Using Simulation to Enhance Existing Methods for Medical Device Training

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ABSTRACT

Existing methods for training the use of cryoablation devices and related procedures often rely upon a combination of eLearning modules, slides, videos, in-person demonstrations, and a physical, real-time device simulator with a beating silicone heart replica. While comprehensive, these methods present a series of challenges and learning gaps. For example, while a physical simulator provides an environment that helps to recreate the tactile feel of the procedure, it is logistically expensive, making it difficult to duplicate and reach a large training base.

One of the more common and effective techniques to treat Atrial Fibrillation (AF) uses a cryoballoon-based ablation device to apply an area of controlled, extreme cold to create scars in the heart tissue, which disrupts or eliminates the erratic electrical signals causing the irregular heartbeat. This procedure, known as cryoablation, requires the operating physician to apply a complex mix of procedural, recognitional, and psychomotor skills to safely and effectively achieve pulmonary vein isolation (PVI). Throughout the procedure, the physician must also utilize a range of imaging techniques to understand proper positioning of the cryoballoon system in relation to the patient's targeted pulmonary vein (PV) in order to successfully navigate the instrument within the heart anatomy.

We describe our app-based cryoablation training simulation, overall design challenges, and our solutions to those challenges. This application can be deployed on commonly available consumer tablets and provides the medical device company a safe, simulation-based environment to learn and practice, as well as teach interested healthcare professionals, various safe and effective steps to the cryoablation procedure.

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INTRODUCTION

Existing methods for learning the techniques to correctly utilize cryoablation catheters for treatment of Atrial Fibrillation (AF) historically rely upon physical training elements that enable a user to practice the cryoablation procedure. An example of such methods that we will focus upon is a tool which couples a to-scale silicone heart model with imaging equipment and a sample cryoablation device to provide facilitated demonstration or hands-on practice of the procedure. While this type of training approach can give physicians and medical device representatives opportunities to practice cryoablation in environments that are physically representative of the procedure, a greater degree of training flexibility is needed.

Figure 1. Existing Silicone Heart Training Model[1]

First, existing forms of practice focuses largely on the kinesthetic elements of the procedure and does not fully stress key cognitive-based decision-making steps. Second, although standardized training and device instructional manuals provide guidance on how a device should be used in ideal conditions, no human anatomy is the same, especially the heart. Pulmonary vessels may differ in shape, size, and distance, creating the need to prepare physicians to adapt in changing conditions. Third, as part of the cryoablation procedure, the physician must perform prescribed and proscribed movements of the catheter. To do so properly requires consideration of the complex interplay between the structure of the heart and the device and how anatomical elements inform the technique. Existing physical heart models do not permit for examining and visualizing the heart during a procedure to gain full understanding of

[1] Image courtesy of Metal Professionals

anatomical orientation. Lastly, as stated above, existing training methods are costly and present logistical challenges that make the distribution of the training difficult.

To that end, our teams identified the need for, and benefits of, developing an app-based cryoablation training simulation that could be easily deployed via iPad devices to address the identified deficiencies with existing training methods. This paper discusses the design and development of our "Cryoballoon PVI Simulation", the challenges we encountered, our solutions to those challenges, and the formative results and future strategies of user acceptance testing.

DESIGN OVERVIEW

The Medtronic team approached Tipping Point Media with the task of addressing two key challenges regarding training physicians and device representatives on the proper use of the Arctic Front™ family of cryoablation catheters. First, the team wanted to create a suite of scenarios that teach users best practices when encountering a variety of conditions during the procedure. Second, the team wanted to achieve greater consistency in language, terminology, and best practices around the use of the cryoablation catheter device. Achieving these two high-level goals would provide numerous benefits, such as improved patient safety through increased understanding of procedure visualization, increased scalability of training at a decreased cost through an easily deployable mobile app, and improved efficacy for HCPs through increased consistency of procedures.

When designing the training app, our team established a set of high-level design goals to guide the overall structure of the training:

- Deliver an engaging, effective learning experience that could be completed in about 12-15 minutes of instruction time.
- Enable the user to dynamically control the level of interactivity during the simulation through toggleable active and passive interactivity modes.
- Feature content that highlights the recommended best practices for approach and device manipulation when encountering certain situations during the procedure, including the standard "*PV Alignment/Ablation/Isolation Technique*", as well as more advanced techniques, including the "*Proximal Seal Technique*", "*Hockey Stick Maneuver*", and "S*egmentation Method*" (see Chun et al., 2009).
- Design and implement a user interface featuring multiple, interactive views that are representative of the key procedure components to build impactful visualization (hemodynamic monitor, 3D heart model, etc.).

Additional non-functional requirements were established, including targeting deployment on first generation or later iPad Airs running iOS 12 or later, implementing an introductory tutorial to orient learners to the use of the app and relevant controls, and collecting training performance measures for future data analysis. With these requirements established, our team developed a detailed storyboard to structure the sequencing of all content, including learning objectives, instructional flow/feedback (where decision points are included), and voice-over required for all narration elements.

Domain Background

AF is the most common form of cardiac arrhythmia, commonly known as an 'irregular heartbeat', which can lead to numerous complications and is estimated to affect approximately 2% of the U.S. population. One of the more common and effective procedures to treat AF is using a cryoablation technique, which applies controlled cold to create scars in the heart tissue to disrupt or eliminate erratic electrical signals causing the irregularity (Chen et al., 2018). During AF, the upper chambers of the heart start beating faster than the lower chambers of the heart. Complications can include increased risk of stroke, symptoms such as tiredness and shortness of breath, and weakening of the lower chamber due to differentials in heart rates across the upper and lower chambers, as depicted in Figure 2 below.

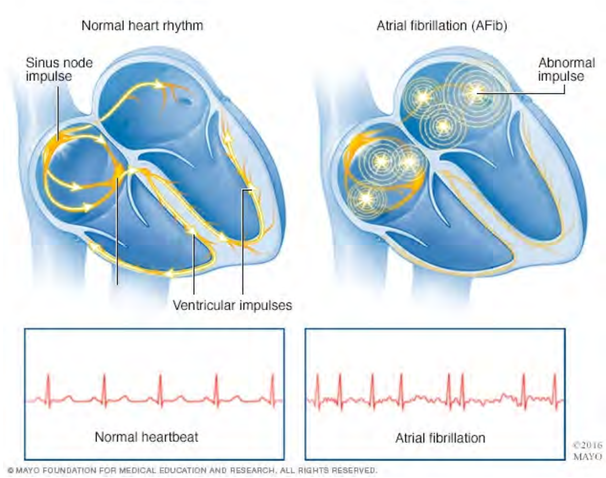
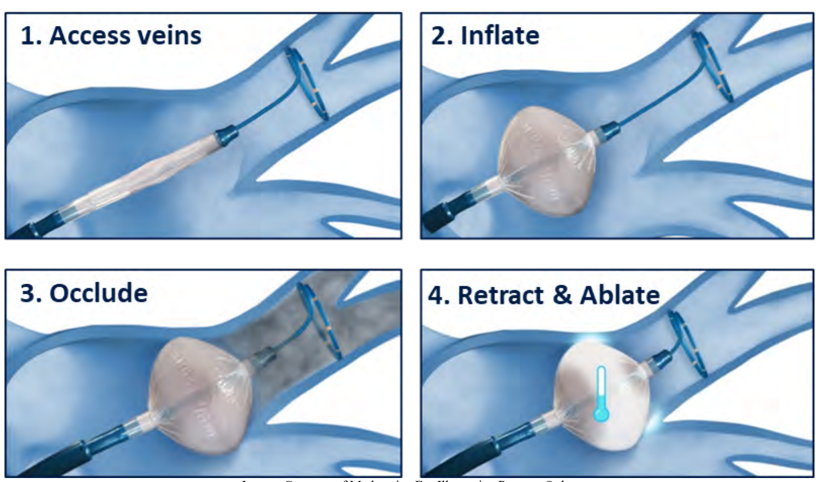


Figure 2. Comparison of Normal Hearth Rhythm to Atrial Fibrillation Rhythm (used with permission[2])

Cryoballoon ablation is a minimally invasive procedure that creates controlled (circumferential) lesions around the pulmonary veins and has emerged as an effective treatment for AF (Kulkarni et al., 2018). It ablates (*i.e.*, removes) targeted heart tissue using a coolant that is delivered through a catheter terminating in a small balloon that, when inflated with coolant, scars heart tissue through direct contact. During the cryoablation procedure, physicians balance three key parameters, including tissue contact and location, ablation duration, and number of cryoapplications (Su et al., 2018). The procedure is primarily first performed on the left superior pulmonary vein (LSPV), then repeated for all remaining pulmonary veins. A mapping catheter is first inserted into the patient and extends into the LSPV to record baseline electrical signals and act as a lead for cryoballoon insertion. Via this guide, the cryoballoon is advanced into the left vein and then inflated and positioned with the goal of achieving PV occlusion. The placement is tested using a standard fluoroscopic imaging technique. Once occlusion is confirmed, liquid nitrous oxide coolant is pumped into the cryoballoon, freezing the tissue it is in contact with in a controlled fashion. There is a subsequent ‘thawing’ process that occurs after the refrigerant delivery and varies in time, based on the characteristics of the freeze. Before moving on with ablation of the remaining pulmonary veins (PVs), pulmonary vein isolation (PVI) must be observed. The mapping catheter is used to identify a set of non-physiologic spontaneous signals within the LSPV and a comparison of pre-, peri- (during) and post-ablation signals is made to confirm the ablation’s success. In total, this maneuver is referred to as ‘PV Alignment, Ablation, and Isolation’.



Images Courtesy of Medtronic. For Illustrative Purpose Only.

Figure 3. Catheter-Based Cryoablation of Pulmonary Veins

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[2] Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved. Source: https://www.mayoclinic.org/diseases-conditions/atrial-fibrillation/symptoms-causes/syc-20350624

Because the anatomic arrangement of PVs can vary across patients, variations on the standard PV isolation technique are sometimes required. Beyond the PV Alignment, Ablation, and Isolation scenario outlined above, our team developed three additional, more advanced scenarios within the app, as described below.

The first of these advanced scenarios features the 'Proximal Seal Technique', in which the user must target the right superior pulmonary vein (RSPV). When ablating any right-sided veins, such as the RSPV, there is an increased risk of phrenic nerve injury (PNI). By using the 'Proximal Seal Technique' approach, the user can facilitate positioning of the cryoballoon at a more proximal end of the vein to achieve adequate occlusion, increasing the distance between delicate external structures and the cryoballoon (Kulkarni et al., 2018). Because the RSPV is targeted in this scenario, use of the 'Proximal Seal Technique' is recommended so that the cryoballoon can maintain a safe distance from the phrenic nerve during cryoablation.

The second advanced scenario features the 'Hockey Stick Maneuver', in which the user must target the right inferior pulmonary vein (RIPV). This scenario begins after transseptal access, at the point where the mapping catheter and inflated cryoballoon are already deployed within the left atrium in an unsuccessful attempt to occlude the RIPV using the standard PV Alignment, Ablation and Isolation method. It is at this point that performing the 'Hockey Stick Maneuver' is recommended as one of the next steps in order to obtain adequate occlusion. Use of this advanced technique can improve contact between the cryoballoon and the inferior PV surface, which may prove to be challenging due to the anatomical positioning of the RIPV (Chen et. al., 2009).

The final advanced scenario features the 'Segmentation Method', in which the user must target the left common pulmonary vein (LCPV). In this scenario, the ostium of the presented LCPV, the therapeutic target ablation area, is 35mm, which is larger than the cryoballoon, which has a maximum diameter of 28mm. Because of this anatomical variation, the recommended approach would be to use the 'Segmentation Method' to divide the cryoablation into 4 segments.

Simulation Design

As seen in the figure below, the "Cryoballoon PVI Simulation" user interface is divided into 5 user interface elements (*i.e.*, panels) and enables the user to interact with and control the training simulation. These interface elements are described below:

- **3D Heart View**: This panel displays an interactive 3D view of the heart. This enables the user to observe the cryoballoon and catheter as they move it into position within the heart. This panel also contains an angiographic projection view. At any point during the simulation, the user can switch between Right Anterior Oblique (RAO), Left Anterior Oblique (LAO), and Anterior-Posterior (AP) fluoroscopic views. Additionally, this panel may switch to a contrast view during key moments of the simulation to present a stylized representation of fluoroscopic image guidance.
- **Hemodynamic Monitor**: This panel presents simulated readings from a mapping catheter and guided phrenic nerve monitor. After the user has positioned the mapping catheter at the PV ostium, signals of electrical activity within the PV will begin to appear. During the simulation, the user can utilize this display to view examples of pre- and post-ablation electrical readings, as well as observe the readings in real time during ablation to visualize the key indicators of successful PVI.
- **Device Simulator**: The device panel enables a user to control and manipulate the simulated cryoablation catheter device. There are three main controllable components of the simulated device, including a mapping catheter, a steerable sheath, and the cryoballoon. This panel enables the user to directly manipulate these elements during the simulation to perform each procedure step of the cryoablation. The device featured in this simulation is based on the Medtronic Artic Front™ family of cryoablation catheters.
- **CryoConsole**: Throughout the simulation, the CryoConsole is used to inflate the cryoballoon, initiate the cryoablation process, and monitor the temperature during a cryoablation. A cryoablation automatically stops at the preset time and the thawing status of the cryoballoon is also observed via the CryoConsole.
- **Instruction/Navigation**: This panel provides the user with instructional information and feedback. It also allows the user to control the flow of the simulation by providing them the ability to skip to the next step or return to a previously completed step.

The simulation's user interface is modal, so elements within the interface can change to better highlight and feature critical focal points throughout the simulation. For example, the 3D Heart View Panel is large during earlier stages in the simulation where the user is inserting the catheter guide, yet once the user is instructed to begin the cryoablation process and must observe information on two additional panels, the 3D Heart View becomes smaller to accommodate the display of both the CryoConsole panel and the Hemodynamic Monitor panel.

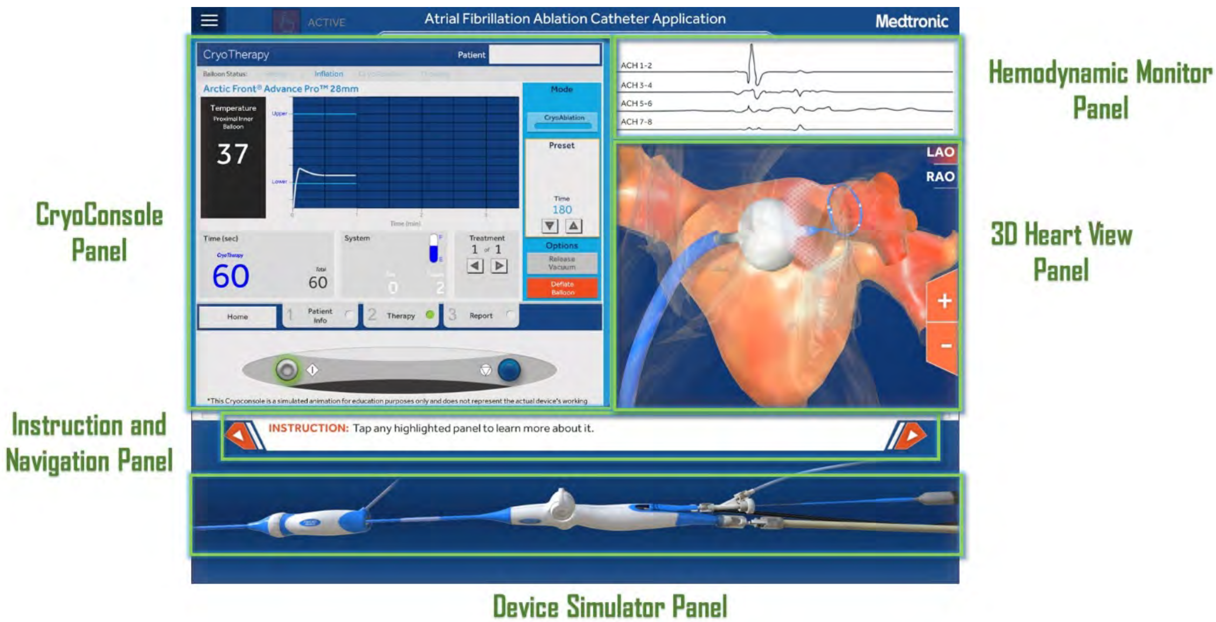

Figure 4. Cryoballoon PVI Simulation App – Primary User Interface

One of the benefits of this form of simulation over traditional silicone-based heart models is that the 3D heart can be manipulated to visualize the relationship between the cryoballoon and the PV ostium as it is being inserted. To that end, we integrated three different modes of 3D heart visualization, including an orientation view, a procedure view, and a contrast view, as depicted in Figure 5 below.

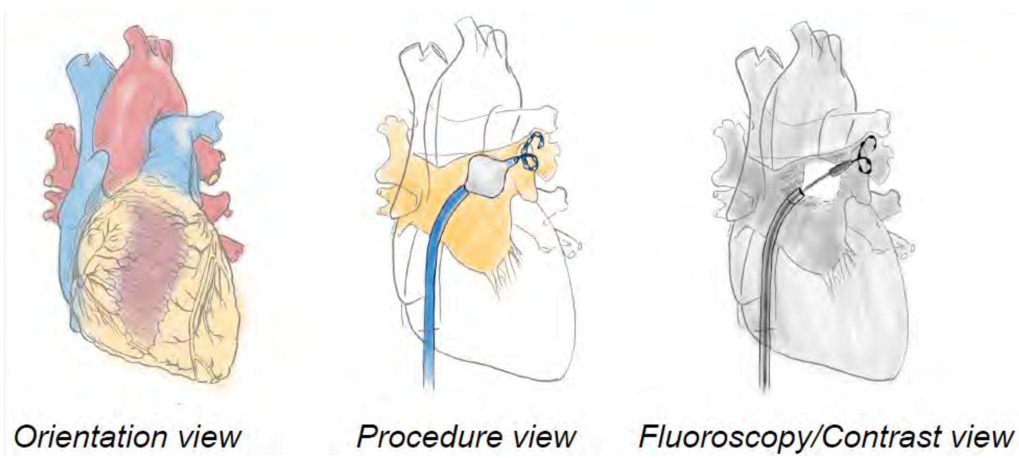

Figure 5. Concept Example of Multiple Stylistic Views of the Heart

Figures 6-9 below show an excerpted set of screenshots from the app to provide a small sample of key steps within the cryoablation procedure. Figure 6 depicts a user moving and adjusting the mapping catheter via the on-screen device controls, with movement of the catheter reflected in the 3D heart view panel.

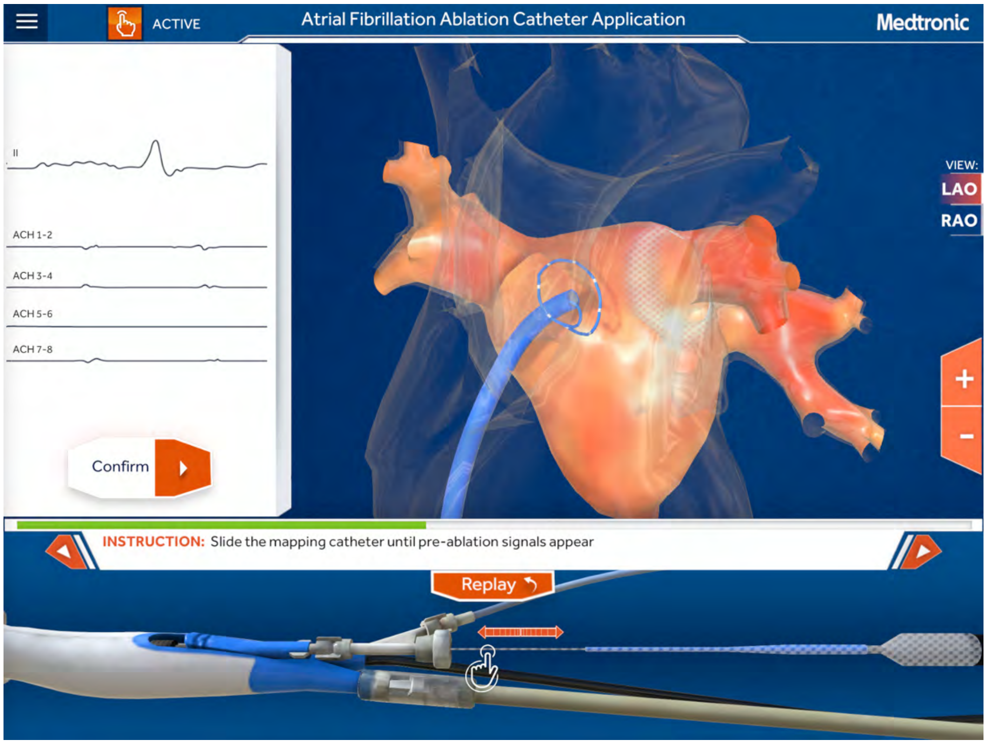

Figure 6. User Sliding Mapping Catheter Until Pre-Ablation Signal Appears in LAO View

Figure 7 depicts a user injecting contrast to confirm occlusion in the LAO view prior to switching to RAO to re-confirm occlusion.

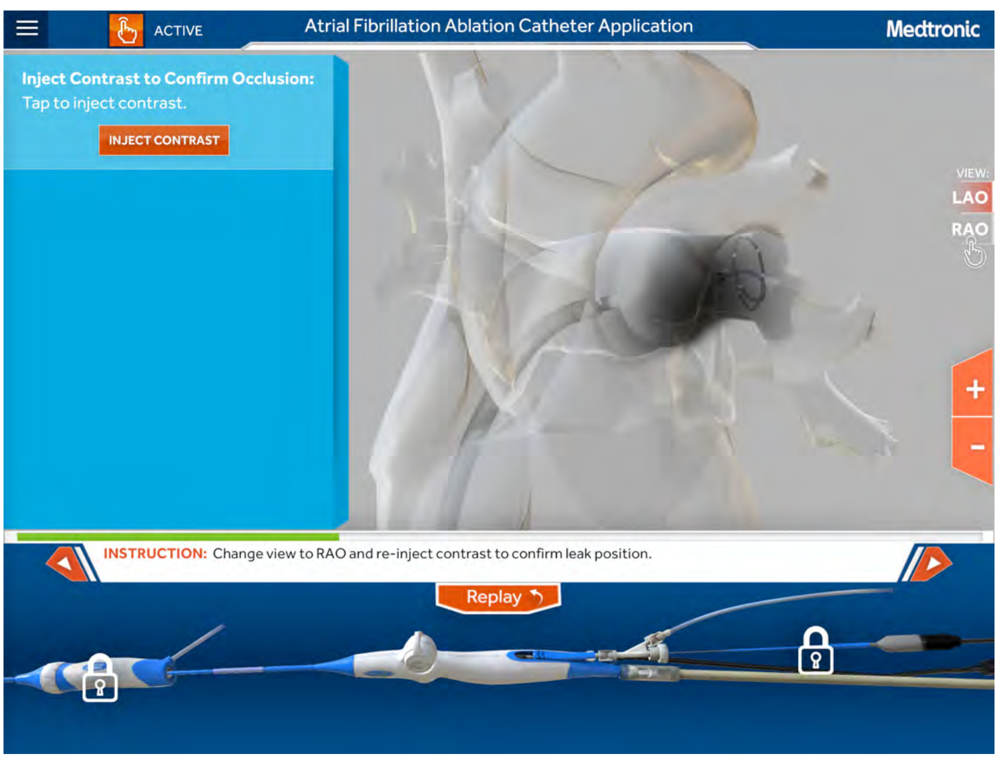

Figure 7. User Injecting Contrast to Confirm Occlusion in Contrast View

Figure 8 depicts a user preparing to initiate the cryoablation procedure via the CryoConsole.

Figure 8. User Preparing to Initiate the Cryoablation Procedure via CryoConsole

Figure 9 depicts the user monitoring the cryoballoon temperature via the CryoConsole during the post-ablation thaw period.

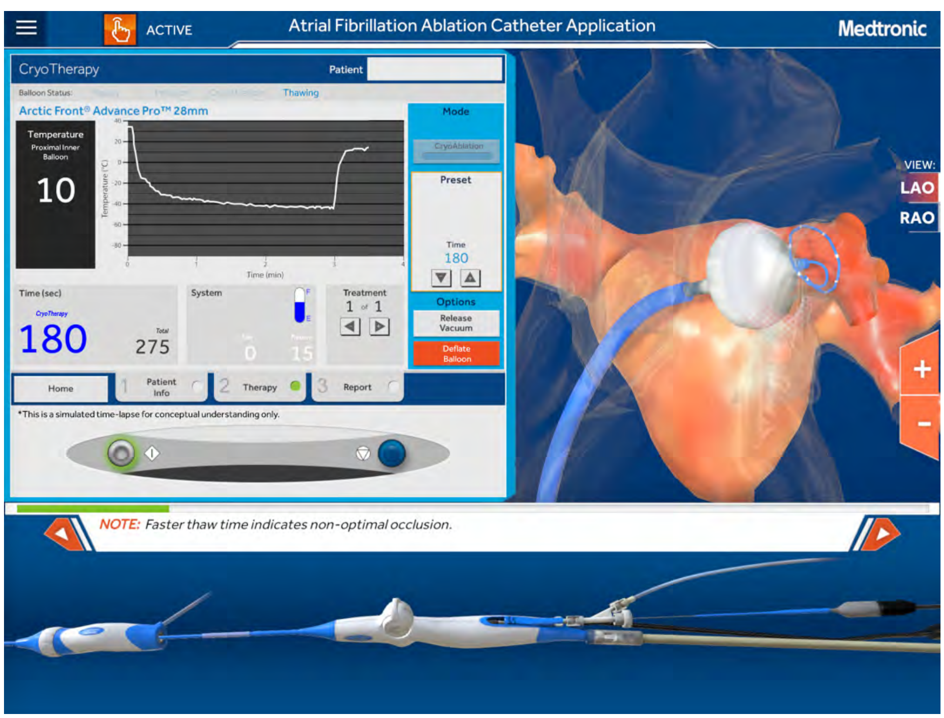

Figure 9. User Viewing Cryoballoon Temperature on CryoConsole During Post-Ablation Thaw

Challenges and Solutions

One of the first design challenges our team encountered was the need to create a simulation that could provide value for multiple target audiences in a variety of use cases. Those included cardiac electrophysiologists, Medtronic representatives, and various allied health professionals, who all have levels of understanding of the device and procedure that ranged from beginner to advanced levels of familiarity. The simulation needed to provide training that could present the content in various levels of detail to support such a range of pre-existing knowledge. The app also needed to be designed in a way that allowed the content to be appropriately accessible for a variety of use case situations. For example, a physician who is a new user to the device may want to view the simulation content in thorough detail to help familiarize themselves fully with the procedure, while Medtronic device representatives may want to access specific procedure steps from the same simulation as a quick refresher on the content before a procedure. This meant that the app needed to be able to provide new users with the detailed content they needed to build a complete baseline knowledge of the procedure, while still giving more experienced users the flexibility to quickly jump right to their desired training content.

We addressed the above challenge by adding a navigation capability that allowed learners to access section divisions and content as needed. By organizing the simulation content structure into sections by procedure step and including an always-accessible navigation menu, the user can jump to any key section or procedure step in a scenario at any time. This enables advanced users to easily and quickly find an exact moment in the procedure as needed. Additionally, by ensuring each procedure step was short and did not exceed 1 minute in length, advanced users or trainers can highlight key information within a procedure step during a facilitated demonstration with a new user without having to wait through tutorial or beginner-level context to get to the moment they need. In contrast, the navigation system and content division allowed our team to include as much procedure context as needed to comfortably prepare a new user with a full contextual picture. The navigation also allows new users to repeat and revisit steps if necessary. Lastly, content can be viewed in two ways, in either an "active" or "passive" mode. "Active" mode allows users to follow along with the procedure in an interactive manner, which is helpful for practice sessions and to provide a learn-by-doing approach. "Passive" mode enables learners to review the content in a non-interactive animation format. This is helpful for those who would like to review the procedure before interactive practice, or for representatives who may want to leverage the animation as a supplementary visual tool during discussions with HCPs. Providing support for both modes that can be accessed through a dynamic toggle gives the user agency with how they would prefer to utilize the training app.

A second design challenge was translating the seat-time of a multi-hour procedure from the real world to a focused, simulated representation. Our solution to address this was to utilize time dilation at key moments, thus leveraging one of the intrinsic features of simulation through a digital platform to create a more efficient demonstration through use of accelerated time-lapse. By creating elements of a scenario where we can show a 3-minute step in a matter of seconds through an accelerated animation, time is saved from a demonstration aspect while still hitting upon the important points. Additionally, creating a system which demonstrates moving pieces of a catheter in 1-2 seconds (when it may take a minute or two in the real-world task due to logistical constraints) allows the training to focus on the most important key messages while doing so in a time-efficient fashion.

A third challenge was the creation of a simulation that could leverage elements of user "free play" to allow them maximal control over exploration of the simulation, while at the same time included enough structure and constraints that production of the training remained efficient and did not rely upon the creation of large quantities of content. This approach, though it required larger upfront programming investment, avoided the need of creating large amounts of animation content and allowed the user "free play" device manipulation. We developed a custom, physics-based rigging system that would reflect the manipulation of the simulated cryoablation catheter within the 3D Heart View Panel as the user controlled the device through interactions on the Device Control panel. This allowed the catheter to move and bend as expected when manipulating the device controls and colliding with geometry within the heart (such as the mapping catheter conforming to fit within the PV or stretching the cryoballoon during to prepare it for retraction).

By carefully designing the timing of when "free play" is made available to the user and constraining the amount of "free play" given, we were able to allow for very interactive, trial-and-error practicing moments while avoiding the user experiencing any unexpected behavior of the simulated device. For example, during the 'Segmentation Method' scenario, the user must position the cryoballoon over a specific target ablation area on the PV ostium by freely manipulating the system's sheath rotation and deflection controls. When the user believes they have it positioned correctly, they must inject contrast for visual confirmation. Users repeat this process until the application confirms they have properly positioned the cryoballoon. While the user is given the opportunity to freely move the sheath rotation and deflection controls and toggle the contrast view on/off, they are limited to these two activated device controls and must work within certain amounts of rotation and deflection. The purpose of these designed constraints is two-fold: first, to avoid visual bugs or inaccuracies caused by unexpected 3D geometry collision clipping, and second, to ensure reiteration of the importance of isolated device controls at this particular procedure step. Controlling the amount of "free play" in this interaction allows users the opportunity to freely explore device manipulation and test their skills in a controlled and focused way, all while presenting realistic real-time device movements. To accommodate the unique timings and physics, we developed the training simulation within the real-time development game engine Unity3D, which also enables streamlining the addition of future content or general app updates.

A fourth challenge was the inclusion of representations of all devices and elements that the HCP must utilize and monitor during the procedure (*e.g.*, an angiographic view of the heart, a fluoroscopic view, and the hemodynamic monitor). To implement all visual elements, two main challenges were presented: first, creating a balance of screen real estate that best utilizes the limited space while still maintaining good interface readability and usability, and second, making each interface element accessible to the user at the appropriate moment to avoid cognitive overload and confusion. Our solution to address this challenge was through careful user interface layout design and animation. We were able to create a complex, yet user-friendly, representation of all panel views for the user to interact with at relevant steps throughout the training. These interactive panels slide in and out of view throughout the simulation, only appearing during the key moments where the physician should be monitoring the visible element. By controlling when each interface element is visible, this ensures the user would not be overwhelmed or confused by excessive user interface; however, by implementing selective interactive elements into each panel, the user is still be provided with a sense of engagement and agency.

Formative Stakeholder Feedback and Future Evaluation Plans

To garner initial feedback on the first version of the "Cryoballoon PVI Simulation" app, we conducted an initial small-scale usability evaluation with a cohort of 5 Medtronic Field Education Specialists to garner formative feedback. The first feedback session was designed to solicit inputs from a group of internal (Medtronic) subject matter experts trained on the use of the cryoablation device and procedure. App feedback for this group included inputs on overall usability, completeness of the training content, and perceived utility of the training experience. A 15-question survey was created to solicit user feedback from these internal stakeholders, including 2 demographic questions and 13 Likert-based questions to collect user-reaction data on the app.

The cohort has extensive experience with existing simulations (*e.g.*, silicone heart model), as 1 of the 5 reported using existing simulations at least 1-3 times per quarter, 3 reported 4-6 times per quarter, and 1 reported more than 7 times per quarter, with all 5 having had experience within the last 30 days. When asked to rate ease of use of the existing silicone heart simulation, 2 members of the cohort reported Extremely Easy, with each of the remaining members reporting decreasing levels of ease (Somewhat Easy, Neutral, Somewhat Difficult). In contrast, when asked to rate ease of use of the "Cryoballoon PVI Simulation" app, 1 member reported Extremely Easy, while the remaining 4 reported Somewhat Easy. Given the formative nature of the evaluation, these early results suggest the "Cryoballoon PVI Simulation" app is easy to use.

Overall qualitative cohort feedback was positive: quotes from the questionnaire describe the app as "[e]asy to use, good visuals, helpful to see it in RAO vs LAO views", that it was "[e]asy to use and [a] great tool to help train employees and customers.", and that the fidelity was deemed positive and described as "very realistic with contrast injection and with catheter simulation." Some areas reported for improvement in future versions included: the length of time when advancing through steps in the tutorial (reported as too lengthy), difficulty with changing between "active" and "passive" modes, and the desire to access different veins within the simulation.

The goal of upcoming evaluations will be to gather qualitative user-reaction data from key stakeholder groups over the course of multiple sessions. The second session will include a small cohort of medical fellows conversant with the procedure to gather similar feedback on usability and perceived utility of the training experience. The third session will occur at an internal summit, which will include over 130 registered customers of Medtronic's cryoablation device. The focus here will be on gathering user feedback on the overall usability of the training app, as well as comparative feedback on the app as compared to existing silicone-based heart simulators.

CONCLUSIONS

Our team successfully designed and developed an advanced cryoablation training simulator that addresses existing challenges and gaps (limited availability of physical training components, costs, logistics of transport, etc.) and helps to create a consistent language between representatives and their customers (*i.e.*, HCPs) with regards to the cryoablation procedure and deviations. Although standardized training and device training manuals provide guidance on how a device should be used in ideal conditions, no human anatomy is the same, especially the heart. Pulmonary vessels may differ in shape, size, and distance, creating the need to prepare representatives and physicians to adapt in changing conditions. Our flexible, easily deployable simulation helps to provide a baseline of "best practices" for the more-common use cases, remaining relevant as they are discovered through simple app updates. Thus, we created an extensible learning platform that covers a suite of procedure deviations and heart anatomy scenarios that would be accessible for all users (representatives, physicians, allied health professionals, etc.) and easy to update with new content.

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