

Visible Patient Planning iOS User documentation



VISIBLE PATIENT PLANNING iOS

Version: 2.3.4

June 2020

Unique device identifier (UDI)

+B373VPPI2340/\$\$72.3.4.



Software instructions for use (in English and other available languages) can be downloaded at https://www.visiblepatient.com/en/go/planning-ios-user-manual. Hard copy of instructions for use can be requested at contact@visiblepatient.com at no additional cost and delivered to the customer within 7 working days.

Indications for use

Visible Patient Planning iOS is intended as a medical imaging system that allows the review, analysis, communication, and interchange of medical data. It is also intended as software for preoperative surgical planning, postoperative control and as software for the intraoperative display of the aforementioned medical data.

This product is not intended for use with or for the primary diagnostic interpretation of mammography images.

The software includes basic tools to manage medical data, including 3D visualization, reading of medical documents, measurements, secured transferring, storing, etc.

It also includes advanced tools to visualize and analyze organ segments which are an approximation of vascular/airway territories for liver, lungs and kidneys.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.



Authorizations



Visible Patient Planning iOS is a medical device software which is CE

marked. It can therefore be used in clinical routine and/or for patient care in member states of the European Union where national regulations are respected (complete list of countries available here: https://www.visiblepatient.com/en/go/planning-ios-countries).

Use of this software is not allowed in countries not mentioned in the list above.

In these countries, the software is considered as a prototype software and thus its use is restricted to communication with the patient, demonstration, research, or educational purposes. Any other use is strictly prohibited, particularly clinical use for diagnostic interpretation or treatment planning on human beings.



Visible Patient

8 rue Gustave Adolphe Hirn 67000 STRASBOURG FRANCE

Contact

Email: <u>support@visiblepatient.com</u> Phone: +33 (0)3 68 66 81 81 Website: <u>www.visiblepatient.com</u>

Contents

1		Indications for use						
2		Cont	traind	dication	6			
3		War	nings	5	6			
	3.2	eral warning	6					
	3.2	2	War	ning about secure IT environment	6			
	3.3	3	War	ning about access to patient data	7			
	3.4	4	War	ning about the display of 3D patient data	7			
	3.5	5	War	ning about anatomical structure volume	7			
	3.6	6	War	ning about vascular and respiratory territory computation	7			
4		Tech	nolo	gical characteristics	8			
	4.2	1	Syst	em requirements and characteristics	8			
		4.1.1	1	Minimum configuration	8			
		4.1.2	2	Recommended configuration	8			
	4.2	2	Арр	lication overview	8			
	4.3	3	Арр	lication modules	8			
		4.3.1	1	Recovery and display of the list of cases	9			
		4.3.2	2	Previsualization of a case and series download	9			
		4.3.3	3	Visualization of a model series	9			
		4.3.4	1	Visualization of a clip series	10			
		4.3.5	5	Visualization of a PDF series	10			
		4.3.6	5	User account management	10			
		4.3.7	7	Application settings	10			
		4.3.8	3	Regulatory information	10			
		4.3.9	Э	Help	10			
		4.3.1	10	Visible Patient links	10			
5		Insta	allatio	on instructions	11			
6		Instr	uctic	ons for use	12			
	6.2	1	How	to register a Visible Patient account	12			
	6.2	2	How	to recover and display your list of cases	13			
	6.3	3	How	to filter and sort your list of cases	14			
	6.4	4	How	to access data of a case	15			
	6.5	5	How	v to visualize a model series	16			

	6.5.2	1	Opening a model series	16
	6.5.2	2	Basic interactions	16
	6.5.3	3	Tools	17
	6.5.4	1	Other actions	18
	6.6	How	v to visualize a PDF series	19
	6.6.2	1	Opening a PDF series	19
	6.6.2	2	Basic interactions	19
	6.7	How	v to visualize a clip series	20
	6.7.2	1	Opening a clip series	20
	6.7.2	2	Basic interactions	20
	6.7.3	3	Tools	20
	6.7.4	1	Display of resection volumes	22
	6.7.5	5	Resection volume computation	22
	6.7.6	5	Estimate of vascular and respiratory territories	23
	6.7.7	7	Other actions	24
	6.8	How	v to update a case	24
	6.9	How	v to delete downloaded series	25
	6.10	How	v to delete registered accounts	27
	6.11	How	v to access application parameters	29
	6.12	How	v to access regulatory information	30
	6.13	How	v to access help information	31
	6.14	How	v to open a Visible Patient link	32
7	Mai	ntena	ance	33
	7.1	Арр	lication update	33
8	Prot	olem	solving	33
	8.1	Gen	eral problems	33
	8.1.2	1	I cannot register my account	33
	8.1.2	2	I am unable to recover my list of cases	34
	8.1.3	3	I am unable to download the series associated to cases	34
	8.1.4	1	I am unable to open a series	35
	8.1.5	5	I am unable to open a Visible Patient link	35
	8.2	3D \	visualization problems	
	8.2.2	1	I am unable to interact with the model	
	8.2.2	2	I am unable to mask an anatomical structure	36
	8.2.3	3	I am unable to visualize volumes associated to clip data	36

1 Indications for use

Visible Patient Planning iOS is intended as a medical imaging system that allows the review, analysis, communication, and interchange of medical data. It is also intended as software for preoperative surgical planning, postoperative control and as software for the intraoperative display of the aforementioned medical data.

This product is not intended for use with or for the primary diagnostic interpretation of mammography images.

The software includes basic tools to manage medical data, including 3D visualization, reading of medical documents, measurements, secured transferring, storing, etc.

It also includes advanced tools to visualize and analyze organ segments which are an approximation of vascular/airway territories for liver, lungs and kidneys.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

2 Contraindication

There is no know contraindication.

3 Warnings

3.1 General warning

Warning: the software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

Never use VP Planning iOS without the advice of a trained health professional.

3.2 Warning about secure IT environment

Warning: Visible Patient demands that the application is installed on a secure device, complying with the rules and regulations of your country.

Never use VP Planning iOS on a device that does not comply with the security policy provided with the application. Failure to comply with security measures may lead to a malfunction of the device, loss of data (medical or personal), damage to their integrity, or exposure to security threats from the computer network. **This can therefore cause minor harm to the patient.**

3.3 Warning about access to patient data

Warning: recovering, updating and accessing medical data is done manually by the user. Always make sure you have the latest revision of a case before accessing medical data. Also make sure to consult the data corresponding to the desired patients.

Never use data that has not been updated or that does not correspond to your patient. Such use may cause minor harm to the patient such as increased surgery duration or useless incisions in tissues during surgery because of incorrect information.

3.4 Warning about the display of 3D patient data

Warning: rendering of transparent structures of a 3D model may evolve in case of update of the operating system or software problem.

Always make sure you have an updated version of the application and the operating system. The use of obsolete software versions may cause minor harm to the patient such as increased surgery duration or useless incisions in tissues during surgery because of incorrect information

3.5 Warning about anatomical structure volume

In the VP Planning iOS application, the volume of anatomical structures is available here:

- in the manager of anatomical structures (or « Organ manager »)
- when selecting an anatomical structure via the selection tool (model series)
- when displaying volumes associated to clip applying simulation (clip series)

Warning: these volumes are computed from medical images. Therefore, accuracy of volumes depends on native image quality (voxel size of the image).

For more information, please refer to the selection on vascular and respiratory territory assessment (see 6.7.6).

3.6 Warning about vascular and respiratory territory computation

Warning: visualization of clip data and associated interactions allowing to simulate clip applying rely on the reconstruction of air space and vascular territories. These territories are computed from certain information visible in the medical image. Therefore, this territory reconstruction is an approximation of reality.

4 Technological characteristics

4.1 System requirements and characteristics

The VP Planning iOS application is designed to run on standard commercially available mobile devices (Apple iPhone or iPad) and through the installed operating system (iOS or iPadOS).

4.1.1 Minimum configuration

- Operating system: iOS 11.0
- Storage: 300 Mo
- Memory: 1 Gb RAM
- Internet: high-speed internet connection

4.1.2 Recommended configuration

- Operating system: iOS 13.3 or iPadOS 13.3
- Storage: 1 Go
- Memory: 2 Gb RAM
- Internet: high-speed internet connection

4.2 Application overview

The VP Planning iOS application is composed of modules dedicated to management and analysis of medical data. It offers a flexible visualization solution to help trained health professionals (including physicians, surgeons and technicians) in assessing patient anatomy and pathology in order to plan therapy or surgery. This software provides tools allowing to display 3D models created by Visible Patient. These models can be displayed according to preferences of health professionals thanks to standard visualization options.

4.3 Application modules

The modules of the VP Planning iOS application can be clustered in four categories:

- Data management
- Data display
- Application configuration
- Help and regulatory information

Category	Functionality
Data management	Recovery and display of the list of cases
Data management	Previsualization of a case and series download
Data display	Visualization of a model series

	1
Data display	Visualization of a clip series
Data display	Visualization of a PDF series
Application configuration	User account management
Application configuration	Application settings
Help and regulatory information	Regulatory information
Help and regulatory information	Help
Data management	Visible Patient links

4.3.1 Recovery and display of the list of cases

The aim of this module is to recover and display the list of cases. The list of cases is recovered from Visible Patient's secure servers. Cases are displayed in the form of cells containing patient identification information (name, identifier, group, date and icon). Cells contain also an icon showing the status of the case (new, open, available locally, updated, unavailable).

Triggering a synchronization makes it possible to recover the new cases and modifications available on the server. The date of the last synchronization is displayed at the top of the case view.

Filtering and sorting tools make locating and opening cases easier.

4.3.2 Previsualization of a case and series download

The aim of this module is to display information relating to a case (name, identifier, group, date, icon and summary). It also allows to download and access the various series.

4.3.3 Visualization of a model series

This module allows to display and interact with a model series. Implemented interactions include rotation, translation and zoom.

Various tools (selection, masking, focus) are available in order to interact with the model. It is also possible to change orientation, list anatomical structures, cancel or replay actions, change colors of the scene, disable interactions and make a screenshot of the scene.

A dedicated view listing the various interactions and available tools is accessible in the hamburger button of the view.

4.3.4 Visualization of a clip series

This module allows to display and interact with clip data. Implemented interactions are the same as in model data visualization.

Beside masking and focus tools which are common to model data visualization, the module includes a tool to simulate clip applying. By tapping a network section of the target organ, it is possible to display and select a simulation of the vascular or respiratory segments supplied by this section. It is possible to deselect a segment by tapping it.

A dedicated view allows to display simulated volumes of resected and remaining parts corresponding to the selection of anatomical segments.

The other tools allowing to control the scene are common to model data visualization.

4.3.5 Visualization of a PDF series

This module allows to display PDF data (modelling report) and to interact conventionally with it (scrolling and zoom).

4.3.6 User account management

This module allows to manage Visible Patient accounts registered in the application. It allows to register new accounts and to select an active account (account for which cases are displayed in the list of cases).

The module also allows to delete data associated to an account.

4.3.7 Application settings

This module allows to access and modify application settings. Moreover, it allows to access the application log and to delete downloaded data.

4.3.8 Regulatory information

This module allows to display all regulatory information (marking, contact, indications for use, approvals, security policy and information on Visible Patient).

4.3.9 Help

This module allows to display information relating to the instruction manual.

4.3.10 Visible Patient links

This module allows to open Visible Patient links within the application. There are two types of links:

- Links allowing to access a case
- Links allowing to facilitate account registration thanks to a prefilling system of the form.

5 Installation instructions

The VP Planning iOS application is installed via the <u>App Store</u> application available on iOS and iPadOS.

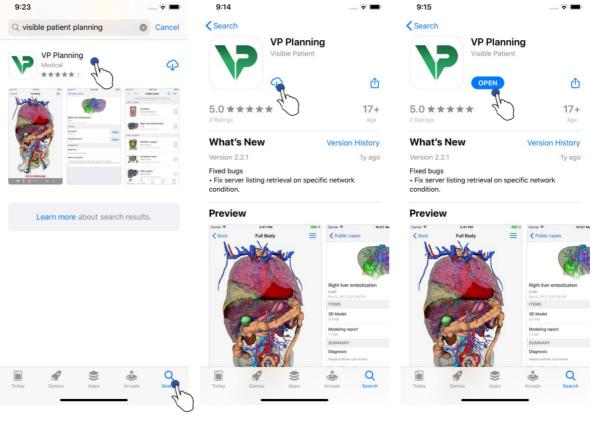


Figure 1: Searching for the application

Figure 2: Application download

Figure 3: Open the application

Once the App Store application is open, search for the "VP Planning" application and open the application view (Figure 1). Then, tap the download icon (Figure 2) and wait for the application to be recovered. Once downloaded, tap the button allowing to open the application (Figure 3).

6 Instructions for use

6.1 How to register a Visible Patient account

5:32	🗢 🔳	5:37		🗢 🔳	5:38	🗢 🔳
Settings Accounts	Edit	Accounts	Server list		Server list Account regist	ration Done
	40	Select which ser	ver you want to connec "Europe")	t to (Default is		40
	Û				Server Europe	0
		Europe	J.	<u>`</u>	Email jean.martin@example.com	
		Europe (pilot sit	tes))	Password •••••	
					Description Pr Jean Martin	
1						
No account registe	red.					
Use the add account button to re	gister an account.					
					q w e r t y	u i o p
					asdfg	h j k l
						b n m 🗵
					123 😂 space	done
Public cases Private cases About	Help Settings					Ŷ
		-				—

Figure 4: List of accounts (empty)

Figure 5: List of servers

Figure 6: Account registration

To register a Visible Patient account within the application, go to the **Configuration** – **Account** view. Once on the account view, tap the action allowing to add an account (Figure 4). This action will launch the display of the list of servers. Select the server on which you have an account (Figure 5). After filling in the requested fields (Email, Password and Description), tap the registration action (Figure 6) to validate the action.

6:02	🗢 🔳	6:03		🕈 🛙	6:54				? 🔳
Private cases	Č Edit	Q 7	Pr Jean Ma	rtin 🗳 Ed	dit Q	₹↓	Pr Jean Mart	tin	🖒 Edit
				2h)			zation: Mar 6, 20	20 at 6:53:5	0 PM
				\bigcirc	LAST 7 D				
					1	Etier # um	ne Bernard		Ine
					1 and		9 f3915 (107) 2020 at 6:53:45		
			~			🕨 🕫 # um		Ime	ne
1+1				1			f3915 (107) 2020 at 6:50:03	PM	
\sim			\sim	/	1.33	Clair	e Fontaine		
						# um	001 9f3915 (107)		(ne
No registered accoun	ıt		You are not synch		A		2020 at 6:37:24	PM	
Register new accou		Use the s	ynchronize button or s synchronize you	wipe the view down to r data.	L:				
<	th								
	\bigcirc								
	印 袋	R	(i)	П ф			(i)		र्े
🖻 🤭 🔿									

6.2 How to recover and display your list of cases

Figure 7: No registered account

Figure 8: No synchronization

Figure 9: Synchronized view

To recover and display your list of cases, go to the *Private cases* view (Figure 7). After registering your account (see 6.1), the view is in a non-synchronized state (Figure 8). Execute a synchronization by using the dedicated button or dragging the view down. The updated list of cases is then displayed and the synchronization date is updated at the top of the view (Figure 9).

6.3 How to filter and sort your list of cases

6:54		🗢 🔳	11:46				11:46		
	Pr Jean Martin	🖒 Edit	Q Bernard	d	0	Cancel		Sorting	Done
Jhugst dr	onization: Mar 6, 2020 at 6	6:53:50 PM	Last sy	nchronization: Mar 6, 2	020 at 6:53:50	PM			
	Étienne Bernard # um003 f1c09f3915 (107)	(new)	LAST 7 DAYS	Étienne Bernard # um003 f1c09f3915 (107)		(new)	Show only local		
	Mar 6, 2020 at 6:53:45 PM			Mar 6, 2020 at 6:53:4	5 PM		Newest		~
	Delphine Berthiaume # um002 f1c09f3915 (107) Mar 6, 2020 at 6:50:03 PM	(new)					Oldest Name (A-Z)		
	Claire Fontaine						Name (Z-A)		
	# um001	new					Group (A-Z)		
Name of	f1c09f3915 (107) Mar 6, 2020 at 6:37:24 PM	\downarrow					Group (Z-A)		
Public cases Pri	Vate cases About He		Public cases Pri	ii About	Help	کې Settings			
Figure	2 10: Filtering and activation	sorting	Fig	ure 11: Filter	ing cases	5	Figure	12: Sorting cas	ses

To activate the filtering of cases, tap the filtering tool (magnifying glass) located at the top of the list of cases (Figure 10). A search field to apply a filter to the list of local cases is then displayed in the navigation bar (Figure 11).

To modify the sorting of cases, tap the sorting tool located at the top of the list of cases (Figure 10). The sorting selection view is then displayed. To modify the selected sorting, tap the sorting name you want to apply (Figure 12). An option allowing to list only cases containing downloaded series is also available at the top of the view.

6.4 How to access data of a case

6:54		? ■	2:48	🗢 🖿	2:50	🗢 🖿
Q ≣↓	Pr Jean Martin	🖒 Edit	Pr Jean Martin		< Pr Jean Martin	
Last sync	hronization: Mar 6, 2020 at 6:	53:50 PM	A STORE FRAM		And The Country	
AST 7 DAYS						
	Étienne Bernard # um003	new	Contract in the second s		Contract of the second s	
11	f1c09f3915 (107) Mar 6, 2020 at 6:53:45 PM					
			Claire Fontaine # um001		Claire Fontaine # um001	
	Delphine Berthiaume		# 0001 f1c09f3915 (107)		# umoo1 f1c09f3915 (107)	
	# um002 f1c09f3915 (107)	new	Mar 6, 2020 at 6:37:24 PM		Mar 6, 2020 at 6:37:24 PM	
	Mar 6, 2020 at 6:50:03 PM		ITEMS		ITEMS	
			3D Model	OPEN	3D Model	OPEN
- CL 12- 12- 12- 12- 12- 12- 12- 12- 12- 12-	Claire Fontaine # um001	\sim	2.4 MB		2.4 MB	
Charles and the	f1c09f3915 (107)	(new)	Clips applying		Clips applying	OPEN
	Mar 6, 2020 at 6:37:24 PM	The	25 MB		25 MB	
		Ú	Modeling report 948 KB	GET	Modeling report 948 KB	OPEN
			SUMMARY	Jh	SUMMARY	1r
			Diagnosis		Diagnosis	1
			Angiokeratoma type 3 name of Klatskin tumor.		Angiokeratoma type 3 name of Klatskin tumor.	
			Important notes		Important notes	
			N/A		N/A	
\diamond	e (i) [[
	te cases About Hels	p Settings				
Figu	re 13: Case select	tion	Figure 14: Series dowr	lload	Figure 15: Opening a se	ries

To access data of a case, select the desired case in the list of available cases (Figure 13). When on the previsualization view of the case (Figure 14), download the series by tapping the **Get** button. Once the data has been downloaded, you can access it by tapping the **Open** button (Figure 15).

6.5 How to visualize a model series

6.5.1 Opening a model series

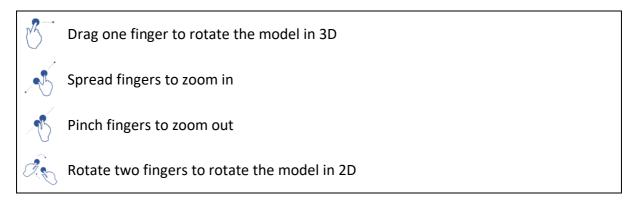
10:07	🗢 🔳,	10:07		🗢 🔳	15:07		🗢 💽
Pr Jean Martin		Back	Claire Fontaine	≡	< Back	Claire Fontaine	=
Claire Fontaine							
# um001 f1c09f3915 (107)							
Mar 6, 2020 at 6:37:24 PM						to VALLAND	1
ITEMS						A STREET	
3D Model 2.4 MB	OPEN						0/
Clips applying 25 MB	GE		liver			Carl Carl	
Modeling report 948 KB	GET					A ANI.	
SUMMARY							
Diagnosis							
Angiokeratoma type 3 name of Klatskin tumor.							
Important notes N/A							
				☆ 🔓	2	★ ■ ¬ ~ = =	¢- 🖯

Figure 16: Opening a model seriesFigure 17: Loading of a model seriesFigure 18: Display of a model series

When the data has been downloaded (see 6.4), tap the **Open** button corresponding to the model series (Figure 16). A progress bar allows to see the progress of data loading (Figure 17). When the data has been loaded, the 3D model is displayed (Figure 18).

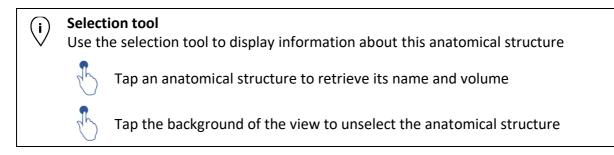
6.5.2 Basic interactions

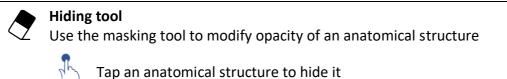
When the model series has been loaded, various basic interactions are available in order to interact with the model:



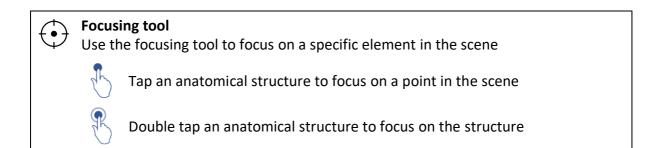
6.5.3 Tools

The toolbar at the bottom of the view offers a set of actions. By tapping the selected tool (Figure 19), the list of available tools is displayed. By selecting the desired tool in that list, the selected tool becomes active. Interactions with the model are then expanded:





Double tap an anatomical structure to change its opacity



6.5.4 Other actions

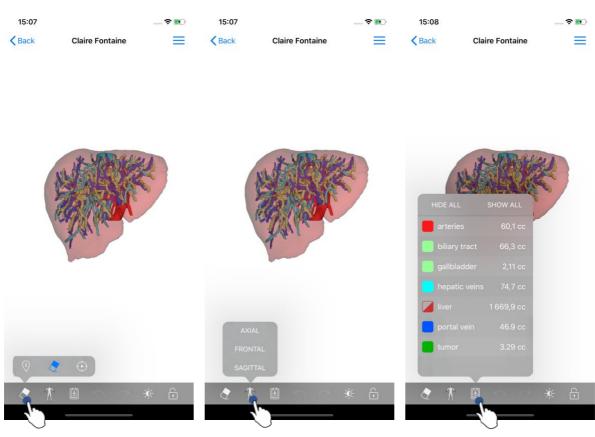


Figure 19: Selection of the visualization tool of the model

Figure 20: Selection of model orientation

Figure 21: Display of anatomical structures of the model

By tapping the marker showing model orientation (Figure 20), it is possible to select in which orientation to display the model (axial, frontal or sagittal).

By tapping the structure management tool (Figure 21), the list of anatomical structures is displayed. This list includes names, colors, opacity and volumes of structures displayed in the scene. By tapping the name of a structure, its opacity is modified. Buttons allowing to display or mask the entire structures are also located at the top of the list.

Buttons (arrows) to cancel and restore an action are also available. The impacted actions only concern the selection and change of structure opacity.

The next button (contrast) allows to modify the background color of the scene.

The last button (padlock) freezes interactions with the scene.

Finally, the hamburger button located in the top right hand corner of the view allows to make a screenshot of the scene and to display a tutorial containing the list of available interactions.

6.6 How to visualize a PDF series

6.6.1 Opening a PDF series

De loss Montin				
Pr Jean Martin		Back	Modeling report	
		Visible Patient 8, rue Gustave Adalphe HIRN 67000 Strasbourg FRAACE +33 (03) 866 68 18 1 info@visiblepatient.com www.tisiblepatient.com		
laire Fontaine		, <u>k</u>	GLOBAL PATIENT VI	SUALISATION
um001 s 09f3915 (107) ir 23, 2020 at 11:42:55 AM			RAPPORT DE MODÉLISATI Date de livraison: 23 mars 2020 Rapport réelisé per 131cdd60be um01-Claire^Fontaine	ON
EMS			ATTENTION	
D Model	GET	c da prises	e repport contient des informations techniques. Il n'a pas de gnostic ou de repport médical. Les décisions de traitement d par un médiccin avec l'apport des informations cliniques et n	raleur de alveet être uficlogiques.
ips applying MB	GET	Numéro Nom du j Groupe	de commande (VPD) um01 patient Claire^For Usability	taine
odeling report MB	OPEN	Produit	ld. 42	els + Clip applying + :t
JMMARY	4.)		Ref. LIV07	
Diagnosis	\bigcirc			
Angiokeratoma type 3 name of Klatskin tumor.		Visible Pi		ogicielle bureautique
Important notes				CE0459 FDA
N/A		Visible Patient Capital sectal : 92 094 € RC8 Blosbourg TI 794-458 125	CONFIDENTIEL 1/5	NAF/APE: 3 BRET 794 458 125 C TXX.Intio-communication: FR 9-C944
		RAPPORT DE MODÉLISATION PR	16NT (senit	
		Modèle 3D (Nom du vpz) um01	Modalité Région cible CT Abdomen	Organe cible Foie
			nostic (fourni par le client)	Tole
		Angiokeratoma type 3 nam		
		Notes importan	tes	
		N/A		

Figure 22: Opening of a PDF series Figure

Figure 23: Display of a PDF series

When the data has been downloaded (see 6.4), tap the **Open** button corresponding to the PDF series (Figure 22). When the data has been downloaded, the PDF is displayed (Figure 23).

6.6.2 Basic interactions

It is possible to interact with PDF data as follows:

- Swipe vertically to scroll the document
- Spread or pinch two fingers to control the zoom of the document
- Swipe two fingers in the same direction to move the document

6.7 How to visualize a clip series

6.7.1 Opening a clip series

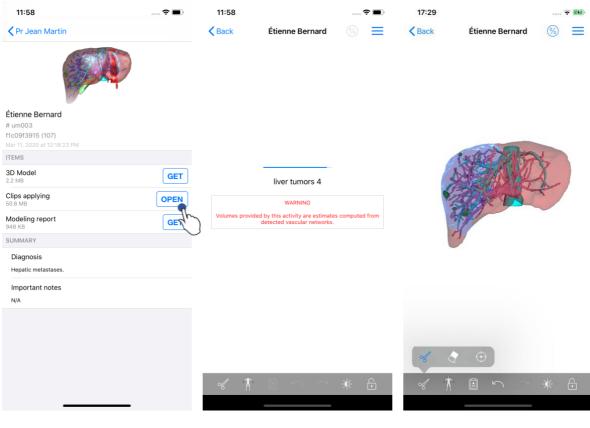


Figure 24: Opening clip data

Figure 25: Loading clip data

Figure 26: Displaying clip data

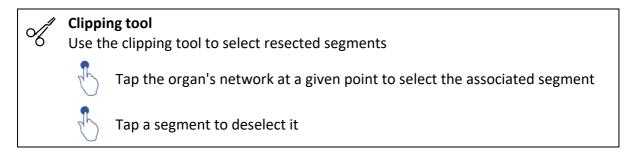
When the data has been downloaded (see 6.4), tap the **Open** button corresponding to the clip series (Figure 24). A progress bar allows to see the progress of data loading (Figure 25). When the data has been loaded, the 3D model is displayed (Figure 26).

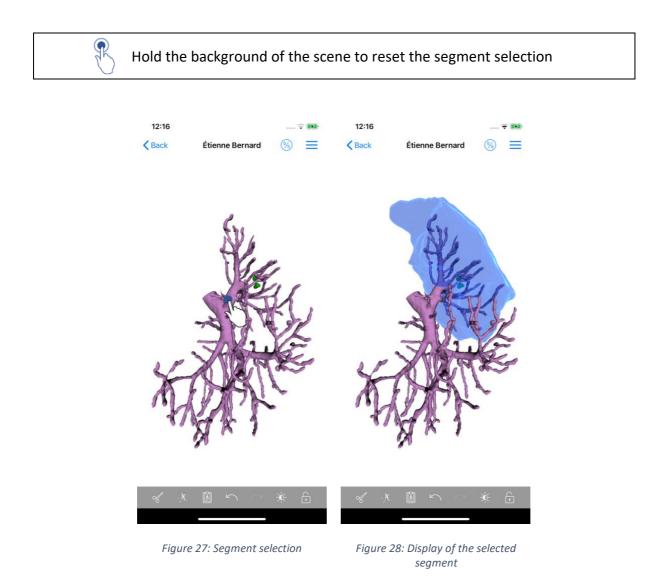
6.7.2 Basic interactions

When the clip series has been loaded, the same basic interactions as for the model series are available (see 6.5.2).

6.7.3 Tools

Beside masking and focus tools (see 6.5.2), the clipping tool is available:





Segment selection is done by tapping the network of the target organ where you want to apply a virtual clip (Figure 27). Vascular or respiratory territory corresponding to the selected section is then displayed (Figure 28). To deselect a segment, just tap on it. To reset the selection of segments, long press on the background of the scene.

6.7.4 Display of resection volumes

17:29 🙃 🖬	17:27 🕈 🖬	17:27 🙃 🕫
< Back Étienne Bernard 🚳 🗮	Étienne Bernard Volumes	Volumes Computation information
<u>A</u> P	PATIENT	GENERAL
	Étienne Bernard	Organ Volume = Entire organ
	GENERAL	Healthy tissue
	Organ 1 284,5 cc (100 %)	Volume = Entire organ - Volume of nodule(s) Percentage computed against the entire organ
	L Healthy tissue 1 282,7 cc (99,86 %)	Nodule(s) Volume = 3D modeled nodules
15000000000	L Nodule(s) 1,77 cc (0,14 %)	Percentage computed against the entire organ
(ALA)	ORGAN	ORGAN
ADDET A		Remaining part
The second second	731,2 cc (56,93 %) Remaining part	Volume = Entire organ – Volume of all displayed segments Percentage computed against the entire organ
-	553,3 cc (43,07 %) Resected part (displayed segments)	Resected part (displayed segments)
		Volume = All displayed segments Percentage computed against the entire organ
	HEALTHY TISSUE	
	731,0 cc (56,99 %) Remaining part	HEALTHY TISSUE
	551,7 cc (43,01 %)	Remaining part Volume = Healthy tissue – Volume of all displayed segments
	Resected part (displayed segments)	without nodule(s) Percentage computed against healthy tissue
		Resected part (displayed segments)
		Volume = All displayed segments without Nodule(s) Percentage computed against healthy tissue
8 2 9		
≪ ↑ 🖹 ∽ ~ ☀ 🖯		
Figure 29: Display of a clip series	Figure 30: Display of volumes linked	Figure 31: Display of volume
	to clip data	computation of clip data

When segments have been selected for resection, the volume display icon (Figure 29) allows to display the view of volumes computed following resection simulation (Figure 30). Information on volume computation (Figure 31) is available by tapping the information button (Figure 30).

There is also a button to capture the volume view in the top right hand corner of the view (Figure 30).

6.7.5 Resection volume computation

Volumes displayed in the General section are computed as follows:

- Organ
 - Volume = entire organ
- Healthy tissue
 - Volume = entire organ Nodule volume
 - o Percentage computed based on the entire organ
- Nodule(s)
 - Volume = Nodule(s) modelled in 3D
 - \circ $\;$ Percentage computed based on the entire organ

The volumes displayed in the **Organ** section are computed as follows:

- Remaining part
 - Volume = entire organ Volume of all visible segments
 - Percentage computed based on the entire organ
- Resected part (visible segments)
 - Volume = All visible segments
 - o Percentage computed based on the entire organ

The volumes displayed in the Healthy tissue section are computed as follows:

- Remaining part
 - Volume = Healthy tissue Volume of all visible segments without Nodule(s)
 - Percentage computed based on healthy tissues
- Resected part (visible segments)
 - Volume = All visible segments inside the Nodule(s)
 - o Percentage computed based on healthy tissues

6.7.6 Estimate of vascular and respiratory territories

The computation of vascular territories corresponding to displayed segments is done upstream by the Visible Patient Suite medical device. The VP Planning iOS application uses the estimate of vascular and respiratory territories in order to compute the remaining and resected parts of an organ (see 6.7.5).

Vascular and respiratory territories proposed within clip data are an approximation of real patient anatomy. The method used to estimate these territories relies on organ vascularization or respiratory system of the organ and the accuracy of the method directly depends on segmentation quality of the tree. Territory estimate stems from following process.

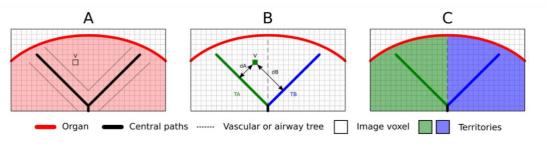


Figure 32: Territory identification process

First, segmentation of the vascular or respiratory system is used to compute central tubular paths (A). Then, these central paths, which represent the tubular structure, are labelled by trained health professionals in order to associate each path to the territory of an organ. For each voxel of the targeted anatomical structure, the method then finds the closest central path and associates the same organ territory (B). Finally, the result of the labelled image is meshed to obtain all territory estimates.

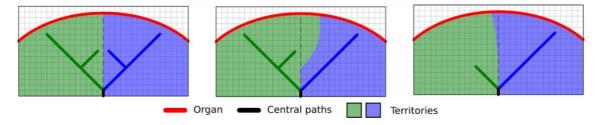


Figure 33: Territory variation depending on central paths of the target organ

Accuracy of the method directly depends on segmentation quality of the vascular or respiratory system. Image resolution, contrast agent diffusion in the vascular system of the organ during image acquisition, etc. can have an impact on territory estimate.

6.7.7 Other actions

The same actions as for visualization of a model series are also available (see 6.5.4).

9:06		🗢 🔳	9:06		? ■	9:07		🕈	•
Q ≣↓	Pr Jean Martin	🖒 Edit	Pr Jean Martin			🗸 Pr Jea	n Martin		
Last syr	nchronization: Mar 11, 2020 at	9:05:41 AM	Ou suit				an act		
LAST 7 DAYS			(SE				SE		
	Étienne Bernard # um003 f1c09f3915 (107) Mar 6, 2020 at 6:53:45 PM	•							
		Th	Étienne Bernard # um003			Étienne B	lernard		
1	Delphine Berthiaume # um002 f1c09f3915 (107) Mar 6, 2020 at 6:50:03 PM	\bigcirc	# um003 f1c09f3915 (107) Mar 6, 2020 at 6:53:45 PM Update the case to access the late	est model versions.				ist model versions.	DATE
A ANT STATE	Claire Fontaine		ITEMS		Th	ITEMS	Case	update	
and a second	# um001 f1c09f3915 (107) Mar 6, 2020 at 6:37:24 PM	\square	3D Model 2.2 MB		OPEN	3D Mode 2.2 MB	series will be dele to download the la update. Be sure to	n of the downloaded ted. You will be able test version after the have a valid internet ection.	PEN
			Clips applying 50.8 MB	NOT AV	VAILABLE	Clips app 50.8 MB	Cancel		BLE
			Modeling report	NOT A	VAILABLE	Modeling 1 948 KB			BLE
			SUMMARY			SUMMARY		\bigcirc	
			Diagnosis Hepatic metastases.			Diagnosi Hepatic m			
			Important notes			Importar N/A	nt notes		
Public cases Pri	\mathbf{V}	ielp Settings							
							-		

6.8 How to update a case

Figure 34: Icon of a case proposing an update



Figure 36: Validation of the update

Cases containing no downloaded series are automatically updated upon synchronization. For cases proposing an update and containing series downloaded on a previous revision, the status icon is updated (Figure 34). In order to update the case, you have to tap the **update** button (Figure 35). When the action has been validated (Figure 36), the case is updated. **Important**: updating a case deletes the series downloaded on the previous revision of the case.

6.9 How to delete downloaded series

12:23	🗢 🔳	12:24		🗢 🖿	12:24			
< Pr Jean Martin		Q ≣↓	Pr Jean Martin	🖒 Edit	Cancel	Pr Jean Martin		Ŵ
on which there are	and a second	Last syn	chronization: Mar 11, 2020 at 12	2:22:06 PM 2h		nchronization: Mar 11, 2020	at 12:22:06 PM	4r
(Selection)		LAST 7 DAYS		\bigcirc	LAST 7 DAYS			
Étienne Bernard		F	Étienne Bernard # um003 f1c09f3915 (107) Mar 11, 2020 at 12:18:23 PM	ļ		Étienne Bernard # um003 f1c09f3915 (107) Mar 11, 2020 at 12:18:23 Pt		
um003		a transmission	Delphine Berthiaume			Delphine Berthiaum	e	
1c09f3915 (107) Aar 11, 2020 at 12:18:23 PM TEMS		P.	# um002 f1c09f3915 (107) Mar 6, 2020 at 6:50:03 PM	ļ		# um002 f1c09f3915 (107) Mar 6, 2020 at 6:50:03 PM	T.	
3D Model	OPEN	1. Martine	Claire Fontaine		1. 100000	Claire Fontaine	20	
ng	OPEN Delete	and the second s	# um001 f1c09f3915 (107) Mar 6, 2020 at 6:37:24 PM	$\langle \mathcal{L} \rangle$	1 al	# um001 f1c09f3915 (107) Mar 6, 2020 at 6:37:24 PM	Ŭ	Ŷ
Modeling report 948 KB	de cen							
Diagnosis								
Hepatic metastases.								
Important notes N/A								
		Public cases Pri	vate cases About Hel	- ~~~	Public cases Pr	ivate cases About		ح ک ettings
-	ing a downloaded	Figure 38	3: Activating select	tion mode	Figure	39: Selecting ar		ıg
se	ries		of cases			downloaded ca	ses	

In order to delete downloaded series, several options are possible.

First, it is possible to delete a downloaded series by dragging the data presentation cell towards the left (Figure 37). You then just have to tap the **delete** action on the right of the cell.

The second option allowing to delete downloaded series consists in activating the edit mode of the list of cases (Figure 38). When activated, select cases of which you want to delete series and validate deletion with the button in the top right hand corner of the view (Figure 39).

2:19	?	2:16		? () ,	12:39	🗢 🔳
Settings Accord	unts Edit	+ < Settings	Accounts	Edit +	Setting	S
					CONNECTION INFORMATION	
Brice Quirion e.quirion@example.com	The V	De C _{om}	✓ Dele	e series Delete	Account Pr Jean Martin	>
Pr Jean Martin jean.martin@example.com	Ch	Pr Jean Marti jean.martin@exa Europe		4D	APPLICATION CONFIGURATION	
					Data collection Manage app data collection	>
					Application log Manage application log	>
					Delete all series	The
					Delete all data Delete acccounts and downloade	d content
Public cases Private cases Abo			\sim \sim	Help Settings	Public cases Private cases About	Halp Settings
Figure 40: Display o	of deletion optic	ons Figure 41	: Deletion of do	ownloaded	Figure 42: Deletion oj	f all downloaded

of an account

series linked to an account

series

It is also possible to delete all series linked to an account. To do so, go to the list of available accounts and drag the account presentation cell towards the left (Figure 40). You then just have to tap the delete series action (Figure 41) and confirm deletion when the confirmation message is displayed.

Finally, it is possible to delete all the downloaded series. To do so, tap delete all series action located in the application settings (Figure 42).

2:16	🗢 🔳	2:15		•••• ?	2:17			? ■
Settings Accounts	Edit +	Settings	ccounts E	dit +	Cancel	Accounts		R
~	Delete series Delete	Pr Brice Quirion brice.quirion@example.co	m	d D	Pr Brice Quirio			2"
r Jean Martin an.martin@example.com _{rrope}	H	Europe Pr Jean Martin jean.martin@example.com Europe	ı		Europe Pr Jean Martin jean.martin@exa Europe		Th	
							\bigcirc	
ê 🖰 i		R B	(i)	\$	R (Ð	\$
olic cases Private cases About	Help Settings	Public cases Private cases	About Help	Settings	Public cases Private	cases About	Help	Settings
Figure 43: Delete d	an account	Figure 44: Activa	nte account se	lection	Figure 45: S	Select and a	lelete ac	count

6.10 How to delete registered accounts

Various functionalities allow to delete an account.

First, a unique account can be deleted through the list of available accounts, dragging the account presentation cell towards the left (Figure 43). You then just have to tap the **delete** action and confirm deletion when the confirmation message is displayed.

The second option allowing to delete accounts consists in activating the edit mode of the list of accounts (Figure 44). When activated, select accounts you want to delete and validate deletion with the button in the top right hand corner of the view (Figure 45).

12:39	∻ ■
Settings	
CONNECTION INFORMATION	
Account Pr Jean Martin	>
APPLICATION CONFIGURATION	
Data collection Manage app data collection	>
Application log Manage application log	>
Delete all series Delete all downloaded content	
Delete all data Delete acccounts and downloaded content	
< 1	G
Public cases Private cases About Help	Settings

Figure 46: Delete all data from the application

Finally, it is possible to delete all accounts and their associated data. To do so, tap **delete all data** action in the application settings view (Figure 46).

6.11 How to access application parameters

12:39	🗢 🔳	5:15		? ■	5:18		🗢 🔳
Settings		Settings Date	a collection		<pre>Settings App</pre>	plication log	団
					Mar 11, 2020 at 5:16:49		
CONNECTION INFORMATION		DATA COLLECTION			 'Account Listing' vie Mar 11, 2020 at 5:16:50 	w controller did show	N
Account Pr Jean Martin	>	Send app usage Automatically send app u	isage		• 'Settings' view contr Mar 11, 2020 at 5:16:53	roller did show	
APPLICATION CONFIGURATION		Help improve our product us about how you use the	s and services by sending d VP Planning app.	ata to	• 'Log Listing' view co Mar 11, 2020 at 5:16:55	ontroller did show	
Data collection Manage app data collection	>	Privacy policy		>	 'Settings' view control Mar 11, 2020 at 5:17:11 P 	roller did show	
Application log	>				 Launched application Mar 11, 2020 at 5:18:00 	DN PM	
Manage application log Delete all series					 App information: Pla Mar 11, 2020 at 5:18:00 	anning 2.3.1-rc1-1211	48.449840
Delete all downloaded content					Device information: Mar 11, 2020 at 5:18:00		
Delete all data Delete acccounts and downloaded co	ntent				• 'EHR Collection (Pul Mar 11, 2020 at 5:18:00	blic cases)' view swit	tched from '
					• 'EHR Collection (Pul Mar 11, 2020 at 5:18:00	blic cases)' view swit	tched from '
					• 'EHR Collection (Priv Mar 11, 2020 at 5:18:00	vate cases)' view swi	itched from
					• EHR Collection (Priv Mar 11, 2020 at 5:18:00	vate cases)' view swi	itched from
					• Data collection enab Mar 11, 2020 at 5:18:00	bled PM	
					• 'EHR Collection (Pul Mar 11, 2020 at 5:18:00	blic cases)' view con	troller did s
					• Application did beco Mar 11, 2020 at 5:18:00	ome active	
					• 'Settings' view conte Mar 11, 2020 at 5:18:35	roller did show	
					• 'Settings' view conti Mar 11, 2020 at 5:18:35	roller did show	
Public cases Private cases About	Help Setting	Public cases Private cases	(i) (i) About Help	Settings	Public cases Private cases	(i) III About Help	Settings
Figure 47: Setting	ys view	Figure 48: Do	ata collection vie	?W	Figure 49: Ap	pplication log	g view

The **Settings** view is accessible in the main menu bar of the application (Figure 47). The view allows in particular to access the account management view and to delete all downloaded series and registered accounts.

The view also allows to access the control view of data collection. By agreeing that Visible Patient collects usage data, you allow the application to be improved.

Finally, the view provides access to the log listing the various actions executed by the application. The log can be emptied by tapping the basket button in the top right hand corner of the view.

6.12 How to access regulatory information

5:37			중 ■
	About		
	7		
	LE PATI		
2.3.2-m	d - March 0	2020	
C	E 0459		
	vice Identifi PI2320/\$\$7		
Ŗ Presc	ription u	se only	
Contact			
Indications for use			
Approvals			
Security policy			
Visible Patient			
			~~~~

Figure 50: View about the application

Regulatory information is available in the **About** view of the application accessible in the main menu bar (Figure 50). Beside information on version and certification, the view provides access to a set of sub-views containing:

- Visible Patient contact information
- Indications for use of the application
- Information on application approvals
- Recommended security policy
- General information on Visible Patient

## 6.13 How to access help information

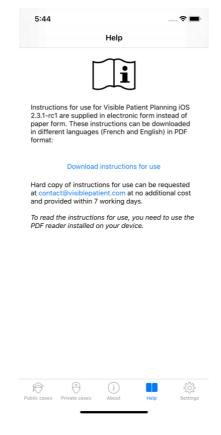


Figure 51: Help view

Information regarding access to the user manual is available in the **Help** view of the application accessible in the main menu bar (Figure 51).

#### 10:38 賜 C AA go.visiblepatient.com Open in VP Planning VP Planning 12 OPEN VISIBLE PATIENT Access the Visible Patient website Or Click on the "OPEN" button at the top of the page to open the Visible Patient Planning mobile applicat Loading case.. Cance 1× VIDEO рното PORTRAIT PANO Ð < Û C Figure 53: Opening a link via Safari Figure 52: QR code scan Figure 54: Loading screen of the link

#### 6.14 How to open a Visible Patient link

Some links provided by Visible Patient can be opened within the application. There are two

• Links allowing to access a case

kinds of links:

• Links allowing to prefill registration information of accounts

To access a link, flash the QR code provided by Visible Patient by using the device of your phone (Figure 52) or use Safari to open the communicated link (Figure 53) using the **Open** button at the top of the page (Figure 53). After the loading screen (Figure 54), you can access the account registration view or the desired case.

**Warning**: to access a private case via a link, you first have to register your account in the application. Your password will be requested to recover the case if it has not yet been recovered during manual synchronization. In case several accounts are registered in the application, you will have to select the account allowing to access the case.

## 7 Maintenance

No maintenance is required for the VP Planning iOS application. Updates are provided via the App Store.

## 7.1 Application update

Under iOS 13 and iPadOS 13, the VP Planning iOS application is automatically updated by default. You will receive no notification about application update. It is however also possible to generate the update manually by visiting the <u>VP Planning iOS</u> application page on the App Store and by tapping the download button.

## 8 Problem solving

## 8.1 General problems

## 8.1.1 I cannot register my account

This section contains the various errors that can be encountered during account registration in the application.

## 8.1.1.1 Technical problem during the display of the server list

**Message:** A technical issue prevents the connection to the server. Please try again later.

**Resolution:** A problem on Visible Patient servers prevents from connecting. Please try again in a few moments. If the problem persists, please contact the Visible Patient support.

## 8.1.1.2 No internet connection

Message: No internet connection available.

**Resolution:** Make sure you have an internet connection (Wifi or LTE) and that the Airplane mode of the device is not activated.

## 8.1.1.3 Incorrect identifiers

Message: Invalid credentials, please check your login and password.

**Resolution:** Make sure you have entered the right email and password on the right server. If the problem persists, please contact the Visible Patient support.

## 8.1.1.4 Account already registered

Message: Account already registered, this account has already been registered.

**Resolution:** The account you want to register has already been registered in the application. You cannot register the same account several times on the same device.

#### 8.1.1.5 Description already used

**Message:** Description already used. The account description must be unique to identify it. Please provide another one.

**Resolution:** The description entered to identify the account is already used by another account. Please enter another one.

#### 8.1.2 I am unable to recover my list of cases

This section contains the various errors that can be encountered during recovery of the list of cases (synchronization).

#### 8.1.2.1 No internet connection

Message: No internet connection available.

**Resolution:** Make sure you have an internet connection (Wifi or LTE) and that the Airplane mode of the device is not activated.

## 8.1.2.2 Data not found

**Message:** Resource not found. A technical issue prevents to recover data from the server. If the problem persists, please contact the Visible Patient support.

**Resolution:** A problem on Visible Patient servers prevents data recovery. Please try the action again. If the problem persists, please contact the Visible Patient support.

## 8.1.2.3 Insufficient storage space

**Message:** Insufficient storage. Please free some space on your device to perform this action.

**Resolution:** Your device does not have sufficient storage space to perform this action. Please free some space on your device and try the action again.

#### 8.1.3 I am unable to download the series associated to cases

This section contains the various errors that can be encountered during series download. Errors described during recovery of a list of cases can also be encountered (see 8.1.2).

#### 8.1.3.1 Corrupted downloaded data

**Message:** Download failed. Downloaded data is corrupted. Please try to download the series again.

**Resolution:** Data has been corrupted during data download. Please download data again. If the problem persists, please contact the Visible Patient support.

#### 8.1.4 I am unable to open a series

This section contains the various errors that can be encountered during opening of a series.

#### 8.1.4.1 Corrupted stored data

**Message:** Opening failed. Data stored on device is corrupted. Please delete and download the series again.

**Resolution:** Data of the series has been corrupted on the device. Please download data again.

#### 8.1.4.2 Insufficient memory to open a clip series

**Message:** Insufficient memory. Impossible to load Clip Applying for this model. For more information, please check system requirements.

**Resolution:** The clip series you are trying to open needs more memory to load than the memory your device features. This problem may occur on devices that do only have 1GB RAM. To access the data, please use a more recent device featuring at least 2 GB RAM.

#### 8.1.5 I am unable to open a Visible Patient link

This section contains the various errors that can be encountered during opening of a Visible Patient link.

#### 8.1.5.1 No internet connection

Message: No internet connection available.

**Resolution:** Make sure you have an internet connection (Wifi or LTE) and that the Airplane mode of the device is not activated.

#### 8.1.5.2 Account required

**Message:** Account required. Please register your account into the application to access this case.

**Resolution:** Make sure you have registered your Visible Patient account in the application before opening that link.

#### 8.1.5.3 Case not available

Message: Unavailable case. This case is not available.

**Resolution:** The case is not available on the server. Please contact the Visible Patient support.

### 8.1.5.4 Unauthorized access

**Message:** Unauthorized access. You are not authorized to display this case. Make sure the correct account is used.

**Resolution:** You are not authorized to display this case. If you think you have the right to access this data, please contact the Visible Patient support.

### 8.1.5.5 Unsupported link

**Message:** Unsupported link. This link is not supported by the application. Make sure to use a valid link.

**Resolution:** The link you are trying to open is corrupted. Make sure to use an up-to-date application, a valid link (with no input error) or an undamaged QR code.

### 8.2 3D visualization problems

This section contains the various errors that can be encountered during visualization of 3D data.

#### 8.2.1 I am unable to interact with the model

If you are unable to interact with the model, make sure interactions are activated (see 6.5.4). If the model is no longer visible in the scene, you can shift the model by tapping one of the orientation buttons (axial, frontal, sagittal).

#### 8.2.2 I am unable to mask an anatomical structure

If you are unable to mask an anatomical structure by tapping it, make sure to use the masking tool (see 6.5.3).

During display of clip data, some structures cannot be masked with the masking tool. Segments can be masked by using the clipping tool (see 6.7.3). The network of the target organ cannot be masked.

## 8.2.3 I am unable to visualize volumes associated to clip data

During visualization of volumes associated to clip data, the following message may be displayed: "Inconsistencies detected during volume computation. No information available." In this case, no volume is displayed in the view. This problem occurs when an inconsistency is detected during volume computation. To solve the problem, please contact the Visible Patient support.