

UNIVERSITAT DE BARCELONA

Final Degree Project

Biomedical Engineering Degree

**“ Validation and optimization of
omnipolar technology in ventricular
ablation procedures “**

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ABSTRACT

This project aims to improve the effectiveness of ventricular tachycardia (VT) ablation procedures by accurately mapping the reentrant channels responsible for the arrhythmia. The study compares different mapping techniques, including bipolar, orthogonal, and omnipolar signals, using the HD Grid catheter and the EnSite X system. Electro-Anatomical Maps (EAMs) created through these techniques are evaluated for their accuracy in identifying channels by comparing them with Cardiac Magnetic Resonance (CMR) maps. The project's findings demonstrate that the omnipolar map, optimized with specific thresholds, exhibits higher correlation with the CMR map, offering reliable and accurate information about the cardiac tissue. Moreover, the comparisons are done also between layers of the ventricle's heart, the layer 50 (which is an average of the pixels of layers 10-50) is identified as the most informative layer, and expanded maximum thresholds allow for a comprehensive understanding of ventricular tissue. The results validate the superiority of the omnipolar technology and emphasize the need for further research and collaboration to advance the field of VT ablation procedures.

Key words: Ablation, Arrhythmias, Bipolar, Border zone tissue, Cardiac Magnetic Resonance (CMR), Catheter, Channels, Core, Corridor, Electrical loop, Electro-Anatomical Maps (EAMs), Endocardium, EnSite X system, gadolinium, HD grid catheter, Healthy tissue, ILAMs (Islands of Late Activation Mapping)layers, LGE-CMR, mapping system, Omnipolar, Orthogonal, radiofrequency energy, reentry, Region of interest (ROI)Scar tissue, segmentation, Thresholds, Tissue characterization, Ventricular tachycardia (VT)

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GLOSSARY OF ABBREVIATIONS

ADAS	Automatic Detection of Arrhythmic Substrate
AV	Atrioventricular
BZ	Border Zone
CMR	Cardiac Magnetic Resonance
EAM	Electro-Anatomical Map
ECG	Electrocardiogram
HD	High-Definition
HD	High-Density
ILAM	Isochronal Late Activation Map
LGE-CMR	Late Gadolinium Enhancement Cardiac Magnetic Resonance
MRI	Magnetic Resonance Imaging
RF	Radiofrequency
ROI	Regions Of Interest
SA	Sinoatrial
SPSS	Statistical Package for the Social Sciences
VT	Ventricular Tachycardia

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INTRODUCTION

MOTIVATIONS AND AIM OF THE PROJECT

It goes without saying that the heart is one of the most important organs in the body, playing a vital role in delivering oxygen to all other organs in the body through the pumping of blood. Any heart malfunction like arrhythmias, can have severe health consequences. One such malfunction and type of arrhythmia is ventricular tachycardia (VT), an abnormal heart rhythm that occurs in the ventricles of the heart, usually the left ventricle.

A heart attack, for example, can cause the formation of scar tissue and a transitional tissue called the border zone (1). **These border zones can create channels or corridors, which generate an electrical loop that leads to sustained ventricular tachycardia (VT) (2).** To address this problem, a minimally invasive procedure known as ablation is used to burn the channels and stop the electrical loop that causes VT.

Ablation is a procedure that entails the use of a catheter to destroy small areas of heart tissue that are responsible for the abnormal rhythm (known as the border zones (BZ), channels or corridors) (3). To ensure that this is done effectively, it is crucial to identify these corridors that are responsible for the arrhythmia. However, this is a complex and challenging task that involves mapping the heart to determine the existence and location of these channels. The HD grid catheter is one of the existing catheters used in this study, to create the mapping. Depending on the filter and algorithm used, we can visualize the mapping in various ways, such as bipolar, orthogonal, or omnipolar. These concepts are further explained in Voltage mapping section, page 15. Although bipolar and orthogonal maps have been used for a long time, the recently emerged omnipolar map shows promising results in accurately mapping these channels.

Additionally, patients undergo a Cardiac Magnetic Resonance (CMR) to visualize the heart's anatomy and distinguish between tissue types using established thresholds (4). The CMR map and the EAM map (created with the catheter) are compared to thoroughly examine the channels.

The motivation for this project, then, relies on the importance of precisely mapping the heart and the channels created by this type of arrhythmia. This is essential to effectively ablate the cause of VT. Therefore, it is imperative to carefully **select the best algorithm for the catheter mapping and set the optimal thresholds for the CMR to accurately identify healthy, core (necrotic tissue), and border zone tissue, thereby defining the channels accurately.** By doing so, we aim to improve the effectiveness of the ablation procedure, reduce the risk of complications, and minimize the likelihood of recurrences for patients.

OBJECTIVES

The primary objective **is to validate the use of the omnipolar technology with HDGrid catheter and EnSite X system (a high-density mapping system) and optimize the thresholds** for tissue characterization during ablation procedures.

The secondary objectives are as follows:

- To analyze and compare CMR maps with EAMs (Electro-Anatomical Maps) created through bipolar, orthogonal, and omnipolar signals, to determine the most accurate and reliable mapping technique.
- To compare EAMs created through omnipolar signals with functional substrate such as Isochronal Late Activation Maps (ILAMs) and channels in CMR, to identify the most precise and accurate method for tissue characterization during ablation procedures.
- To identify new and better thresholds for tissue characterization.
- To compare all the above for the 5 first layers of segmentation of the endocardium.

By achieving these objectives, the project aims to provide valuable insights into the use of different catheter configurations and mapping techniques in ablation procedures for ventricular tachycardia. The findings of this study can potentially lead to the development of more effective and efficient ablation procedures and improve patient outcomes.

SCOPE AND LIMITATIONS

The scope of this project includes exporting EAM maps in Abbott (precision ablation technology) and comparing the different maps created by applying various filters and algorithms to the same HD grid catheter; these different configurations/algorithms will create a bipolar map, orthogonal or omnipolar map. Additionally, the study will evaluate the accuracy of these different catheter configurations by analyzing the CMR and EAM data and establishing new thresholds for tissue characterization through ADAS software's new features. Statistical analyses of the data, including the thresholds, will be performed to determine the optimal catheter configuration and thresholds for each corresponding catheter and each of the five layers of the endocardium segmentation. The study will examine each data set for each catheter configuration in-depth.

However, the project is subject to certain limitations. The slow speed of the software utilized, and the lack of time due to the TFG schedule may limit the amount of data that can be analyzed within the project timeline, potentially restricting the number of patients that can be included. As a result, the study's outcomes may not be generalizable to a larger population. The study also does not contemplate the creation and identification of the EAMs or ILAMS, either the EAM and CMR map fusion nor the details of the statistics development.

STRUCTURE AND METHODOLOGY

STRUCTURE OF THE TEAM AND THE WORK

ROLES

This project involves the help and work of Paz Garre (TFG tutor and biomedical engineer in Hospital Clínic), Sara Vázquez (Cardiologist in Hospital Clínic and director of the project), Roger Borràs (statistician in Hospital Clínic) and Lali Sarrias (author of the TFG and biomedical engineering student).

PATIENTS

This section presents the demographic and clinical characteristics of the 14 patients included in the study aimed at improving the effectiveness of ventricular tachycardia (VT) ablation procedures.

The study included a total of 14 patients, all of whom were male, accounting for 92.85% of the population. The patients' ages ranged from 65 to 78 years, with a mean age of 65.78 years and a standard deviation of 15. The average weight of the patients was 85.07 kg, with a standard deviation of 24.02. Moreover, the following baseline characteristics were assessed for the patients:

Baseline characteristics	Total population (n=14)
Male sex	92.85%
Age (years)	65,78±15
Weight	85,07±24,02
Hypertension	71.42%
Dyslipidemia	78.57%
Diabetes	28.57%
Smoker	14.28%
Ischemic cardiomyopathy	92.85%
DAI	100%

Table 1 Baseline characteristics of the patients studied

The patients included in the study exhibited a high prevalence of male sex, ischemic cardiomyopathy, and comorbidities such as hypertension, dyslipidemia, and diabetes, all of them possessed a DAI. These demographic and baseline characteristics provide important context for the evaluation of mapping techniques and their correlation with cardiac magnetic resonance (CMR) maps in the subsequent analysis.

METHODOLOGY

The following steps were followed for the accomplishment of the project:

- **Identification** of the patient's maps that we will be working on: Dra. Sara Vázquez will be responsible for this part of the project, as she will review each case and identify the ILAMs. This does not fall into the scope of the project.
- **Export EAM maps in Abbott:** exporting the EAM maps from Abbott (precision ablation technology) to analyze the data further.
- **Importing maps in ADAS:** importing the EAM maps into ADAS software.
- **CMR and EAM Fusion:** fusing the CMR with the EAM maps in ADAS software to create detailed and accurate maps. The fusion process helps to identify the location and

characteristics of the reentrant channels and differentiate between healthy, border zone, and core tissue.

- **Data Collection:** collecting data from the study patients using SPSS software. Data collection includes:
 - Date of ablation procedure
 - Total area CMR in grams
 - Invalid area in grams: noise area
 - Border zone area in grams
 - Scar (core area) in grams
 - Number of channels and their length and mass (mm and grams)
 - Minimum optimized threshold in mV
 - Maximum optimized threshold in mV
 - Total correlation for normal thresholds (0,5- 1,5 mV)
 - Total correlation for new thresholds
 - Number of ILAMS in each map
 - Nearest channel in each ILAM
 - Minimum distance from nearest channel to ILAM (mm)

For each variable, measurements were taken for the bipolar, orthogonal or HDW, and omnipolar catheters across all layers, including 10%, 20%, 30%, and the endocardium layer (layer 50) (which represents the median of pixels of the layers from 10% to 50%).

- **Statistical Analysis:** to identify the differences between maps and the layers and determine new thresholds for tissue characterization.
 - Find the correlation between EAM maps (bipolar, orthogonal/HD wave, omnipolar) and CMR maps. To determine the best map configuration. Using *Imer* and *emmeans* functions of the *CorrelatTotal* variable
 - Find the correlation between EAM maps (bipolar, orthogonal/HD wave, omnipolar) and their layers (10, 20, 30, 50) with CMR maps. To determine the best layer to look for when calculating the channels. Using *Imer* and *emmeans* functions of the *CorrelatTotal* variable
 - Find the mean of the minimum and maximum threshold for each layer for each map. Using *Imer* and *emmeans* functions of the *ThresholdMin* and *ThresholdMax* variable.
 - Find the mean minimum distance to the nearest channel for the ILAMs for each map (not layers). Using *Imer* and *emmeans* functions of the *Distancia_Channel* variable.
- **Discussion:** discussing the findings of the project to be able to take out conclusions

BACKGROUND

GENERAL CONCEPTS

ELECTRICAL SYSTEM OF THE HEART

The heart is a complex organ that is responsible for pumping blood throughout the body. It has an electrical system that controls its rhythmic contractions, which are necessary to maintain normal cardiac function. The electrical signals originate in the sinoatrial (SA) node and are propagated through the atria, leading to atrial contraction. The signals then pass through the atrioventricular (AV) node and into the ventricles, resulting in ventricular contraction. Thanks to these contractions, the blood is driven into the aorta and to the rest of the body (5).

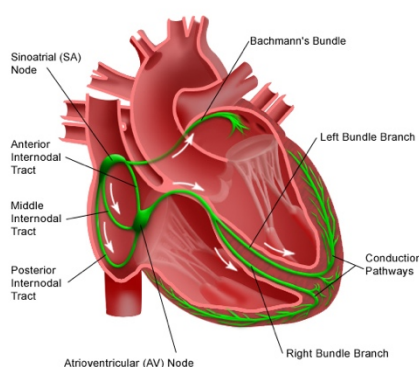


Figure 1 Anatomy of the heart and its electrical system

VENTRICULAR TACHYCARDIA

Ventricular tachycardia (VT) is a type of arrhythmia in which the heart's electrical system malfunctions, causing the ventricles to contract too quickly and inefficiently. This can lead to a lack of oxygen in the body, which can cause fainting, dizziness, or even death. **VT can be caused by a variety of factors, including ischemic heart disease, heart failure, and valvular heart disease (6).**

The mechanisms of VT are complex and multifactorial. One possible mechanism, and the focus of this project, is **reentry, which occurs when fibrotic tissue develops within the ventricle, primarily resulting from heart attacks but also associated with heart disease and other conditions that contribute to the formation of fibrosis and the emergence of zones with delayed conduction pathways, leading to repetitive firing of the ventricles, then an abnormal irregular heartbeat is created leading to VT.** Another possible mechanism is automaticity, which occurs when abnormal cells in the heart's electrical system start firing spontaneously, leading to an irregular heartbeat (7).

In this project we will focus specially on the reentry mechanism which is caused by the channels that are wanted to be ablated.

ABLATION

Ablation is a medical procedure used to treat arrhythmias such as ventricular tachycardia. It involves the use of a catheter to deliver radiofrequency energy to specific areas of the heart tissue that are responsible for causing the arrhythmia, the channels. The goal of ablation is to create scar tissue in the heart that blocks the abnormal electrical signals, restoring normal heart rhythm. In general terms, the channel needs to be ablated (8).

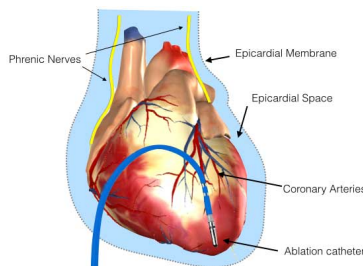


Figure 2 Scheme of catheter doing ablation in left ventricle

The procedure is usually performed in a hospital cardiac catheterization laboratory by a cardiac electrophysiologist, a specialist in the diagnosis and treatment of heart rhythm disorders. Here are the general steps involved in the ablation procedure (9):

- **Pre-procedure evaluation:** Before the procedure, the patient undergoes a comprehensive evaluation, including a physical examination, Cardiac Magnetic Resonance (CMR), electrocardiogram (ECG), echocardiogram, and other tests to determine the underlying cause and location of the ventricular tachycardia. This information is used to plan the ablation procedure.
- **Preparation:** The patient is given sedation and local anesthesia to numb the groin or arm area where the catheter is inserted.
- **Catheter insertion:** The catheter is inserted through a small incision in the groin or arm and guided into the heart under X-ray guidance. Once the catheter is in place, the electrophysiologist uses a mapping system to create a detailed 3D map of the heart's electrical system.
- **Energy delivery:** The electrophysiologist uses the mapping information to identify the specific area or areas of the heart responsible for the ventricular tachycardia, the reentrant channels. Energy is then delivered through the catheter tip to destroy or modify the tissue causing the abnormal electrical signals.

MAPPING SYSTEM AND CATHETERS

LGE-CMR

Before starting the procedure, the physician will want to have as much information as possible in order to know where the channels are to ablate them. That is why it is crucial to differentiate them first from healthy and scar (necrotic) tissue. Different techniques are used but if there is the opportunity, the patient will have a Late Gadolinium Enhancement Cardiac Magnetic Resonance (LGE-CMR) to do so (10).

LGE-CMR is a non-invasive imaging technique that can be used to detect areas of scar tissue in the heart. The technique involves injecting a contrast agent containing gadolinium into the patient's bloodstream, which enhances the contrast between the blood pool and the heart muscle tissue. The patient is then placed inside a magnetic resonance imaging (MRI) machine that produces a strong magnetic field and radio waves to capture images of the heart. Then the contrast agent is injected, it accumulates in areas where the blood flow is slow or blocked, such as areas of damaged or scarred heart muscle tissue. This causes delayed enhancement in those areas, which can be visualized on the MRI scan as bright white areas (because gadolinium is white). The presence and extent of delayed enhancement can indicate the location, size, and severity of myocardial damage or disease (11).

In other words, the bright or white areas on the LGE-CMR image indicate damaged or scarred heart muscle tissue, while the black areas indicate healthy tissue. The grey border zone tissue represents the transition area between healthy and damaged tissue, targeted for ablation.

The analysis of the tissues is done with ADAS software which applies visualization thresholds to the pixel intensity (IIR) in LGE-CMR images to identify healthy tissue, border zones, and scar tissue based on the percentage of black pixels in each area. The percentages represent the black pixel percentage in each myocardial area where **healthy tissue is identified by pixels with signal intensity between 0-40% white, border zones by 40-60% white, and scar tissue by 60-100% black signal intensity. So, the whiter, the more scarring.** Before identifying the type of tissue with these percentages, the image must be segmented in order to take only the ROIs.

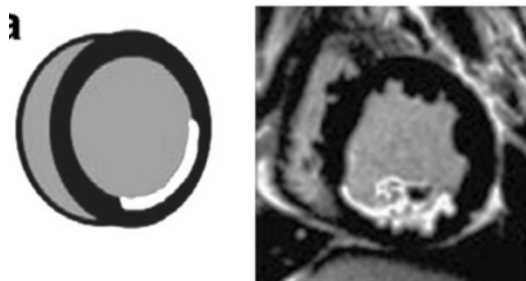


Figure 3 Example of an LGE-CMR where the scar tissue can be seen clearly as the white part

SEGMENTATION

Segmentation involves extracting a region of interest (ROI) to visualize the cardiac structure in three dimensions. This process enables a detailed examination of the chambers, valves, and other anatomical components of the heart. Once the ROI is extracted, specific thresholds can be applied to assess fibrosis within these chambers.

In this study, segmentation involves dividing the heart or ventricle of interest into layers because the thickness of the heart walls varies from the endocardium to the epicardium and so the results and analysis depends on the depth of the wall we are looking at. By segmenting the layers, it becomes possible to differentiate the channels and determine their position and tissue

characterization. In ADAS, the software used for this purpose, segmentation is done in 10% increments ranging from 10% to 90%.

During the ablation procedure, the catheter is moved inside the heart, and it becomes more sensitive, detecting the first layers more accurately. Therefore, **the layers that are studied are the 10% layer, 20%, 30%, and 50**. Note that it is not layer 50% but 50. That is because in this study, the layer 50% is not studied. It is studied the median of the pixels of the five first layers (10%-50%), that is essentially the median of the endocardium. The image below shows an example of this segmentation (18).

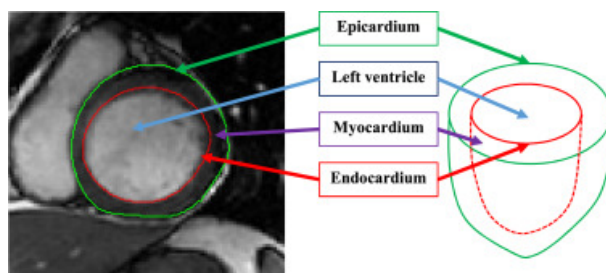


Figure 4 Scheme of left ventricle segmentation into different layers to separate the wall from the endocardium to the epicardium

To have a better understanding of the evolution of the images and their analysis, here are the different steps taken to go from the raw CMR image to the 3D model.

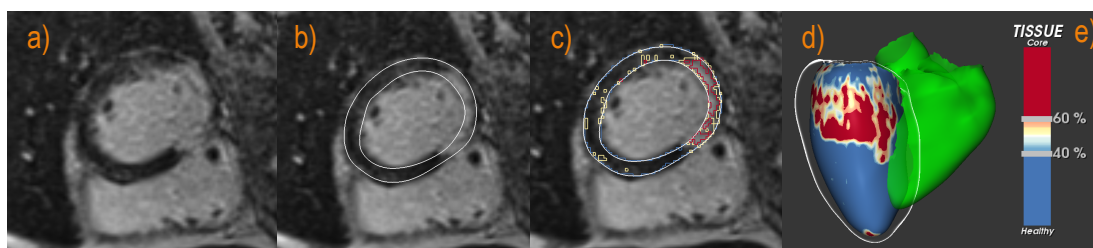


Figure 5 Steps from LGE-CMR raw image to 3D model using ADAS

The first image (a) shows the raw CMR with black and white parts (gadolinium “taking action”), the second image (b) shows the segmentation where it can be distinguished the endocardium (inner circle line) and epicardium (outer circle line). The third image (c) shows the ADAS analyzing each pixel and marking the healthy tissue (black) in blue, the dead tissue (white) in red and the border zone tissue (grey) in the colors in between red and blue seen in the fifth image (e), which is the thresholds that ADAS uses (0-40% healthy-blue, 40-60% border zone-colors, 60-100% dead tissue-red). Lastly, the fourth image (d) shows the 3D model that is made thanks to the LGE-CMR image and the ADAS segmentation and analysis.

MAPPING WITH HD GRID CATHETER

The procedures of mapping and ablation are done using catheters. A catheter is a long, thin, flexible tube that is inserted through a vein or artery in the groin or neck and advanced up to the heart. The catheter has one or more small electrodes at its tip that can measure the electrical signals produced by the heart.

One of the catheters, and the one used in this study, is the HDGrid catheter; a type of catheter used to create a detailed map of the electrical activity in the heart. It differs from other catheters because it has a net of electrodes that can provide more accurate and detailed information about the heart's electrical activity (12) (13).

VOLTAGE MAPPING

When the catheter is placed inside the heart, the electrodes come into contact with the heart tissue, and the electrical signals generated by the heart are transmitted to the catheter. These electrical signals can be measured and recorded by the electrodes, allowing physicians to create a map of the heart's electrical activity. **The mapping catheter is moved through the heart to perform a voltage map, which identifies areas with high voltage as healthy tissue or low voltage as dead tissue.**

This map is anatomical in nature and is **based on the amplitude of the signal, where values above 1.5 mV are considered healthy and values below 0.5mV are considered dead.** The catheter's electrodes are also used to deliver energy to the heart tissue, creating small scars or lesions that disrupt the abnormal electrical signals. This process is called ablation and can restore normal heart rhythm and eliminate the symptoms associated with arrhythmias.

In the case of the HD Grid, it can be programmed with different algorithms to provide different types of voltage maps: bipolar, orthogonal or omnipolar.

- The bipolar map algorithm uses the two electrodes located at either end of the catheter shaft to measure the electrical activity between these two points. This map shows the voltage and signals measured in only **one direction**.
- The orthogonal map algorithm uses multiple electrodes located along the catheter shaft, which allows for more accurate and detailed mapping of the heart's electrical activity. The electrodes are positioned perpendicular to the catheter shaft, which enables mapping of the electrical activity in **multiple directions**.
- The omnipolar map algorithm uses multiple electrodes that are positioned in a spherical array at the tip of the catheter. This design allows for simultaneous mapping of the electrical activity in **all directions** and provides a more comprehensive and detailed map of the heart's electrical activity.

That is why the principal hypotheses stated in this project that the omnipolar catheter is better than the other catheters is because it provides a more detailed and accurate voltage and activation map. However, the choice of catheter and algorithm will depend on the specific needs of each patient and the expertise of the electrophysiologist performing the procedure (14) (15).

The image below shows an example of voltage map with its colors scale from one of the patients studied. The scale shows the thresholds mentioned: above 1,5 mV healthy tissue (purple), below 0,5 mV dead tissue (grey) and in between different colors (16). The colors then are represented in the ventricle map where it can be seen little yellow points, which are the voltage points, the points where we have taken the voltage information. And the different color zones.

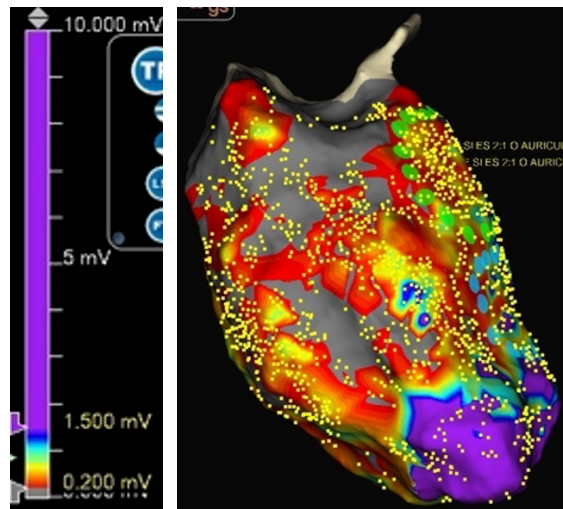


Figure 6 Voltage map using Ensite X and the mV threshold color scale

ACTIVATION MAPPING

Another method to identify regions of interest (ROIs) is the activation map, which will identify the electrical signals in the heart. Pathological signals are characterized by their irregular, long, and rare nature. Usually, these pathological signals will follow and coincide with a channel. Unlike the voltage map, the signal map requires the signals to be marked one by one and are like colored points on the map and not a map itself. That is why the Isochronal Late Activation Map (ILAM) was created.

It is a mapping technique that uses different colored points on the map that are based on the time it takes for electrical signals to travel through the heart tissue. However, the speed of the signal is neither good nor bad; rather, it is the presence of multiple colors in the same area that is significant. If there are three or more colors within an area of less than 1 cm^2 , it indicates a deceleration zone, which is an area where the electrical signals slow down. These colors, unlike the voltage map, aren't based on a mV threshold but a time thresholds (in milliseconds) since it measures the time, the acceleration and not the voltage. This information is particularly useful because it helps identify regions of the heart that may be contributing to abnormal heart rhythms, even if they do not have an obvious structural abnormality. ILAM is **currently a popular mapping technique because it focuses more on the heart's functionality rather than its anatomy** (17).

The image below shows a voltage map of the left ventricle with colored points, the ILAMs. There is a clear deceleration zone (3 colors in less of a 1 cm^2) marked with the circle of blue points. The channel most likely will fall inside this circle. Also, it can be seen the color scale in ms.

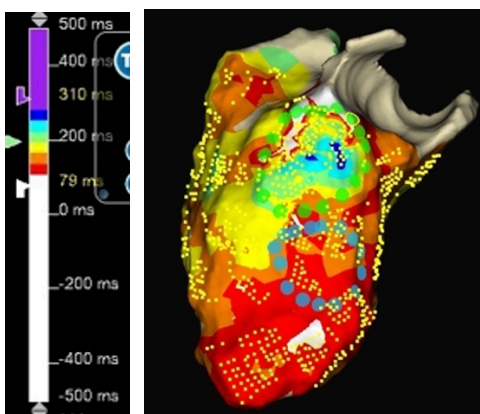


Figure 7 Activation map with ILAMs and the time threshold color scale

STATE OF THE ART

The history of catheters for ventricular tachycardia (VT) ablation has been marked by significant technological advancements that have improved safety, efficacy, and accuracy of the procedure. The first catheter-based RF ablation for VT was performed in the early 1980s using a single electrode catheter to deliver RF energy to the endocardial surface of the ventricles. Over the next few decades, significant progress was made in catheter technology and ablation techniques, including the introduction of three-dimensional (3D) mapping systems in the 1990s. This development enabled more precise localization of the VT substrate by creating a 3D model of the heart that could guide the ablation catheter to the exact location of the VT substrate (19).

In the early 2000s, magnetic navigation systems were introduced, allowing for real-time 3D visualization of the catheter and its location within the heart. This technology enabled the operator to navigate through complex anatomical structures with greater precision (20).

Around the same time, the use of cardiac magnetic resonance imaging (MRI) and late gadolinium-enhanced cardiac MRI (LGE-CMR) for VT substrate mapping emerged. LGE-CMR allowed for the identification of areas of scar tissue in the heart that could be targeted during the ablation procedure (21).

In recent years, there has been a shift towards the use of multi-electrode catheters and more advanced mapping systems to improve the accuracy of VT substrate mapping and increase the success rates of the procedure. These new mapping systems provide real-time feedback on the location and characteristics of the VT substrate, allowing the operator to adjust the ablation strategy as needed (22). HD grid catheter made by Abbott, Penta catheter made by Carto, and Orion catheter made by Boston Scientific are examples of catheters with variable electrodes and distribution.

In the past, the same thresholds for tissue characterization have been used in ventricular tachycardia (VT) ablation procedures because they were developed based on studies using bipolar catheters. However, with the introduction of new catheters such as the HD grid omnipolar, there is a need to recalculate the thresholds for these new technologies. The thresholds for tissue

characterization in VT ablation procedures typically rely on late gadolinium-enhanced cardiac magnetic resonance imaging (LGE-CMR) to identify areas of healthy tissue, border zone tissue, and dead tissue. The thresholds to identify the tissues in the LGE-CMR images are: Healthy tissue 0-40%, border zone tissue is 40-60%, and dead tissue is 60-100%. In addition to LGE-CMR, voltage thresholds are also used to determine the health of the tissue. Voltage thresholds typically consider values above 1.5mV as healthy tissue and values below 0.5mV as dead tissue (23).

STATE OF THE SITUATION

Now that the HD Grid by Abbott exists and l'Hospital Clínic has this partnership with Abbott, we aim to be pioneers in studying the differences between maps (bipolar, orthogonal and omnipolar) that the HD Grid is able to do and also in computing the best new thresholds for tissue recognition. Our study is being conducted at the Arrhythmias Unit in Hospital Clínic, where they treat approximately 50 VT ablation patients per year. Each patient undergoes an LGE-CMR for mapping and analysis of channels before ablation.

The catheter used in this study is the **HDGrid catheter from Abbott**, which is an omnipolar catheter that can be modified to function as either a bipolar or orthogonal catheter for the purposes of comparison. **Our hypothesis is that the omnipolar catheter is superior due to its broader range of voltage and signal identification.** We intend to conduct extensive research to evaluate this hypothesis and identify the best thresholds for this catheter.

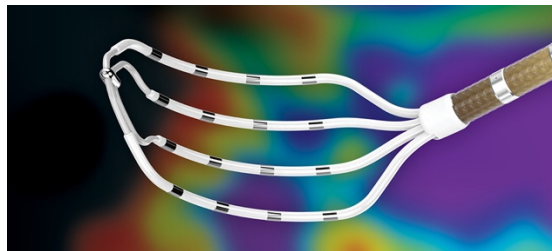


Figure 8 Tip of HDGrid catheter showing the multiple electrodes

The mapping process is carried out using the Abbott EnSite X software, which is optimized to work with the HD grid catheter mentioned earlier. The Abbott EnSite X system is a medical device used in electrophysiology procedures, specifically for mapping and visualizing the electrical activity of the heart. The system provides detailed information about the heart's electrical signals, which is important for diagnosing and treating various cardiac conditions. In the case of this project, it is used the Ensite X with the **voxel mode**.

Voxel mode is a feature of the Abbott EnSite X system that allows for three-dimensional visualization of cardiac structures and electrical signals. It works with the fusion of EAM mapping with CMR mapping, which is what it is done in this study.

In voxel mode, the EnSite X system creates a high-resolution, detailed representation of the heart by dividing the cardiac tissue into small volumetric units called voxels. Each voxel represents a tiny volume of tissue and contains information about the electrical activity recorded at that location. By analyzing the electrical data from multiple voxels, doctors can identify abnormal electrical patterns, locate arrhythmias, and plan the optimal placement of catheters or ablation therapy.

On the other hand, the **segmentation of data is performed using ADAS software**, which has a partnership with the clinic, allowing them to use the software for free and work together towards achieving the study's objectives.



Figure 9 Abbott brand logo



Figure 10 ADAS brand logo

As mentioned earlier, segmentation occurs in 10% increments, ranging from 0% to 90%. However, for this project, our focus is on the movement of catheters within the endocardium. Therefore, we are specifically interested in **five layers: 10%, 20%, 30%, and 50**. It's worth noting that the final layer is not at 50% but denoted as 50. Instead of using the 50% layer, we chose to examine the median of the layers between 10% and 50%. This approach provides an average representation of the endocardium, which we refer to as layer 50.

MARKET ANALYSIS

MAPPING SYSTEMS

The market for 3D mapping systems used in cardiac ablation procedures is dominated by several major players, including Biosense Webster with their CARTO system, Abbott with their EnSite X system, Boston Scientific with their Rhythmia system, and CardiInsight from Medtronic.

One of the most widely used mapping systems in the market is the **CARTO system from Biosense Webster**, a subsidiary of Johnson & Johnson. This system uses a magnetic field to track the position of a catheter within the heart and generate a 3D map of the cardiac chambers. The CARTO system is known for its high accuracy and reliability and is widely used in clinical practice for the treatment of arrhythmias (24).



Figure 11 CARTO mapping system

Another popular mapping system is the **EnSite NavX system from Abbott**, which is used for both diagnostic and therapeutic purposes. The EnSite system uses a combination of electroanatomic mapping and fluoroscopy to create a 3D map of the cardiac chambers using the Voxel mode, explained in the previous section (State of the situation, page 18). In recent years, Abbott has introduced several new catheters with advanced features, such as the HD Grid catheter, which allows for high-density mapping and improved signal resolution (25).



Figure 12 EnSite mapping system

Boston Scientific's Rhythmia system is another advanced mapping platform that has gained popularity in recent years. This system uses a high-density basket catheter to map the entire cardiac chamber in a single beat, allowing for faster and more accurate mapping. The Rhythmia system is known for its advanced features, such as the ability to automatically generate 3D maps and visualize the electrical activation patterns of the heart (26).



Figure 13 Rhythmia mapping system

Medtronic's new mapping system is called **CardioInsight** and uses a non-invasive multi-electrode vest to map the heart's electrical activity in 3D. The shirt is designed to fit different body sizes and cover the entire chest of the patient. The electrodes of the shirt capture the heart's electrical activity from multiple angles and positions, and this information is processed to generate a 3D map of the heart's electrical activity. This system is less invasive than conventional mapping systems that require the insertion of a catheter into the heart, which could improve the patient's experience and reduce the risk of complications (27).



Figure 14 CardioInsight mapping vest

CATHETERS

The **HD Grid catheter by Abbott** is a high-density mapping catheter with a net of electrodes that can create a detailed map of the heart's electrical activity. The HD Grid catheter is designed to provide more accurate and precise mapping of the heart than traditional catheters. The HD Grid catheter has three mapping algorithms: bipolar, orthogonal, and omnipolar. The catheter's unique design allows for simultaneous mapping of the electrical activity in all directions and provides a more comprehensive and detailed map of the heart's electrical activity (28).

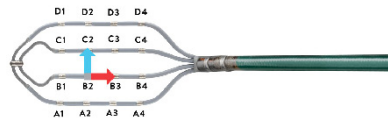


Figure 15 Omnipolar HD Grid catheter

The **Carto Penta catheter** is a high-density mapping device that provides detailed maps of the heart's electrical activity. Unlike traditional catheters, the Penta catheter is equipped with five branches or legs, and each leg contains a total of 20 electrodes, allowing for more precise mapping. However, because the electrodes move, it is difficult to determine their exact location and the direction of the signals they detect, making it challenging to calculate the distance and position of the source (29) (30).



Figure 16 Carto Penta catheter

The **Orion catheter** made by **Boston Scientific** is a high-density mapping catheter that can create detailed maps of the heart's electrical activity. The Orion catheter has 64 electrodes (31).



Figure 17 Orion catheter

SEGMENTATION

Moving on to segmentation brands and commercial houses, there are several commercial software programs available that perform CMR segmentation for VT ablation, including ADAS and Inheart.

ADAS (Automatic Detection of Arrhythmic Substrate) (32) is a software program developed by researchers at Johns Hopkins University that automatically segments CMR images into healthy, border zone, and scar tissue regions. The software uses a combination of intensity-based

thresholding and a supervised machine learning algorithm to classify the regions of the heart tissue. ADAS has been validated in several studies and has been shown to have high sensitivity and specificity for identifying areas of myocardial scar.

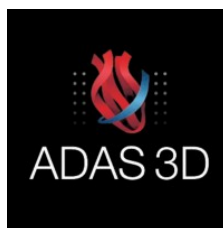


Figure 18 ADAS software logo

Inheart is another software program that performs CMR segmentation for VT ablation. It uses a combination of manual and automated segmentation techniques to create a 3D model of the heart and identify regions of scar tissue. Inheart has been used in several clinical studies and has been shown to accurately identify areas of myocardial scar and improve the success rates of VT ablation procedures (33).



Figure 19 inHeart segmentation software logo

CONCEPTION ENGINEERING

This study encompasses a methodology consisting of several steps that we will now explore in more detail, providing a comprehensive overview of conception engineering:

1. Identification of the patient's maps that we will be working on
2. Export EAM maps in Abbott
3. Importing maps in ADAS
4. CMR and EAM Fusion
5. Data Collection
6. Statistical Analysis
7. Discussion

-
1. Firstly, the identification of patient maps is crucial for this study. However, it falls outside the scope of the project, as the prepared maps will be provided for analysis.

MAPPING SYSTEMS

2. Next, for the mapping systems, a comparison table has been made to help us choose the best mapping system.

Mapping system	Features	Advantages
Biosense Webster's CARTO system	<ul style="list-style-type: none"> - Uses magnetic field for catheter tracking and 3D mapping - High accuracy and reliability - Widely used for arrhythmia treatment 	<ul style="list-style-type: none"> - Provides precise and reliable mapping - Established track record in clinical practice
Abbott's EnSite X system	<ul style="list-style-type: none"> - Combines electroanatomic mapping and fluoroscopy for 3D mapping - Introduction of advanced catheters (e.g., HD Grid catheter) - Diagnostic and therapeutic capabilities 	<ul style="list-style-type: none"> - Offers comprehensive mapping solution - High-density mapping and improved signal resolution - Accurate diagnosis and treatment planning
Boston Scientific's Rhythmia system	<ul style="list-style-type: none"> - Uses high-density basket catheter for mapping - Automatically generates 3D maps - Visualizes electrical activation patterns 	<ul style="list-style-type: none"> - Faster and more accurate mapping - Advanced automatic mapping and visualization features

Medtronic's CardioInsight	<ul style="list-style-type: none"> - Non-invasive mapping using a multi-electrode vest - Captures electrical activity from multiple angles and positions 	<ul style="list-style-type: none"> - Reduces invasiveness and potential complications - Enhanced patient experience - Comprehensive 3D mapping of heart's electrical activity
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Table 2 Comparison of mapping systems

We have selected **Abbott** as our preferred mapping system for exporting EAM (Electro-Anatomical Mapping) maps, as it plays a crucial role in accurately identifying and visualizing reentrant channels within the heart. Abbott's mapping system offers a range of advanced features and configurations, including bipolar, orthogonal, and omnipolar mapping options. These features facilitate comprehensive comparative studies and provide valuable insights into mapping techniques.

In addition, the EnSite X system utilizes electroanatomic mapping and fluoroscopy, enabling accurate and detailed 3D mapping of the cardiac chambers. This comprehensive visualization aids in precise diagnosis and effective treatment planning.

CATHETER

When it comes to the catheters, we conducted a thorough comparison to determine the best option. The findings are summarized in the table below:

Mapping system	Features	Advantages
HD Grid catheter by Abbott	<ul style="list-style-type: none"> - High-density mapping catheter with a net of electrodes - Three mapping algorithms: bipolar, orthogonal, and omnipolar - Simultaneous mapping in all directions - Provides detailed and comprehensive map of heart's electrical activity 	<ul style="list-style-type: none"> - More accurate and precise mapping - Enhanced diagnostic and treatment capabilities - Advanced mapping algorithms
Carto Penta catheter	<ul style="list-style-type: none"> - High-density mapping device with 20 electrodes - Provides detailed maps of heart's electrical activity 	<ul style="list-style-type: none"> - Higher electrode count for more precise mapping
Orion catheter by Boston Scientific	<ul style="list-style-type: none"> - High-density mapping catheter with 64 electrodes - Creates detailed maps of heart's electrical activity 	<ul style="list-style-type: none"> - Offers higher electrode count for increased mapping detail

Table 3 Comparison of catheters

Our collaboration with Abbott provides us with invaluable access to their cutting-edge technology, including the **HD Grid catheter**, which plays a crucial role in ensuring the success of our project. This partnership allows for the exchange of knowledge and fosters technological advancements that benefit both our research project and Abbott's ongoing innovations. Overall, the HD Grid catheter by Abbott surpasses the Carto Penta catheter and the Orion catheter in terms of its advanced mapping capabilities, simultaneous mapping in multiple directions, and comprehensive mapping algorithms.

SEGMENTATION

- When it comes to importing maps and selecting the appropriate segmentation software, making the right choice is crucial for obtaining high-quality data. To assist in this decision-making process, here is a table comparing different segmentation software options:

Mapping system	Features	Advantages
ADAS (Automated Detection of Scar)	<ul style="list-style-type: none"> - Utilizes intensity-based thresholding and supervised machine learning algorithm - Automatically segments CMR images into healthy, border zone, and scar tissue regions - Validated in multiple studies - High sensitivity and specificity for identifying areas of myocardial scar 	<ul style="list-style-type: none"> - Precise classification of heart tissue regions - Improved targeting and treatment planning for VT ablation - Reduced dependence on manual input - Validated performance
Inheart	<ul style="list-style-type: none"> - Combination of manual and automated segmentation techniques - Creates 3D model of the heart and identifies scar tissue regions - Used in clinical studies - Accurate identification of areas of myocardial scar 	<ul style="list-style-type: none"> - Effective in identifying scar tissue regions - Utilized in enhancing success rates of VT ablation procedures

Table 4 Comparison of segmentation software

We have selected **ADAS** as the preferred segmentation software for importing the maps in our project. This decision is based on several factors, including ADAS's longstanding collaboration with the hospital and the establishment of a strong working relationship. ADAS offers comprehensive tools that are essential for our needs, such as data segmentation, fusion of CMR data with EAM maps, fusion analysis, and facilitating comparative studies.

One of the key advantages of ADAS is its ability to accurately identify and differentiate between healthy tissue, border zones, and scar tissue. This precise segmentation is crucial for performing ablation procedures with utmost precision. ADAS achieves this through the utilization of a supervised machine learning algorithm, which automates the segmentation process and reduces

the reliance on manual input, minimizing potential subjectivity. The software's high sensitivity and specificity, validated through rigorous studies, further enhance confidence in its accuracy and reliability for identifying myocardial scar areas.

4. Prior to data collection, the fusion of CMR and EAM maps takes place. However, the fusion process itself is not within the scope of this project, as we will be provided with the fusioned maps for analysis.
5. During the data collection phase, a multitude of variables and measurements will be taken into account. Each variable will be evaluated for the bipolar, HDW, and omnipolar catheters across various layers, including 10%, 20%, 30%, and the endocardium layer 50 representing the median from 10% to 50%.
6. Subsequently, statistical analysis will be employed to analyze the collected data:
 - a. Correlation of EAM maps with CMR map
 - b. Correlation of each layer of each EAM map with CMR map
 - c. New mean lower and upper thresholds
 - d. Minimum mean distance to the nearest channel for each map
7. Finally, the findings derived from the statistical analysis will be thoroughly discussed.

DETAIL ENGINEERING

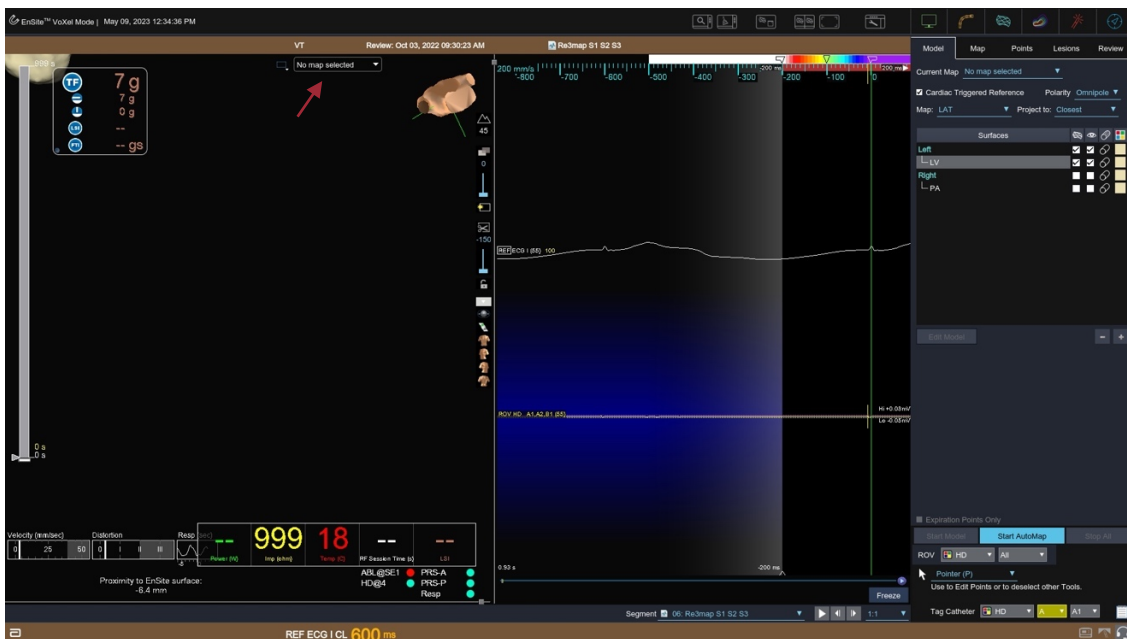
IDENTIFICATION OF MAPS TO BE EXPORTED

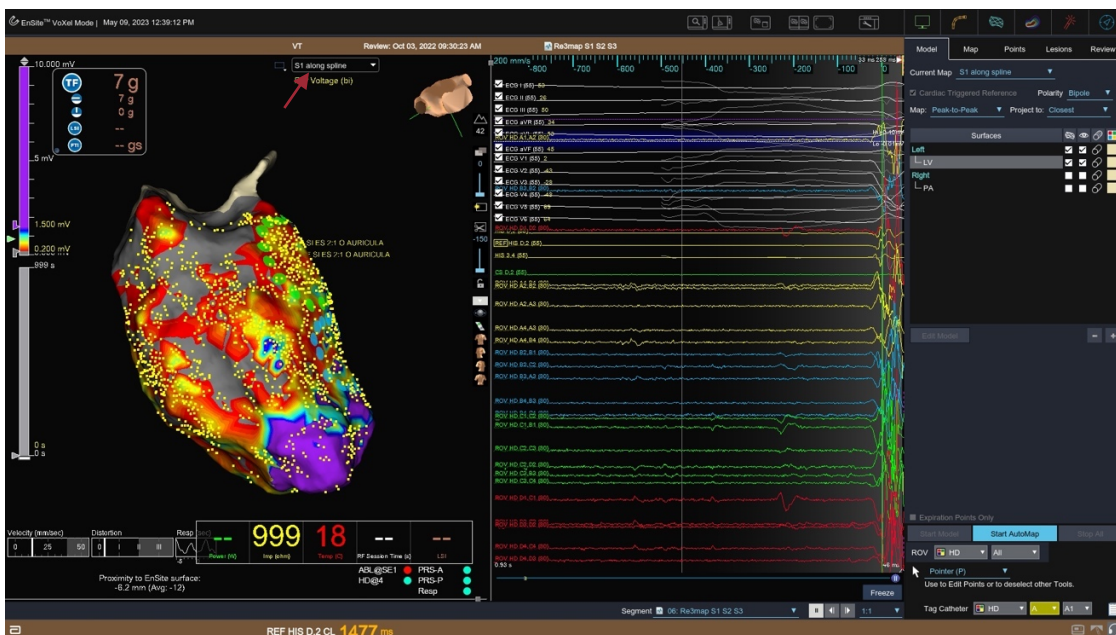
Dra. Sara Vázquez created an Excel spreadsheet containing a comprehensive list of patients, where she denoted those who underwent the ILAMS procedure in a designated column. To identify the patients who underwent this specific procedure, the Excel sheet should be reviewed and those marked "Yes" in Sara's ILAM column should be selected. These selected patients can then be evaluated in the Abbott software. The excel is attached in the annex.

EXPORT MAPS FROM ABBOTT

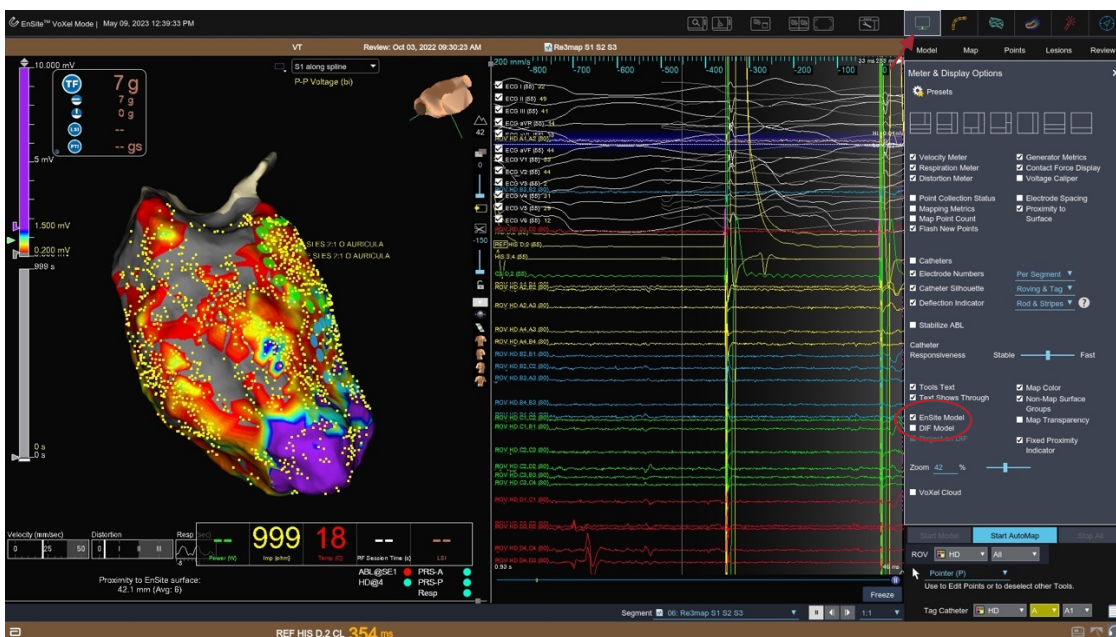
Abbott is a software system that serves as the platform for all the procedures conducted. It is also the place where the maps are stored. Therefore, in order to access the maps, we need to retrieve them from this software.

1. Open a study and look for the patient's history number or date of ablation.
2. Select Omni 1, HDW 1, or Along 1 on the map selection.

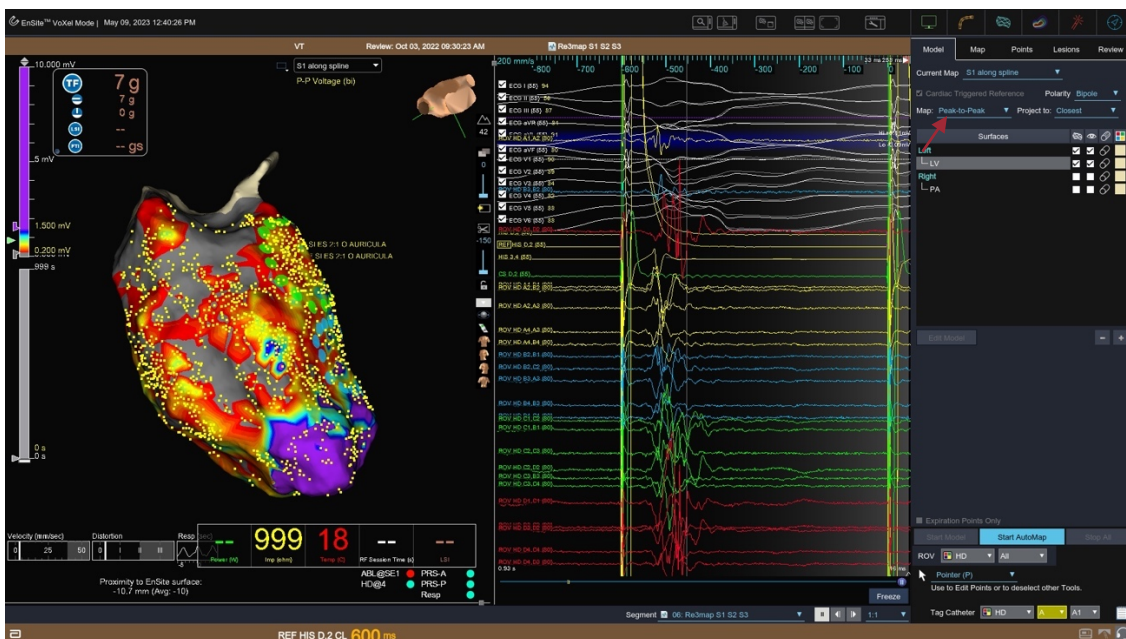




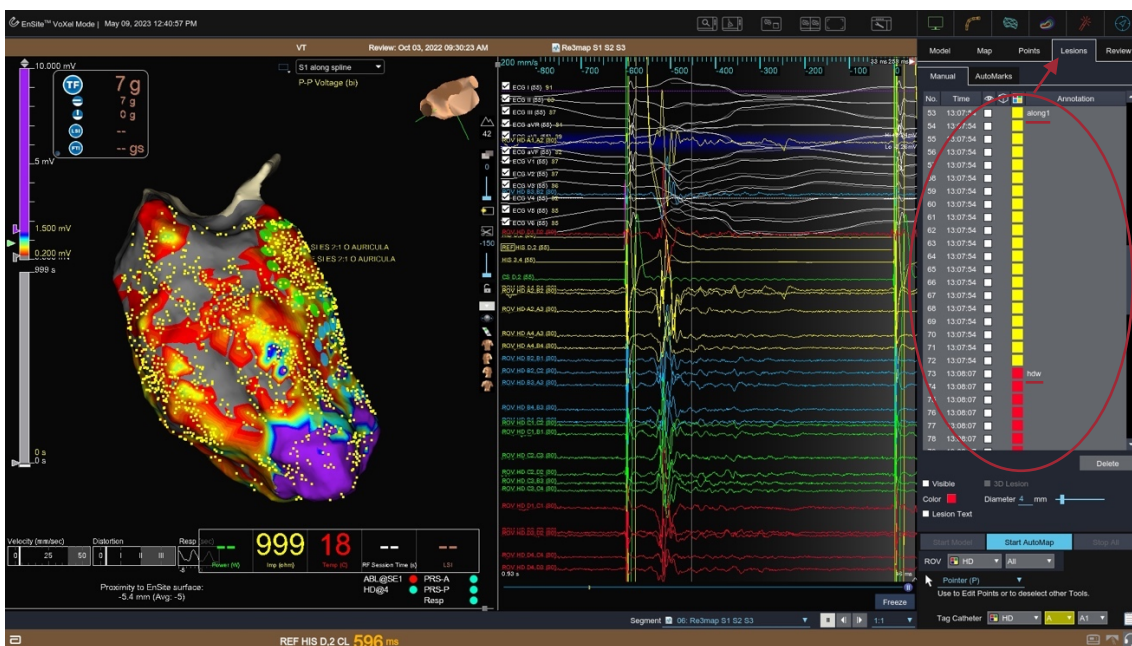
3. Go to the computer button to click DIF and Ensite.



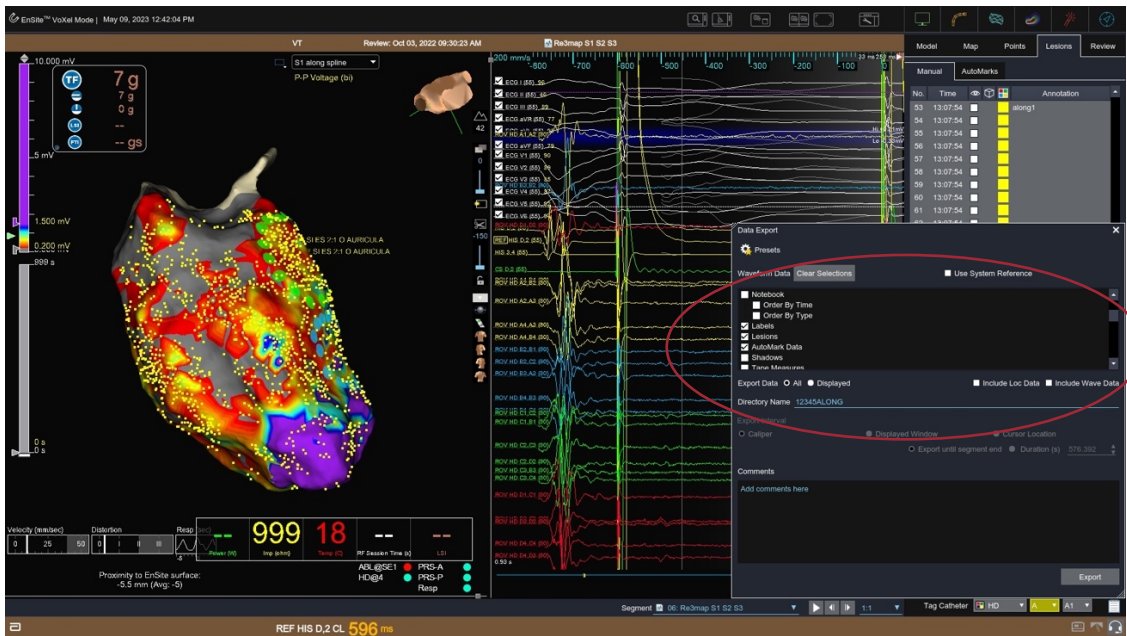
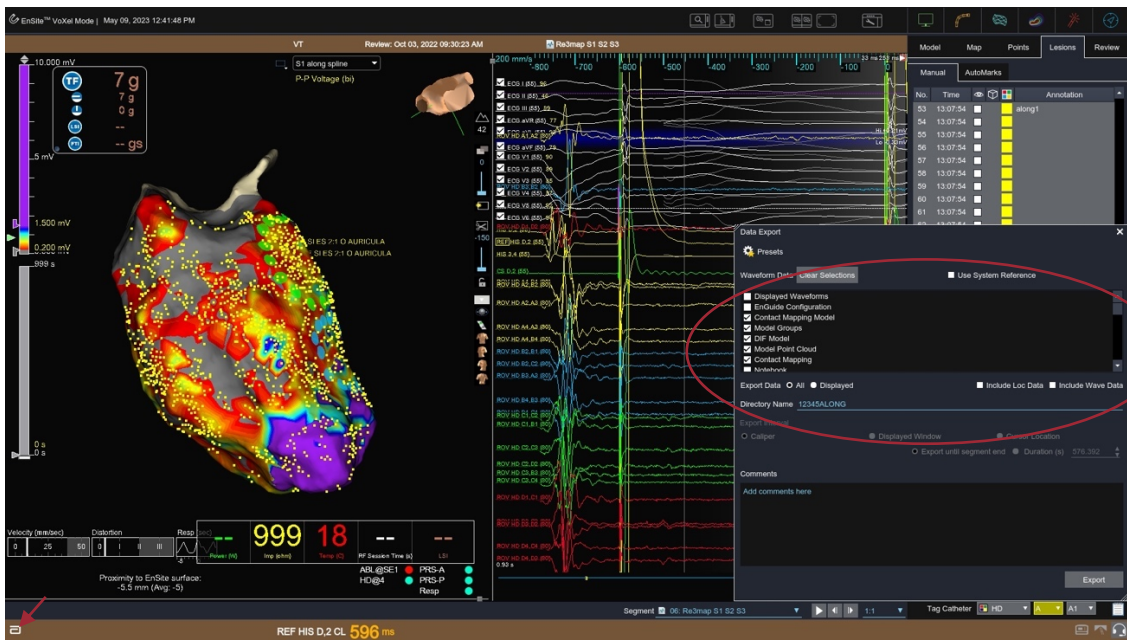
4. Select Collect peak to peak data.



- Note at the excel the first ILAM for each map and their color to later differentiate them in the lesions button. Select these ILAMS.



- Export the map: select the following → contact mapping model, model groups, DIF model, model point cloud, contact mapping, labels, lesions, and automark data. Select All and write in directory name the patient's history number and map type.



7. Repeat steps 2-7 for each map.

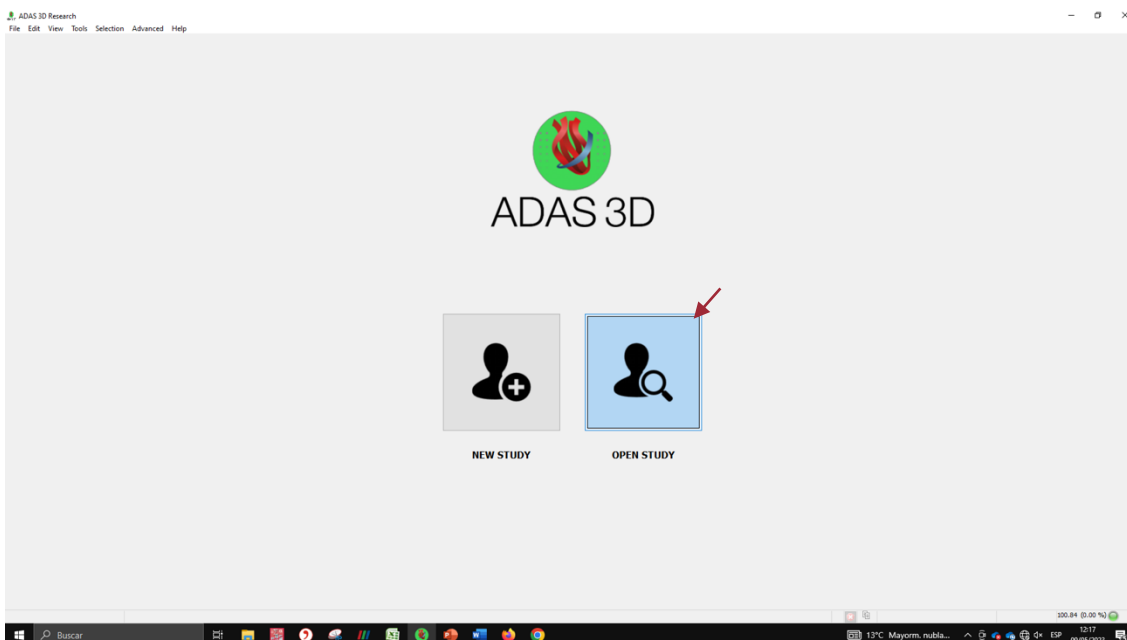


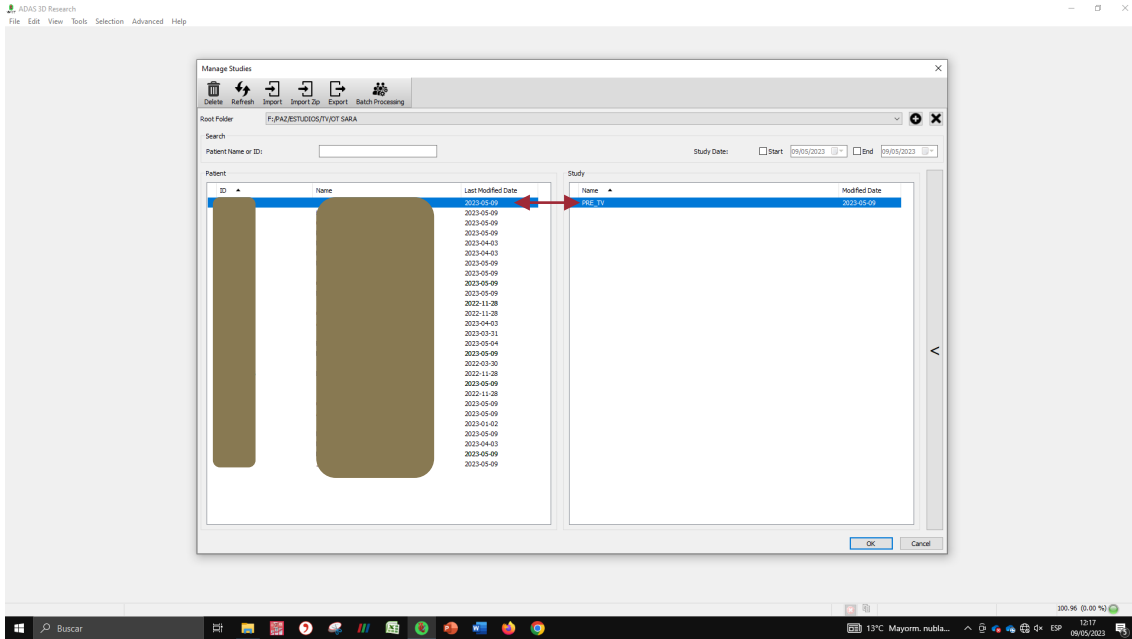
8. When done, click on End the study.
9. When finish with all the maps, go to the initial page and click on Archive to select the maps that want to be exported in a USB drive.

IMPORTING MAPS IN ADAS

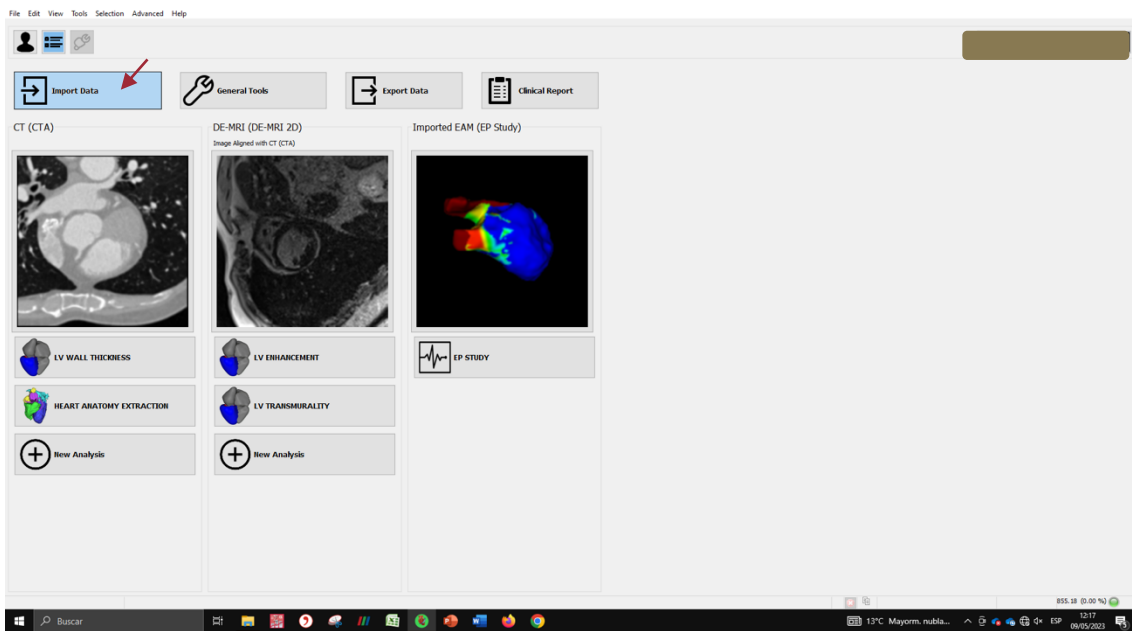
To upload a specific EP study, we need to follow these steps:

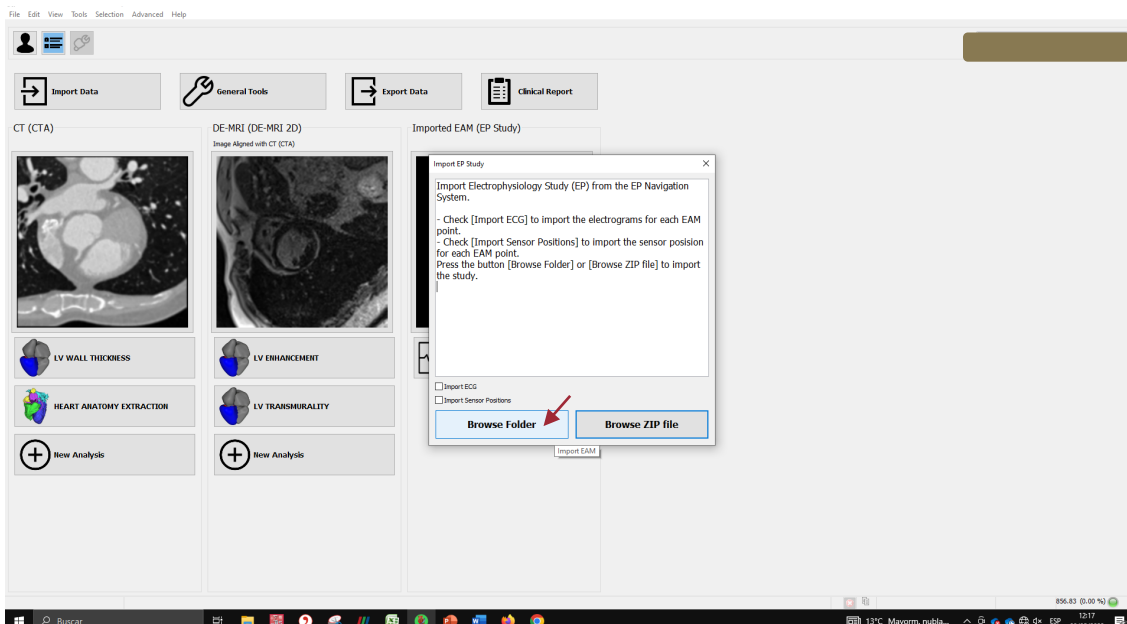
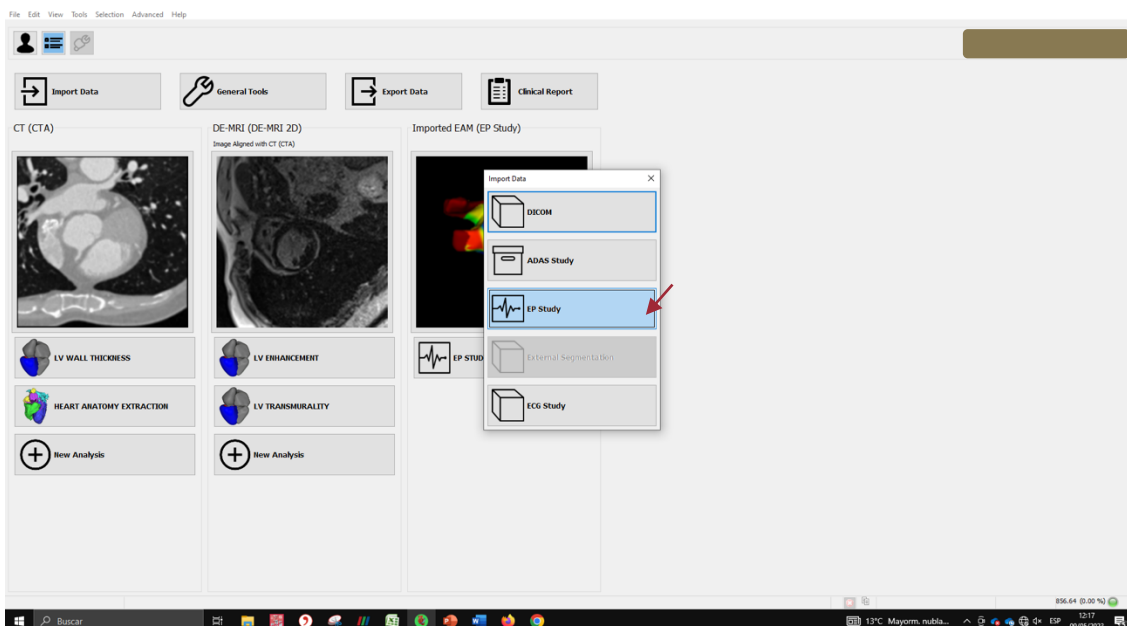
1. Open the existing study.





2. Select the EP study that we want to upload.





3. The fusion of the CMR and the maps will then be ensured to guarantee accurate results.

DATA COLLECTION IN SPSS

HOW SPSS DOCUMENT IS STRUCTURED

The cases will be arranged in rows, with each case comprising 24 rows in total: for each map (bipolar/along, orthogonal/HDW/hdwave, omnipolar), there will be two different versions: the “old” map (with the old thresholds 0.5-1.5mV) and the “new” map (with the new thresholds). Additionally, we will have four rows dedicated to each of the different layers we will study, namely 10, 20, 30, and 50. This means that each map will have a total of eight rows, and each case (consisting of three maps) will have a total of 24 rows.

Variables in Data mode

let	NHC	DateAblation	SIGNALS	Número	fusionRMM	DateCMR	TipoCMR	Comentarios	Total_Area_MRI	Invald_area_MRI	BZ_Area_MRI	Scar_Area_MRI	ChannelsCMR	LongC1	MassC1	LongC2
94			OMNI_NEW_20													
95			OMNI_NEW_30													
96			OMNI_NEW_50													
97		11/29/2021	BIP_10	19		09/16/2021			151.39	0	20.69	6.29	2	28.31	36	69.29
98			BIP_20													
99			BIP_30													
100			BIP_50													
101			BIP_NEW_10													
102			BIP_NEW_20													
103			BIP_NEW_30													
104			BIP_NEW_50													
105			HDWAVE_10													
106			HDWAV_20													
107			HDWAV_30													
108			HDWAV_50													
109			HDWAV_NEW_10													
110			HDWAV_NEW_20													
111			HDWAV_NEW_30													
112			HDWAV_NEW_50													
113			OMNI_10													
114			OMNI_20													
115			OMNI_30													
116			OMNI_50													
117			OMNI_NEW_10													
118			OMNI_NEW_20													
119			OMNI_NEW_30													
120			OMNI_NEW_50													
121		09/13/2021	BIP_10	27		12/18/2020		COPADA	237.76	0	40.25	24.17	4			295.24
122			BIP_20													
123			BIP_30													
124			BIP_50													
125			BIP_NEW_10													
126			BIP_NEW_20													
127			BIP_NEW_30													
128			BIP_NEW_50													
129			HDWAVE_10													
130			HDWAV_20													
131			HDWAV_30													
132			HDWAV_50													
133			HDWAV_NEW_10													

More variables in Data mode

let	NHC	DateAblation	assC10	ThresholdMin	ThresholdMax	CorrelatTotal	Number_ILAMs_Basal	ILAM1canaCercano	Distancia1MinChannel	ILAM2canalascerc	Distancia2Minchannel	ILAM3canalascerc	Distancia3MinC
94			O										
95			O										
96			O										
97		11/29/2021		.50	1.50	.58	4.00	2.00	5.34	2.00	5.03	2.00	
98				.50	1.50	.53							
99				.50	1.50	.51							
100				.50	1.50	.52							
101				.05	1.13	.63							
102				.05	1.13	.63							
103				.05	1.13	.66							
104				.05	1.13	.74							
105				.50	1.50	.49							
106				.50	1.50	.47							
107				.50	1.50	.48							
108				.50	1.50	.49							
109			HDW	.06	.86	.55							
110			HDW	.06	.76	.55							
111			HDW	.06	.14	.59							
112			HDW	.06	.14	.59							
113				.50	1.50								
114				.50	1.50								
115				.50	1.50								
116				.50	1.50								
117			O										
118			O										
119			O										
120			O										
121		09/13/2021		.50	1.50	.37	3.00	2.00	0	2.00	0	2.00	
122				.50	1.50	.36							
123				.50	1.50	.34							
124				.50	1.50	.37							
125				.12	10.05	.48							
126				.12	.75	.48							
127				.12	.75	.48							
128				8.06	10.05	.42							
129				.50	1.50	.34							
130				.50	1.50	.32							
131				.50	1.50	.31							
132				.50	1.50	.41							
133			HDW	.09	10.96	.53							

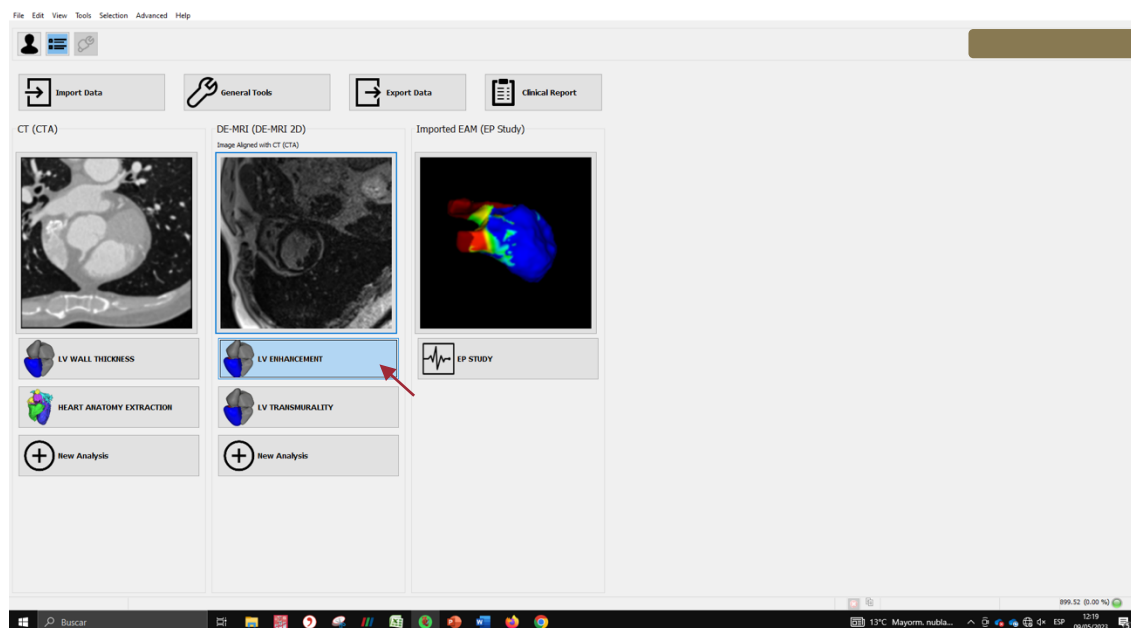
The columns contain the variables, which represent the data of interest that we will annotate based on the findings and calculations obtained from the ADAS.

Nombre	Tipo	Anchura	Decimales	Etiqueta	Valores	Pérdidos	Columnas	Alineación	Medida	Rol
1	fel	Numerico	8	0	(0, No.)	Ninguna	3	Derecha	✓ Escala	Entrada
2	FEIC	Numerico	8	0		Ninguna	7	Derecha	Desconocido	Entrada
3	DateAbilacion	Fecha	10	0	Fecha de la abl.	Ninguna	9	Derecha	Desconocido	Entrada
4	SIGNALS	Numerico	2	0	(2, BIP, 10)	Ninguna	12	Derecha	Desconocido	Entrada
5	Número	Numerico	8	0		Ninguna	8	Derecha	Desconocido	Entrada
6	BasioRMM	Numerico	8	0	(0, No.)	Ninguna	8	Derecha	Desconocido	Entrada
7	DateCMR	Fecha	10	0	fecha reso	Ninguna	9	Derecha	Desconocido	Entrada
8	TipocMR	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
9	Comentarios	Cadena	100	0		Ninguna	22	Izquierda	Nominal	Entrada
10	Total_Area	Numerico	8	2	gramos totales In	Ninguna	15	Derecha	Desconocido	Entrada
11	Invali_d area	Numerico	8	2	invalidos para r.	Ninguna	8	Derecha	✓ Escala	Entrada
12	BZ_Area_MR	Numerico	8	2		Ninguna	12	Derecha	Desconocido	Entrada
13	Scor_Area	Numerico	8	2		Ninguna	13	Derecha	Desconocido	Entrada
14	QuantifCMR	Numerico	8	0	número de can.	Ninguna	12	Derecha	Desconocido	Entrada
15	LongC1	Numerico	8	2	longitud canal1	Ninguna	13	Derecha	Desconocido	Entrada
16	MassC1	Numerico	8	2	masa canal1	Ninguna	13	Derecha	Desconocido	Entrada
17	LongC2	Numerico	8	2		Ninguna	11	Derecha	Desconocido	Entrada
18	MassC2	Numerico	8	2		Ninguna	11	Derecha	Desconocido	Entrada
19	LongC3	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
20	MassC3	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
21	LongC4	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
22	MassC4	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
23	LongC5	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
24	MassC5	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
25	LongC6	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
26	MassC6	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
27	LongC7	Numerico	8	2		Ninguna	8	Derecha	Desconocido	Entrada
28	MassC7	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
29	LongC8	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
30	MassC8	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
31	LongC9	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
32	MassC9	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
33	LongC10	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
34	MassC10	Numerico	8	2		Ninguna	8	Derecha	✓ Escala	Entrada
35	ThresholdM	Numerico	8	2		Ninguna	14	Derecha	Desconocido	Entrada
36	ThresholdMn	Numerico	8	2	mejor umbral p.	Ninguna	15	Derecha	Desconocido	Entrada
37	ComentTotal	Numerico	8	2		Ninguna	13	Derecha	Desconocido	Entrada
38	Number_EA	Numerico	8	2		Ninguna	19	Derecha	Desconocido	Entrada
39	ILAM1canal	Numerico	8	2	Nombre del can.	Ninguna	17	Derecha	Desconocido	Entrada
40	Distancia1	Numerico	8	2		Ninguna	18	Derecha	Desconocido	Entrada
41	ILAM2canal	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
42	Distancia2	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
43	ILAM3	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
44	Distancia3	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
45	ILAM4	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
46	Distancia4	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
47	ILAM5	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
48	Distancia5	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
49	ILAM6	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
50	Distancia6	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
51	ILAM7	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
52	Distancia7	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
53	ILAM8	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
54	Distancia8	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
55	ILAM9	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
56	Distancia9	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
57	ILAM10	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
58	Distancia10	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
59	ILAM11	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
60	Distancia11	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
61	ILAM12	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
62	Distancia12	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
63	ILAM13	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
64	Distancia13	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
65	ILAM14	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
66	Distancia14	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
67	ILAM15	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
68	Distancia15	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
69	ILAM16	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
70	Distancia16	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
71	ILAM17	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
72	Distancia17	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
73	ILAM18	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
74	Distancia18	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
75	ILAM19	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
76	Distancia19	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
77	ILAM20	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
78	Distancia20	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
79	ILAM21	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
80	Distancia21	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
81	ILAM22	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
82	Distancia22	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
83	ILAM23	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
84	Distancia23	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
85	ILAM24	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
86	Distancia24	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
87	ILAM25	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
88	Distancia25	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
89	ILAM26	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
90	Distancia26	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
91	ILAM27	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
92	Distancia27	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
93	ILAM28	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
94	Distancia28	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
95	ILAM29	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
96	Distancia29	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
97	ILAM30	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
98	Distancia30	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
99	ILAM31	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada
100	Distancia31	Numerico	8	2		Ninguna	17	Derecha	Desconocido	Entrada

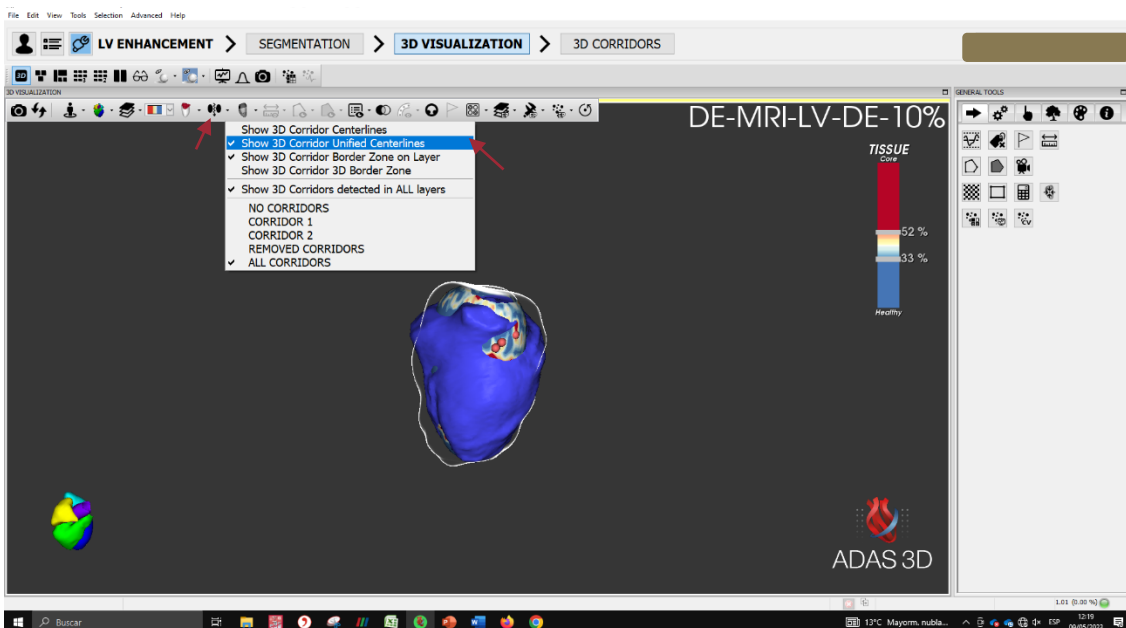
CORRIDORS

To collect data on the corridors, we will gather the mass (in grams) of healthy tissue, core, and border zone from the CMR, along with information on the number of channels, as well as their length and mass. This data will be used to compare the actual corridors (detected from the CMR) with those detected by each map (bipolar, orthogonal, and omnipolar), and establish correlation with the ILAMS of each map. The steps followed were:

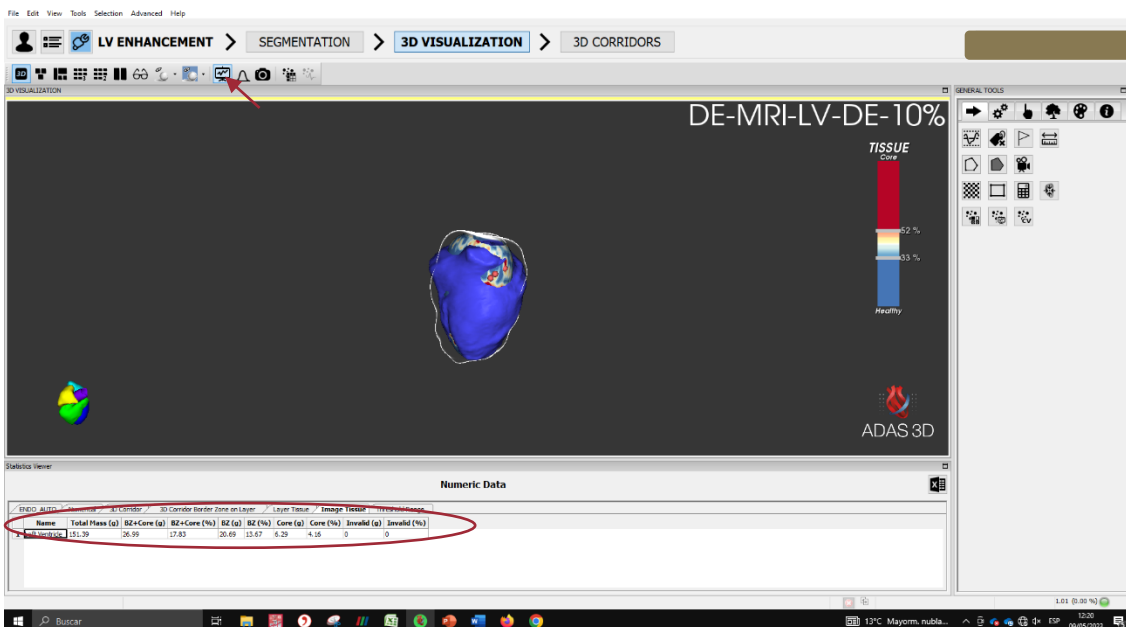
1. Begin by opening the CMR case.



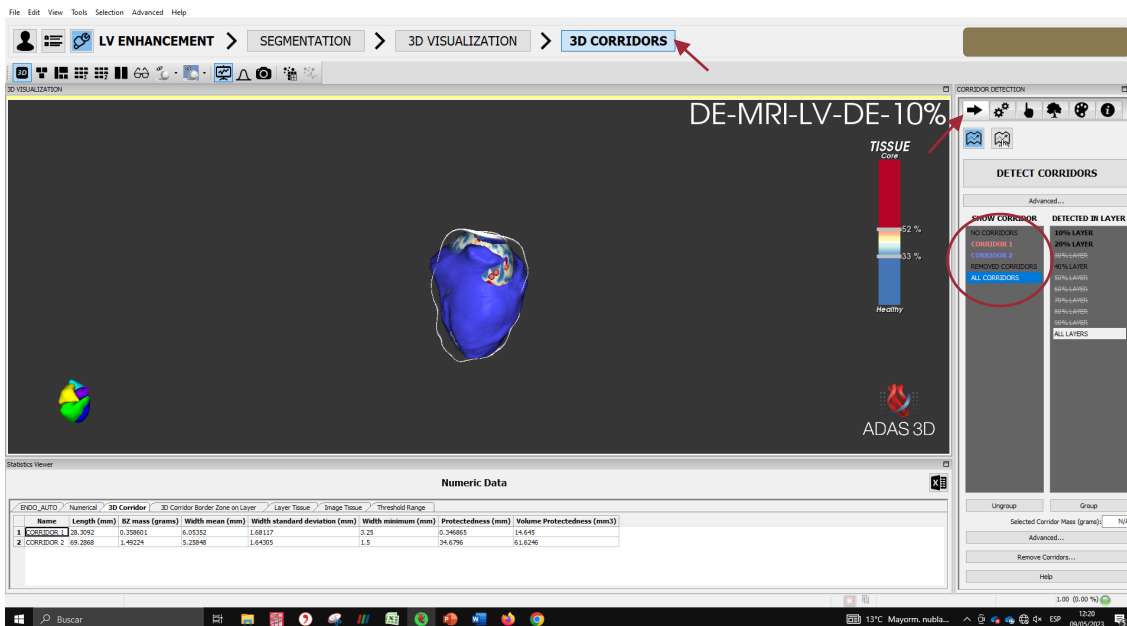
2. Click on the channel drawing button and click unified center lines. This process serves to combine the various branches of a given corridor and treat it as a single entity when determining its length.



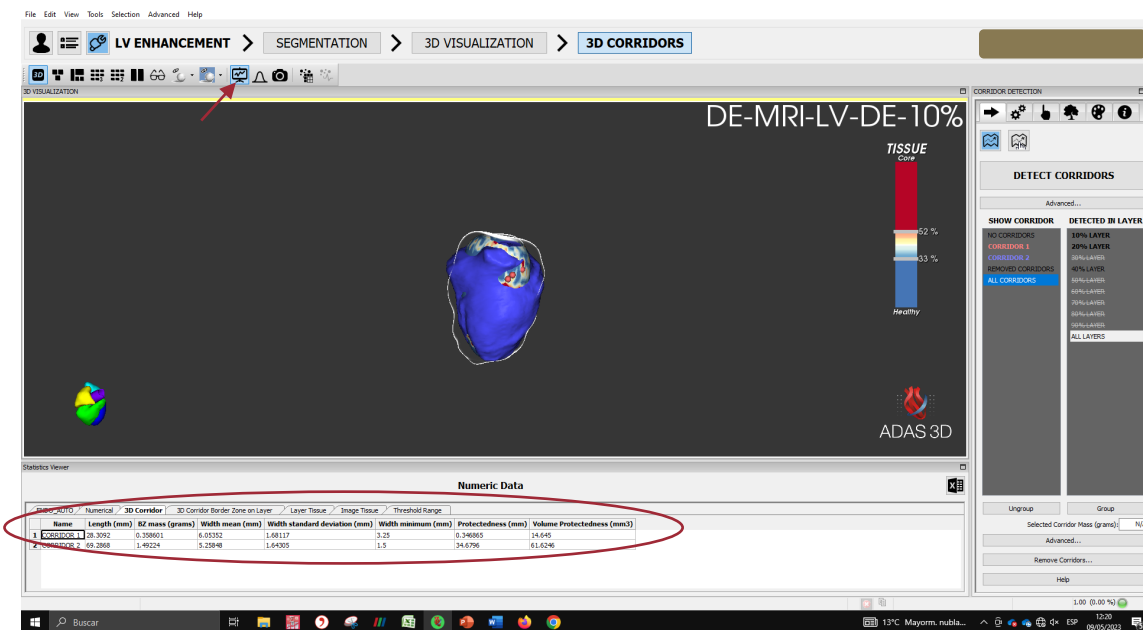
3. Click on TV button to access the numerical data: total number of corridors, as well as the mass of the border zone, core tissue, and invalid areas.



4. In the last tab at the top of the interface, locate the 3D corridors list to determine the number of corridors.



5. Go again to the numerical data in 3D corridors tab to access the weight of the corridors.



It is important to note that at times, a fully black area may be classified as healthy when, in fact, it is a dead area. This occurs when an area is completely burned and does not allow gadolinium to pass, resulting in it being undetected in the CMR and appearing black, as completely healthy. However, it is important to recognize that the area is not viable and should be considered dead instead of healthy tissue or a potential corridor.

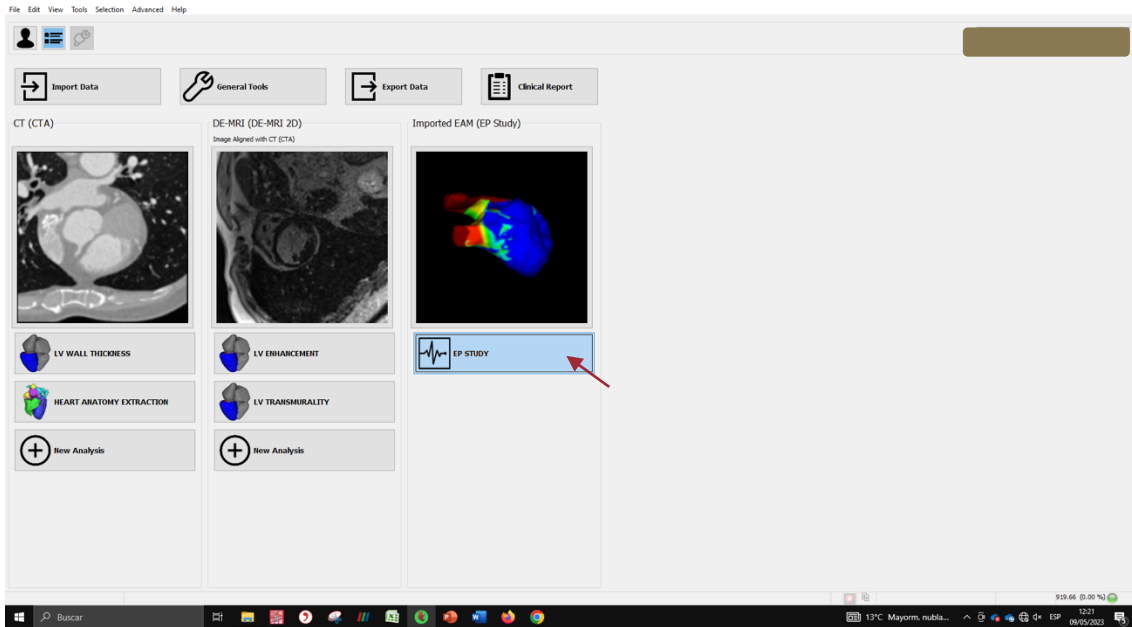
THRESHOLDS

This stage includes evaluating the precision of each map against the CMR and establishing updated thresholds based on their accuracy for each map (bipolar, orthogonal, and omnipolar). Additionally, each map will be evaluated for all four layers mentioned earlier.

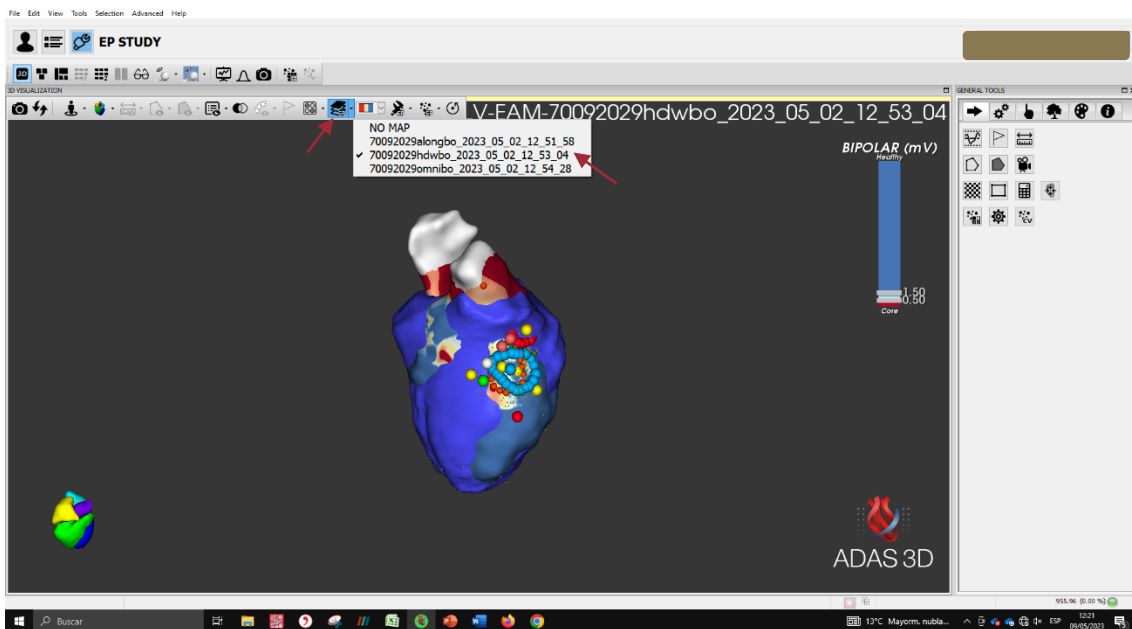
ACCURACY OF 0,5-1,5 MV THRESHOLDS

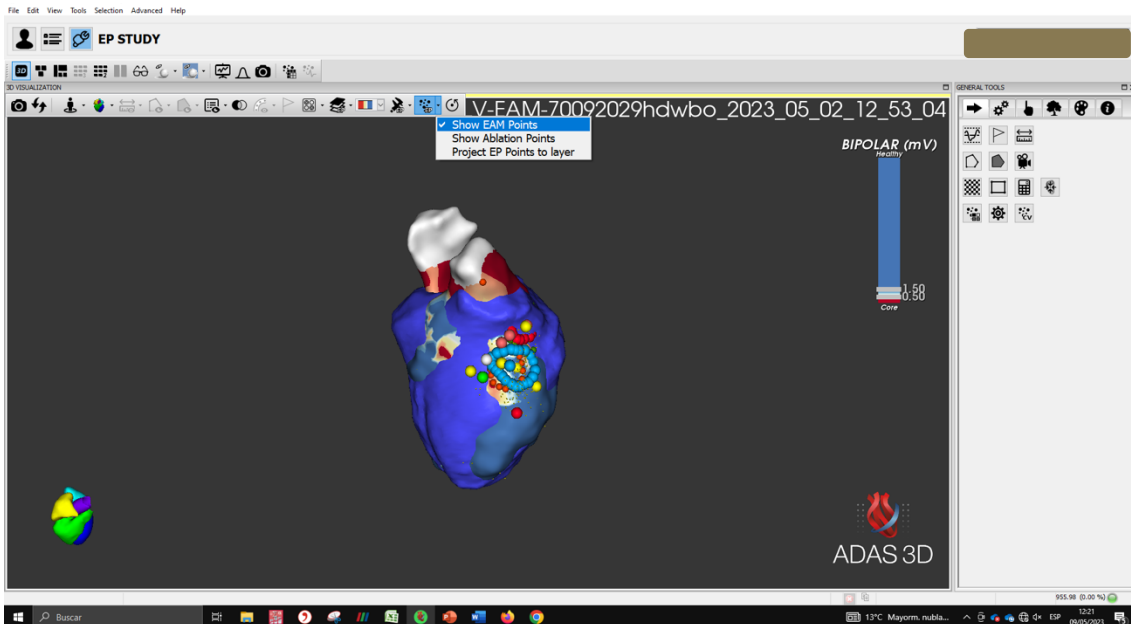
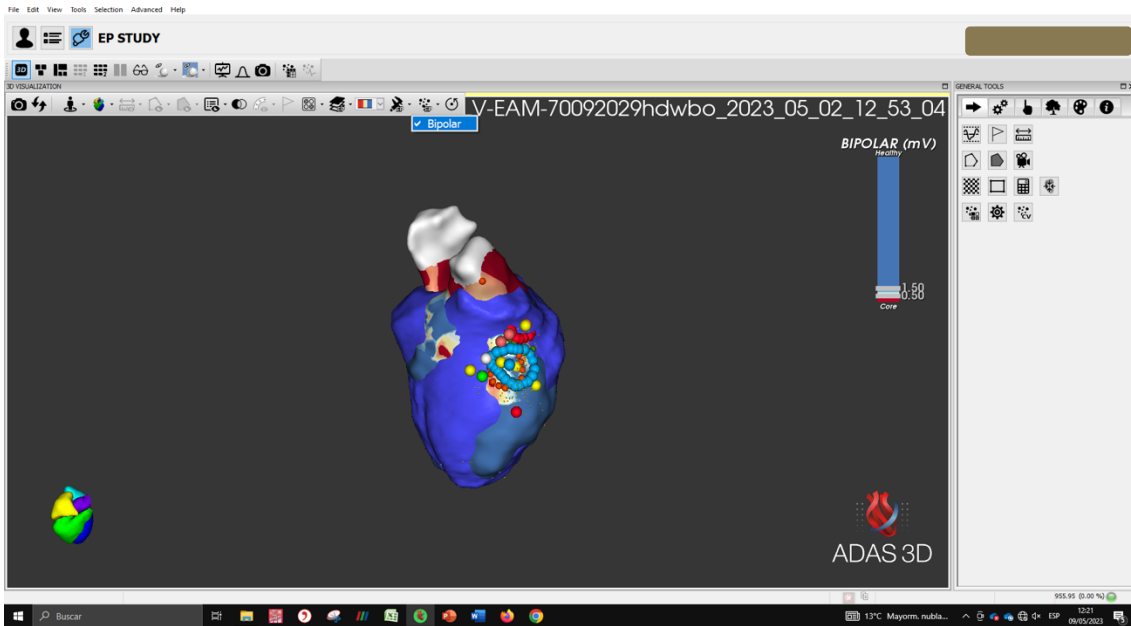
The accuracy of all layers across all maps has been measured using the thresholds that have been established thus far, which are between 0.5-1.5 mV. Steps followed:

1. Open EAM map for each case.

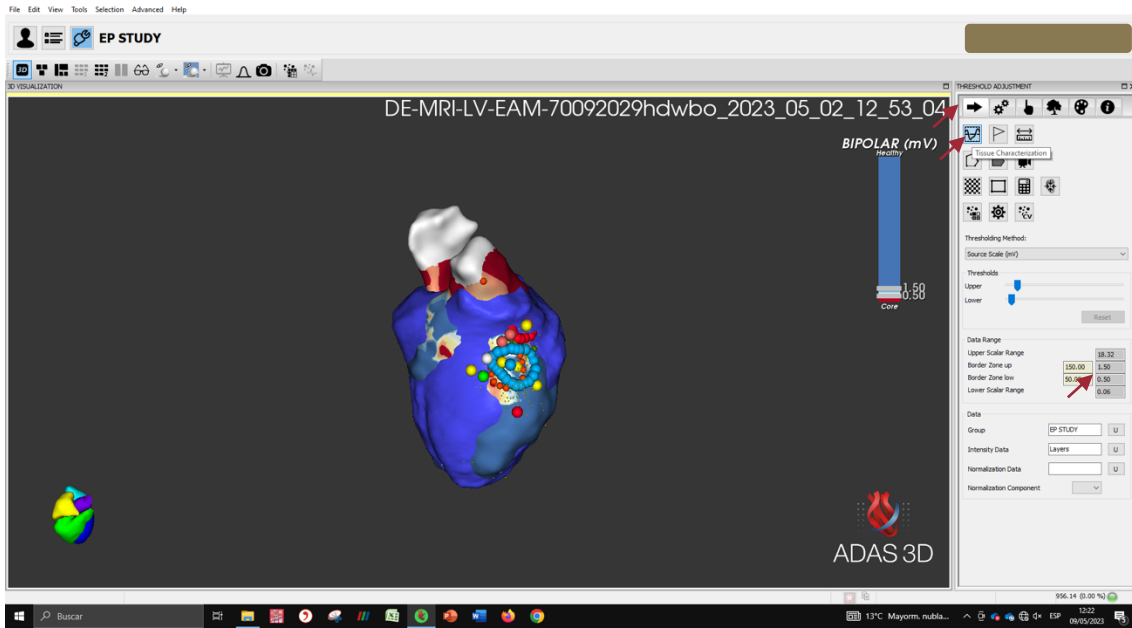


2. Select the map to collect the data from (bipolar, orthogonal, omnipolar)

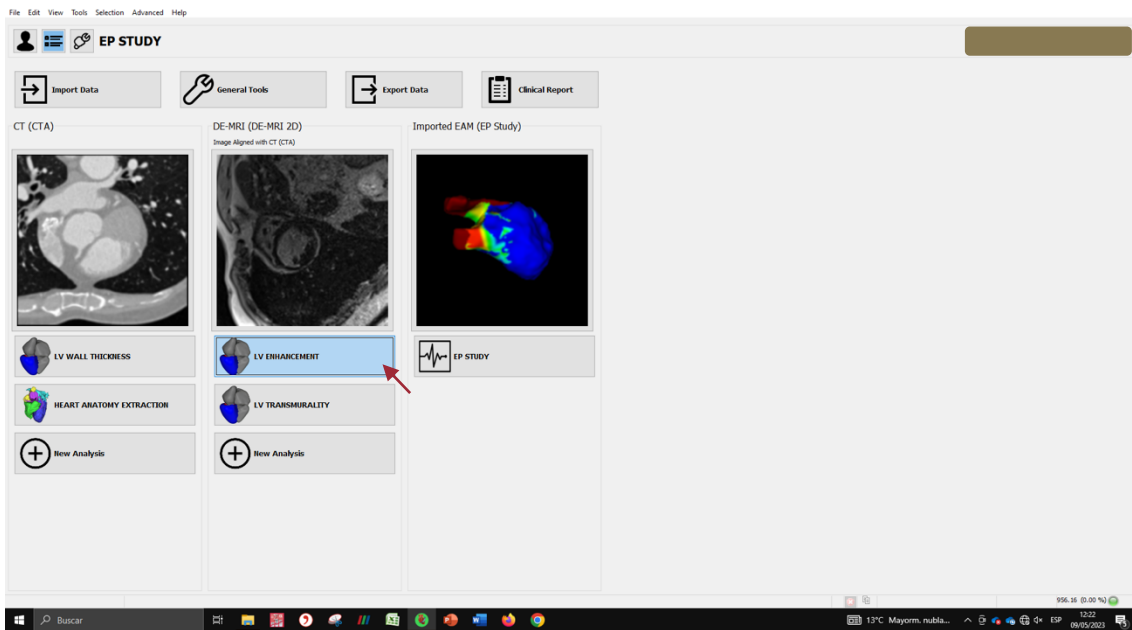


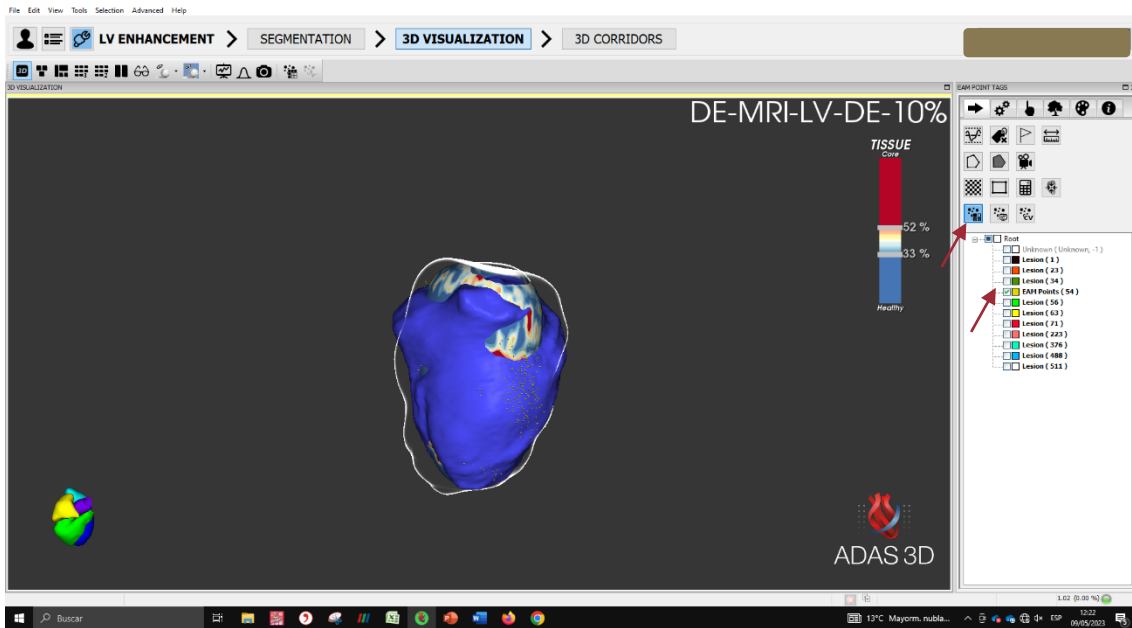


3. Click on the button shown and establish the 0,5 and 1,5 thresholds.

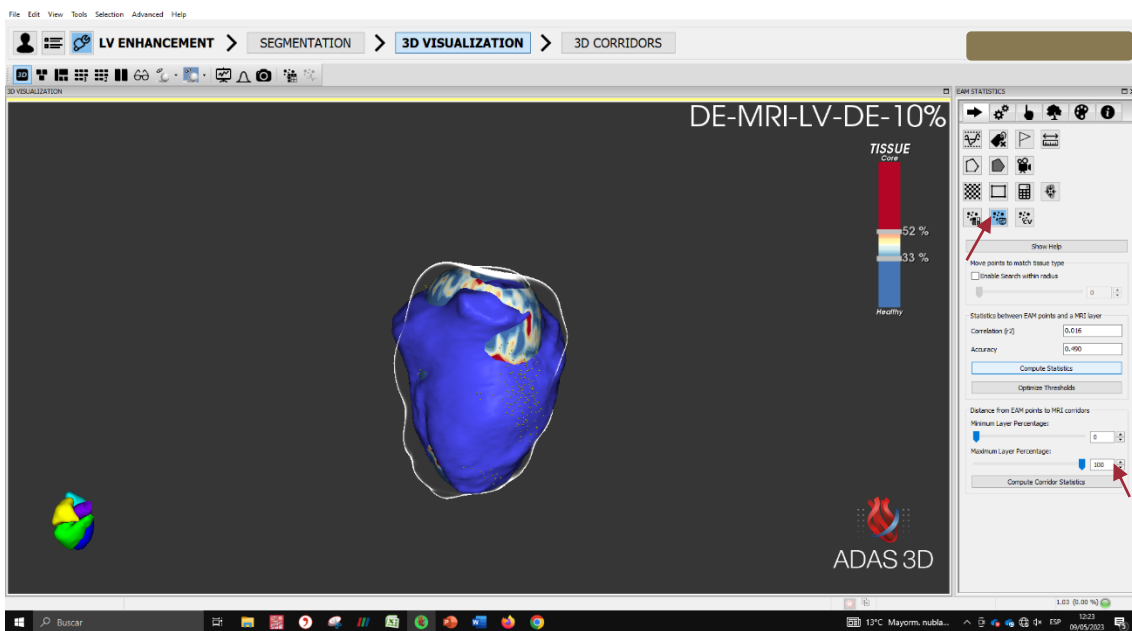


4. Go back to the enhancement CMR and select the EAM points in the dots button.

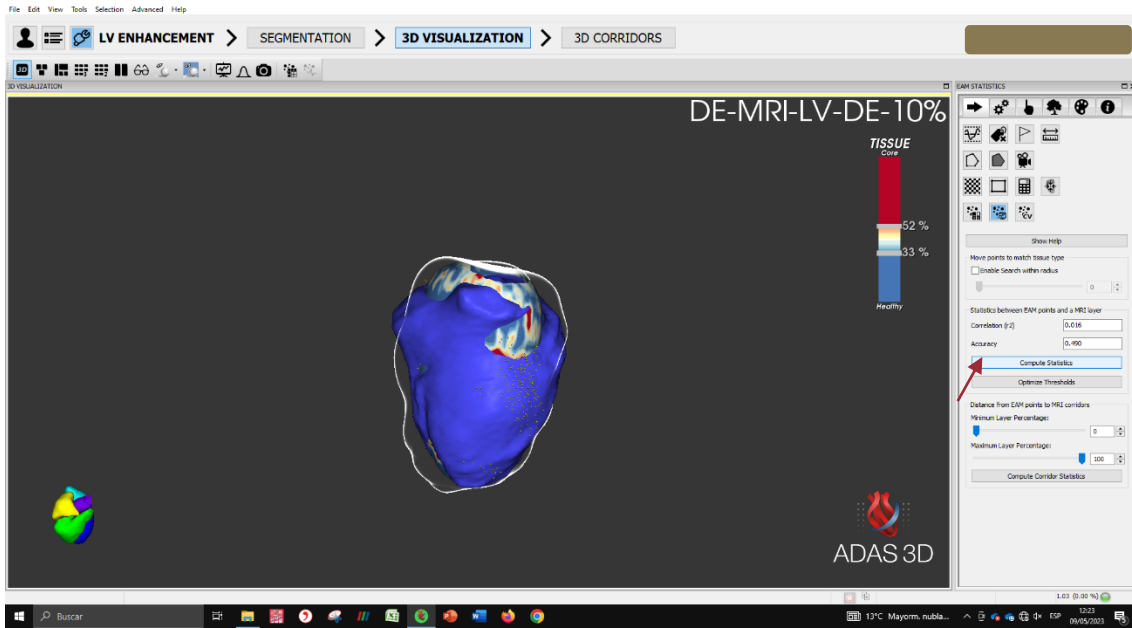




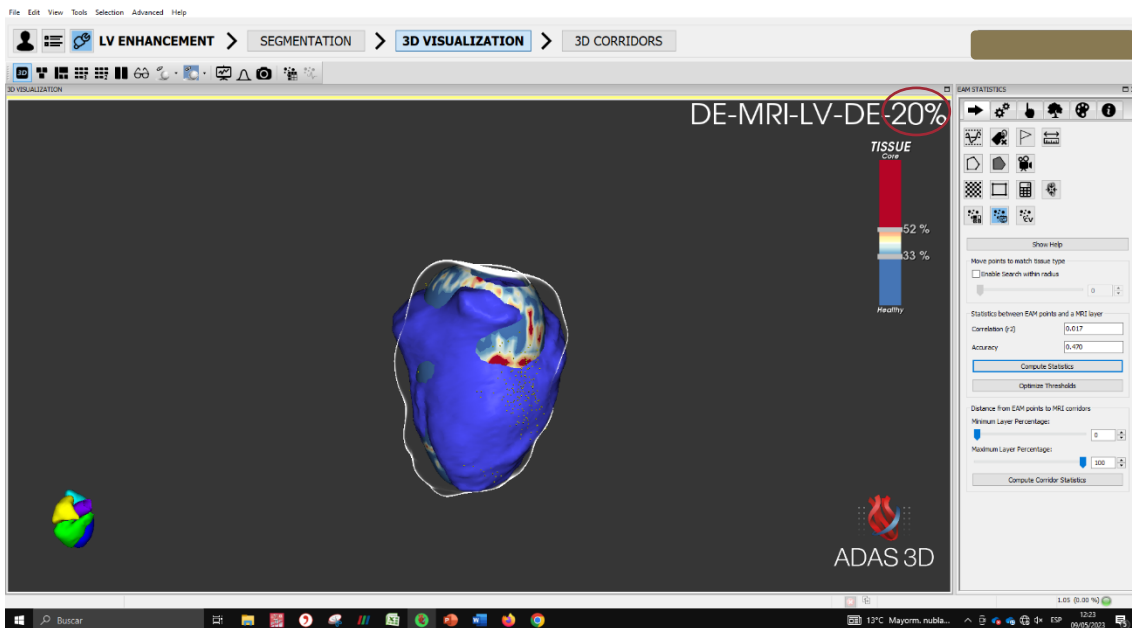
5. In the next button, assign the value from 0 to 100 to obtain the calculations for all points.

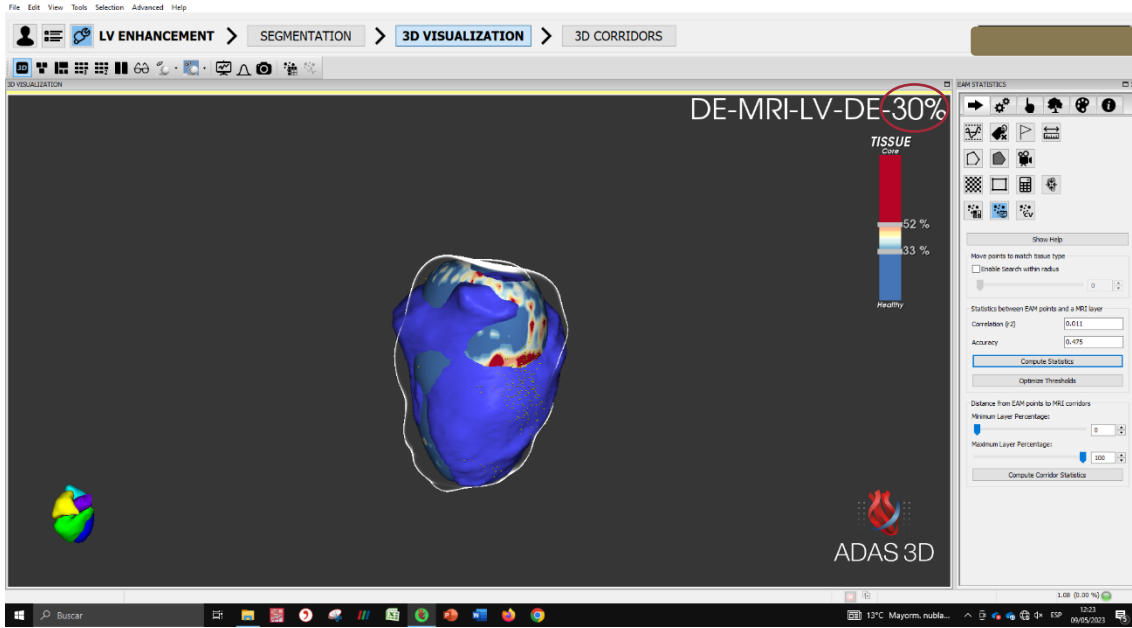


6. Click on compute statistics to determine the accuracy. This data will go to the correl_total column in the SPSS.

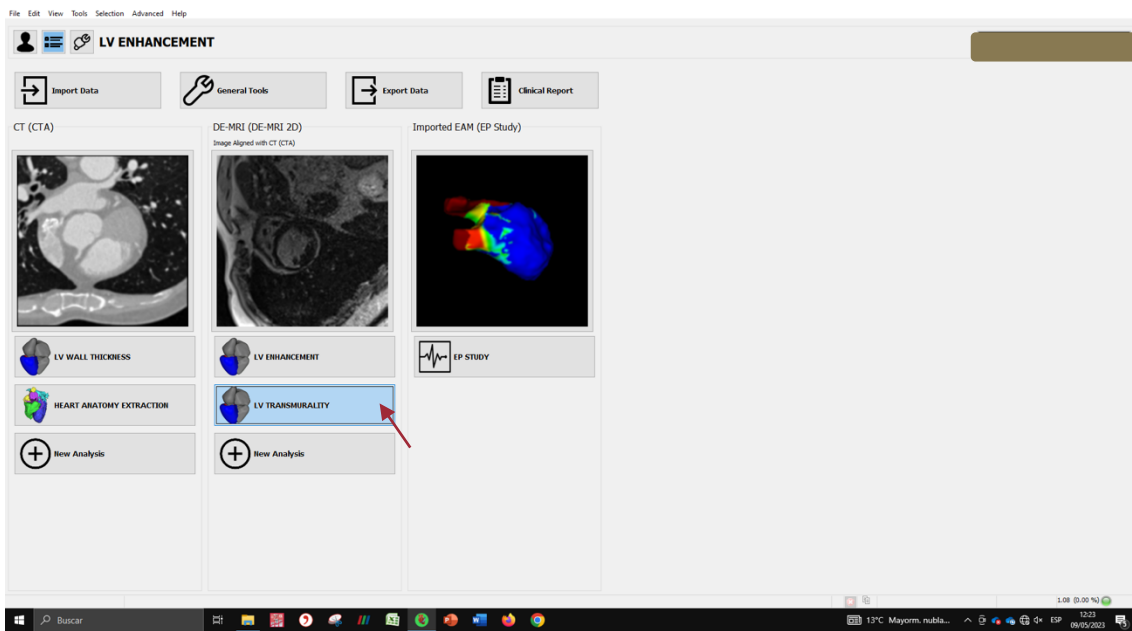


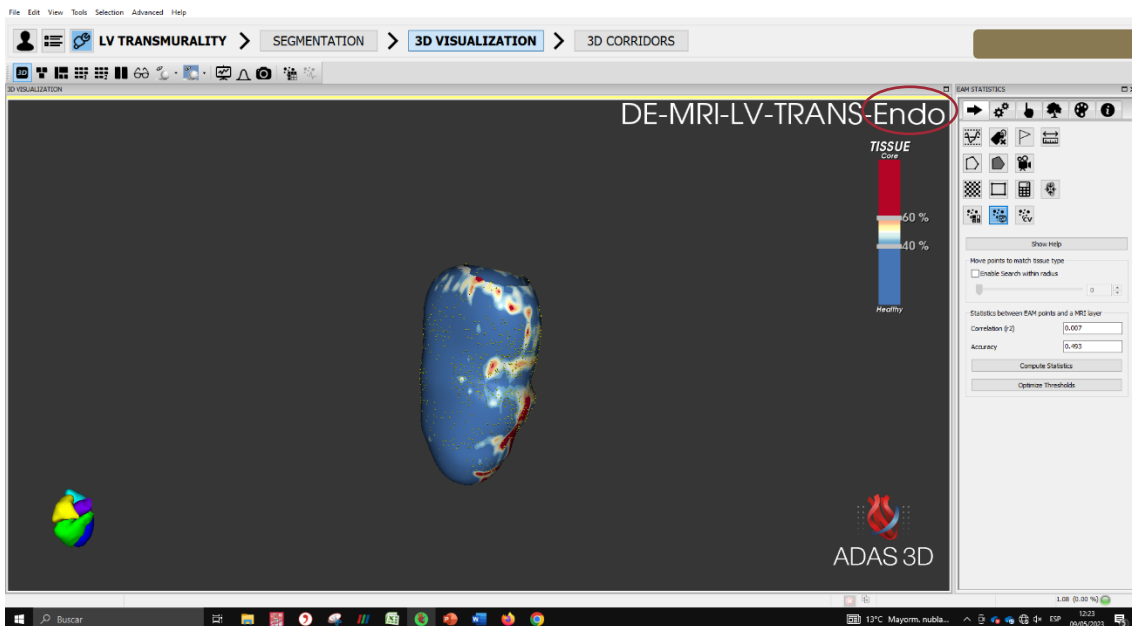
7. Do this again for each layer.





8. For the layer 50 (endo layer) go to LV transmuralty and to the steps from 4 to 6 again.



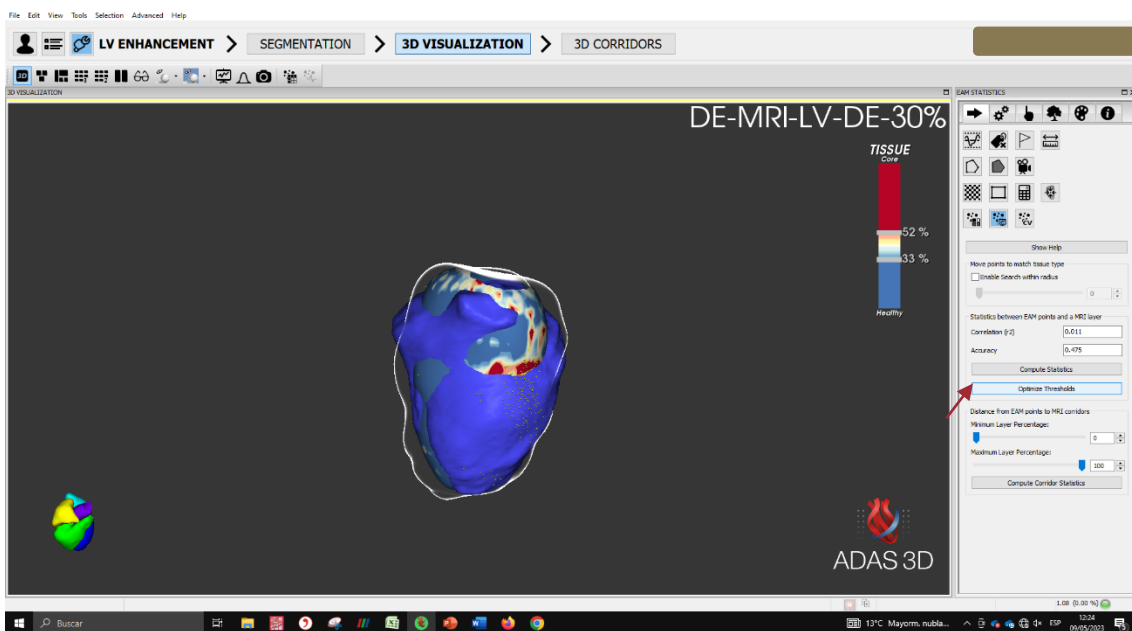


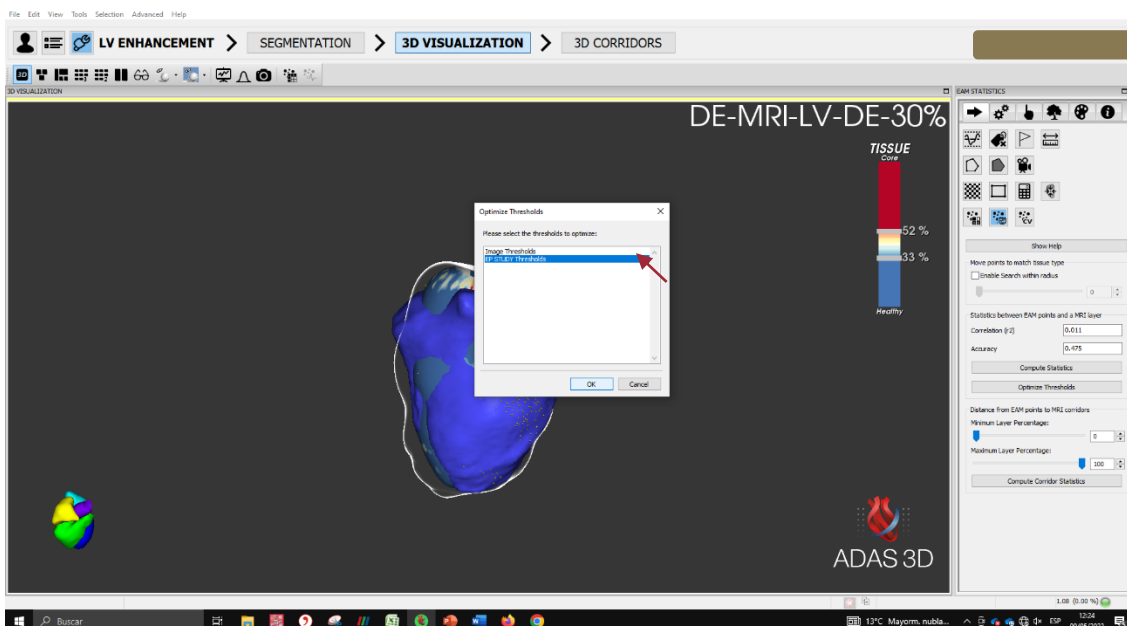
9. To steps 2 to 7 for each map.

NEW THRESHOLDS AND ACCURACY

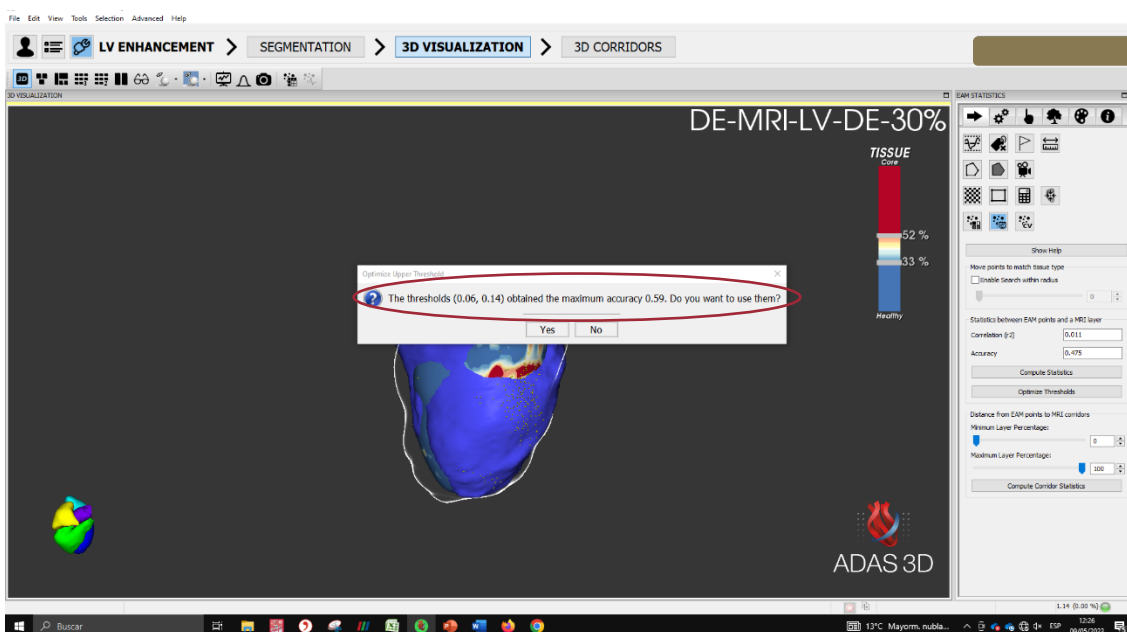
The accuracy data will be collected but this time with the new thresholds. That is why first it is needed to compute the new thresholds and then compute the new accuracy.

1. Follow steps 2 to 5. Then, in step 6, click on optimize thresholds and select EP study in the merging window. Note that the map we want to adjust is the EAM map, not the CMR map, as we are certain of its accuracy.





2. The newly generated results will show the updated thresholds and their corresponding accuracy.



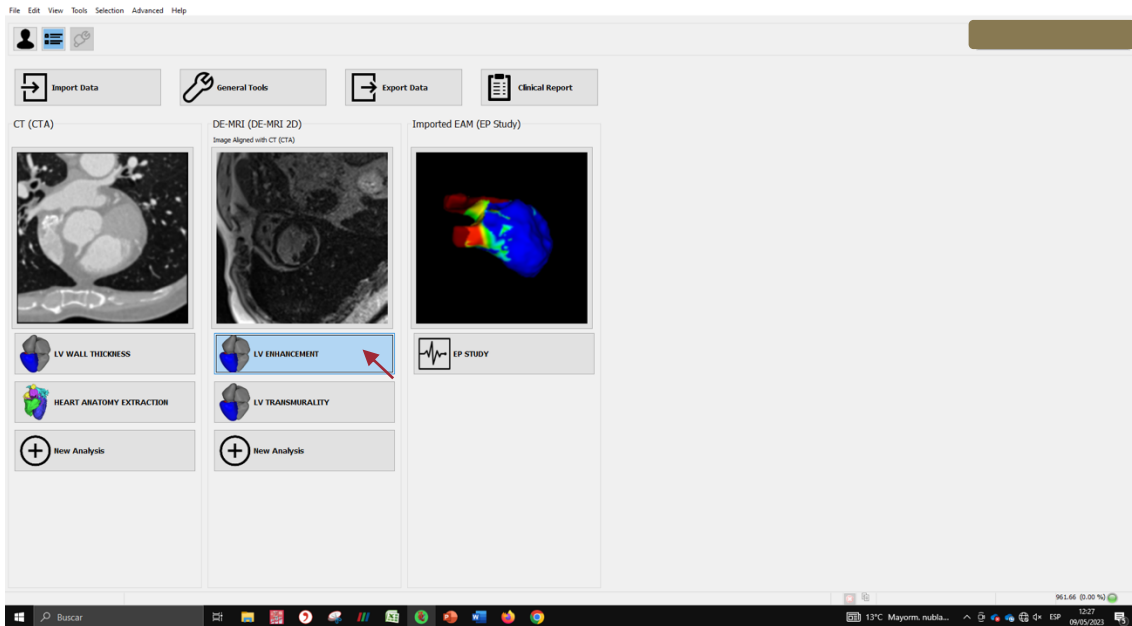
3. Add the data in the SPSS document.
4. Repeat this process for every layer and map.

ILAMS

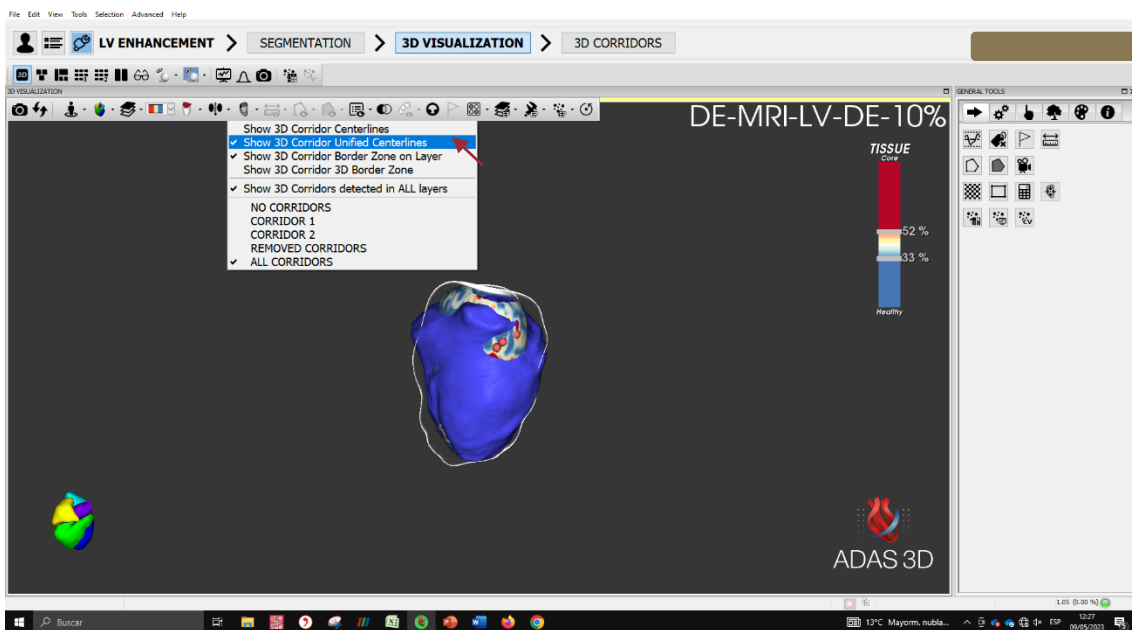
The ILAMS are the locations for each map that are considered possible channels due to a deacceleration in the signal propagation. Therefore, if we compare the ILAMS with the supposedly real corridors from the CMR map it could be determined which map (catheter configuration) is better.

In this part, the number of ILAMS for each map and their minimum distance to the nearest channel. Steps followed:

1. Open the CMR



2. Make sure the unified centerlines button is selected.



3. Select all corridors and all layers.



4. Select tissue layer 10% to view all the maps in the 3D, also select automatic 3D corridors and corridor labels.



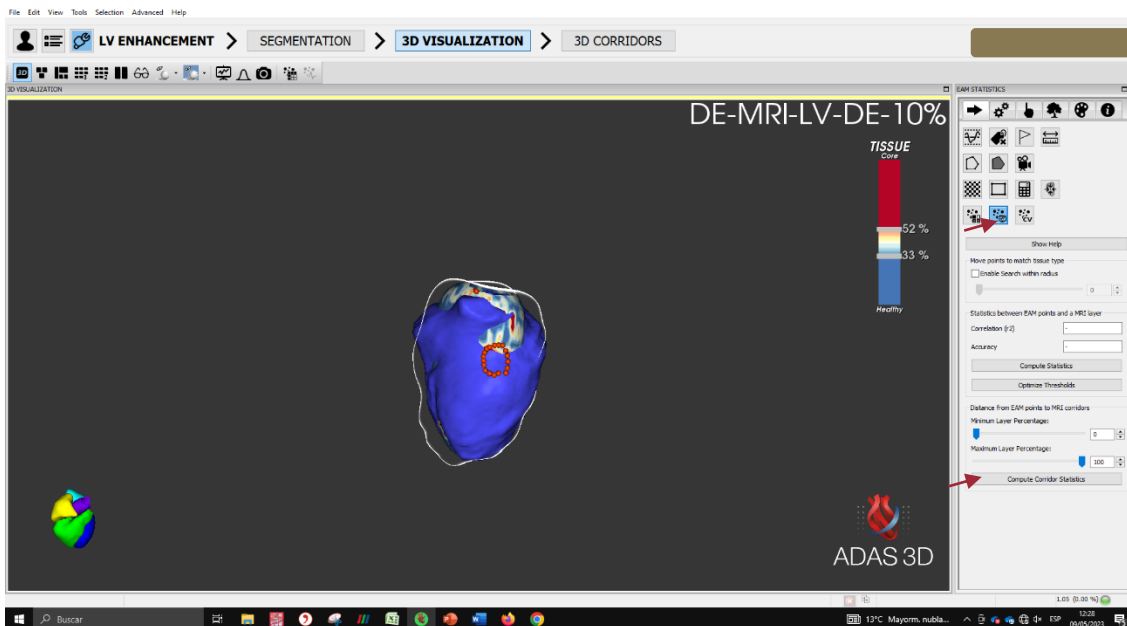
5. Select just a single ILAM each time.



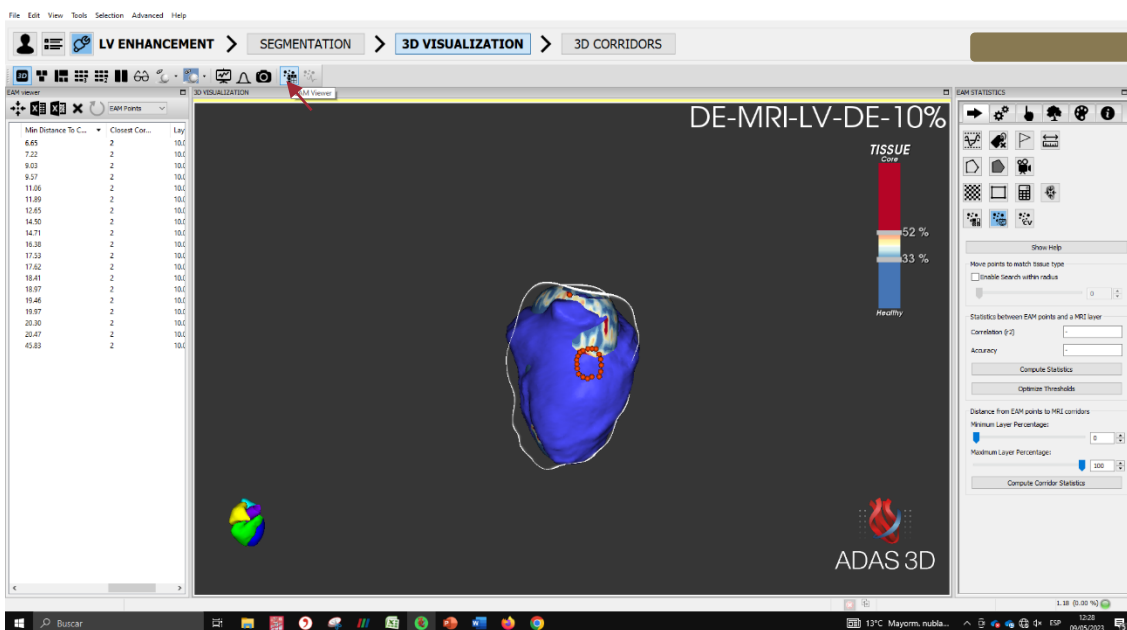
6. Assign the value from 0 to 100 to obtain the calculations for all points.



7. Click on compute corridor statistics.



8. Click on numerical data button to see the data: the nearest corridor and its minimum distance.



9. Add in the SPSS document and repeat steps 5 to 8 for each ILAM. And for each map.

RESULTS

The following section presents the results obtained from the validation and optimization of omnipolar technology in ventricular ablation procedures. The used data from the collected data includes total area of CMR in grams, invalid area (noise), border zone area, scar (core) area to compare with the EAM maps. Also, minimum and maximum optimized thresholds in millivolts (mV), total correlation for normal thresholds (0.5-1.5 mV), total correlation for new thresholds to calculate the new optimal thresholds. And number of ILAMs (Isochronal Late Activation Map) in each map,

nearest channel in each ILAM, and minimum distance from the nearest channel to ILAM in millimeters (mm).

The results were obtained using the code provided in the annex.

GENERAL MAP CORRELATION

The first set of results focuses on the correlation between each map type (bipolar, orthogonal, and omnipolar) and the CMR map based on the thresholds used. The comparison involves both the "old" maps (0.5-1.5 thresholds) and the "new" maps (optimized thresholds). These results provide a measure of the overall correlation of the maps with the CMR map, irrespective of the thresholds used. A visual representation of the results is provided through a plot.

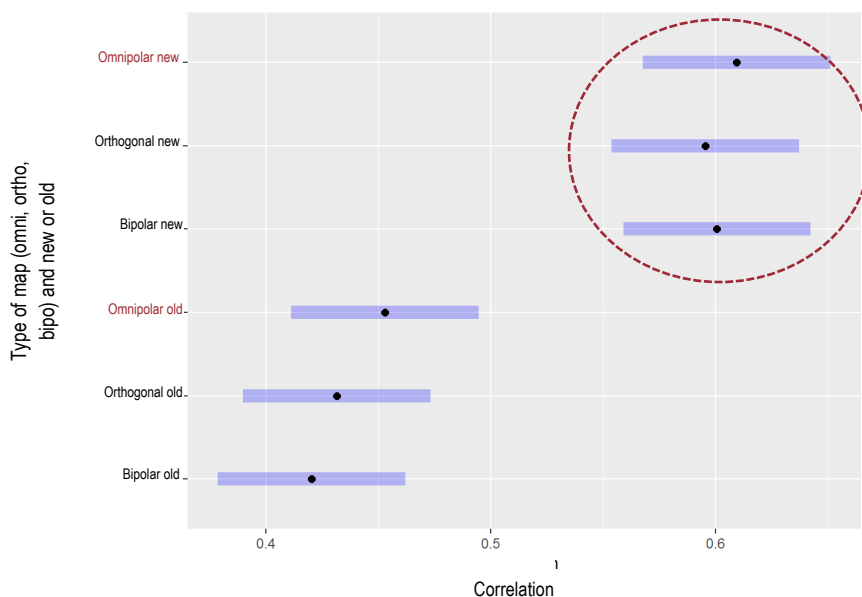


Figure 20 Correlation of old and new maps (omnipolar, orthogonal, bipolar) with CMR map

Analysis of the plot reveals that the **new maps exhibit higher correlation values compared to the old maps.**

Among the new maps, the **omnipolar map demonstrates the highest correlation** with a value of 0.609, followed by the new bipolar map with a correlation of 0.601, and the new orthogonal map with a correlation of 0.595.

Similarly, among the old maps, the omnipolar map shows the highest correlation with a value of 0.453, followed by the orthogonal map with a correlation of 0.432, and the bipolar map with a correlation of 0.420.

While the omnipolar map consistently outperforms the other maps, it is noteworthy that the **orthogonal map often exhibits correlation values close to those of the bipolar map**, contrary to the initial hypothesis.

Additionally, the results demonstrate that all the old maps exhibit a negative correlation with their respective new versions. The implications of these findings are discussed further.

CORRELATION OF MAP LAYERS

In this section, we explore the correlation between each layer of the maps and the CMR map. Specifically, data from layers 10, 20, 30, and an average of layers 10 to 50 (referred to as layer 50) were analyzed. The analysis focuses on the new maps, as the correlation of the layers in the old maps has already been established. A summary table is provided to facilitate comparison.

	10%	20%	30%	50
Bipolar	0,596	0,6	0,593	0,613
Orthogonal	0,596	0,596	0,593	0,596
Omnipolar	0,602	0,606	0,602	0,627
Mean	0,596	0,6	0,593	0,613

Table 5 Summary of correlation of each layer (10, 20, 30, 50) from each map (bipolar, orthogonal, omnipolar) with CMR map and their mean value

From the summary table, it is evident that the **omnipolar map consistently displays the highest correlation across all layers**. Notably, the results confirm that **layer 50 yields the highest correlation**, which is a significant finding. The presence of the new ADAS feature that calculates this correlation helps validate the importance of layer 50 in providing valuable information. Furthermore, layer 20 exhibits the second-highest correlation, followed by layer 10, while layer 30 appears to have the lowest correlation.

THRESHOLDS

The analysis of thresholds focuses on each layer of the maps, utilizing the data derived from the optimized thresholds. Visual examination of the results does not reveal any discernible pattern followed by the layers or maps.

However, it is noteworthy that the **lower threshold generally remains close to the previous threshold value of 0.5**. The highest minimum threshold is observed in the bipolar map at layer 50 with a value of 0.872, while the lowest minimum threshold occurs in the bipolar map at layer 20 with a value of 0.374.

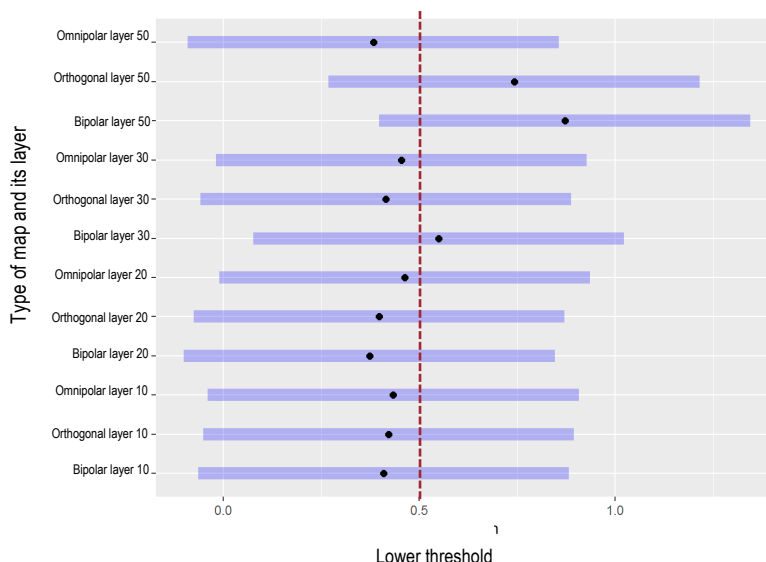


Figure 21 New mean lower threshold for each layer for each map

Concerning the **upper threshold**, **no clear pattern** emerges among the maps either. Nevertheless, it is evident that all the **maximum thresholds surpass the previously used value of 1.5**. The highest maximum threshold is observed in the bipolar map at layer 50 with a value of 3.14, while the lowest maximum threshold is found in the orthogonal map at layer 30 with a value of 1.72. In other words, even the lowest maximum threshold exceeds the value of 1.5.

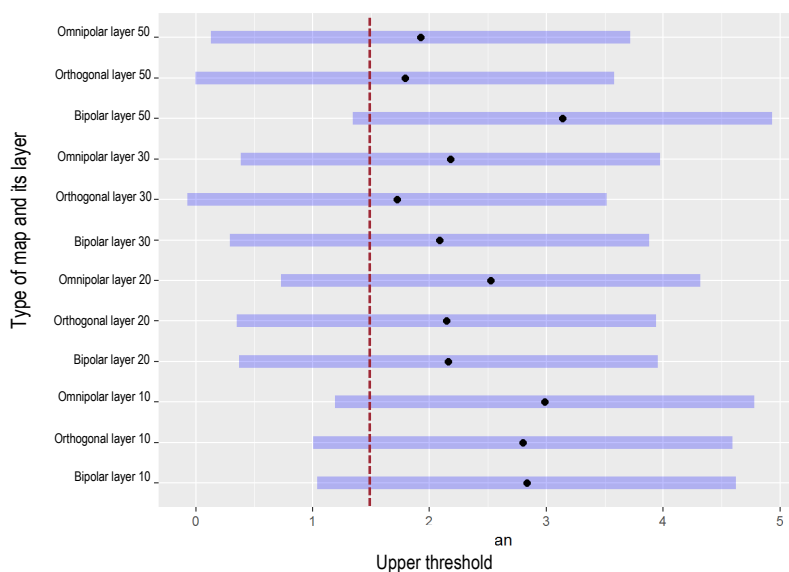


Figure 22 New mean upper threshold for each layer for each map

ILAMS

Finally, the ILAMs were analyzed to study their characteristics. As the ILAM data was not initially arranged in rows, it was grouped according to map types, and the average distances between the ILAMs and the channels were calculated. The results for each map type (without considering layers) are presented in a plot.

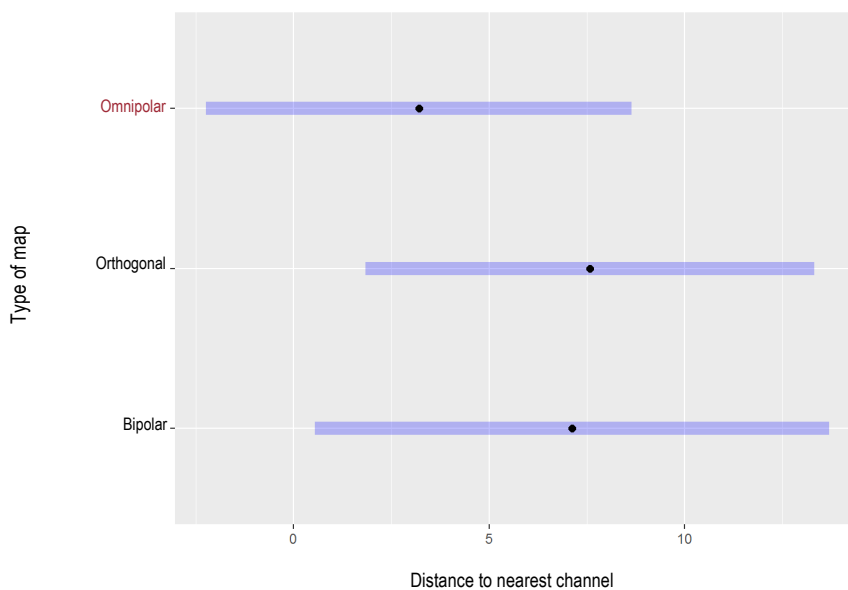


Figure 23 Mean distance to nearest channel for each map

The plot clearly demonstrates that the **omnipolar map exhibits the shortest distances between the ILAMs and the channels**, aligning with expectations. In theory, the omnipolar map is considered the most reliable, thereby resulting in closer proximity to the actual channels. The bipolar map follows, and lastly, the orthogonal map. However, it is important to note that these findings should be interpreted with caution due to limited patient data, as indicated by the **p-value being greater than 0.05**. Further investigation is necessary to provide more robust conclusions regarding these results.

DISCUSSION

GENERAL MAP CORRELATION

The results confirm our initial hypothesis that the omnipolar technology outperforms the other mapping techniques, as it consistently exhibits higher correlation with the CMR map. This higher correlation validates the effectiveness of the omnipolar map in accurately calculating voltage differences and generating reliable maps. Comparatively, the old maps demonstrate a negative correlation with their respective new maps, indicating that the new maps are superior in terms of accuracy and reliability. This also indicates that the optimization of thresholds has significantly improved the accuracy of the maps.

It is worth noting, however, that the orthogonal map often displays correlation values similar to those of the bipolar map. This is unexpected, as we anticipated more distinct differences between the two, with the orthogonal map being the second best and the bipolar map being the worst.

CORRELATION OF MAP LAYERS

The analysis of map layer correlation confirms the consistent superiority of the omnipolar map across all layers. This emphasizes the reliability and effectiveness of the omnipolar technique in capturing activation patterns within the ventricles. **Notably, layer 50 consistently demonstrates**

the highest correlation, which aligns with expectations since it represents the average of the pixels from layers 10 to 50. This comprehensive view of the ventricular tissue makes layer 50 (which is important to recall that is the median of the pixels of the 5 first layers, the endocardium) particularly informative and valuable for ventricular ablation procedures.

Furthermore, the correlation analysis reveals that layer 20 closely follows layer 50 in terms of correlation and then layer 10 ranks third in correlation. In contrast, layer 30 consistently exhibits the lowest correlation. This can be attributed to its greater distance from the endocardium, which is the region where the catheter passes through and where electrical signals are most concentrated. The reduced sensitivity of layer 30 to electrical signals explains its lower correlation compared to other layers.

THRESHOLDS

The absence of clear patterns in the threshold analysis highlights the need for more extensive data and patient samples to draw definitive conclusions. **Currently, we can only suggest that the best threshold for ventricular ablation procedures is one tailored specifically to each individual patient.** This individualized approach ensures the most accurate and effective treatment.

Upon examination, it is evident that the optimized **lower thresholds remain near the previously used threshold value of 0.5 mV.** This indicates that the optimization process has not significantly deviated from the established threshold standards commonly employed in ventricular ablation procedures. However, the **maximum thresholds of the new maps surpass the previous threshold value of 1.5 mV. This signifies that the optimized thresholds now allow for the capture of a broader range of electrical signals.**

ILAMS

The analysis of ILAMs provides compelling evidence supporting the superiority of the omnipolar technology. The results clearly demonstrate that **the ILAMs in the omnipolar map are closest to the nearest channels,** indicating its high reliability and accuracy in capturing the true spatial relationship within the ventricles.

However, it is important to acknowledge the limitations of the study, including the restricted availability of patient data and the higher p-value. These factors call for caution when interpreting the results and emphasize the need for further investigation with a larger sample size. Conducting additional research will enable us to draw more definitive and conclusive findings regarding the relationship between ILAMs and the nearest channels in different mapping techniques.

APPLICATIONS

The results and findings of this project have significant applications in the field of ventricular mapping and ablation procedures. Some potential applications include:

- **Enhanced Mapping Techniques:** The study demonstrates the superiority of the **omnipolar** mapping technique in terms of correlation with the CMR map and proximity to the nearest channels. This finding highlights the potential of the omnipolar map to provide more reliable and accurate information about activation patterns in the ventricles. Clinicians can leverage this technique to improve the precision and effectiveness of ventricular mapping procedures.
- **Selection of Informative Map Layers:** The analysis of map layer correlation reveals the importance of specific layers, particularly **the median of the first 5 layers (called in this study layer 50)**, in capturing informative data about the ventricular tissue. By considering the correlation of different layers, before the ablation when evaluating and studying the maps, what it will be more like the reality it will be the median of these 5 layers and then during the ablation to see the specific thresholds for each patient.
- **Optimization of Thresholds:** Although the threshold analysis did not yield clear patterns, it suggests that individualized thresholds tailored to each patient are essential for effective ventricular ablation procedures. Clinicians can utilize the previously established threshold value of **0.5 mV** as a reference while considering the **expanded range of upper thresholds** allowed by the optimized thresholds. This expanded range enables the capture of a broader range of border zone tissue.
- **Validation of Mapping Techniques:** The project provides validation for the effectiveness of different mapping techniques, including omnipolar, bipolar, and orthogonal mapping. The higher correlation values observed with the omnipolar map support its reputation as a reliable technique capturing a broader range of electrical signals.
- **Future Research and Collaboration:** The study highlights the need for further investigation with a larger sample size to validate and extend the current findings. Collaborations with organizations like ADAS and Abbott offer opportunities for future research and development of software and mapping technologies. Continued research in this field can lead to advancements in ventricular mapping and ablation procedures, ultimately benefiting patient outcomes and minimizing recurrences.

EXECUTION SCHEDULE

This section explores the strategies implemented to optimize project organization and enhance productivity.

The successful execution of any project, including the one at hand, relies on meticulous organization and thoughtful planning of tasks and timelines. Without effective project management, distractions can hinder progress and derail the project, diverting attention away from established objectives. A clear comprehension of what needs to be accomplished and when is crucial for fostering a productive and efficient work environment. Hence, it is imperative to recognize the significance of project management and planning throughout the development process.

The subsequent sections delineate three techniques employed to organize this project, highlighting their purpose and benefits. These techniques include the utilization of a Work Breakdown Structure (WBS), a Program Evaluation and Review Technique that incorporates the Critical Path Method (PERT-CPM), and a GANTT diagram.

WORK BREAKDOWN STRUCTURE (WBS)

The Work Breakdown Structure (WBS) involves breaking down the project scope into smaller, manageable tasks. The primary work groups are grouped together as packages, and further divided into smaller tasks necessary to complete them. This hierarchical decomposition of work into packages facilitates a clear delineation of the project scope and provides a visual representation of the workload within each package. It is crucial to follow these steps to ensure a systematic progression in the project's development.

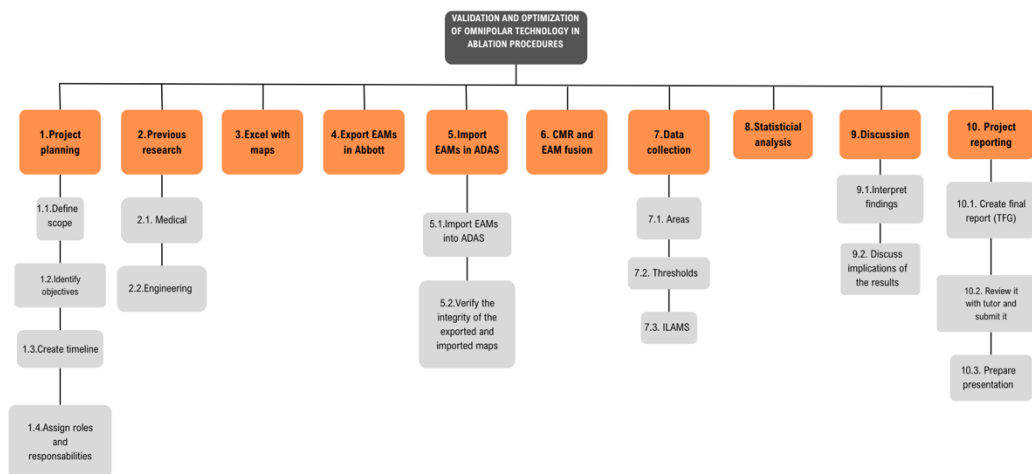


Figure 24 Work breakdown structure scheme

As seen, the project is divided into 10 work packages. Each package includes multiple tasks that must be completed to ensure the package's fulfillment. To understand better the specific details and requirements of each task, a WBS dictionary has been developed.

DICTIONARY

ID	Name	Description
----	------	-------------

1 Project Planning		
1.1	Define project scope	Define the boundaries of the project, including its objectives, deliverables, and limitations
1.2	Identify project objectives	Identify the goals and objectives that the project aims to achieve.
1.3	Create project timeline	Develop a timeline for the project that includes all necessary tasks, milestones, and deadlines
1.4	Assign roles and responsibilities	Assign tasks and responsibilities specially of the author

2 Previous research		
2.1	Medical	Conduct research on ventricular tachycardia, ablation, and other relevant medical topics.
2.2	Engineering	Conduct research on catheters, mapping, and other relevant engineering topics.

3	Identification of maps	Dra. Sara Vázquez will handle the identification of the maps that we will use in the project. After determining which maps to export, import, etc., we will create a detailed table, such as an excel spreadsheet. The table is crucial for effective organization and tracking of patient maps and relevant information. This approach will enable proper monitoring of map-related activities, including data extraction, import/export operations, and other essential tasks throughout the project
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4 Export EAM maps in Abbott

Export EAM maps from Abbott software in a hard drive

5 Importing maps in ADAS

5.1	Import EAM maps into ADAS	Import EAM maps from Abbott into ADAS software with the hard drive.
5.2	Verify the integrity of the imported maps	Check the accuracy and completeness of the imported maps to ensure that they are correct and suitable for analysis

6	CMR and EAM Fusion	To integrate the data from CMR map with the data from EAM map to obtain a complete map of the heart and specially its channels
---	---------------------------	--

7 Data Collection

7.1	Areas	Collect data on the total area, invalid area, border zone area, and scar area all in grams, as well as the number of channels with their length and mass in millimeters and grams
7.2	Thresholds	Calculate and collect the data of new minimum and maximum optimized thresholds, the total correlation for normal thresholds (0.5-1.5), and total correlation for the new optimized thresholds
7.3	ILAMS	Collect data on the number of ILAMS, the nearest channel in each ILAM, and the minimum distance from the nearest channel to ILAM in millimeters

8	Statistical Analysis	<p>Perform statistical analysis on the collected data using appropriate methods using lmer and emmeans functions with the appropriate variable for each finding:</p> <ul style="list-style-type: none"> • Correlation of EAM maps with CMR map • Correlation of each layer of each EAM map with CMR map • New mean lower and upper thresholds • Minimum mean distance to the nearest channel for each map
---	-----------------------------	---

9 Discussion		
9.1	Interpret the findings	Interpret the results of the statistical analysis and draw conclusions about the project's objectives and goals
9.2	Discuss the implications of the results	Discuss the potential implications of the project's findings.

10 Project Reporting		
10.1	Create a final report (TFG)	Compile all project information and data into a final report, the TFG per se.
10.2	Review it with tutor and submit it	Review the report with the project tutor (Paz Garre) and submit it for evaluation, 6 th of June 2023.
10.3	Prepare the presentation	Prepare a presentation of the project's findings and results to be evaluated as a part of the TFG's evaluation. Week of the 12 th of June.

Table 6 WBS dictionary

PERT-CPM DIAGRAM

To ensure efficient task coordination and timely project completion, a PERT-CPM diagram has been created. This diagram provides a visual representation of the tasks, their respective timings, and their interdependencies. It identifies the order in which tasks must be carried out, distinguishing between precedence and subsequent tasks. By computing the "early" and "late" times, the critical path can be determined, which determines the project's duration. These concepts will be elaborated on in the following section. Firstly, a table detailing the chronological dependencies and durations of each task has been prepared.

ID WBS	ID PERT	Abbreviated title	Previous activity	Time (days)
1.1	A	Scope	-	1
1.2	B	Objectives	A	1
1.3	C	Timeline	B	1
1.4	D	Roles	C	1
2.1	E	Medical	D	3
2.2	F	Engineering	E	5
3.0	G	Identification maps	F	28

4.0	H	Export	G	10
5.1	I	Import	H	2
5.2	J	Verify import	I	1
6.0	K	Fusion CMR-EAM	J	5
7.1	L	Area	K	3
7.2	M	Threshold	L	3
7.3	N	ILAM	M	3
8.0	O	Statistics	N	5
9.1	P	Interpret results	O	2
9.2	Q	Discuss	P	2
10.1	R	Write TFG	F, Q	124 (4 months)
10.2	S	Review and submit	R	3
10.3	T	Presentation	S	5

Table 7 Tasks precedencies and timings

Based on these task dependencies, the chronological order of tasks is established. This ensures that a task cannot commence until its preceding task has been completed, although multiple tasks can be performed simultaneously. In this case, it is seen that all activities are sequential and so can't start before the previous has finished except for activity R which can start when F is done although will also need the end of Q to finish. By calculating the early and late times, we can determine the critical path.

To gain a better understanding of these concepts, let's define each of them:

- Early time: The minimum time required to complete a task. It represents the earliest possible moment at which a task can begin.
- Late time: The latest allowable time for completing a task. It represents the maximum time a task can reach before causing a delay.
- Critical path: The sequence of activities that, if delayed, would impact the final project timeline. It is the longest path in terms of duration and has a direct influence on the overall project schedule.

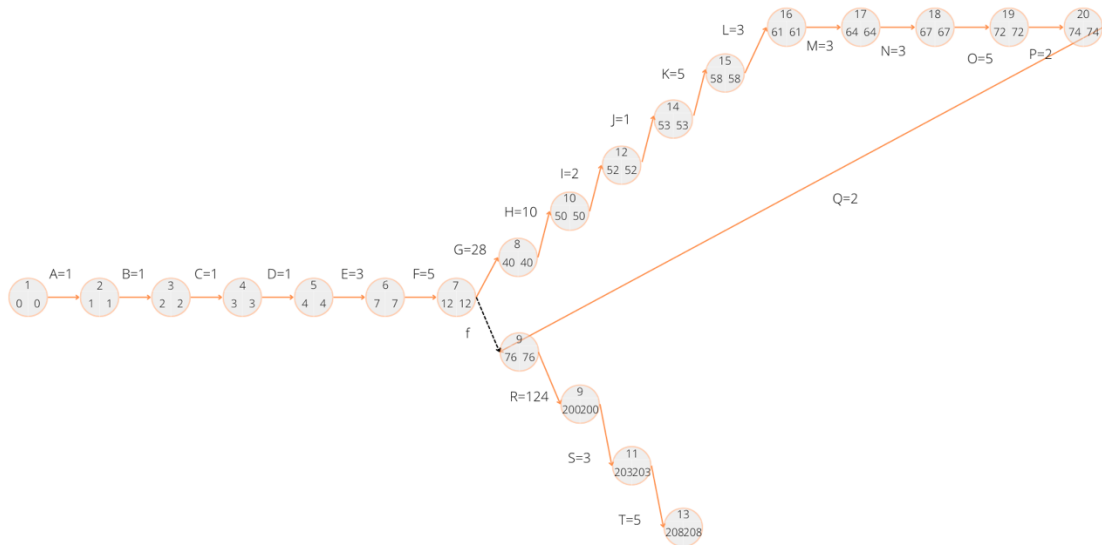


Figure 25 PERT-CPM diagram

The critical path of our project involves all activities, which makes sense because is mostly a sequential project where each activity must start once the previous has finished. It is seen that activity R that has F and Q as previous activities which does not affect the path. As seen in the diagram, the project would take 208 days.

GANTT DIAGRAM

The GANTT diagram is used to present the sequence of tasks over time, providing a visual representation of the project's progression. This diagram allows us to easily identify the start and end dates of each activity, the duration allocated to each task, any overlapping activities, and, most significantly, establish the project's overall start and finish dates. This graphical representation offers a comprehensive understanding of the temporal evolution of the project.

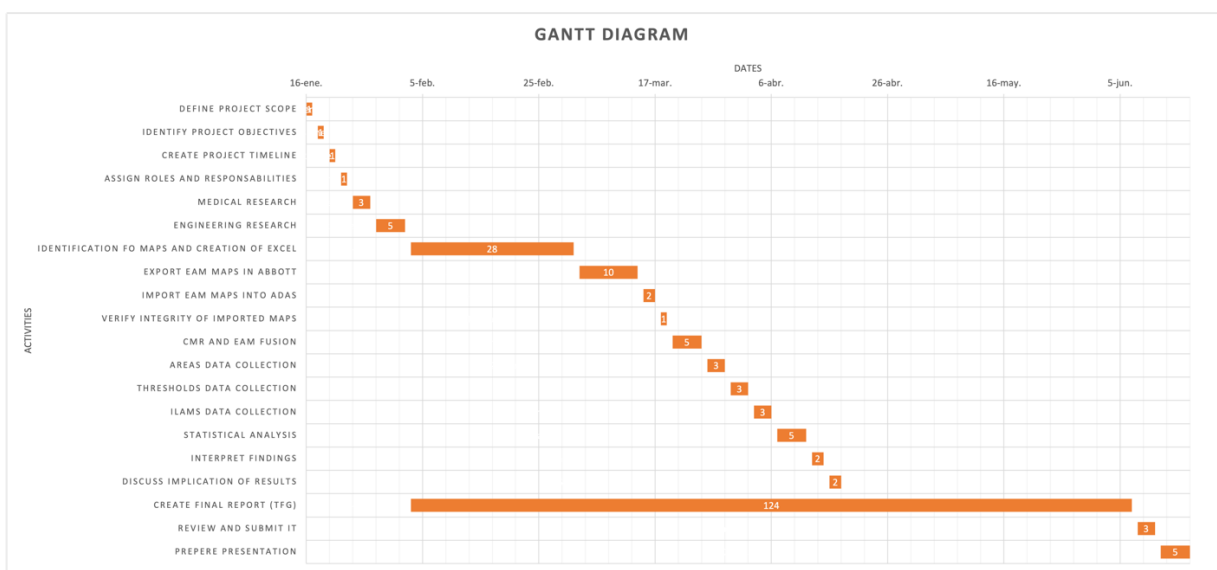


Figure 26 GANTT diagram

The project's timeline is set **from January 16th to June 7th**, culminating in the submission of the TFG report. Thus, the project's duration spans slightly **less than five months**. Notably, the writing of the TFG report is the lengthiest task within the project.

TECHNICAL VIABILITY

The technical viability of combining Late Gadolinium Enhancement Cardiovascular Magnetic Resonance (LGE-CMR), HD Grid catheters from Abbott, and segmentation from ADAS for ventricular tachycardia ablation is a promising approach.

LGE-CMR is a non-invasive imaging technique that provides detailed information on the distribution and extent of fibrosis in the myocardium, which can be useful for identifying the regions of interest for ablation. This analysis is done with ADAS, which is a software that can provide advanced image processing and segmentation capabilities, which can aid in identifying the areas of interest within the heart and assist in the planning and guidance of the catheter ablation procedure.

HD Grid catheters allow for high-resolution mapping of the electrical activity in the heart, which is crucial for identifying the arrhythmia and accurately targeting the ablation therapy.

Studies have shown promising results for the use of LGE-CMR, HD Grid catheters, and ADAS segmentation in ventricular tachycardia ablation. For example, a study published in the Journal of Cardiovascular Electrophysiology in 2020 (34) reported a success rate of 91% using LGE-CMR in combination with HD Grid catheters and ADAS segmentation for ventricular tachycardia ablation.

However, there are potential limitations to the use of this approach. For instance, LGE-CMR may not be appropriate for all patients, and there may be contraindications or limitations for its use in certain cases. In addition, there may be a learning curve for medical professionals who are not familiar with the use of HD Grid catheters or ADAS software, and the cost of the necessary equipment and software may be a barrier for some healthcare facilities.

Overall, it can be stated that the project is technically viable. Furthermore, a SWOT analysis has been conducted to study better this viability.

SWOT ANALYSIS

STRENGTHS

In terms of internal strengths, the project is significant in the field of ventricular tachycardia ablation and mapping systems. The use of HD Grid catheter from Abbott is advantageous as it provides more accurate and detailed mapping system than other methods. The differences between various catheter types could lead to new insights into ventricular tachycardia ablation. The combination of LGE-CMR, HD Grid catheters, and ADAS segmentation allows for a comprehensive and targeted approach to ventricular tachycardia ablation. ADAS software provides advanced image processing and segmentation capabilities, which can aid in the planning and guidance of the catheter ablation procedure.

WEAKNESSES

In terms of internal weaknesses, obtaining accurate and reliable data may pose a challenge for the project due to the limited time and number of patients available for study. The project may have

limited applicability outside of ADAS software and HDGrid catheter from Abbott. LGE-CMR may not be appropriate for all patients, and there may be contraindications or limitations for its use in certain cases.

OPPORTUNITIES

As for external opportunities, the results of the project could lead to improvements in the design and implementation of mapping systems used in ADAS, which could potentially lead to new treatment approaches for ventricular tachycardia. The project could attract funding or partnership opportunities from industry stakeholders interested in improving ADAS and catheter technologies. The combination of LGE-CMR, HD Grid catheters, and ADAS segmentation may allow for more effective and targeted ventricular tachycardia ablation, leading to improved patient outcomes.

THREATS

As for external threats, the project may encounter unexpected technical or logistical challenges that could delay or derail progress. The project may not yield significant findings or results, leading to potential disappointment or lack of interest from stakeholders.

Below, a table summarizing the technical viability explained above:

		Strengths	Weaknesses
Internal		<ul style="list-style-type: none"> Addresses important issue in ventricular tachycardia ablation and mapping systems. HD Grid from Abbott provides more accurate and detailed mapping. Investigating different catheter types may lead to new insights. LGE-CMR provides non-invasive imaging of myocardial fibrosis. HD Grid catheters allow high-resolution mapping. ADAS software provides advanced image processing and segmentation 	<ul style="list-style-type: none"> Requires large number of patients and time. Obtaining accurate and reliable data may pose a challenge. Limited applicability outside of ADAS and HDGrid catheter LGE-CMR may not be appropriate for all patients.
	External	Opportunities	Threats
		<ul style="list-style-type: none"> Improvements in mapping systems for ADAS New treatment approaches for ventricular tachycardia Attract funding or partnership opportunities. More effective and targeted ventricular tachycardia ablation 	<ul style="list-style-type: none"> Unexpected technical or logistical challenges Potential lack of significant findings or results

Table 8 Summary of SWOT analysis

ECONOMIC VIABILITY

The project demonstrates economic viability as it does not incur any direct costs. The mapping process and identification are already completed, requiring no additional expenses. Moreover, the center conducts the CMR as part of the procedure, eliminating the need for additional payments. Additionally, the collaboration with ADAS and Abbott for software development further enhances the project's financial benefits. This win-win situation allows them to receive valuable feedback for their product while we can leverage their software without incurring any monetary expenses. This mutually beneficial collaboration ensures that both parties can achieve their goals without any financial burden.

LEGISLATION AND REGULATION

It is crucial to consider legislation and regulation when dealing with projects that involve personal information from patients.

The Spanish Agency for Medicines and Medical Devices (AEMPS) is responsible for regulating medical research involving human subjects in Spain. The agency is responsible for ensuring that any research involving human subjects complies with the principles of Good Clinical Practice (GCP) and the ethical principles outlined in the Declaration of Helsinki. This includes ensuring that the study is scientifically sound and that the risks to human subjects are minimized (35).

The use of personal data, including the heart mapping and the patient personal information included, in medical research is regulated by the General Data Protection Regulation (GDPR) and the Organic Law on Data Protection and Guarantee of Digital Rights (LOPDGDD) in Spain. The GDPR provides strict rules on the processing of personal data, including requirements for explicit consent, data security, and data anonymization. The LOPDGDD provides additional regulations on the processing of personal data, including rules on the use of biometric data (36).

To ensure compliance with these regulations, medical researchers in Spain must obtain explicit consent from patients for the use of their personal data in research. This consent must be informed, voluntary, and revocable at any time (37). In addition, researchers must take appropriate measures to protect the confidentiality and security of patient data and provide patients with the right to access and correct their data (38).

Ethical considerations are also crucial in medical research involving human subjects. In Spain, the Spanish Biomedical Research Act (Ley de Investigación Biomédica) regulates medical research involving human subjects and outlines the ethical principles that must be followed. These principles include obtaining informed consent from patients, protecting patient confidentiality, and ensuring that the benefits of the research outweigh any potential risks (39).

Finally, data anonymization is a critical consideration in medical research to protect patient privacy. In Spain, the GDPR requires that personal data be processed in a way that ensures appropriate security and confidentiality and that any identifiable personal data be anonymized or pseudonymized to protect the privacy of patients. Researchers must take appropriate measures to ensure that patient data is properly anonymized to prevent the identification of individual patients (40).

CONCLUSIONS

Regarding the most significant and crucial aspect, namely the study's results, it can be concluded that:

- The maps with the new thresholds, particularly the omnipolar map, showed higher correlation values with the CMR map compared to the old maps, indicating **improved accuracy and reliability**.
- The **omnipolar map** consistently outperformed the orthogonal and bipolar maps in terms of correlation, while the orthogonal map often showed correlation values similar to the bipolar map.
- **The median of the 5 first layers (in this study called layer 50)** consistently exhibited the highest correlation, followed by layer 20 and layer 10, while layer 30 had the lowest correlation due to reduced sensitivity to electrical signals.
- The optimized **lower** threshold for mapping remained close to the previously used threshold value of **0.5 mV** but the optimized **upper threshold increased** allowing for capturing a broader range of electrical signals.
- The **omnipolar map** demonstrated the closest proximity of Islands of Local Activation Mapping (**ILAMs**) to the nearest channels, indicating its reliability and accuracy in capturing the true spatial relationship within the ventricles.

Moreover, numerous conclusions can be drawn from the project and its various sections. Regarding each section, the following conclusions can be made:

- The project **successfully aimed to enhance the effectiveness of ablation procedures** for ventricular tachycardia (VT) by accurately mapping reentrant channels responsible for the arrhythmia.
- The use of the **HD Grid catheter and the EnSite X system**, along with different mapping techniques such as bipolar, orthogonal, and omnipolar signals, was investigated in the study.
- Electro-Anatomical Maps (**EAMs**) created through these techniques were **compared** with Cardiac Magnetic Resonance (**CMR**) maps to evaluate their accuracy in identifying channels.
- The findings contribute to the development of more effective ablation procedures and improved patient outcomes in the field of VT treatment.
- The project's results have **important applications** in ventricular mapping and ablation procedures, emphasizing the need for further research and collaboration to advance the field and improve patient outcomes.
- The project is **economically and technically viable** as it leverages existing collaborations without additional financial burden.
- Legislation and regulation, including AEMPS, GDPR, LOPDGDD, and the Spanish Biomedical Research Act, govern the use of patient personal information and require informed **consent, data protection**, and ethical considerations in medical research.

FUTURE WORK

Based on the findings and limitations discussed in this project, several avenues for future research and development can be explored to further enhance the understanding and treatment of ventricular tachycardia (VT). The following are some potential areas of focus:

- **Live Wavefront Visualization:** Conducting a study using omnipolar technology to visualize live wavefronts with each heartbeat can provide valuable insights into the electrical activity and dynamics of the heart during ventricular tachycardia (VT).
- **Long-Term Clinical Outcomes:** Comparing the outcomes of older patient populations who underwent ablation using traditional techniques (bipolar, orthogonal) with newer patient populations who received ablation exclusively with omnipolar technology can help assess the long-term effectiveness and benefits of the latter approach.
- **Threshold Database Analysis:** Expanding the patient cohort and conducting a comprehensive analysis of the thresholds used in tissue characterization during ablation procedures can help identify patterns and establish more accurate and reliable threshold values, particularly for the upper threshold. Collaboration among multiple centers can enhance the statistical power of the analysis and improve the generalizability of the findings.
- **Integration of Advanced Technologies:** One potential area of focus for future research is the integration of advanced technologies, such as artificial intelligence (AI), to enhance the fusion of Cardiac Magnetic Resonance (CMR) and Electro-Anatomical Maps (EAM). This integration can improve the accuracy and reliability of identifying critical regions associated with ventricular tachycardia (VT). Additionally, AI can assist in the identification and analysis of Isochronal Late Activation Maps (ILAMs), which are currently manually performed by cardiologists.

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ANNEXES

CODE AND RESULTS

LIBRARIES NEEDED

```

library(ggplot2)
library(gridExtra)
library(RcmdrMisc)
library(foreign)
library(survival)
require(rms)
require(tidyverse)
require(lme4)
library(multcomp)
library(emmeans)
library(readxl)
library(visdat)
library(randomForest)
library(corrplot)
library(FactoMineR)
library(rms)
library(rpart)
library(pROC)
library(partykit)
library(plyr)
library(lmerTest)
library(pbkrtest)
library(car)
library(gtsummary)
library(epiDisplay)
library(survminer)
library(pROC)

setwd("C:/Users/rborras/Desktop/1. ROGER/791. OT UMBRALES")

```

```
dades <- read.spss("OT_Lali_PAZ_Roger.sav", use.value.labels=TRUE, max.value.labels=Inf, to.data.frame=TRUE)
names(dades)
```

VARIABLES STUDIED

```
## [1] "fet"          "NHC"          "MAPA"
## [4] "NEW"          "CAPA"         "SIGNALS"
## [7] "ThresholdMin" "ThresholdMax" "CorrelatTotal"
## [10] "Notas"        "NOTAS0"       "NOTAS1"
## [13] "NOTAS2"       "DateAblation" "Número"
## [16] "fusionRMN"    "DateCMR"      "TipoCMR"
## [19] "Comentarios"  "Total_Area_MRI" "Invalid_area_MRI"
## [22] "BZ_Area_MRI"  "Scar_Area_MRI" "ChannelsCMR"
## [25] "LongC1"       "MassC1"       "LongC2"
## [28] "MassC2"       "LongC3"       "MassC3"
## [31] "LongC4"       "MassC4"       "LongC5"
## [34] "MassC5"       "LongC6"       "MassC6"
## [37] "LongC7"       "MassC7"       "LongC8"
## [40] "MassC8"       "LongC9"       "MassC9"
## [43] "LongC10"      "MassC10"      "Number_ILAMs_Basal"
## [46] "ILAM1canalCercano" "Distancia1MinChannel" "ILAM2canalmascerc"
## [49] "Distancia2Minchannel" "ILAM3canalmascerc" "Distancia3MinChannel"
## [52] "ILAM4canalmascerc" "Distancia4MinChannel" "ILAM5canalcercano"
## [55] "Distancia5minchannel"
```

GENERAL MAP CORRELATION

```
# Fit a linear mixed-effects model
model_int <- lmer(CorrelatTotal ~ MAPA*NEW + (1|NHC), data=dades)

# Calculate estimated marginal means
emmeansmodel_int <- emmeans(model_int, ~MAPA*NEW)

# Print the estimated marginal means
emmeansmodel_int

# Create a plot of the estimated marginal means
```

```
plot(emmeansmodel_int)
```

```
## MAPA NEW emmean SE df lower.CL upper.CL
## BIP no 0.420 0.02 20.5 0.379 0.462
## HD_WAVE no 0.432 0.02 20.5 0.390 0.473
## OMNI no 0.453 0.02 20.5 0.411 0.495
## BIP si 0.601 0.02 20.5 0.559 0.642
## HD_WAVE si 0.595 0.02 20.5 0.554 0.637
## OMNI si 0.609 0.02 20.5 0.568 0.651
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

CORRELATION OF MAP LAYERS

```
model_int <- lmer(CorrelatTotal ~ MAPA*NEW*CAPA + (1|NHC), data=dades)
emmeansmodel_int <- emmeans(model_int, ~ MAPA*NEW*CAPA)
emmeansmodel_int
plot(emmeansmodel_int)
```

```
## MAPA NEW CAPA emmean SE df lower.CL upper.CL
## BIP no 10 0.413 0.0267 61.7 0.359 0.466
## HD_WAVE no 10 0.422 0.0267 61.7 0.369 0.476
## OMNI no 10 0.446 0.0267 61.7 0.392 0.499
## BIP si 10 0.596 0.0267 61.7 0.543 0.650
## HD_WAVE si 10 0.596 0.0267 61.7 0.543 0.650
## OMNI si 10 0.602 0.0267 61.7 0.549 0.656
## BIP no 20 0.421 0.0267 61.7 0.367 0.474
## HD_WAVE no 20 0.430 0.0267 61.7 0.377 0.484
## OMNI no 20 0.456 0.0267 61.7 0.402 0.509
## BIP si 20 0.600 0.0267 61.7 0.547 0.653
## HD_WAVE si 20 0.596 0.0267 61.7 0.542 0.649
## OMNI si 20 0.606 0.0267 61.7 0.552 0.659
```

```
## BIP no 30 0.428 0.0267 61.7 0.375 0.482
## HD_WAVE no 30 0.436 0.0267 61.7 0.382 0.489
## OMNI no 30 0.459 0.0267 61.7 0.406 0.513
## BIP si 30 0.593 0.0267 61.7 0.539 0.646
## HD_WAVE si 30 0.593 0.0267 61.7 0.539 0.646
## OMNI si 30 0.602 0.0267 61.7 0.549 0.656
## BIP no 50 0.420 0.0267 61.7 0.366 0.473
## HD_WAVE no 50 0.438 0.0267 61.7 0.385 0.491
## OMNI no 50 0.451 0.0267 61.7 0.398 0.505
## BIP si 50 0.613 0.0267 61.7 0.559 0.666
## HD_WAVE si 50 0.596 0.0267 61.7 0.543 0.650
## OMNI si 50 0.627 0.0267 61.7 0.574 0.681
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

THRESHOLDS

```
dades_new <- subset(dades, NEW == 'si')
model_min_1 <- lmer(ThresholdMin ~ MAPA*CAPA + (1|NHC), data=dades_new)
emmeansmodel_int <- emmeans(model_min_1, ~ MAPA*CAPA)
emmeansmodel_int
plot(emmeansmodel_int)
Minimum
## MAPA CAPA emmean SE df lower.CL upper.CL
## BIP 10 0.409 0.235 44.3 -0.06410 0.883
## HD_WAVE 10 0.422 0.235 44.3 -0.05125 0.896
## OMNI 10 0.434 0.235 44.3 -0.03910 0.908
## BIP 20 0.374 0.235 44.3 -0.09982 0.847
## HD_WAVE 20 0.398 0.235 44.3 -0.07553 0.871
## OMNI 20 0.464 0.235 44.3 -0.00982 0.937
## BIP 30 0.550 0.235 44.3 0.07661 1.023
## HD_WAVE 30 0.415 0.235 44.3 -0.05839 0.888
## OMNI 30 0.455 0.235 44.3 -0.01839 0.928
## BIP 50 0.872 0.235 44.3 0.39875 1.346
## HD_WAVE 50 0.743 0.235 44.3 0.26947 1.216
```

```
## OMNI 50 0.384 0.235 44.3 -0.08982 0.857
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95

Maximum
## MAPA CAPA emmean SE df lower.CL upper.CL
## BIP 10 2.83 0.88 31.8 1.0376 4.63
## HD_WAVE 10 2.80 0.88 31.8 1.0041 4.59
## OMNI 10 2.99 0.88 31.8 1.1919 4.78
## BIP 20 2.16 0.88 31.8 0.3684 3.96
## HD_WAVE 20 2.14 0.88 31.8 0.3512 3.94
## OMNI 20 2.52 0.88 31.8 0.7305 4.32
## BIP 30 2.09 0.88 31.8 0.2919 3.88
## HD_WAVE 30 1.72 0.88 31.8 -0.0702 3.52
## OMNI 30 2.18 0.88 31.8 0.3855 3.97
## BIP 50 3.14 0.88 31.8 1.3455 4.93
## HD_WAVE 50 1.79 0.88 31.8 -0.0045 3.58
## OMNI 50 1.92 0.88 31.8 0.1305 3.72
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

ILAMS

```
dades_longitud_canal <- dades[,c("NHC", "MAPA", "NEW", "CAPA",
                               "Distancia1MinChannel", "Distancia2Minchannel", "Distancia3MinChannel", "Distancia4MinChan
                               nel", "Distancia5minchannel")]

dades_longitud_canal_res <- dades_longitud_canal %>% pivot_longer(cols = Distancia1MinChannel:Distancia5minc
                               hannel, names_to = "NUM_CANAL", values_to = "Distancia_Channel")

dades_longitud_canal_res <- subset(dades_longitud_canal_res, NEW == 'no')
dades_longitud_canal_res <- dades_longitud_canal_res[complete.cases(dades_longitud_canal_res), ]
dades_longitud_canal_res$MAPA <- droplevels(dades_longitud_canal_res$MAPA)
dades_longitud_canal_res$NEW <- droplevels(dades_longitud_canal_res$MAPA)
```

```

dades_longitud_canal_res$CAPA <- droplevels(dades_longitud_canal_res$CAPA)
head(dades_longitud_canal_res)

model_min_3 <- lmer(Distancia_Channel ~ MAPA + (1|NHC), data=dades_longitud_canal_res)
emmeansmodel_int <- emmeans(model_min_3, ~ MAPA)
emmeansmodel_int
plot(emmeansmodel_int)

```

```

## MAPA  emmean  SE  df lower.CL upper.CL
## BIP    7.12 3.25 37.6  0.539  13.70
## HD_WAVE 7.58 2.78 23.7  1.834  13.32
## OMNI    3.20 2.61 20.2 -2.248  8.65
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95

```