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SCOTI—a new device for identification of tracheal intubation

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Summary

A new lightweight device for the detection of placement of a tracheal tube in the trachea or oesophagus is described. The devi utilises a sonic technique detecting resonating frequencies in an open (trachea) or closed (oesophagus) structure. Evaluation of t device in a clinical environment is described and it has been shown to be capable of verifying the correct placement of the trache tube in the trachea in 98% of patients studied. Further evaluation of this intubating aid appears justified.

Key words

Intubation; tracheal.
Equipment; sonomatic confirmation of tracheal intubation (SCOTI).

In cases of difficulty in tracheal intubation, such as in patients with anatomical abnormalities of the face or chin, or patients with upper airway obstruction due to infection or tumour, the anaesthetist may be concerned over the correct placement of the tube. Failure to recognise incorrect placement can result in hypoxia and death [1].

In the present study, we have evaluated a prototype device using a sonic technique (SCOTI: Sonomatic Confirmation of Tracheal Intubation) which purports to be able to differentiate between tube placement in the upper airway (correct site) and the oesophagus (incorrect site). The device was developed by Drs H. Akerson of Costa Rica and J. Riopelle of New Orleans, USA. Its mechanism of action depends upon the recognition of a resonating frequency which varies with the presence of the tracheal tube in an open structure (trachea) or closed structure (oesophagus). A liquid crystal display (LCD) is built into the SCOTI apparatus, which displays a numerical value relating to the resonating frequency produced, and this value is termed the 'SCOTI value'. In addition, the machine contains an audible alarm system.

Prior to all studies, the apparatus was shown to comply with the standards laid down by BS 5724.

Methods

Description of apparatus

The tracheal tube is connected to the SCOTI apparatus (Fig. 1) using the right-angled adapter. SCOTI self-calibrating following depression of the on–off switc providing that the hole at the end of the tracheal tube completely occluded. The apparatus contains three separa systems for the instantaneous detection of tracheal oesophageal intubation: light emitting diode (LED) a LCD displays and an audible alarm.

During the calibration phase, the LED rapidly flash between red, yellow and green, the LCD numeric displ shows a number between 0 and 99 and the audible ala remains quiet. Once calibration is complete, the LE displays a red colour and the LCD digital readout a val between 0 and 15. If the finger is now removed from the e of the tracheal tube, the LED immediately changes to gre and the LCD digital readout shows a number of 20 or mo If either display fails to perform in the way described, indicates that one or more of the different connections are n secure. After removal of a finger from the end of the tut the audible alarm starts with a continuous clear tone of higher frequency.

Once calibrated, the tracheal tube (attached to SCOT can be introduced in the normal manner. If trache intubation is successful, the LED turns green, the LC digital readout displays the same number as that obtained the time of calibration and the audible alarm emits tv beeps. If the oesophagus is intubated, the LED turns red, t LCD displays a value between 0 and 15, and the audit alarm emits a loud and continuous signal.

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SCOTI is protected by US Patent 5,331,967; with European and Japanese patents pending.
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The sensing device as shown is 143.5 mm in length, and 67.3 mm in radius. The diameter of the connecting tube is 22.0 mm and the internal diameter 15.0 mm. The output sound has a frequency of 281–900 Hz and a power of <200 mW. The machine runs off a single 9 volt alkaline battery, with an input current of 45 mAmps.

Patients and methods

After obtaining informed consent from surgical patients and with the approval of the Central Oxford Research Ethnics Committee, we recruited 90 patients (age range 18–70 years, all weighing less than 130% of ideal weight with respect of their height). Patients were premedicated or not according to the clinical practice of the anaesthetist in charge of the case. Premedication was with temazepam, or ranitidine and metoclopramide. No patient received anticholinergics or opioids. All subjects were adult patients (of both sexes) in whom there was a clinical indication for airway instrumentation. Patients were not studied if there was a history of gastric reflux (or symptoms thereof), or where the patients were currently receiving drugs known to affect smooth muscle activity.

The apparatus was evaluated in the following manner. Ninety patients (44 male) were randomly allocated to regimen A or B. After a sleep dose of thiopentone or propofol, the patients all received a standardised dose of the neuromuscular relaxant vecuronium (0.1 $mg.kg^{-1}$). Anaesthesia was then maintained by controlled ventilation using a facemask with an inspired gas mixture of 67% nitrous oxide in oxygen supplemented by isoflurane (0–1%). Two minutes after the relaxant had been administered, the upper airway was instrumented using one of two regimens.

During the first phase of our evaluation, the trachea was intubated under direct vision and the SCOTI value (value 1) recorded. The tracheal tube was then taken out and placed again under direct vision in the oesophagus (value 2). A third reading was then made once the patient had been re-intubated (value 3, regimen A). During the second phase, the tracheal tube was initially placed under direct vision in the oesophagus (value 1), and then replaced in the trachea (value 2, regimen B).

Statistical methods

From the first phase of the evaluation, the measurements were used to determine the range of SCOTI values with the tracheal tube placed in the oesophagus and trachea. Comparison of values following tracheal and oesophageal intubation was by calculation of mean values and their associated 95% confidence limits. Assessment of values from male and female subjects was made using non-parametric statistics. The reproducibility of measurements made with the tracheal tube attached to SCOTI in the trachea was made by comparing values 1 and 3 (phase one). In all studies, statistical difference was taken as a p value less than 0.05. Data are shown as mean (95% CI) unless otherwise stated.

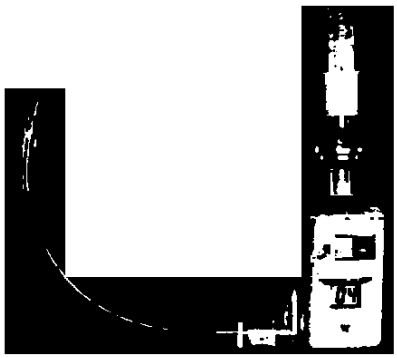

Fig. 1. The SCOTI apparatus (MK II).

Results

The conduct of anaesthesia and airway management was uneventful in all 90 patients.

In the 31 patients studied using regimen A, the mean SCOTI value with the tracheal tube in the trachea was 49.2 (95% CI: 35.7–66.7), and in the oesophagus 8.1 (4.1–12.1); $p < 0.01$. There was no overlapping of the 95% confidence limits for tracheal and oesophageal intubation. There were no differences in baseline values (SCOTI value 1) between male and female patients and therefore for both phases of this evaluation all subjects have been grouped together.

Comparison of values with the tracheal tube in the trachea before and after oesophageal intubation similarly showed no difference: before −49.2 (35.7–66.7); after −49.7 (36.8–62.6). The overall mean value for the two tracheal intubation was 49.5 (36.7–62.0). There is no overlapping of the confidence limits at the 5% or 1% level of significance and there were no significant differences between values obtained in male and female subjects.

In one patient (a female) the SCOTI value during oesophageal intubation was 30. This was in the green zone (>20 units), but we can offer no explanation for this apparent outlier. Post anaesthesia, there were no reported incidences of throat trauma and no other sequelae.

Discussion

The assessment of the correct placement of the tracheal tube can be made in two ways: first, using clinical signs confirming tracheal intubation (visualisation of tube passing through the cords; auscultation over the trachea, apices, bases and epigastrium; observation of chest movements; palpation of tracheal tube movement within the trachea; reservoir bag compliance and the lack of progressive abdominal distension; lack of cyanosis; and the presence of water vapour condensing in the breathing system during expiration) and second, using tests for detecting accidental oesophageal intubation [1]. The latter include measurement of expired carbon dioxide tension [2, 3], the negative pressure test described by Wee and Williams and Nunn [4, 5], oxygen saturation, use of the fibreoptic light wand [6], or fibreoptic inspection [7]. SCOTI clearly fits into this latter group of tests.

Our preliminary evaluation suggests that SCOTI may allow differentiation between tracheal tube placement in the trachea as against the oesophagus. However, the one incidence of a SCOTI value of 30 associated with oesophageal placement of the tracheal tube is of concern, but may represent faulty technique during the learning phase of this study.

Greater reassurance as to the usefulness of the technique would appear to be provided by our repeated movements following placement of SCOTI in the trachea. As with all new pieces of equipment, its reliability and utility are only partially assessed by controlled clinical or laboratory studies. Hence we would offer caution against the widespread adoption of this aid to intubation before it has undergone more extensive field evaluation. Our value, of 98% correct verification of the placement of the tracheal tube in the trachea, compares well with the 97% verification for tube placement using palpation of the tube in relation to the intra-arytenoid groove described by Charters and Wilkinson [8].

References

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Note added in proof

Following this initial evaluation, a production model of the SCOTI device is being marketed in the UK by Peulon (UK) Ltd, Abingdon, Oxon.

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New Method for Endotracheal Intubation

A new method for endotracheal intubations has been developed by Heart Akerson with the help of Dr. James Riopelle of Charity Hospital in New Orleans and Dr. Wilson León of Hospital San Juan de Diós in San Jose, Costa Rica. The goal of this project has been to develop a device that indicates whether the tube is in the trachea or in the esophagus while the tube is being inserted rather than after the intubation is complete and the respiration equipment is connected and operating. Also, it is hoped that this device could be manufactured for a low enough cost to make it available worldwide wherever intubations are done such as operating rooms, emergency rooms, "crash carts" and ambulances.

Sonomatic Confirmation Of Tracheal Intubation (SCOTI)

SCOTI (U.S. Patent #5,331,967) is a small battery operated device that connects to the end of the tracheal tube during intubation. It produces sounds in the normal audio range and determines whether the tube is in the trachea or the esophagus with special algorithms. The result is displayed with a light which is green when the tube is in the trachea and red when it is in the esophagus. The color of the light is updated 100 times a second so the perceived feedback is instant and continuous allowing for the anesthesiologist to make many rapid "trial and error" intubation attempts in a few seconds, a process which would take several minutes without this device. After the intubation SCOTI is disconnected and the respiration equipment connected. This is the first device which can actually help with the intubation process while it is happening! SCOTI also has an LCD readout which displays a number between 0 and 100 which allows the operator to interpret the output of the algorithm himself. This also allows for large amounts of data to be gathered in the field which is being used to improve the device. SCOTI also contains an audible indicator that gives the operator the information of the lights and LCD. SCOTI automatically configures itself when it is turned on to operate with whatever size tube and attachments that are hooked to it.

SCOTI is currently 145.0mm X 63.5mm X 62.5mm and weighs 300 grams. The tracheal tube can be hooked directly to SCOTI or have adaptors and tubes between it and SCOTI. A disposable bacteria filter can be used to avoid the risk of contamination between patients. A corrugated tube can be used to minimize the weight in the operators hand. If this tube is used then SCOTI can sit on the operating table by the patients head, be strapped to the operators arm or belt or be held by an assistant. The common 9 volt battery will last several weeks in an operating room and will indicate when it is getting low with enough charge left to do a typical days work.

Test Results

Method

These tests were performed in the operating rooms of Hospital San Juan de Dios in San Jose, Costa Rica. This Hospital has 20 operating rooms for adults and is operated by the Seguro Social of Costa Rica. These tests were approved by the Internal Review Board and encouraged by the Chief Anesthesiologist and the Chief Surgeon. Consent was obtained from the patients after the process and its risks were discussed.

A Hudson bacteria filter was hooked to SCOTI. To this was hooked a 15 mm by 76 cm corrugated flexible tube. To the end of this was hooked a 15mm right angle adaptor. To this was hooked the tracheal tube which was between 6.0 and 10.0 mm as these tests were for adults. SCOTI was taped to the operating table next to the right side of the patients head so that the anesthesiologist could see SCOTI while he was intubating.

When the tracheal tube sterile package was opened the tube was only pulled half way out so that the tip was still in the package. Then the end of the tube and the Murphy's eye were closed by pinching them between the thumb and the forefinger through the sterile package. Then SCOTI was turned on and the holes held closed until the indicator light stopped flashing indicating that configuration was complete. The reading on the LCD readout was recorded with the end of the tube open and with the end of the tube closed (making sure to also cover the Murphy's eye).

Then the tube was intentionally inserted into the patients esophagus and the LCD readout was recorded. Then the tube was inserted into the trachea and the LCD readout recorded. Then SCOTI with its filter, corrugated tube and right angle adaptor were disconnected and the respirator was connected and the operation proceeded. No pulse oxymetry or capnography were available but the tracheal intubation was confirmed and monitored by the normal methods used at this Hospital, i.e. breath sounds, pulse rate, blood pressure, respirator pressure, etc. Since all normal methods of confirming tracheal intubation were used and the results of SCOTI were used for experimental data only, the patients were exposed to no additional risk as a result of this experiment.

Results

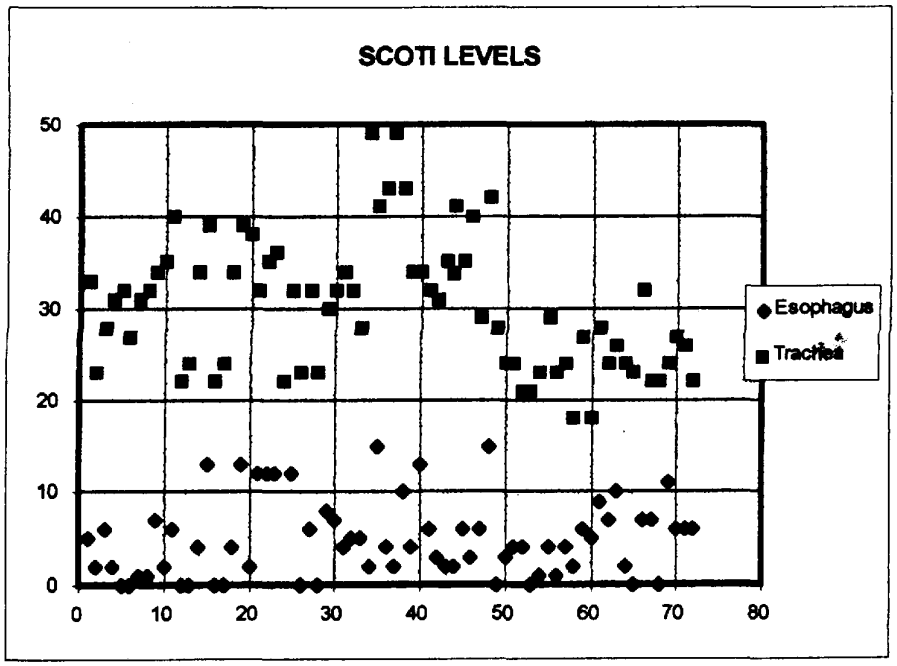
The test included 72 patients and the results can be seen in the table and on the graph. With the indicator light level set to show red below 16 and green above 20 SCOTI was red on 100% of the cases in the esophagus and green on 70 of the cases in the trachea. The band between 16 and 20 was considered an error or unreliable band in which the indicator light was yellow as happened on two cases in the trachea.

Data, Hospital San Juan de Dios

Case #	Tube	Sex	Build	Age	Esophagus		Trachea		Open	Class	Grade	Wt.KG	Date
1	7.5	F	fat	47	5	R	33	G	46				4/01/93
2	7.5	F	fat	47	2	R	23	G	51				1/22/93
3	7.5	F	fat	30	6	R	28	G	46				1/22/93
4	7.5	F	med	58	2	R	31	G	46				1/22/93
5	7.5	F	med	75	0	R	32	G	41				1/22/93
6	7.5	F	fat	40	0	R	27	G	36				1/22/93
7	7.5	F	fat	35	1	R	31	G	24				1/22/93
8	7.5	M	fat	58	1	R	32	G	46				1/22/93
9	7.5	M	slim	17	7	R	34	G	42				2/19/93
10	7.5	M	slim	58	2	R	35	G	34				2/19/93
11	7.0	F	med	29	6	R	40	G	37				2/19/93
12	7.0	F	med	40	0	R	22	G	30				3/17/93
13	7.0	M		19	0	R	24	G	30				3/17/93
14	7.0	M	slim	23	4	R	34	G	38				3/17/93
15	7.0	F	med	19	13	Y	39	G	40				3/17/93
16	7.0	F	med	40	0	R	22	G	22				3/22/93
17	7.0	M		19	0	R	24		24				3/22/93
18	7.0	M	slim	23	4	R	34	G	34				3/22/93
19	7.0	F	med	19	13	Y	39	G	39				3/22/93
20	7.5	F	slim	45	2	R	38	G	38				3/22/93
21	7.5	M	med	40	12	Y	32	G	47				3/30/93
22	7.5	F	slim	25	12	Y	35	G	46				3/31/93
23	7.5	F	slim	26	12	Y	36	G	40				3/31/93
24	8.0	M	fat	37			22	G	38				4/14/93
25	7.5	F	med	22	12	Y	32	G	44				4/14/93
26	7.5	M	fat	20	0	R	23	G	34				4/16/93
27	7.5	M	med	82	6	R	32	G	45				4/9/93
28	8.0	M	fat	40	0	R	23	G	32				4/9/93
29	7.5	M	fat	53	8	R	30	G	40	4	1	75	5/11/93
30	7.5	F	med	58	7	R	32	G	38	3	3	65	5/11/93
31	6.0	F	slim	8	4	R	34	G	32	2	1	25	5/11/93
32	7.5	F	med	34	5	R	32	G	38	1	1	65	5/12/93
33	7.5	F	fat	73	5	R	28	G	54	2	1	70	5/13/93
34	7.0	F	med	19	2	R	49	G	52	4	2	56	5/14/93
35	7.5	F	med	23	15	G	41	G	47	2	2	55	5/14/93
36	7.5	F	thin	17	4	R	43	G	47	3	1	45	5/14/93
37	7.0	F	thin	24	2	R	49	G	45	4	1	45	5/14/93
38	7.0	F	thin	14	10	Y	43	G	48	2	3	45	5/16/93
39	7.0	F	med	29	4	R	34	G	41	3	2	70	5/16/93
40	7.5	F	med	36	13	Y	34	G	54	3	3	55	5/16/93
41	7.0	M	fat	59	6	R	32	G	48	4	2	95	5/18/93
42	7.5	M	fat	23	3	R	31	G	48	3	1	80	5/23/93
43	7.5	M	thin	39	2	R	35	G	45	2	2	70	5/23/93
44	7.5	M	fat	34	2	R	41	G	48	2	4	80	5/23/93
45	6.0	M	child	7	6	R	35	G	28	2	2	31	6/02/93
46	7.5	M	thin	14	3	R	40	G	49	2	1	40	6/06/93
47	7.0	F	med	15	6	R	29	G	43	2	1	55	6/07/93
48	7.5	F	thin	52	15	Y	42	G	52	2	1	50	6/09/93
49	7.0	M	med	23	0	R	28	G	39	2	1	50	6/09/93
50	7.0	F	med	47	3	R	24	G	31	4	3	45	6/09/93
51	7.5	F	med	20	4	R	24	G	30	2	1	60	6/09/93
52	7.0	F	fat	50	4	R	21	G	24	2	1	80	6/12/93

53	7.5	F	fat	21	0	R	21	G	27	3	1	75	6/17/93
54	6.5	F	med	19	1	R	23	G	26	1	1	55	6/19/93
55	6.5	F	med	17	4	R	29	G	48	4	4	50	6/19/93
56	7.5	M	med	17	1	R	23	G	29	2	2	75	6/25/93
57	7.0	F	med	45	4	R	24	G	44	1	1	58	7/01/93
58	7.0	F	med	25	2	R	18	G	22	2	1	65	8/10/93
59	7.0	F	thin	30	6	R	27	G	27	2	3	60	8/13/93
60	7.5	F	fat	62	5	R	18	G	33	1	2	75	8/15/93
61	7.0	F	med	25	9	R	28	G	34	1	1	55	8/16/93
62	8.0	M	fat	47	7	R	24	G	32	1	1	70	8/17/93
63	7.0	F	med	25	10	R	26	G	28	1	1	50	8/17/93
64	7.5	F	med	37	2	R	24	G	31	2	1	60	8/18/93
65	7.5	M	thin	15	0	R	23	G	32	2	1	45	8/22/93
66	7.5	M	med	16	7	R	32	G	35	1	1	55	8/23/93
67	7.5	F	med	39	7	R	22	G	26	1	1	70	9/24/93
68	7.5	F	med	47	0	R	22	G	26	1	1	65	9/24/93
69	7.5	M	med	32	11	R	24	G	30	1	1	70	9/26/93
70	7.0	F	med	27	6	R	27	G	31	1	1	50	10/01/93
71	7.5	F	med	75	6	R	26	G	27	1	1	75	10/04/93
72	7.5	M	med	35	6	R	22	G	30	1	1	75	10/08/93
			Minimum		0		18		22				
			Maximum		15		49		54				
			Average		5		30		37.63				
			Standard Deviation		4		7		8.683				
			# Cases		72								

All tests done with Hudson filter, 15mm X 76cm corrugated tube and angle between SCOTI and tube.



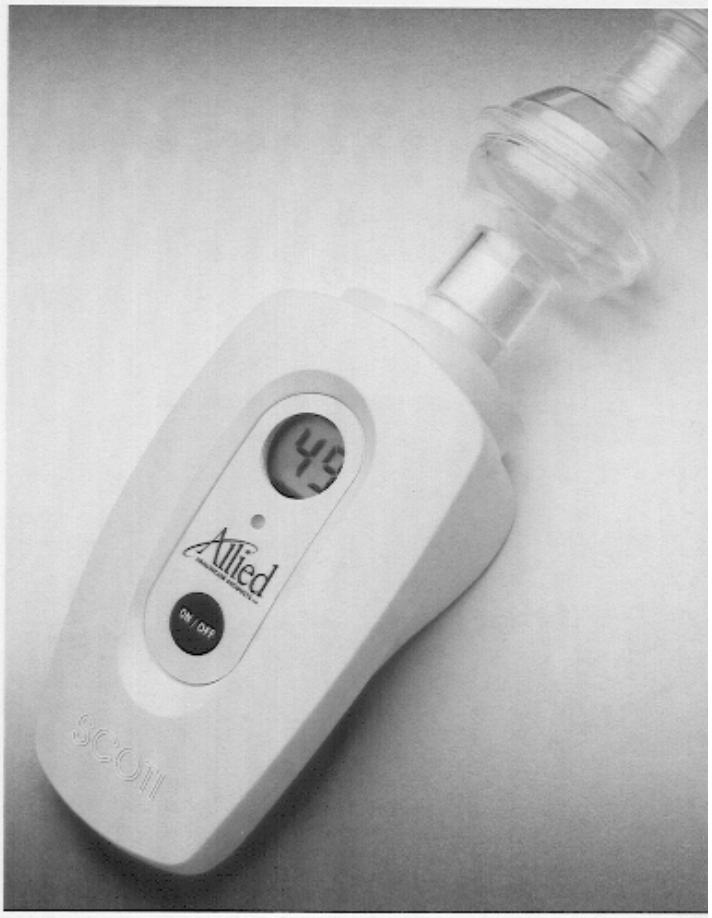
Conclusions

In addition to the above tests several patients were used to simulate blind intubations. SCOTI was configured in the "Reverse" mode. When the patient was intubated only a small amount of pressure was exerted on the Laryngoscope so that the glottis was not visible. The anesthesiologist used the color of the light from SCOTI to know when the tube was in the trachea. Then enough pressure was exerted on the Laryngoscope to expose the glottis to confirm if the intubation was successful. In 100% of these cases the intubation was successful and did not take any longer than normal.

Although the database is small it is very encouraging. More tests are continuing with the same methods as well as with different configurations of attachments. Also tests are being started with infants and children.

Clinical tests have also been completed by St Barts Hospital in London England and John Radcliff Hospital in Oxford, England with similar results. Their results will be published separately.

SCOTI (Sonomatic Confirmation of Tracheal Intubation)



Because every second counts in critical situations, SCOTI (Sonomatic Confirmation of Tracheal Intubation) provides paramedic, ambulatory and hospital healthcare workers with instantaneous confirmation of endotracheal tube placement during emergency intubation.

Using proven, state-of-the-art soundwave technology, SCOTI distinguishes the differing structures of the trachea and esophagus in "*Real Time*," providing an audible and two visual signals–both LCD and LED displays–to confirm that you've placed the endotracheal tube in the correct position which allows you to oxygenate/ventilate your patient without delay.

Allied's portable, battery-operated unit has a compact design that easily fits in your existing intubation kit and requires no extensive training to achieve reliable and accurate results every time you intubate. Most importantly, its single-patient use circuits are inexpensive and prevent contaminants from entering the SCOTI module.

Model No. L1000: SCOTI (complete)
(endotracheal tube not included)

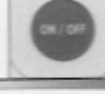
SCOTI (Sonomatic Confirmation of Tracheal Intubation)

INSTANTANEOUS DETECTION OF TRACHEAL OR ESOPHAGEAL INTUBATION- Utilizing reliable, technologically advanced soundwave applications, SCOTI provides "*Real Time*" assistance to effectively distinguish tracheal from esophageal intubation in emergency situations and allow immediate oxygenation/ventilation of the patient.

QUICK AND EASY TO USE- SCOTI's small, lightweight, battery-powered unit fits into any existing intubation kit easily. A minimal amount of training is required to secure accurate and instantaneous results every time.

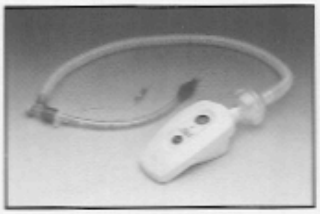
COST EFFECTIVE AND SAFE- Especially sensitive to today's healthcare concerns, SCOTI is safe for use by EMS agencies and trained hospital staff and is designed to minimize the risks of contamination for patients. Single-patient use circuits are inexpensive and prevent contaminants from entering the SCOTI module.

IDEALLY SUITED FOR DIFFICULT ENVIRONMENTS- Rugged in its design, SCOTI's easy to hear and read displays make it an essential tool in dimly lit or nighttime emergency situations. Its LED display brightly shines green confirming tracheal intubation, or red when the tube is placed in the esophagus. As a secondary backup, the unit's illuminated LCD display will read 20 or higher when intubation is done correctly and 15 or less when the endotracheal tube is in the esophagus. In addition, a continuous audible sound confirms that the tube is positioned correctly, whereas a low-pitched bleep warns that the tube needs to be repositioned.

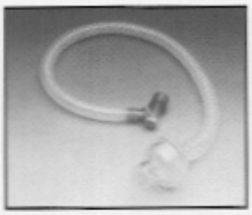
Confirmation Function		Successful Intubation	Unsuccessful Intubation	Indeterminant Intubation
LCD Visual		20 or Higher	15 or Lower	16-19
Colored Lamp Visual		Green	Red	Orange
Audible Speaker		High-Pitched Continuous	Low-Pitched Bleep	Mid-Range Bleep

REPLACEMENT PARTS:

L1001-001	Single-patient use sound circuit, assembled. Includes: bacteria filter, flexible tube and swivel elbow with 15mm ID termination. Case of 24 sets.
L1001-002	Operator's Manual



L1000 SCOTI (complete)
(endotracheal tube not included)



L1001-001 Single-patient use sound circuit
(case of 24 sets)

SPECIFICATIONS

Height: 6.8 inches
Width: 3.2 inches
Depth: 2.5 inches
Weight: 0.75 pounds
Output:
Sound Frequency- 281-900 Hz
Power- < 200 mW
Battery- 9 volt Alkaline
Input Current: 45 mA

Life Support Products by Allied

1720 Sublette Ave. • St. Louis, MO 63110
Domestic (800)225-4577 or (800) 444-3940 • FAX (800) 477-7701
International (314) 268-1683 • FAX (314) 771-5183
http://www.alliedhpi.com • GLOBAL SUPPORT OF LIFE
P/N L909005-002
5M; 5-'96

SCOTI

A Device for Confirmation of Endotracheal Intubation

OPERATOR'S MANUAL

ALLIED HEALTHCARE PRODUCTS
1720 SUBLETTE AVE.
ST. LOUIS, MO 63110, U.S.A.
TELEPHONE: (314) 771-2400

L1001-002, APR. 1996

PRECAUTIONS

WARNING:	Indicate situations that may cause serious injury if instructions are not followed.
CAUTION:	Indicate situations that may damage the device or other equipment.
NOTE:	Indicate points of particular interest for more efficient and convenient operation.

CAUTION: Feceral law restricts this device to sale by or on the order of a physician.

WARNING: Read this entire manual, before using the device.

WARNING: When SCOTI is connected to a patient, it is recommended that a qualified practitioner be in attendance at all times to react to an alarm or other indications of a problem.

WARNING: A defective or suspected defective SCOTI must not be used. It should be returned to *Allied Healthcare Products* immediately.

WARNING: Do not use SCOTI when the battery is low. See 6.4 REPLACE BATTERY.

NOTE: SCOTI has been tested to 10,000 feet (3048 m).

WARNING: Do not use SCOTI on spontaneously breathing patients.

WARNING: Use only Allied Healthcare disposable components in the sound pathway. Do not sterilize SCOTI. For cleaning, see 5 CLEANING & MAINTENANCE.

WARNING: If a malleable intubation stylet is to be used, a cross-sectional area greater than 75% of the internal area must remain open for sound transmission within the endotracheal tube. There must be an airtight seal where the stylet enters the airway.

WARNING: SCOTI must be used only with the endotracheal tube that was used in the calibration procedure. If a replacement endotracheal tube is to be used, the calibration procedure must be repeated.

CAUTION: Do not open the device. SCOTI contains no internal, user serviceable components. Attempting to open the unit will void the warranty. Service should be performed by qualified service personnel only. The manufacturer assumes no liability for any malfunction or failure if the device is tampered with. Replace battery through the bottom door. See 6.4 REPLACE BATTERY.

TABLE OF CONTENTS

1 INTRODUCTION

Unrecognized and inadvertent esophageal intubation, can result in gastric insufflation and lack of oxygen. SCOTI (Sonomatic Confirmation Of Tracheal Intubation) is designed for use during endotracheal intubation, to indicate whether the endotracheal tube is in the trachea or the esophagus.

SCOTI is a small, battery operated electronic device, that is attached to the proximal end of the endotracheal tube. The unit comes with a battery. SCOTI continuously analyses the acoustic properties of the volume of air just beyond the distal end of the endotracheal tube. SCOTI is, in essence, a blocked tube sensor - differentiating between the esophagus, which is soft and collapses and the trachea, which is rigid and open. Working by sound, it detects, instantaneously and continuously, during intubation, whether the endotracheal tube is in the trachea or esophagus.

Suitable for use with both adults and children, SCOTI utilizes LED and LCD displays, with an audible indicator/alarm, to confirm tracheal or esophageal intubation.

WARNING: SCOTI can be used with endotracheal tubes having a 6 mm, or larger, inside diameter

NOTE: SCOTI is only designed for apneic patients and will not work on a breathing patient.

2 SINGLE PATIENT USE SOUND CIRCUIT (See Figure 1)

SCOTI does not come in direct contact with the patient, so only appropriate cleaning procedures are required. (See 5 CLEANING and MAINTENANCE) The hardware used to sonically connect SCOTI to the endotracheal tube, is referred to as the sound circuit. The sound circuit consists of the following components;

SCOTI is always used in conjunction with a bacteria filter, (one included) having a 22 mm female connector at one end and a 22 mm male connector on the other end. A 15 mm inside diameter, flexible plastic tube, 800 mm in length, (one included) is used with a 22 mm female adapter at one end and a 15 mm inside diameter, female adapter at the other end. Finally a plastic, 15 mm, swivel elbow adapter, (one included) is attached to the required size of endotracheal tube.

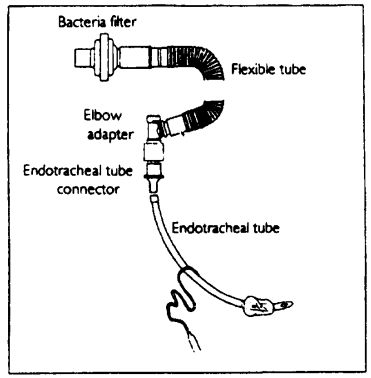


Figure 1 - Sound Path

NOTE: See 9 REPLACEMENT PARTS, for additional disposable supplies available from *Allied Healthcare Products.*

NOTE: If SCOTI will not calibrate, See 9 TROUBLE SHOOTING.

3 SET-UP and OPERATION

Install the 9 volt alkaline battery supplied. See 6 BATTERY.

3.1 Set-Up

a. Attach the bacteria filter end, of the sound circuit, to SCOTI.

b. Connect the endotracheal tube connector to the elbow adapter.

c. If a stylet is not required, carefully open the sterile pack containing the selected, internal diameter, endotracheal tube and attach the tube to the elbow adapter. See Figure 1

d. If a stylet is to be used, proceed with either method below;

Loose Stylet Method - set-up - without the stylet - as in 3.1.c, above. This method is less likely to waste the sound circuit, if the patient coughs secretions through the endotracheal tube. However, this method does not allow for continual monitoring.

Stylet Puncture Method - swab the rubber cap, of the swivel elbow, with alcohol. Puncture the rubber cap by inserting the sterile stylet. Set-up as in 3.1.c, above.

NOTE: Maintain sterility by ensuring that the patient end of the endotracheal tube, stays within the sterile pack. (See Figure 2)

3.2 Calibration Procedure

a. Tightly and completely occlude the patient end of the endotracheal tube with two fingers, while it is still in the sterile pack. Turn SCOTI "ON" by depressing the front keypad. SCOTI will take a few seconds to self-calibrate. While doing so, it is essential that the fingers continue to occlude the end of the endotracheal tube. If the hole at the end of the endotracheal tube is not completely covered, or if one of the connectors is not attached securely, SCOTI will not calibrate correctly. If a Murphy eye is present, this should also be tightly and completely occluded. (See Figure 2)

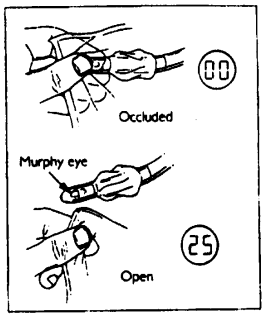


Figure 2

b. SCOTI is equipped with LED and LCD displays and an audible indicator/alarm. (See Table 1)

c. During the calibration process, the LED will rapidly flash between RED and GREEN. The LCD will display random characters which represent the calibration process and are not significant to the end user. The audible indicator/alarm will remain silent.

d. After a few seconds of the calibration process, the LED will display a RED color, the LCD digital readout should show 00 or 01 and the audible alarm will emit a low pitch beeping. (See Figure 2) Remove fingers within 3 seconds (or unit will shut off) and the LED will turn GREEN, completing the calibration process. If this does not occur, See 9 TROUBLE SHOOTING. To recalibrate, briefly turn SCOTI OFF and repeat the calibration procedure.

NOTE: SCOTI will shut-off if not properly calibrated. See 9 TROUBLE SHOOTING.

3.3 Sensitivity Test

Withdraw the tip of the endotracheal tube from it's sterile disposable wrapper and check that, with the tube tip exposed to open air:

a. SCOTI emits a continuous, high pitched tone and
b. The LED is GREEN and
c. The LCD reads 22 or higher.

WARNING: If after repeated attempts, SCOTI fails to calibrate to 00 or 01 and to indicate a reading of 22 or higher during the sensitivity test: DO NOT USE THE DEVICE TO CONFIRM ENDOTRACHEAL INTUBATION.

WARNING: DO NOT stretch the flexible tubing after calibration. Stretching can cause potentially erroneous readings on the LCD display.

WARNING: DO NOT attempt to calibrate SCOTI if there is visible moisture in the sound circuit.

4 INTUBATION PROCEDURE (See Table 1)

Table 1: Intubation Indicator Guide

LED color	LCD reading	Audible Indicator	Intubation Condition
GREEN	20-99	Hi-pitch continuous	Trachea
ORANGE	16-19	Mid-range beeping	Indeterminate
RED	00-15	Low pitch beeping	Esophagus

4.1 Locate SCOTI near the patient's head. Insert the endotracheal tube in the normal manner. If a stylet is used, proceed with either method below;

Loose Stylet Method - after SCOTI is calibrated, (See 3.2.d) (1) disconnect SCOTI and the sound circuit from the endotracheal tube - do NOT turn OFF, (2) intubate with the stylet in the usual manner. (3) After intubation, remove the stylet and (4) reattach SCOTI and the sound circuit, to assess intubation of the trachea. Continue to 4.2.

Stylet Puncture Method -after SCOTI is calibrated, (See 3.2.d) intubate in the usual manner. The stylet must remain in place, through intubation confirmation - 4.5 below. NOTE: If the patient coughs secretions into the sound circuit and/or stylet, both must be replaced and SCOTI recalibrated. The obstruction will invalidate SCOTI's calibration and the stylet will no longer be sterile.

4.2 SCOTI is programmed to detect certain threshold levels and change the LED from GREEN to RED. Between these levels, the LED will turn ORANGE which should be interpreted as the device cannot determine the placement of the endotracheal tube with certainty.

4.3 Inadvertent blockage of the endotracheal tube lumen, by any material, may cause SCOTI to work improperly. Refer to Table 1 - Intubation Indicator Guide.

a. If the trachea is successfully intubated:
   1. The LED will be GREEN and
   2. The LCD digital readout will be 20 or higher and
   3. SCOTI will emit a high pitched, continuous tone.

b. If the esophagus is intubated;
   1. The LED will be RED and
   2. The LCD digital readout will be 15 or lower and
   3. SCOTI will emit a low pitched beep.

In this case, the endotracheal tube must be withdrawn from the patient and the process repeated.

c. If the intubation is indeterminate;
   1. The LED will be ORANGE and
   2. The LCD digital readout will be 16-19 and
   3. SCOTI will emit a mid-range beep.

In this case, either withdraw endotracheal tube from patient and repeat the process or use other methods to verify.

4.4 Should SCOTI be accidentally turned OFF during intubation, disconnect, leaving the endotracheal tube in place. If there is doubt, with regard to the correct placement of the endotracheal tube, SCOTI should be recalibrated using an endotracheal tube exactly the same as the one in use.

4.5 When SCOTI has confirmed that endotracheal intubation has been successful, disconnect the sound circuit from the endotracheal tube and connect the breathing system in the usual manner.

4.6 SCOTI can be turned OFF. Briefly press the ON/OFF pad.

5 CLEANING and MAINTENANCE

5.1 For inquiries regarding the servicing or repair of your SCOTI or any problems not described in this manual, contact the Service Dept at *Allied Healthcare Products, Inc.* 800-411-5136. SCOTI contains no internal, user serviceable components. Attempting to open the unit will void the warranty. For battery replacement, See 6 BATTERY.

5.2 SCOTI can be cleaned by wiping the exterior with a cloth.

CAUTION: DO NOT STERILIZE SCOTI.

6 BATTERY

6.1 Changing the battery - SCOTI is supplied with a 9 volt alkaline battery. When changing the battery - no tools are required - simply open the plastic door on the back of SCOTI and replace the battery.

6.2 Battery Life - The battery will provide up to seven hours of continuous use.

6.3 Low Battery - SCOTI is equipped with a low battery indicator. When the battery charge is low, the LED will flash, so that the LED is "ON" for only 50% of the time. A decimal point will also be visible between the digits. The readings are still reliable in this state and the intubation can be completed with confidence. The battery should be changed immediately upon completion of the intubation.

6.4 Replace Battery - If the battery charge is very low, the LED and the alarm become disabled, while the digital display will continue to operate. In this case, the reading from SCOTI should not be considered reliable and the battery replaced immediately.

CAUTION: Remove the battery during storage - a leaking battery can be corrosive.

WARNING: Used or defective batteries contain corrosive and toxic material. Dispose according to local ordinances.

7 SPECIFICATIONS

Height:	6.8 inches
Width:	3.2 inches
Depth:	2.5 inches
Weight:	0.75 pounds

Output Sound Frequency:	281 - 900 Hz
Sound Power:	< 200 mW
Battery:	9 volt Alkaline
Input Current:	45 mA

8 REPLACEMENT PARTS

L1000 SCOTI, complete

L1001-001 Single Patient Use Sound Circuit, Assembled, includes: bacteria filter, flexible tube and 75° swivel elbow with 15 mm ID termination. Carton of 24 sets

L1001-002 Operator's Manual

9 TROUBLE SHOOTING

Symptom	Possible cause
No function Visible decimal point	No or low battery, See 6 BATTERY
Unit shuts-off	Unit not properly calibrated, See 3.1 CALIBRATION PROCEDURE
Will not calibrate	1. Failure to maintain a tight occlusion of the tip of the endotracheal tube (and Murphy eye, if used) during calibration. 2. An air leak at a connector in the sound pathway, or hole in tubing. 3. Sound pathway incorrect. a. Flexible tubing too long, too short or incorrect inside diameter. b. Inside diameter of endotracheal tube is too small. c. Diameter of stylet is too large for endotracheal tube. d. Bacterial filter has excessive acoustical impedance.

SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES

The Investigational Device Exemption (IDE) regulations [21 CFR part 812] describe two types of device studies, "significant risk" (SR) and "nonsignificant risk" (NSR). An SR device study is defined [21 CFR 812.3(m)] 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. An NSR device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the Institutional Review Board (IRB) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure. For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the IRB are required. In addition, informed consent must be obtained for either type of study [21 CFR part 50].

Distinguishing Between SR and NSR Device Studies

The effect of the SR/NSR decision is very important to research sponsors and investigators. SR device studies are governed by the IDE regulations [21 CFR part 812]. NSR device studies have fewer regulatory controls than SR studies and are governed by the abbreviated requirements [21 CFR 812.2(b)]. The major differences are in the approval process and in the record keeping and reporting requirements. The SR/NSR decision is also important to FDA because the IRB serves, in a sense, as the Agency's surrogate with respect to review and approval of NSR studies. FDA is usually not apprised of the existence of approved NSR studies because sponsors and IRBs are not required to report NSR device study approvals to FDA.

If an investigator or a sponsor proposes the initiation of a claimed NSR investigation to an IRB, and if the IRB agrees that the device study is NSR and approves the study, the investigation may begin at that institution immediately, without submission of an IDE application to FDA. If an IRB believes that a device study is SR, the investigation may not begin until both the IRB and FDA approve the investigation. To help in the determination of the risk status of the device, IRBs should review information such as reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria, and monitoring procedures. The sponsor should provide the IRB with a risk assessment and the rationale used in making its risk determination [21 CFR 812.150(b)(10)].

SR/NSR Studies and the IRB

The NSR/SR Decision

The assessment of whether or not a device study presents a NSR is initially made by the sponsor. If the sponsor considers that a study is NSR, the sponsor provides the reviewing IRB an explanation of its determination and any other information that may assist the IRB in evaluating the risk of the study. The IRB may ask the sponsor for information such as a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the IRB deems necessary to make its decision. The IRB should ask the sponsor whether other IRBs have reviewed the proposed study and what determination was made. The sponsor should inform the IRB of the Agency's assessment of the device's risk if such an assessment has been made. The IRB may also consult with FDA for its opinion.

The IRB may agree or disagree with the sponsor's initial NSR assessment. If the IRB agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE application to FDA. If the IRB disagrees, the sponsor must notify FDA that a SR determination has been made. The study can be conducted at that institution as a SR investigation following FDA approval of an IDE application.

The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses a SR, an IRB must consider the nature of the harm that may result from use of the device. Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device. Two examples follow:

- The study of a pacemaker that is a modification of a commercially-available pacemaker poses a SR because the use of any pacemaker presents a potential for serious harm to the subjects. This is true even though the modified pacemaker may pose less risk, or only slightly greater risk, in comparison to the commercially-available model. The amount of potential reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing whether the study can be approved.

- The study of an extended wear contact lens is considered SR because wearing the lens continuously overnight while sleeping presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR .

FDA has the ultimate decision in determining if a device study is SR or NSR. If the Agency does not agree with an IRB's decision that a device study presents an NSR, an IDE application must be submitted to FDA. On the other hand, if a sponsor files an IDE with FDA because it is presumed to be an SR study, but FDA classifies the device study as NSR, the Agency will return the IDE application to the sponsor and the study would be presented to IRBs as an NSR investigation.

IRB and Sponsor Responsibilities Following SR/NSR Determination

If IRB decides the study is Significant Risk:

1. IRB Responsibilities:

   - Notify sponsor and investigator of SR decision
   - After IDE obtained by sponsor, proceed to review study applying requisite criteria [21 CFR 56.111]

2. Sponsor Responsibilities:

   - Submit IDE to FDA or, if electing not to proceed with study, notify FDA (CDRH Program Operations Staff 301-594-1190) of the SR determination;
   - Study may not begin until FDA approves IDE and IRB approves the study.
   - Sponsor and investigator(s) must comply with IDE regulations [21 CFR part 812], as well as informed consent and IRB regulations [21 CFR parts 50 and 56].

If the IRB decides the study is Nonsignificant Risk:

1. IRB proceeds to review study applying requisite criteria [21 CFR 56.111]

2. If the study is approved by the IRB, the sponsor and investigator must comply with "abbreviated IDE requirements" [21 CFR 812.2(b)], and informed consent abd IRB regulations [21 CFR parts 50 and 56].

The Decision to Approve or Disapprove

Once the SR/NSR decision has been reached, the IRB should consider whether the study should be approved or not. The criteria for deciding if SR and NSR studies should be approved are the same as for any other FDA regulated study [21 CFR 56.111]. The IRB should assure that risks to subjects are minimized and are reasonable in relation to anticipated benefits and knowledge to be gained, subject selection is equitable, informed consent materials and procedures are adequate, and provisions for monitoring the study and protecting the privacy of subjects are acceptable. To assure that the risks to the subject are reasonable in relation to the anticipated benefits, the risks and benefits of the investigation should be compared to the risks and benefits of alternative devices or procedures. This differs from the judgment about whether a study poses a SR or NSR which is based solely upon the seriousness of the harm that may result from the use of the device. Minutes of IRB meetings must document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.

FDA considers studies of *all significant risk devices to present more than minimal risk*; thus, full IRB review for all studies involving significant risk devices is necessary. Generally, IRB review at a convened meeting is also required when reviewing NSR studies. Some NSR studies, however, may qualify as minimal risk [21 CFR 56.102(i)] and the IRB may choose to review those studies under its expedited review procedures [21 CFR 56.110].

Examples of NSR/SR Devices

The following examples are provided to assist sponsors and IRBs in making SR/NSR determinations. The list includes many commonly used medical devices. Inclusion of a device in the NSR category should not be viewed as a conclusive determination, because the proposed use of a device in a study is the ultimate determinant of the potential risk to subjects. It is unlikely that a device included in the SR category could be deemed NSR due to the inherent risks associated with most such devices.

21 CFR PART 812 : INVESTIGATIONAL DEVICE EXEMPTIONS

PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513-

FR Update

516, 518-520, 701, 702, 704, 721, 801 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371, 372, 374, 376, 381); secs. 215, 301, 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b-263n).

Source: 45 FR 3751, Jan. 18, 1980, unless otherwise noted.

21 CFR Subpart A : General Provisions

Subpart A General Provisions

21 CFR § 812.1 : Scope.

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the act and regulations issued thereunder: Misbranding under section 502, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under

FR Update

section 721.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

21 CFR § 812.2 : Applicability.

§ 812.2 Applicability.

(a) General. This part applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in paragraph (c) of this section.

(b) Abbreviated requirements. The following categories of investigations are considered to have approved applications for IDE's, unless FDA has notified a sponsor under § 812.20(a) that approval of an application is required:

(1) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:

(i) Labels the device in accordance with § 812.5;

(ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under Part 50 and documents it, unless documentation is waived by an IRB under § 56.109(c).

(iv) Complies with the requirements of § 812.46 with respect to monitoring investigations;

(v) Maintains the records required under § 812.140(b) (4) and (5) and makes the reports required under § 812.150(b) (1) through (3) and (5) through (10);

(vi) Ensures that participating investigators maintain the records required by § 812.140(a)(3)(i) and make the reports required under § 812.150(a) (1), (2), (5), and (7); and

(vii) Complies with the prohibitions in § 812.7 against promotion and other practices.

(2) An investigation of a device other than one subject to paragraph (e) of this section, if the investigation was begun on or before July 16, 1980, and to be completed, and is completed, on or before January 19, 1981.

(c) Exempted investigations. This part does not apply to investigations of the following categories of devices:

(1) A device, other than a transitional device, in commercial distribution immediately

before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of Part 807 in determining substantial equivalence.

(3) A diagnostic device, if the sponsor complies with applicable requirements in § 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.

(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

(5) A device intended solely for veterinary use.

(6) A device shiped solely for research on or with laboratory animals and labeled in accordance with § 812.5(c).

(7) A custom device as defined in § 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

(8) An intraocular lens. An intraocular lens shall not be used unless it is subject to an approved IDE under Part 813 or an approved application for premarket approval under section 515 of the act.

(d) Limit on certain exemptions. In the case of class II or class III device described in paragraph (c)(1) or (2) of this section, this part applies beginning on the date stipulated in an FDA regulation or order that calls for the submission of premarket approval applications for an unapproved class III device, or establishes a performance standard for a class II device.

(e) Investigations subject to IND's. A sponsor that, on July 16, 1980, has an effective

INSIDE

ACEP NEWS
American College of Emergency Physicians
Volume 15, Number 10 November 1996

FDA/NIH announce final regulations

Informed consent for emergency research guidelines

On Oct. 2, 1996, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) released final regulations that would, according to narrow and specific criteria, permit the waiver of informed consent for emergency and critical care research involving human subjects. These regulations became effective on Nov. 1, 1996.

These final rules make it easier for promising experimental drugs and medical devices to be studied in persons who are in life-threatening situations and unable to give informed consent for their use. As a companion document, NIH has published an "Emergency Research Consent Waiver," applicable to all agencies of the Department of Health and Human Services (HHS).

These policies establish narrow limits for allowing research without informed consent in certain studies involving emergency medical conditions, and harmonize these standards throughout the HHS. The final regulations may offer the best hope in cases when critically ill, unconscious persons, with no readily available legal representative to give consent, cannot be successfully treated through conventional means, but might benefit from a promising experimental intervention.

The final rule defines the main conditions under which patients may be enrolled in clinical trials without their consent. This includes a requirement that an independent physician and an institutional review board (IRB) — a committee of experts and lay persons established to review research — agree that the clinical trial addresses a life-threatening situation and that other criteria are met.

Among the other criteria are:

- The individual has to be in a life-threatening situation.
- Available treatments are unproven or unsatisfactory.
- The research cannot practically be carried out otherwise, and is necessary to determine the safety and effectiveness of the intervention.
- It is not feasible to obtain informed consent from the patient or the patient's legal representative.
- The risks and benefits of the experimental procedure are reasonable compared to those associated with the patient's medical condition and standard therapy.

The proposal also includes additional protections such as consultation with the community, public disclosure of the study design and attendant risks prior to its commencement, and disclosure of study results when completed. The FDA will also review the protocol design and other information on the proposed therapy before the study is allowed to proceed.

The "Emergency Research Consent Waiver," authorized by the Secretary of HHS and published as a companion document to the FDA final rules, applies to the basic HHS policy for protection of human research subjects. It contains the same criteria covered by the FDA rules for permitting this research to proceed.

These new policies were developed in response to growing concerns from organizations, including ACEP, that the current regulations were making high quality

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research in emergency circumstances difficult or impossible to carry out at a time when the need for such research is increasingly recognized. In October 1994, the college participated in the Coalition Conference of Acute Resuscitation and Critical Care Researchers to discuss the current regulations regarding informed consent for participation in research. ACEP's Board of Directors subsequently endorsed the consensus document that was developed from this conference. In January 1995, former college President Richard Aghababian, MD, testified at a Public Forum on Informed Consent in Clinical Research Conducted in Emergency Circumstances that was jointly sponsored by the FDA and the NIH. He stated that the circumstances under which research activities may take place when informed consent cannot be obtained is an issue that needed further examination and clarification.

The FDA reports that their proposed rule, published on Sept. 21, 1995, received more than 90 comments and was broadly supported by 19 leading medical, patient advocacy, and industry groups. Based on the comments they received, the FDA expanded, in final regulations, the procedures to be followed by IRBs and investigators in attempting to obtain informed consent from the patient's legal representative or to inform the patient's family about the research.

In ACEP's comments to the proposed rule, the college made five recommendations to the FDA. These recommendations and the FDA's response is described below:

1. The regulations should be expanded to allow waiver of consent not only for new devices or drugs, but also for new uses for existing devices and drugs, as well as for new therapeutic techniques. The FDA responded that the regulation does apply to studies involving already marketed products that are regulated by the FDA. However, the regulation does not apply to research that is outside of the FDA's regulatory jurisdiction, such as studies involving products not subject to FDA regulation. The amount of information required by the FDA for approval of an application involving new uses for existing devices or drugs under their jurisdiction will vary depending on the particular intervention, especially the relative risk associated with the intervention.
2. The regulations should be expanded to apply not only to conditions which are life-threatening, but also to conditions that involve the strong potential for serious and permanent disability. The FDA responded that although the Medical Device Amendments limit this exception to life-threatening situations, the agency and the IRB will need to judge each clinical investigation individually to determine whether it meets the criteria of the law and regulations. The criteria contained in the rule do not require that the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before consent from a legally authorized representative is feasible. Life-threatening includes diseases or conditions where the likelihood of death is high unless the course of the disease or condition is interrupted. The FDA clarifies that the final rule would apply in situations involving people with conditions such as stroke or head injury, which may result in long-term survival, but where the individuals are at increased risk of death due to infection, pulmonary embolism, progression of disease, etc. However the waiver provision is not intended to apply to persons who are not in an emergency situation (e.g., individuals who have been in a coma for a long period of time and for whom the research intervention should await the availability of a legally authorized representative of the subject).
3. ACEP commented that the requirements for Independent Data and Safety Monitoring Boards (DSMB) will prove too costly for small research projects. Therefore ACEP suggested that IRBs be permitted to evaluate the size, complexity and risk of the projects they consider, and based on those evaluations, recommend that the functions of data safety and monitoring be performed by separate groups of various appropriate individuals. The FDA states that the DSMB is a very necessary protection for the human subjects participating in this type of research. They further state that the cost of operating such committees does not need to be prohibitive and that the cost is justified by the protections provided by having such a committee. They note, however, that an already established committee, such as an IRB, could serve as a data monitoring committee as long as that committee was constituted to perform the duties of a data monitoring committee and operated as such separately and distinctly from its IRB activities.
4. ACEP stated that the FDA should clarify what is required in terms of appropriate community consultation and reporting through either the preamble to the regulations, or in guidance documents to IRBs. In the preamble to the regulation, the FDA provided some clarification on requirements for community consultation. The FDA reports that community consultation is likely to be multifaceted and to use a number of mechanisms. It is the responsibility of the IRB to ensure the adequacy of the community consultation and disclosure requirements set out in the regulations. Furthermore, the FDA does not dictate who must pay the costs of the community consultation and reporting, but anticipates that the sponsor of the research would normally incur these costs.
5. ACEP recommended that the FDA allow for federal preemption of existing state or local law governing informed consent that might limit or preclude participation in research in circumstances that otherwise could be authorized by IRB's acting

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in accordance with these proposed rules. The final rule does not allow for preemption of existing state laws governing informed consent. The FDA states that preemption of state law would prevent the application of state or local law that requires additional protections to research subjects, and as such, would be inconsistent with existing federal policy for the Protection of Human Subjects and inconsistent with the notion of community norms, on which this regulation is based.

For more information on this issue, contact Roslyne Schulman, ACEP's regulatory representative, at 800-328-0610, ext. 3014. ■