

# Case Study: Endocare's Cryotherapy Treatment Planning System

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## Business Problem

The Cryocare CS System is a Tissue Ablation system intended for use in open, minimally invasive or endoscopic procedures in areas such as general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The Cryocare CS System is accompanied by a Cryocare Treatment Planning System (CryoTPS) which is designed to be used as a console application for planning, guidance and delivery of cryoablation treatment.

The CryoTPS was originally a standalone application interfacing only with the Cryocare CS System without any capability to communicate with the hospital's Information Systems (HIS) or PACS for patient related information. Additionally, the CryoTPS was limited to merely displaying the patient's ultrasound images during the procedure without any predictive capability of how a particular treatment plan would affect the tissues and its adjoining organs. This enabled doctors with only a low level of confidence in the treatment plan and limited the use of this form of treatment to a few specialists.

## Concept Value Statement

Endocare had the desire to develop a next-Gen version of the CryoTPS that would provide doctors with a console application that could generate 3-D anatomical images from the ultrasound regions of interest and simulate the effect of a prepared treatment plan with visual representation of cryo ice-ball formations. This would not only elevate the confidence levels of the doctors performing the procedure but also reduce the need to perform corrective plan modifications during the procedure, thus reducing patient trauma and post surgery recovery time.

In addition, communication of the CryoTPS with HIS and PACS would provide the doctors with the patient's prior studies, images and reports, and the technologists with the Patient Worklist – thus reducing human effort and errors.

## Business Considerations

The solution provided should conform to the following technical considerations:

- **Hardware Interface compatibility:** The CryoTPS should replace its predecessor smoothly without warranting changes on the Cryocare CS system hardware.
- **Surgical environment:** The CryoTPS is meant to be deployed in a surgical environment. The application should be designed with proper consideration given to the user's limitations in

interacting with it in such an environment. Choice of interfacing hardware (monitor, keyboard, mouse, etc.) should be factored in while designing the application.

- **Distributed Architecture:** The value of the CryoTPS is increased if it is able to provide technologists with Patient Worklists prior to surgery and doctors with the capability to retrieve and visualize the patient's prior studies. Image and data exchange between the CryoTPS and the systems in the hospital should be seamless and driven towards providing a holistic, patient-centric view to the doctor.

## Requirements & Constraints

The Next-Gen CryoTPS application should have the following features:

- **DICOM/HL7 Gateway:** This module would be responsible for the acquisition of patient data from the various DICOM and HL7 entities in the hospital such as HIS, RIS, PACS, modalities, etc. The acquired data is to be made available for processing via the TPS archive. This module is also responsible for exporting treatment related information to the outside world.
- **Acquisition Module:** This module would be responsible for capturing of data from various hardware interfaces such as ultrasound probes, temperature probes, cryoprobes, and imaging modalities. The acquired data is to be made available for processing via the TPS archive.
- **System Control Unit:** This module directly controls the external hardware interfaces such as ultrasound probes, temperature probes, cryoprobes, and to interface with the CryoCare System hardware. It receives control inputs from the Treatment Delivery Module and Acquisition Module.
- **Viewer Module:** An authorized user of the CryoTPS application interacts with it via the Viewer Module. This module, in conjunction with the Treatment Planning, Guidance and Delivery modules provides the platform required by the user to:
  - ✓ View live data feeds from acquisition probes such as Ultrasound and temperature
  - ✓ View and manipulate acquired images
  - ✓ Draw and edit Regions of Interest (ROIs) on acquired images – ROI modeling
  - ✓ Generate 3D anatomical simulations based on the ROI models and treatment plan – 3D modeling
- **Treatment Planning Module:** This module should allow the user to create a treatment plan based on the acquired images and ROI models. The plan can be computed automatically or manually. Application should allow plan to be revised at any point during treatment. The treatment planning module should save the plan to the TPS archive for future reference.
- **Treatment Guidance:** This module should allow the user to guide probes in a live acquisition environment as per the created treatment plan. User can make corrections to the plan during this step. These changes should be saved to the TPS archive for future reference.
- **Treatment Delivery:** This module should allow the user to perform Treatment Delivery as per the created plan. The user can assign protocols for delivery and execute the plan. This component interacts with the System Control Unit to issue commands for treatment delivery.

## The Solution

SoftLink worked rigorously in understanding the finer points of a Cryoablation treatment procedure and the pain areas that doctors experience as part of treatment workflow. Several areas in the workflow were identified which could be streamlined through the next-gen CryoTPS software so that doctors have access to everything that they need for the surgery at one place.

The Next-Gen CryoTPS concept application provided the doctors and technologists with simple solutions to correlate the physical cryo grid used for inserting cryoprobes to the image space. Ultrasound images were acquired and recorded for clinical assessment and treatment. ROI modeling was developed alongside so that the anatomical structures could be accurately rendered in 3D simulations. These developments could be accomplished quickly due to SoftLink's grasp of the domain and its expertise in the medical image manipulation and display area.

SoftLink's DICOM and HL7 communication stacks allowed the CryoTPS to easily communicate with hospital systems for patient images and data which allowed a patient centric access to doctors for treatment planning and delivery and mitigated the issues of them having to shuttle between the surgery, the treatment planning/delivery software and patient's images. The TPS Archive which acts as a central repository for the application was designed to store Images, Algorithms, LUTs, and other information that the application requires for calculations and display from time to time.

The entire application was designed for deployment on a surgical touch screen monitor. This allowed the doctors to interact with it, right from patient registration through treatment planning, guidance and delivery, without the need of keyboard and mouse thus eliminating sources or bacterial contamination in a sterile surgical environment.

In short, SoftLink's domain knowledge and technical expertise made it possible for Endocare to upgrade their CryoTPS software to a next-Gen version which addressed all their business and technical needs just within a few months.