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**Title**

Comparison of Depth of Sedation Performance between SedLine and BIS during General Anesthesia: Data Collection and Analysis

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**Authors**

Vo, Linda  
Kim-Lim, Penelope  
Jones, James  
et al.

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# Comparison of Depth of Sedation Performance between SedLine and BIS during General Anesthesia: Data Collection and Analysis

## Introduction

Electroencephalogram (EEG) monitoring has the potential to become a robust tool to characterize anesthetic depth. The goal is to develop a streamlined neuromonitoring tool that would allow clinicians to make real-time assessments and to titrate anesthetic delivery. Anesthetic overdosing can cause postoperative delirium and mortality, while underdosing can cause intraoperative awareness and pain. Of particular interest is excessively deep anesthesia, which is reflected by a burst suppression pattern on EEG monitors. Fortunately, proprietary algorithms have been developed to transform the raw EEG waveforms into a dimensionless number that quantifies the patient's level of consciousness. Examples of these monitors are the Bispectral Index (BIS) monitor and the Sedline monitor which produces patient state index (PSI) values.

**Question:** How do the PSI (SedLine) and BIS perform in the setting of imminent burst suppression during general anesthesia?

## Design

While prior studies have compared different brain function monitors by placing multiple sensors on the patients' foreheads simultaneously, this data is difficult to interpret due to crowded and inaccurate placement of the sensors. Our study is distinct in using an individual electrode connected to a custom designed interface box that can combine and split signals, allowing simultaneous data gathering for two different brain monitoring systems.

- Prospective, non-blinded, non-randomized study conducted at a single institution
- Aged  $\geq 18$  years
- American Society of Anesthesiologists (ASA) class I-III patients presenting for elective surgical or non-surgical procedures requiring general anesthesia
- Exclusion: Any deformities or devices preventing application of EEG sensors to patient's forehead; Developmental delay

## Objectives

- (1) Collect data on 100 patients using individual generic sensors connected to a custom-built passive interface box, which allows for concurrent performance of BIS and SedLine monitors
- (2) Analyze processed EEG performance in the 5 minutes prior to the onset of burst suppression pattern on raw EEG (indicating an overly deep level of anesthetic sedation).

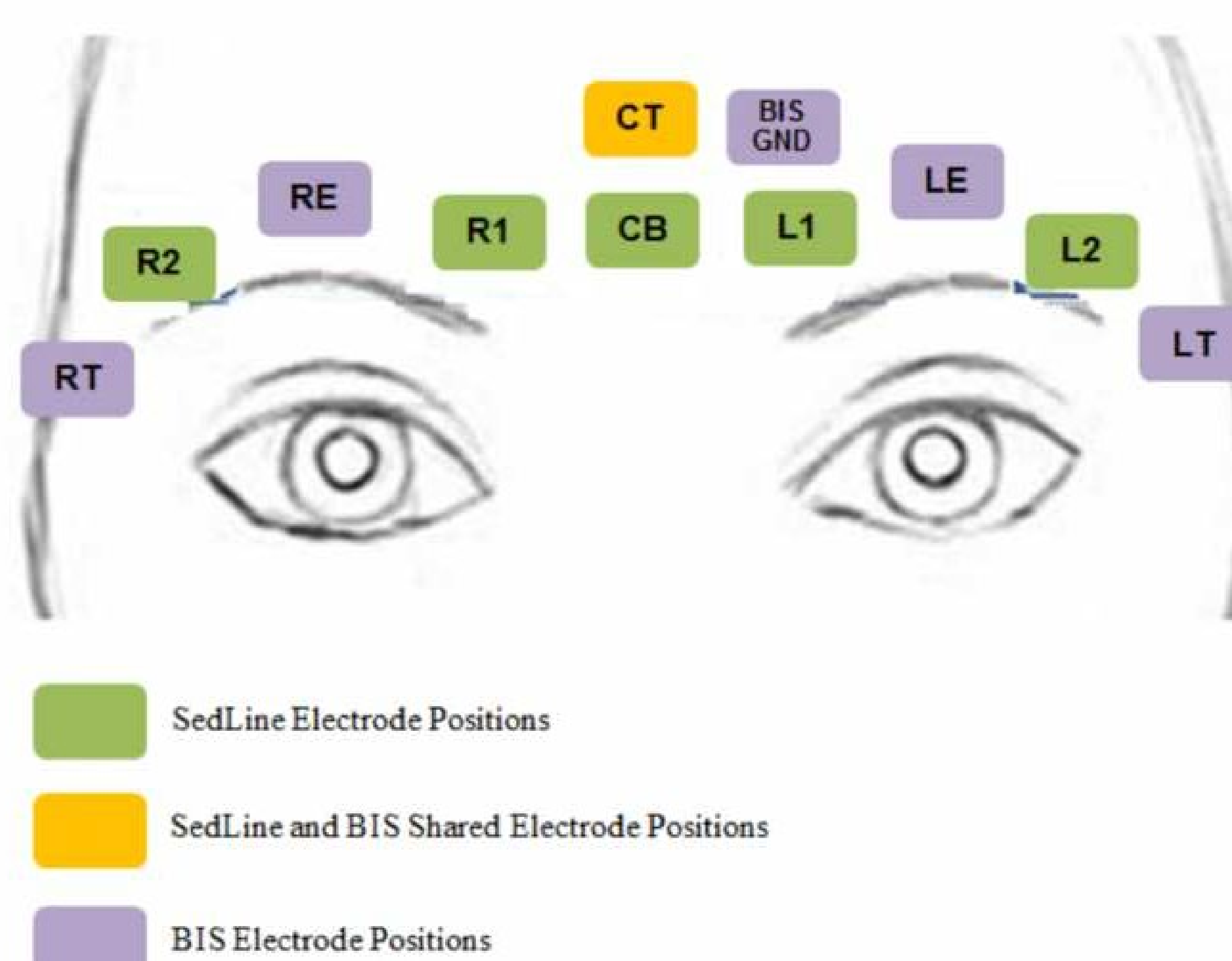


Figure 1: Sensor Placement

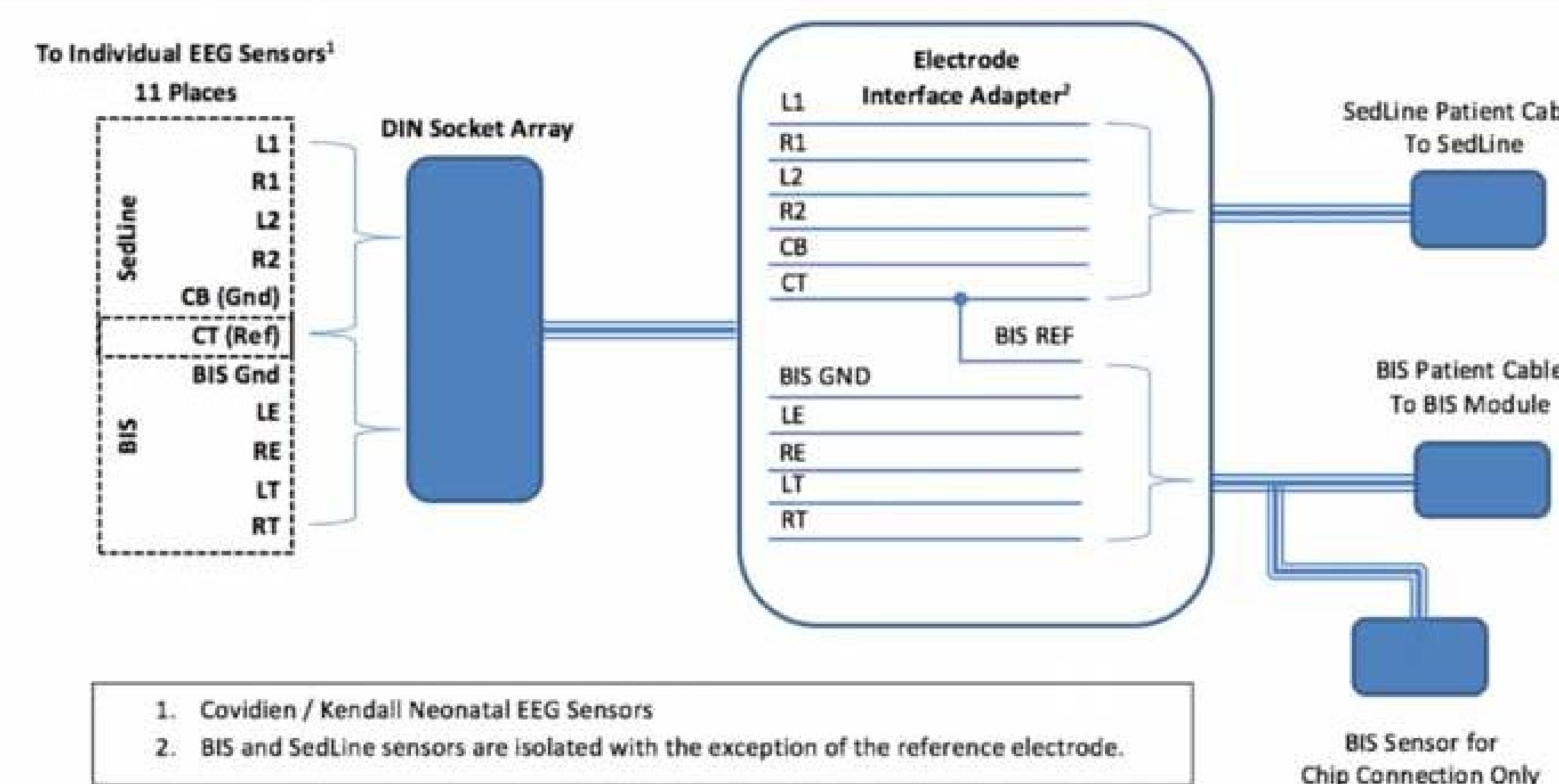


Figure 2: Custom-built interface box

## Challenges Encountered

- Legal approval from the lawyers of the Medtronic (BIS) and Masimo (SedLine) monitors - RESOLVED
- Waiting for equipment delivery – RESOLVED
- Repair of equipment used in data collection – RESOLVED
- Concordance among screeners of the raw EEG waveforms for burst suppression
  - Need additional training - RESOLVED



Figure 3: Equipment Setup

Characteristics of Patients Included in Study	
Age (years), mean ( $\pm$ SD)	58 ( $\pm$ 15)
Female gender, n (%)	43 (43)
Height (cm), mean ( $\pm$ SD)	172 ( $\pm$ 10)
Weight (kg), mean ( $\pm$ SD)	87 ( $\pm$ 18)
ASA Physical Status Class, n	
I	3
II	45
III	52

Table 1: Characteristics of Study Population

## Results (In Progress)

- Developed an individual electrode connected to a custom designed interface box that can combine and split signals, allowing simultaneous data gathering for two different brain monitoring systems.
- 100 patients were enrolled in this prospective, non-blinded, non-randomized study
- Successful data collection using BIS and SedLine monitors
- Reviewers of burst suppression on raw EEG completed training
  - Initiated marking of raw EEG data for burst suppression by 4 independent reviewers

## Further Study

Next Steps: Finish Data Analysis

- Establish inter-reviewer concordance on marking raw EEG data for burst suppression
- Analyze the 5 minutes of processed EEG prior to burst suppression on raw EEG
- Raw EEG readings will be correlated with the dimensionless values of the brain function monitors (processed indices from BIS and SedLine monitors)
- Data will be analyzed using chi-square test and kappa statistic

## Acknowledgements

Masimo, Inc provided support for the construction and assembly of the data collection hardware and software.