

**A multicenter evaluation of the SCOTI device  
for real-time determination of tracheal tube placement  
during emergency airway management**

**Research protocol and prototype IRB application**

**December 1996**

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## Introduction

### 1.1 Summary

- Title.....A multicenter evaluation of the SCOTI device for real-time determination of tracheal tube placement during emergency airway management.
- Design .....Multicenter prospective cohort observational study.
- Setting .....Sites where emergency tracheal intubation is performed. Emphasis will be on intubations within hospital emergency departments. However, patients may be enrolled from any hospital location. One prehospital service is enrolled in the working group, which consists of fifteen centers.
- Sample.....A total target of one thousand patients, aged 12 years and older, will be enrolled. The enrollment period will be approximately one year.
- Analysis.....This study will compare the efficacy of the Sonometric Confirmation of Tracheal Intubation (SCOTI) monitoring device with standard methods of determining endotracheal tube placement during emergency intubation. Measurements will be made from the SCOTI screen during intubation.
- Treatment...None. During this trial, SCOTI measurements will be taken solely for the purposes of observation. Intubation maneuvers will be performed in the same manner as they would without SCOTI. Standard confirmation methods will be used to determine final endotracheal tube placement. Patient treatment will not be altered.
- Outcomes ...Comparison of SCOTI performance in determining endotracheal tube placement with standard methods of placement confirmation.
- Objective ....To determine whether SCOTI is a technological advance over standard methods of endotracheal tube placement confirmation, providing potentially more rapid and more accurate determination of incorrect endotracheal tube placement during emergency intubation.

### 1.2 Background

Intubation of the trachea is performed to ensure a patent and protected airway or to permit positive pressure ventilation in the critically ill patient. A well-known hazard of tracheal intubation is inadvertent placement of the endotracheal tube in the esophagus. Adverse effects of this error include failure to provide adequate tissue oxygenation to sustain life and inflation of the stomach with consequent regurgitation of gastric contents, spillage of these contents into the patient's tracheobronchial tree, and production of severe, potentially life-threatening pneumonitis.

Routinely-used clinical methods of attempting to distinguish correct from incorrect placement of an endotracheal tube include the following maneuvers:

- visualization of the tube tip traversing the glottic opening during direct laryngoscopy
- observation of chest excursion
- auscultation of breath sounds
- measurement of exhaled carbon dioxide concentration during attempts to ventilate the patient via the tube
- use of pulse oximetry to monitor the patient's arterial oxygen saturation immediately following intubation
- chest radiography

Each of these methods has drawbacks. It is often difficult to see the tube tip traverse the glottic opening during direct laryngoscopy. The reliability of observing chest wall movement and auscultating for breath sounds is compromised by obesity and pulmonary disease involving lung hyperin-

flation (such as in chronic obstructive pulmonary disease or active asthma). Auscultation, the oldest of traditional methods used, has been demonstrated to be of little benefit in distinguishing esophageal from endotracheal tube placement.<sup>1</sup> Chest radiography is time consuming and has been demonstrated only helpful for distinguishing esophageal intubation if it is performed in the oblique or lateral position.<sup>2</sup> Exhaled carbon dioxide measurement, either by colorimetric disposable devices,<sup>3</sup> or real-time spectrography, fails in cardiac arrest patients, who may not exhale carbon dioxide.<sup>4</sup> All the methods listed except direct visualization of tube insertion through the glottis require discontinuation of laryngoscopy and an attempt to ventilate using the endotracheal tube. This results in gastric insufflation if the tube inadvertently lies within the esophageal lumen.<sup>5</sup>

Early in this decade, a method of rapidly discriminating tracheal from esophageal intubation was described which took advantage of an important anatomical difference between the trachea and esophagus; namely, that air can be aspirated from an endotracheal tube lying with the former but not the latter. Use of what has been termed an esophageal detector device (EDD) does not require insufflation of the stomach to recognize esophageal intubation.<sup>6,7,8,9,10,11,12</sup> The method does, however, require discontinuation of laryngoscopy and removal of the malleable intubating stylet if one was used. The device has also been reported to falsely indicate esophageal tube placement following correct tracheal intubation of morbidly obese patients, small children, or in cases where the endotracheal tube is inserted past the patient's carina into a mainstem bronchus.<sup>13,14,15</sup>

Recently, a second generation electronic EDD, termed SCOTI (for Sonometric Confirmation of Tracheal Intubation), was introduced into medical practice. Like first generation EDDs, it takes advantage of the anatomical difference between esophagus and trachea, distinguishing an air-filled trachea from a collapsed esophagus and thus obviating the need for discontinuation of laryngoscopy to confirm correct or incorrect tube placement. In the case of esophageal intubation, this specifically eliminates the aspiration morbidity associated with gastric insufflation, a necessary step in the traditional methods used to determine whether an endotracheal tube inadvertently lay in the esophagus. The SCOTI device, currently marketed in England, Europe, and Canada, measures the energy required to propagate sound of a selected resonant frequency into an endotracheal tube. Using digital logic, it is capable of distinguishing the two distinct acoustic environments of an open versus an obstructed endotracheal tube tip. This is exactly the method used by first generation EDDs, but is a marked advance in that it performs and signals an obstructed tube tip (corresponding to inadvertent esophageal intubation) instantaneously and in real-time, *during not following*, the actual process of intubation. Like first generation EDDs, which are simple mechanical suction bulbs, this device eliminates the potential morbidity-inducing step of test-ventilating a patient to check for inadvertent esophageal intubation. Unlike these earlier EDDs, however, SCOTI provides instant and real-time confirmation of tracheal intubation during the actual intubation procedure itself, thereby allowing intubation to be performed much more rapidly than with any previous method. This is particularly true in emergency patients, who due to the preexisting morbidity necessitating intubation have critically depleted physical reserves and thus present a particular challenge to the treating physician.

The SCOTI device is a small battery-operated apparatus which connects to the end of the endotracheal tube during intubation. It produces low frequency sounds and determines whether the attached endotracheal tube is in the trachea or the esophagus with special algorithms based on impedance of audio energy through tubing. The result is displayed in three ways; via an LED which turns green when the tube is in the trachea and red when it is in the esophagus, via a separate continuous audio signal, and via specific readouts on an LCD screen. Both LED color and audio feedback are updated several hundred times per second so perceived real-time feedback is instantaneous and continuous allowing the intubating physician to make many rapid "trial and error" intubation attempts in a few seconds, a process which would take several minutes without SCOTI. After the intubation SCOTI is disconnected and the respiration equipment connected. This is the first device which can actually

provide feedback on endotracheal tube location in real-time while the intubation process is underway.

SCOTI is 145 mm x 64 mm x 63 mm and weighs 300 grams. The endotracheal tube is connected via a flexible disposable tube and bacterial filter to SCOTI, to avoid the risk of contamination between patients. In addition, the corrugated tube minimizes the weight in the operator's hand. SCOTI automatically configures itself to operate with the case-unique endotracheal tube assembly each time it is utilized. It may be placed by the patient's head, strapped to the operator's arm or belt, or held by an assistant. It is powered by a nine-volt battery which provides several weeks of heavy use. A low battery indicator is built into the device.

Use of SCOTI involves performance of the following steps:

- SCOTI is connected to the endotracheal tube selected for use in a patient via a disposable length of corrugated tubing.
- The end-hole and side Murphy eye hole of the endotracheal tube to be used is aseptically occluded by pinching these closed while the tube is still within its sterile commercial package.
- SCOTI is turned on. "Confirmation" of correct operation is made by observing that the SCOTI LCD screen reads 00 or 01, the LED glows red, and the external speaker emits a high-pitched, rapidly beeping tone. This "configuration" step takes approximately two seconds.
- The tube tip and Murphy eye hole are unpinched. A "test" of SCOTI function is performed by now checking that the LCD gives a reading of at least 22, its LED glows green, and a high-pitched continuous tone is emitted from the external speaker. This "test" step takes approximately one second.
- Tracheal intubation is initiated as it would normally be performed, with suction, available Trendelenburg positioning, and cricoid pressure. In cases of rapid sequence intubation (RSI), appropriate medications are administered to facilitate sedation and paralysis.
- During the process of intubation, attention is also given to the SCOTI auditory signal, LED color, and LCD screen reading. The visual observations may be noted by an observer.
- Following intubation, the LCD screen reading is noted as a final confirmation of tracheal placement.
- The endotracheal tube is connected to a self-inflating bag or other manual breathing circuit and the patient is ventilated via the tube.
- Standard methods of confirming endotracheal tube position are used now in conjunction with the SCOTI observations to reconfirm tracheal placement of the endotracheal tube.

### **1.3 Previous studies**

The technique of Sonomatic Confirmation of Tracheal Intubation has been previously studied at the John Radcliffe Hospital in Oxford, at St. Bartholomew's Hospital in London, and at the San Juan de Dios Hospital in San José, Costa Rica.

The results of the Oxford study were published in the journal, *Anesthesia*, in 1995.<sup>16</sup> [See Appendix D.] The results of the London study were presented at the World Congress of Anesthesiologists in

1996.<sup>17</sup> The results of the San José study were presented at the annual meeting of the American Society of Anesthesiologists in 1994. [See Appendix E.] All three reports have described the method as useful, but the number of subjects in each study was small and none were conducted in the emergency setting.

#### 1.4 Rationale

SCOTI and the technology it represents has applications for intubation in any setting. However, the current study puts particular emphasis upon SCOTI application in the emergency setting. Historically, anesthesiologists have been considered experts in airway management. Indeed, previous SCOTI human trials have obtained data from the operating theater, where complete control of the clinical setting was easiest to maintain.

It is, however, the emergency setting where SCOTI has its greatest potential application. Like anesthesiologists, emergency medicine physicians must be experts in airway management. The emergency medicine emphasis, however, is on airway management in the unstable critically ill patient, who has not the benefit of preoperative fasting, premedication, guaranteed preoxygenation, who may indeed be combative, and who may present with distorted airway anatomy due to severe trauma. In the operating theater, advanced monitoring equipment such as real-time spectrographic capnometry is available for each case. In the emergency department, the only equipment for confirmation of endotracheal tube placement may be a stethoscope. Thus, these two settings for advanced airway management differ fundamentally in their resources, patient populations, and patient conditions.<sup>18</sup>

Despite its technology, SCOTI is a relatively inexpensive reusable device, built for heavy, repeated, and rugged use such as is present in the emergency or developing world setting. Estimated cost is under \$500 which favorably compares to cost of real-time capnography, the anesthesiology gold-standard for operating room tube confirmation, of over \$50,000. The device is also relatively simple in its circuitry, owing to an elegant design based upon novel audiosonic physical principles, allowing it to be housed in a small industrial-duty package.

There are several reasons why SCOTI could be especially useful in the emergency department:

- The sonomatic method is the fastest method of determining the site of endotracheal tube insertion, equaled only by direct visualization of the endotracheal tube tip traversing the glottic orifice — a highly unreliable method except in the hands of very experienced intubators.
- Patients whose tracheas are intubated in the emergency department typically have not fasted overnight prior to performance of this procedure. Since sonomatic identification of esophageal intubation does not entail gastric inflation, this technique reduces the risk of aspiration pneumonia in such patients requiring emergency tracheal intubation. Such aspiration is associated with high morbidity. (The reported mortality rate for such aspirations has been between 50 and 90 percent.<sup>19</sup>)
- Patients requiring tracheal intubation in the emergency department often have compromised pulmonary function, so life-threatening hypoxemia can occur very soon after bag-valve-mask ventilation is discontinued and performance of tracheal intubation is attempted. Since, with SCOTI, confirmation of the position of the endotracheal tube tip occurs in real-time as the tube is inserted, recognition of incorrect tube placement is much more rapid than with any traditional method of confirming tube position. [See Appendix C for a complete discussion of this issue.] In less time than would be required for recognition of a *single* tube placement error using conventional tube confirmation techniques, many such placement errors could be recognized and corrected, using SCOTI.

- Practitioners who must perform emergency tracheal intubations have fewer opportunities to practice this technique than practitioners who daily perform this procedure in the operating room. The time that the sonometric method saves in the detection of erroneous tracheal intubation could be especially valuable to such caregivers.
- Patients in cardiovascular collapse or full cardiac arrest often do not exhale sufficient carbon dioxide to permit reliable confirmation of tracheal intubation by the technique of exhaled capnometry.<sup>4,20</sup> In addition, capnometric confirmation has failed to detect endotracheal tubes inadvertently placed in the posterior pharynx rather than correctly placed in the trachea.<sup>21,22</sup> Since SCOTI is based on anatomic rather than physiologic parameters, it is superior to exhaled capnometry in confirming the position of an endotracheal tube in such patients.

### **1.5 Objectives**

The current trial follows several human studies and one publication demonstrating SCOTI's advance over traditional methods of tube placement confirmation.<sup>16</sup> The purpose of this trial is to provide a definitive database of its utility based on a statistically robust number of uses. It is hypothesized that SCOTI presents an improvement in patient care, particularly in the emergency setting, for critical airway management.

Thus, the primary objective of this study is specifically to gather data on the accuracy of SCOTI when compared to traditional methods of endotracheal tube placement confirmation. A secondary objective of this study is to gather subjective comments from trial participants, mostly practicing emergency physicians, on the overall utility of SCOTI for facilitation of patient care in the setting of emergency airway management. Specific information to be answered from these comments include the best method of using SCOTI during emergency endotracheal intubation and suggestions for both hardware and software enhancements.

### **1.6 Multicenter Collaboration**

The current study is a multicenter collaboration of academic centers in the United States and Canada, the bulk of which are comprised of hospital emergency departments. The current list of participating centers is given in 7.1. This list may be expanded as the study progresses. Identical protocols and data collection methods will be used simultaneously at each center.

## **Study Procedure**

### **2.1 Overview**

This is an initial prospective multicenter observational trial designed to gather a large number of cases comparing SCOTI feedback readings with traditional methods of endotracheal tube placement confirmation. The estimated enrollment is approximately one thousand patients, and the estimated period of enrollment is one year, although both of these estimates are dependent on actual site volumes. Data collection will be via an observer present during emergency intubations in the emergency setting, primarily in hospital emergency departments. No alteration of actual intubation methodology is built into this study design, in order that this design may meet FDA criteria for non-significant risk investigational device classification. Patient enrollment will be automatic, triggered by any indication for emergency intubation. Because of the emergency nature of the clinical scenario which is being studied, patients will not be able to provide consent. Thus, waiver of consent is sought below.

### **2.2 Inclusion Criteria**

Subjects will be all patients believed to be 12 years old or older who require tracheal intubation. Exact inclusion age criteria may be altered among participating institutions. The study is primarily conducted on emergency patients presenting in hospital emergency departments. However, inclusion may also be altered to include patients requiring intubation elsewhere, including the prehospital setting, intensive care units, operating rooms, or other portions of the hospital setting.

### **2.3 Exclusion Criteria**

Subjects who do not require tracheal intubation, or who fall below the age criteria specific to the respective participating institution are excluded from this study.

### **2.4 Description of Procedures**

A patient selected for inclusion in this study will be tracheally intubated exactly as s/he would have been in other circumstances except that the end of the endotracheal tube to be inserted will have been connected by a length of corrugated tubing to the SCOTI device capable of distinguishing tracheal from esophageal intubation on the basis of the acoustical nature of the environment at and just beyond the endotracheal tube .

Prior to using SCOTI to discriminate tracheal from esophageal intubation in a patient, the operator will perform the following steps to ensure that the device is functioning properly and that the sound pathway is airtight. [See also Appendix F, SCOTI Operator's Manual]:

- The operator will connect SCOTI to the endotracheal tube to be used via a disposable sound pathway consisting of a bacterial filter, a short length of corrugated tubing, and a right-angle elbow adapter. If a stylet is to be used, it is also inserted at this point.
- The operator will aseptically occlude the end and side hole of the endotracheal tube to be used. This is accomplished by pinching the tube's two orifices while the tube tip still lies within its original sterile packaging.
- The operator will "configure" the device by pressing SCOTI's "on" button. He will ensure that the LCD screen reads 00 or 01, the LED glows red, and the external speaker emits a rapidly beeping, low-pitched tone (indicating that the acoustical condition present at the endotracheal

tube tip has been studied and will serve as the model for esophageal tube placement). Time for completion of this step is normally about two seconds.

- The operator will “test” the device by unpinching the tube tip and Murphy eye, removing the tube tip from its commercial package, and ensuring that SCOTI’s LCD gives a reading of at least 22, SCOTI’s LED glows green, and its external speaker emits a continuous high-pitched tone (indicating that the acoustical condition present at the endotracheal tube tip is perceived to be compatible with tracheal intubation). Time for its completion is normally less than one second.

Following device “configuration” and “test,” the operator will perform tracheal intubation. If the intubation is being performed as the culminating step of a rapid sequence intubation technique, the emergency department’s standard protocol for performing this procedure will be used.

During insertion of the endotracheal tube, an observer will note the information being presented by SCOTI’s external speaker, LED, and LCD. This observer will record SCOTI’s LCD reading once the endotracheal tube has been inserted to the appropriate depth, using the data collection sheet.

- If SCOTI indicates tracheal intubation (high-pitched, continuous tone from external speaker, green LED, LCD reading 22 or more), an attempt is next made to ventilate the patient using the tube. Tube position is then confirmed by traditional methods. These include auscultation of breath sounds, use of an esophageal detector device other than SCOTI, use of a disposable colorimetric CO<sub>2</sub> detector, pulse oximetry, chest radiography, and real-time capnometry.
- If SCOTI indicates esophageal (low-pitched rapidly beeping tone, red LED, LCD 15 or less) or indeterminate (intermediate-pitched beeping tone, LED yellow, LCD 15-21) placement of the endotracheal tube, the operator (or, in the case of a resident physician, the supervising attending physician) will decide whether or not to attempt to ventilate the patient using the endotracheal tube as currently positioned.

The physician responsible for the care of the patient being intubated will at all times retain full control of the authority to continue using or discontinue using SCOTI. If SCOTI continues to be used, the observer will continue to collect data on SCOTI’s performance during each intubation attempt.

SCOTI’s performance will also be studied in patients in whom resuscitation was unsuccessful. Sonomatic measurements will be taken in such patients using the endotracheal tube that was inserted during the resuscitation effort. In addition, SCOTI measurements will be taken following insertion of the tracheal tube into the esophagus. In these patients, additional data to be obtained from the endotracheal tube in position will include SCOTI measurements taken with the tube tip in the mid trachea, in a mainstem bronchus, and just beyond the glottic opening. Data to be obtained from the endotracheal tube inserted into the patient’s esophagus will include measurements with the endotracheal tube at 15, 20, and 25 cm past the patient’s incisors.

## **2.6 Time Frame**

The estimated study period is one year, depending on the volume of enrollment.

## **Data Collection**

### **3.1 Case Data**

- Data to be collected are tabulated in the Data Collection Sheet [Appendix B]. Nine categories of data collection are included and are detailed below.
- Data collector information: initials of the intubating practitioner (with professional level) and data recorder.
- Patient information: patient number (for FDA use), gender, age, weight, height, and general physique.
- Place of intubation.
- Indications for intubation.
- Intubation data: spontaneous breathing during intubation, medications used for intubation, endotracheal tube size, presence and size of nasogastric tube, presence and size of stylet.
- Method of final confirmation of endotracheal tube placement in the trachea.
- SCOTI calibration data.
- Live patient SCOTI data: LCD readings taken during intubation, space reserved for comments.
- Recently deceased patient SCOTI data: LCD readings taken from the trachea and esophagus in patients unsuccessfully resuscitated, space reserved for comments.

### **3.2 Data Collection and Monitoring**

Data gathered at each site will be sent as it is collected to the Data Coordinating Center (currently, Mount Auburn Hospital, Cambridge). Data tracking and analysis will be performed as the study progresses, and will be available to the study investigators via the Internet.

## **Statistical Considerations**

### **4.1 General Design Issues**

Design of this study is prospective and observational. The intent of design was to provide parallel data from the SCOTI device during actual emergency intubations without changing the process of intubation. Standard methods of tube placement confirmation are utilized for final determination of tube position. By directly comparing these parallel data arms, the accuracy and overall utility of SCOTI will be determined.

### **4.2 Sample Size**

Approximately one thousand patients will be enrolled.

### **4.3 Data Analysis**

During the study initial data analysis will be available to all investigators via the Internet. This analysis will include nonparametric examination of the range of SCOTI readings consistent with esophageal or endotracheal tube placement. In addition, a continuous listing of SCOTI accuracy statistics compared to a standard of traditional confirmation methods will be made available to all investigators.

Final data examination will involve parametric and nonparametric statistical analysis on all data collected. Based on available evidence that SCOTI is an accurate method in most patients, the most useful data will be the incidence of erroneous or indeterminate device readings when compared to traditional methods of endotracheal tube placement confirmation.

## Human Subjects

### 5.1 Institutional Review Board

This protocol as well as any subsequent modifications will be reviewed by the institutional review board (IRB) of each participating center. IRB approval will be received before initiation of the study at each site. In addition, the study will be conducted in accordance to the Declaration of Helsinki guidelines for human subject research.<sup>23</sup>

The intent of the study design was to provide parallel data from the SCOTI device during emergency intubations without changing the actual process of intubation, qualifying it by means of its non-invasive nature as a non-significant risk device, and the study as a minimal risk investigation. Because this study does not involve any change in patient care, it meets “minimal risk” criteria and should undergo expedited IRB review.

### 5.2 Potential Risks and Benefits

For patients requiring intubation in the emergency department, the alternative to participation of the study is to undergo tracheal intubation without using SCOTI, using currently available methods of endotracheal tube position confirmation.

Patients enrolled in this study may benefit from use SCOTI for the reasons stated in sections 1.2 and 1.4.

Potential disadvantages to participation include the following:

- Cross-contamination of patients with respiratory pathogens. This problem should be completely prevented by use of a different, clean, new disposable sound pathway in each patient.
- Erroneous determination of endotracheal tube position. There should be no adverse consequence of such an error since SCOTI will be used only to make a preliminary determination of the position of the endotracheal tube while it is being inserted. The information supplied by SCOTI is unique in that no other monitoring device is able to provide preliminary determination of tube position during the process of intubation. Any such information should aid, rather than complicate, intubation, especially in difficult cases where direct visualization of vocal cords is impossible. Final determination of tube placement will rely on standard non-SCOTI methods currently in use and considered standard of care.
- Harmful delay in tracheal intubation due to inclusion in the study. This risk is minimal, for two reasons. First, data collection during intubation will not be performed by the intubating practitioner but by an observer. Second, the time required to configure and test SCOTI is only a few seconds (see section 2.4). If unforeseen delays due to SCOTI present themselves, and these delays are judged potentially harmful to the patient by the treating physician, SCOTI will not be used during the case in question.

### 5.3 Patient Confidentiality and Release of Information

The results of the study will be published. The privacy of subjects enrolled will be protected and subjects will not be identified in any way. The medical records related to this study, however, are available to the Food and Drug Administration.

### 5.4 Waiver of Informed Consent

The circumstances under which endotracheal intubation is performed in the emergency department rarely permit the procurement of fully informed consent. The method by which tracheal intubation is performed in a patient will not be materially altered by the patient's inclusion in this study and, as indicated by previous studies, patients enrolled in the study are likely to benefit from the more rapid confirmation of endotracheal tube position possible from use of the sonomatic method. This is with particular regard to the risk of arterial oxygen desaturation and aspiration pneumonitis, which are presently high risks using traditional methods of tube confirmation alone. Because of the study design, no patient enrolled in this study should experience delay in endotracheal intubation or tube confirmation. Thus, the request has been made to the IRB that the requirement for obtaining informed consent for participation in this study from either the patient to be intubated or any member of the patient's family be waived. The treating physician will instead make the determination as to whether any individual patient is a candidate for enrollment in the study.

The FDA has recently approved such waiver of informed consent for emergency and critical care research involving human subjects. [See Appendix I.]

## Investigational Device Considerations

### 6.1 Institutional Review Board

As stated in section 5.1, this protocol as well as any subsequent modifications will be reviewed by the institutional review board (IRB) of each participating center. IRB approval will be received before initiation of the study at each site.

### 6.2 Nonsignificant Risk Device

The SCOTI device is approved in Europe and Canada for patient use. It is, however, still considered an investigational device in the United States. As such, it meets FDA criteria for a “nonsignificant risk” (NSR) device.

As defined by the FDA, “an NSR device investigation is one that does not meet the definition for a significant risk study.” [See Appendix G.] A “significant risk” (SR) device study is defined “as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.”

SCOTI meets none of these state SR criteria, and thus qualifies as an NSR study device.

### 6.3 IDE Documentation and Procedures

In addition, SCOTI meets FDA criteria for “exempted investigations” as detailed in FDA Investigational Device Exemptions Document 21 CFR †812.2(c) Exempted investigations [Appendix H], which gives among other criteria, the following criteria for exemption from Investigational Device Exemptions (IDE) classification:

- (3) A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR †809.10(c) and if the testing:
  - (i) Is noninvasive,
  - (ii) Does not require an invasive sampling procedure that presents significant risk,
  - (iii) Does not by design or intention introduce energy into a subject, and
  - (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

In light of the multicenter nature of this study, it is conceivable that certain IRBs will grant this study “exempted investigation” classification, while others may grant “nonsignificant risk” study classification. Documentation will be maintained at the NSR level required by the FDA, termed the “Abbreviated IDE requirements” and outlined in 21 CFR †812.2(b) [Appendix G]. An IDE application along with required study monitoring documentation was prepared for this study by Allied Health, Inc., a former manufacturer of this device, and is currently administered by the principal investigators. As this study has been designed as an NSR investigation, documentation is maintained primarily for unanticipated adverse effects and potential FDA monitoring.

Centers whose IRBs are unable to approve NSR or “exempted investigation” classification will be dropped from the study, in order to maintain uniformity in data collection and study protocols.

## Study Organization

### 7.1 SCOTI working group and Site Information

Manitoba: University of Manitoba Health Sciences Centre (Doug Eyolfson, MD; Atul Kapur, MD)  
Massachusetts: Mount Auburn Hospital (James Li, MD)  
Minnesota: Hennepin County Medical Center (Richard Gray, MD)  
Missouri: St. John's Regional Health Center (Alan Clark, MD)  
New York: The Brooklyn Hospital Center (Phil McPherson, MD; Barry Brenner, MD PhD)  
Ohio: Akron General Hospital (Lynn White, MS)

### 7.2 Data Coordinating Center

Mount Auburn Hospital in Cambridge will function as data coordinating center. Contact information for the primary study principal investigator follows.

James Li, MD  
Department of Emergency Medicine  
Mount Auburn Hospital  
330 Mount Auburn Street  
Cambridge, MA 02238

Phone 800/895-4318  
Fax 617/725-0531  
E-mail jamesli@warren.med.harvard.edu

### 7.3 Writing Committee

The study principal investigator will select the members of this committee and chair its conference calls.

### 7.4 Publications and Authorship

The primary paper will be written by the Writing Committee (section 7.3) and will be authored by "The SCOTI Working Group." At the end of the paper, the study committees will be noted, along with all collaborating sites and investigators. Investigators' names will be presented in alphabetical order by state using the following format:

State: Hospital (name of investigator, names of co-investigators, coordinator; number of enrolled subjects)...

Sites with one hospital may name up to four investigators (including the site's principal investigator), whereas sites with two affiliated hospitals may name up to five investigators (including the site's principal investigator).

For secondary publications, the individuals proposing the idea will be listed by name, with authorship order determined by the site investigator. The primary study investigator and leader of the data coordinating center will be the final author of secondary papers, which will be written "on behalf of the SCOTI Working Group." The reader will be referred to the primary paper for the complete list of participating sites and investigators. This approach is fair since it shares credit between numerous sites but also acknowledges those individuals who made the extra contribution required to complete a secondary analysis.

## **7.5 Financial Information**

Equipment for the study will be provided by Dr. Heart Akerson, a private individual and inventor of the device. Principal investigators involved in this study are not employees of Dr. Akerson and have neither financial interest in the outcome of this study nor are being paid by Dr. Akerson for participation.

Participation in this study, for enrollees, will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. Because of the non-invasive and observational nature of this study, complications are not anticipated. However, costs of study-related unforeseen complications must be met by the subject.

## **7.6 Non-negligent Liability**

Because this is an observational non-invasive study, there should be no ground for lawsuits resulting from participation in this multicenter study. The principal investigators will not be liable for any injuries resulting from medical negligence.

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## **Appendices**