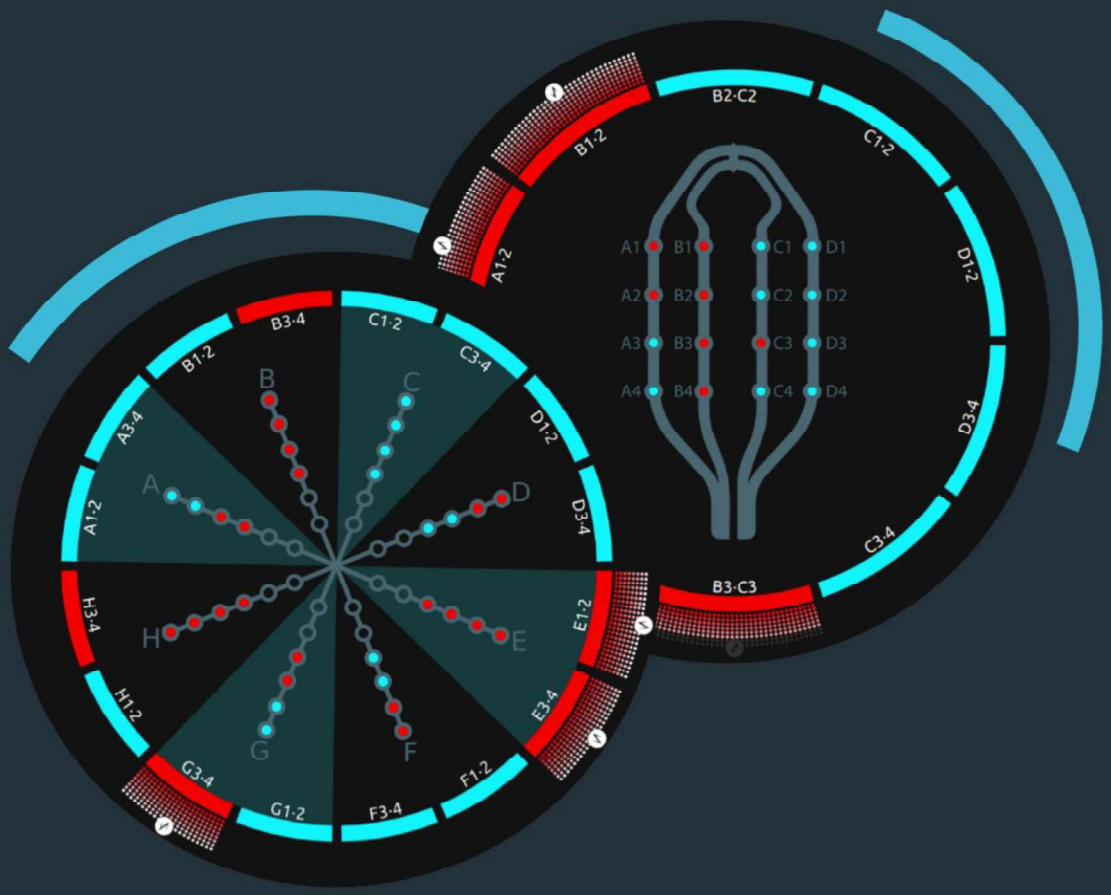
VOLTA

AF-Xplorer™ II

SYSTEM USER MANUAL



EU EN VERSION

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PLEASE READ THIS DOCUMENT CAREFULLY BEFORE USING THE VOLTA AF-XPLORER II SYSTEM

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List of Abbreviations

AC	Alternating Current
A/D	Analog to Digital
AF	Atrial Fibrillation
AI	Artificial Intelligence
AT	Atrial Tachycardia
CS	Coronary Sinus
DC	Direct Current
DEs	Dispersed Electrograms
ECG	Electrocardiograms
EGM	Electrograms
EP	Electrophysiology
GE	General Electric
IC	Intra-Cardiac
PCI	Platform Component Interconnect
ROI	Regions Of Interest
SW	Software
UI	User Interface

CHAPTER I – INTRODUCTION

This document is the user manual for Volta AF-Xplorer II decision support system (Ref: A003), including the software application and platform, a device designed and manufactured by Volta Medical.

This document is intended to be read by healthcare professionals who are involved in the use of the Volta AF-Xplorer II such as:

- Electrophysiologists, primary operators of the device and its application,
- Medical personnel, to monitor and engage with the software in accordance to the electrophysiologist's instructions,
- Hospital Administrator, to manage operator accounts (enable or disable account, reset operator password),

This document describes the unique capabilities of Volta AF-Xplorer II and provides guidance on its safe and effective use.
The content assumes users have a prior experience with the use and configuration of EP Recording Systems and with 3D Mapping Systems.
Therefore, only features that are specific to the Volta AF-Xplorer II medical device are covered in this manual, specific to software version V 3.1.x of Volta AF-Xplorer II.

CHAPTER II – SYMBOLS AND INDICATIONS

2.1 – TECHNICAL CHARACTERISTICS

2.1.1 – PHYSICAL CHARACTERISTICS

General		
Use	Indoor only	
Environmental conditions	Temperature	15° to 35° Celsius
	Humidity	10% RH to 80% RH, non condensing
	Input Voltage	-10V to +10V
	The product cannot be used in an environment rich in oxygen or in presence of inflammable components.	
	Vibration	0.5Gms (5-500Hz) (HDD)
	Shock	10 G with 11ms duration, half sine wave
	Atmospheric pressure	60 kPa to 106 kPa
Environmental conditions for Storage and Shipping	Temperature	-20° to 60° Celsius
	Humidity	5% RH to 85% RH, non condensing
	Vibration	2G
	Shock	10 G with 11ms duration, half sine wave
	Atmospheric pressure	60 kPa to 106 kPa
Lifetime	Volta AF-Xplorer II device	5 years
Dimensions	180mm x 214mm x 240mm	

2.1.2 – ELECTRICAL CHARACTERISTICS

Computer		
Power	Type	ATX/AT
	Input Voltage	19~24 VDC, 8A~6.5A
	Output Voltage (USB port)	5VDC 500mA per port
	Power Consumption	150W to 220W (With Add on Card)
Certifications	EMC	CE/FCC Class A, CCC, BSMI
	Safety	UL, CCC, BSMI
AC-DC Power switching adaptor		
Input	Voltage	100 - 240V
	Frequency	50 - 60HZ
	Current (Max)	3A
Certifications	EMI/EMC	FCC part 15 Class B, EMC
	Safety	CB, UL/cUL, TUV

2.1.3 – EMC LABELING

The following tables present data regarding compliance of Volta AF-Xplorer II device with IEC60601-1-2, 4th edition.

<table>
<tr><th colspan="5">Emissions</th></tr>
<tr><td colspan="3">RF Emissions
CISPR11</td><td colspan="2">Group 1, Class A</td></tr>
<tr><td colspan="3">Harmonic current emissions IEC 61000-3-2</td><td colspan="2">Not applicable</td></tr>
<tr><td colspan="3">Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3</td><td colspan="2">Not applicable</td></tr>
<tr><th colspan="5">Immunity</th></tr>
<tr><th>Tests</th><th colspan="2">Requirements</th><th colspan="2">Level of compliance</th></tr>
<tr><td>Electrostatic discharge
IEC 61000-4-2</td><td colspan="2">± 8 kV contact
± 2/4/8/15 kV air</td><td colspan="2">± 8 kV contact
± 2/4/8/15 kV air</td></tr>
<tr><td>Radiated RF EM
IEC 61000-4-3</td><td colspan="2">3V/m
(professional healthcare facility environment)
80MHz-2.7GHz
80% AM at 1kHz</td><td colspan="2">3V/m
80MHz-2.7GHz
80% AM at 1kHz</td></tr>
<tr><td rowspan="8">Proximity fields from RF wireless communications equipment IEC 61000-4-3</td><td>Frequency (MHz)</td><td>Modulation</td><td>Required level (V/m)</td><td>Compliance level (V/m)</td></tr>
<tr><td>385</td><td>Pulse Modulation
18 Hz</td><td>27</td><td>27</td></tr>
<tr><td>450</td><td>Pulse Modulation
18 Hz</td><td>28</td><td>28</td></tr>
<tr><td>710-745-780</td><td>Pulse Modulation
217 Hz</td><td>9</td><td>9</td></tr>
<tr><td>810-870-930</td><td>Pulse Modulation
18 Hz</td><td>28</td><td>28</td></tr>
<tr><td>1720-1845-1970</td><td>Pulse Modulation
217 Hz</td><td>28</td><td>28</td></tr>
<tr><td>2450</td><td>Pulse Modulation
217 Hz</td><td>28</td><td>28</td></tr>
<tr><td>5240-5500-5785</td><td>Pulse Modulation
217 Hz</td><td>9</td><td>9</td></tr>
<tr><td>Electrical fast transients/bursts
IEC 61000-4-4</td><td colspan="2">Alimentation: ± 2 kV
Input/output lines: ± 1 kV
Repetition frequency: 100 kHz</td><td colspan="2">Alimentation: ± 2 kV
Input/output lines: ± 1 kV
Repetition frequency: 100 kHz</td></tr>
<tr><td>Surges
IEC 61000-4-5</td><td colspan="2">Line to line:
± 0.5 kV, ± 1 kV
Line to ground
± 0.5 kV, ± 1 kV, ± 2 kV</td><td colspan="2">Line to line:
± 0.5 kV, ± 1 kV
Line to ground
± 0.5 kV, ± 1 kV, ± 2 kV</td></tr>
<tr><td>Conducted disturbances induced by RF fields
IEC 61000-4-6</td><td colspan="2">3 V 0.15 MHz – 80 MHz
6 V in ISM bands between 0.15 MHz and 80 MHz
80 % AM at 1 kHz</td><td colspan="2">3 V 0.15 MHz – 80 MHz
6 V in ISM bands between 0.15 MHz and 80 MHz
80 % AM at 1 kHz</td></tr>
</table>

<table>
<tr><td>Power frequency magnetic field immunity
IEC 61000-4-8</td><td colspan="2">30A/m</td><td colspan="2">30A/m</td></tr>
<tr><td>Voltage Dips and Interruptions:
IEC 61000-4-11</td><td colspan="2">0 % UT; 0.5 cycle
A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
0 % UT; 1 cycle at 0°
70 % UT; 25/30 cycles at 0°
0 % UT; 250/300 cycles</td><td colspan="2">0 % UT; 0.5 cycle
A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
0 % UT; 1 cycle at 0°
70 % UT; 25/30 cycles at 0°
0 % UT; 250/300 cycles</td></tr>
<tr><td rowspan="3">Proximity Magnetic Fields
IEC 61000-4-39</td><td>Frequency</td><td>Modulation</td><td>Required level (V/m)</td><td>Compliance level (V/m)</td></tr>
<tr><td>134,2 kHz</td><td>Pulse modulation 2,1kHz</td><td>65</td><td>65</td></tr>
<tr><td>13,56 MHz</td><td>Pulse modulation 50kHz</td><td>7,5</td><td>7,5</td></tr>
</table>

2.2 - SYMBOLS AND DESCRIPTION

	**Warning**: This symbol is used to warn the user about a potential risk associated with the use of the product that may have consequences on patient or user safety.
	**Caution**: This symbol is used to indicate that a caution is necessary when operating the device, without any consequences on patient or user safety.
	Refer to the instruction manual.
	Manufacturer name YYYY-MM-DD corresponds to the date of manufacture
	Product reference
	Product serial number
	Medical device
	Crossed out wheelie bin indicates separate treatment from general waste at end-of-life EU Directive 2012/19/EU
	Electrostatic sensitive device

2.3 - WARNINGS

Please, carefully read the indications below, to ensure that the device is used in the best conditions and in complete safety.

2.3.1 – GENERAL WARNINGS

	All users require training before using the product.
	Read all safety instructions carefully and keep this User Manual for reference.
	Do not modify or open the equipment. Service or repairs must be performed by a qualified Volta medical representative only. Any modifications to the system will require safety re-evaluation.

2.3.2 – ELECTRICAL DANGERS

	Avoid voltage over ±10V DC for the A/D converter PCI card.
	Disconnect this equipment from any AC outlet before cleaning. Use a damp cloth. Do not use liquid or spray detergents for cleaning.
	For plug-in equipment, the power outlet must be located near the equipment and must be easily accessible.
	Make sure the voltage of the power source is correct before connecting the equipment to the power outlet with an earthed connection.
	If the equipment is not used for a long time, disconnect it from the power source to avoid damage by transient overvoltage.
	Never put any liquid into an opening. This may cause fire or electrical shock.
	To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
	Remove the power cord to fully turn off the device.
	Connect only items that have been specified as part of the Volta AF-Xplorer II device or that have been specified as being compatible with Volta AF-Xplorer II device.
	Communication cable must be connected to 60950-1 input signal port or 60601-1 signals with following insulation: 1MOOP 230V.
	The equipment must be directly connected to wall outlets without the use of a power strip. An improper connection may cause electrical hazards.
	The device shall not be connected to the same multi-socket as the third-party devices to which it is connected.

2.3.3 – ELECTROMAGNETIC INTERFERENCES AND ELECTROSTATIC DISCHARGES

	This equipment is sensitive to electrostatic discharges. Please avoid manipulating the equipment if not necessary and especially during use.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
	Use of accessories, transducers, and cables other than those specified or provided by Volta Medical of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	Portable RF communications equipment should be used no closer than 30 cm to any part of the Volta AF-Xplorer II device, including cables specified by Volta Medical. Otherwise, degradation of the performance of this equipment could result in the above warning.

2.3.4 – ENVIRONMENT

	Keep this equipment away from humidity.
	Put this equipment on a reliable surface during installation. Dropping it or letting it fall may cause damage.
	Do not leave this equipment in an environment where the storage temperature is under -40° C (-40° F) or above 60° C (140° F), as it may damage the equipment.
	The openings on the enclosure are for air convection. Protect the equipment from overheating. DO NOT COVER THE OPENINGS.
	Position the power cord so that people cannot step on it. Do not place anything over the power cord.
	Avoid places exposed to salty air, with corrosive gas or with an organic solvent atmosphere.
	Avoid places where there are lots of vibration and shocks.
	Some Volta AF-Xplorer II device warnings are acoustics so screen speakers must be always turned on and adjusted to a level in order to be audible at 2 meters.

2.3.5 – CYBERSECURITY

	The system is designed to be connected only to official identified third party systems. Any connection to other endpoints is strongly discouraged.
	Do not disclose your credentials
	Only identified accessories and usb mass storage for maintenance activities shall be plugged to the system.
	Do not make any physical changes to the system. If you witness such a situation (screws unscrewed, hard disk removed) please inform Volta Medical immediately.
	If the system is withdrawn, stored information will not be retained (except logs) and a factory reset will be performed.
	In case of impossible connection with your credentials or in case of unexpected settings changes please contact your local Volta Medical representative.

2.4 - MALFUNCTIONS

If any of the following situations arises, immediately stop using the device. Try to identify or eliminate the cause of the malfunction using the description in this document (Chapter VII – TROUBLESHOOTING/RESIDUAL ANOMALIES). If it is not possible to identify the cause or eliminate the malfunction using this document, cease device operation and call a Volta Medical Representative (see Manufacturer section, at the end of this document).

- The power cord or plug is damaged.
- Liquid has penetrated the equipment.
- The equipment has been exposed to moisture.
- The equipment does not work well, or you cannot get it to work according to the user's manual.
- The equipment has been dropped and damaged.

CHAPTER III – PRODUCT DESCRIPTION

3.1 - GENERAL DESCRIPTION AND PRINCIPLE OF OPERATION

3.1.1 – GENERAL DESCRIPTION

The Volta AF-Xplorer II device is a decision support system composed of a non-sterile reusable medical device, a computing platform and a software application. The computer is manufactured by Advantech (external manufacturing site) and then assembled and configured by Volta Medical (internal manufacturing site).

Volta AF-Xplorer II is connected to existing electrophysiology acquisition systems through custom-made connection cables (DSUB and Octopus) or ethernet cables, provided by Volta Medical.

Volta AF-Xplorer II decision support system processes real-time analysis of intracardiac atrial electrograms (EGMs) based on a data-driven approach for identification of spatio-temporal dispersed EGMs during cardiac electrophysiology procedures. This solution relies on artificial intelligence (AI) techniques, such as deep and machine learning. The algorithm has been trained on a large database of EGMs collected from centers in Europe and the USA. The data has been annotated by expert electrophysiologists from both geographies.
Targeting spatio-temporal electrogram dispersion in a cardiac ablation procedure has shown to be beneficial versus pulmonary vein isolation alone as these areas are indicative of AF drivers.
Spatio-temporal dispersion is defined as an ensemble of intracardiac electrograms forming a localized sequential activation in a distinct area, in which clusters of three or more adjacent bipolar electrograms show an intracardiac activation spanning the entire AF cycle length. This pattern suggests localized reentrant-like conduction, indicative of a role in initiating or maintaining AF (Deisenhofer et al. Artificial intelligence for individualized treatment of persistent atrial fibrillation: a randomized controlled trial. *Nature Medicine*, 2025).

Volta AF-Xplorer II is manufactured by Volta Medical located at 65 Avenue Jules Cantini 13006 Marseille, FRANCE.
Volta AF-Xplorer II is used in the operating room or electrophysiology laboratory during an ablation procedure but is not intended to be placed in the sterile field and has no applied part.
Physicians should not move the Volta AF-Xplorer II computer during the procedure, Volta AF-Xplorer II information is duplicated on a secondary medical screen or on an operating room widescreen (Figure 1).
Volta AF-Xplorer II is monitored by the medical personnel or the medical staff according to the physician's instructions.

Figure 1: Principle of operation: Volta AF-Xplorer II interface (upper left corner of the widescreen) presents operators with a simple color coding of signals of interest: blue for no dispersion; red for a high likelihood of dispersion; white indicator at the top of the gauge (shown by the Volta 'bolt' icon): indicates highly stable dispersion.

3.1.2 – PRINCIPLE OF OPERATION

The application is installed on a computing platform at Volta Medical's manufacturing site and configured by a Volta Medical's representative on site at installation.
The application supports digital signal input coming from the platform and acquired either from an EP recording system (through an analog/digital converter or directly in digital format) or from a 3D mapping system (directly in digital format).

The application supports two tagging configurations depending on the input source:

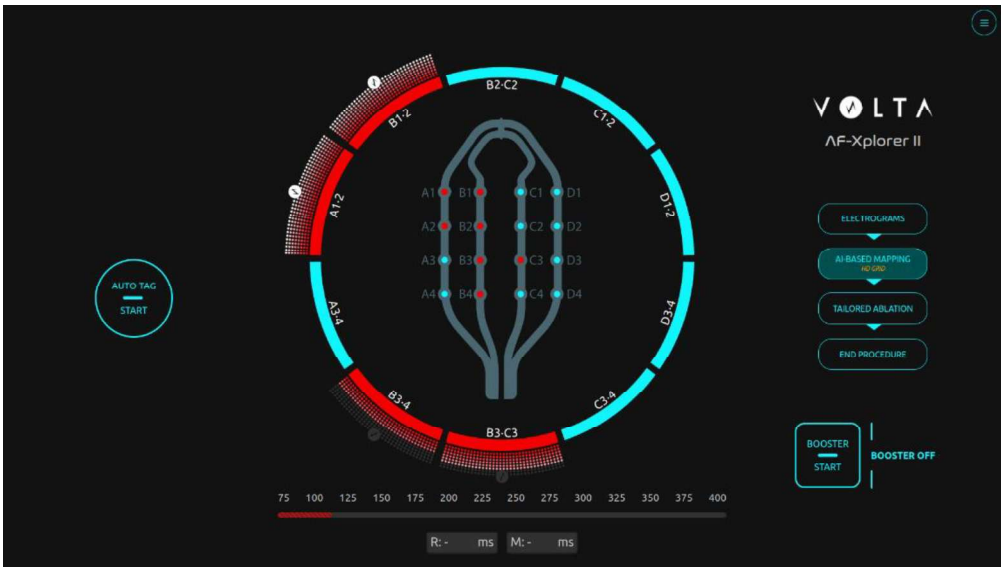
- When directly connected to an EP recording system, the tagging of regions of interest (ROI) is manual.
- When directly connected to a 3D mapping system, the tagging of ROI is either manual or automatic. In automatic mode, the software directly sends the tags to the 3D mapping system, where they appear on the 3D maps without additional intervention.

For each mapping catheter, the application displays the bipoles of interest at a given time during the procedure.

Operating mode:

1. While moving the mapping catheter, the user observes the Volta AF-Xplorer II display regularly.
2. When bipoles start to blink on the display, the user stabilizes the mapping catheter.
3. If the bipoles of interest are confirmed as dispersed by the software, sound- and color- coded guidance on the outer circular schematic is provided. The user may also wait a few additional seconds to identify highly stable dispersion points, indicated by a filling gauge with an indicator at the top (represented by a Volta 'bolt' icon).
4. Depending on the configuration:
    - The user may manually tag the associated locations on the 3D mapping system (available for all input sources)
    - The associated locations are automatically tagged on the 3D shell of the atria in the 3D mapping system (available only when directly connected to the mapping system).

Ultimately, by repeating these 4 simple steps, the electrophysiologist may obtain a map of all dispersed areas in the mapping system.



3.2 - INTENDED PURPOSE

Volta AF-Xplorer II assists operators in the real-time manual or automatic annotation of 3D anatomical and electrical maps of human atria for the presence of multipolar intra-cardiac atrial electrograms exhibiting spatio-temporal dispersion during atrial fibrillation (AF) or atrial tachycardia (AT).

The Volta AF-Xplorer II application is intended to be used, in addition to conventional approaches, to support the electrophysiologist during AF and AT ablation procedures.

3.3 – INTENDED USERS

The Volta AF-Xplorer II device shall be used by trained users only.

Users	User Functions
Electrophysiologist	Software monitoring Clinical decision with the support of information provided by the software
Medical Personnel (e.g. biomedical engineer or nurses)	Software monitoring according to Electrophysiologist's instructions
Hospital Administrator	Operator account management

3.4 – INTENDED PATIENT POPULATION

The system can be used on adult patients who are eligible for AF or AT ablation procedures.

3.5 - CONTRAINDICATIONS

The Volta AF-Xplorer II system has no specific contraindications beyond those associated with a left atrial catheter ablation procedure (e.g. presence of left atrial thrombus).

3.6 - PERFORMANCE AND SAFETY

The main clinical functions of the Volta AF-Xplorer II application are the detection and annotation in real-time, of dispersed regions during atrial fibrillation or atrial tachycardia catheter ablation procedures.

The essential performances of the Volta AF-Xplorer II is freedom from over detection and/or misdetection of EGMs dispersion areas. Over detection or misdetection may increase the number of ablations delivered and subsequently the ablation complication rate.

All safety considerations, cautions and warnings that apply to the general use of the medical system in an operating room or electrophysiology laboratory apply while using Volta AF-Xplorer II. There are no known potential adverse events associated with the use of Volta AF-Xplorer II.
The system must be installed in a hospital environment, outside the patient environment and in compliance with medical electrical device IEC 60601-1 and IEC 60601-1-2 standards.

NOTE Volta AF-Xplorer II system is classified class A according to CISPR 11. The characteristics of this equipment make it suitable for use in industrial areas and hospitals and should not be used in a residential environment where it could not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Complications associated with AF ablation procedures are well documented and anticipated (e.g. stroke, perforation, fistula, cardiac tamponade, phrenic nerve damage, periprocedural thromboembolic event, vascular complications).
The use of Volta AF-Xplorer II in normal conditions is not expected to increase the likelihood of any adverse effect that might otherwise occur during a radiofrequency catheter ablation procedure for AF/AT.

NOTE Any serious incident that has occurred in relation to Volta AF-Xplorer II shall be reported to Volta Medical and the Competent Authority of the Member state in which the user is established.

3.7 - COMPLIANT USE AND CLINICAL BENEFITS

Volta AF-Xplorer II is a decision support system intended for use as an adjunct to physician clinical judgment and training.
The use of this device is restricted to:

- Electrophysiologists trained by Volta Medical for the use of Volta AF-Xplorer II.
- Electrophysiologists under the control of a proctor (electrophysiologists already trained by Volta Medical) or a Volta Medical representative.

Training sessions are provided to the electrophysiologists by a Volta Medical Representative after each new installation or software upgrade. If a non-trained electrophysiologist would like to be trained by Volta Medical for the use of Volta AF-Xplorer II, please contact your local Volta Medical representative.

Any inappropriate use is forbidden.

To protect patients, third parties, other operators, assistants and themselves from all danger:

- Only use non-defective products and according to its intended purpose.
- Avoid all contamination of/by the product.
- Check the safety of operation and the condition of the device before each use, specifically the connection cables.
- Appropriately store the device and keep it in good working conditions.

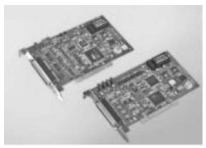
Particular attention shall be paid to acquisition systems connection and catheters integrity (not manufactured by Volta Medical).

The expected benefit for the patients is a better overall clinical management of their AF by performing a tailored catheter ablation and improving reproducibility between operators performing AF ablations. AF and AT are considered different conditions of the same disease, AF encompasses underlying ATs.

3.8 - LIST OF COMPONENTS AND OPTIONAL ACCESSORIES

NOTE Accessories are provided by Volta Medical

Component Name	Part Number	Description	Picture	Medical Device or Non-Medical equipment
Volta AF-Xplorer II application	EU: 901007 CH: 901008	Software processes real-time analysis of intracardiac atrial EGMs		Volta AF-Xplorer II medical device

Computer + Analog/Digital Converter PCI Card + TPM		Computer with Intel Core i7-7700 CPU (8MB cache, up to 4.20 GHz, RAM 32 GB) Analog/digital 16 channels converter PCI card. Each channel provides a ±10 V measurement range at a 24-bit resolution. The converter has a maximum sample rate of 10 kS/s and features programmable hardware filters. The TPM (Trusted Platform Module) is a security embedded ship in the computer which provides a cyber-security protection.	  	
Computer AC/DC switch converter	EU: 901010 or CH: 901013	Computer power supply. AC/DC converter		
Computer AC/DC switch converter / Screen Power Cord EU	EU: 901011 Or CH: 901014	Computer / Screen power cord		
Optional Accessories supplied by Volta Medical				
DSUB Connection Cable H005	EU: 999014 CH: 999029	Connection cable between the analog output of an EP Recording System (see compatibilities in next section 3.9) and the analog input of the computer. Analog DB37 to DB37 Male/Male		Medical Device

Octopus Connection Cable H007	EU : 999015 CH: 999030	Connection cable between the analog output of an EP Recording System (see compatibilities in next section 3.9) and the analog input of the computer. Analog DB37 to 16 pins Male/Male		Medical Device
Keyboard (Interchangeable)	AZERTY: 998003 or QWERTY: 998004 or QWERTZ: 998005	AZERTY Keyboard with USB connection to computer Or QWERTY Keyboard with USB connection to computer Or QWERTZ Keyboard with USB connection to computer		*Non-medical equipment*
Mouse (Interchangeable)	998009	Mouse with USB connection to computer		*Non-medical equipment*
Screen	EU: 998001 Or CH: 998018	23.8" screen full HD 1920x1080 75Hz. 16:9 ratio. Speakers 2x2W, HDMI and DP inputs.		*Non-medical equipment*
Touchscreen and power cord	EU: 998022 Or CH:998024	15.6" touchscreen full HD 1920x1080. 16:9 ratio. Speakers 2x2W, HDMI and DP inputs. Tactile PCAP technology device.		*Non-medical equipment*
Stand for Touchscreen	EU/CH: 998025	Adjustable display height tilt swivel		*Non-medical equipment*
Ethernet Connection Cable	2m : 998010 5m : 998011 10m : 998012 20m : 998013	RJ-45 connection between Abbott EnSite X and GE CardioLab workstations and Volta AF-Xplorer II Lengths: 20 / 10 / 5 / 2 meters		*Non-medical equipment*
Speaker Set	EU/CH: 998026	External Speakers jack connection		*Non-medical equipment*

HDMI Splitter kit	EU/CH: 998016	HDMI splitter with power cable, and 30cm HDMI cable		*Non-medical equipment*

3.9 – COMPATIBILITIES

The application supports two types of acquisition systems: it can either be connected to an EP recording system (in analog or digital mode) or to a 3D mapping system (in digital mode).

3.9.1 – COMPATIBLE ACQUISITION SYSTEMS

3.9.1.1 – Communication with an EP recording system

The tagging of region of interest (ROI) is manual. To be correctly used, the Volta AF-Xplorer II must be directly connected to the acquisition systems mentioned below and used with the multipolar cardiac mapping catheters described below (section 3.9.2).

Analog communication :

Volta AF-Xplorer II is labeled for use with either of the two following EP recording systems:

- LabSystem Pro (Boston Scientific)
- CardioLab (GE HealthCare).

Digital communication :

Volta AF-Xplorer II is labeled for use with GE CardioLab version 9.0.
When connected to the CardioLab EP Recording system: digital data are routed to the platform through an ethernet cable and transferred to the application.

3.9.1.2 – Communication with a mapping system

Volta AF-Xplorer II is labeled for use with Abbott EnSite X DWS from version 3.1.
When connected to the Ensite X 3D mapping system: digital data are routed to the platform through an ethernet cable and transferred to the application.

3.9.2 – COMPATIBLE CATHETERS

Volta AF-Xplorer II is labeled for use with multipolar catheters meeting the following specifications:

Type of catheter for mapping	List of **compatible high density multi-electrodes mapping catheters** with **electrode size** (diameter for circular, length for rectangle/square) between **0.4mm and 1mm:** • **PentaRay Nav** (Biosense Webster) • **Advisor HD Grid** (Abbott), **Advisor HD Grid X** (Abbott) • **Intellamap Orion** (Boston Scientific) • **OctaRay 2-2-2**, **OctaRay 2-5-2**, **OctaRay 3-3-3** (Biosense Webster) • **Lasso 20** (Biosense) • **Affera Sphere-9** (Medtronic) Other compatible multi-electrode catheter: • **FARAWAVE NAV** (Boston Scientific)
Type of coronary sinus catheter	- Electrode size: 1mm - Inter-electrode spacing: 2-3 mm - Number of selected dipoles: 2 or 5

3.9.3 – COMPATIBLE SIGNALS

The signal that is acquired by the Volta AF-Xplorer II must meet the following characteristics to ensure compatibility with the device:

Analog Input Specifications:
32 single-ended or 16 differential analog inputs, or a combination of single-ended and differential analog inputs amounting to 16 inputs.
Input Range: Bipolar: ±5 V / Unipolar: 0-5 V

Digital Input Specifications:
Digital Signal input through the Live Export or LiveSync communication interface between the EnSite X workstation and Volta AF-Xplorer II.
Digital Signal input through the CardioLab communication interface between GE CardioLab system and Volta AF-Xplorer II.

Use of the compatible catheters and acquisition systems listed above according to their cleared labeling, produces a signal which meets these general signal characteristics.

Further, the device should only be used with catheters and acquisition systems that are compatible with each other, consistently with their labeling.

3.9.4 – COMPATIBLE DISPLAYS

Volta Medical provides a screen display which has the following minimum characteristics:

Size of the screen	Classic Monitor: At least 17" 16:9 Touchscreen: At least 15.6" 16:9
Resolution of the screen	At least 1080p for both types of screens
Type of the screen	Flat color external classic screen or touch screen located near the computer including digital video input (HDMI or equivalent)
Integrated speakers	Yes with at least 3 Watts

A secondary screen can be connected to Volta AF-Xplorer II and shall meet the same resolution as the primary one.

Only the HDMI output of the workstation is usable, do not use the VGA output.

CHAPTER IV – INSTALLATION AND MAINTENANCE

Please, note that the Volta AF-Xplorer II system installation and maintenance must be performed by a Volta Medical service representative.

The following details are indicated to ensure the proper functioning of the installed device.

4.1 – HARDWARE INSTALLATION

Integrity of each component of the Volta AF-Xplorer II system must be checked before installation and use.

As mentioned in the Compatibilities section, below are detailed hardware installation diagrams and connections to third-party devices:

4.1.1 SETUP WITH ACQUISITION SYSTEM

4.1.1.1 – Setup with the LabSystem Pro EP Recording System (Boston Scientific)

All the equipment shall be connected as shown below:

Please, note that the analog output box 16 channels is associated with the Boston Scientific LabSystem Pro EP recording system (sold separately by Boston Scientific representative or distributor).

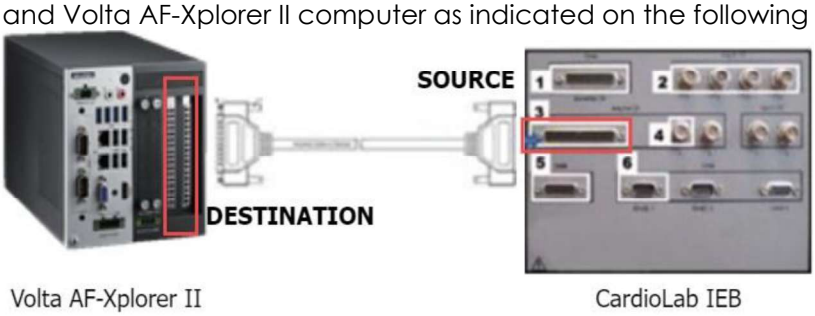
Each pin of the OCTOPUS cable is numbered, and each number must correspond to the analog output box plug number.

4.1.1.2 - Setup with the CardioLab EP Recording System (GE HealthCare)

A. Direct analog connection with GE EP recording system

All the equipment shall be connected as shown below:

DSUB37 connection cable (Ref. 999014/999029) must be connected between the analog output (3) on CardioLab™ IEB and Volta AF-Xplorer II computer as indicated on the following diagram:



The DSUB cable has 2 connectors labeled "Source" and "Destination".
Be careful to respect the DSUB cable direction of connection:

- "Source" side must be connected to CardioLab
- "Destination" side must be connected to Volta AF-Xplorer II

B. Connection to GE EP recording system through Analog output box

All the equipment shall be connected as shown below:

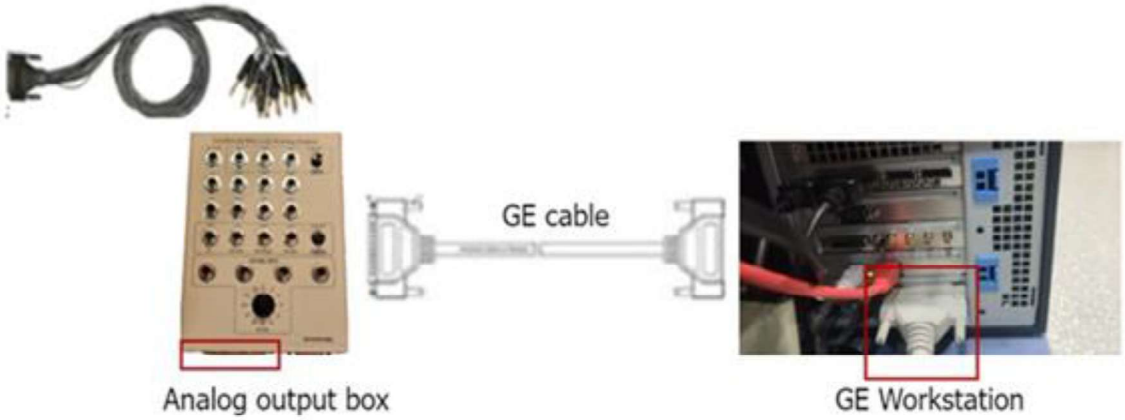
Please note that the analog output box 16 channels is associated with the GE CardioLab EP recording system (sold separately by GE HealthCare representative or distributor).

Octopus connection cable must be connected between the GE Workstation via the analog output junction box provided by GE **(Ref. 2010476 – CardioLab/Mac-Lab Analog Output**) and Volta AF-Xplorer II computer.

Each pin of the OCTOPUS cable is numbered, and each number must correspond to the analog output box plug number.

Example of an OCTOPUS connection to GE CardioLab with analog output box:

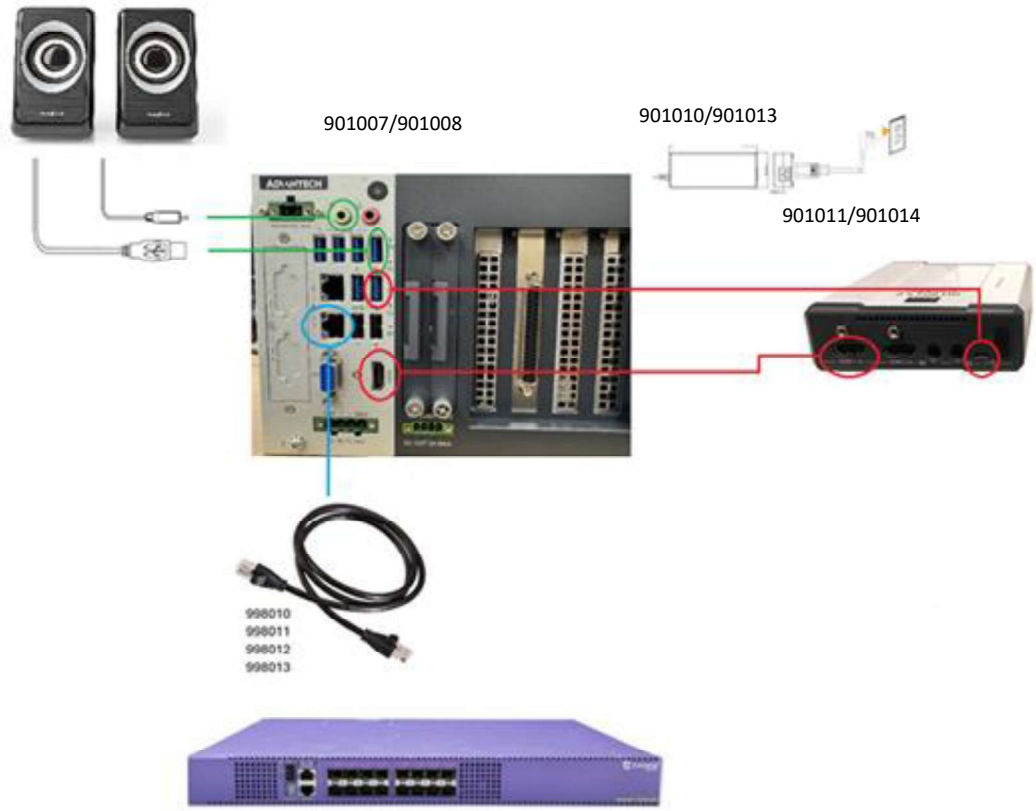
999015/999030

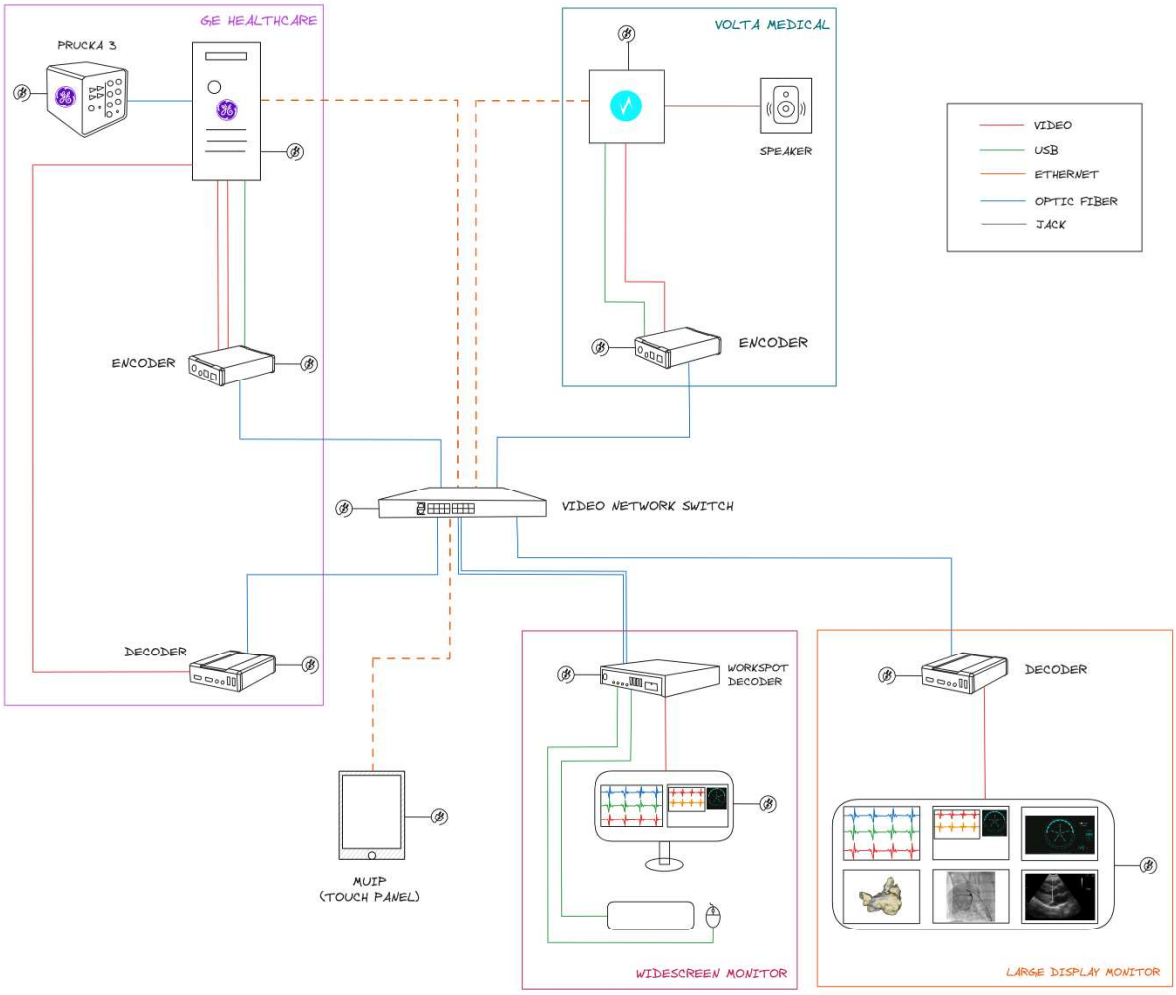


C. Set-up for digital communication with GE CardioLab (v9.0):

All the equipment shall be connected as shown below:

998026





Both Volta AF-Xplorer II and GE CardioLab systems are connected to the EP Command Center.
The EP Command Center allows display and control of multiple devices on a single monitor. It removes the need for multiple sets of monitors, keyboards and mice and allows users to switch between the Volta AF-Xplorer II and GE CardioLab with the UI controls. The screen layout can be customized according to user's preferences.
The EP Command Center integration will also enable easier connection of the Volta user interface to the large display monitor (also known as the boom).

Focus on Volta AF-Xplorer II connections:
- Sound: via jack cable (and USB for power)
- Display: via HDMI cable connected to a Volta-dedicated **Encoder MNA-420**
- Control: via USB-micro USB cable connected to a Volta-dedicated **Encoder MNA-420**
- Signals: via ethernet cable connected to **Ethernet port 1** on the Volta AF-Xplorer II workstation and **Video Network 16 ports switch**.

4.1.1.3 – Setup with Abbott Ensite X DWS (v3.1)

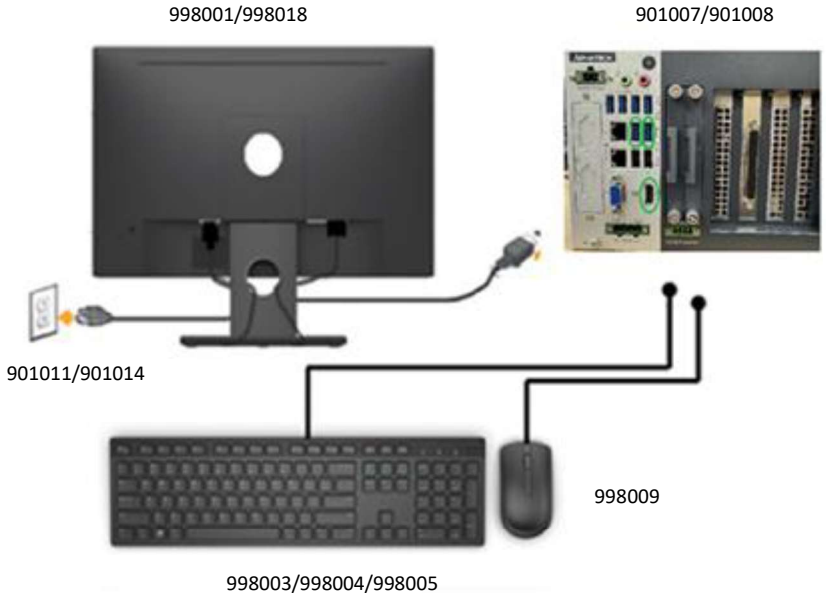
The ethernet cable must connect Ethernet port 2 on the Volta AF-Xplorer II workstation and the DATA port of the EnSite X DWS.

Volta AF-Xplorer II
workstation
Ethernet - Port 2

EnSite X DWS
Ethernet – DATA Port

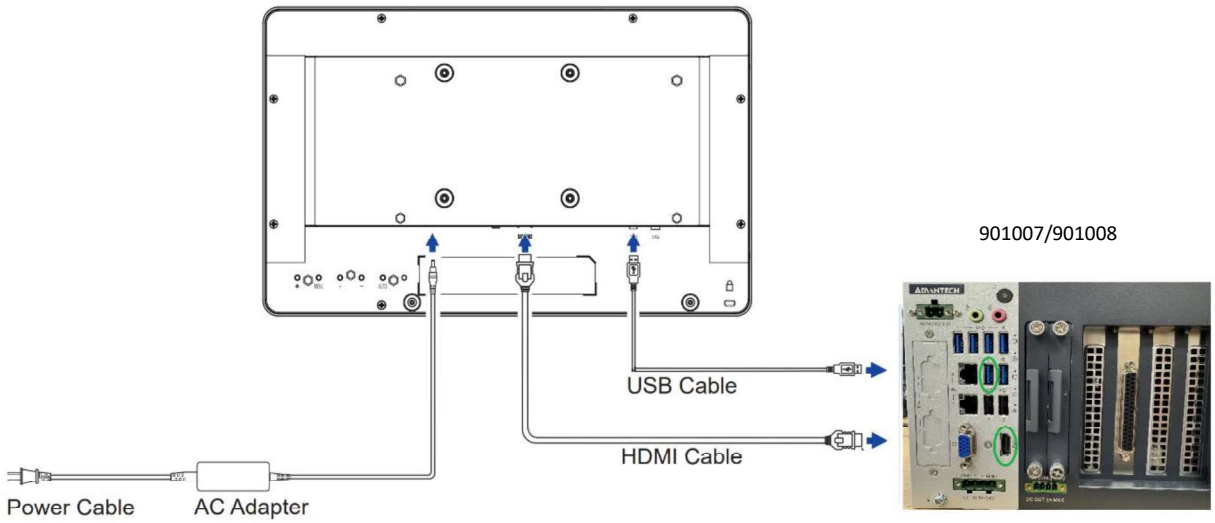
4.1.2 SETUP WITH ACCESSORIES

Set-up with Monitor, keyboard and mouse



Set-up with Touchscreen (iiYama model)

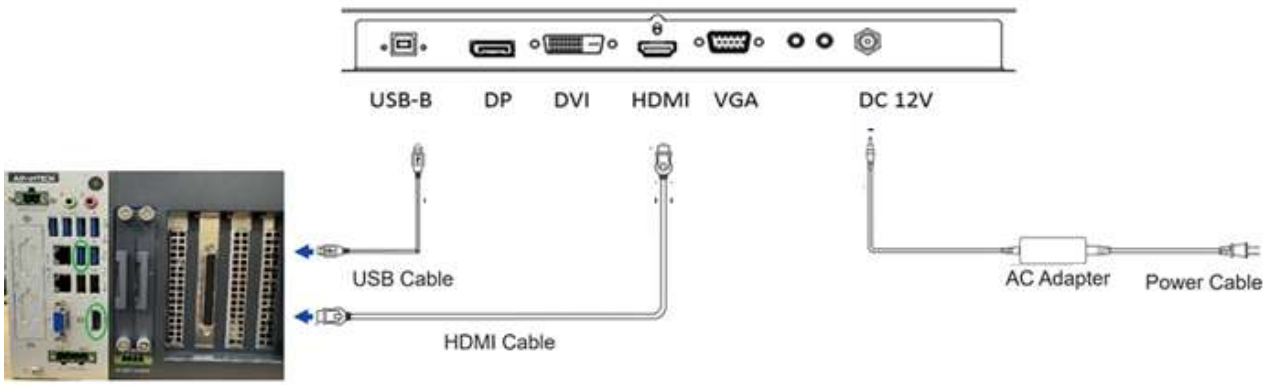
998022/998024



901007/901008

Set-up with Touchscreen (Acula model)

998022/998024



Optional speakers

998026

901007/901008

4.1.3. CONNECTION TO MULTIPLE SCREENS

Methodology for multiple screens connection:
All the connection configurations indicated have been tested following these steps, which ensure that all screens will display the interface with the proper resolution. **We recommend using (or setting) Full HD (1920x1080) resolution only.**

a) Turn off all screens and the computer to be connected.
b) Disconnect all the cables from screens, splitter, and computer.
c) Connect all the materials again.
d) Turn on the screens and the computer.

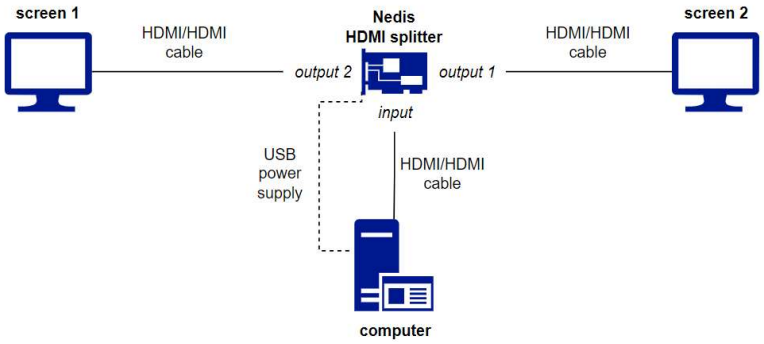
These steps must be performed each time the setup has to be modified.

Tested HDMI splitters:

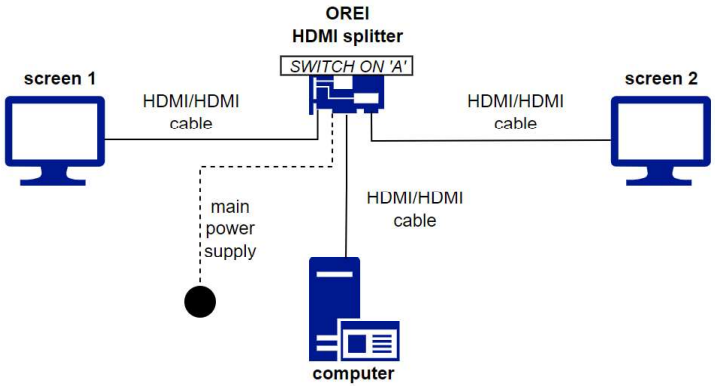
Accessories	Brand	Volta Medical Reference
HDMI splitter – USB powered	Nedis	998016
HDMI splitter – main connection powered	Orei	107002

Connection diagrams and information with tested splitters:
Only the HDMI output of the workstation is usable, do not use the VGA output.

HDMI screens – with Nedis splitter



HDMI screens – with OREI splitter



4.2 – EP RECORDING AND 3D MAPPING SYSTEM CONFIGURATION

To use the Volta AF-Xplorer II in analog mode, the configuration of the EP recording system is the following according to the mapping catheter type:

CHANNEL	PENTARAY / LASSO 20P	HD GRID HD GRID X	BASKET 64P	OCTARAY 2-5-2	OCTARAY 3-3-3	OCTARAY 2-2-2	FARAWAVE NAV	AFFERA SPHERE-9
1	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
2	1-2	B2-C2	B4-5	A3-A4	A3-A4	A1-A2	1-2	D4-T
3	3-4	A3-A4	C3-4	B3-B4	B3-B4	B1-B2	2-3	P4-D4
4	5-6	B3-B4	D3-4	C3-C4	C3-C4	C1-C2	3-4	D3-D4
5	7-8	C3-C4	E3-4	D5-D6	D5-D6	D5-D6	4-5	P3-D3
6	9-10	D3-D4	F3-4	D3-D4	D3-D4	D1-D2	5-1	D2-D3
7	11-12	D1-D2	G4-5	E3-E4	E3-E4	E1-E2	/	D2-T
8	13-14	C1-C2	F5-6	F3-F4	F3-F4	F1-F2	/	P2-D2
9	15-16	B1-B2	E5-6	G3-G4	G3-G4	G1-G2	/	D1-D2
10	17-18	A1-A2	D5-6	A5-A6	A5-A6	A5-A6	/	P1-D1
11	19-20	B3-C3	C5-6	H3-H4	H3-H4	H1-H2	/	D4-D1
12	CS 1-2	CS 1-2	CS 1-2	CS 1-2	CS 1-2	CS 1-2	CS 1-2	CS 1-2
13	CS 3-4	CS 3-4	CS 3-4	CS 3-4	CS 3-4	CS 3-4	CS 3-4	CS 3-4
14	CS 5-6	CS 5-6	CS 5-6	CS 5-6	CS 5-6	CS 5-6	CS 5-6	CS 5-6
15	CS 7-8	CS 7-8	CS 7-8	CS 7-8	CS 7-8	CS 7-8	CS 7-8	CS 7-8
16	CS 9-10	CS 9-10	CS 9-10	CS 9-10	CS 9-10	CS 9-10	CS 9-10	CS 9-10

In digital mode, the catheter's configuration is retrieved by the Volta AF-Xplorer II from the connected signal acquisition system.
List of bipoles to configure for use in digital mode according to the compatible catheters:

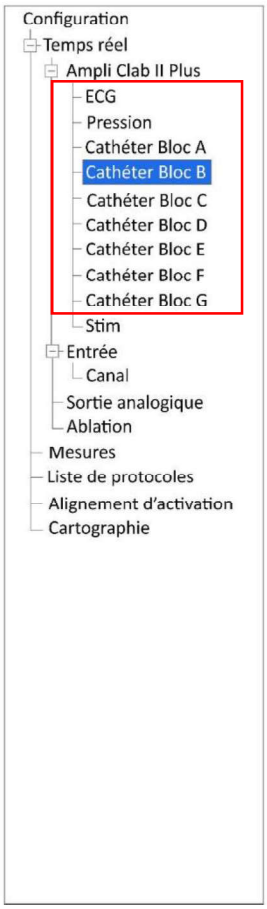
CHANNEL	PENTARAY / LASSO 20P	HD GRID HD GRID X	BASKET 64P	OCTARAY 2-5-2	OCTARAY 3-3-3	OCTARAY 2-2-2	FARAWAVE NAV	AFFERA SPHERE-9
1	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
f2	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
3	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
4	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
5	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
6	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
7	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
8	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
9	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
10	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
11	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
12	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead	ECG lead
13	1-2	B2-C2	B4-5	A1-A2	A1-A2	A1-A2	1-2	D4-T
14	3-4	A3-A4	C3-4	A3-A4	A3-A4	A3-A4	2-3	P4-D4
15	5-6	B3-B4	D3-4	B1-B2	B1-B2	B1-B2	3-4	D3-D4
16	7-8	C3-C4	E3-4	B3-B4	B3-B4	B3-B4	4-5	P3-D3
17	9-10	D3-D4	F3-4	C1-C2	C1-C2	C1-C2	5-1	D2-D3
18	11-12	D1-D2	G4-5	C3-C4	C3-C4	C3-C4	CS 1-2	D2-T
19	13-14	C1-C2	F5-6	D1-D2	D1-D2	D1-D2	CS 3-4	P2-D2
20	15-16	B1-B2	E5-6	D3-D4	D3-D4	D3-D4	CS 5-6	D1-D2
21	17-18	A1-A2	D5-6	E1-E2	E1-E2	E1-E2	CS 7-8	P1-D1
22	19-20	B3-C3	C5-6	E3-E4	E3-E4	E3-E4	CS 9-10	D4-D1
23	CS 1-2	CS 1-2	CS 1-2	F1-F2	F1-F2	F1-F2	/	CS 1-2
24	CS 3-4	CS 3-4	CS 3-4	F3-F4	F3-F4	F3-F4	/	CS 3-4
25	CS 5-6	CS 5-6	CS 5-6	G1-G2	G1-G2	G1-G2	/	CS 5-6
26	CS 7-8	CS 7-8	CS 7-8	G3-G4	G3-G4	G3-G4	/	CS 7-8
27	CS 9-10	CS 9-10	CS 9-10	H1-H2	H1-H2	H1-H2	/	CS 9-10
28	/	/	/	H3-H4	H3-H4	H3-H4	/	/
29	/	/	/	CS 1-2	CS 1-2	CS 1-2	/	/
30	/	/	/	CS 3-4	CS 3-4	CS 3-4	/	/
31	/	/	/	CS 5-6	CS 5-6	CS 5-6	/	/
32	/	/	/	CS 7-8	CS 7-8	CS 7-8	/	/
33	/	/	/	CS 9-10	CS 9-10	CS 9-10	/	/

4.2.1 - GE CARDIOLAB™ CONFIGURATION:

Analog output configuration

To perform the GE CardioLab configuration to be used with Volta AF-Xplorer II system, the appropriate protocol shall be selected (AF procedures, 3D Mapping System, multipolar catheter mapping, 10 poles coronary sinus catheter).

The configuration shall be done via the configuration protocol menu , on an empty page (i-th page). Note that the signal page is empty when no number is applied in the corresponding column, in all blocs and ECG.
Example below page 7 is empty on Bloc B.



Réglages de l'affichage | Réglages du matériel

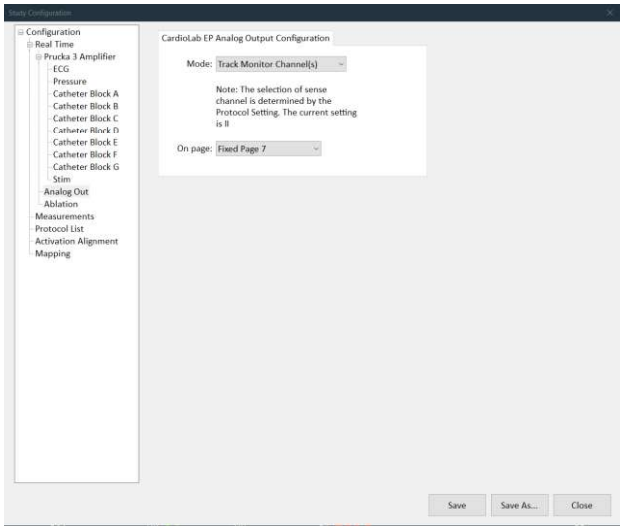
Echelle: 1/8

Canal	Etiquette	Clip	Couleur	Afficher pages # 1	2	3	4	5	6	7	8	Toujours enreg.
33	C1-C2/13-14					3	4	5				Oui
34	C2-C3							5			8	Oui
35	C3-C4/7-8					3	4	5				Oui
36	D1-D2/11-12					3	4	5			8	Oui
37	D2-D3							5				Oui
38	D3-D4/9-10					3	4	5			8	Oui
39	D1-D1							5				Oui
40	C2-D2							5			8	Oui
41	C3-D3							5			8	Oui
42	C4-D4							5				Oui
43	B1-C1							5				Oui
44	B2-C2/1-2					3	4	5				Oui
45	B3-C3/19-20					3	4	5				Oui
46	B4-C4							5				Oui
47	Stim 3											
48	Stim 4											
	Nombre de signaux par page			12	11	19	19	12	13	0	18	

Following the bipole list of the catheter to configure and except ECG, bipoles shall be clicked in the right order in the selected empty column (the number of the column will be displayed at each line). Bipoles can be distributed on several blocks.

Once the bipoles configuration is complete, ensure on the signal display page that signals are in the correct order, according to the list, except the ECG. If needed, signals can be re-organized on the page directly.
This additional display check ensures that the bipoles are sent in the right order from the EP recording system to the Volta AF-Xplorer II System.

Once the page is properly set-up, go to Analog output and select "fixed page" (i-th page described above). Apply changes and save configuration.



ECG, Mapping and CS catheter gain values must be reported into Volta AF-Xplorer II system settings.

Below are some recommendations:

Recommendations GE CardioLab	Gains	High-Pass	Low-Pass	Notch Filter
ECG	2500	0,5 Hz	50 Hz	YES
Mapping catheter	≥ 5000	30 Hz	100 Hz	YES
CS Catheter	2500	30 Hz	100 Hz	YES

The configuration page is different from the display page, as there is no ECG signal displayed.
The display page shows relevant bipoles for the operator (the 10 selected bipoles of the mapping catheter, CS signals and ECG channel(s)).

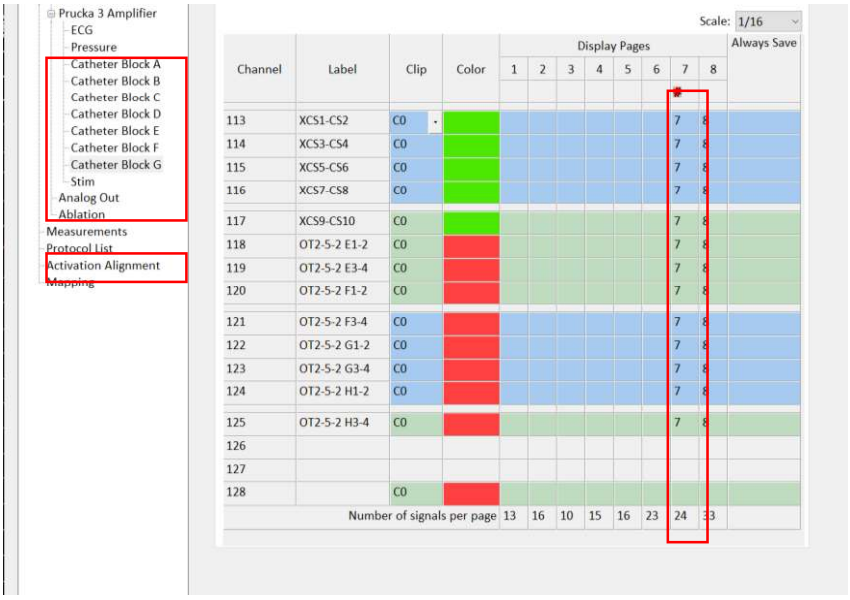
Note: The ECG channel sent to the Volta AF-Xplorer II system is the 'sense channel', identified on the ECG page by a "S" beside the channel name. The Sense channel is a channel sent to a stimulation device.
The user selects a channel by highlighting it with the mouse and pressing 'S' key.
This channel shall not be modified for the Volta AF-Xplorer II configuration.

In case of connection through the Analog output box, the box needs to be configured as follows:
- The dial is set to the configuration page number used for Volta AF-Xplorer II on the CardioLab.
- Both switches on the box are flipped to CLAB AMP (not PDM.)

Digital output configuration :

Before starting any CardioLab configuration, ask confirmation to GE HealthCare Service representative that the Volta catheter list has been uploaded on the CardioLab, and that all channels are configured with required catheter bipoles.

Find a new empty page (i-th page): check that the column number of the page is empty as below in all blocs and ECG. For example here, the page 7.
Important: This page must be different than the one for the analog configuration (if created) as different bipoles will be displayed on it.



Click in the column of the page you have selected, in the corresponding lines of the bipoles which will be displayed by Volta AF-Xplorer II (the number of the column will appear on each line). Select:

- All 12 ECG leads
- Mappings channels as indicated in the previous digital configuration table
- 5 CS channels as indicated in the previous digital configuration table

For each mapping and CS channels, go to Catheter settings tab and select the proper Catheter name and Catheter label (i.e. bipole name).

Once the properly bipoles are selected:

- Look at the Volta AF-Xplorer II bipoles display page on the EP recording system (the i-th page)
- Organize the display of the bipoles on the page in the corresponding order of the corresponding mapping catheter, then the coronary catheter.

This additional display check allows to visually validate the signals sent by GE CardioLab correspond to the ones received by Volta AF-plorer II.

Once the page is properly set-up, apply changes and save configuration.

Important : Ensure that each protocol is properly configured as starting a procedure Volta AF-Xplorer II with GE CardioLab, mapping catheter configuration depends on the selected protocol.

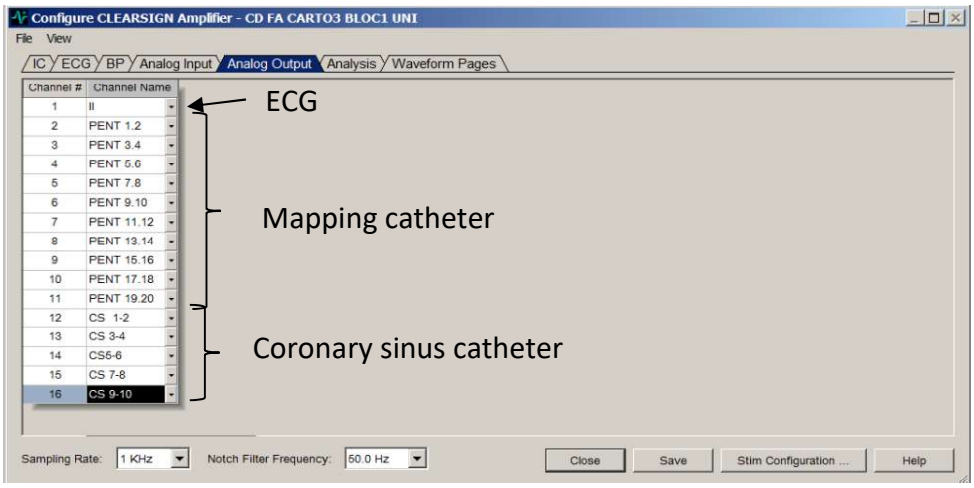
4.2.2 - BOSTON SCIENTIFIC LAB SYSTEM™ PRO CONFIGURATION:

To perform the Lab System Pro configuration for use with the Volta AF-Xplorer II system, the appropriate protocol shall be selected (AF procedures, 3D Mapping System, multipolar catheter mapping, 10 poles coronary sinus catheter).

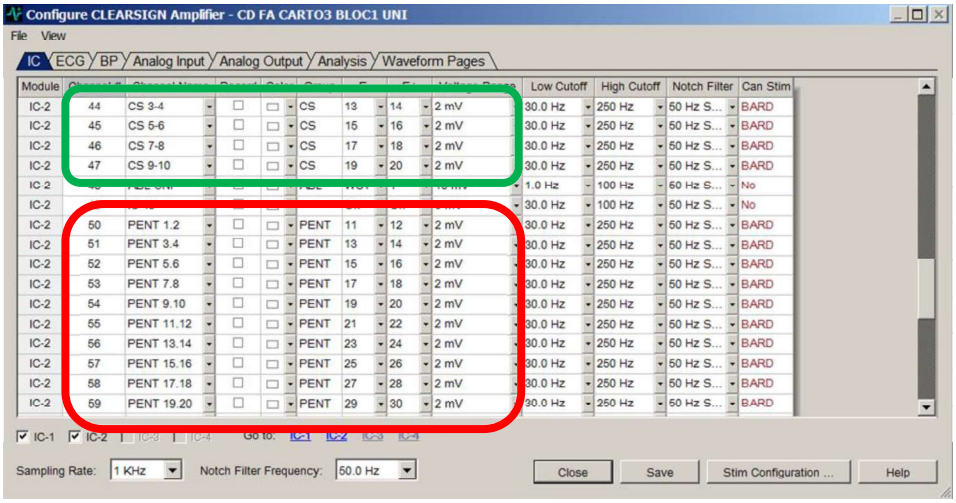
The configuration shall be done via the amplifier menu, by selecting 'Configure'.

In the Analog output tab, the 16 analog output channels shall be configured as follows:

- 1: ECG
- 2 to 11: Mapping catheter dipoles
- 12 to 16: CS catheter dipoles 1-2 to 9-10



ECG, Mapping and CS catheter voltage range values from ECG and IC tabs must be reported into the Volta AF-Xplorer II system settings.



Below are some recommendations:

Recommendations Boston Lab System Pro	Voltage range	High-Pass	Low-Pass	Notch Filter
ECG	5 mV	0,5 Hz	50 Hz	YES
Mapping catheter	1 mV	30 Hz	100 Hz	YES
CS Catheter	2 mV	30 Hz	100 Hz	YES

4.2.3 - ENSITEX MAPPING SYSTEM CONFIGURATION:

To use the Volta AF-Xplorer II with EnSite X Mapping system, ensure that a valid Live Export or Live Sync license provided by Abbott is available on the EnSite X DWS.

4.3 – Volta AF-Xplorer II system configuration

To perform system configuration that is not available through the Operator or Hospital Admin account, please contact a Volta Medical service representative.

CHAPTER V - USE OF VOLTA AF-XPLORER II

Integrity of each component of the Volta AF-Xplorer II system must be checked before any use of the device.
Particular attention shall be paid to acquisition systems connection and catheters integrity (not manufactured by Volta Medical).

5.1 - AUTHENTICATION

Three types of users can access Volta AF-Xplorer II:

- Operator (trained EP performing procedures or bio-medical Engineer/nurses assisting the physicians).
- Hospital Administrator (hospital staff performing some user accounts management operations).
- Service users (Volta Medical representatives that can access the back office of the application)

After having turned on Volta AF-Xplorer II, the user should authenticate using his/her personal login and password.
Depending on their profile they will have access to different menus:

- Operators have access to the main screen and settings.
- Hospital administrators have access to the "manage users" tab.
- Services can access all menus.

At first connection, login and password are identical but once the user is logged into the application, he will be asked to create a new password (between 12 and 50 characters).
Once login and password fields have been filled, click on login.
Do not disclose your credentials to anyone.

NOTE If a user failed to log in 10 times consecutively, he would have to wait 30 seconds before being able to log in again. If he failed 10 times again the timeout will be doubled.

5.2 - EP RECORDING SYSTEM SETTINGS

NOTE Initial system Configuration MUST be performed by a Volta Medical representative ONLY.

Before starting a new procedure, the operator shall perform several settings on the appropriate EP Recording system as described in the table below.

<table>
<tr><th></th><th colspan="2">CardioLab Acquisition System (General Electric)</th><th>LabSystem Pro Acquisition System (Boston Scientific)</th></tr>
<tr><th></th><th>Digital Mode</th><th>Analog Mode</th><th></th></tr>
<tr><td rowspan="2">Signal acquisition protocol selection</td><td colspan="2">If the procedure is not started:
- Open a new procedure,
- A pop-up window will automatically ask for the signal acquisition protocol.
If a procedure is already started: Go to Configure tab > Switch</td><td>Go to Amplifier tab > Load</td></tr>
<tr><td colspan="3">For both EP recording systems, select the appropriate protocol corresponding to:
- AF procedures
- 3D Mapping System
- multipolar catheter mapping
10 poles coronary sinus catheter.</td></tr>
<tr><td>Gains and filters verification</td><td>N/A</td><td>Once the study is launched, go to the Settings menu by clicking on the icon 
Go to the ECG tab > Equipment's setup
Note the ECG gain.
Go to the corresponding blocks where the mapping and CS catheters are configured> Equipment's setup.
Note the Mapping and CS gains.
The bipoles can be spread over several blocks.

Check that the information on Volta configuration page is correct.</td><td>Once the study is launched, go to Amplifier tab > Configure.

Go to the IC tab.
Note the Mapping and CS gains.

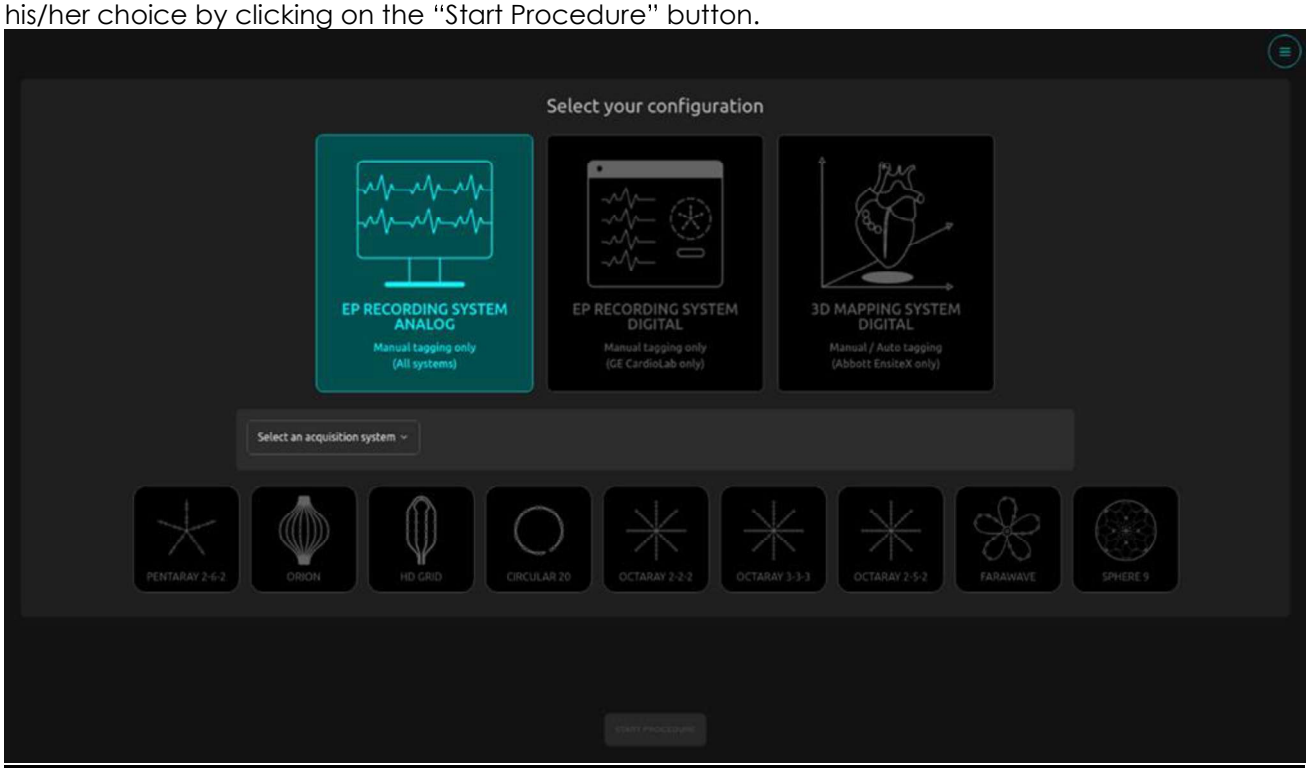
Go to the ECG tab.
Note the ECG gains.</td></tr>
<tr><td rowspan="2">Gains and filters values recommendations</td><td>N/A</td><td>Gains:
ECG: 2500
Mapping catheter: > 5000
CS catheter: 2500

Warning – Gains should not be modified during the procedure.</td><td><u>Voltage ranges:</u>
ECG: 5 mV
Mapping catheter: 1 mV
CS catheter: 2 mV</td></tr>
<tr><td>N/A</td><td colspan="2">Filters for both EP recording systems:
ECG:
- Highpass: 0,5 Hz
- Low pass: 50 Hz
Mapping:
- High pass: 30 Hz
- Low pass: 100 Hz
CS:
- High-pass: 30 Hz
- Low-pass: 100 Hz
Notch filter: YES (not applicable for digital)</td></tr>
</table>

5.3 – VOLTA AF-XPLORER II SETTINGS

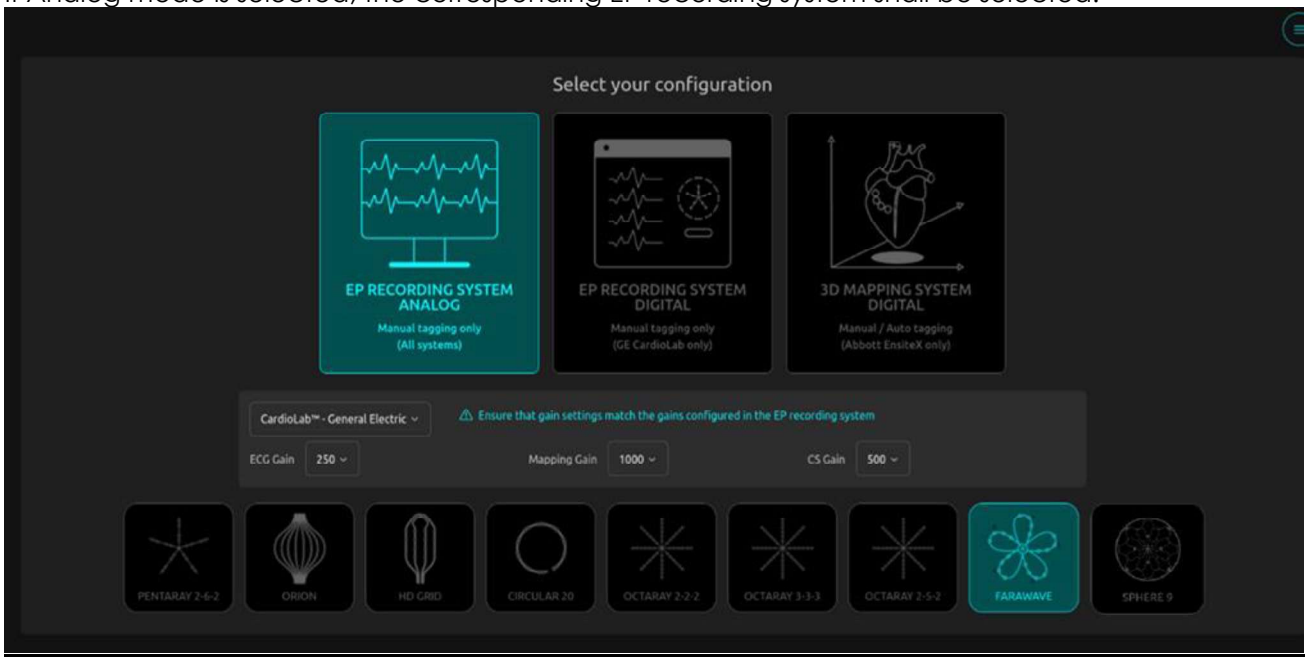
5.3.1 - SELECT CONFIGURATION MODE

To start a procedure, the operator shall select the relevant mode (analog or digital) and validate his/her choice by clicking on the "Start Procedure" button.



5.3.2 – ACQUISITION SYSTEM

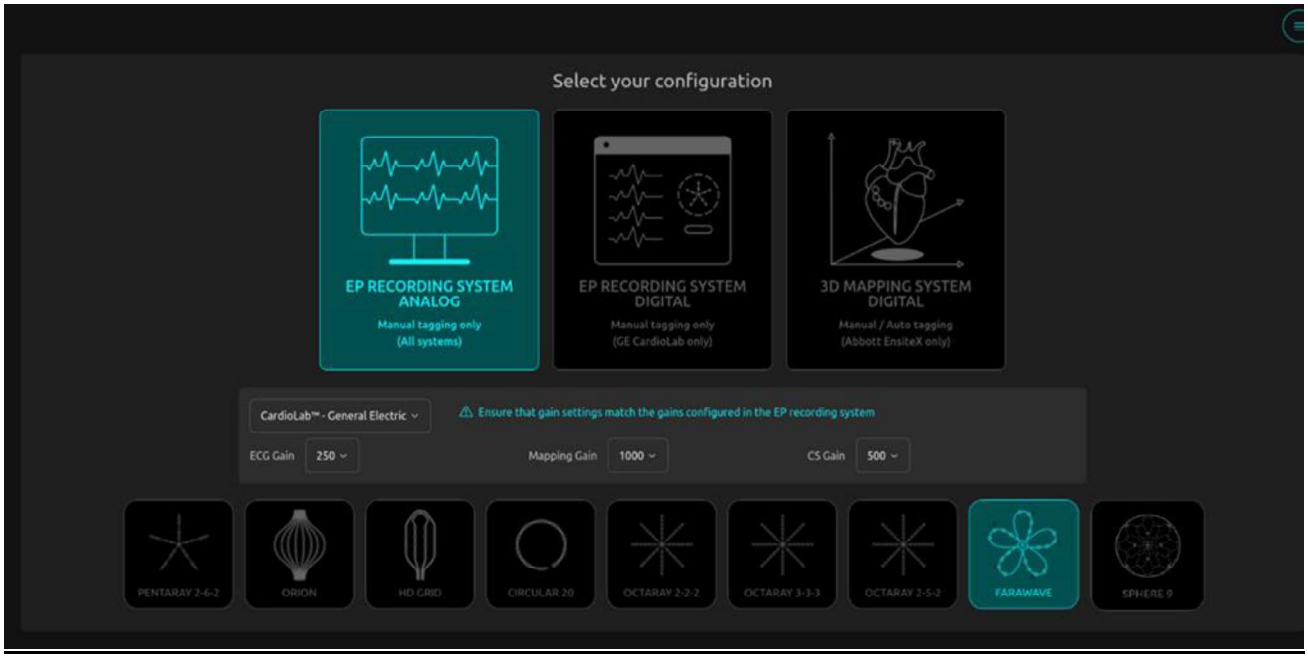
If Analog mode is selected, the corresponding EP recording system shall be selected.



NOTE In digital mode, the acquisition system does not need to be selected since Volta AF-Xplorer II can only be connected to Abbott EnSite X 3D mapping system or GE CardioLab acquisition system.

5.3.3 – MAPPING CATHETER

If Analog mode is selected, in the settings window, select the desired mapping catheter according to the procedure.

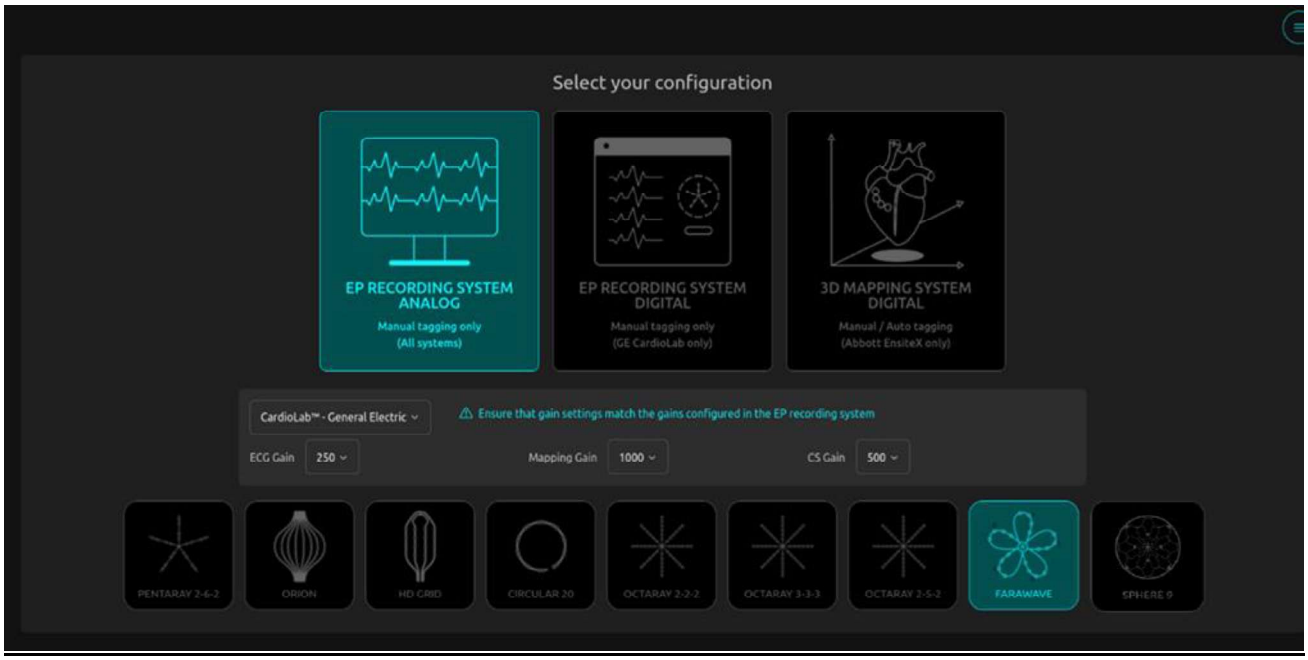


NOTE In digital mode, mapping catheter is automatically inferred on Volta AF-Xplorer II via Abbott EnSite X 3D mapping system or GE CardioLab acquisition system.

5.3.4 – GAINS CONFIGURATION AND PROCEDURE START

In analog mode, please configure the gain values as follows:

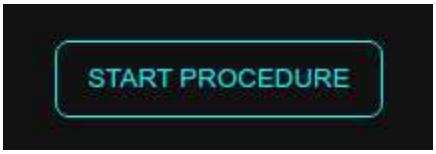
- If ECGs and IC signals come from the GE CardioLab™ or the Boston LabSystem Pro™, gain values in Volta AF-Xplorer II application must correspond to the ones registered in the corresponding EP Recording system.



Gains are editable at any time during the procedure. Especially, in CardioLab™ by increasing or decreasing the signal amplitude of catheter bipoles on the real-time display interface or by modifying the gain value in the amplifier configuration.
The new gain values must be reported in Volta AF-Xplorer II application.
Once modification is performed, click on save settings and then on apply changes.
If gains modification is performed during the procedure, the initialization step shall be performed again.

NOTE In digital mode, no gain settings are required.

Once settings steps are performed, the user shall click on start procedure.



In digital mode, the procedure should only be started once a compatible catheter is connected, configured and ready for the first mapping.

HD Wave configuration mapping catheter polarity shall be configured on Abbott Ensite X system before starting the procedure.

5.4 – SIGNALS VALIDATION

Click on the initialization button to start signal validation.

On the Electrograms page, check that all signals (ECG and IC tracks) are correct and correlated to those on the EP recording system.
If a mapping catheter electrode exhibits noise, we recommend replacing it to ensure accurate detection of spatio-temporal dispersion.

NOTE Amplitude and signal window duration can be modified to optimize signals visualization and comparison with the EP recording system.

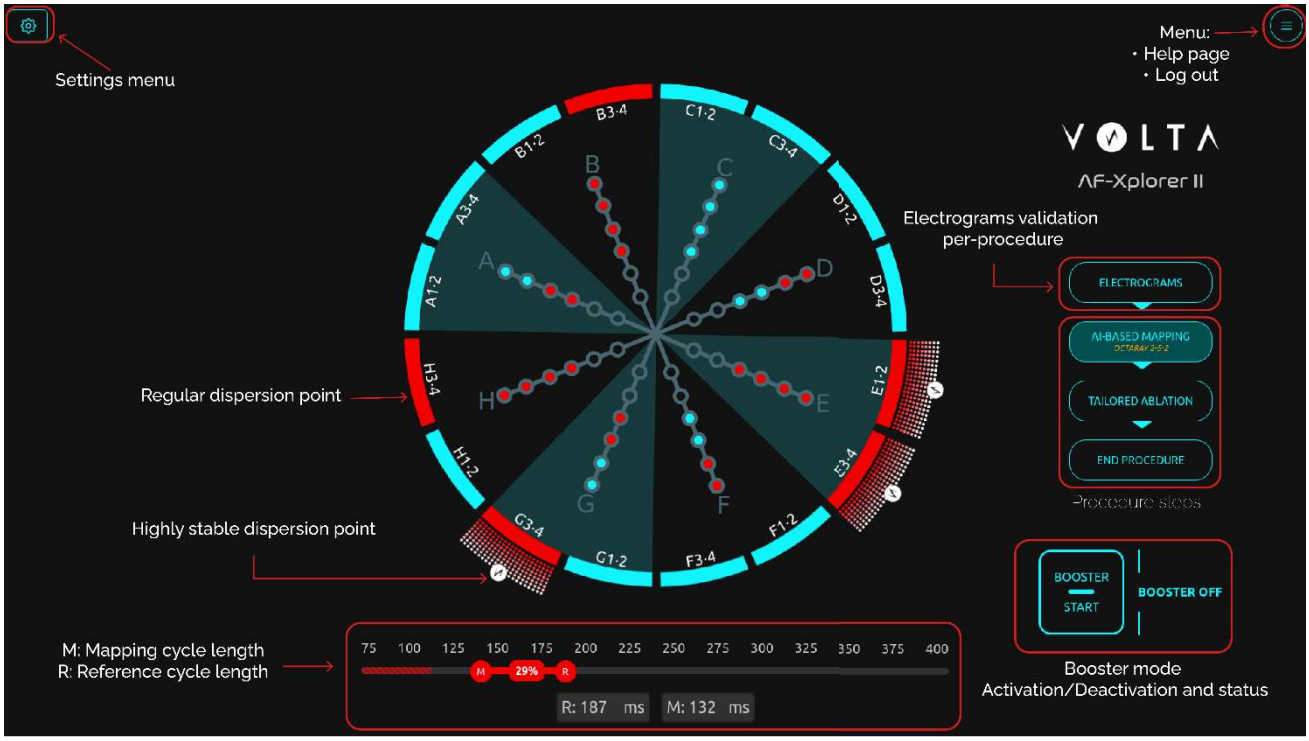
It is mandatory to wait 15 sec for Volta AF-Xplorer II to initialize. Once it is done, press validate to open the real-time user interface.

NOTE Signals page can be displayed at any time during procedure clicking on Electrograms button

5.5 – MAPPING PHASE

Click on the "AI-based mapping" button to create an accurate dispersion map.

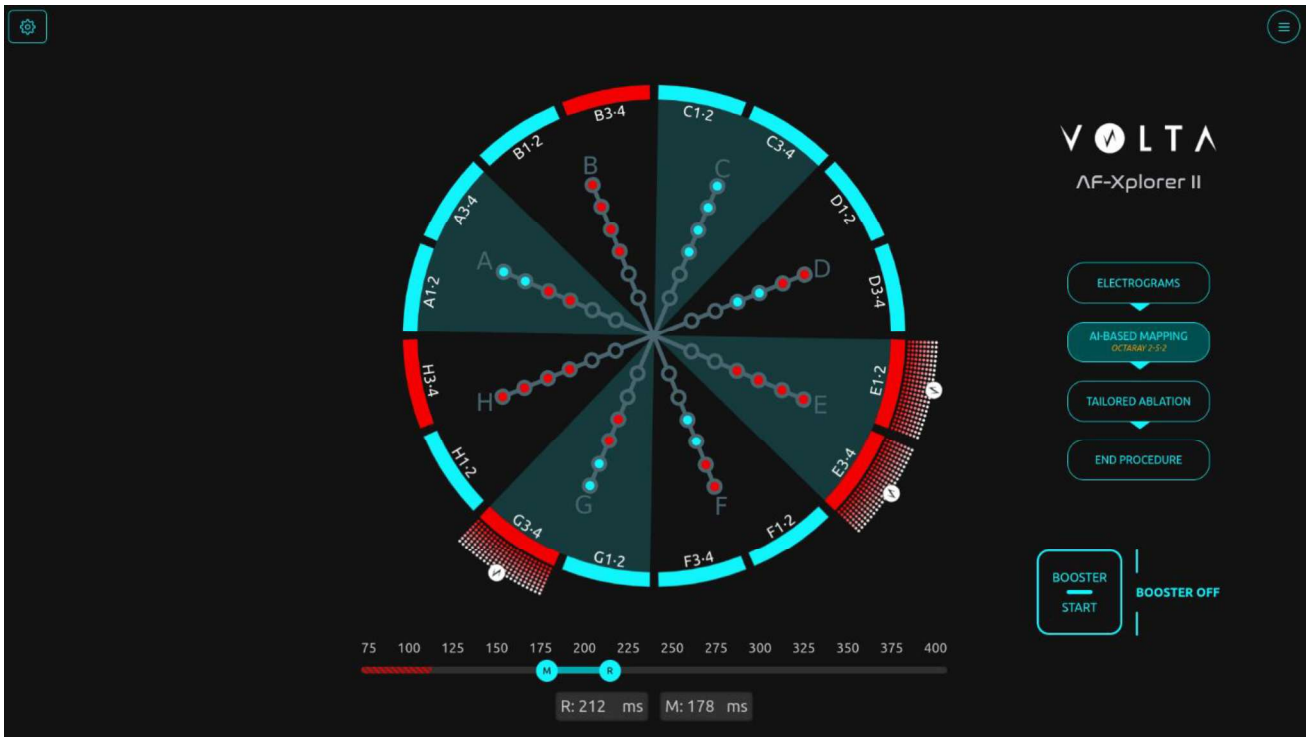
5.5.1 – EP RECORDING SYSTEM COMMUNICATION – MANUAL TAGGING



For each catheter, the software displays the electrodes of interest for dispersion mapping.
After clicking on the "Mapping" button, the mapping with Volta AF-Xplorer II proceeds as follows:

- While moving the catheter in the atria, the user regularly looks at the display.
- When the mapping catheter is in a non-dispersed area, the electrodes of the catheter on the Volta AF-Xplorer II display are colored in **blue**.
- When the catheter is in a dispersed area, the electrodes of interest turn **red** and a sound is emitted (double finger snap), so that the user knows he has to stabilize the catheter.
- If the electrodes of interest are confirmed by the software on the outer frame of the interface, the user **may manually tag the associated locations** using any 3D navigation system, regardless of its manufacturer.
- To go beyond the standard dispersion analysis, the system can provide an additional analysis to identify highly stable areas among EGMs classified as dispersed. This advanced analysis is based on the stability of dispersion in time and intensity for each bipole.
    - To do so, the mapping catheter should be stabilized over the area of interest for a minimum of 5 seconds (15s max)
    - If a bipole exhibits highly stable dispersion over the extended time period, a **gauge will appear and gradually fill up**. When a highly stable dispersion point is identified, an **indicator lights up in white at the top of the gauge.**
    - These highly stable points may then be tagged with a different color on the 3D Navigation system, to differentiate them from the standard points.

- These steps are repeated until the mapping is complete.



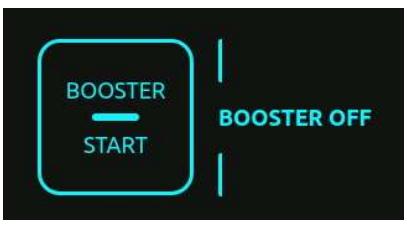
The operator should perform a complete mapping of both atria with a maximum point density. Also, the mapping catheter should be moved slowly, and the operator should ensure the mapper handling the 3D navigation system has localized the points on the map before moving the catheter.

The mapping catheter should be stabilized over the area of interest for a minimum of 3 seconds for an optimal analysis of the dispersion points displayed on the outer frame, and 5s to 15s maximum for the additional analysis of the highly stable dispersion points, before tagging the points on the 3D map. Special attention is recommended in areas that are difficult to map (left atrium ridge, left inter atrial septum, etc.)
The operator must apply good contact with the atrial tissue to avoid far-field signal acquisition.

At the end, the user may obtain intracardiac atrial maps with dispersion indications based on Volta AF-Xplorer II analysis and electrophysiologist validation.

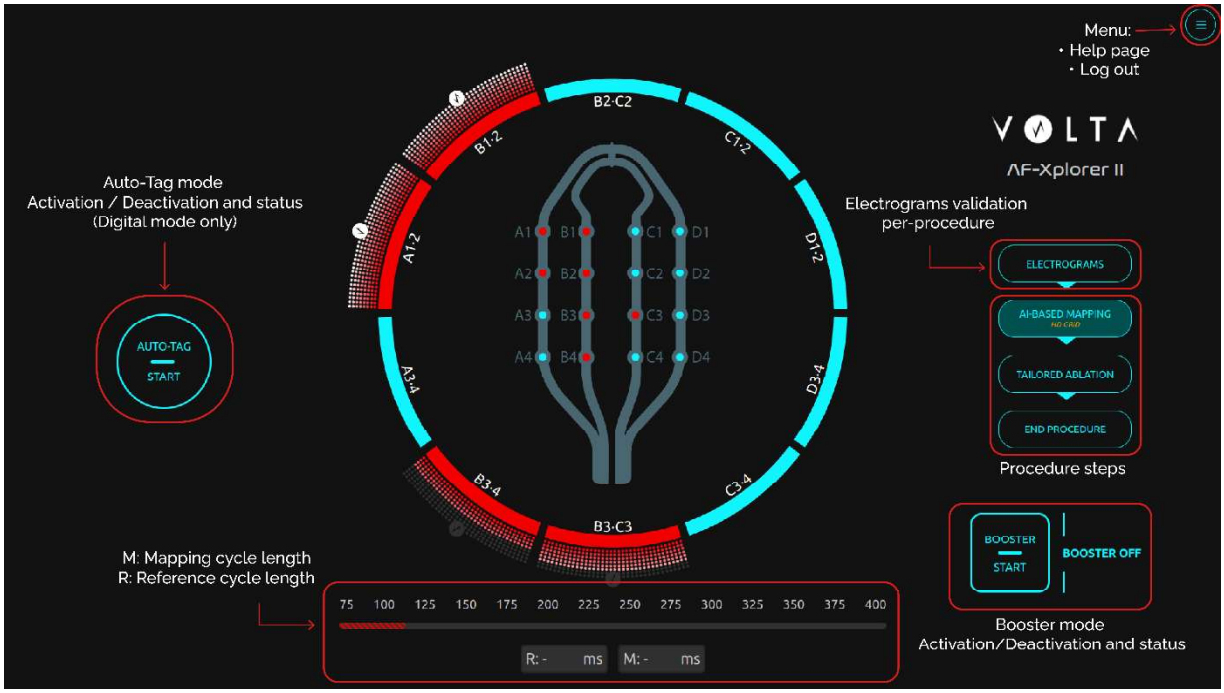
Note: To have a different appreciation of the distribution of intra-cardiac atrial dispersed electrograms during mapping, the Booster Mode may be activated to increase software sensitivity. The booster mode may be switched ON when mapping slow AF (CL > 230 ms) or AT. (see section 5.5.4 of this document).

On the main page, booster mode status is indicated as follows:



Users shall ensure that the catheter does not move due to the patient's residual breathing.

5.5.2 – 3D MAPPING SYSTEM COMMUNICATION – AUTO-TAGGING



Direct connection with a 3D Mapping System allows digital signal input, enabling both manual and automatic tagging of ROI. Currently this is an optional modality, and is only available with the Abbott Ensite X mapping system that has the LiveSync module activated.

Auto-tagging is deactivated by default. If the operator intends to perform mapping using auto-tagging, the button auto-tag start shall be pressed. A sound is emitted to confirm auto-tagging is activated.

The points leaving from the auto-tagging button correspond to the number of tags sent in real time to the Ensite X system and allow physicians to know when a tag has been sent.

If the mapping phase is performed manually, instructions provided in section 5.5.1 shall be followed.

For each catheter, the software displays the electrodes of interest for dispersion mapping. After clicking on "Mapping" button, the mapping with Volta AF-Xplorer II proceeds as follows:

- While moving the catheter in both atria, the user regularly looks at the display.

- When the mapping catheter is in a non-dispersed area, the electrodes of the catheter on the Volta AF-Xplorer II display are colored in **blue**.
- When the catheter is in a dispersed area, the electrodes of interest turn **red** and a sound is emitted (double finger snap), so that the user knows he has to stabilize its catheter.
- If the electrodes of interest are confirmed by the software on the outer frame of the interface:
    - A sound is emitted if previously all pads were blue.
    - Volta AF-Xplorer II application will automatically tag the associated locations on the 3D map visible on the Ensite X DWS if automatic tagging is activated.
    - To go beyond the standard dispersion analysis, Volta AF-Xplorer II can provide an additional analysis to identify highly stable areas among EGMs classified as dispersed. This advanced analysis is based on the stability of dispersion in time and intensity for each bipole.
        - To do so, the mapping catheter should be stabilized over the area of interest for a minimum of 5 seconds (15s max).
        - If a bipole exhibits highly stable dispersion over the extended time period, **a gauge will appear and gradually fill up**. When a highly stable dispersion point is identified, an indicator lights up in white at the top of the gauge.

- Tags are automatically sent with lesion label to Abbott Ensite X system: "*name of the bipole*" for dispersion points and "**H-***name of the bipole*" for highly stable dispersion points. These tags are automatically sent in lavender. The color can be changed to a different color on the Ensite X system depending on the user preference to better differentiate the two types of point.

These steps are repeated until mapping is complete.

The operator should perform a complete mapping of both atria with a maximum point density. Also, the mapping catheter should be moved slowly, and the operator should ensure the points have been correctly tagged on the map before moving the catheter.

The mapping catheter should be stabilized over the studied area for a minimum of 3 seconds for an optimal analysis of the dispersion points displayed on the outer frame, and 5s to 15s maximum for the additional analysis of the highly stable dispersion points, before the points are automatically tagged

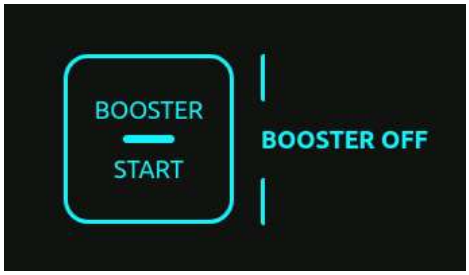
on the 3D map. Special attention is recommended in areas that are difficult to map (left atrium ridge, left inter atrial septum, etc.)

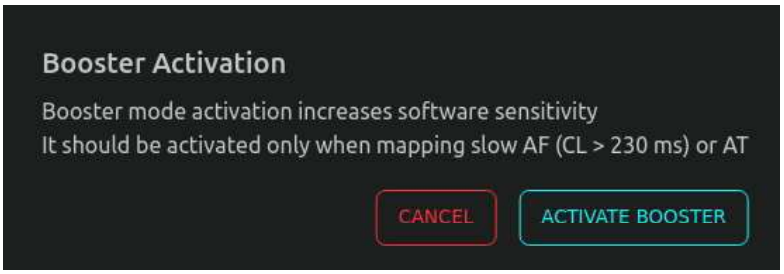
The operator must apply good contact with the atrial tissue to avoid far-field signal acquisition.

At the end, the user may obtain intracardiac atrial maps with dispersion indications based on Volta AF-Xplorer II analysis.
The electrophysiologist shall validate the dispersion map performed by Volta AF-Xplorer II application.

NOTE To have a different appreciation of the distribution of intra-cardiac atrial dispersed electrograms during mapping, the Booster Mode can be activated to increase software sensitivity. The booster mode may be switched ON when mapping slow AF (CL > 230 ms) or AT (see section 5.5.4 of this document).

On the main page, booster mode status is indicated as follows:





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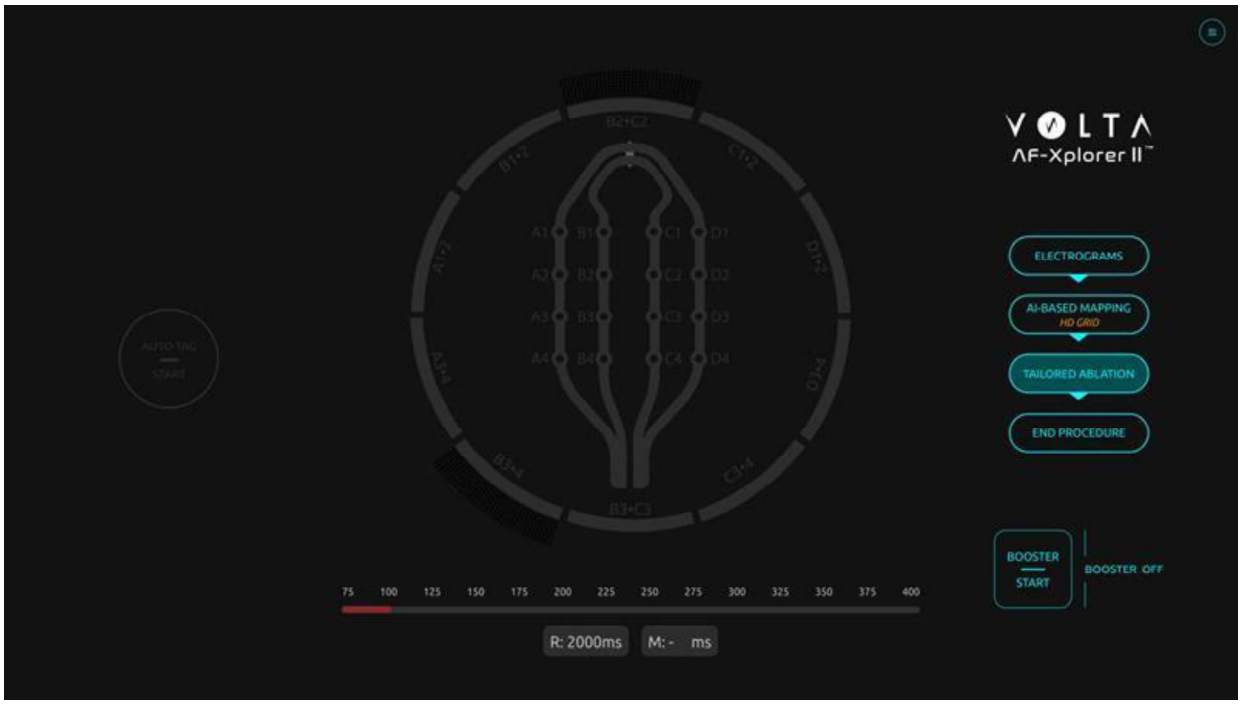
NOTE In digital mode, the maximum number of lesions recorded on the Abbott Ensite X system is 1024.

Users shall ensure that the catheter does not move due to the patient's residual breathing.

5.5.3 – ABLATION

During ablation, dispersion information is not displayed anymore, and intra-cardiac mapping cycle length (LCL) is deactivated.

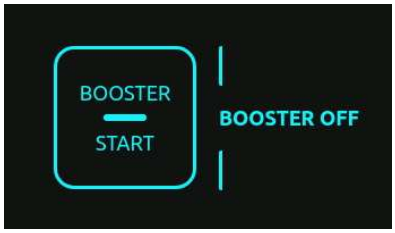
Ablation phase is performed independently from Volta AF-Xplorer II.

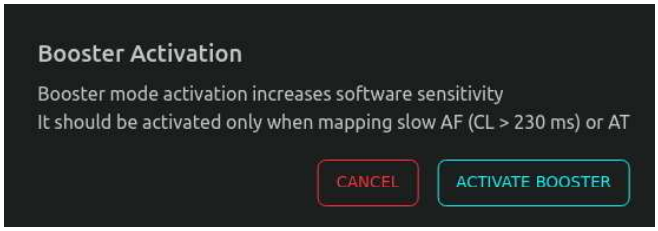


5.5.4 – REMAPPING AND ATRIAL TACHYCARDIA MAPPING

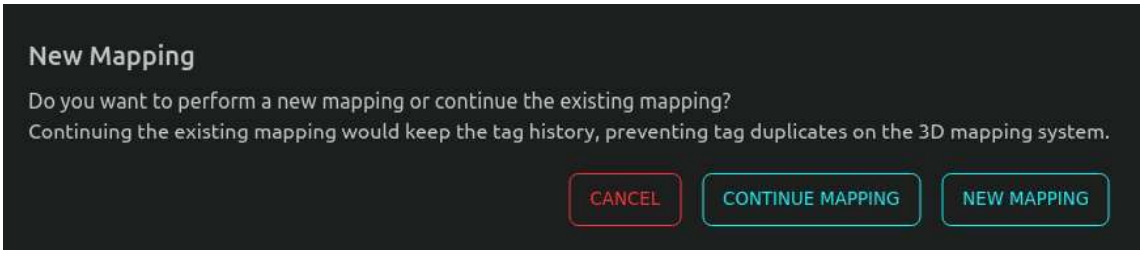
NOTE To have a different appreciation of the distribution of intra-cardiac atrial dispersed electrograms during mapping, the Booster Mode can be activated to increase software sensitivity. The booster mode may be switched ON when mapping slow AF (CL > 230 ms) or AT (see section 5.5.4 of this document).

On the main page, the booster mode is indicated as follow:





Specific case of digital mode: user can either select continue mapping (previous tags are taken into account) or select new mapping to start a new dispersion map (previous tags are ignored).



5.5.5 – END PROCEDURE

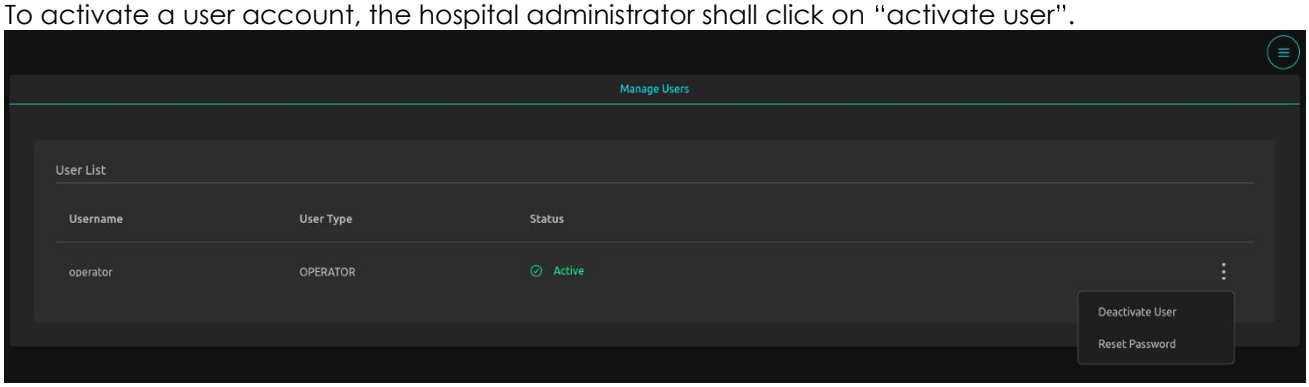
Once the patient's procedure is finished, please end the procedure, and select "logout" or "start a new procedure". Once logged out, the operator will be able to shut down the computer safely.
A validation message will be displayed to confirm the action.

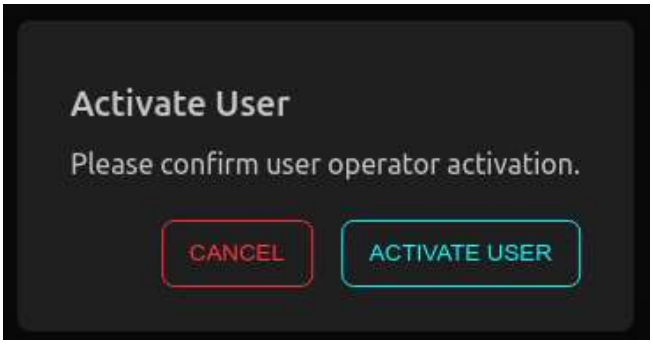
If the Volta AF-Xplorer II application is not closed, and the computer stays inactive for three hours **with a user logged in**, the user will be logged out and the authentication page will be displayed.

If the Volta AF-Xplorer II application is not closed and the computer stays inactive for three hours **without any user logged in**, the computer will automatically switch off. In that case, a warning message will be displayed five minutes before to indicate that the computer will shut down.

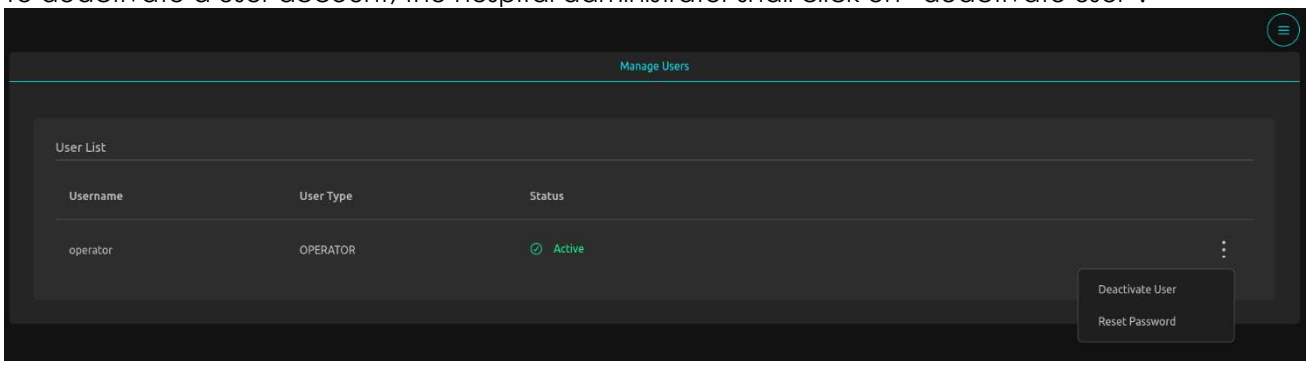
CHAPTER VI – HOSPITAL ADMINISTRATOR PERMISSIONS

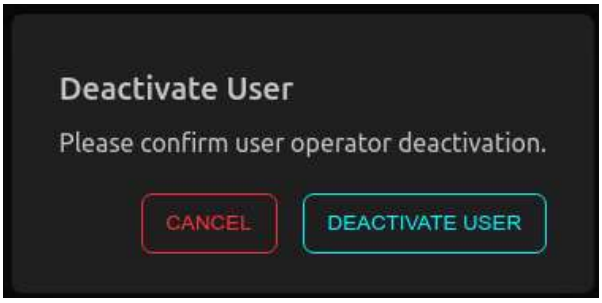
Hospital Administrator profile manages operator accounts (enable or disable account, reset operator password).
To activate a user account, the hospital administrator shall click on "activate user".



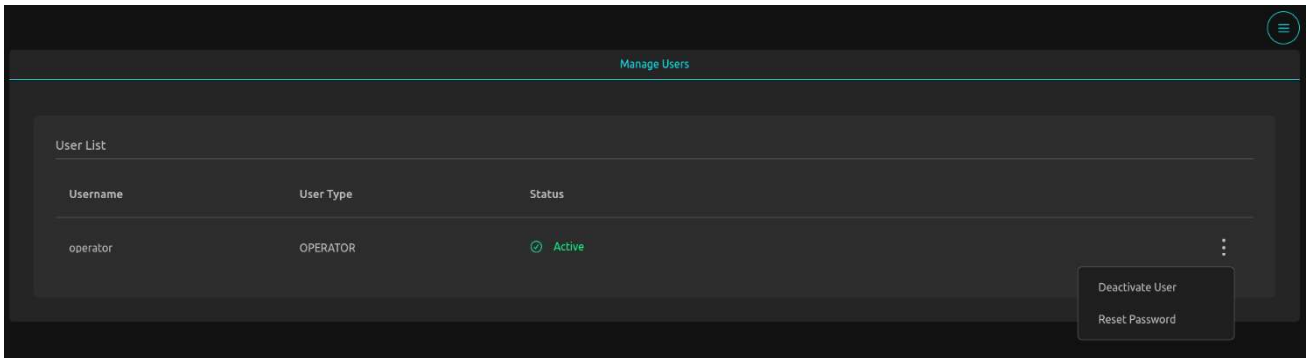


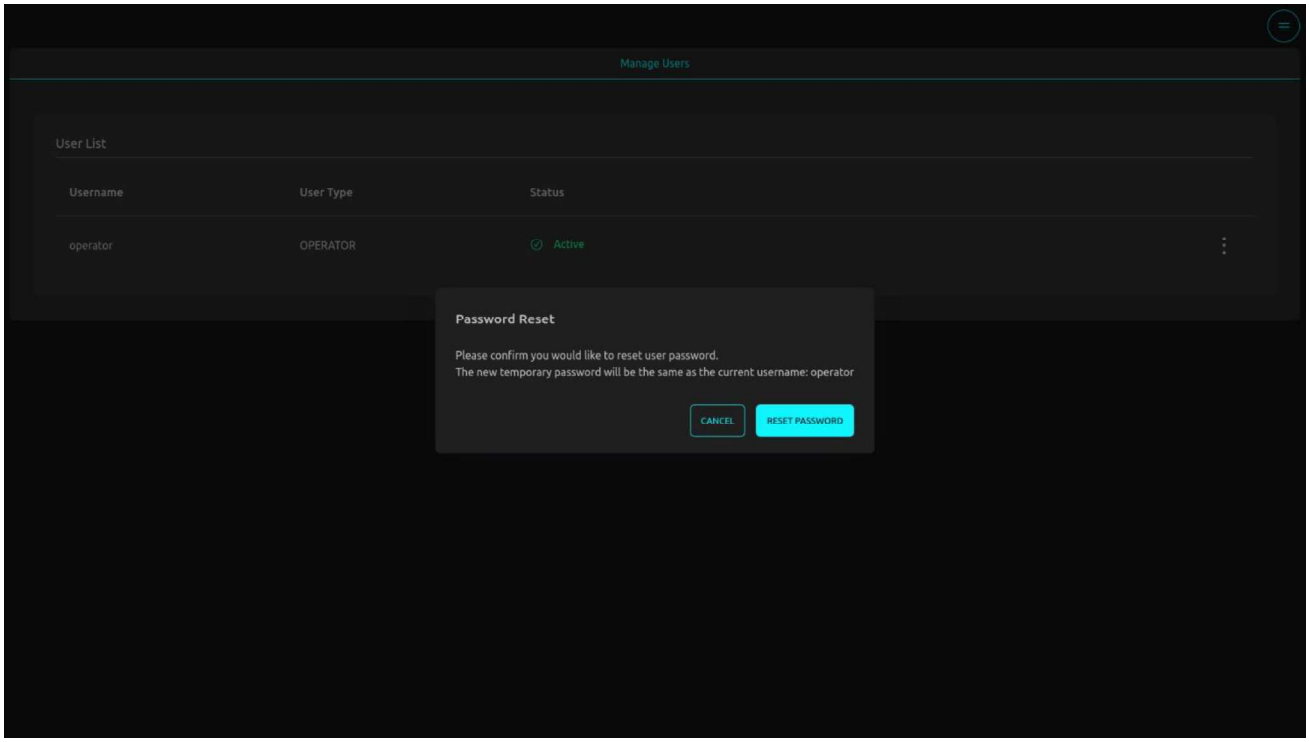
To deactivate a user account, the hospital administrator shall click on "deactivate user".



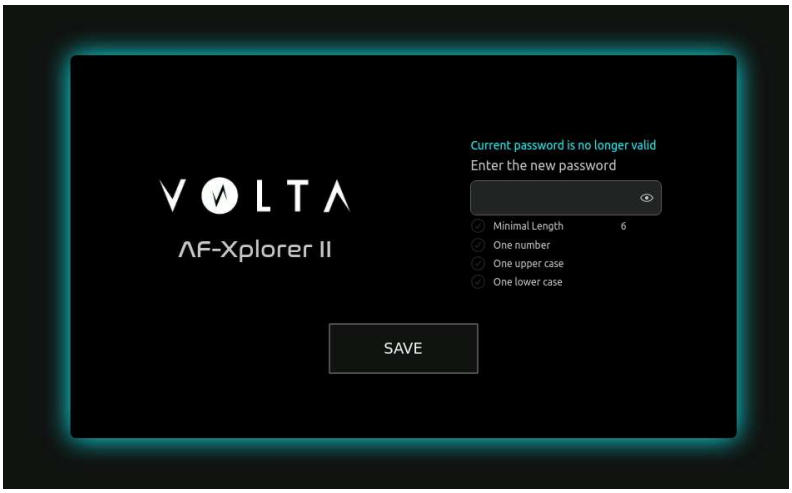


To reset a user password hospital administrator shall click on reset password.





When a user's password is reset, the password used to login is identical to his/her username . The user will then be asked to create a new password matching the password policy (between 12 and 50 characters) and click on "update password." The password policy is set by a service account at the installation of the machine and defines specific requirements such as minimum length, uppercase and lowercase letters, numbers, and symbols.



CHAPTER VII – TROUBLESHOOTING/RESIDUAL ANOMALIES

Identified issues categories:

- Display issue : black screen, freeze, resolution
- Sound
- Authentication
- Before or during a Digital procedure
- Before or during an Analog procedure

If this troubleshooting information do not solve your issue or for exceptional cases, please contact your Volta Medical service representative.

Display issue:

Issue	Actions
Screen	Connect the screen to the main Turn on the screen Check if HDMI is selected as input Test the power supply plug
Workstation	→ Workstation light off: workstation off and not powered → Workstation light red: workstation off but powered → Workstation light green: workstation on   Connect the workstation to the main Turn on the workstation Test the power supply plug
Display resolution issue	Please, refer to multiple displays connection in the installation and maintenance chapter.

Sound issue:

The sound comes from speakers of the screen or additional speakers. The computer does not have integrated speakers.
Make sure that the screen's speakers or additional speakers are on and that the sound level is not muted.

Authentication issue:

Created users (Operator and Hospital Admin) are listed in the 'Manage User' tab, displayed in the Hospital Admin session. Ensure that an account has been created and is active for the issued account.

In case of wrong password or login, make sure that the username and password are written correctly, paying attention to lowercase, uppercase (oO, iI, lL), special characters, numeric keypad lock according to the password requirements set by the service user. Keyboard layout used shall corresponds to configured system layout.

Passwords can be reset through the Hospital Admin account. Refer to section VI.

To create a new account, please contact your Volta Medical service representative.

Issue before or during a procedure in digital mode:

Note that the analog mode of the Volta AF-Xplorer II system is still available in case of issue with digital mode.

Error message or Issue	Action
Failed to connect to EnSiteX: certificate error – Contact Volta to update the certificate	The validity of the certificate is expired. Contact your Volta Medical service representative.
Failed to connect to CardioLab: certificate error - Contact Volta to update the certificate	
Digital Communication Error – Abbott Live Export License error. Please verify that the Live Export is correctly configured on the Abbott EnSite and retry.	The Volta AF-Xplorer II detects that the Live Export or Live Sync license on the EnSiteX is not configured properly. Contact your Abbott service representative.
Failed to connect to EnSiteX– Check that a study has correctly been started on the EnSiteX .	The study on Volta AF-Xplorer II must be launched after the start of the study on the EnSite X or CardioLab.
Failed to connect to CardioLab - Check if a study is running on CardioLab	
Failed to connect to EnSiteX – Check if the ethernet cable is connected properly to port 2 on Volta AF-Xplorer II system and to the data port on EnSite X.	Refer to installation chapter for connection details between Volta AF-Xplorer II and EnSite X/CardioLab. If the issue is persisting: - change the ethernet cable - restart Volta AF-Xplorer II system.
Failed to connect to CardioLab - Check if the ethernet cable is connected properly to port 1 on Volta AF-Xplorer II system and to the data port on CardioLab	
No CS catheter detected. Please, ensure that the CS catheter is connected and configured correctly on the EnSite X. Please also make sure that the CS catheter is labeled correctly.	Connect the CS catheter. Ensure that the CS catheter is named "CS" or "SC" on the EnSite X or that the correct catheter name has been set in CardioLab study configuration. Restart the procedure, and if the issue is persisting, restart the Volta AF-Xplorer II system.
No CS catheter detected. Please ensure that the CS catheter is connected and configured correctly on CardioLab. Please also make sure that the CS catheter is labeled correctly	
No compatible mapping catheter detected. Please ensure that a compatible mapping catheter listed in the user manual is connected.	Compatible catheters for Abbott digital procedure: HD GRID – REFLEXION HD Compatible catheters for GE digital procedure: All mapping catheters listed in section 3.9.2 Connect the compatible mapping catheter. If the issue is persisting, - disconnect the compatible mapping catheter and reconnect it - restart the Volta AF-Xplorer II computer
Digital communication error – Check if Ensite X is up and running and that the Volta system is connected to it. If the problem persists, please contact Volta.	It indicates a signal transmission break happened for more than 1 s. If the issue is persisting, restart the computer.
Digital communication error - Check if CardioLab is still up and running and a study is still running on it	

Failed to connect to EnSiteX: Unknown error - Check EnSite X is up and running and that the Volta system is connected to it. If the problem persists, please contact Volta.	Contact your Volta Medical service representative.
Digital communication error - Check if CardioLab is up and running and that the Volta system is connected to it. If the problem persists, please contact Volta	
CardioLab communication error - Configuration changes during a study are not possible.	Cardiolab study configuration shall not be changed once a procedure has been started on the Volta AF-Xplorer II system.
Digital communication error - Configuration has more than one mapping catheter	Open the CardioLab study configuration and check that only one mapping catheter has been selected for the mapping channels sent to Votla AF-Xplorer II system.
We detected that the system is not stable. This means the computer is slowing down or that there is latency in the signals. Please wait for the message to disappear. If the problem persists after a few seconds, please restart the computer.	- Wait for the error message to disappear - Restart the system if the error message persists
After an error message, software freeze on : 	Press the power button of the computer to turn it off. Press it again to turn it on. If the powering off does not work, disconnect the power supply during 5s and reconnect before turning on the system.
Volta AF-Xplorer II screen freeze	Bug in the live export feature due to which the signals are not received properly from the Ensite X If there are no errors raised on Volta AF-Xplorer II and yet the software seems to be unresponsive, the configuration should be verified, and the procedure should be restarted If the user is unable to still restart the procedure after verifying the configuration, the user should change to analog mode for the rest of the procedure

Issue before or during a procedure in analog mode:

Issue	Action
Signals are not consistent between the EP recording system signal page and the Volta AF-Xplorer II Electrograms page	Verify the EP recording system connection and configuration following the Installation and Maintenance Chapter. Verify that the parameters are correctly reported in the Volta AF-Xplorer II system settings page. Make sure that the cable is properly connected: - DSUB: o Source = EP recording system o Destination = Volta AF-Xplorer II - OCTOPUS:

	Pin numbers must correspond between the cable and the analog output box Refer to EP recording system user manual to ensure a correct connection of the device.
Noise on received signals	Verify the proper connection of the body surface ECG electrode to the patient. It is recommended to turn off the notch filters during the verification To reduce noise, use recommended filter settings. Keep all signal cables (ECG, catheter cables, tubing, ablation, etc.) as far away as possible from AC fields (3D mapping system components, monitors, isolation transformers, power supply, etc.).

CHAPTER VIII – CLEANING

Clean the device with a soft cloth and non-flammable and non-explosive agents only. Make sure that moisture is prevented from entering the device.

Do not clean the system components with disinfectants that contain surfactants.
Do not clean system components with bleach.
Do not apply cleaners while the system is warm to the touch.
Do not sterilize system components.
Do not immerse system components in liquid.

CHAPTER IX – STORAGE AND HANDLING

The electro-medical device cannot be used in an environment rich in oxygen or the in presence of inflammable components. Please refer to §2.1 for additional information.

Indoor use only.

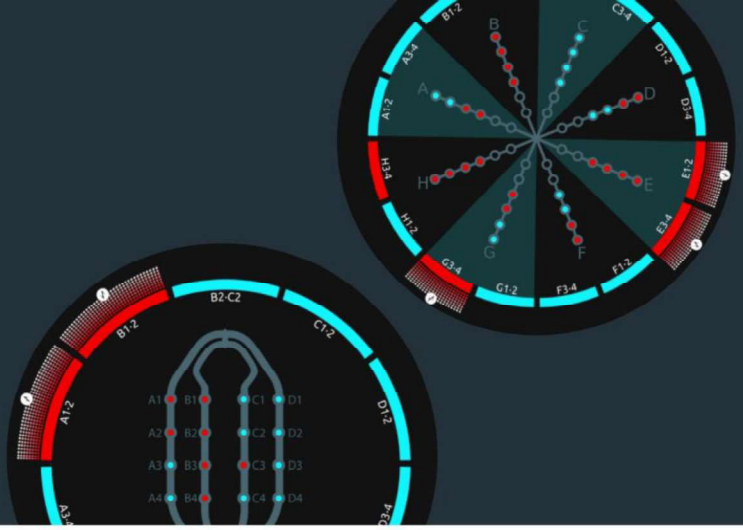
The converter is sensitive to electrostatic discharges.
Please avoid manipulating the converter if not necessary and especially during surgery.

CHAPTER X – MAINTENANCE AND MONITORING

If maintenance on the Volta AF-Xplorer II needs to be performed or the system replaced, the device is recovered by a Volta Medical representative, and if necessary, appropriately recycled (in accordance with the WEEE Directive 2012/19/EU).

Before reaching the end-of-life of the device, maintenance is scheduled by a Volta Medical representative to recover the device for appropriate recycling (in accordance with the WEEE Directive 2012/19/EU).

VOLTA MEDICAL



MANUFACTURER INFORMATION

PATENTS

Volta Medical has filed several patents in the field of computer assisted surgery. The product described here is based on some of these patents.

MODIFICATION

The information given in this document is subject to modification without notice. We have done our utmost to ensure the accuracy of the information given in this document.

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