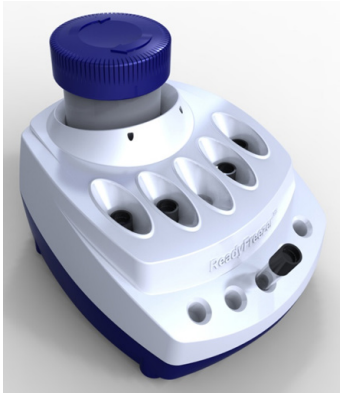
**Project Name:** ReadyFreezer™
**Application:** Rapid Cryopreservation System for Tumor Biopsies
**Customer:** PADT Medical with Funding from the NIH

# READYFREEZER: ACCELERATING CLINICAL SPECIMEN COLLECTION



From 2009 to 2010 PADT developed the ReadyFreezer Specimen Collection System under a grant from the NIH

## BACKGROUND

Presently, tumor biopsies often sit for an hour or more before being preserved. Unfortunately, during that period, the molecular profile within the specimen decays, and biomarker information may be lost. The ReadyFreezer is a tabletop unit that snap freezes specimens immediately upon resection. This provides pathologists and researchers with a more accurate understanding of the tumor biology as it exists in-vivo. Over time, this understanding will advance therapeutic choices and drug development.

## NIH GRANT

PADT Medical was awarded a grant from the National Cancer Institute as part of the Small Business Innovation Research Program (SBIR) to develop the ReadyFreezer. PADT was chosen due to the technical innovations of our proposal, our world class facilities, the credentials of our engineering staff, and our experience bringing medical devices to market with FDA clearance.

## PROJECT CHALLENGE

Researchers have many options for fast freezing tissue samples (i.e. liquid nitrogen); however, these options are not safe or practical for clinical use due to infrastructure and handling obstacles. Our challenge was to achieve rapid and consistent freezing using an intuitive stand-alone device that can be inventoried with biopsy instruments.

PADT's goal was to achieve rapid, consistent, freezing of a core biopsy and maintain the frozen sample until it is delivered to the freezer lab

## DISCIPLINES EMPLOYED

Mechanical Engineering

Industrial Design

Thermal Simulation

Verification Testing

Collaboration with a Leading Cancer Research Center



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without using either dry ice or LN2 (liquid nitrogen). The device had to accommodate samples acquired from a variety of biopsy and surgical instruments, taken from any organ, and in any setting, from the operating room to a small clinical setting. In addition, the device had to be user friendly and intuitive to be adopted into common practice by researchers and clinicians.

## PROCESS AND SOLUTION

PADT engineers met with clinical and research professionals to develop product requirements, and to learn about biospecimen life cycles and associated preservation challenges to ensure that key biomarkers were preserved.

The first task was to perform feasibility testing of multiple cryogenic freezing options to ensure rapid and consistent tissue freezing. Testing was conducted on multiple refrigerants, and various CryoVial materials. In addition to physical testing, we utilized PADT's in-house computer simulation service to perform thermal analysis of the various CryoVial materials and configurations. Freeze rates were compared to snap freezing in LN2, the current gold standard for tissue preservation.

The second task was to develop a cost effective housing to deliver the cryogen safely and efficiently to the vials containing the tissue samples. Operator safety and material properties were primary design considerations. Flow analysis was used to optimize cryogen flow rates and vial placement while minimizing splashing. Materials and housing configurations were chosen to maximize the freeze duration time (minimize cryogen depletion) for transport to a permanent freezer.

An industrial designer was utilized to ensure an aesthetic, user friendly and ergonomic platform for the device. We utilized PADT's in-house rapid prototyping services to evaluate and improve design concepts.

## SUMMARY OF DEVICE

The device is feasible and can be developed and commercialized as a simple class 1 device that can be easily supplied to clinics and research facilities.

Features and Applications of ReadyFreezer:

- Practical, rapid cryopreservation of biospecimens
- Convenient, safe, low cost alternative to LN2
- Reusable base with easily installed, disposable, commercially



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available CryoCanisters

- 5 cryoports for preserving up to 5 samples at one time
- Snap freeze in less than 1 minute
- Each CryoCanisters provides -26C bath for 1 hour

## TISSUE PRESERVATION ANALYSES

Extensive testing at a leading cancer center has confirmed that the ReadyFreezer biomarker preservation results are similar to the tissue preservation obtained with snap freezing in liquid nitrogen.



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