

CORRECTED FORM REC'D VIA E-MAIL - 02/09/11
ORIGINAL FORM REC'D VIA FEDEX - 01/25/11 - PROCESSING
DATE

ETHYLENE OXIDE STERILIZERS
AIR GENERAL PERMIT NOTIFICATION FORM

Part III. Notification of Intent to Use General Permit

Prior to filling out this form, please read the instructions provided at the end of the form. Send completed form to the address listed in the instructions and keep a copy of the form for your files.

Facility Name and Location

1. Facility Owner/Company Name (Name of corporation, agency, or individual owner): Medtronic Inc.
2. Site Name (For example, plant name or number): Medtronic Inc. EtO Sterilization Facility
3. Hazardous Waste Generator Identification Number: 0310379-003
4. Facility Location: Street Address: 6743 Southpoint Drive, North City: Jacksonville County: Duval Zip Code: 32216 - 6218
5. Facility Identification Number (DEP Use ONLY - do not fill in): 0310379-004

Responsible Official

6. Name and Title of Responsible Official: Name: Emmanuel Dujarric Title: Sr. Director Operations
7. Responsible Official Mailing Address: Organization/Firm: Medtronic Inc. Street Address: 6743 Southpoint Drive, North City: Jacksonville County: Duval Zip Code: 32216
8. Responsible Official Telephone Number: Telephone: (904) 332-8556 Fax: (904) 332-8321

Facility Contact (If different from Responsible Official)

9. Name and Title of Facility Contact (For example, plant manager): Tiffany Hickson , EHS Officer
10. Facility Contact Address: Street Address: 6743 Southpoint Drive, North City: Jacksonville County: Duval Zip Code: 32216
11. Facility Contact Telephone Number: Telephone: (904) 296-9600 ext. 6704 Fax: (904) 332-8321

Facility Information

1. Ethylene oxide sterilization unit description.

(a) How many ethylene oxide sterilization units do you have on-site?

For each unit on-site, please provide the following information:

Vent Type	Date Initially Purchased From Manufacturer	Status	Control Device Required	Date Control Installed (if same as purchase date, write "SAME")
SC	October 2010	New	Yes	SAME
SC	October 2010	New	Yes	SAME
AR	October 2010	New	Yes	SAME

*VENT TYPE KEY: SC = Sterilization Chamber CE = Chamber Exhaust AR = Aeration Room

(b) Control devices are required, but not yet installed

2. (a) What was the total amount of ethylene oxide purchased in the latest 12 months? tons

(b) If less than 12 months, how many? months

Check why it is less than 12 months: New owner: New facility:
Did not keep records:

3. What control technology is required for sterilization units pursuant to this general permit?
(Indicate with an "X".)

Acid-water scrubber Other
Catalytic oxidation unit None required
Thermal oxidation unit

4. Equipment Monitoring and Recordkeeping Information

Check all logs which are required to be kept on-site in accordance with the requirements of this general permit:

- (a) Purchase receipts for ethylene oxide purchases
- (b) Temperature monitoring for oxidizer units
- (c) Liquor tank level monitoring
- (d) Concentrations of ethylene glycol in scrubber systems
- (e) Exhaust concentrations of ethylene oxide
- (f) Performance testing
- (g) Instrument calibration

5. Surrender of Existing DEP Air Permit(s)

Please indicate with an "X" the appropriate selection:

I hereby surrender all existing DEP air permits authorizing operation of the facility indicated in this notification form; the DEP air permit number(s) are:

No DEP air permits currently exist for the operation of the facility indicated in this notification form.

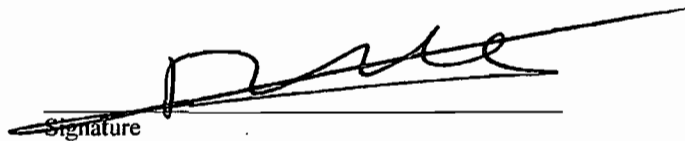
Responsible Official Certification

I, the undersigned, am the responsible official, as defined in Part II of this form, of the facility addressed in this notification. I hereby certify, based on information and belief formed after reasonable inquiry, that the statements made in this notification are true, accurate and complete. Further, I agree to operate and maintain the air pollutant emissions units and air pollution control equipment described above so as to comply with all terms and conditions of this general permit as set forth in Part II of this notification form.

I will promptly notify the Department of any changes to the information contained in this notification.

Emmanuel Dujarric

Print name of responsible official


Signature

2.9.11
Date

¹ There is an existing permit for facility number: 0310379-003 that will remain in effect until completion of the new facility at which time this permit will be surrendered/extended unless otherwise instructed.

Dibble, Dickson

From: Cuthbertson, Jamie [jamie.m.cuthbertson@medtronic.com]
Sent: Wednesday, February 09, 2011 2:39 PM
To: Dibble, Dickson
Cc: Steve Plante; Hickson, Tiffany; Dujarric, Emmanuel
Subject: AIR GENERAL PERMIT MEDTRONIC0001.pdf - Adobe Acrobat Professional
Attachments: AIR GENERAL PERMIT MEDTRONIC0001.doc; AIR GENERAL PERMIT MEDTRONIC0001.pdf

Importance: High

Dear Mr. Dibble:

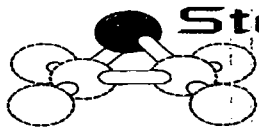
Attached please find the revised Form No. 62-213.900(3) Effective: 2/24/99 as requested. I have attached both a PDF and a Word Document. Please let me know if you need anything else.
Regards,
Jamie Cuthbertson

Jamie Cuthbertson
Sr. Facility Space planner/Project Manager | Medtronic Surgical Technologies
6743 Southpoint Dr. North I Jacksonville, FL 32216
Office: 904-279-3230
Cell: 904-400-3899

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<http://emaildisclaimer.medtronic.com>



**Sterile
Technologies, Inc.**

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(518) 793-7077 • FAX (518) 793-8357
www.steriletech.com



RECEIVED

JAN 25 2011

**Bureau of Air Monitoring
& Mobile Sources**

19 January 2011

Mr. Richard Dibble
General Permits Section
Bureau of Air Monitoring and Mobile Sources, MS 5510
Department of Environment Protection
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Dear Mr. Dibble,

As per your instructions enclosed is the completed DEP Form No. 62-213.900(3) for your and the departments review and approval. This is the Air Permit Application for the MEDTRONIC, Inc. (MEDTRONIC) new 100% Ethylene Oxide Sterilization (ETO) facility which will be located at 6743 Southpoint Drive, North, Jacksonville, Florida 32216, Duval County. The new facility will be attached to the existing distribution warehouse.

MEDTRONIC currently operates a similar permitted sterilization facility at the same address. The facility Number is 0310379-003 using OXYFUME 2000 gas mixture. This mixture will be no longer produced by the end of 2012 and obsolete by the end of 2015. This facility uses one four (4) pallet sterilizer with a reclaiming system.

Once the new facility is commissioned, validated and all stack testing completed MEDTRONIC will inform the State of Florida that the existing facility is shut down and request that the existing permit be extended to cover the new facility. The current facility will be replaced by the new "State of the Art" 100% ETO sterilization facility.

The new sterilization facility will operate using one (1) four (4) pallet and one (1) two (2) pallet new sterilizers. In addition the facility will use one (1) small aeration room. The sterilizer vacuum pumps and the aeration room exhausts will be connected to a Catalytic Oxidizer to treat the ETO emissions from the sterilization process.

This information and documents enclosed (please see index) are required by the State of Florida to obtain a permit to operate the MEDTRONIC "State of the Art" Sterilization facility.

This facility will support the MEDTRONIC medical device manufacturing and packaging facilities.

ETHYLENE OXIDE STERILIZERS
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2. Site Name (For example, plant name or number): Medtronic Inc. EtO Sterilization Facility
3. Hazardous Waste Generator Identification Number: 0310379-003
4. Facility Location: Street Address: 6743 Southpoint Drive, North City: Jacksonville County: Duval Zip Code: 32216
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Responsible Official

6. Name and Title of Responsible Official: Name: Emmanuel Dujarric Title: Sr. Director Operations
7. Responsible Official Mailing Address: Organization/Firm: Medtronic Inc. Street Address: 6743 Southpoint Drive, North City: Jacksonville County: Duval Zip Code: 32216
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Facility Information

1. Ethylene oxide sterilization unit description.

(a) How many ethylene oxide sterilization units do you have on-site?

For each unit on-site, please provide the following information:

Vent Type	Date Initially Purchased From Manufacturer	Status	Control Device Required	Date Control Installed (if same as purchase date, write "SAME")
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*VENT TYPE KEY: SC = Sterilization Chamber CE = Chamber Exhaust AR = Aeration Room

(b) Control devices are required, but not yet installed

2. (a) What was the total amount of ethylene oxide purchased in the latest 12 months? tons

(b) If less than 12 months, how many? months

Check why it is less than 12 months: New owner: New facility: Did not keep records:

3. What control technology is required for sterilization units pursuant to this general permit?

(Indicate with an "X".)

- Acid-water scrubber Other
- Catalytic oxidation unit None required
- Thermal oxidation unit

4. Equipment Monitoring and Recordkeeping Information

Check all logs which are required to be kept on-site in accordance with the requirements of this general permit:

- (a) Purchase receipts for ethylene oxide purchases
- (b) Temperature monitoring for oxidizer units
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- (d) Concentrations of ethylene glycol in scrubber systems
- (e) Exhaust concentrations of ethylene oxide
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I, the undersigned, am the responsible official, as defined in Part II of this form, of the facility addressed in this notification. I hereby certify, based on information and belief formed after reasonable inquiry, that the statements made in this notification are true, accurate and complete. Further, I agree to operate and maintain the air pollutant emissions units and air pollution control equipment described above so as to comply with all terms and conditions of this general permit as set forth in Part II of this notification form.

I will promptly notify the Department of any changes to the information contained in this notification.

Emmanuel DUTARRIC

Print name of responsible official

1-24-11

Signature

Organization

Date

Identification

Address

City

Responsible Official
Dutarric

Responsible Official
Medtronic Inc.
Methuen

Phone Number
32-8556

Home/Respo
Contact (E)
Officer

Address

Phone Number
36-9600

¹There is an existing permit for facility number: 0310379-003 that will remain in effect until completion of the new facility at which time this permit will be surrendered/extended unless otherwise instructed.

I. Introduction:

The facility will house a total of two (2) sterilizers. The daily usage of 100% ETO will be 30 pounds/day.

Running at full capacity with two (2) sterilizers 365 days per year MEDTRONIC will use a total 10,950 pounds of ETO per year.

The new sterilizer vacuum pumps exhaust and the aeration room will be evacuated into a Catalytic Oxidizer System (Oxidizer) manufactured by LESNI A/S of Denmark.

The ETO removal efficiency of the LESNI A/S Oxidizer is 99.9%.

The ETO oxidizer operating temperature will be monitored and recorded in order to assure proper operating parameters and the specified destruction and removal of ETO from the sterilization process exhaust stream. The system temperature monitoring devices will be calibrated using NIST traceable standards.

The Oxidizer is heated with natural gas.

The emissions from the sterilizers and aeration room will vent through one (1) single stack.

Steam is used in the process to provide heat and humidity in order to enhance product sterilization. The steam will be delivered by the two (2) 30 Hp boilers. Natural gas will be used to heat the boilers.

II. Process Description:

The process will be typical for ETO sterilization at other industrial sterilization facilities. Sterilization is carried out as a batch process, consisting generally of a steam conditioning period and introduction of steam, introduction of ETO, introduction of Nitrogen, followed by a sterilization period, then evacuation of the sterilization chamber, Nitrogen, and Air washing to remove residuals. Upon loading the product into the sterilization chamber, the chamber is sealed and the air is evacuated. Steam, ETO and Nitrogen are added resulting in a concentrations of 200 -600 mg/l. The sterilization process exposure will last up to a maximum of 2 - 15 hours. After the sterilization process the ETO/ Nitrogen mixture is evacuated from the sterilizer by the vacuum pumps system and pumped into the Oxidizer. Nitrogen and Air are then allowed to enter the sterilizer bringing the chamber to atmospheric pressure. The chamber is always evacuated through the Oxidizer. Multiple evacuations will occur in order to remove product residuals prior to opening of the sterilizer door. The sterilizers will not be operate if the Oxidizer is not is not on line.

III. Facility Emissions:

Maximum annual usage of ETO at this facility will be 10,950 pounds per year.
The following are the calculations of ETO emissions from the facility
Following the Oxidizer:
Total Annual ETO Usage: 10,950 pounds worst case.
Operating Days per Year = 365

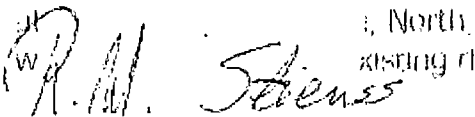
$$\frac{10,950 \text{ pounds} \times 1 \text{ Year} \times 1 \text{ Day} \times 0.999 \times 0.001}{365 \times 24} = \frac{10.93905}{8,760} =$$

= 0.00124875 Pounds per hour at the premises.
= 0.02997 Pounds per day at the premises.
= 0.00547 Tons per year at the premises.

Where: 0.999 = fraction of ETO vented to the scrubber.
0.001 = fraction of ETO not removed by the scrubber operating at 99.9% efficiency.

Please review the above information as soon as possible and let us know if the permit application is correct and complete. Please call me if you have any questions or require further information at 518 793 7077 Ext. 21 or 518 796 3821 (cell).

Best Regards,



Roman M. Stiens
President
Sterile Technologies, Inc.
63 Park Road
P. O. Box 4742
Queensbury, New York 12804

CC: Mr. Emmanuel Dujarric
Sr. Director Operations
Medtronic, Inc.
6743 Southpoint Dr. North
Jacksonville, FL 32216

Enclosure: DEP Form No. 62-213.900(3) Effective: 2/24/99
Lesni Sales Brochure & Medtronic Inc. Unit Specification
Fulton Boiler Specification
Facility Layout (footprint)



The Air Purification People

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CO150 A/S

General Description

The LESNI Catalytic abator systems are installed to purify exhaust air from production facilities or processes contaminated with organic compounds, which does not contain any components that can poison the catalyst.

The organic pollutants are converted into CO₂ and H₂O on condition that all pollutants are compounds containing only carbon, hydrogen, nitrogen and oxygen.

The plant performs well within limit legislations such as 1,8 mg/Nm³ (1 ppm), 1,0 mg/Nm³ and also 0,5 mg/Nm³ (TA-Luft).

Ethylene oxide abatement in medical devices sterilization

The LESNI A/S catalytic abator two step system has been specifically developed to eliminate the need for using chemicals (sulphuric acid) and to stop the generation of waste (glycol) while offering a total solution for cleaning all fugitive emissions from the degassing and aeration of sterilized product, as well as the high concentrated vent exhaust from the vacuum pumps containing EO (Ethylene Oxide).





The first step is the EO Balancer, where water is circulated from a buffer tank over a column, to generally equalize the variation in the incoming concentration of EO; such that when levels of incoming EO are high, the system absorbs EO in the water and when levels of incoming gas are low the system strips EO out from the water.

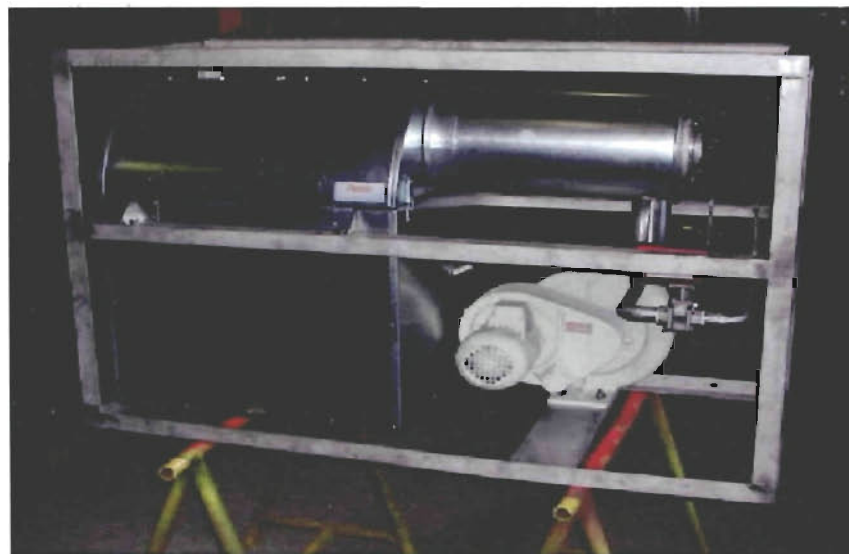
The second step is a catalytic abatement where the equalized concentration of EO is converted (catalytically oxidised) into CO₂ and H₂O.

The process air coming from the balancer is preheated first from a heat recovering air to air pre heater and then the temperature just before the catalytic bed is raised to the needed controlled temperature for the catalyst to complete the conversion of the EO over a gas fired heater (electric or steam also could be used).

The extract fan installed after the catalytic abator; provide necessary suction for extracting the process air through the system; thus keeping the complete plant operation under negative pressure.

The plant is controlled by a control system from which all operating, supervising and controlling of the plant are performed. The control panel shall be installed in a suitable place near to the operating technician or allow some functions to be remotely controlled.

In the control panel are all the needed terminals for connection to the balancer, catalytic abator and any other external communication.



Ethylene oxide abator (EO Disposer) for hospital sterilizers

LESNI has also developed a special version of the standard catalytic abator for decomposing of EO (Ethylene Oxide) from small (hospital type) sterilizer / aerator, in which the EO is converted into H₂O and CO₂.

The process air coming from the sterilizer is injected (pressurised) to the catalytic abator after the fan and just before the catalytic bed the temperature of the exhaust is raised to the needed controlled temperature over an electrically powered heater.

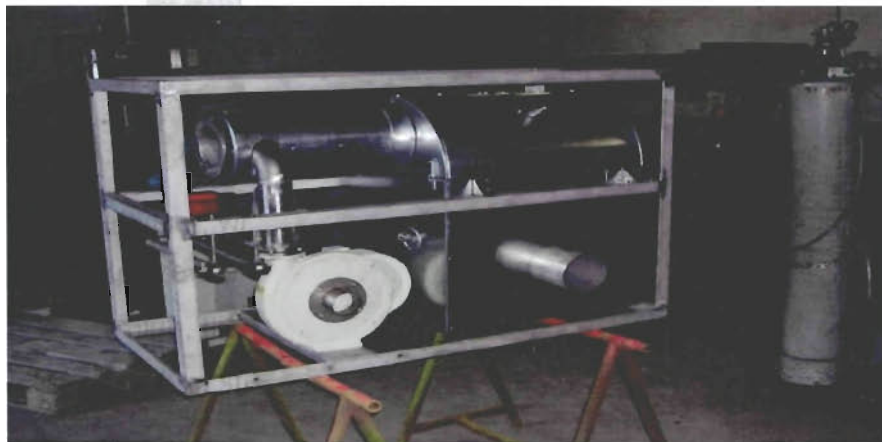
The LESNI catalytic abator has a damper system that switches the plant to emergency bypass at any unacceptable pressures or temperatures monitored in the plant.

The plant is controlled by a control system from which all operating, supervising and controlling functions of the plant are performed. The control panel shall be installed in an unclassified area related to the operating personal. In the control panel are the needed terminals for connection signals from the catalytic abator for external communication.

The LESNI system will be designed to obtain the purification required by the authorities with the highest degree of security and efficiency.

Functions

The LESNI A/S catalytic abator plants for conversion of ETO are always supervised and operated from the control panel. All switches, instruments and indicators are situated on the panel and are also indicating the actual running mode.



The needed extract for maintaining the airflow through the Catalytic Abator Plant for conversion of ETO is supplied from a fan on the inlet duct to the abator.

ETO loaded gas from vacuum pump is lead to the catalytic abator over an injector injecting after the main fan. The needed supplementary air is taken from a separate duct on the fan inlet. The diluting air can be connected to the degassing area.



The Air Purification People

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7190 Billund
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C050 A5

Medtronic Inc. Catalytic Oxidizer & Balancer Specification

The system is controlled by a PLC located in the control room of the plant. The two pallet chambers will use 10 pounds of EtO per cycle and the four pallet chamber will use 20 pounds per cycle. Each cycle will be 15 hours with in chamber.

The system is designed to operate 1 time each per day, seven days per week, and fifty two weeks per year. An aeration room sized at 200 cubic feet will be added to the design with a minimum of 7 air changes per hour. The aeration room will only be used occasionally, not more than 4 cycles per week.

For

The operation. This will give 30 pounds per each 15 hour period for current demand. The system is designed to operate 1 time each per day, seven days per week, and fifty two weeks per year. An aeration room sized at 200 cubic feet will be added to the design with a minimum of 7 air changes per hour. The aeration room will only be used occasionally, not more than 4 cycles per week.

Chambers will run 1 time each per day, seven days per week, and fifty two weeks per year. An aeration

room sized at 200 cubic feet will be added to the design with a minimum of 7 air changes per hour. The

aeration room will only be used occasionally, not more than 4 cycles per week.

The system is designed to operate 1 time each per day, seven days per week, and fifty two weeks per year. An aeration room sized at 200 cubic feet will be added to the design with a minimum of 7 air changes per hour. The aeration room will only be used occasionally, not more than 4 cycles per week.

For this scenario we will deliver 1 Catalytic Abator for ethylene oxide with airflow of app. *300 Scfm /*
app.510 Nm³/h, complete according to the enclosed flow sheet no. 07102-001 and the data and specifications mentioned below.

The package is designed to cope with full loading of EtO, while treating also all exhaust vents from the hot box cells with balance air from the sterilizer rooms. The overall plant performance is subject to emission standards demanding less than **1 ppm** or less than **1.8 mg/Nm³** from the abatement plant exhaust.

The package includes delivery of complete balancer and Catalytic Abator plant, capable of handling and purifying ethylene oxide toxic emission from the degassing chambers and the sterilizer rooms, in addition to the concentrated vents from vacuum pumps.

General Data / Specification

<p>Airflow</p>	<p>300 Scfm or 510 Nm³/h</p>	<p>Eton / sterilizer</p>	
<p>2 sterilizers per</p>	<p>1x4 pallet & 1x2 pallet</p>	<p>Eton / day</p>	<p>app. 30 lb.</p>
<p>Number of cycles</p>	<p>2 per 24 hours</p>	<p>Concentration of Eton to Catalytic Abator</p>	<p>max. 4 g/Nm³</p>
<p>Temperature</p>	<p>app. 104°F or 40 °C</p>	<p>Operating temperature</p>	<p>app. 302 °F or 150 °C</p>
<p>Operation</p>	<p>7 days /week; 24 h/d</p>	<p>Purification</p>	<p>less than 1ppm or 1,8 mg/Nm³</p>
<p>Pollutants</p>	<p>Ethylene Oxide (Eton)</p>		

Power / Utility Data			
Electrical consumption	app. 20 kW	natural gas consumption	app. 35.32 - 70.63 cu ft./hr.
Electricity	3x 480 V; 60 Hz		
Approximate Dimensions (Abator& Balancer)			
Length	6.1 m	Width	2.0 m
Height	3.5 m	Weight	5 tons(including water)

The combined SIT purification system offered is based on our proven and developed "state of the art solution" which we have successfully supplied over the last 20 years to many Eton sterilizing companies.

These plants perform well within limit legislations; for this plant we shall guarantee 1 ppm or 1.8 mg/Nm³, while operating safely, efficiently and with high reliability.

The purification system is designed to handle and purify ethylene oxide toxic emissions from all of the

following areas:

- The hot box cells
- Vacuum pump vent lines
- Sterilizer rooms

Note:

1. From the safety point of view, we insist that vacuum pumps are stopped when our plant

goes into bypass, so that Eton levels do not escalate in the balancer. If you are allowed to

discharge Eton directly to the atmosphere, then actuated diverting bypass valves should

be installed by you to discharge vacuum pumps into another bypass stack.

2. We draw your attention to the fact that ONLY the balancer will be suitable for zone 1

classification, whereas only the sump with liquid could only be considered zone 0.

3. The Catalytic Abator is NOT classified, and statutory rules will apply in the layout and

positioning of all components.

SPECIFICATIONS:

1.1)	1 piece	<p>Compact tower packed absorber type LKV, with integral column and sump tank made of</p> <p>AISI 304, complete with one circulating pump, instruments and fittings etc.</p>
1.1)		<p>The following built-in parts are included in the absorption column:</p> <ul style="list-style-type: none"> • 2 maintenance nozzles for inspection • Tower packing supporting plate • Mass transfer zone • Scrubbing liquid distributor • Large surface droplet and mist eliminator
1.2)	1 piece	<p>Large 2 m³ sump tank complete with:</p>

		<ul style="list-style-type: none"> • Solenoid valve for fresh water • Up to 2 individual connections for the vacuum pump vent exhaust from the sterilizers. The provision by SIT includes nozzles, complete with diffusers. • Level indicator with adjustable measuring contacts and control • Extra redundant level switch for low level • Overflow and drain nozzle • Screen for level transmitter
1.3)	1 piece	Centrifugal pump incl. motor 3 x 480 V, 60 Hz, IP 55.
1.4)	1 piece	<p>The pump suction and pressure lines are complete with:</p> <ul style="list-style-type: none"> • Hand valves • Pressure indicator

		<ul style="list-style-type: none"> • Flow switch • Temperature indicator • Pressure switch • Other nozzles, fittings, and valves
2)	1 piece	<p>Extract fan, complete with EExd motor and V-belt drive. The fan should provide and maintain low suction pressure at the inlet to the abatement plant around 1" water gauge.</p> <p>The fan will also be acoustically enclosed to keep the noise level below 85 dB (A) at a distance of 1 m.</p>
3)	1 piece	<p>Infra-red LEL gas detector "Dräger-Polytron" for measuring the concentration before the catalytic oxidizer.</p>
4)	1 piece	<p>Low concentration gas detector type Dräger-Polytron / Electrochemical type sensor"</p>

		installed after the Abator offering a continuous 4 to 20 signal.
5)	1 piece	Air to air heat exchanger for pre-heating of the inlet air: Heat recovery app. 65%

Standard 100 pt

Level 1, 300 w/

Standard 100 pt

Level 1, 300 w/

Standard 100 pt

Level 1, 300 w/

Standard 100 pt

Level 1, 300 w/

6)	1 piece	Electric heater complete with thyristor and regulators
6)	1 piece	Gas burner (natural gas), complete with gas train arrangement, valves and regulators.
7)	1 piece	Abator, complete with catalyst for low temperature operation. For the catalyst we guarantee a working time of 16,000 hours or max. 2 years. We draw your attention to the fact that gases containing silicone or phosphors can poison the catalyst.
8)		All interconnecting pipes, ducts, fittings, and instruments for the plant.
9)		Insulation material for the plant, 50-150 mm thick in places with cladding.
10)		Bypass diverting actuated valves for emergency.
11)	1 piece	Special receiver tank to collect overflow from the balancer installed at a higher level

		<p>allowing natural draining back to the sump of the balancer. Condensate from vacuum pumps (if water seal type) can also be pumped to this over flow tank. The overflow tank (approx. 100 lit.) will also have an actuated valve, which will be operated by the level switch.</p>
12)	1 piece	<p>Compressed air buffer tank to provide necessary compressed air supply to the plant in emergency.</p>
13)		<p>Control and switch cabinet for operating and control of the plant, complete with adjustment for the electric heater with Allen Bradley or equal PLC system:</p> <ul style="list-style-type: none"> • The control panel will generally comprise one switch panel containing motor starters and all necessary hard-wired signals, and PLC for operating and control of the plant. All hard-wired signals will also be indirectly linked to the PLC in the

panel.

- The PLC will be supplied with compact operator touch panel, which will be free, issued for installation in the control room or on the main panel.
- Customer will complete the wiring and all necessary communication between the plant skid and main switch panel.
- Customer will complete wiring between the operator panel and the switch panel through an Ethernet bus.
- Customer will wire any additional signals and alarms to Customer own operating and control system.
- Critical alarms will be available on terminals and are "fail-safe" hard-wired signals. These signals are required to stop vacuum pumps and divert flow to emergency

		<p>exhaust, while exhaust fan continues running. These signals are part of the safety</p> <p>of the total system.</p>
14)		<p>The necessary junction boxes for all digital and analogue signals will also be supplied and installed at the plant skid. Wiring from all instruments, motors, etc. to these junction boxes will be completed by SIT.</p>
15)		<p>Stack approx. 8 m, so that the point of exhaust is 2 m above roof level. Two monitoring points are included, and the analyser should be accessible from the supporting platform.</p>
16)		<p>Steel supporting structure, complete with access platforms and stepladders with supporting brackets for all air ducts within the scope of supply and the stack.</p>
17)		<p>Project progress review meetings on site and in our offices to cover various aspects of the</p>

project. We anticipate scheduling about two meetings.

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18)		Mechanical and electrical erection of the plant (within skid area only) by SIT team of fitters.
19)		Delivery ex works excluding freight, custom duties, and taxes (as unknown).
20)		Submission of risk analysis study for the plant.
21)		Customer must ensure permitted access to site for trucks and cranes.
22)		FAT and SAT, including IQ, OQ, and PQ of SIT plant <u>without</u> software validation to be agreed on.
23)		<p>Service engineer for running in the plant and commissioning and setting up for operation generally covering the following checks and tests:</p> <ul style="list-style-type: none"> • Delivery test including physical inspection of the plant • Process indicators and controls

- Alarms
- Timers
We... ..
- Interlocks
- Safety valves and functions
- Input and output signals
- Test of all measuring instruments
- Mechanical and electrical functions of all equipment
- Training of operators and engineers

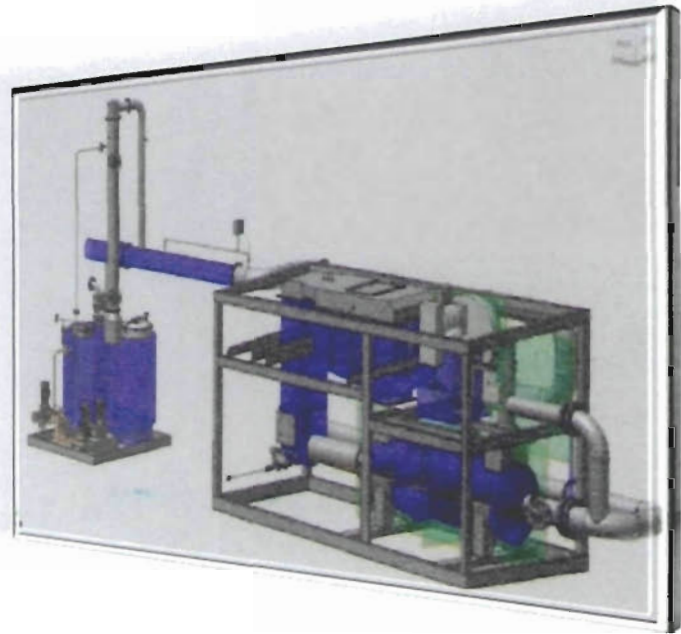
Complete detailed engineering and delivery of documentation for the control and maintenance, in English language, consisting of the following sections:

- General description
- Operating manual
- Maintenance and adjustment
- Maintenance program and check list
- Commissioning Item list and components documentation
- Drawings
- Safety instructions

Delivery test include

- CE certificate

- Alarm list



REFERENCES:

- B. Braun, France und Vietnam
Le. O.

- Isotron, Ireland and Malaysia
... ..

- Mallinckrodt, Ireland
... ..

- Abbott Labs, Ireland
... ..

- Unomedical, Denmark
... ..

- Life Net, US
... ..

- Becton Dickinson, France . actions

EXCLUSIONS:

- Foundation and civil works.

- Packaging and delivery to site.

- Custom duties and local taxes.

- Cranes and lifting equipment on site for positioning and assembly.

- Silencer in the stack, if necessary.

- Electrical cables and wiring between skid and main switch panel and through to operator panel.


- Supply and connection of utilities and other services, including compressed air, natural gas,

electricity, and calibration gas for analysers and Ethernet connections, if needed.

DELIVERY TIME:

- Delivery ex works – 6 months from final order.
- Installation and setting up – 3 weeks from delivery to site.
- Final hand-over of plant and documentation, not later than 3 weeks from installation.
- Time of delivery with reservations against conditions we do not control.



Capacity			(BHP)	30
(Lb.-steam/hr.)	1035		(kilowatts)	300
(Kg-steam/hr.)	470			
			Design Pressure	
Fuel Type	Natural Gas		(lb./in ²)	
Control Voltage	110/60/1		(kg/cm ²)	150
Burner Voltage	220 - 460/60/3 ³		(bar)	10.55
				10.34

³ Medtronic to confirm voltage

<u>Standard Features</u>	<u>Standard Trim</u>
Complete 'On-Off Fulton' burner assembly with 1/2" NPT	Blow down valves for water column
Control panel complete with wiring diagram	Water gauge glass protector
Operating pressure control	Steam safety valve
High limit pressure control	Water Stop Valve
Two low water cutoff devices (probe type)	Water check valve (spring type)
Water column with water gauge glass assembly with 1/2" NPT	Blow down valve (Y-type)
	Stack adapter with gasket
Instruction manual and ASME certificate	Steam pressure gauge assembly with
Low Pressure Steam outlet & Safety Valve (15 psig)	inspection cocks

Return System:

Includes the Optional Self-Actuated Steam Pre-Heat Kit & Optional 304 Stainless Steel Tank Material

Quantity	1		Pump voltage	220 - 460/60/3
Model	HTL-60		Capacity	
Type	Horizontal		(Gallons)	46
# of pumps	24		(Liters)	175

<u>Standard Components</u>	<u>Standard Trim</u>
Tank has 1/4" steel with 3/16 heads	Float valve assembly with ball & rod

4 Pumps sized for 15 BHP, Low Pressure

Welded stand	Water sight glass and valve assembly
Pump and motor assembled and piped	NEMAN 1, 3 ph panel with motor starters, H.O.A. CCT & lights
Strainer and shut off valve piped in line	Grundfos Pump

Blow-Down Separator

Includes the Optional Self-Actuated Cooling Kit

Quantity: 1	Model: F-30
Meets or exceeds ASME code	Compact size and easy to install
Low maintenance	Durable heavy gauge steel construction
Baffle plate design to absorb steam flash	3x4 Hand hole for clean-out and

and pressure	inspection
<p>Large steam vent opening</p>	Cold water inlet
	Bottom drain opening for sludge removal

Water softener⁵

Horizontal

Quantity	1	Model	FB-300-900
----------	---	-------	------------

⁵ Medtronic to test the water supply for quality, hardness, & minerals and provide these results to Sterile Technologies, Inc. to

assure that manufacturer is aware of operating conditions and that boiler is set up according to operating conditions.

Voltage	110/60/1		Make up water design pressure range:	
Min capacity			(psig)	125
(grains)	40,000		(kg/cm2)	8.8
(ppm)			(bar)	8.6
Max capacity				
(grains)	60,000		Salt storage	
(ppm)			(pounds)	320
			(kilograms)	145

M 4F z.c.de

Standard Features

Twin fiberglass alternating chemical tanks for uninterrupted service

All-brass motor-driven control valve with fully adjustable regeneration cycles

Rigid polyethylene brine tank with dust cover

Self-adjusting backwash controller

Built in bypass for continuous service during regeneration cycle

Deluxe Chemical Feed System; to include:

One (1) 50 Gallon Polyethylene Tank with Lid

One (1) PROPORTIONING Chemical Metering Pump

One (1) Tank Agitator with Stainless Steel Agitator

One (1) Set of Suction/Discharge Tubing Including Quill

One (1) Water Meter 110/60/1

M

30,000

M

30,000

System Capacity	50 Gallons	Pump Rated Pressure	215 PSI
Pump Capacity	0.5 GPH	Pump/Agitator Voltage	110/60/1



Skid Mounting of Two (2), ICX-30, One (1), HTL-60 Duplex, One (1), F-30 Blow-Down Separator, One (1), FB-600-900 Water Softener, and One (1), Chemical Feed System on a Structural Steel Skid, All Piped and Wired with Single Source Power (includes fused disconnect), Single Source Water, Single Source Steam and Single Source Drain

Medtronic to test the water supply for quality, hardness, & minerals and provide these results to

Sterile Technologies, Inc. to assure that vendors are aware of operating conditions.

Lead/Lag Boiler Control System to include:

ModSync lead/lag control

Yokogawa pressure control for steam pressure signal transmission

Alarm signal relay (flame failure, low water, hi/lo gas pressure)

Alarm & lights on boiler panel

Boiler Room must be under neutral or slightly positive pressure. Adequate combustion air for

proper boiler operation is required.

All Quoted Prices are Net in U.S. dollars Ex-Factory Pulaski, NY.

Pricing Validity - 30 days.

SE [unclear] (2) ICX 30, One

Standard Factory Delivery Schedule: Approximately 8 – 12 weeks after receipt of purchase

Or [unclear] Water Softener, 1

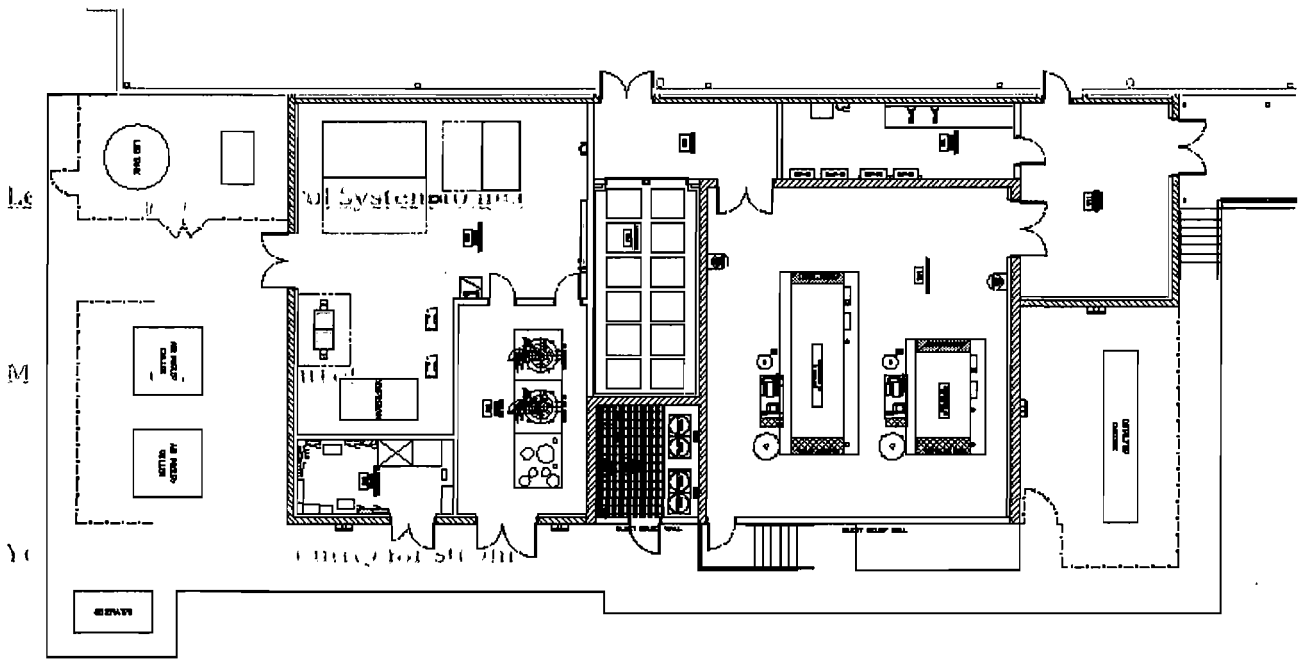
order. Actual delivery schedule may vary.

SK [unclear] Wired with Single

W [unclear] Steam and Single

Medtronic Inc. Facility Drawing (footprint)

N310194.DD Medtronic JAX - Biologic Tech/10194_drawing.dwg, 4/18/2011 9:11:26 AM



AI 1 fabric entrance, low

AI 1 floor panel

57

76

FedEx Express US Airbill

FedEx Tracking Number

8712 7425 8470

Form ID No.

0215

SPH32

Sender's Copy

1 From Please print and print hard.
 Date 1/24/11 Sender's FedEx Account Number 0322-0756-1

Sender's Name JAMIE CUTHBERTSON Phone (904) 296-9600

Company MEDTRONIC ENT

Address 6743 SOUTHPOINT DR N

City JACKSONVILLE State FL ZIP 32216-6218

2 Your Internal Billing Reference WBS 009327600

3 To Recipient's Name MR. Richard Dibble Phone (904) 279-3230

Company GENERAL PERMITS SECTION BUREAU OF AIR MONITORING AND MOBILE SOURCES MS 5510

Address DEPT- OF ENVIRONMENT PROTECTION

Address 2600 BLAIR STONE ROAD

City TALLAHASSEE State FL ZIP 32399-2400

0414362882

4a Express Package Service

FedEx Priority Overnight Next business morning.* Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Standard Overnight Next business afternoon.* Saturday Delivery NOT available.

FedEx 2Day Second business day.** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Express Saver Third business day.* Saturday Delivery NOT available.

4b Express Freight Service

FedEx 1Day Freight Next business day.** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx 2Day Freight Second business day.** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx 3Day Freight Third business day.** Saturday Delivery NOT available.

5 Packaging

FedEx Envelope* FedEx Pak* FedEx Box FedEx Tube Other

6 Special Handling and Delivery Signature Options

SATURDAY Delivery

No Signature Required

Direct Signature

Indirect Signature

Does this shipment contain dangerous goods?

No Yes Yes Dry Ice Cargo Aircraft Only

7 Payment Bill to:

Sender Recipient Third Party Credit Card Cash/Check

Total Packages Total Weight Total Declared Value*

fedex.com, 1.800.GoFedEx 1.800.463.3339



Store your addresses at **fedex.com**
 Simplify your shipping. Manage your account. Access all the tools you need.

PULL-AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE. NO POUCH NEEDED.

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FedEx US Airbill
Express
FedEx
Tracking
Number

8712 7425 8470

Form
ID No.

0215

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 1/24/11 FedEx Tracking Number 871274258470Sender's Name JIMIE PUTHBERTSON Phone 904 296-4600Company NEOTOMIA INCAddress 1708 BLUE POINT DR N Dept./Floor/Suite/RoomCity JACKSONVILLE State FL ZIP 32216-6518

2 Your Internal Billing Reference

WBS 009321.000

3 To

Recipient's Name MR. Richard Dibble Phone 904 279-5230Company GENERAL PERMITS SECTION
AND MOBILE SOURCES MISSIO
DEPT. OF ENVIRONMENT PROTECTION
HOLD Weekday Print FedEx location address below. NOT available for FedEx First Overnight.
HOLD Saturday Print FedEx location address below. Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.Address 2600 BLAIR STONE ROAD Dept./Floor/Suite/RoomCity TALLAHASSEE State FL ZIP 32399-2400
Print FedEx location address here if HOLD option is selected.City TALLAHASSEE State FL ZIP 32399-2400
0414068899

8712 7425 8470

4a Express Package Service

* To most locations.

Packages up to 150 lbs.

 FedEx Priority Overnight
Next business morning.* Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected. FedEx Standard Overnight
Next business afternoon.* Saturday Delivery NOT available. FedEx First Overnight
Earliest next business morning delivery to select locations.* Saturday Delivery NOT available. FedEx 2Day
Second business day.* Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected. FedEx Express Saver
Third business day.* Saturday Delivery NOT available.

4b Express Freight Service

** To most locations.

Packages over 150 lbs.

 FedEx 1Day Freight
Next business day.** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected. FedEx 1Day Freight Booking Nc. FedEx 2Day Freight
Second business day.** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected. FedEx 3Day Freight
Third business day.** Saturday Delivery NOT available.

5 Packaging

* Declared value limit \$500.

 FedEx Envelope* FedEx Pak*
Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak. FedEx Box FedEx Tube Other

6 Special Handling and Delivery Signature Options

 SATURDAY Delivery

NOT available for FedEx Standard Overnight, FedEx First Overnight, FedEx Express Saver, or FedEx 3Day Freight.

 No Signature Required

Package may be left without obtaining a signature for delivery.

 Direct Signature

Someone at recipient's address may sign for delivery. Fee applies.

 Indirect Signature

If no one is available at recipient's address, someone at a neighboring address may sign for delivery. For residential deliveries only. Fee applies.

Does this shipment contain dangerous goods?

0 in box must be checked.

 No Yes

As per attached Shipper's Declaration.

 Yes

Shipper's Declaration not required.

 Dry Ice

Dry Ice, 9 UN 1845

x _____ kg

Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or placed in a FedEx Express Drop Box.

 Cargo Aircraft Only

7 Payment Bill to:

Enter FedEx Acct. No. or Credit Card No. below.

Obtain Recip.

Acct. No. Sender
Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card Cash/Check

Total Packages

Total Weight

Credit Card Auth.

*Our liability is limited to \$100 unless you declare a higher value. See the current FedEx Service Guide for details.

553

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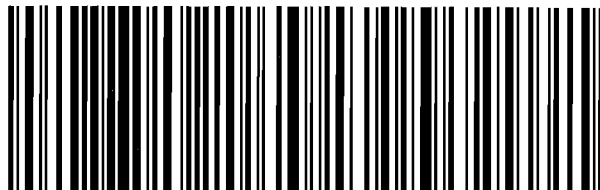
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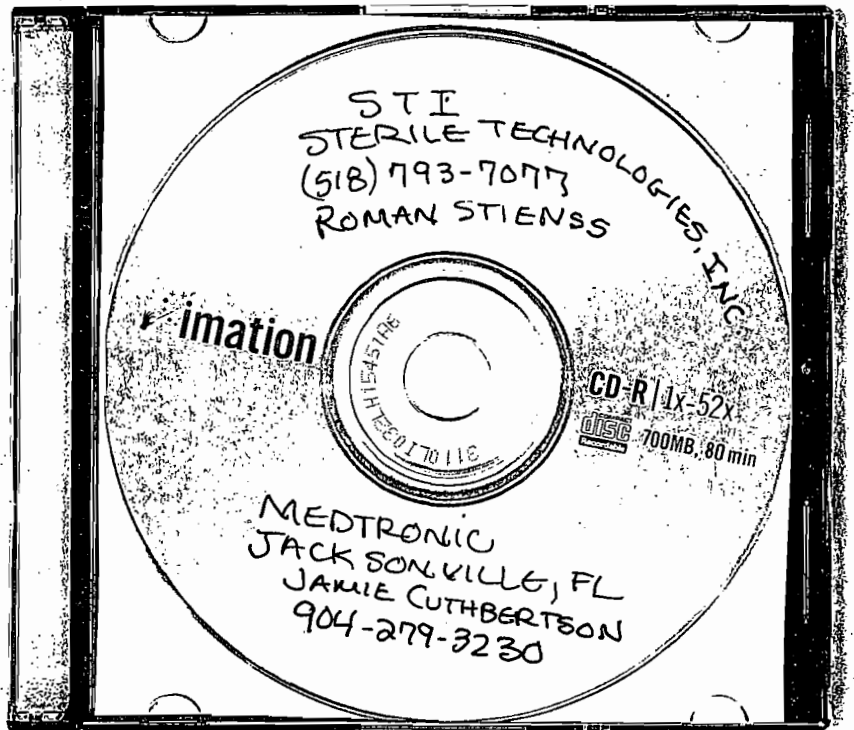


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