

VIVO™ Remote Support Platform – Novel Approach to Provide Ongoing Clinical and Technical Support to Create Pre-procedure Localization Maps for PVC/VT Ablations

Background

Clinical and technical support of mapping systems during ablation procedures have historically been provided by medical industry as part of the service end users have come to expect. The COVID-19 pandemic has created an opportunity for the medical device industry to address how they will be able to continue to provide the same level of support while adjusting to new restrictions related to non-essential personnel entering the hospitals.

To address the new paradigm, in March 2020 Catheter Precision (CPI) launched the VIVO™ Cyber Secure Remote Support (CSRS). This new platform allowed CPI to remotely create patient specific pre-procedure localization maps to identify the onset of PVC/VT in real time.

Between March and July 2020, Catheter Precision personnel remotely supported a total of 16 VIVO cases at 4 centers.

Facility	Physician	Number of Cases
Erasmus Medical Center, Rotterdam, NL	Tamas Szil Torok, MD	11 Cases
Royal Brompton Hospital, London, UK	Professor, Sabine Ernst	2 Cases
Northern General Hospital, Sheffield, UK	Justin Lee, MD Nick Kelland, MD	2 Cases
University Medical Center, Groningen, NL	Yuri Blaauw, MD	1 Cases

Table 1: Centers using the Cyber Secure Remote Support (CSRS)

Adopted Workflow to Provide Realtime Clinical Support

Step 1 - Upload Cardiac CT/MRI and Create Patient Specific Model

Hospital designated VIVO super user uploads the acquired cardiac CT/MRI, routinely obtained for VT/PVC ablation procedures, within 24 hours prior to the procedure. Once uploaded, the super user launches the CSRS platform and a CPI clinical team member creates a patient specific model from the scan without assistance from the EP Lab staff or physician. Once complete, the new model can then be reviewed by the physician for finalization.

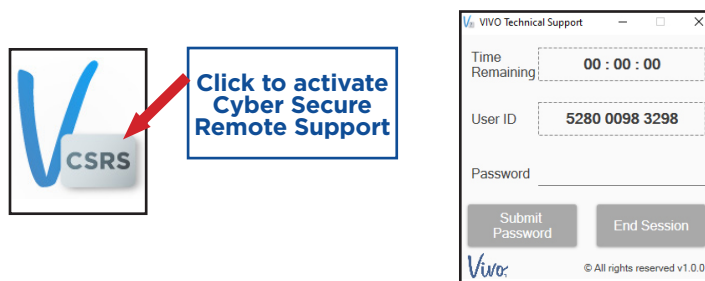


Figure 1: The Icon used to launch the CSRS platform and the login screen provides a secure access to the CPI Clinical Team Member

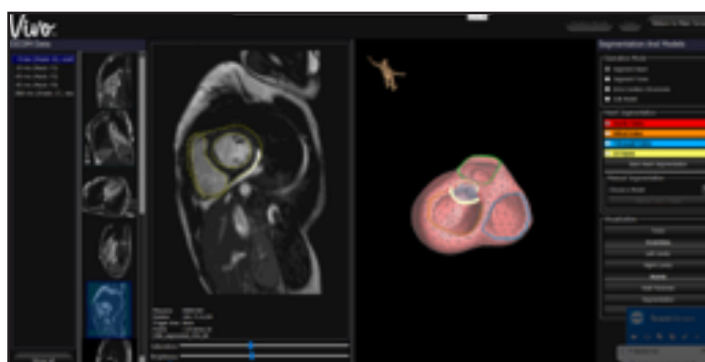


Figure 2: Completed Cardiac Model ready for physician review

Step 2 – Patient Setup and Arrival into the EP Lab

EP lab staff will activate the CSRS application and allow CPI clinical support team to access the case.

The patient will be prepped for an ablation procedure and after the 12 lead ECG electrodes and the VIVO Positioning Patches are in place, the EP lab staff will take a 3D photograph using the VIVO camera. This process will take less than 3 minutes. A CPI clinical team member will then merge the 3D image onto the segmented scan, without assistance from the EP Lab staff.



Figure 3: Image taken with the 3D photo showing the 12 lead ECGs and the VIVO Positioning Patches

Step 3 – Obtain ECG and Create Localization Map

Once the clinical VT/PVC has been captured, the EP lab staff will export the tracing to a USB and import it into the VIVO system and the remote CPI clinical support team will perform a real time analysis and finalize the VIVO localization map in approximately 10 minutes.

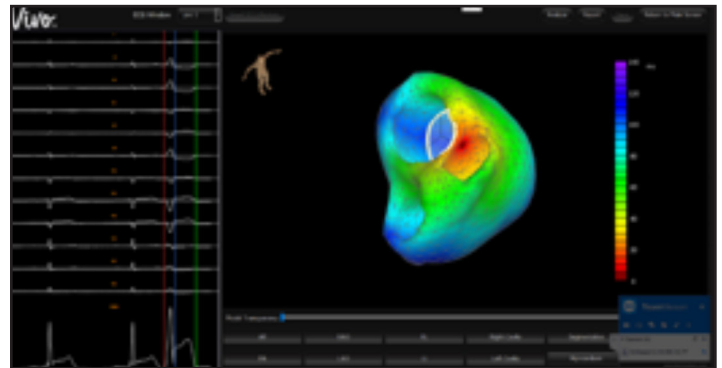


Figure 4: Final VIVO Localization Map. The red indicates the earliest point of activation of the ventricular arrhythmia.

Conclusions

- VIVO localization maps can be successfully created via the newly launched CPI CSRS clinical and technical support platform.
- The CSRS platform allows CPI the opportunity to continue to provide the same level of support and service to the EP lab physicians and staff while reducing the number of non-essential staff entering the EP lab.
- Creating a localization map remotely can be done quickly in real time with little burden to the EP lab staff or physician.

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