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Timing requirements	N/A
<b>Physical characteristics</b>	
Code language	Action-Script, Mxml, Php for the application. (inside FlexBuilder 3) Html, Php, Javascript for the Home website.
Platform	Windows XP and 7 for the development. For the exploitation : Windows, Mac OS, Linux or Solaris Platform The application is running on the internet Browser on the client side like: MS Explorer, Mozilla Firefox, Apple Safari, Google Chrome, Opera.
Operating system	Windows XP, Windows Vista, Windows 7, MacOS X, Linux.
Packaging, ...	None. This application is available over the internet network, at the link: <a href="http://www.intimamedia.com">http://www.intimamedia.com</a> .
<b>Hardware configuration</b>	
Processing unit	IMT Web Hosting server ( <a href="http://www.grita.fr/">http://www.grita.fr/</a> ), and the user computer.
Time zone	All time zones accepted. Technical assistance is at (GMT +1:00).
Network infrastructure	Secure communication over the internet network through a https connection. A connection of the user computer to the internet network is required.
RAM	None.
Hard drive	None.
CD	None.
Monitor	None.
Keyboard	None.
Mouse	None.
Other such as footswitches board	None.
Cable	None.
<b>Other environment requirements</b>	
Need for compatibility with upgrades	N/A
Need for compatibility with multiple SOAP or other device versions.	Adobe Flash Player (last version) installed on the user computer. Analog To Digital converter (Dazzle) Drivers for Usb port if ultrasound device is connected to the PC.

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<b>B) SOFTWARE SYSTEM INPUTS AND OUTPUTS</b>	
Data characteristics (e.g., numerical, alpha-numeric, format)	Numerical: Ultrasound images in DICOM or JPEG format. Alpha-numeric: Patient data and measures.
Ranges	Ultrasound images only, encoded in monochrome in 8 or 16 bits, or colour coded in RGB in 24 bits.
Limits	N/A
Defaults	N/A
Others	N/A
<b>C) INTERFACES BETWEEN THE SOFTWARE SYSTEM AND OTHER SYSTEMS</b>	
	N/A
<b>D) SOFTWARE-DRIVEN ALARMS, WARNINGS, AND OPERATOR MESSAGES</b>	
Alarms	N/A
Warnings	See table 1
Operator messages	See table 2
<b>E) SECURITY REQUIREMENTS</b>	
Compromise of sensitive information	Patient sensitive information is encrypted in the database.
Authentication	Login (user Email) and password.
Authorization	User password.
Audit trail	
Communication integrity	
Other	N/A
<b>F) USABILITY ENGINEERING REQUIREMENTS THAT ARE SENSITIVE TO HUMAN ERRORS AND TRAINING</b>	
Support for manual operations	Tutorial is made of video recordings for demonstration of the functions of the application. A manual (Pdf format) is available

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Human-equipment interactions	Basic interaction between human and computer.
Constraints on personnel	None
Areas needing concentrated human attention	None
Other	
NOTE 5 Information regarding usability engineering requirements can be found in IEC 60601-1-6.	
<b>G) DATA DEFINITION AND DATABASE REQUIREMENTS</b>	
– form	- 1 DataBase.
– fit	
– function	Base structure is issued from the database used by the Software M'Ath.
<b>H) INSTALLATION AND ACCEPTANCE REQUIREMENTS OF THE DELIVERED MEDICAL DEVICE SOFTWARE AT THE OPERATION AND MAINTENANCE SITE OR SITES</b>	
	Check box on the website to confirm that the user is a medical practitioner, or participates as a sonographer in a clinical trial.
<b>I) REQUIREMENTS RELATED TO METHODS OF OPERATION AND MAINTENANCE</b>	
	Training – Hotline – Maintenance
<b>J) USER DOCUMENTATION TO BE DEVELOPED</b>	
	IntimaMedia.com user guide
<b>K) USER MAINTENANCE REQUIREMENTS</b>	
	N/A
<b>L) REGULATORY REQUIREMENTS</b>	
See Plan de développement Logiciel DM Rev.20120312 #4.1	
<b>STANDARDS AND OTHER APPLICABLE DOCUMENTS</b>	
See Plan de développement Logiciel DM Rev.20120312 #4.1	

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**WHERE APPLICABLE, INFORMATION DERIVED FROM PREVIOUS SIMILAR DESIGNS**

**OTHER ESSENTIAL REQUIREMENTS**

CNIL declaration

**2. SOFTWARE REQUIREMENT SPECIFICATION**

The following table provides the detailed software requirement specification.

Ref SPEC	SPEC sub- system	Requirement specification	SW	HW	Other	Criticality
1		<i>Web Application : General</i>				
	1	<i>The graphical design of the application will be linked to the IMT company graphic chart.</i>	X			
	2	<i>Increase the quality of the application graphical design for a commercial and professional exploitation.</i>	X			
	3	<i>Application will be optimized for screens of 1440 x 900 pixels.</i>	X			
	4	<i>The application will be referenced by search engines (like Google) and others. Because Swf files generated by Flex Builder for Flash Player are not read by Google (at this time).</i>	X			
	5	<i>Statistics on the website traffic of the application will be available.</i>	X			
	6	<i>The release of a new version of the application will be invisible for the users.</i>	X			
	7	<i>The application should be used by several different users at the same time.</i>	X			
	8	<i>Application will run on all the current web browsers, and operating systems.</i>	X			
	9	<i>Data will be stored in a MS SQL Server database.</i>	X			

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Ref SPEC	SPEC sub-system	Requirement specification	SW	HW	Other	Criticality
	10	Use of the Flex Framework Cairngorm to have a better code maintainability.	X			
2		Graphical User Interface : General				
	1	The application will start by a home page to choose between the medical practitioner (MP) and the clinical study (CS) web application version.	X			
	2	The application will provide messages for useful information to the user.	X			
	3	A top right button will allow to logout of the session.	X			
	4	Country flags will allow changing the current language.	X			
	5	User will have to certify that he (she) is a medical physician to access to the MP version, or that he (she) is involved in a clinical study to access to the CS version.	X			
3		Graphical User Interface : Home Part				
	1	A new user will register himself to use the application by filling a web based form with its main information. The information shall concern the : - Center - Sonographer. - Ultrasound device.	X			
	2	If the user forgets his password, IMT will automatically display to him the password. (After he answers to 2 secret questions).	X			
	3	The user will enter his email and its password to access to the main application parts, else the other parts are disabled.	X			
	4	At the account creation, the user will also check a box to accept the application license.	X			
	5	If a given user is connected for the second time to the application, its Email value will be displayed in the Login field.	X			
4		Graphical User Interface : Tutorial Part				

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Ref SPEC	SPEC sub-system	Requirement specification	SW	HW	Other	Criticality
	1	Tutorial videos will be available for the user to learn how to use the application.  Tutorial topics are: - Scale. - IMT Measure. - Distance Measure. - Surface Measure.	X			
5		Graphical User Interface : Patient Part				
	1	The patient data will be : - Identification. - Atherosclerosis Risk factors. - Personal history - Drugs. - Cardiovascular examination.	X			
	2	The user will search for the former patients, he (she) entered in the application. He (she) will create a new visit for this former patient, or edit the images and data of a past visit.	X			
	3	The visit number value in the application will be controlled automatically by the program.	X			
6		Graphical User Interface : Acquire Part (MP/CS)				
	1	To access to this acquire tab, the patient tab will be completed.	X			
	2	The user can download image from its hard drive, or an USB key on its computer to the server.	X			
	3	The application will capture image coming from an ultrasound device connected to its computer.	X			
	4	The application will display in Live the stream of the ultrasound device connected to its computer. And the user will freeze the stream to acquire an image.	X			
	5	If they are several video devices connected to the application, the user can select in this list of device.	X			

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Ref SPEC	SPEC sub- system	Requirement specification	SW	HW	Other	Criticality
	6	The application will be able to create and manage drawings representing plaques, stenosis or occlusion. These drawings are positioned on the artery graphics to the right situation.	x			
	7	This drawing will be erased by the user if needed.	X			
	8	The application will provide an area to display uploaded or captured images and fields to drag and drop these images to its anatomical position.	X			
	10	When we add an occlusion in a segment, the underlying lesions are deleted after a confirmation.	X			
	11	Plaque and stenosis could be positioned on the same segment of the artery.	X			
7		Graphical User Interface : Measure Part				
	1	The user will select one image of the visit inside an image list.	X			
	2	In this tab, the user will define a scale for the current image.	X			
	3	In this tab, the user will perform an IMT measurement.	X			
	4	In this tab, the user will perform a distance measurement.	X			
	5	In this tab, the user will perform a surface measurement.	X			
	6	For a given visit, the scales of the different images are saved when they are done. When we click on the image, the already done scale is recall.	X			
	7	The scale cursor has a line that the user should place on the vertical line scale of the image. This scale cursor is displayed only on the image part. After the first click, the cursor could not move in horizontal.	X			
8		Graphical User Interface : Report Part (MP)				
	1	The user will click on a button to generate the Pdf visit report.	X			
	2	There are 2 types of reports: The IMT Scan Report and the M'Ath type report. The first Pdf report is made with 2 images of CCA Right and Left.	X			

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Ref SPEC	SPEC sub- system	Requirement specification	SW	HW	Other	Criticality
		<p>This is the IMT Scan report.</p> <p>The Pdf report will be similar as the one generated by the software M'Ath, and will be made of 3 pages:</p> <ul style="list-style-type: none"> <li>- Page 1: Images and drawings.</li> <li>- Page 2: Array of normal values and graphics.</li> <li>- Page 3: Information for the patient.</li> </ul>				
	3	The user will click on a button to send by Email to its patient the Pdf visit report.	X			
	4	The user will click on a button to download Acrobat Reader to display the report.	X			
	5	The report should contain the IMT, the surface and the stenosis degree for each position.	X			
9		Dicom and JPEG images files				
	1	The application will be able to read DICOM images.	X			
	2	The application will be able to read JPEG images	X			
10		Measurements				
	1	The Web application will use the same code source as the one used by the software M'Ath (build as a library called LibIMT) to measure the IMT.	X			P1, U1, 10.1, 10.2, 10.3
	2	<p>The application will be able to measure the Intima-Media thickness (IMT) and to provide the following results:</p> <ul style="list-style-type: none"> <li>- QI (Quality Index)</li> <li>- IMT maximum value.</li> <li>- mean IMT,</li> <li>- standard deviation of IMT,</li> <li>- Number of points.</li> </ul>	X			P1, U1, 10.1, 10.2, 10.3
	3	For the IMT measure, the application will help the standardized measurement. There are warnings if the QI is lower than 50%, and if the distance is not between 10 and 11 mm.	X			P1, U1, 10.1, 10.2, 10.3
	4	The application will provide a tool to perform manual measurements of distances.	X			P1, U1, 10.1, 10.2, 10.3

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Ref SPEC	SPEC sub-system	Requirement specification	SW	HW	Other	Criticality
	5	The application will provide a tool to perform manual measurements of surfaces.	X			P1, U1, 10.1, 10.2, 10.3
11		Calibration				
	1	The application will use calibration information embedded in Dicom files.	X			P1, U1, 10.1, 10.2, 10.3
	2	In case of absence of calibration information in Dicom files (which could be the case for some Dicom images of t 'Secondary Capture type') or JPEG images the application will provide a tool to manually set the calibration.	X			P1, U1, 10.1, 10.2, 10.3
12		Images and Data securities				
	1	Patient first name, Patient last name will be encrypted when stored to the Database.	X			P1, U1
13		Internationalization				
	1	The application will be available in the following languages: English, French.	X			
14		Installation				
	1	Installation of the web application on the user computer will be minimized.	X			
	2	Application will ask automatically to install Flash Player (last version) if it's not installed on the user computer.	X			
15		Visit Modification				
	1	A visit can be modified after its creation.	X			
16		Application version ID				
	1	An application version number is displayed on the application main window to verify that the user use the last version.	X			

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<i>Ref SPEC</i>	<i>SPEC sub- system</i>	<i>Requirement specification</i>	<i>SW</i>	<i>HW</i>	<i>Other</i>	<i>Criticality</i>

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**Table 1: Warning messages.**

<b>Warning ID</b>	<b>Message</b>
ALREADYSTENOSIS	You already set a stenosis at this site .
ALREADYOCCLUSION	You already set an occlusion at this site
ALREADYPLAQUE	You already set a plaque at this site
ENTERALLFIELDS	Please enter all the required fields (*)
SHOULDBECONNECT	You should be connected to access this part
AGREELICENCE	You should agree to the License to register
LOGINUNKNOWN	Your login is unknown
NEEDREGISTER	You need to register
NOMBREIMAGESWARNING	Thank you to acquire 6 images.
DISTANCEWARNING	Thank you to draw a distance between 10 and 11mm for IMT measurement.
INDEXQUALITEWARNING	One or both Quality Index are under 0.5. Do you want to make another image acquisition or measure to improve it?
CHECKLICENCE	You must accept the License to login.
LICENCEEXPIRED	Your License has expired, please check your subscription or contact IMT
NOECHOGRAPH	No video signal detected
VISITALREADYEXIST	This visit already exists in the Database
MEASUREALREADYEXIST	A measurement has already been done for this site. Do you want to replace it?
SOURCEVIDEOMAX	Maximum number of video sources is 5
MAJINFOSPATIENT	You have modified patient information, do you want to save it?
VISITEEXISTE	This visit already exists.
StudyLIMITVISIT	For the Study, the maximal number of visits is equal to n.( REVOIR CE MESSAGE)
UNKNOWNSTUDY	Study name unknown. Please contact the hotline at +33 9 53 70 68 or send an Email from the @ button on the top of the home page.

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**Table 2:** Operator messages.

<b>Message ID</b>	<b>Message</b>
<i>ENTEREMAIL</i>	<i>Enter your Email Address</i>
<i>REMEMBERME</i>	<i>Remember me</i>
<i>LICENCE</i>	<i>To participate to this study, you should be a medical doctor or a sonographer. The author, editor and distributors of this application 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 application and its distributors cannot also be held liable for damages resulting from the use or the impossibility of using this software: loss of data, bodily injury and financial loss of any kind whatsoever. The editor guarantees that the software conforms to the tutorial accompanying it. Information contained in the tutorial may be subject to modification without notice.</i>
<i>IAGREE</i>	<i>I agree with the above conditions and requests.</i>
<i>DRAGANDDROP</i>	<i>Click on this window to freeze the image, and drag and drop the image to its corresponding site.</i>
<i>CLICKREPORT</i>	<i>Click on the icon to display and print your visit report:</i>
<i>CONSULTEMAIL</i>	<i>Please go to your mailBox to get your password</i>
<i>PAWSEND</i>	<i>Your password has been sent by Email</i>
<i>NEWPATIENTMSG</i>	<i>To create a new patient, you must transfer the data of the current patient or Logout.</i>
<i>PATIENTSTUDYTIA</i>	<i>If you don't know at the inclusion the patient ID number, just type CC0000. Send by Email at TIARegistry@iimt.fr the patient ID firstname lastname, sex and the date of visit as soon as you know it..</i>
<i>CLEANARTERES</i>	<i>All plaques and stenoses have been removed, do you want to redraw them. ?</i>