Application for amendment to exempt device registration application document

IonScan series

IonScan 500DT series

Sabre series

Sabre Centurion series

Sentinel series

Smiths Detection
2202 Lakeside Blvd.
Edgewood, MD 21040

September 24, 2015

smiths detection
bringing technology to life

Smiths Detection
2202 Lakeside Boulevard
Edgewood, Maryland 21040, USA
T: +1 410 612 4000
F: +1 410 510 9496
www.smithsdetection.com

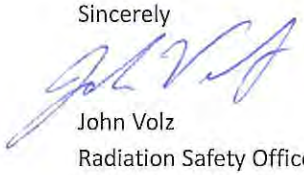
United States Nuclear Regulatory Commission
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 20852-2738
Attn: Celimar Valentin-Rodriguez, PH.D.

Date: 9/24/2015
RE: Amendment SSDR# NR-0163-D-102-E

Dear Ms. Valentin-Rodriguez

Please find attached an amendment for device registration number NR-0163-D-102-E application document. The first document below is a word document with track changes turned on to help with review. Also included is the same document locked down in PDF. Last is the quality section based on the Smiths Detection Watford ISO 9001 system.

Sincerely



John Volz
Radiation Safety Officer
Smiths Detection Edgewood
Phone: 410-612-2535

Applicant:

The applicant for this device registration is:

Smiths Detection Inc.
2202 Lakeside Blvd
Edgewood, MD 21040
USA

Manufacturer:
Devices listed in this application are manufactured by:

Smiths Detection
459 Park Ave.
Bushey, Hertfordshire WD23 2BW
United Kingdom

Distributors:
Smiths Detection – Edgewood
2202 Lakeside Boulevard
Edgewood, MD 21040
USA

Roles:
The Edgewood, MD facility of Smiths Detection, Inc. will be the primary sales and distribution office in the US for Smiths Detection. In addition to sales and distribution, the Edgewood, MD site will also provide service and repair of the devices listed in this application. For Sentinel model, service personnel will be dispatched to the customer site for basic service and repair.

The Watford, UK facility of Smiths Detection' is the sole manufacturer of the devices listed in this application. All devices are initially exported from this site to the Edgewood, MD sites for distribution in the US. All source removal and exchanges will be performed at both sites.

Licenses for all facilities are included as Attachment A.

Models:
From:
Smiths Detection currently offers 4 desktop (movable) explosives / threat detectors:
IonScan 500DT (2-15mCi sources)
IonScan 400B
IonScan Document Scanner
IonScan LS

They offer 4 portable models:
Sabre 4000
Sabre 4000FR
Sabre EXV
MMTD
Sabre 5000

They offer 3 fixed models:
Sabre Centurion
Sabre Centurion II
Sentinel II

These devices are currently distributed to persons exempt from regulation in the US and as licensable devices in Canada. Registration certificates from the US MD and Canada are included as Attachment B.

Each model fits into one of the following device series. The details of these series are outlined in the construction and design section of this application.
IonScan Series
IonScan 500DT series
Sabre series
Sabre Centurion series
Sentinel series

Product "Industry Name"
The industry name for the devices listed in this application is "Threat Detection Systems" which incorporate an Ion mobility spectrometer (IMS). These devices are used for the protection of life and property.

Principal Use Code: N-Ion generator, chromatography

Leak Testing:
This application is to request that Smiths Detection's explosives detectors be allowed to be distributed to persons exempt from regulatory requirements. Therefore, leak testing will not be required for end users of the devices.
There have been no reported failures of leak tests from the field in the 15 years in which Smiths Detection has been producing devices listed in this application. See attachment M.
Smiths Detection. Will perform leak tests as part of the manufacturing and servicing process to assure that new products and products which have been serviced, respectively, are free from removable contamination prior to their distribution, export, or return to customer. Leak testing will be performed to meet the requirements of ISO 9978.

Applicable NRC regulations for distribution:
All devices will be initially distributed in accordance with 10 CFR 32.26.
(This remains as is, unchanged)

Radionuclides and maximum activities:
All devices except the IonScan 500DT: incorporate a single sealed source of Ni^{63} with a nominal activity of 15mCi. The IonScan 500DT incorporates 2 IMS systems, which in turn contain a sealed source of Ni^{63}, each with a nominal activity of 15mCi for a total maximum activity per device of 30 mCi.
(This remains as is, unchanged)

Source Manufacturers:

Manufacturer: QSA Global
Model: NBC
Radionuclide: Ni^{63}
Activity: 15mCi (555MBq)
Physical form: plated foil

Manufacturer: NRD
Model: N1001
Radionuclide: Ni^{63}
Activity: 15mCi (555MBq)
Physical form: plated foil

Manufacturer: Eckert and Ziegler
Model:
Radionuclide: Ni63
Activity: 15 mCi (555MBq)
Phyiscal form: palted foil

See drawing number 2810640, included in Attachment C.

Foil sources are only received and installed into the IMS drift tube at the Mississauga facility. The facility is regulated and licensed by the Canadian Nuclear Safety Commission, (CNSC), and complies with the CNSC's requirements.
Device registrations for both of these models of sources are included in this application as Attachment C.

Construction and Design:

Custom devices:
None of the devices listed are custom devices.

Construction:
All devices included in this application incorporate an Ion Mobility Spectrometer (IMS) to determine the chemical makeup of substances being analyzed by the device. There are two basic IMS designs: the IonScan 400B, and the Sabre 4000. The IMS's in all devices are nearly identical to either of these IMS designs. Each IMS is similar in design and is identical in function. A product tree is included as Attachment D to demonstrate the relationship of the subassemblies to the device.

Each device draws in a sample of air that may contain vapor or particulate of chemical substances. The air is then heated to vaporize any particulate, and drawn into the IMS system. The sample air then passes through the NI^{63} source which ionizes the molecules. The ionized molecules then proceed down the drift tube to the collector. Once the molecules contact the collector, software calculates the time of flight and correlates it with the suspected molecule. A schematic of the function of the IMS systems is included as Attachment E.

The table below illustrates the relationship of each model to its IMS type and device series. It also summarizes the location of use of each device, (movable, portable, or fixed), the nominal activity of Ni63, and the intended use of each device.

Model	IMS type	Device Series	Location	Nominal	Use

				Activity Ni-63 per instrument	
IonScan 400B	400B	IonScan	Desktop, Movable	15mCi	Explosives, Narcotics
IonScan LS	400B	IonScan	Desktop, Movable	15mCi	Chemical analysis
IonScan Document scanner	400B	IonScan	Desktop, Movable	15mCi	Explosives, Narcotics
IonScan 500DT	400B	IonScan DT	Desktop, Movable	30mCi	Explosives, Narcotics
Sabre 4000	Sabre	Sabre	Portable	15mCi	Explosives, CWA, Narcotics, TIC
Sabre 4000FR	Sabre	Sabre	Portable	15mCi	CWA, TIC
Sabre EXV	Sabre	Sabre	Portable	15mCi	Explosives
MMTD	Sabre	Sabre	Portable	15mCi	Explosives, CWA, Narcotics, TIC
Sabre 5000	Sabre	Sabre	Portable	15mCi	Explosives, CWA, Narcotics, TIC
Sabre Centurion	Sabre	Saber Centurion	Fixed	15mCi	CWA, TIC
Sabre Centurion II	Sabre	Sabre Centurion	Fixed	15mCi	CWA, TIC
Sentinel II	400B	Sentinel	Fixed	15mCi	Explosives, Narcotics

IonScan 400B Series

The IonScan series detection systems are desktop devices that are used to detect explosives, narcotics, chemical warfare agents, and toxic industrial chemicals. The substances detection varies with the model of device. The IonScan-LS is a device which uses an IonScan 400B as its foundation, and is used in laboratories to analyze chemical makeup of substances.

IonScan 500DT Series

The IonScan DT series has the same function as the IonScan series, but uses two separate IMS systems to better analyze the substances being analyzed. Each of these IMS systems is identical to that of the IonScan 400B.

Sabre series

The Sabre series are portable devices that are used to detect explosives, narcotics, chemical warfare agents, toxic industrial chemicals. The substances detected vary with the model of device. The Sabre 4000, Sabre 4000FR, Sabre EXV, and Sabre 5000 are based on the Sabre 4000 model, but provide different detection capabilities due to software and hardware configurations.

The MMTD is a reinforced version of the Sabre, used for detection of explosives, CWA's, narcotics, and TIC's in harsh environments such as military outposts, and Customs locations. The IMS is the same as the Sabre, however, it is enclosed to prevent damage from impacts and other environmental effects.

Sabre Centurion series

The Sabre Centurion series detection systems are fixed devices connected to building HVAC systems or placed in public areas to monitor air threats. These systems utilize the Sabre's IMS system.

Sentinel Device

The Sentinel devices are fixed walk-through devices placed at locations where persons are screened for narcotics or explosives, such as prisons and airports, respectively. These systems use the IonScan IMS system to perform the substance analysis.

Device brochures are included in this application as Attachment K.

Size and weights

To illustrate the size and weight of each device, outline drawings of the devices are included as attachment F with the source location highlighted. The table below provides a summary of these drawings:

Model	Height (in)	Width (in)	Length (in)	Weight (lbs)
IonScan 400B	13.7	13.06	16.0	49.6
IonScan LS	32.9	16.7	25	112.4
IonScan Document Scanner	13.7	16.7	16.0	50.7
IonScan 500DT	19.5(screen up)	17.4	16.1	46.3
Sabre 4000	6.3	4.5	16.0	7.7
Sabre 4000FR	6.3	4.5	16.0	7.7
Sabre EXV	6.3	4.5	16.0	6.6
MMTD	8.8	8.1	19.2	16.1
Sabre 5000	6.3	4.5	16.0	7.7
Sabre Centurion	16.9	10.6	19.5	28.7
Sabre Centurion II	16.9	10.6	19.5	28.7
Sentinel II	90.0	42.9	74.0	2661

Design Details

Each device, except the Sabre 4000, Sabre 4000FR, Sabre EXV, Sabre 5000, Sabre Centurion I, and Sabre Centurion II, contains a detector assembly, which contains an IMS drift tube assembly, which in turn, contains the Ni^{63} source.

Each source (drawing #2810640) is formed into a cylindrical shape and placed in a source holder made of brass. The brass holder is also gold plated to help with conductivity and has an added benefit of corrosion inhibition. Each IMS tube receives a single source, encapsulated by the IMS tube's components. The tube is stainless steel and the spacers surrounding the source holder are ceramic and will not allow any beta radiation to escape.

Source installation and removal procedures are only performed at Smiths Watford, UK and Edgewood, MD facility.

The holder is placed into a ceramic spacer within the IMS tube and capped with a ceramic plate. The plate is held in place with screws.

For all devices except for the Sabre 4000, Sabre 400FR, Sabre EXV, and Sabre 5000, the IMS drift tube assembly is then inserted into a detector module, source end first. The IMS drift tube assembly is fastened to the detector module with tamperproof screws. The shell of the detector module is aluminum and it contains insulation to allow the IMS heater to work efficiently.

For the Sabre 4000, Sabre 4000FR, Sabre EXV and Sabre 5000, the IMS tube assembly is mounted directly to the inside of one half of the device housing. The remaining half is then fastened to the first half with tamperproof screws.

For the Sabre Centurion I and Sabre Centurion II, the IMS tube assembly is mounted within the Centurion's outer enclosure with tamperproof screws. The enclosure is steel and is supplied with a lock to prevent unauthorized entry. Assembly drawings for each IMS detector and device are included as Attachment G.

Engineering Details

The heaters in the IMS systems are regulated to various temperatures depending upon the series / model. Each model is also equipped with hardware and / or software controls to prevent heater runaway. The table below outlines the temperatures for each series.

Products temperature conditions				
Product	IMS normal operating temperature		Shutoff runaway temperature	
	Inlet temp	Drift tube temp	Hardware control	Software control
400B	290C	240C	330C	320C
Sabre	190C	130C	None	210C
500DT	Tube1 = 285C	Tube 1 = 240C	T1=T2=325C	T1=T2=315C
	Tube 2= 245C	Tube 2 = 110C		
Sentinel	290C	240C	330C	320C

As demonstrated in this table no heater will ever exceed 330C. Each source is rated for a minimum of 44C, and therefore is sufficient for the temperature rating of the heaters in each device.

Tamperproof features

Tamperproof features have been implemented in the devices to restrict access to the source. The following table highlights the drawings and item numbers of the tamperproof hardware used in each device:

Device	Drawing	Hardware
IonScan 400B	4810769	#116
	4810768	#85
IonScan 500DT	4816104	#41, 46, 50
	4816105	#41, 46, 50
	4817092	#12
	4816800	#5, 12
Sabre series	4816600	Sheet 1 #2, 24
	4816600	Sheet 3 #2, 34,35
Centurion	4815374	#8, 13
MMTD	4820726	#6, 19
	4820800	#7, 23
Sentinel	4818294	#115, 116
	4817837	#15
	4819890	#32
	4815733	#11

The Centurion and Sentinel devices have keyed latched (locks) on access panels to assure that only properly trained personnel are able to gain access to the interior of the device for maintenance purposes.

A copy of Smiths Engineering Change Order showing the details of the tamperproof hardware is included as Attachment H.

Source classification and shielding

The source manufactured by QSA Global has received an ANSI classification of 77C4X212, where the pressure rating “X” was tested to 5kPa absolute. The source manufactured by NRD, has been in production for nearly 45 years since the approval of its SSDR. The NRD source has been subjected to 400-450C without degradation. These sources are now made by Eckert and Ziegler.

None of the Smiths Detection devices in this application employ a shutter or allow direct access of the user to the radioactive source. Because there is no shutter, tere is also no indicator light, or interlock. Each device however does have a display screen which shows the device’s operating status. The operator sees that the device is powered on when this display screen is active / lit.

Since the sources used in Smiths devices are Ni63 the average energy of the beta radiation is about 17keV (max energy is 66keV), and the sources are housed in metal tubes, no radiation is expected to penetrate the surrounding components. Therefore there is no expected dose from the device, and no other safety features are required.

The sources in Smiths devices are Ni63 which is deposited / plated onto a nickel or nickel alloy foil. This foil is placed in a gold plated brass housing, which in turn is placed into a ceramic shield. Corrosion is not expected to be significant between any of these components. In addition the air entering the IMS

system is first drawn through a desiccant to reduce the moisture content of the air. This further reduces the risk of corrosion between components. Shielding is provided by the inherent properties of the materials that surround that source and source holder.

Smiths devices do not contain faraday plates.

Labeling

Each detector module of each device is labeled with a trefoil and a label stating: CAUTION: RADIOACTIVE MATERIAL. These are durable self-adhering labels made from vinyl and aluminum, and are present to warn servicers of the device where the radioactive source is housed.

Vinyl and 0.002" thick aluminum labels are self-adhesive and 0.032 aluminum labels are riveted to the device.

Each device will also have a label which states that the device is compliant with 10 CFR 32.27 and the end user is not subject to any regulatory requirements. These are also durable self-adhering aluminum labels with the exception of the Sabre EXV, MMTD. The label for these devices is 0.032" thick and is riveted to the device.

Trefoils and cautionary labels are present on the IMS system of each device as well.

Point of sale labels are placed on the packages for initial shipments.

Attachment I contains samples, drawings, locations and photos of labels for each device and the point of sale label. There is also a spread sheet which outlines the labels placed on each device and the method of attachment.

Conditions of Use

All devices have an expected useful working life of 10 years. When products are determined to be beyond their useful life Smiths Detection offers to take back the products at the time as an effort to demonstrate environmental consideration. However Smiths Detection does recognize that these devices are granted "exempt" status, the devices may be discarded as normal refuse according to the US NRC regulations.

Maximum working and storage conditions

Model	Minimum operating	Maximum operating	Maximum operating	Minimum storage temp	Maximum storage temp	Maximum storage

	temp		temp							
	F	C	F	C	%RH	F	C	F	C	%RH
IonScan 400B	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing
IonScan LS	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing
IonScan Document scanner	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing
IonScan 500DT	32	0	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre 4000	32	0	113	45	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre 4000FR	32	0	113	45	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre EXV	32	0	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing
MMTD	20	-7	130	54	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre 5000	32	0	113	45	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre Centurion	41	5	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing
Sabre Centurion II	41	5	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing
Sentinel II	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing

Tables showing the expected normal temperature, vibration, and impact for use, handling, storage and transport are included as Attachment J.

IonScan 500DT, IonScan 400B

The IonScan 500Dt and IonScan 400B are desktop (movable) devices that have the ability to detect trace amounts of explosives and narcotics. The IonScan 400B has been in production for more than 10 years. The IonScan 500DT is the newer model but performs the same functions as the IonScan 400B. They are intended for typical indoor ambient conditions or in outdoor conditions protected from rain and dust, and that do not exceed the stated operating conditions. These devices are normally operated where AC power is accessible; however an optional DC power pack is available to allow limited portability.

These devices are used by the military, Federal security agencies (such as the TSA), police and sheriff's departments, and other private and public security agencies for detecting threats of explosives and assuring building, transportation, and personal safety.

The user of the device wipes a sample area of an item such as a handbag, wallet, attaché, etc., with a wipe swatch or swab. The wipe or swab is then introduced to the device. The device vaporizes the sample and takes the vapors into the sampling IMS system. The IMS analyzes the chemical make-up of the sample and provides the user with the identification of any illicit substances found.

Likewise these devices are also used by Customs departments and correctional facilities to search for narcotics.

IonScan Document scanner

The IonScan document scanner is an IonScan 400B with an optional attachment to screen documents. This device can be used by the aforementioned agencies for the respective explosive and narcotic detection, respectively.

IonScan LS

The IonScan LS is based on the IonScan 400B and has been adapted for chemical analysis. The IonScan LS is primarily used by pharmaceutical companies to assure cleanliness of processing equipment, quality of their products, and search for containments in mixtures. Detecting contaminants in drug mixtures allows the manufacturer to minimize any reactions by the recipients of the drugs, and avoid potential illnesses or injuries from them.

The user of the IonScan LS places samples in vials and loads them in to a feeder. The feeder then brings them to the thermal desorption or injection system of the device. Either of these systems will vaporize the sample and introduce the vapors to the IMS. The IMS then analyzes the chemical make-up of the system and presents this information to the user.

Sabre 4000 / 5000

The Sabre 4000 / 5000 is a portable device which is used for detection of explosives or narcotics vapor. As with the IonScan 400B and IonScan 500DT, this device is used by private, public and government agencies. The Sabre 4000 /5000 is intended to be used indoor or outdoor conditions where dust and rain are not a concern.

The Sabre has two different methods or collecting samples: particles and vapor. For those substances which are odoriferous enough to be detectable by vapor, the Sabre may be utilized by simply brining the device in to that atmosphere. For other substances, a wipe may be taken in the area where a substance is suspected and placed in the nose of the Sabre. The Sabre will then vaporize the substance and take in the vapors. The vapors then enter the IMS where they are analyzed and information is displayed to the user.

Sabre 4000FR

The Sabre 4000FR is identical to the Sabre 4000, but it is configured for the detection of only chemical warfare agents (CWAs) and toxic industrial chemicals (TICs). No mechanical changes to the IMS and detection system are made to the base Sabre 4000.

Sabre EXV

The Sabre EXV is based on the Sabre 4000, but provides limited detection capability of explosives and peroxides. The device is configured electronically and no mechanical changes to the IMS and detection systems are made to the base Sabre 4000.

MMTD (Multi-mode Threat Detector)

The MMTD is an enhanced version of the Sabre 4000. Its components and assemblies have been reinforced to withstand more physical abuse such as drops, impacts, and bumps. It is rated with IP (Ingress Protection) rating 54, and is more resistant to dust and water. This device is mainly marketed to military customers and detects trace levels and vapors of explosives, narcotics, CWAs and TICs.

Sabre Centurion and Sabre Centurion II

The Sabre Centurion and Sabre Centurion II are fixed air system monitors. These devices are permanently mounted inside buildings or transportation vehicles, such as ships and subways, and connected to the air handling equipment. They collect samples of air moving through the HVAC systems and analyze them for CWAs and TICs. The devices may also be electronically connected to the buildings or vehicles security system.

Sentinel II

The Sentinel II is a fixed walk through portal detection system, designed to screen people for trace levels of explosive or narcotics. The Sentinel II may be used for screening people entering secure or military facilities, correctional facilities, public events, passengers at airports, or outdoor areas which are protected from dust and moisture.

A person is directed to enter the unit and pause while inside. The unit then blows air downward on to the person and draws this air in through vents / plenums near the person's feet. The air is drawn through a "pre-concentrator" which collects any particles and then exhausted out the top of the device. The particles on the pre-concentrator are then vaporized and delivered to the IMS, which analyzes them. Once analyzed the device will display whether or not a substance of interest was detected, if no substances are detected the device will then allow the person to proceed.

Device brochures are included as Attachment K.

Every device contains an IMS system which in turn contains the NI63 sealed source, with the exception of the IonScan 500DT which contains two individual IMS systems. Each IMS system alone provides sufficient shielding to prevent bate radiation from escaping. However when placed in a device, the device itself provides additional shielding. Since beta radiation from Ni63 travels only 1 inch in air and will not penetrate the outer layer of skin no significant external dose is expected from the device. And since the source is a plated foil an internal dose is also improbable.

Prototype testing and History

In order to assure that its devices are as safe as reasonably achievable, Smiths Detection has performed testing on the detector modules (and the IMS assembly for the Sabre models). Each module and assembly has been subjected to tests equivalent to those listed in ANSI N.542 or ISO 2919. The results show that these assemblies meet the requirement of these testing standards.

Smiths performed testing on the IMS assembly of its Sabre 4000 device. The IMS system was tested to the ISO 2919:19999 standard and was determined to meet the requirements of a classification of C.32222. A copy of the test report provided by QSA Global is included as Attachment L.

To summarize the results, the IMS assembly was subjected to the following conditions ans leak tests after each segment of testing as outlined in the attached results.

Test	Conditions
Temperature “3”	-40c to +180c
Pressure “2”	25kPa to atmospheric
Impact “2”	50g from 1m
Puncture “2”	1g from 1m
Vibration “2”	25 to 500Hz@49m/s^2

Each leak test showed less than 200 Bq of removable contamination.

The Sabre 4000 IMS assembly is used in the following models:
Sabre 4000
Sabre 4000FR
Sabre EXV
MMTD
Sabre 5000
Centurion I
Centurion II

Except for the MMTD the IMS is contained within the enclosure or shell of the device. Within the MMTD model the IMS is contained in an additional enclosure to further reduce the risk of damage to the IMS system.

Initially Smiths had tested its IonScan 400B IMS assembly to ANSI N.43-6 and ISO 2919 with respective classifications of 77C32211 and C32211. Smiths recognized that further testing would assist in proving that the devices meet stricter safety requirements. Smiths performed an engineering analysis to demonstrate the IonScan 400B IMS assembly is comparable to the Sabre 4000 IMS assembly. Smiths maintains that the classification of the IonScan 400B IMS assembly is ISO 2919: 1999 C.32222. The engineering analysis provided by QSA Global is included as Attachment L.

The IonScan 400B IMS assembly is utilized in the following models:
IonScan 400B
IonScan Document Scanner
IonScan LS
Sentinel II
Note: the IonScan 500DT contains 2 IMS systems each identical to the IonScan 400B's.

Smiths Detection (formerly Barringer Research, Ltd.) has been producing detection systems since the early 1990's. In that time, Smiths is unaware of any incidents or failures related to the radiation safety of its devices. Additionally there has never been a positive leak test result from the field reported to Smiths.

The Table below outlines the years in which the devices within this application have been produced and the estimated total quantity of each model distributed in that timeframe. This Table has been extracted from a statement from Smiths, which is included as Attachment M.

Model / Series	Years produced	Est. Quantity Distributed
IonScan 400B	1999- Present	>8000
IonScan 500DT	2006- Present	>500
MMTD	2009- Present	>20
Sabre 4000 / 5000 series	2004- Present	>4000
Sabre Centurion series	2005- Present	>250
Sentinel II	2002- Present	>200

Smiths threat detection systems are utilized by federal, state, and local security agencies, as well as private and public entities to assure the safety and security of the public and private citizens. They are comparable to other devices produced by other manufacturers, which perform identical functions.

Radiation Profiles:

Because the devices contain a Ni-63 sealed source incorporated into the IMS tube assembly, the radiation level surrounding the devices is indistinguishable from background. Since the beta particles are low energy and will only travel 1" in air, the inherent shielding of the components surrounding the source prevent betas from escaping the IMS system. There is no difference in the shielding or expected dose rates between the generally licensed or exempt devices. To assure conformity to the exempt regulations, Smiths needs only to install additional tamperproof hardware and new regulatory labels.

Accidental Dose Calculations

Under normal conditions of handling, storage, and use of these devices, the radioactive material contained in the devices will not be released or inadvertently removed from the source housing. It is highly improbable that any person will receive, in any period of one year, a radiation dose in excess of 10% of the limits specified in 10 CFR 20.1201 (a), 10 CFR Part 20 or Equivalent Agreement State Regulations.

Under accident conditions such as fire or explosion associated with handling, storage, and use of the analyzers, it is also highly unlikely that any person would receive an external radiation dose or committed effective dose in excess of regulatory limits.

Smiths has provided dose calculations to demonstrate that the expected dose from the devices during normal operation are nil, and has also provided dose estimates based upon accident conditions. These calculations are included as Attachment N.

Quality Assurance

Materials and components are inspected by the Quality Assurance Department to assure that they meet the required specifications. Materials and components are inspected per an inspection plan, which could be a first article inspection, 100% inspection, representative sampling, or qualified vendor inspections. Whichever method is chosen, the QA holds responsibility to assure that materials and components are correct.

Mechanical components are fastened together with bolts, nuts and other fasteners. Wherever critical, torque specifications are utilized to assure that devices will remain intact with normal use. Torque specifications are set by the engineering staff at Smiths. It is the ultimate responsibility of the QA department to assure that mechanical assembly procedures are followed.

Electronic and electrical components are soldered, connected or bolted in place as appropriate.
It is also the ultimate responsibility of the QA department to assure that electrical and electronic assembly procedures are followed.

Final inspections and tests are performed on each device once it is completed. Nonconformities are noted and corrected. If the non-conformities become frequent, they are discussed with Engineering, and Engineering Change Orders (ECO's) are processed as necessary.

Devices are also tested once they have been serviced, to assure that functionality has been restored.

Customer complaints are also logged and reviewed. Whenever necessary, ECO's are processed to corrective design changes.

The QA manual for Smiths Detection is included in this application as Attachment O.
The Watford, UK facility has received ISO 9001 certification as has the Edgewood, MD facility. Both of these certificates are included as Attachment P.

Installation:

All of Smiths' portable and movable devices do not require special installation. However, Smiths provides training to its customers regarding the setup and use of these devices.

As for its fixed devices, (the Sentinel II, Sabre Centurion, and Sabre Centurion II), Smiths provides the installation of these devices at customer sites, to assure that they are assembled, installed, and operating properly.

The weight of the Sentinel II is approximately 1775 Ibs. (805 kg) and requires no mounting or attachment to the facility other than electrical. Since the Sentinel II operates on *208/220* V AC and must be hard wired, it requires a qualified electrician to connect the device to the proper electrical circuit. Prior to the electrician performing this task, Smiths service personnel will assure that all other grounding and electrical connections within the device are made. A copy of the Sentinel II's installation procedure is included as Attachment Q. Note: Sentinel II components and subassemblies are shipped in crates as one shipment, e.g. Crate 1 of 3,2 of 3, 3 0f 3.

The Sabre Centurion and Sabre Centurion II must be physically mounted to the building or vehicle, and are connected to 110-120 V AC through a normal power cord and outlet. The systems are also connected to the building's or vehicle's HVAC/ventilation system by means of a small diameter tube to allow samples of air to pass through the device. A copy of the Sabre Centurion's Installation Manual is also included in Attachment Q.

Accompanying Documentation:

With the shipment of each device, Smiths provides a copy of the leak test results performed at the manufacturing facility in Watford. Each device is also shipped with an operator's manual, and a document explaining that the device is an exempt device.

Leak test results

In order to demonstrate that each device is safe to use and free from removable contamination, each device is supplied with the leak test results from the test performed at the factory. As per ISO 9978: 1992, leak tests shall verify that removable contamination levels are below 0.005 uCi (185 Bq)/100 cm^2 . An example of a leak test certificate is included as Attachment R.

Operators manuals

Operators manuals with appropriate warnings and regulatory references are supplied with the initial shipment of each device. Information regarding how to contact Smiths Detection is included in the manual. A copy of each manual is included in Attachment S.

Exempt document

Smiths will provide each customer a document explaining that the devices are exempt from

US NRC regulatory requirements and that no action is required on the part of the end user. A copy of this letter is included in Attachment R.

Servicing:

Since Smiths devices are approved as exempt, end users will only be allowed to perform certain maintenance tasks, such as changing filters, cleaning sampling areas, etc., which are not in proximity to the source. All other servicing will be performed by Smiths at its Watford, UK, Mississauga, ON facility, or the facility of Smiths contractor, MedGraphix, located in Pinebrook, NJ, and ISG, located in NJ with the exception of source exchanges which will only be performed at its Mississauga, ON facility, Watford, UK, facilities. Maintenance tasks that end users are allowed to perform are listed in each device's operators manual.

The Sabre Centurion and Sabre Centurion II are systems, which are mounted within an enclosure. The enclosures have a door which allows access to the systems components and maintenance items. This door is equipped with a lock to prevent unauthorized users access to the internal components. Smiths will provide maintenance training only to those persons who will perform this maintenance on the devices. Only these persons who have received training will be provided a key to access the internal components of the system.

For some products, such as the Sentinel II, Smiths will provide on-site service and repair.

Foreign Vendors:

Drop ship

Smiths devices will be distributed through the Edgewood, MD facility. Devices directly shipped to customers in the US from both the Watford, UK and Toronto, CA facilities are under the control and record keeping of the Edgewood, MD facility.

QA in the US:

Since Smiths is one company with one global manufacturing systemthe quality assurance (QA) program is similar in design to that of all other Smiths facilities. The Edgewood, MD facility is the primary distributor and service center in the US for Smiths devices. It has incorporated a QA program to assure that distribution and service are well documented. As stated previously, Smiths Edgewood, MD facility has received ISO 9001 certification.

Proprietary information:

Smiths requests all drawings and documents marked "Proprietary" to be withheld from public information. These drawings should be withheld to assure that Smiths' competitors do not have access to this information, and, because the device is used in a manner that protects national security, any person does not become aware of potential methods of defeating the device.

List of attachment

A	Mississauga, ON license (CNSC)	
	Warren, NJ Facility license (NRC)	
	Edgewood, MD license (MDE)	
	Edgewood, MD license (NRC)	
	Watford, UK license	
B	Mississauga, ON Device Registration (CNSC)	
	Edgewood, MD Device Registration (NRC)	
C	Smiths source drawing	
	NRD source registration	
	QSA Global Source registration	
	Eckert and Ziegler source registration	
D	Product tree	
E	IMS schematic	
F	Outline drawings	
G	Assembly drawings	
H	Tamperproof ECO	
I	Labels	
J	Use condition tables	
K	Product brochures	
L	Prototype testing reports and analysis	
M	Smiths leak test reports and analysis	
N	Dose calculations	
O	QA Manual and procedures	
P	Mississauga, ON, Edgewood, MD andWatford, UK ISO 9000 certificates	
Q	Installation procedures	
R	Leak test example	
S	Operators manuals	

Model	Min use handling temp		Max use handling temp		Max use handling temp	Min storage temp		Max storage Temp		Max storage	Min transport temp		Max transport temp		Max transport
	F	C	F	C	RH (%)	F	C	F	C	RH (%)	F	C	F	C	RH (%)
IonScan 400B	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing	-40	-40	158	70	95 non-condensing
IonScan LS	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing	-40	-40	158	70	95 non-condensing
IonScan	32	0	104	40	95 non-	32	0	140	60	95 non-	-40	-40	158	70	95 non-

document scanner					condensing					condensing					condensing
IonScan 500DT	32	0	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sabre 4000/5000	32	0	113	45	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sabre 4000FR	32	0	113	45	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sabre EXV	32	0	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
MMTD	20	-7	130	54	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sabre Centurion	41	5	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sabre Centurion II	41	5	104	40	95 non-condensing	-4	-20	158	70	95 non-condensing	-40	-40	158	70	95 non-condensing
Sentinel II	32	0	104	40	95 non-condensing	32	0	140	60	95 non-condensing	-40	-40	158	70	95 non-condensing

Temperature ratings per device

Model	Max use vibration	Max Handling vibration	Max Storage Vibration	Max transport vibration
IonScan 400B	None expected	None expected	None expected	500HZ@49m/s^2
IonScan LS	None expected	None expected	None expected	500HZ@49m/s^2
IonScan document scanner	None expected	None expected	None expected	500HZ@49m/s^2
IonScan 500DT	None expected	None expected	None expected	500HZ@49m/s^2
Sabre 4000, 5000	None expected	None expected	None expected	500HZ@49m/s^2
Sabre 4000FR	None expected	None expected	None expected	500HZ@49m/s^2
Sabre EXV	None expected	None expected	None expected	500HZ@49m/s^2
MMTD	None expected	None expected	None expected	500HZ@49m/s^2
Sabre Centurion	Typical building vibration	Typical building vibration	None expected	500HZ@49m/s^2
Sabre Centurion II	Typical building vibration	Typical building vibration	None expected	500HZ@49m/s^2
Sentinel II	Typical building vibration	Typical building vibration	None expected	500HZ@49m/s^2

Maximum allowable vibration per device

Model	Max use impact	Max handling impact	Max storage impact	Max transportation impact
IonScan 400B	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected
IonScan LS	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected
IonScan document scanner	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected

IonScan 500DT	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected
Sabre 4000, 5000	Equivalent force of 50g dropped from 1m	Equivalent force of 50g dropped from 1m	None expected	None expected
Sabre 4000FR	Equivalent force of 50g dropped from 1m	Equivalent force of 50g dropped from 1m	None expected	None expected
Sabre EXV	Equivalent force of 50g dropped from 1m	Equivalent force of 50g dropped from 1m	None expected	None expected
MMTD	Equivalent force of 50g dropped from 1m	Equivalent force of 50g dropped from 1m	None expected	None expected
Sabre Centurion	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected
Sabre Centurion II	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected
Sentinel II	None expected	Equivalent force of 50g dropped from 1m	None expected	None expected

Maximum impact per device