2021

Biopticon Corporation
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Biopticon
Discovery through imaging

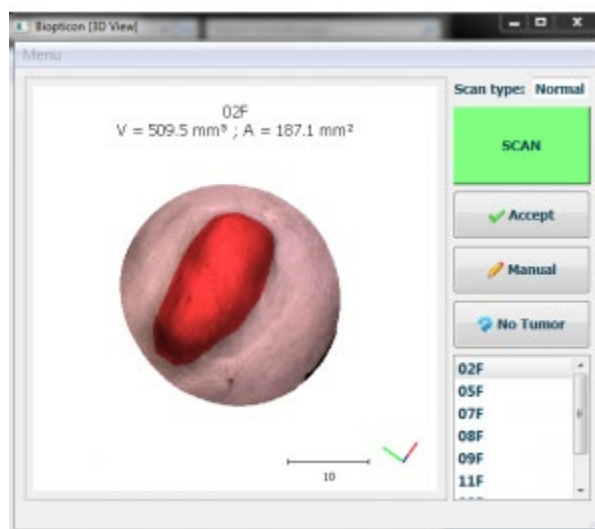# ROI Analysis of the Tumor Management System
Version 1

This document summaries the benefits of the Tumor Management system by using the data obtained by the users and their experiences on the use of the system.

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1. Introduction

The Tumor Management System consists of the TumorImager™, used for rapidly and noninvasively imaging subcutaneous tumors on un-anesthetized mice used in preclinical oncology studies, and TumorManager™, a comprehensive study management program that integrates seamlessly with the TumorImager™ system and other devices (including calipers) for managing all aspects of a study from protocol creation, data acquisition and analysis, to final reports.

2. The Challenge

In preclinical oncology research, the effectiveness of a compound is tested in animal models. The compound is administered to mice with subcutaneous tumors and the size of those tumors is monitored over time. Statistical analysis of this data determines the effectiveness of the compound. Making accurate and repeatable measurements is critical to reaching statistical significance in a study. Currently, a technician uses electronic calipers to manually measure the length and width of the tumor, and the height is typically assumed to be equal to the width in the formula used to calculate volume.

3.   Existing Technology

The current technique for measuring tumor size on large numbers of un-anesthetized mice is to use hand calipers and then either manually enter the results or use electronic calipers linked to a computer. The challenges to obtaining accurate and repeatable measurements are twofold. Tumors often grow in irregular shapes and may even become necrotic. Also, assuming the height is equal to the width in the formula to calculate volume can introduce significant error. There is also user bias built into the manual measurement methodology since studies have shown that multiple technicians often obtain different results when measuring the same tumor.

Other techniques including Ultrasound, Fluorescence Imaging or CAT are available to accurately measure tumors in mice, but they are slow and expensive since they require the mice be anesthetized and/or injected with imaging agents, and each 3-D image must be analyzed manually. None of these methods are, therefore, suitable for high-throughput studies.

4.   Biopticon's Solution

The TumorImager^{TM} scans the tumor in less than 1 second and measures the volume of the tumor accurately regardless of its shape, while eliminating user bias. TumorManager^{TM} is a comprehensive study management program which automatically captures all data, eliminating transcription errors and allowing users to review and analyze real-time data at any point in the study.

5.   Benefits

5.1   Use Case for the Scientist:

The improved accuracy and precision achieved with the TumorImager^{TM} (see table labeled "Accuracy" below) has been demonstrated to result in measurement of higher sensitivity to drug responses. As seen from this table, while calipers overestimate the tumor volume by about 34%, the imager underestimates it by about 4% and this is mainly due to the volume of the embedded section of the tumor. The improved sensitivity of the measurements typically results in statistical significance being reached 3 to 10 days earlier than in studies utilizing manual measurement techniques (see table labeled "Efficacy" below). The ability to detect drug response which calipers fail to see can reduce false positives and lost opportunity costs due to the premature or inconclusive conclusions about drug efficacy that would be otherwise be made. Furthermore, the saved tumor pictures provide useful visual information about the tumor growth. As demonstrated in the Financial ROI Projections section below, significant financial savings can be achieved by shortening study length, and productivity gains are made possible since more studies can be completed per year with the same human resources and fewer animals.

5.1.1 Accuracy

	Total No of Tumors	Caliper		TumorImager™	
		Slope	R²	Slope	R²
Average	40	1.88	0.96	0.96	0.92

5.1.2 Efficacy

Tester	Caliper		TumorImager™	
	Total No of Cases	Days Seen Earlier	No of Cases	Days Seen Earlier
	1	4	7	3-10

5.2 Use Case for the User:

The system is faster than calipers, reducing the time the user must spend in contact with the animals. Use of the TumorImager™ system reduces repetitive strain injury risks, is easy to learn, and is convenient to use. The following table demonstrates this significant reduction in user bias. The average coefficient of variance among users making the same tumor measurements is about 3 times smaller in the case of imager.

5.3 User Dependency

	Total No of Tumors	Total No of Users	Caliper		TumorImager™	
			Standard deviation	CV %	Standard deviation	CV %
Average	67	18	152.4	19.1	34.2	6.8

5.4 Use Case for the Business Manager:

Use of the TumorImager™ and TumorManager™ systems reduces the number of animal models required for each study, thereby reducing animal and labor costs. It improves productivity by allowing a facility to conduct more studies per year and reduces the risk of generating false negative results by detecting drug responses that calipers miss.

6. Financial ROI Projections

	Lab Volume		
	High	Med	Low
Studies per year	50	35	24
Animals per study	70	70	60
Animal cost savings/year	$35,000	$24,000	$14,000
Labor cost savings/year	$42,000	$29,000	$17,000
Total 5 year cost savings	$322,000	$207,000	$95,000

7.   Summary

The Biopticon Tumor Management System offers scientists unparalleled improvement in sensitivity and statistical power so that better decisions can be made faster on drug candidates. Users of the system gain workflow efficiency with an easy to use system, while reducing the risk of repetitive strain. For the business manager, the system makes sound financial sense with a near term positive return on capital invested.