M'AthCloud® User Guide





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M'AthCloud®, available on the Internet, is a tool for quantifying normal or pathological vascular structures, in semi-automatic or manual mode on ultrasound images

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A- SPECIFICATIONS for USE

Destination: Quantification of the measurement of normal and pathological arterial structures (atherosclerosis) from ultrasound images collected by B-mode ultrasound.

Clinical Benefit: In terms of positive impact on patient health care and inassociation with the various risk factors for atherosclerosis, it includes:

- ♣ The measurement of geometric parameters of superficial arteries:
 - the Intima media thickness (EIM) in mm of the distal wall of the common carotid artery and the comparison with reference values according to age, sex and the populations concerned.
 - the thickness and area of atheroma plaques in mm and mm2
 - measurement of the degree of stenosis (reduction in% of the useful diameter of the artery)
 - measurement of the distensibility of the artery in% (variation in diameter during the cardiac cycle)
- ♣ The contribution to the diagnosis of the risk of atherosclerosis (HDL-C, PA, ..) and thus to the predictive value on the risk of stroke and heart attack.
- ♣ The proposal for a public health tool to assess individually the cardiovascular risk (personalized medicine) and in clinical research the efficacy and safety of medicinal substances for the treatment of atherosclerosis and the safety of other drugs in terms of vascular.

Operating principle: Image analysis and display software using algorithms of semi-automatic detection and identification of anatomical image and structures Ultrasound images collected by B-mode ultrasound.

- A Calculation of distances, areas according to the dimension of the pixel recorded in the image.
- A Comparison of measurements obtained on the image of a patient with reference values according to age, sex and type of population.

Clinical Performance: Medical effect allowing the destination to be reached as indicated by the manufacturer, and thereby produce clinical benefit for patients: General Safety Requirements and Performances whose compliance must be confirmed by clinical data:

The relevant general safety and performance requirements set out in Annex I in normal conditions of use of a device (see below § 15), as well as the evaluation of the effects secondary undesirable (Not Applicable: diagnostic device without interaction with the patient) and the acceptable risk / benefit ratio referred to in Annex I, Sections 1 and 8.

Indirect medical effect (resulting from its technical or operating characteristics, including diagnostic): From ultrasound images collected by B-mode ultrasound,

- Measurement of the intima media thickness (EIM) d in mm of the distal wall of the common carotid artery and comparison with normal values according to age and types of populations:

French study PARC: Arterial wall and cardiovascular risk.

American study ARIC Arteriosclerosis Risk In Communities

Latin America CARMELA study (Risk Factor Multiple Evaluation in LA)

- Measures the thickness and area of atherosclerotic plaques in mm and mm2-
- Measures the stenosis degree (reduction in% of the useful diameter of the artery
- Measurement of the distensibility of the artery (% variation of D during the cardiac diastole-systole cycle)

Target users: The M'Ath® Family Software is aimed at doctors specializing in vascular pathology (Cardiologists, Neurologists, Vascular doctors, Vascular surgeons, Radiologists, Sonographers, etc.), and technicians who have received training in '½ day on the use of the software.

Target patient population: Adults Men / Women from 30 years old with or without atherosclerosis risks factors. Genetic metabolic diseases in children (clinical research)

B-PRODUCT INFORMATIONS



IMT Manufacturer 15bis rue de Marignan 75008 Paris France (+33)1 45 78 11 11

Support: support@iimt.fr Serious Event : mail to prrc@iimt.fr



Manufactured on 03/26/2021



Warning: It is mandatory to read and print the user manual before using this software. Especially the intended use.

Intended use:



Imaging of vessels and quantification of atherosclerosis to aid in the diagnosis: only the doctor will be able to make any decision with respect to the patient, based on all the elements in his possession, of which these results will only be a part. Biometry applied to normal and pathological images collected by Doppler ultrasound in the medical field (precise, rapid, reproducible measurements on a large number of samples).

Users:

Physicians specialized in vascular pathology, cardiologists, sonographers and technicians who have received a half day training.



Compliant with Directive 93/42EEC on Classe IIa medical devices.



Medical Device



Unique Device ID : 03760264690214

C-WARNINGS

The author, publisher and distributors of the software cannot be held responsible for the diagnosis made from the measurements taken and in general from the decisions made by the doctor.

The software publisher and its distributors can also not be held responsible for damages resulting from the use or the inability to use this software or the equipment that supports it: loss of data, bodily injury, financial loss of whatever nature it is. The publisher guarantees the software's compliance with the accompanying written documents.

The publisher accepts no responsibility for any malfunction associated with the installation of other software without its approval. The information in this manual is subject to change without notice.



Training adapted to the use of this product will be offered to you when taking subscription.



It is important to read and print this manual before using the software.

Any reproduction of this manual is strictly prohibited and may be subject to legal action.

D-SAFETY MEASURES

Please read the following information carefully before using the software.



This app should only be used by trained users.

This app does not provide diagnostics. It is only intended to help practitioners in the assessment of vascular disease by allowing them to perform precise measurements.



The consistency of the results depends on the quality of the images acquired.

The user must ensure the quality of the images acquired before making measures. A quality index allows him this evaluation for the measurement of Intima Media Thickness (IMT)

E-OPERATING SYSTEMS

M'AthCloud® works on Mac et PC . 3 Internet browsers can be used :

Microsoft Edge, Google chrome, and Safari.

The minimal screen resolution must be 1420x820 pixels

F-USER LICENCE

M'AthCloud® application is accessible at https://www.ipsocloud.com. The user logs with an email address and password that he himself defines when registering. Access to features is only possible after acceptance of the terms of use and purchase of credits.



These data are strictly personal, and the user may not under any circumstances communicate them to a third person.

G- MEDICAL CONTEXT

Ultrasound imaging has benefited in recent years from remarkable developments by improving the definition and density of the biological structures analyzed. Vascular ultrasound has demonstrated its interest through the non-traumatic nature of this examination and the quality of the examination. The information it provides on vascular structures. The quantification of the parameters characterizing these structures appeared to us to be fundamental in order to better define the spatial dimensions of the vessels visualized.

Thanks to the M'AthCloud software, the sonographer, the practicing physician and the patient can benefit from an accurate and reproducible evaluation of the data of the vascular ultrasound examination. As you will see by reading this manual, the use is simple, the results are immediate and the simultaneous archiving of the measurements allows a security and a saving of appreciable time.

The necessary training is essential and accessible to doctors or technicians trained in its use.

This software makes it possible to perform the measurements useful during the performance of a vascular ultrasound examination in a patient. It also makes it possible to follow the evolution of the pathology over time, to compare images with each other and to print a synthetic patient file highlighting the images that the user will have selected The practitioner can select the territory concerned: carotid artery, abdominal aorta, upper or lower limbs.

It can also be used in clinical studies. It then allows harmonization of data collection and processing, simplified access and therefore easier study participation.

H- MODES OF USE

M'AthCloud® is an application accessible on the site www.ipsocloud.com from any computer or station connected to the Internet. This software enables measurements of the carotid intima media thickness as well as thickness and area of atheromatous plaques, and measurements of distance and area of vascular structures.

It is available in two different modes:

- **Practitioner** mode, its purpose is then to help the doctor measure the various vascular parameters at from ultrasound images and produce a quantified report evaluating the pathology observed.
- Clinical Studies mode with the same functionalities. However, it is focused on the organization and management of data from different centers in multicentre studies. It achieves a major progress in data management, avoiding repetitive tasks and allowing real-time evaluation of the progress of the study, and of the activity of the various investigators and reviewers concerned.

I-REGISTRATION

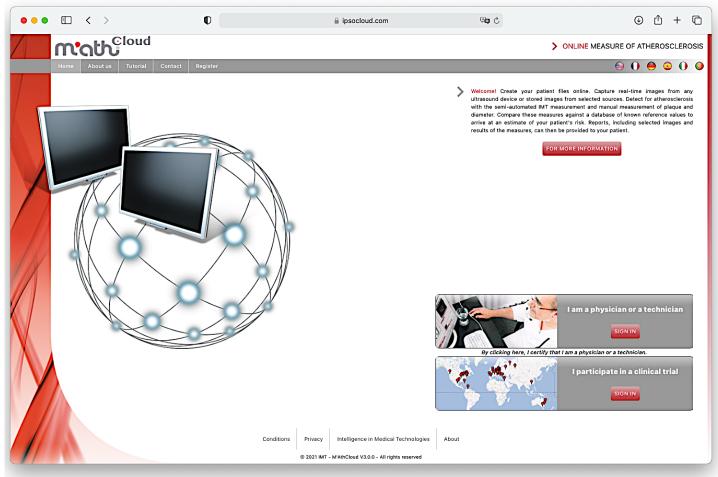


Fig. 1 Home

On the home page (Fig. 1) of the secure site www.ipsocloud .com, the user clicks on Physician or button and will have to complete the registration form (Fig. 2).

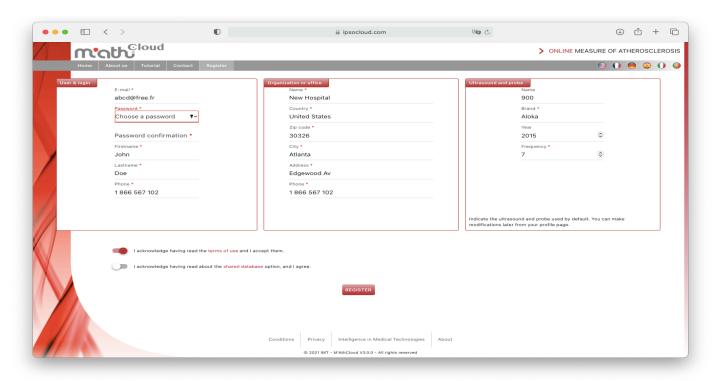
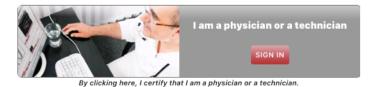


Fig.2 Registration

This form includes the informations of the User, the Medical Structure and the Equipment used. After validation of this information, the user will receive from IMT, on his email address, a link allowing him to access M'AthCloud® as soon as he has signed his license agreement and paid for the credits he wishes to order. When logging in again, click on the connection button corresponding to the Physician (Fig 3.a) then log in from the "Physician" box (Fig 3.b)

He is then invited to click on the button REGISTER

Fig 3.a Sign In



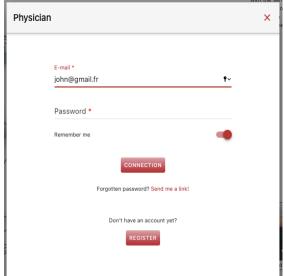


Fig 3.b Connexion

If the user is already registered, he can connect with his password and email. (Fig. 2)

With the "Remember" option, you don't have to re enter your email address for next login.

If you forget your password, click on "forgot password", you will receive by Email a connection link to be able to reset your password.

You have to accept the conditions of use and to have already bought credits to get access to the application.

The minimal resolution of the screen must be 1420x820 pixels. (D-Operating System -page 3)

I. USE



1.1 Creation of the registration of new patients and visits

The creation of new patients can take place in 2 modes:

- 1- New patient: the user fills in the necessary fields and creates the file (Fig. 4)
- 2- New Patient imported from a PACS: allows you to import patients and visits from a PACS (Fig. 5) On this page are listed the patients already registered from which can be made new visits.

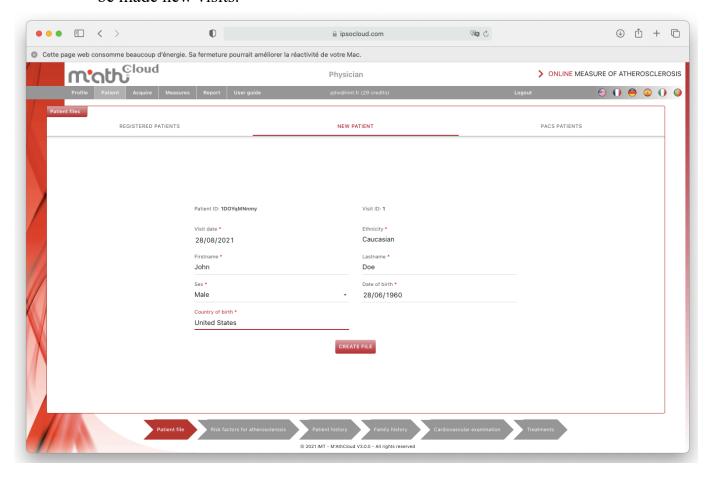


Fig. 4 New Patient

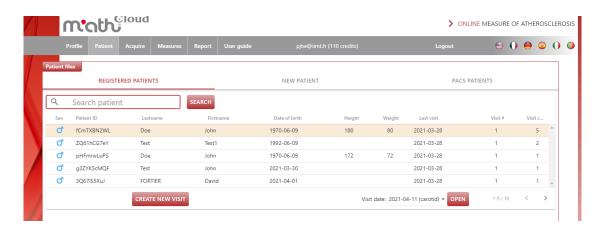


Fig. 5 List of registered Patients





Fig.5 Patients PACS

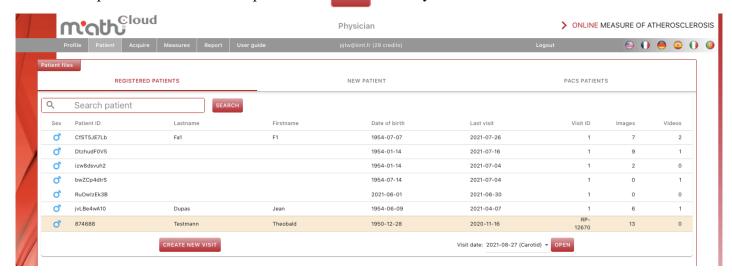
1- Patient Menu

1.2 Creation of a new visit from patients already registered (Fig. 6)

Select a folder and click on CREATE NEW VISIT. You can then save the clinical file or go directly to the main menu

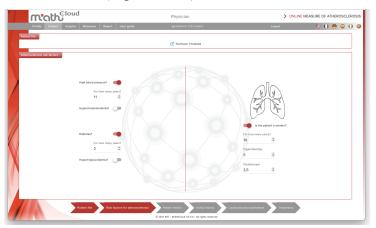
Acquire to choose the arterial field and the images or videos to save for the new visit.

A drop-down list next to the open button open allows you to view and select all the visits recorded.



1.3 Recording of Clinical Data

By clicking on the "clinical data" tabs at the bottom of the page Risk factors, personal and family history and cardiovascular examination can be recorded for each visit (Fig. 7,8,9,10).



Properties Property Record Contract Name of Contract Name

Fig.7 Atherosclerosis Risk Factors



Fig.9 Family History
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Fig.8 Personal History

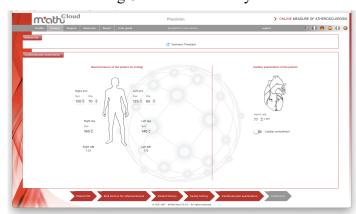
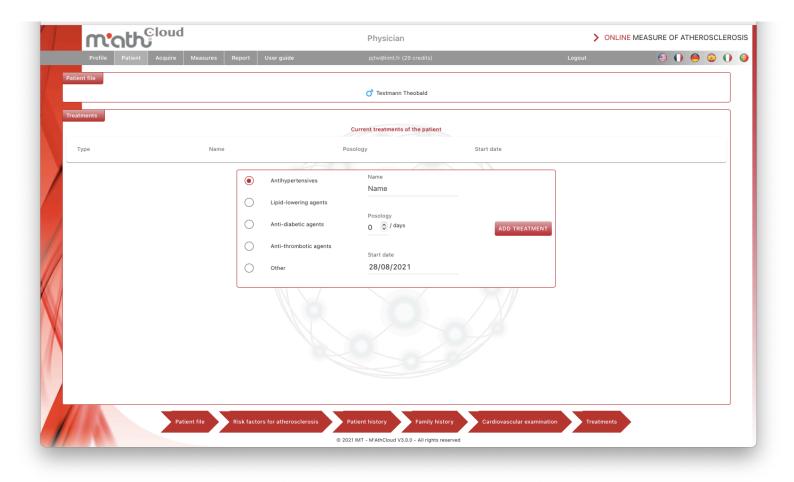


Fig.10 Cardio Vascular Examination Author P-J. Touboul © 2015-2021





2.1 Choice of the territory

Before uploading images or videos, the choice of arterial territory associated with corresponding graphic representations are proposed, 4 choices are possible:

Fly over the region of interest using the mouse to choose one of them. (Fig. 11)

- 1 Cervical arteries
- 2 Arteries of the upper limbs
- 3 Abdominal aorta
- 4 Arteries of the Lower Limbs

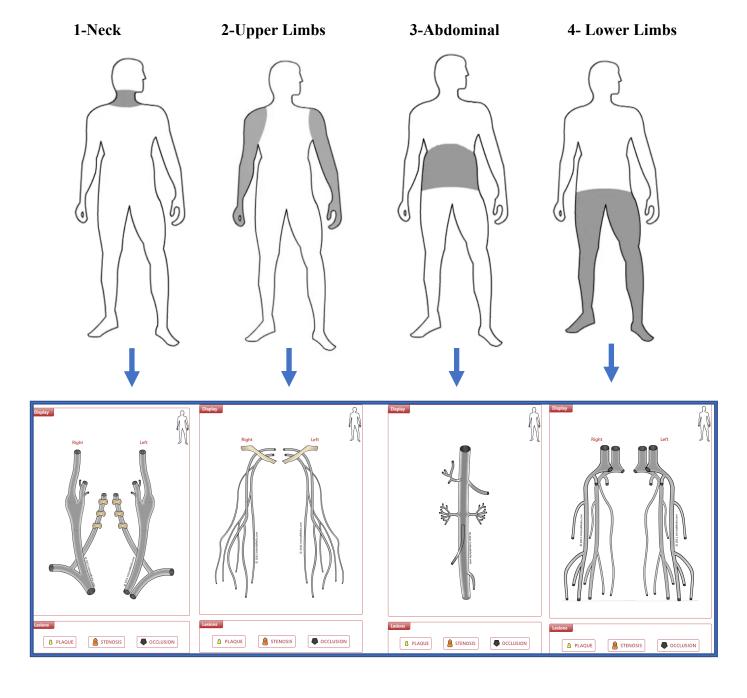


Fig.11 Choice of the vascular field

2.2 Acquisition et archiving Images and Videos

M'AthCloud® software can process images in JPEG and DICOM format of all sizes. The images can be acquired from the video stream or from a folder located on a logical drive (C, D, USB stick or CD ROM).

The selected image or video is displayed in the middle part of the screen.

On the right side, in the the chosen topography. (Fig. 12)

In the graphic frame, you can return to the choice of arterial territory by clicking on If you want to archive this image, you must use the mouse to hover over the various arterial segments located in the area. These will automatically light up in red, displaying the name associated with it under the corresponding area.

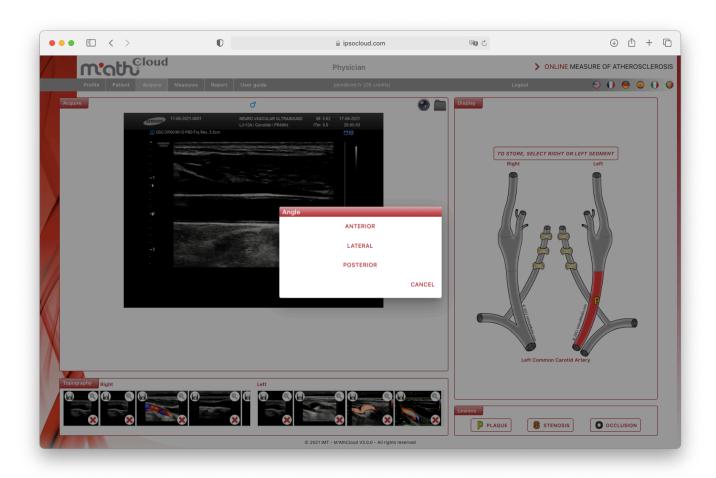
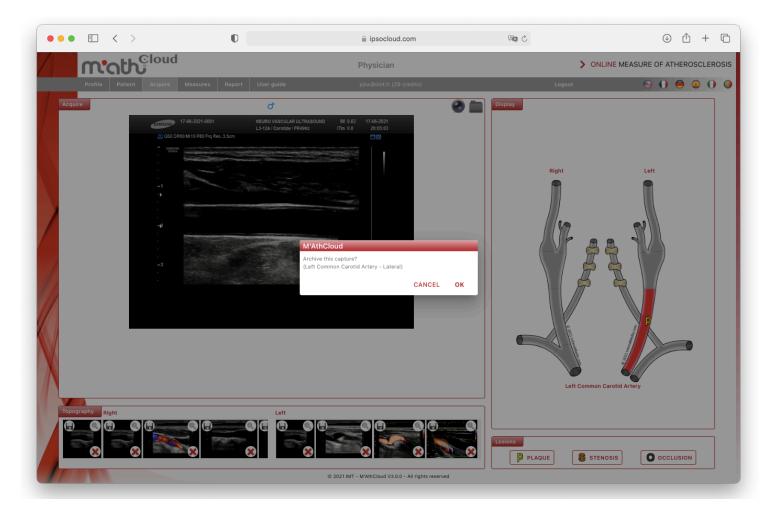


Fig.12

The archive message will stop flashing as soon as you click on one of the segments. A message box will then ask you to choose the orientation of the Anterior, Lateral or Posterior probe (Fig. 12), then to confirm the archiving of this image (Fig13). If the information in the message box does not match the desired topography, you can cancel and start the operation again.



Dans l'espace topographie, sous l'image apparaît alors la vignette correspondant à cet archivage Cette vignette porte sur ses bords trois icones (Fig.14):









Fig 14 Thumbnails



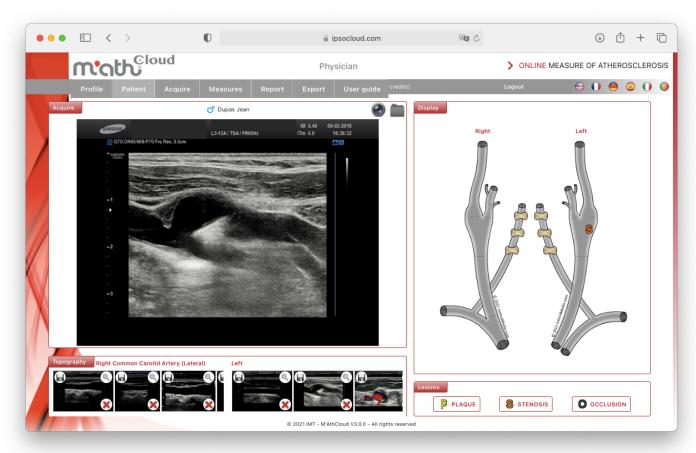


Fig.15 Positioning of Left Stenosis

2.3 Positioning of Plaques, stenoses and occlusions, sténoses et occlusions

Below each diagram of the carotid artery are the following symbols Fig. 15:

 \mathbf{P} = Plaque \mathbf{S} = Stenosis \mathbf{O} = Occlusion

To indicate the location of a plaque, a stenosis or an occlusion, on the arterial diagram above, click on the corresponding button, the cursor takes the form of the associated drawing then drag on to the known position of this anomaly. The drawing symbolizes this anomaly (In the case of an occlusion, the entire section is colored black)

You can cancel these symbols \mathbb{P} , \mathbb{S} or \mathbb{O} by a double clic on the icone.

It is possible by hovering over the thumbnails to display the different topographies and make sure all images have been saved. It is then possible to pass immediately or subsequently to the various desired measurements.

3.1 Calibration: Two types of image format are accepted: JPEG and DICOM.

- 1- If the image format is JPEG, the calibration will have to be done manually. Click on the first image to be measured, it will then appear in the center of the screen. First, the image must be calibrated:
 - Click on the button the cursor turns into a cross
 - From the upper edge of the line representing the scale, which is to the right or left of the image click then drag vertically downwards over the entire height of the scale,
 - When you click again, the green line should be superimposed on the scale. The detection of first and last mark are automatic.
 - Check by measuring that the detection of the markers is correct, do not hesitate to start over if this seems doubtful to you.
 - If the detection of the points or lines of the scale is poor, repeat the detection line by shifting slightly Right or Left.
 - A message box will ask you to enter the distance in mm corresponding to that displayed between the two points (Fig. 18). This must always be an integer.
 - In all cases you will see the distance in mm corresponding to the detection displayed

(Fig. 19).

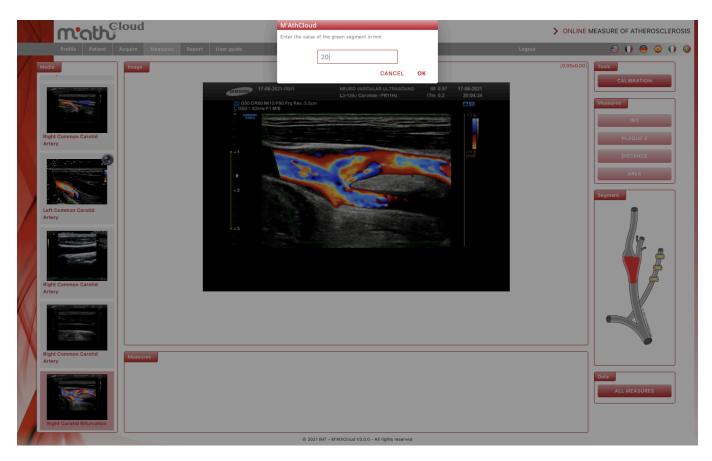


Fig.16 Enter Scale value in mm





Fig.17 Calibration JPEG

 $\dot{\mathbb{N}}$

You have to do an automatic calibration for each image, because it is enough to modify the settings or zooming in so that the scale is no longer correct.



2-If the image format is of the DICOM type, the calibration is automatically performed, However for safety and for your comfort a floating vertical segment of 20mm (Fig 18) is displayed so that you can verify if necessary the size of the real scale dysplayed on the screen.

In case it does not comply, the measurement must not be done.

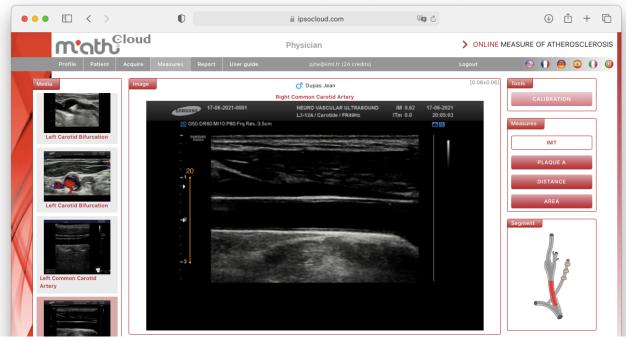


Fig.18 DICOM Calibration

3.2 Intima Media Thickness (IMT) and QI

It is conventionally measured at the level of the common carotid artery at a distance from the bifurcation on a rectilinear segment of the deep wall (or distal wall on the ultrasound image), on a length of about 10mm. (Mannheim Consensus Cerebro Vascular Disease 2011).

3.2.1 Semi Automatic mode

For the IMT measurement, click on the button in the measurements section area in the measurements section area in the measurement section area in the IMT is clearly visible. The drawn segment remains red until its length reaches 10mm. When the line is drawn from left to right, the measurement is made on the lower wall (or Far wall) of the artery, from right to left, the IMT measurement will be made on the upper wall (or Near wall).

Detection lines are shown in the image (orange for the blood-intima interface, and green for, the media-adventitia interface). (Fig.19)

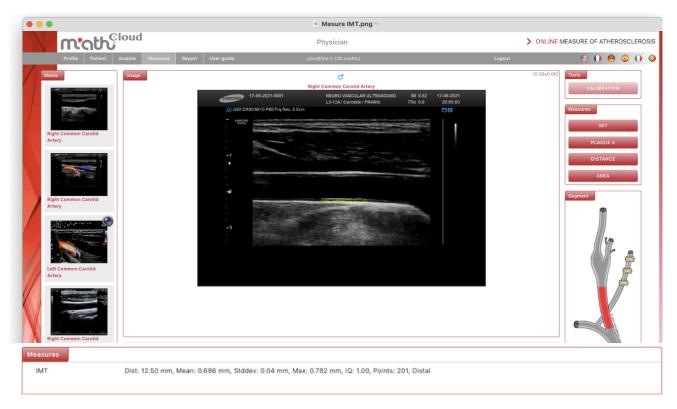


Fig 19 IMT Measurement

The results displayed below the image are:

- 1. **Dist**: The distance over which the measurement was taken (12.5mm),
- 2. **Mean**: The average of the thickness over all the measurements (0.686mm)
- 3. **StDev**: The standard deviation (average in mm of the deviations observed around the mean)(0.04mm)
- 4. **Max**: The maximum value of the thickness (0.782mm)
- 5. **QI**: The measurement quality index, (between 0 and 1)(1)
- 6. Pts: Number of points detected on the wall to carry out the measurement. 100
- 7. **Situation**: Far(Distal) or Near l(Proximal) walls.

3- Measures Menu

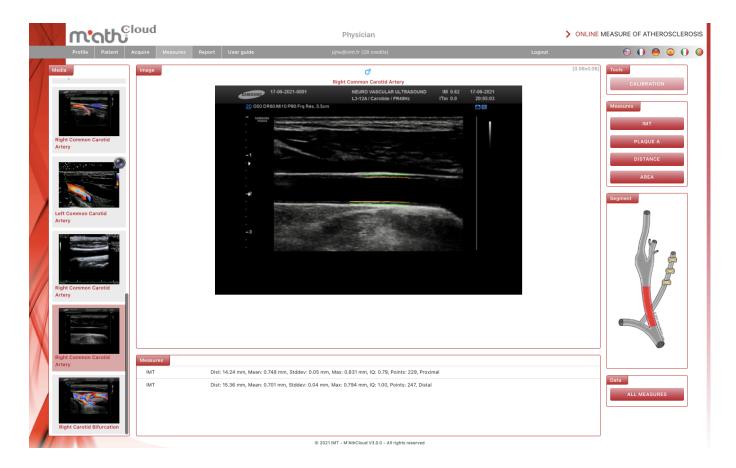


Fig.20 Near and Far walls measurements

3.2.2 Use and Meaning of the Quality Index: QI

It is used to assess the quality of the measurement of the intima media thickness. IQ is calculated for each measurement. It allows for measurement failures to be taken into account and must be evaluated over a segment 10 mm long. The IQ varies from 0 to 1.

Below 0.3, it indicates poor image quality.

Above 0.5, it means that the measurement could be carried out successfully over a distance greater than half of the segment analyzed (5mm over 10).

If the Quality Index is too low or if the segment length is not long enough, the results will be displayed in red.



We recommend to redo and improve image acquisition when the QI is less than 0.5.



To obtain a complete report of the IMT, you must record the 2 common carotid arteries under Lateral angle the one that corresponds to the measurement in lateral incidence of the distal wall of the common carotid artery

3- Measures Menu

3.3 Plaque measurement:

Plaque measurements can be performed automatically or manually on images in grayscale (Black and White) or in Color (Color or Power Doppler).

When you click on the plaque button, select the "Automatic" mode PLAQUE A

3.3.1 Automatic Mode

The measurement of the plaques depends on the quality of the recorded image and the angle under which it is analyzed. So 4 recommendations are important:

- 1 Achieve optimal echogenity, which matches what you see, of the blood-intima interface.
- 2 Acquire the image under an angle allowing the best visualization of the superficial and deep walls of the vessel.
- 3 Adjust the proximal and distal gain so that the lumen has no saturation, avoiding intra-luminal artefacts and while keeping sufficient dynamics that the wall interfaces light are clearly delimited.

Click on the button PLAQUE A. The mouse pointer is replaced by a white cross, the successive clicks make it possible to delimit the adventitial edge of the plate over its entire length.

To end the definition of this edge, double click on the last point (Fig. 21)

A white circle then appears and should be placed in the arterial lumen in front of the plaque, in an artifact-free region, click again. (Fig. 22)

- o The contour of the plaque is automatically detected (Color or Greyscale mode).
- o The measurement results are automatically updated
- o Only the last measurement carried out is kept.
- o You can renew your measurement if you wish.
- o If the edge detection does not match what you see, do not hesitate to repeat the measurement or perform a manual measurement by clicking the **MAREA** button



Fig. 21: Automatic plaque measurement

3- Measures Menu



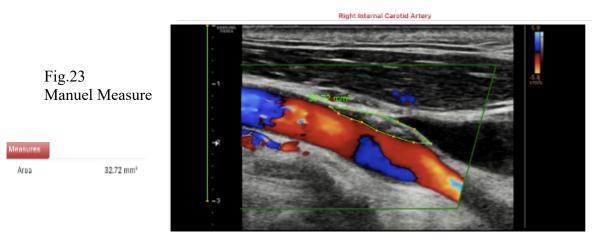
Fig.22: Automatic plaque measurement

Measures are dysplayed as follow:

- 1 Area: Total surface of the plaque [32.52 mm2]
- 2 Max thickness: This is the maximum thickness of the plate [2.44 mm]
- 3 **Mean Thickness**: Average of elementary measurements [1.62 mm]
- 4 **Plaque length**: This is the length of the plaque on longitudinal view [17.30 mm]
- 5 Number of measurements: Number of measurements taken along the plate [333]

3.3.2 Manuel Mode

This is an area measurement determined manually by the user. From the chosen image click on the "Area measurement" button AREA . A cross appears on the screen in place of the cursor. Position the cross on the image at the starting point of the measurement. Click as many times as necessary, thus marking the different points of the polygon, and going to the end point of measure. Double click to mark the end of the contour. A polygon appears on the screen, representing the area to be measured. The result is given in a table to the right of the screen. (Fig.23)



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3.4 Distance

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

From the selected image click on the button DISTANCE

Position the cursor at the starting point of the measurement and click once. Then go to the end point of measurement and make another clic. A line appears on the screen, representing the measured distance. The result is given in a table on the right of the screen. The message box allows to qualify the distance type. (Fig.24)

When taking several distance measurements, only the last result remains displayed.



Fig.24 Distance type

3.5 Surface

This is an area measurement determined manually by the user. From the chosen image click on the button Across appears on the screen in place of the cursor. Position the cross on the image at the starting point of the measurement. Click as many times as necessary, thus marking the different points of the polygon, and going to the end point of measure. Double click to mark the end of the . A polygon appears on the screen, representing the area to be measured. The result is given in a table to the right of the screen.

3.6 All Measures

By clicking on the button view a general table grouping all the measurements carried out. The following table appears. (Fig 25)

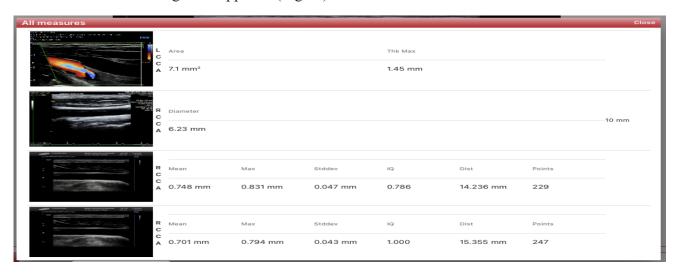


Fig. 25 All measures (IMT-Plaque Area-Distances)

4- Report Menu

In this page the user can click on the icon to generate a report of the visit in PDF format.

After clicking, a first page is displayed with an impression of the arterial diagrams and the position of each selected image. (Fig. 26)

Check the accuracy of this data before printing the final report.

On a second page, there is a summary table of all the measurements of the IMT which have been done.

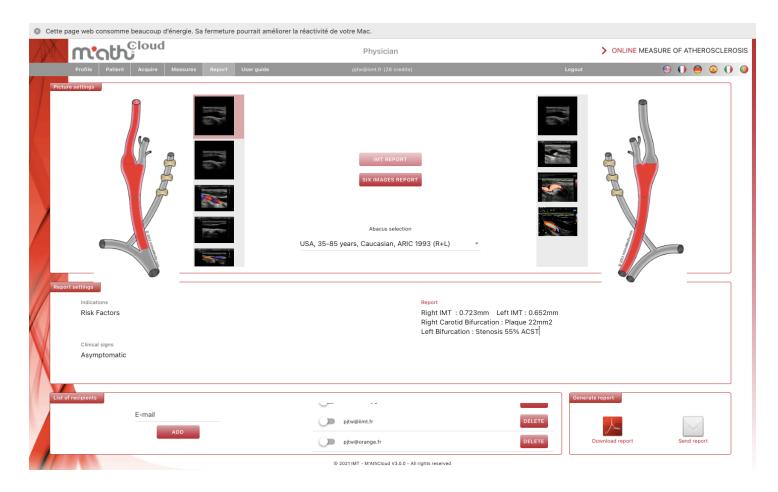
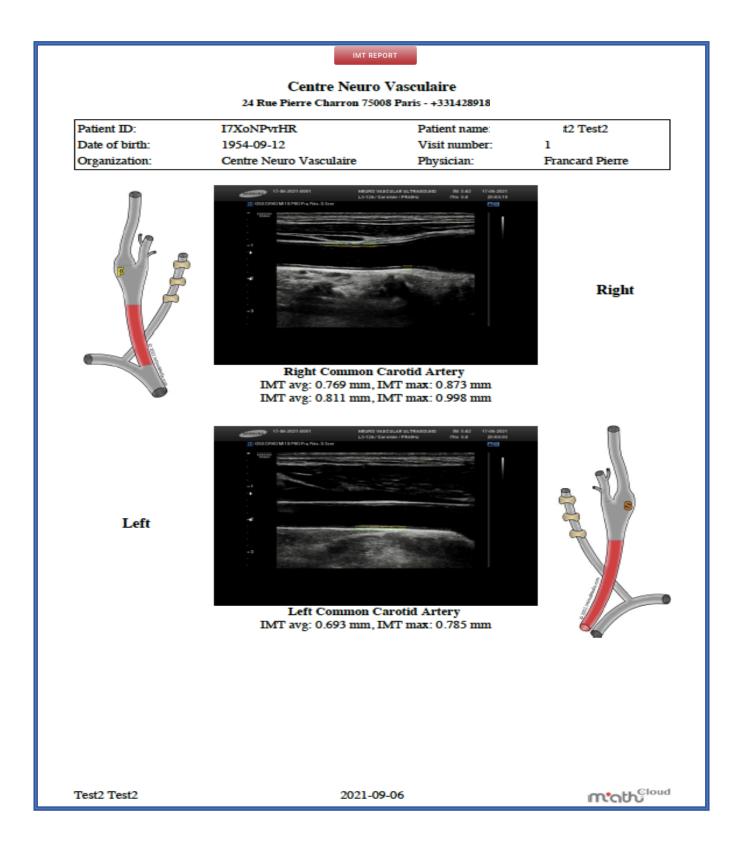


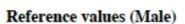
Fig.26 Report overview

This report can be either:

- printed in PDF format to be given to the patient or archived in his file. Use your browser's print command.
- sent by email as a PDF file or a zip file.

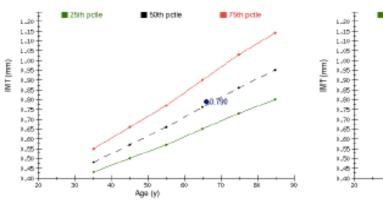
To obtain a complete report of the IMT, you must record the 2 common arteries in Lateral incidence and choose the one that corresponds to the measurement in lateral incidence of the distal wall of the common carotid artery.

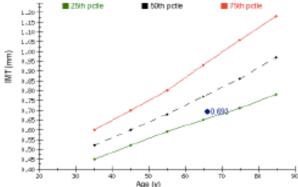




Age	25th petle		50th petle		75th petle	
	R	L	R	L	R	L
35	0.43	0.45	0.48	0.52	0.55	0.6
45	0.5	0.52	0.57	0.6	0.66	0.7
55	0.57	0.59	0.66	0.68	0.77	0.8
65	0.65	0.65	0.76	0.77	0.9	0.93
75	0.73	0.71	0.86	0.86	1.03	1.06
85	0.8	0.78	0.95	0.97	1.14	1.18

USA, 35-85 years, Caucasian, ARIC 1993 (R+L). Extrapolated values below 45 and over 65





Indications

Risk factors

Clinical signs

Asymptomatic

Report

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.

TT1954

2021-09-06

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.

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SIX IMAGES REPORT

Centre Neuro Vasculaire

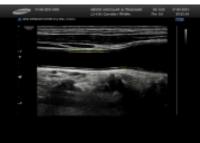
24 Rue Pierre Charron 75008 Paris - +33142891818

Patient ID: I7XoNPvrHR Patient name: Test2 Test2

Date of birth: 1954-09-12 Visit number: 1

Organization: Centre Neuro Vasculaire Physician: Francard Pierre





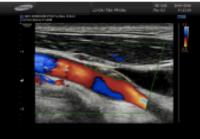
Right Common Carotid Artery IMT avg: 0.769 mm, IMT max: 0.873 mm IMT avg: 0.811 mm, IMT max: 0.998 mm



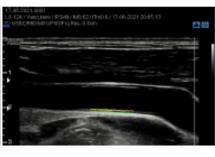
Left Carotid Bifurcation Diameter: 8.3 mm







Right Carotid Bifurcation Plaque: 28.39 mm², Thickness max: 2.5 mm



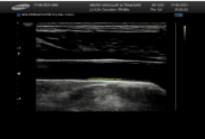
Left Common Carotid Artery IMT avg: 0.674 mm, IMT max: 0.747 mm







Right Common Carotid Artery



Left Common Carotid Artery IMT avg: 0.693 mm, IMT max: 0.785 mm



Test2 Test2

2021-09-06



To export all the Data of all the patients, you have to click on "Export" button on the top main menu. A file in csv format will be downloaded on your computer. You have also the possibility to download all the images and videos.

Profile	Patient	Acquire	Measures	Report	Export	User guide
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K - Characteristics of the M'AthCloud® Application

- Playback and import of images in JPEG and DICOM format of all sizes.
- Compatible with any type of ultrasound machine
- Organized management of the ultrasound examination
- ♣ Average download time of a stored image: a few seconds
- ♣ Average image capture acquisition time: 1s
- ♣ Validated on Microsoft Edge, Safari, Google Chrome.
- French and English. (German Italian Portuguese and Spanish being translated)
- ♣ Quality index (QI) to assess the quality of image acquisition.
- Semi-automatic and precise measurement of Intima Media Thickness.
- ♣ Semi-automatic and manual plate surface measurement.
- ♣ Sending reports over the Internet in encrypted Zip file.
- Requires HDS (health data approval) hosting, HIPAA compliant
- **↓** Tool allowing the centralization of data in clinical studies.
- ♣ Dedicated back office for CRO and Pharma

L- Notifications on serious Events

In accordance with Regulation (EU) 2017/745 Art.87 and 88, the Manufacturer must notify the competent authorities of "any serious incident concerning devices made available on the Union market, with the exception of the expected side effects which are clearly documented in the product information and quantified in the technical documentation and which are the subject of a trend report in application of Article 88". Therefore, and even if these events are unlikely, we strongly recommend that you inform us of any serious incident without delay at: prrc@iimt.fr or by telephone (+33 1 45 78 11 11) of the following serious incidents:

Any incident that has directly or indirectly resulted, is likely to have resulted in or is likely to result in:

- a) the death of a patient, user or any other person;
- b) a serious deterioration, temporary or permanent, of the state of health of a patient, a user or any other person;
- c) a serious threat to public health;

You can also report these serious incidents to your Competent Authority or that of your patient.