcx …) or sequences, which are not associated with a recording, click on the icon:

4. Storage in a selected directory: Click on the floppy disk icon:

VIDEO ACQUISITION

1 To store a video sequence in the patient file click on the [+] button, a video recording of 5

seconds will start and ends automatically

2 To store a video sequence out of a patient file click on the button [image] the filename should

be entered at the end of the recording of 5 seconds

3 Description of the video toolbar and buttons:

Reward   Pause   Read   Select start / end   Progression Bar

Reward to Start   Previous   Next   End   Frame counter

Record
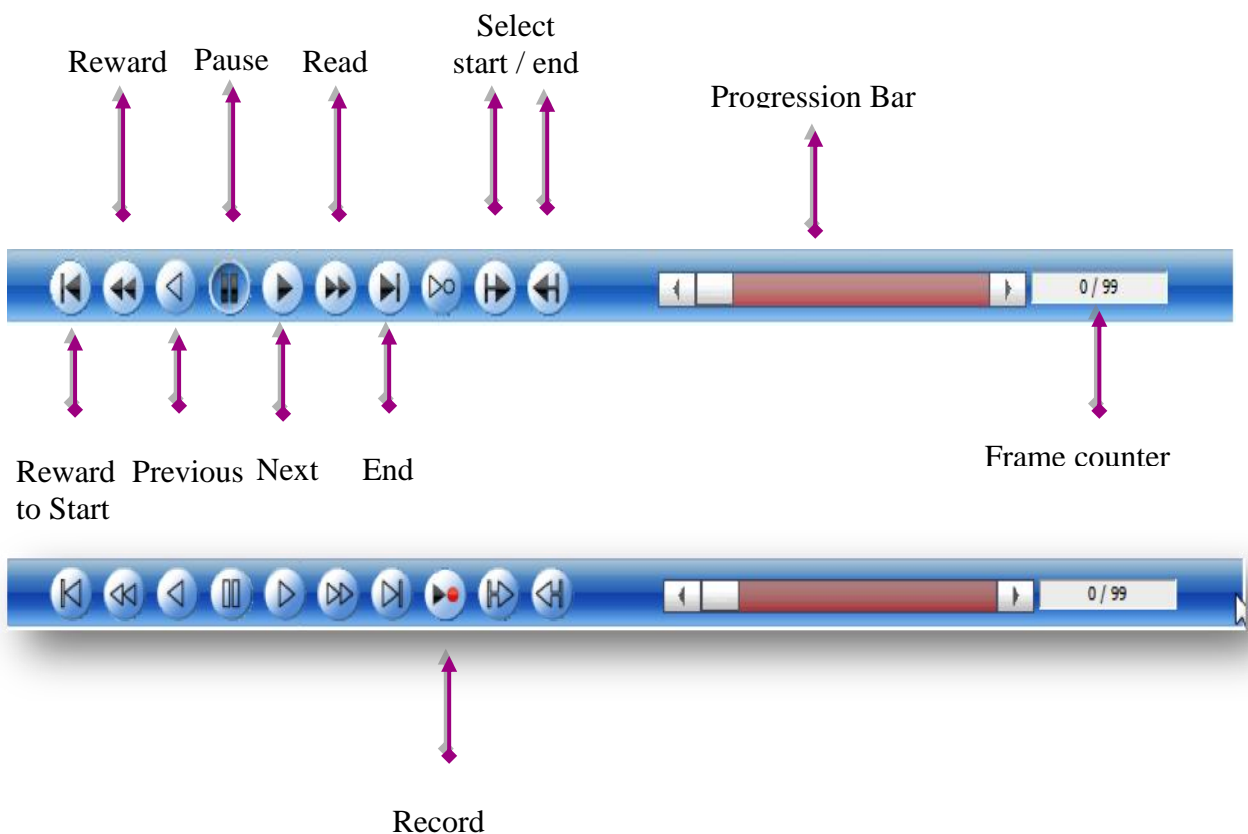
5. MEASUREMENTS

Different types of measurements are available. Semi-automatic and manual measurements.

Semi-automatic measurements:

1 Mean Intima Media Thickness (I.M.T.)

2 Arterial diameter.

3 Thickness, Area and Density of a plaque.

4 Stenosis degree in cross section.

5 Distensibility.

Manual measurements:

1 Distance between two points.

2 Rectangular area.
`
3 Elliptical area.

4 Polygonal area.

5 Measurement by Density profile.

SEMI AUTOMATIC MEASUREMENTS

Characteristics: They are associated with a patient card and automatically archived. These measurements can be accessed by buttons of the toolbar or by the main menu "Measure".
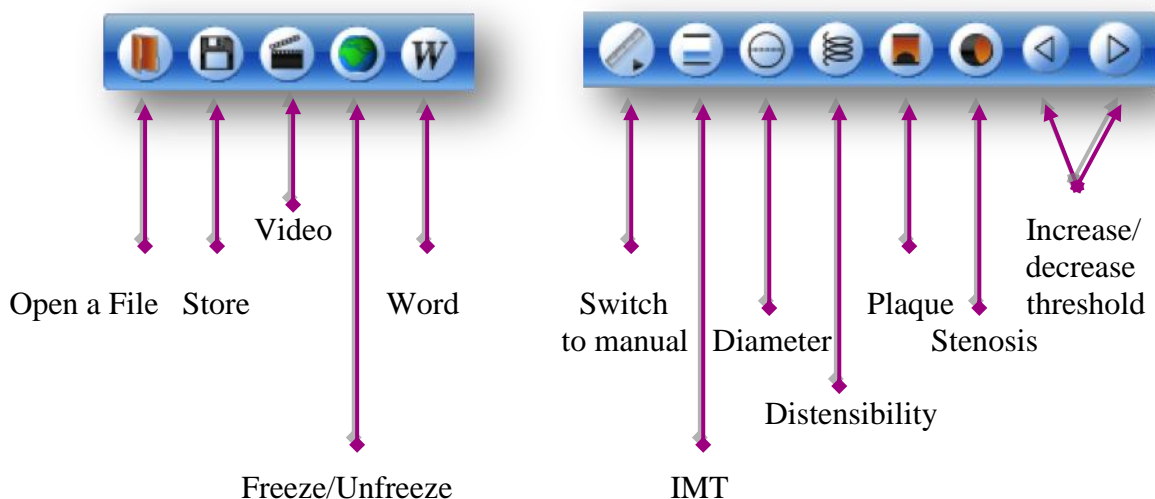
NOTE: The scale must be checked on the toolbar before starting a measurement.

 Measurements are expressed in mm with 2 or 3 decimals.

The Quality Index (QI)

The quality index is calculated for each IMT measurement. It takes into account measurement failures and should be evaluated on a 10mm long segment.

The quality index value is between 0 and 1. When the QI is below 0.3, it is probably due to a bad image acquisition. Above 0.5, it means that the measurement has been successfully taken over a distance greater than half of the segment analyzed (the length should be 10mm).

When the quality index is lower than 0.5 we recommend to capture another image or choose another arterial segment

INTIMA MEDIA THICKNESS MEASUREMENT

It is traditionally measured on the far wall of the common carotid artery.

To measure the IMT, click on the button , or under "Measure", choose "Wall", and

then "Intima Media Thickness"
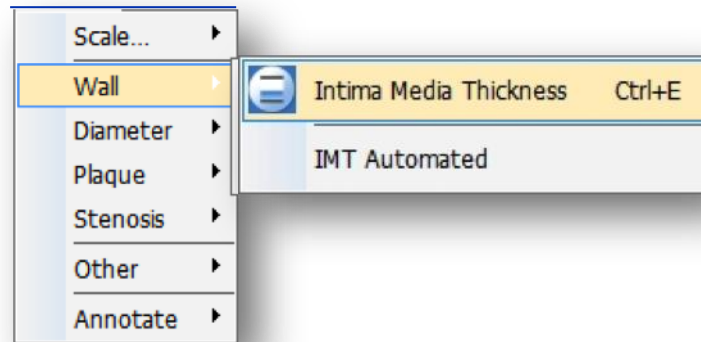
✛ Trace a line parallel to the vessel close to the far or the near wall over a distance of 10

mm on an arterial segment where the intima-media structure is visible. When the line is

traced from left to right, the measurement is made on the far wall of the artery. From

right to left, the I.M.T measurement will be taken on the near wall.

✛ Automatic detected interfaces lines are represented on the image (yellow, intima-blood

interface and mauve for the media-adventitia interface).

✛ Use of the function "IMT Automated" adjusts the parallelism between the line drawn

by the operator and the arterial wall .Calculation of the thickness is immediate. To

activate it, check in the menu "IMT Automated".
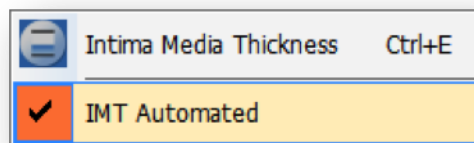
✛ To obtain a complete CIMT report you must store both common carotid artery scanning as
   CCA- Lat.- FW-LV which stands for CCA Lateral Incid., Far wall, Longitudinal View.
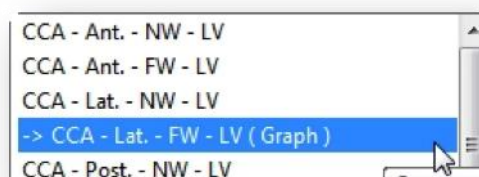
INTIMA MEDIA THICKNESS
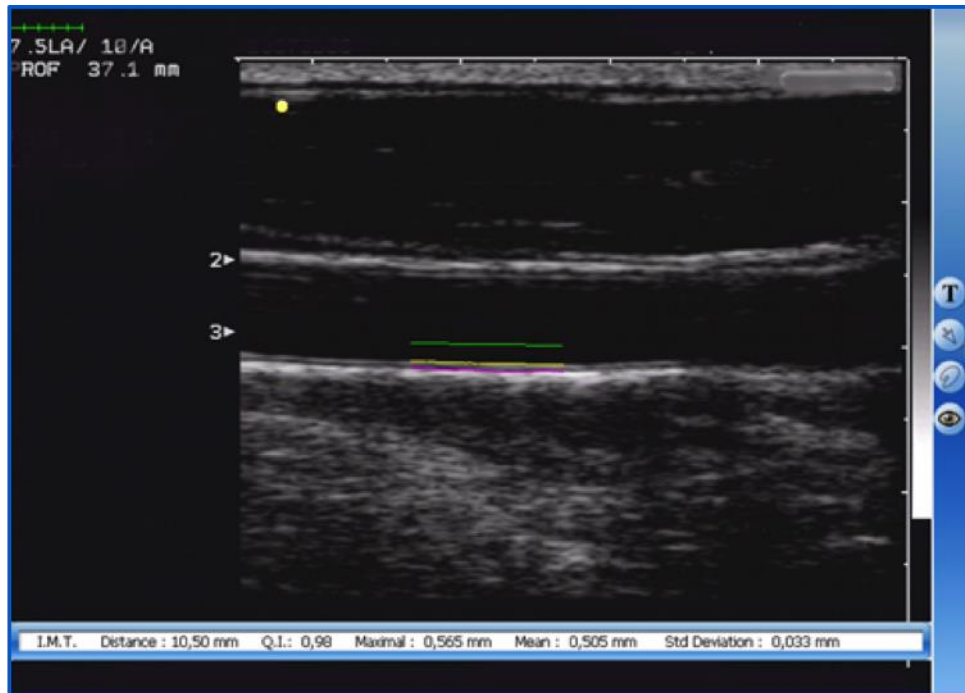
The values displayed represent:

1   **Distance**: Distance measured (in mm) [10.5mm]

2   **QI**: The quality index of the measurement. [0.98mm]

3   **Maximal**: Maximum value of the thickness in mm. [0.565mm]

4   **Mean**: Average thickness in mm for all the measurements. [0.505mm]

5   **Standard Deviation**: Average of observed deviations around the average. [0.033mm]

DIAMETER MEASUREMENT

➕ Select in the Menu "Measures", "Diameter", and "Image"
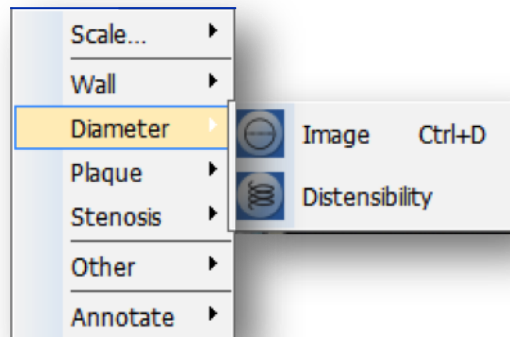
➕ Trace a line of 2 to 5 mm in the center of the artery and parallel to the walls, in a region where near and far walls are visible.

➕ The two lines automatically displayed correspond to media adventitia interfaces

I.Q. : 0,92   A/Adventice Moy : 6,919 Std:0,046 mm   I/Intima   Moy : 5,588 mm   Std: 0,078 mm
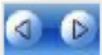
A line of results appears on the screen, and should be read as follows:

1 **Diameter:** length of segment over which the measurement was taken [6 mm]

2 **QI:** the quality index of the measurement [0.92]

3 **A/Adventitial mean**: Mean Inter adventitial diameter in mm [6.919 mm]

4 **Std**: Standard Deviation of A/Adventitia measurement [0.046 mm]

5 **I/Intimal mean**: Mean Inter intimal diameter in mm. [5.588 mm]

6 **Std**: Standard Deviation of the I/Intima measurement: [0.078mm]

PLAQUE MEASUREMENT

➕ To measure a plaque with the semi-automatic tool, choose in the Menu "Measure",

"Plaque" and then "Semi-automatic", or click on .
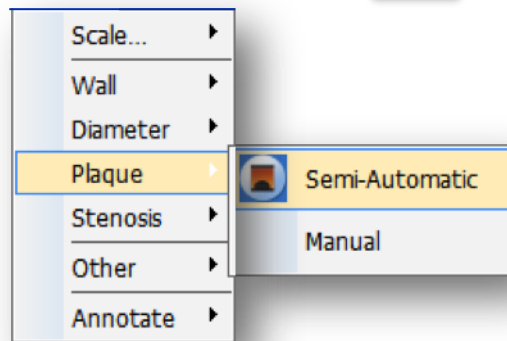
➕ A cross replaces the mouse pointer on the screen.

➕ Trace a line corresponding to the plaque outline on the adventitial wall.

➕ To follow this outline, click one time and continue. To end this line, double click on the

last point.

➕ A grey disk appears, which must be placed in the arterial lumen facing the plaque,

➕ Then click again.

➕ The arterial lumen outline of the plaque is automatically detected in color or black and

white modes.

➕ You can adjust the detection threshold of the plaque outline in black and white

mode. Click on one of the buttons respectively to decrease or increase

threshold value. Measurements are automatically updated

➕ To make a manual measurement, select in the Menu "Measure", "Plaque" and then

"Manual". Fig.2
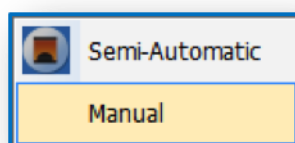
PLAQUE MEASUREMENT

.
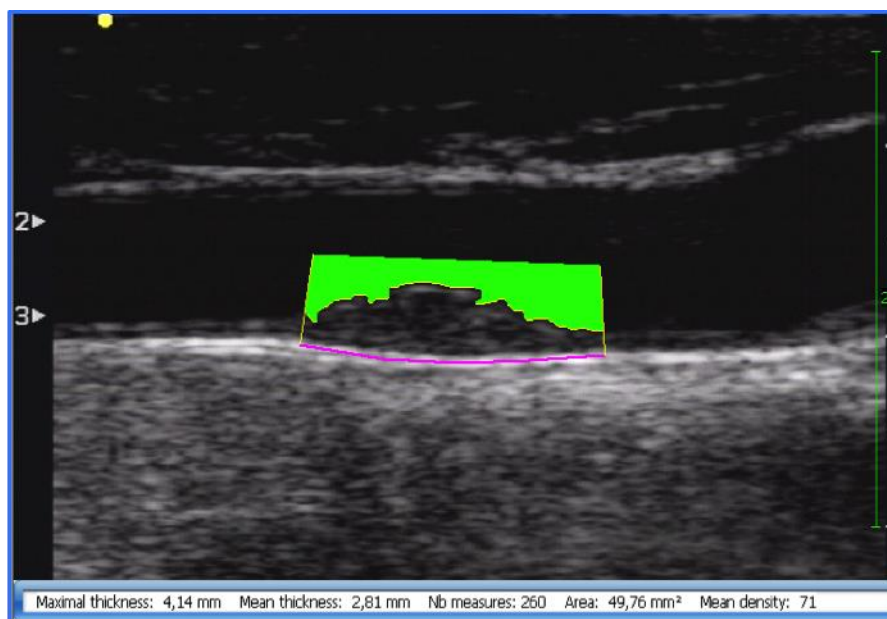
Figure1: Semi-automatic plaque measure.

Measurements are displayed as follows:

1 **Maximal thickness**: This is the maximal thickness of the plaque [4.14 mm]

2 **Mean thickness**: [2,81 mm]

3 **Number of measurements**: Measurements done along the plaque [260]

4 **Area** in mm^2: Total plaque area [49,76 mm²]

5 **Mean density**: Mean pixel grey scale value from 0 to 256, reported with a theoretical

reference value of 0 when the scanning mode is in color, and the average density of the

disk on a black and white scanning mode: [71]
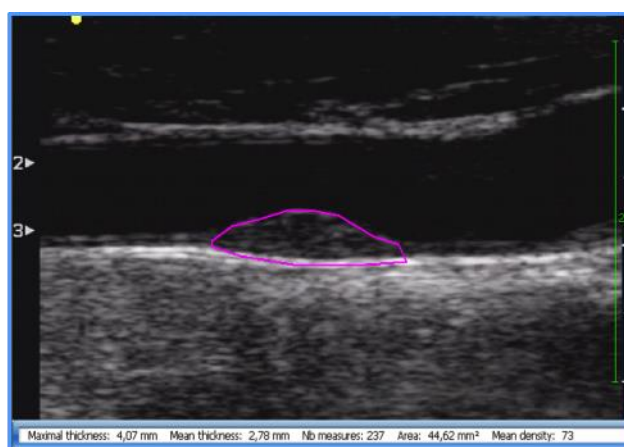
Figure 2: Manual plaque measurement.

STENOSIS DEGREE

This measure can be done on color flow or black and white images.

- ➕ Select in the main menu "*Measure*", then "*Stenosis*" or click on the corresponding

  icon

- ➕ The operator to the external contour of the vessel must adjust the mauve circle.
- ➕ Move the cursor out of the circle. The label GO appears on the screen.
  - o For a color flow image click and see the results
  - o For a black and white image, a grey disk appears that the operator should place in
    the arterial lumen and then click, the detection threshold can be adjusted with
      (cf plaque). Results are automatically updated.

1 **Stenosis degree:** % of obstructed area [73%]
2 **Vessel area**: [92.18 mm²]
3 **Stenosis Area:** Area of the plaque [67.22 mm²]
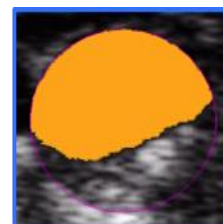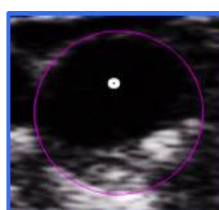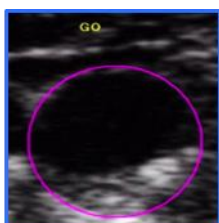
DISTENSIBILITY

1 Recommendations for video acquisition:

To measure brachial or carotid distensibility, you should:

- o Record 5 seconds of video
- o Check the quality of the recording, intima-media thickness should be correctly visualized during at least 3 cardiac cycles
- o Adjusts gain settings to avoid intra luminal artifacts.
- o Select the best quality with the functions provided.

2 To launch the distensibility function: click in the main menu on *"Measure", "Diameter", "Distensibility"* or on icon
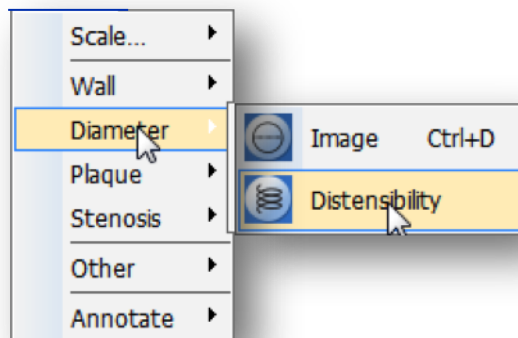
3 To start the measure:

Draw a segment of 2 to 5 mm. If you choose a short segment it should be less than 2 mm,

if the segment is over 2 mm it will automatically go to 5 mm

4 Navigation

To navigate in the video sequence, you can use:

- ➢ The scroll button of the mouse: upward to move forward and down to move backward
- ➢ The video control bar.
- ➢ In the graphic window (green curve), you can select the image corresponding to any value on the distensibility curve.
- ➢ The last two modes can also be activated by the right and left arrows to go forward or back in the sequence.

DISTENSIBILITY

5 Results

- On the left side of the screen, the distensibility curve appears at the end of the reading. The curve displays the values of the inter adventitial diameter in mm on the abscissa and frames from 1 to 100 on the ordinate axis.

- Maximum (white points circled in red- arrow 1) and minimum (white points circled in blue- arrow 2). Inter adventitial diameters (A/A) can be detected automatically when acquisition is of good quality .If the Quality index is > than 0.2, the point is green, 0.1 to 0.2, yellow and <0.1 red. (arrow 3).

- Maximum and minimum values are automatically detected in the cardiac cycle. The distensibility coefficient [9.54%] is calculated as the average of detected values. A/A max: [7.69 mm] and A/A min: [6.95 mm]
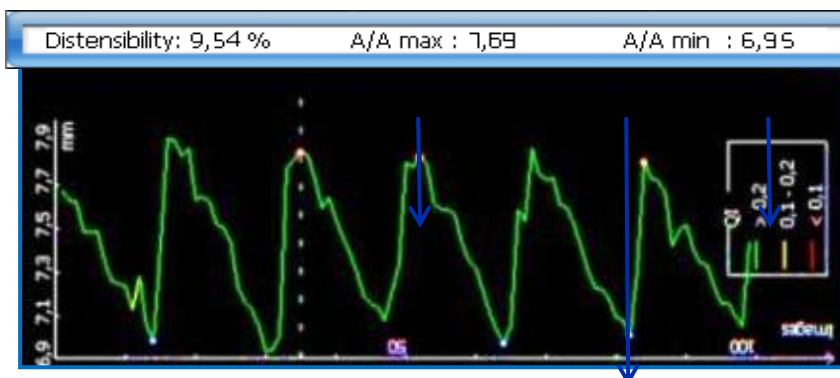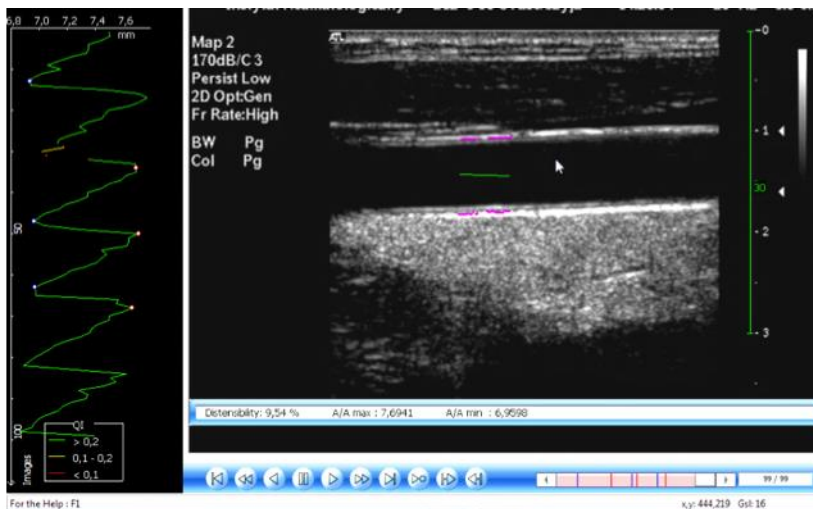
DISTENSIBILITY
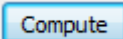
6 Adjustments:

You may have to make some manual adjustments to insert or delete maximum or minimum values
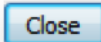
➕ To delete a maximum or a minimum, click on the circled red or blue point and make a right mouse click to select Delete current.

➕ To delete all the values, make a right mouse click and select Delete all.

➕ To insert a maximum or a minimum, click on the corresponding point on the curve, the image will be displayed to visualize the quality of edge detection, then make a right mouse click and select Insert maximum or minimum.

➕ When you select a frame on the curve the mean A/A value in mm can be displayed with the frame number by a right mouse click. (F17: Amen = 5, 22)

➕ To recalculate the final values click on **Compute**

➕ To store the data click on **+**

➕ To close the graphic windows, click on **Close**

MANUAL MEASUREMENTS

Density Profile

Switch to automatic
measurements

Areas (Rectangle, Ellipse, polygon)
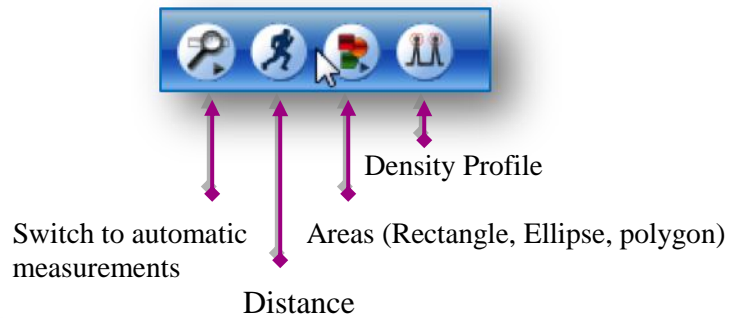
Distance

1 Distance:

It is the distance measurement between two points determined manually by the user.

From the chosen image click on the button

A cross appears on the screen. Place the cross on the image at the starting point of the

measurement. Left mouse click and release, move the cursor to the final point of

measurement and make a left mouse click. A green line is displayed on the screen, which

represents the distance measured between the two points. The measure in mm is automatically

displayed on the bottom of the screen. The result window disappears as soon as another

measurement is taken.

2 Areas:

A rectangular, elliptic or polygonal area can be measured on the image.

A simple on this icon   will give you the choice to select the type of area

Rectangular
Elliptic
Polygonal
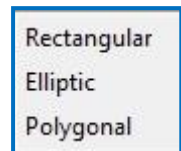
DENSITY PROFILE MEASUREMENT

1 Principle:

Based on the interaction between the operator and gray scale profile, this function allows the distance measurement with a high degree of accuracy due to the visual assistance provided by the density profile image analysis.

2 Use: The function is provided by a click on this icon

3 Measure:

Draw a line perpendicular to the structure to be measured. A window appears showing the density profile along this line. Move the mouse cursor along this line and click to specify the points where you want to make the measurement. To end the measurement, double-click with the left mouse button. To cancel the measurement,

make a right mouse click.

4 Options:

1. Only 2 points are given, the distance between these 2 points will be computed (a)

2. 3 or 4 points are given, the information will correspond to (b and c) where:

    o **Arterial Lumen** is the size of the arterial lumen in mm.

    o **Arterial Diameter** is the diameter size in mm.

    o **Stenosis Degree**: ECST computed in %
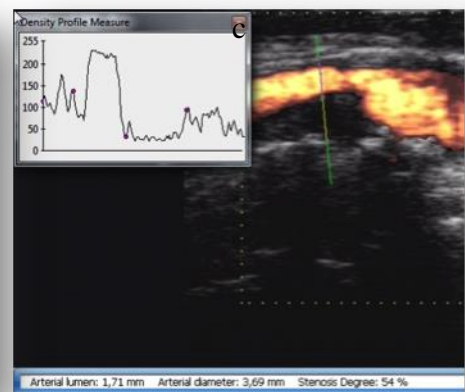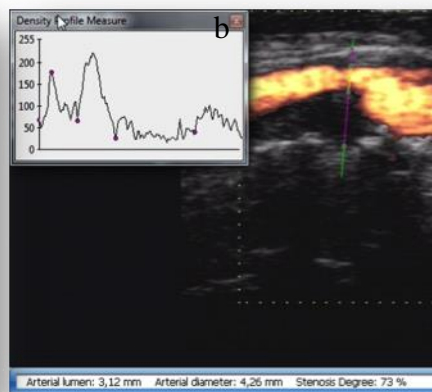
ANNOTATIONS

Annotations can be inserted on the image and then printed during report editing.
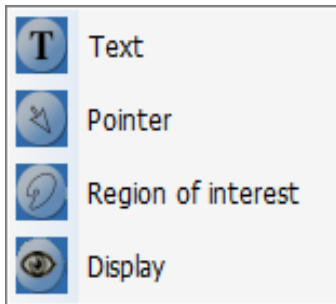
T Text	Insert of a text.
Pointer	Insert of an arrow.
Region of interest	Insert of a region of interest
Display	Displays or masks annotations
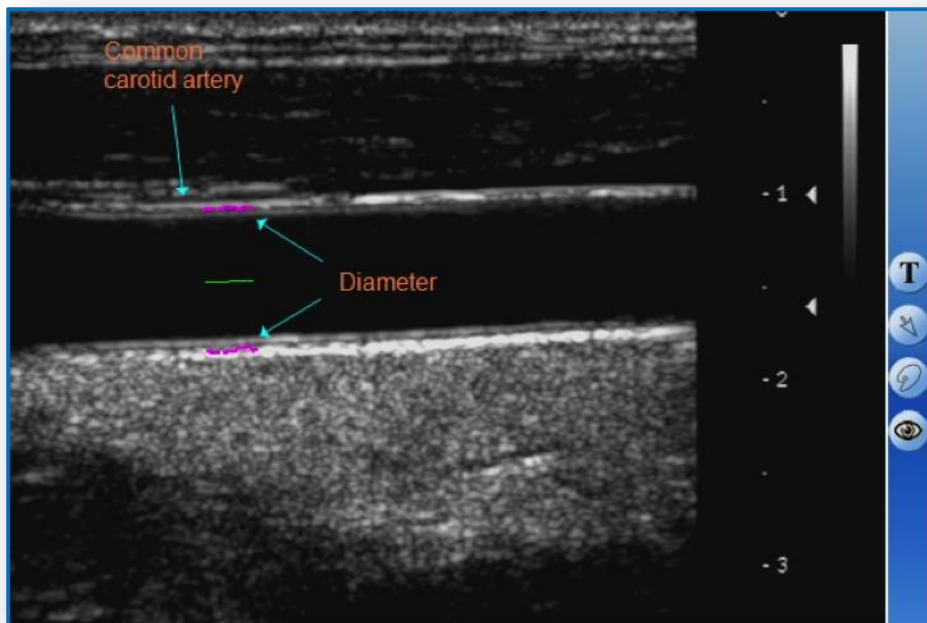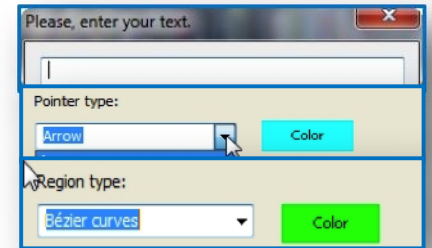
6 .REPRODUCIBILITY PROCEDURE (SR)

1. Introduction: Ultrasound examination highly depends on the angle of the ultrasound beam under which the vessel is scanned. To reduce measurement variability, the M'Ath SR procedure will be detailed below. It can be applied to intima media thickness plaque and stenosis degree follow up. The assistance provided to the sonographer helps him to obtain comparable angle at 2 successive examinations.

2   Procedure:

  ➢ At the first examination:

    -   Patient file and visit creations follow the same procedure.

    -   When the sonographer stores image he will be asked to choose with or without mask.
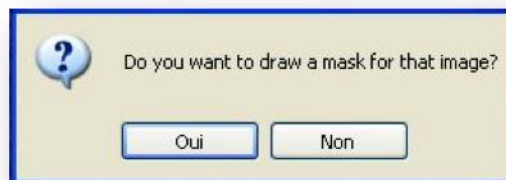
    -   If you click on "*Yes*", the cursor changes to a pencil allowing drawing the mask made of the main outlines located on the adventitial layer of the artery.

    -   The line is made of consecutive clicks on the left mouse button.

    -   A double right mouse click ends the current drawing and starts another line.
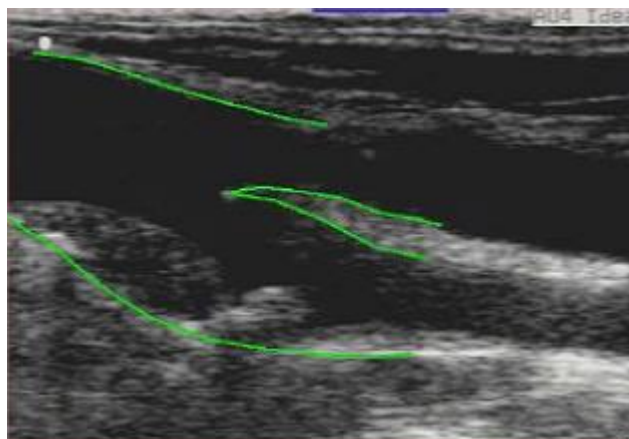
    -   When the mask has been drawn, click on image storage

- Then, fill the measurement side and situation box that stores the side, the head position of the patient during the ultrasound scanning and the probe angle relative to the body.
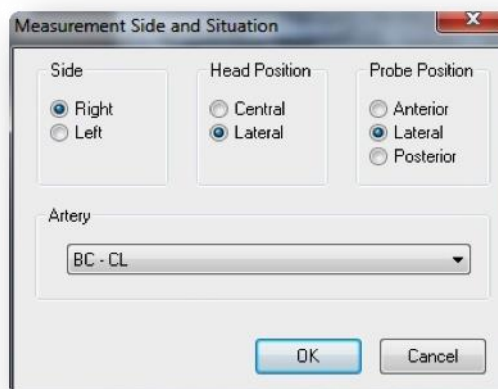
➢ At the follow up visit

- Select the patient file and validate

- Select the last visit

- Display stored images

- Double click on the thumbnail corresponding to the region you want to check.

- Create a new visit and start the acquisition mode

- Then you have to superimpose the arterial outlines with the pre-defined mask

Mask   Superimposition
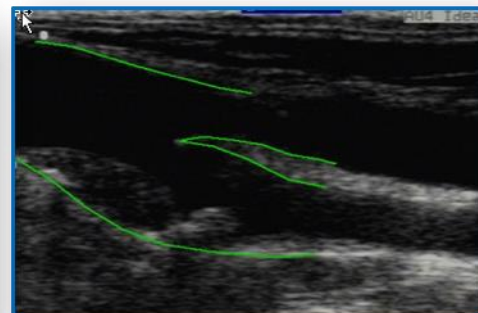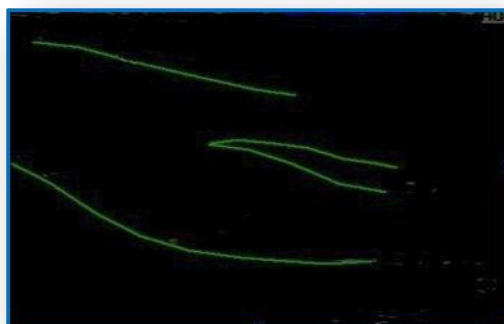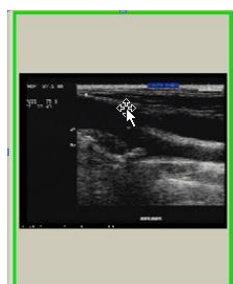
NB: You have the possibility to improve the mask at the second examination. If you do it, you will have to retrieve the last visit for the next examination, to obtain the last mask.

You can display or hide the mask using this icon

7. M'Ath PACS version

1 Introduction:

This version is dedicated to measurements done on images received from PACS . M'Ath PACS

can be installed on a virtual PC to receive DICOM images from pre specified PACS , and send

back images and DICOM pdf reports to this or another PACS.

2 Functions :

Semi automatic intima media thickness , from files received and possibility to send back pdf reports.

3 Examination Reader Guide in 10 points :

To launch the application , double click on the M'Ath PACS 3.2.1 shortcut on the desktop.
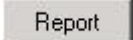
If not previously done , all the examinations which have been performed but not sent the day

before will be resent to the pre specified PACS.

Before starting , the reader needs to set the AE titles , IP address and port for reception and

sending of images and reports. (Fig c)

a. Click on the file icon to get the list of the patients sent for reading. (Fig d)
b. Click on the patient you want to analyze in the patient list. (Fig d)
c. All the images are displayed as thumbnails (You can move through the thumbnails with the mouse wheel , the right and left arrow , and the bottom rule. (Fig e)
d. Select the first scan you want to analyze by a click (a blue frame will circle it).
e. Then select the IMT measurement button or go to the menu "Measure"
f. Trace a line parallel to the vessel close to the far or the near wall over a distance of 10 mm on an arterial segment where the intima-media structure is visible.
g. When the line is traced from left to right, the measurement is made on the far wall of the artery. From right to left, the I.M.T measurement will be taken on the near wall.
h. Automatic detected interfaces lines are represented on the image (yellow, intima-blood interface and mauve for the media-adventitia interface).If the measurement is successful you must have a QI = or > than 0.5
i. A message box will ask you to check the side and confirm that you validate this measurement and the thumbnail frame will change into green. (Fig f)
j. You will have to specify the Ethnicity (on starting or later) and the side you are reading or each processed image (Fig g).

4 Report:

Before creating the report you must check that organization and phone fields are correctly filled on the patient card panel. (Fig h)

Click on [Report] the button

The results of the measurements are automatically stored in the DICOM tags and in he DICOM jpeg report. The pdf report shows on page 1 the 2 common carotid artery scanings with the graphics of the IMT detection (Fig i), on page 2 the graph on which are represented the dots corresponding to the right and left IMT measurements according to age , sexe and race of an American population* (ARIC Study) (Fig j) and on page 3 , optional informations and recommendations. (Fig k)

*References values are extrapolated below 45 and over 65 years.

5 DICOM Reception / Sending:

DICOM Images reception should be done after M'ATH PACS launch.

Check for correct PACS reception and sending configuration (under the Menu File).

When images of a patient file have been processed , you could see the pdf report and the 2 images and DICOM jpeg will be automatically sent back to the selected PACS.

A pdf report is automatically saved under the folder report (shortcut Data)

6 Credits :

On the bottom right of the state bar , you can see 3 items :

1 **Measures** provide you the number of clicks done , one click corresponds to one IMT

measurement. (Fig l)

No more than 1 credit will be added for the same image during the same reading procedure.

These credits can be ordered at any time. The support can upload the number of credits

ordered within 48h. They are available for each session and must be uploaded with the

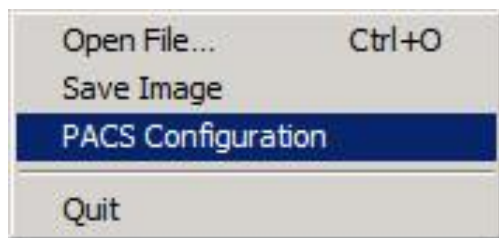counter application. (Fig m) which can be runned from administrator session.

2 **Remaining** provides the number of the number of IMT measurements

3 **Warning** is set at 100 value which means that 50 patients

   can be performed before the application stops working.

a. PACS Configuration

b. Patients list
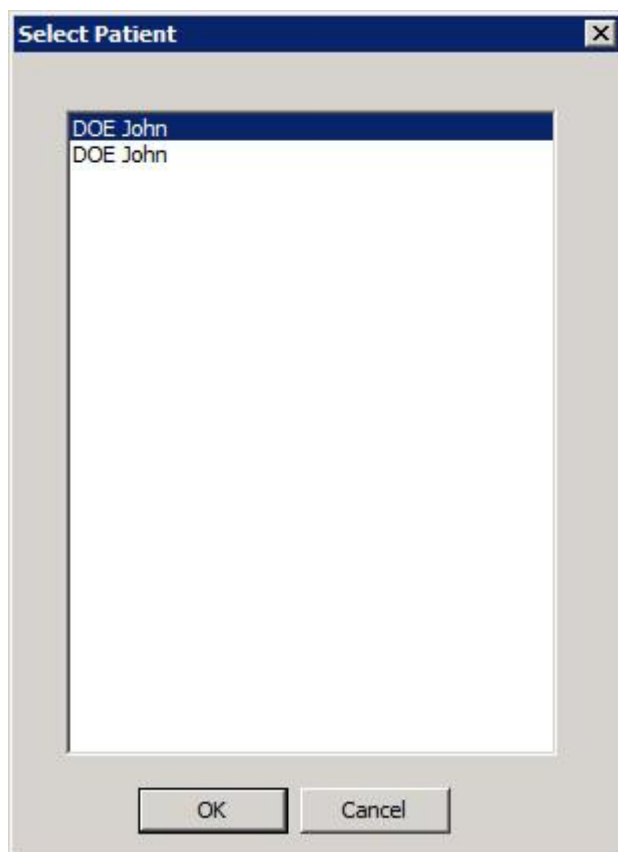
   c. Thumbnails : Blue for selection , green for processed
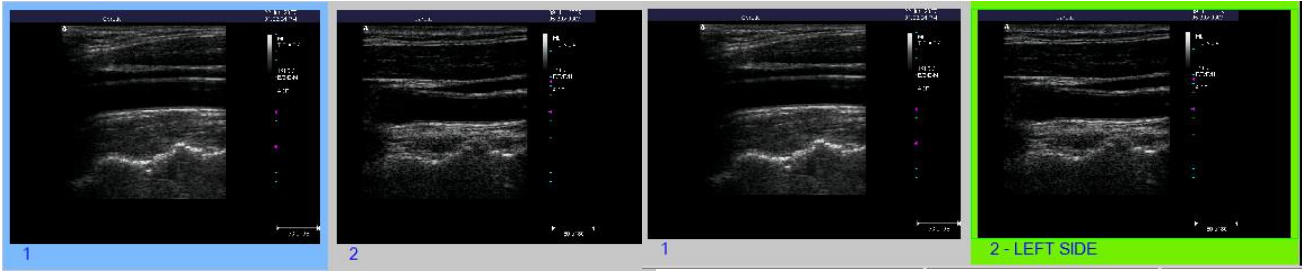
d. Side selection

e. Select Ethnicity

f. Patient and organisation card

Last Name Doe
First Name John
Birth Date 5/ 7/1963
Sex ⊙ Male ○ Female
Ethnicity

Organisation Medquest ← Select the Ethnicity

Phone (404) 808-1842 ← To Edit

Technical support: support@iimt.fr

Intelligence in Medical Technologies

Report ← Generate the Report

A - Definitions :

(1) IMT is a double-line pattern visualized by echography on both walls of the CCA in a longitudinal view.
(2) Plaque is a focal structure encroaching into the arterial lumen of at least 0.5 mm or 50% of the surrounding IMT value, or demonstrates a thickness > 1.5 mm as measured from the intima-lumen interface to the media-adventitia interface.

B - Measurement Location :

(1) IMT should be measured preferably on the far wall of the CCA at least 5 mm below its end.
(2) Along 10 mm length of a straight arterial segment, a high-quality image acquisition is required for reproductible serial measurements.

Carotid Intima Media Thickness Ultrasound Report

Patient Name: DOE John	DOB: 06/07/1963, 52 yrs	Patient ID: 04-338742
Study Date: 06/22/2007	Acc. No.: 04-1690829	
Referring MD: YoungTimothyMD	Sonographer:	
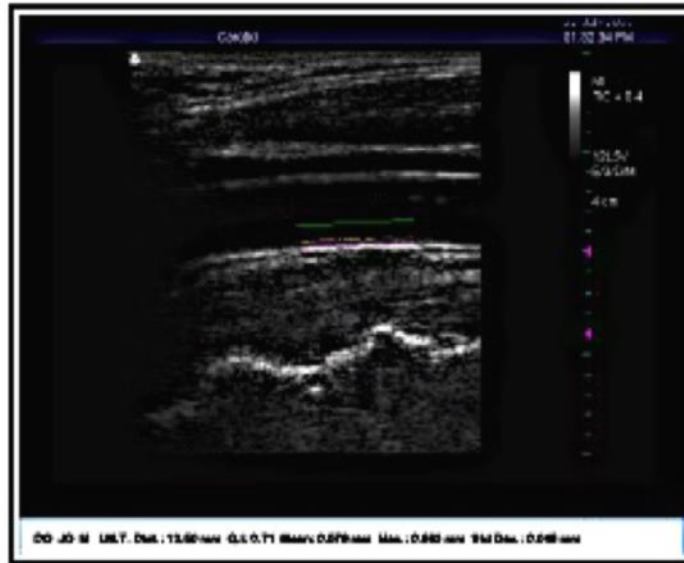
R - IMT. Distance = 12.50 mm, QI = 0.71, Mean = 0.578 mm, Max = 0.663 mm
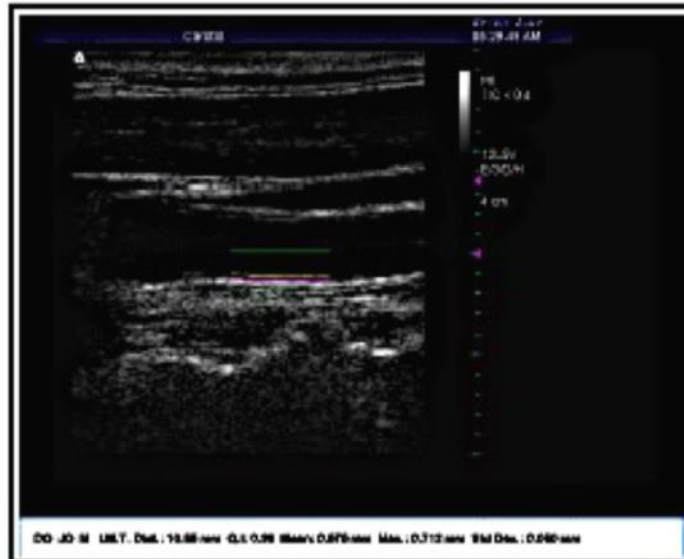
L - IMT. Distance = 10.55 mm, QI = 0.98, Mean = 0.575 mm, Max = 0.712 mm

DOE John   08/09/2016

mAth
PACS 3.2.1
Page 1

Carotid Intima Media Thickness Ultrasound Report

Age		35	40	45	50	55	60	65	70	75
25th Peti	R	0.430	0.465	0.500	0.535	0.570	0.610	0.650	0.690	0.730
	L	0.450	0.485	0.520	0.555	0.590	0.620	0.650	0.680	0.710
50th Peti	R	0.480	0.525	0.570	0.615	0.660	0.710	0.760	0.810	0.860
	L	0.520	0.560	0.600	0.640	0.680	0.725	0.770	0.815	0.860
75th Peti	R	0.550	0.605	0.660	0.715	0.770	0.835	0.900	0.965	1.030
	L	0.600	0.650	0.700	0.750	0.800	0.865	0.930	0.995	1.060

_____ : ARIC Reference Values from G. Horward and al. Stroke 1993; 24; 1297-1304, Men, Caucasian.

---- : Extrapolated values.

Right CCA IMT : Mean = 0.578 mm, Max = 0.663 mm

Left CCA IMT : Mean = 0.575 mm, Max = 0.712 mm
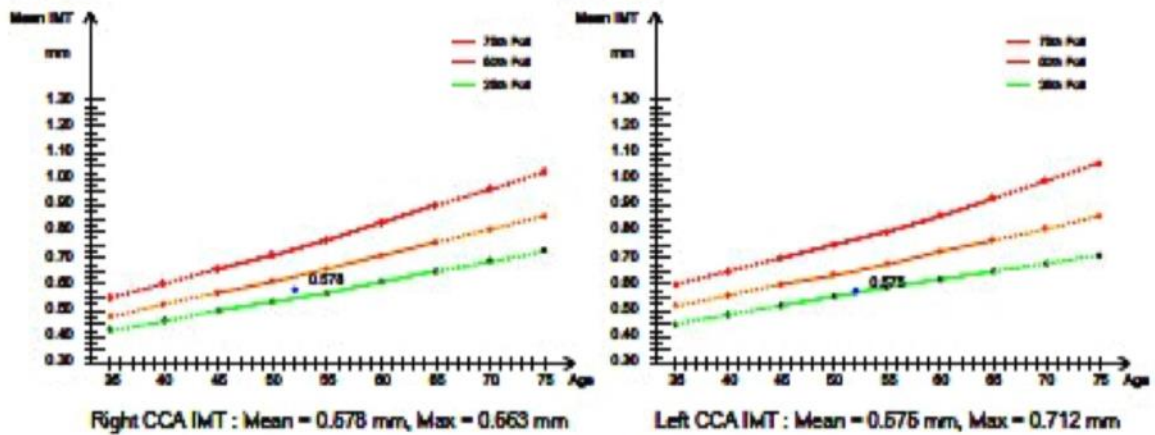
Conclusion :

Signature:

DOE John   08/09/2015

mTath
PACS 3.2.1
Page 2

Intima media thickness measurement (IMT)

What is IMT ?

Intima media thickness is made of the 2 first internal layers of the arterial wall: the intima, very thin layer which protects the artery from local deposits of blood components and the media composed of muscle cells which increase their number with high blood pressure.

Its representation on ultrasound image a regular double line pattern well seen on the far wall of the common carotid artery. Plaque is a focal encroachment into the arterial lumen.

Why is it important ?

The non modifiable risk factors that may influence IMT values are age sex and genetics, High blood pressure, lipids, diabetes and smoking are the modifiable factors on which life style modifications and drugs can be recommended.

Increased IMT can predict clinical outcomes as myocardial infarction and stroke. This has been validated by many prospective studies.

How is it measured ?

The conclusions of an international consensus of experts initiated in 2004 and revised in 2006 have precisely defined carotid IMT and plaque. This consensus recommends measuring IMT at the lower level of the carotid artery called common carotid.

In practice, the ultrasound examination of the carotid artery consists in freezing an image of this artery and automatically measuring it with a software. The results are expressed as the mean value over a 10mm segment of common carotid artery.

When to measure Intima Media Thickness ?

The presence of atherosclerosis risk factors, that is mainly arterial hypertension, dyslipemia, diabetes, smoking or overweight, comes with an increase of IMT in many cases and even more if they are associated.

This measurement shows great information on subjects who have one or more risk factors as it reveals when increased a target organ damage and facilitates the individual cardio-vascular risk evaluation.

However, there is no need to watch its evolution outside of epidemiological or interventional studies.

Suggestions for maintaining a healthy vascular system.

- Stop smoking.
- Eat a healthy, low fat diet.
- Talk to your doctor if you are overweight to plan the best weight loss strategy for you.
- Maintain good cholesterol levels.
- Maintain blood pressure in a normal range.
- Exercise regularly - even a moderate walking program can be effective.

m'Ath 3.2.1

REPORT, Doc   06/02/2012   Page 3

j. Credits State Bar

k. IMT Counter

8. EXAMINATION REPORT

1 Introduction:

The functions associated to the examination report allow a large flexibility of editing and print out. You can create CIMT reports or more extensive reports including 3 to 12 images Reference values tables and graphs including percentiles according to age and sex allow to address personalized report. Print out includes not only images and conclusion but also all the measurements and drawings of IMT, plaque and stenosis when they have been measured.

Before starting report section, it is appropriate to install a printer and connect it to your PC.

2 Report Editing:

g. To start report click on Edit in the section Report
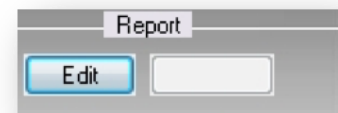
h. You will have to choose the type of report
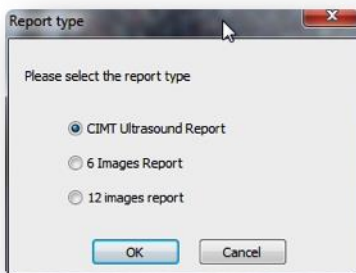
i. On the bottom of the display is the list of images that you can select and move by drag and drop to a specified site
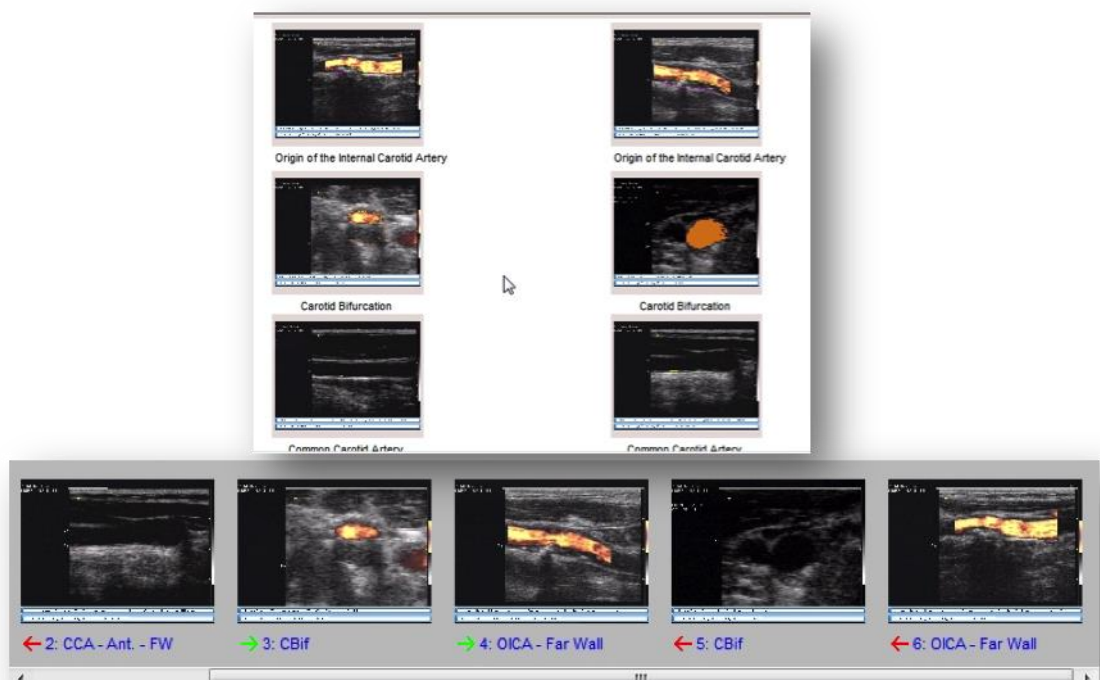
j.   Click on Tables

k.   This windows allows table selection, if not applicable check the box : No

     Table, if you wish to keep this table by default check the first box
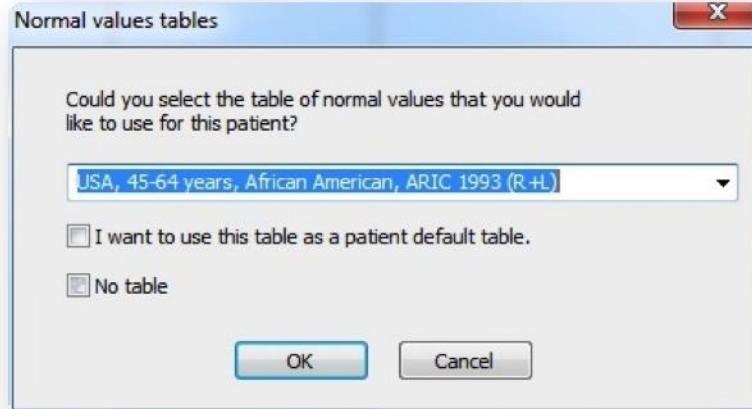
l.   Fill the following file including the report and check the box below the

     report if you which to include the General recommendations.
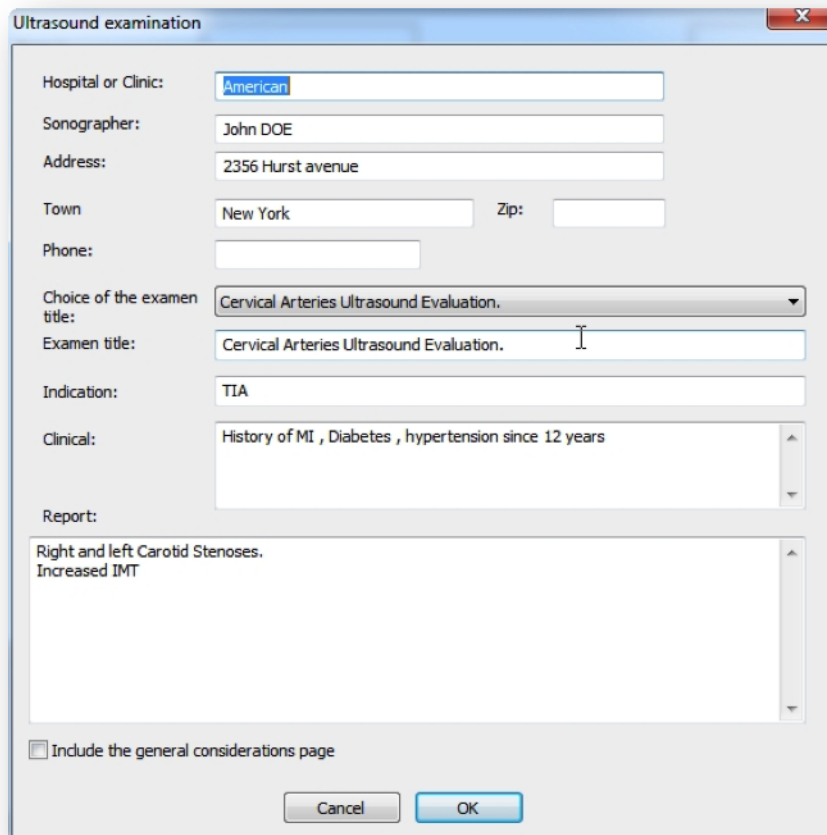
REPORT

```
CCA - Ant. - NW - LV
CCA - Ant. - FW - LV
CCA - Lat. - NW - LV
-> CCA - Lat. - FW - LV ( Graph )
CCA - Post. - NW - LV
                              Common
```
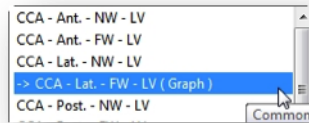
m. A dialog box will propose a complementary print out of the table of results.

> ? Do you want to print the table of results?
>
> Yes   No
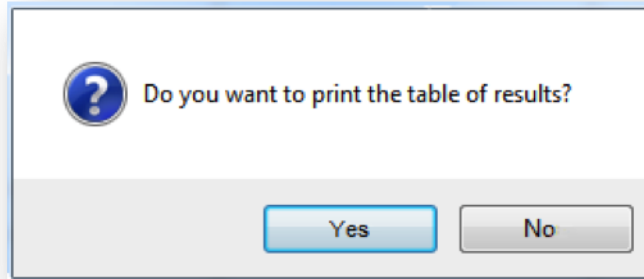
n. This window gives you the final information on the pdf created.

> (i) The report creation is on progress and will be automatically stored as a pdf file (Last Name - First Name - Year - Month - Hour - Folder N°). If you want to recall it, go to the desktop shortcut "Reports".
>
> OK
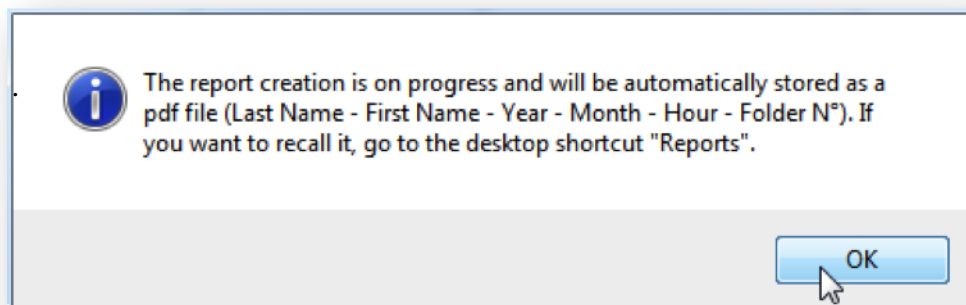
IMAGES REPORT

Cervical Arteries Ultrasound Evaluation.

Patient ID: 4
DOB: 01/01/1962, 50 yr
Referring MD: ,
Clinical:
Indication:

Patient Name: REPORT, Doc
Study Date / Visit N°: 05/20/2012 / 1
Sonographer: John DOE
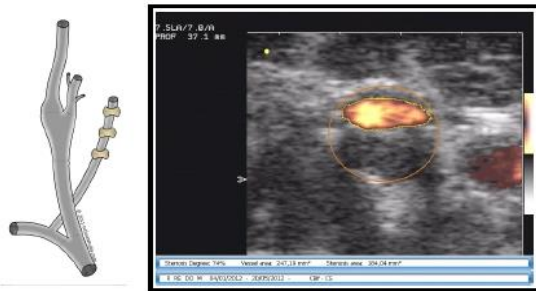
R - Carotid Bifurcation
Stenosis Degree = 74 %

L - Carotid Bifurcation
Stenosis Degree = 42 %
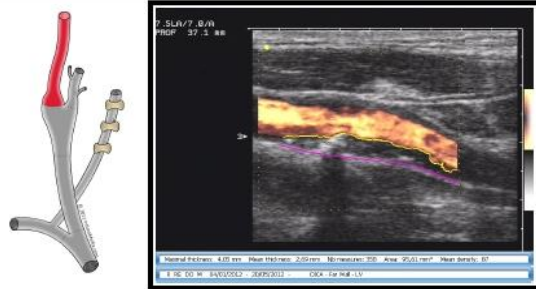
R - Origin of the Internal Carotid Artery
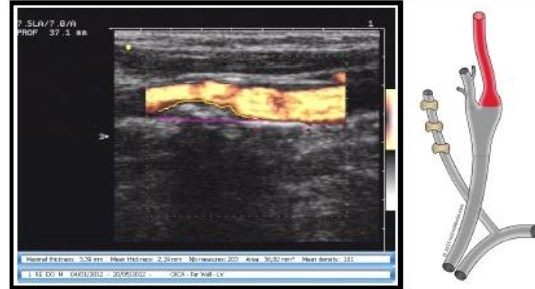
L - Origin of the Internal Carotid Artery
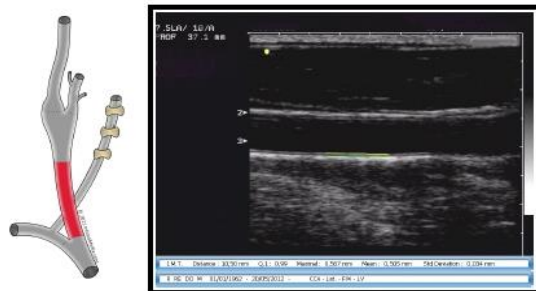
R - Common Carotid Artery
Intima Media Thickness = 0,505 mm

L - Common Carotid Artery
Intima Media Thickness = 0,783 mm

M'Ath 3.2.1

REPORT, Doc   06/02/2012   Page 1

GRAPH and MEASURES

Mean

Mean IMT mm vs Age graph with 75th percentile, 50th percentile, 25th percentile curves; point 0,644 plotted.
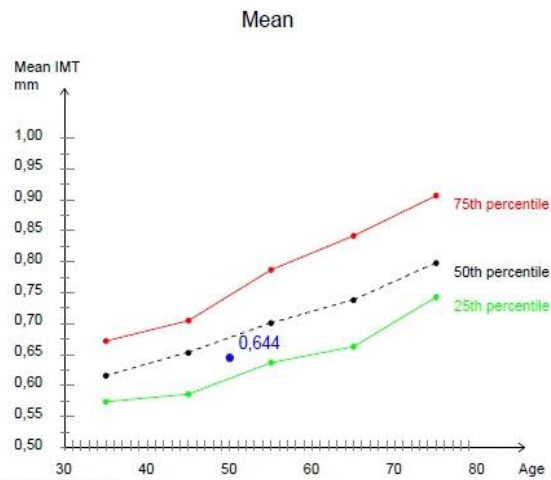
Table: Europe, France, 30-79 years, PARC 2009 (Mean)

Summary of Semi-Automatic measurements

		Common Carotid Artery Incidence : Anterior		Common Carotid Artery Incidence : Lateral		Common Carotid Artery Incidence : Posterior		Mean IMT	Carotid Bifurcation		Internal Carotid Artery	
		R	L	R	L	R	L		R	L	R	L
IMT Far Wall (mm)	Mean	0,505	0,779	0,505	0,783			0,643				
	Max.	0,567	0,898	0,567	0,903			(4 Measures)				
Plaque Thickness	Max. (mm)										4,05	3,39
	Area (mm²)										95,607	36,821
Stenosis degree CS (%)									74	42		

Conclusion :

The information and or results provided herein should not be used during any medical emergency or for the diagnosis or treatment of any medical condition. A licensed physician should be consulted for diagnosis and treatment of any and all medical conditions. Your Doctor should interpret this IMT results in conjunction with your other risk factors. Risk factor modifications should be made with the consultation of your Doctor. Call 911 for all medical emergencies.

Signature:

M'Ath 3.2.1

REPORT, Doc 06/02/2012 Page 2
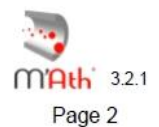
GENERAL INFORMATION

This information can be skipped on the report.

Intima media thickness measurement (IMT)

What is IMT ?

Intima media thickness is made of the 2 first internal layers of the arterial wall: the intima, very thin layer which protects the artery from local deposits of blood components and the media composed of muscle cells which increase their number with high blood pressure.

Its representation on ultrasound image a regular double line pattern well seen on the far wall of the common carotid artery. Plaque is a focal encroachment into the arterial lumen.

Why is it important ?

The non modifiable risk factors that may influence IMT values are age sex and genetics, High blood pressure, lipids, diabetes and smoking are the modifiable factors on which life style modifications and drugs can be recommended.

Increased IMT can predict clinical outcomes as myocardial infarction and stroke. This has been validated by many prospective studies.

How is it measured ?

The conclusions of an international consensus of experts initiated in 2004 and revised in 2006 have precisely defined carotid IMT and plaque. This consensus recommends measuring IMT at the lower level of the carotid artery called common carotid.

In practice, the ultrasound examination of the carotid artery consists in freezing an image of this artery and automatically measuring it with a software. The results are expressed as the mean value over a 10mm segment of common carotid artery.

When to measure Intima Media Thickness ?

The presence of atherosclerosis risk factors, that is mainly arterial hypertension, dyslipemia, diabetes, smoking or overweight, comes with an increase of IMT in many cases and even more if they are associated.

This measurement shows great information on subjects who have one or more risk factors as it reveals when increased a target organ damage and facilitates the individual cardio-vascular risk evaluation.

However, there is no need to watch its evolution outside of epidemiological or interventional studies.

Suggestions for maintaining a healthy vascular system.

- Stop smoking.
- Eat a healthy, low fat diet.
- Talk to your doctor if you are overweight to plan the best weight loss strategy for you.
- Maintain good cholesterol levels.
- Maintain blood pressure in a normal range.
- Exercise regularly - even a moderate walking program can be effective.

9. SHORTCUTS

1. Main menu:

Open File:	Ctrl + O
Print:	Ctrl + I
IMT measure:	Ctrl + E
Diameter measure:	Ctrl + D

2. Patient File:

Create a new file:	Ctrl + N
Search for a patient:	Ctrl + Enter
To access the next file:	Ctrl + right arrow
To access the previous file:	Ctrl + left arrow
To go forward by 10 files:	Ctrl + Up
To go back by 10 files:	Ctrl + Down arrow

3. Graphic mode:

Freeze:	Space bar
Store:	Enter
Record an image under:	Ctrl + S
IMT measurement:	Ctrl + D

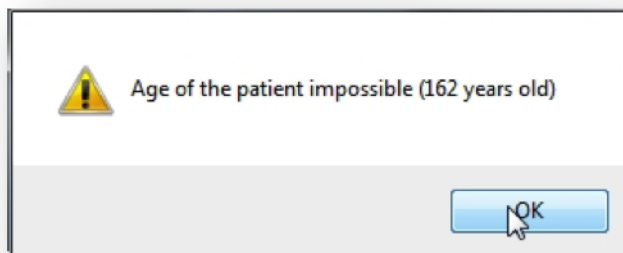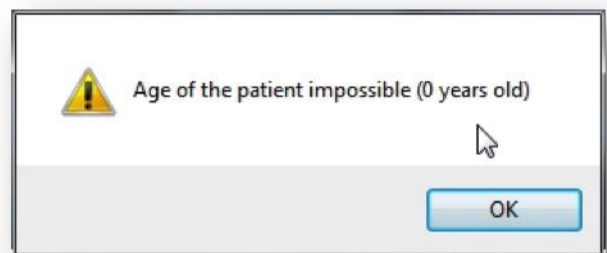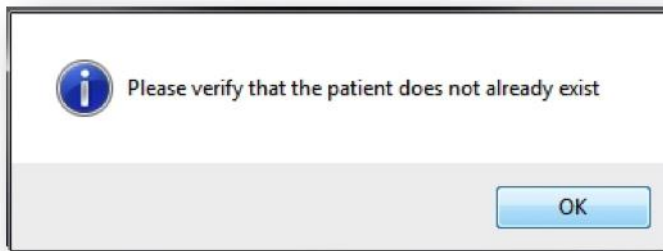**Video mode:**

|	
Move to the previous frame:	Up or Left arrow
Move to the next frame:	Down or Right arrow
Record a sequence:	Enter

III. TROUBLESHOOTING

TROUBLESHOOTING

1. Error messages creating a new patient file

   These windows appear when some errors occur at the file edit.

   Please verify that the patient does not already exist

   Select the sex (male / female)

   Set patient's last name

   Age of the patient impossible (0 years old)

   Age of the patient impossible (162 years old)

2. Error messages when creating a report

   The tables have a range of age, some error message may occur if the age of the patient

   is out of the range of the corresponding reference table.

   The patient IMT mean value is out of the table values

   The patient age is out of the table values
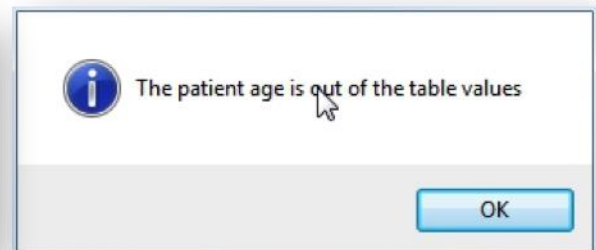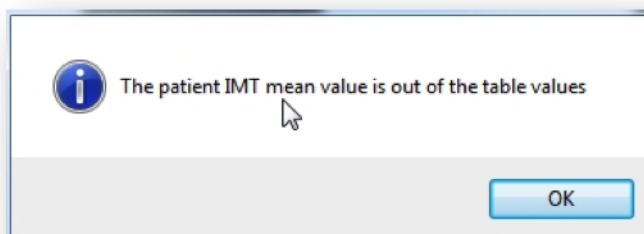
IV. M'Ath Software Features

MAIN CHARACTERISTICS

- Real time Video Acquisition;

- DICOM Automatic calibration.

- Multi-lingual (English, French, Italian, German, Spanish)

- Automatic edge detection algorithms for IMT, plaque, distensibility and stenosis degree.

- IMT Quality index.

- Measurement of the Average Intima Thickness.

- Measurement of the degree of stenosis in cross sectional and longitudinal view

- Semi-automatic plaque thickness and area measures.

- Distensibility measurement on video sequence.

- Real time analysis of images and sequences

- Reproducibility function. (SR) (M'Ath SR section)

- PACS Modality (M'Ath PACS Section)

- Files exportation.

- Images and videos storage;

- Patient database (Access);

- Automatic calculation of the mean value of Right and Left common carotid arteries;

- Reporting including reference values in US, France, Latin America, Italy ….

- Editing and documented print out of the patient (pdf).

- Used by more than 2000 centers or physicians in more than 50 countries