MADM™

Anesthesia Delivery Module

Operator's Manual

Table of Contents

Table of Figures

List of Tables

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1. Notices

Contact Information

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Manual Part Number

The part number for the MADM™ Operator's Manual is P/N 124764.

MADM™ Serial Number

MADM™ unit serialization is as follows: MADMYYYYMMXX where:

YYYYY = Year of manufacture (e.g. 2015)
MM = Month of manufacture (e.g. 10 = October)
XX = Sequential Numbering (e.g. 01, 02, 03)

Patents Notice

MADM™ is covered by one or more US and international patents and patents pending.

Copyright Notice

Technical Support

For technical support, please contact Thornhill Research Inc. directly.

MADM™ Intended Use

MADM™ is intended to deliver volatile anesthetic to a patient when placed in either circle or open anesthetic circuits. It vaporizes isoflurane and sevoflurane and delivers the vaporized anesthetic agent into the inspiratory limb of the breathing circuit.

MADM™ is also intended to monitor respiratory rate, CO_2, and the anesthetic gases isoflurane and sevoflurane. It is intended to be connected to a patient breathing circuit for monitoring of patients to whom it is delivering volatile anesthetic gases.

MADM™ Intended Environments

MADM™ is intended to be operated in hospitals.

MADM™ Intended Use Population

The intended patient population is adults who weigh more than 40 kg.

Contraindications

MADM™ is subject to any contraindication to inhaled anesthetics.
The device is contraindicated for use with Nitrous Oxide Carrier gas.

MADM™ Intended Users

MADM™ is intended to be used by:

- Trained physicians
- Anesthesiologists

MADM™ Duration of Use

MADM™ is intended to be used for the duration of anesthetic delivery.

Restriction Notice

US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

Declaration of Conformity Notice

MADM™ complies with the Medical Device Directive MDD 93/42/EEC and carries the CE Mark as shown.

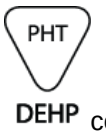
CE
0086

MADM™ also conforms to the following Technical Standards:

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-8
ISO 80601-2-13
ISO 80601-2-55

For more information on these standards, see *Standards Compliance* on *page 37*.

Hazardous Materials Notice

MADM™ may contain phthalates. Any device or article displaying this symbol 

contains the phthalate di (2-ethylhexyl) phthalate (DEHP). Phthalates are classified as carcinogenic, mutagenic or toxic to reproduction.

In addition, patient-applied breathing tubes, face masks, etc., that are used with MADM™ (but which are not shipped with the device nor supplied by Thornhill Research Inc.) may also contain the phthalate DEHP or be made from the plastic PVC which produces dioxin when incinerated, a known carcinogen. In order to reduce the potential risk from phthalates, long term exposure should be avoided in the treatment of children and pregnant or nursing women.

In addition, latex may be present in some products, or they may be composed of latex. It has been found that latex can cause allergic reaction.

MADM™ users are advised to be aware of these issues and avoid using accessories that contain hazardous materials. All accessories containing hazardous materials are required to be labeled as such.

Disposal Instructions

MADM™ and its components are not suitable for regular trash disposal. Follow local guidelines for proper disposal of medical devices.

Any accumulated fluids should be disposed of as biological waste according to local guidelines.

Calibration gas and exhausted anesthetic should be scavenged with an anesthetic scavenger compliant with IEC 60601-2-13.

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2. Classification, Symbols, Cautions and Warnings

MADM™ is classified as portable, internally powered (battery mode), Class I ME Equipment (via PSU).

MADM™ is a medical device intended for use only by or under the order of a physician.

Personnel operating this equipment are responsible for reading and thoroughly understanding all product documentation provided. Service of this instrument is restricted to trained personnel only.

Statements throughout the product documentation have special significance as explained in the following table.

Icon & Type	Explanation
 ***NOTE:***	*Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment.*
 **CAUTION!**	**A CAUTION INDICATES THAT THERE IS A POSSIBILITY OF DAMAGE TO THE PRODUCT OR OTHER EQUIPMENT ATTACHED TO IT.**
 **WARNING!**	**A WARNING MEANS THAT THERE IS A POSSIBILITY OF PERSONAL INJURY TO THE OPERATOR OR PATIENT.**

Table 1: Manual Icons

Product Labels Symbols

SYMBOL	DESCRIPTION
	Caution. Read accompanying documentation.
	Follow instructions for use.
	Do not reuse (single use only).
	No latex used in the manufacture of this product.
	Defibrillation-proof Type BF applied part

SYMBOL	DESCRIPTION
CE 0086	CE Mark with notified body number
C US 244588	Canadian Standards Association (CSA) certification mark. Indicates product has been tested under a formal process and that it meets the safety and/or performance requirements of applicable standards.
Rx ONLY	Device restricted to sale by or on the order of a licensed medical practitioner.
PHT DEHP	Device contains the phthalate di (2-ethylhexyl) phthalate (DEHP).
IPX1	Degree of ingress protection
REP	Authorized Representative
	Manufacturer
	Date of manufacture
REF	Reference or Model Number
SN	Serial Number
NON STERILE	Non sterile; material can not be guaranteed to be free of contamination.

Table 2: Product Label Symbols and Descriptions

Warnings

	**WARNING! IN CASE OF ANESTHETIC WORKSTATION FAILURE, THE LACK OF IMMEDIATE ACCESS TO APPROPRIATE ALTERNATIVE MEANS OF VENTILATION CAN RESULT IN PATIENT INJURY.**
	**WARNING! TO AVOID RISK OF ELECTRIC SHOCK, MADM™ MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.**
	**WARNING! MADM™ SHOULD NOT BE POSITIONED SO AS TO MAKE IT DIFFICULT TO DISCONNECT IT FROM THE POWER SUPPLY.**
	**WARNING! A BIOPHYSICAL MONITORING DEVICE SHOULD ALWAYS BE USED TO MEASURE AND MONITOR A PATIENT'S VITAL SIGNS WHEN USING THE MADM™ SYSTEM.**
	**WARNING! REUSE OF ANY SINGLE-USE COMPONENT MAY INTRODUCE A RISK OF CROSS-INFECTION AND ADVERSELY AFFECT DEVICE PERFORMANCE.**
	**WARNING! THE OPERATOR SHOULD DISCONNECT THE ANESTHETIC DELIVERY SYSTEM FROM THE PATIENT BREATHING CIRCUIT IF THE MINUTE VENTILATION IS SIGNIFICANTLY DIFFERENT THAN EXPECTED.**
	**WARNING! THE MADM™ SYSTEM SHOULD NOT BE USED IF THERE IS SIGNIFICANT DISCREPANCY BETWEEN THE ANESTHETIC DIAL SETTING AND THE DISPLAY OF THAT ANESTHETIC CONCENTRATION ON THE GUI SCREEN.**
	**WARNING! SKIPPING A MADM™ CALIBRATION RUNS THE RISK OF OVER OR UNDER DELIVERING ANESTHETIC.**
	**WARNING! ALWAYS HAVE A BACKUP METHOD OF DELIVERING ANESTHETIC TO THE PATIENT AVAILABLE.**
	**WARNING! REFER TO AND FOLLOW ALL WARNINGS AND CAUTIONS ON THE LABELING OF THE INTENDED VOLATILE AGENT.**
	**WARNING! MADM™ DELIVERS INHALATIONAL ANESTHETICS INCLUDING ISOFLURANE AND SEVOFLURANE WHICH CAN BE LEAKED INTO THE OPERATING ROOM ENVIRONMENT DURING PATIENT CIRCUIT DISCONNECTIONS OR OTHER EVENTS. TO MINIMIZE POTENTIAL UNINTENTIONAL EXPOSURE, ANESTHETIC SHOULD ONLY BE DELIVERED IN A WELL VENTILATED AREA.**
	**WARNING! MADM™ IS NOT INTENDED TO BE USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**
	**WARNING! NO MODIFICATION OF THE EQUIPMENT IS ALLOWED.**
	**WARNING! SOUND PRESSURE LEVELS OF AUDITORY ALARM SIGNAL THAT ARE LESS THAN AMBIENT LEVELS CAN IMPEDE OPERATOR RECOGNITION OF ALARM CONDITIONS.**
	**WARNING! IF THE PATIENT INFORMATION DISPLAY AREA INDICATES THAT A SENSOR OR SENSORS ARE OUT OF CALIBRATION, DO NOT ADJUST THE ANESTHETIC DIAL SETTING IN AN ATTEMPT TO COMPENSATE.**

	**WARNING! MADM™CONTAINS NO USER SERVICEABLE PARTS. DISSASSEMBLY OR SERVICING BY AN UNQUALIFIED PERSON WILL VOID THE WARRANTY AND MAY CAUSE THE DEVICE TO MALFUNCTION AND SERIOUSLY HARM THE PATIENT OR OPERATOR.**
	**WARNING! USE OF ACCESSORIES NOT SUPPLIED WITH MADM™, OR NOT SPECIFICALLY LISTED IN THIS DOCUMENT, MAY ADVERSLEY AFFECT DEVICE PERFORMANCE AND HARM THE PATIENT OR OPERATOR.**
	**WARNING! OPERATION OF MADM™ OUTSIDE SPECIFIED TEMPERATURE RANGE MAY RESULT IN UNDERDELIVERY OF ANESTHETIC TO THE PATIENT.**
	**WARNING! DO NOT USE OR CHARGE A DAMAGED BATTERY.**
	**WARNING! DO NOT USE MADM™ WITH A CARRIER GAS CONTAINING NITROUS OXIDE AS THIS MAY RESULT IN SIGNIFICANT OVERDELIVERY.**
	**WARNING! ALTHOUGH MADM CONTINUES TO DELIVER ANESTHETIC DURING A SCREEN FAILURE, THE OPERATOR SHOULD SWITCH TO AN ALTERNATIVE MEANS OF ANESTHETIZING THE PATIENT AS SOON AS POSSIBLE.**
	**WARNING! DO NOT ADJUST THE MADM™ CONTROL DIAL BASED ON DISPLAYED INSPIRED OR END TIDAL VALUES.**

Cautions

	**CAUTION! US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED MEDICAL PRACTITIONER.**
	**CAUTION! CONNECT ONLY THE RECOMMENDED ANESTHESIA AND CO_2 MONITORING SENSOR TO THE ANESTHESIA AND CO_2 MONITORING SENSOR PORT.**
	**CAUTION! USE ONLY THE POWER SUPPLY AND BATTERY BASE SUPPLIED WITH THE SYSTEM AND LABELED FOR USE WITH MADM™.**
	**CAUTION! DURING DISCONNECTION OF THE MALE ADAPTER FROM THE CANISTER, AND THE BOTTLE ADAPTER FROM THE BOTTLE, SMALL AMOUNTS OF ANESTHETIC AGENT WILL ESCAPE INTO THE ENVIRONMENT.**
	**CAUTION! OPERATION OF MADM™ OUTSIDE OF SPECIFIED LIMITS MAY CAUSE INACCURATE DELIVERY.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH AN ANESTHETIC GAS SCAVENGING TRANSFER AND RECEIVING SYSTEM THAT COMPLIES WITH ISO/IEC 80601-2-13.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC BREATHING CIRCUITS THAT COMPLY WITH ISO/IEC 80601-2-13.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC WORKSTATIONS OR COMPONENTS THEREOF THAT COMPLY WITH ISO/IEC 80601-2-13.**

	**CAUTION! MADM™ IS NOT MRI COMPATIBLE, AND USE NEAR STRONG MAGNETIC FIELDS MAY INTRODUCE A SIGNIFICNT HAZARD.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC VENTILATORS THAT COMPLY WITH ISO/IEC 80601-2-13.**
	**CAUTION! REMOVAL OF THE PATIENT OR INLET SENSOR FROM THE CIRCUIT TO REPLACE THE ADAPTER WILL RESULT IN MADM™ DISCONTINUING THE DELIVERY OF ANESTHETIC. THIS SHOULD ONLY DONE AT THE POINT IN THE OPERATION WHERE ANESTHETIC DELIVERY CAN BE DISCONTINUED FOR 30 SECONDS OR MORE.**
	**CAUTION! REUSE OF SINGLE-USE COMPONENTS INCLUDING BOTH THE INLET SENSOR AND AIRWAY ADAPTERS MAY RESULT IN INACCURATE ANESTHETIC DELIVERY OR FAILURE TO DETECT DANGEROUS ANESTHETIC DELIVERY LEVELS.**

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3. Acronyms and Abbreviations

Acronym / Abbreviation	Term
dBA	A measure of sound pressure using an "A-weighting filter" which roughly corresponds to the inverse of the 40 dB (at 1 kHz) equal-loudness curve.
GUI	Graphical User Interface
ISO	Isoflurane
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MAC	Minimum Alveolar Concentration
MADM™	Mobile Anesthetic Delivery Module
SEV	Sevoflurane

Table 3: Acronyms and Abbreviations

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4. The MADM™ System

System Description

The MADM™ system consists of a *Control and Display Unit*, an *Anesthesia and CO_2 Monitoring Sensor*, and a *Medical Grade Power Supply*.

Control and Display Unit

The *Control and Display Unit* consists of a user interface, an information display screen, an anesthetic reservoir, a precision pump and heater, and flow and gas sensors.

Anesthesia and CO_2 Monitoring Sensor

The *Anesthesia and CO_2 Monitoring Sensor* is located on the inspiratory tube near the patient's mouth. It measures the content of the patient's inhaled and exhaled gas in order to allow it to be displayed on the screen. The anesthesia and CO_2 monitoring sensor is connected to the side of MADM™.

Medical Grade Power Supply

A single medical-grade power supply (Elpac Power System™, model # MWA065024A) powers the system.

CAUTION! CONNECT ONLY THE RECOMMENDED ANESTHESIA AND CO_2 MONITORING SENSOR TO THE ANESTHESIA AND CO_2 MONITORING SENSOR PORT.

System Overview and Technical Description

System Block Diagram

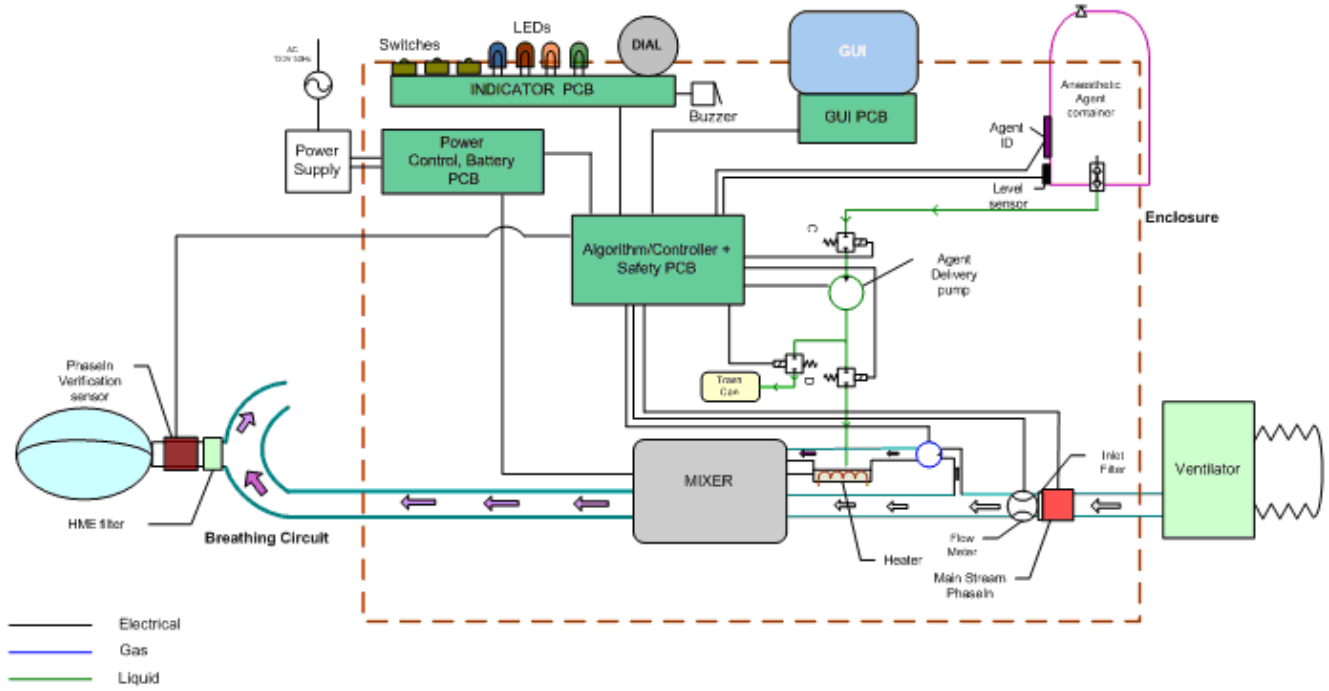


Figure 1: System Block Diagram

Device Description

The main components of MADM™ are shown below. The *Anesthesia and CO_2 Monitoring Sensor* and the *Power Supply* are considered accessories to the *Control and Display Unit.*

Control and Display Unit

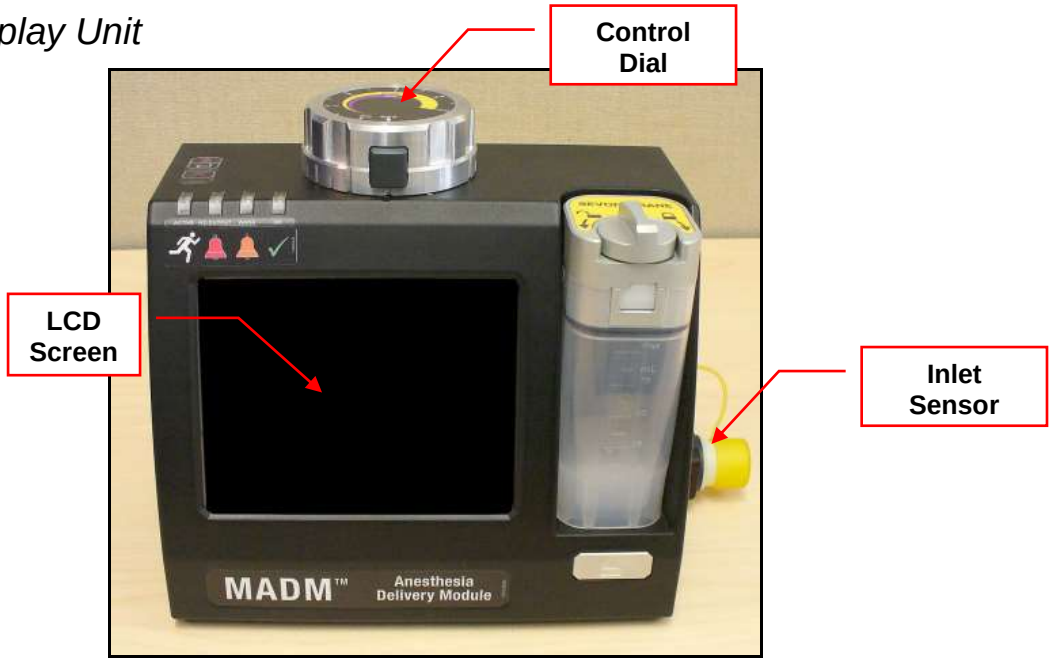


Figure 2: MADM™ Control and Display Unit

The *Control and Display Unit* is operated by turning the control dial *counter-clockwise* until the desired concentration of inspired anesthetic is reached. The button on the dial has to be pressed in and held before the dial will move from a parked/stopped position. The same procedure must be followed when putting the dial into the parked/stopped position.

INLET SENSOR

The *Inlet Sensor* is used to measure the composition of all inflow gases to MADM™. The *Inlet Sensor* is automatically compensated for changes in barometric pressure within its specified operating range.

***NOTE**: If the error message "Inlet Sensor: Unspec Acc" (Unspecified Accuracy) is displayed, the minute ventilation (VE) may not be within stated accuracy specifications.*

LCD Screen

Information from several categories is displayed in various areas of the LCD screen. For more information, see the section *User Interface Controls and Functions* beginning on *page 21*.

Anesthesia and CO_2 Monitoring Sensor

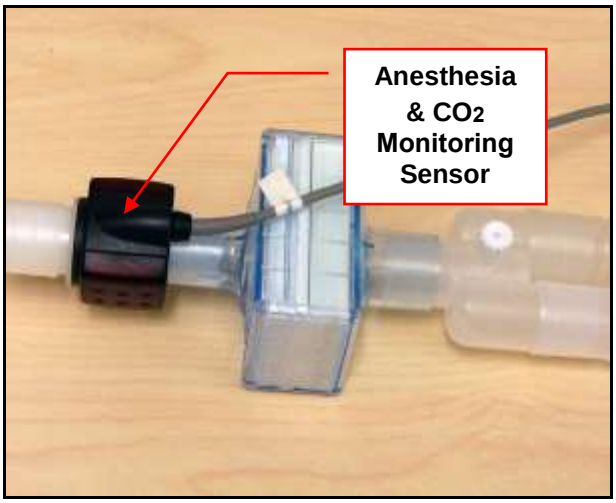


Figure 3: Anesthesia and CO_2 Monitoring Sensor

The *Anesthesia and CO_2 Monitoring Sensor* (a.k.a. *Patient Sensor*) is attached to the patient filter which is connected ahead of the patient circuit at the Y-piece. The sensor is used to measure inspiratory and expiratory anesthetic and carbon dioxide concentrations. These values are displayed on the LCD screen on the front of the MADM™ *Control and Display Unit*.

In addition, the screen shows the precise target inspired concentration, battery level, and details of any alarm/warning conditions. Also displayed are respiratory rate and minute ventilation. The *Anesthesia and CO_2 Monitoring Sensor* is automatically compensated for changes in barometric pressure within its specified operating range.

***NOTE**: If the error message "Patient Sensor: Unspec Acc" (Unspecified Accuracy) is displayed, the following readings may not be within stated accuracy specifications: FIA and FETA Iso, FIA and FETA Sevo, $PICO_2$ and $PETCO_2$.*

Power Supply

The Elpac Power System™ (model # MWA065024A), a single medical-grade power supply, powers the system.

WARNING! MADM™ SHOULD NOT BE POSITIONED SO AS TO MAKE IT DIFFICULT TO DISCONNECT IT FROM THE POWER SUPPLY.

The system also contains an embedded battery to provide uninterrupted function in the event of a temporary power loss. It is recommended that the battery be used only in this situation. MADM™ can run on battery power for a maximum of 30 minutes at ambient temperature (18°C to 25°C).

A separate battery base is optionally provided which includes a hot-swappable battery capable of powering MADM™ for up to 2.5 hours of normal use. For more information see, *The MADM™ Battery Base and Battery* beginning on *page 46.*

Functional Description

MADM™ measures the flow and composition of the gas delivered to the patient via its internal sensors and adjusts its internal liquid delivery pump to control the concentration of gas exiting the system. Fresh gas dilutes the gas exhaled from the patient, and MADM™ automatically tops up the gas in the inspiratory flow.

Precautions

Unlike a traditional vaporizer, when adjustments to the MADM™ vaporizer are made, concentrations change very quickly and do not require over-pressuring to wash out the circuit. As a result, the dial on the MADM™ only needs to be set to the target inspired anesthetic concentration.

It must be emphasized in training not to set the target anesthetic concentration above what is desired for an inspiratory concentration AT THAT TIME, and that the concentration should be adjusted periodically to reflect the different stages of surgical stimulation.

MADM™ Accessories

The following table lists the accessories used with the basic MADM™ unit.

PICTURE	TRI P/N	DESCRIPTION
	124723	Anesthetic Canister – Sevoflurane **Manufacturer:** Thornhill Research Inc.

PICTURE	TRI P/N	DESCRIPTION
	124630	Anesthetic Canister – Isoflurane **Manufacturer:** Thornhill Research Inc.
	124660	Anesthesia and CO_2 Monitoring Sensor **Manufacturer:** Thornhill Research Inc.

PICTURE	TRI P/N	DESCRIPTION
	124328	Airway Adaptor (for mouth and inlet sensor) **Manufacturer:** Masimo Corporation PN # 106220
	124810	Power Supply **Manufacturer:** Elpac Power Systems PN # MWA065024A

PICTURE	TRI P/N	DESCRIPTION
	125782	External Battery Charger/Base **Manufacturer:** Thornhill Research Inc.
	125746	MADM™ Battery **Manufacturer:** Bent-Tronics P/N BT-70757G

PICTURE	TRI P/N	DESCRIPTION
	125128	Handle and Clamp **Manufacturer:** Thornhill Research Inc.

Transporting MADM™

Observe the following when transporting MADM™:

1. All tubing should be detached from MADM™.
2. Anesthetic canisters should be ejected and drained.
3. Any other removable components should be detached.
4. MADM™ should be securely packed in its carrying case.

5. User Interface Controls and Functions

Startup Screen

When MADM™ is first started, the *Startup* screen is presented. Initially it is shown in warm-up mode. The warm-up process can take up to two minutes. After warm-up is complete, the calibration of the system's Algorithm and Safety processors can be done.

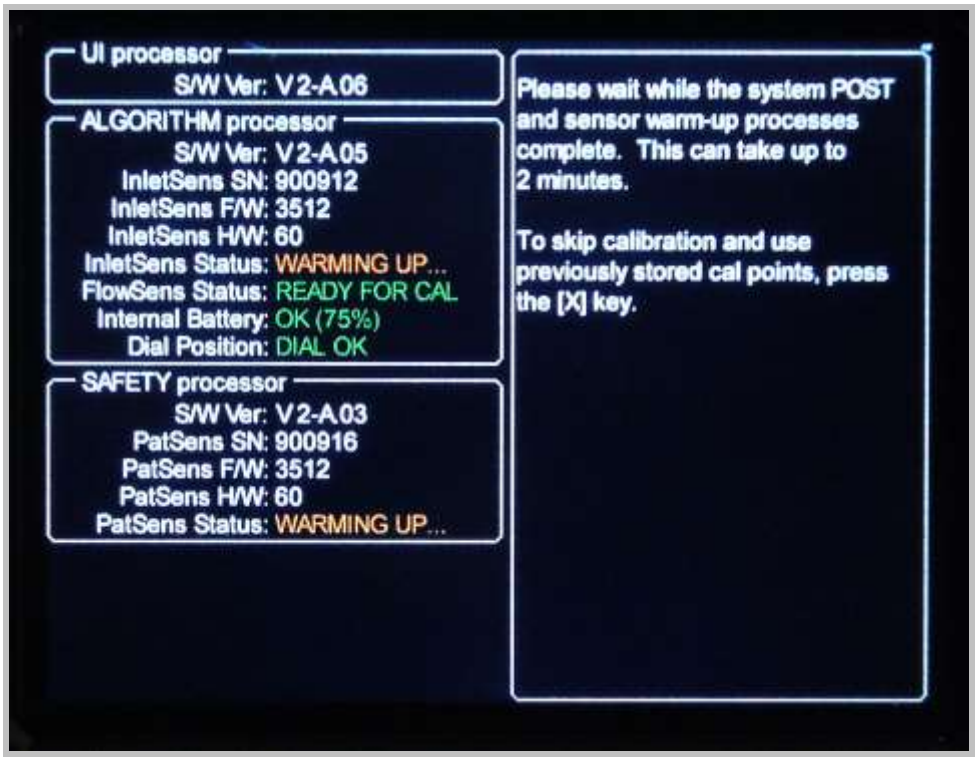


Figure 4: Startup Screen – Warm-up Mode

NOTE: *To skip calibration and use previously stored calibration points, press the [X] key on the top left of MADM™.*

Once warm-up is complete, The *Startup* screen will presented as shown below and calibration can be done.

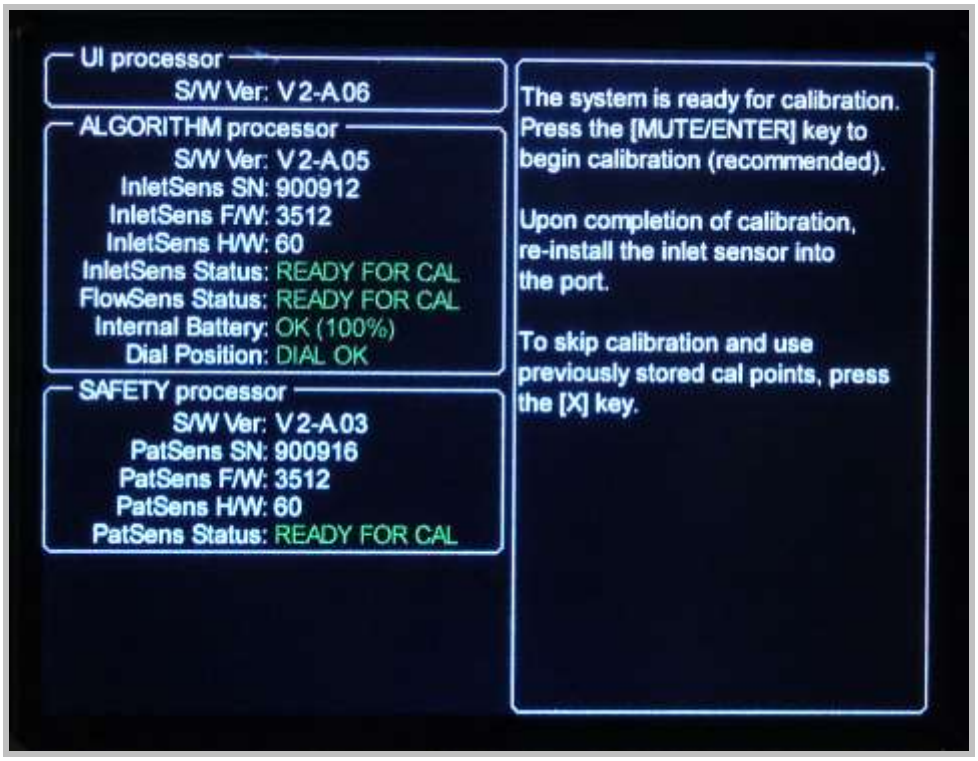


Figure 5: Startup Screen – Ready for Calibration

This *Startup* screen indicates the status of the device's three internal processors. The user need only be concerned with two of these processors, the *Algorithm* processor and the *Safety* processor, which are used for calibration. The *Algorithm* processor calibrates two internal sensors, one for concentration of anesthetic (either isoflurane or sevoflurane) and the other for amount of flow. The *Safety* processor calibrates the sensor at the patient's mouth, which measures concentration of both anesthetic and CO_2.

As directed by the screen, before performing the calibration the user should flush all traces of anesthetic from MADM™ if it has been used recently, cap the inlet and outlet ports, and remove the inlet sensor.

***NOTE*:** *Flushing of MADM™ should be done with air.*

To calibrate the sensors, press the [MUTE/ENTER] key (the key on top of the device and closest to the back, or farthest from the user, when the user is facing the device). This key is used both to calibrate the sensors and mute the alarms.

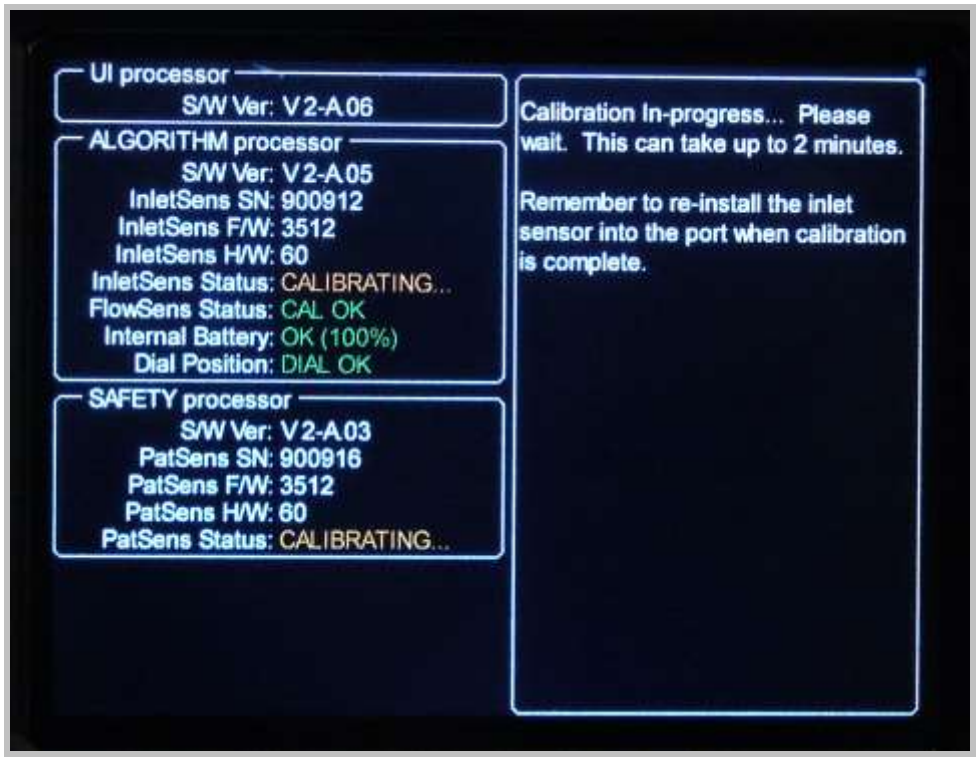


Figure 6: Startup Screen – Calibrating

NOTE: *To skip calibration and use previously stored calibration points, press the [X] key on the top left of MADM™.*

WARNING! SKIPPING A MADM™ CALIBRATION RUNS THE RISK OF OVER OR UNDER DELIVERING ANESTHETIC.

Information Screen

After the calibration is complete (or skipped), the *Information* screen is presented.

Figure 7: Information Screen – No Alarms

If an error is detected, the above screen will soon be followed by another one indicating an error and showing an alarm.

Figure 8: Information Screen – One Alarm

In the screen above, a high alarm is shown at the top right indicating that a canister is not present in MADM™. The # 3 beside it is location specific and is also shown beside the empty canister icon (circled in red) to indicate the location of the error.

If additional errors are detected, the screen will be updated to show the additional errors and alarms and to identify the locations of the errors. In the screen below, an additional medium alarm is shown for a Patient Sensor: Circuit Disconnect Detected error. The # 4, again location specific, is shown beside the head representation to indicate the location of the error.

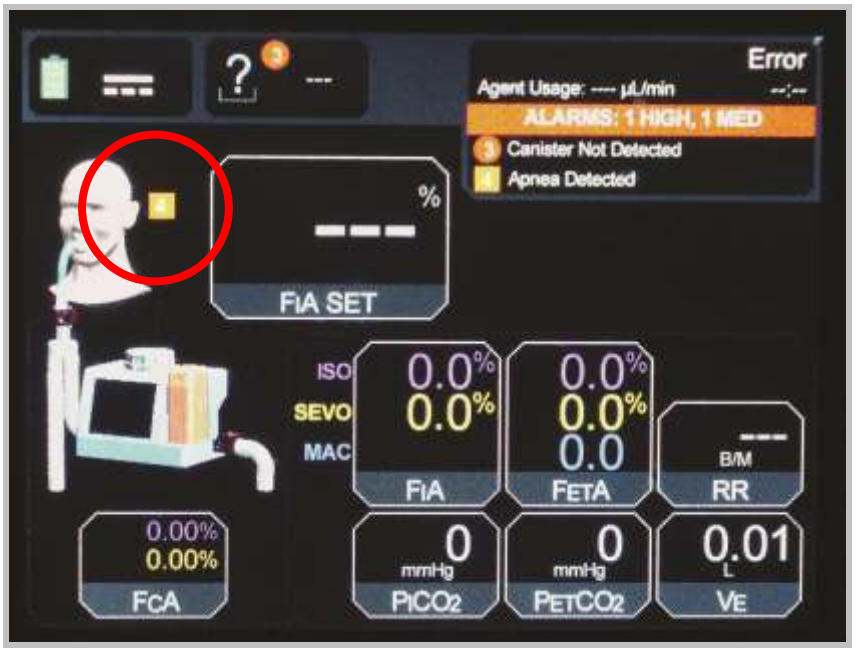


Figure 9: Information Screen – Two Alarms

In the following screen, three alarm levels are shown – High, Medium and Low. The third error, Operating On Internal Power, generates a Low alarm. The # 2 beside it is again location specific and is also shown beside the Battery Icon at the top left to indicate the location of the error.

Figure 10: Information Screen – Three Alarms

***NOTE:** If multiple errors occur in the same location, only the color and symbol representing the highest priority alarm will be shown in the location.*

Location of Alarm Descriptors

Descriptor Number	Location
1	Battery
2	External DC
3	Canister
4	Patient
5	Patient Sensor
6	MADM™ Unit
7	Inlet Sensor
8	Ventilator/Breathing Circuit
9	FIA Iso
10	FiA Sevo
11	FETA Iso
12	FETA Sevo
13	FETA MAC
14	FIA Set

Information Screen Icons

The following table explains the icons and text shown (or that could be shown) at the top left of the Info screen.

Icon /Text	Explanation
	Battery Level Status
	Power Status – Wall power is connected to the Elpac Power System™ and power system is supplying DC power to MADM™.
	Power Status – Wall power is disconnected (Error). MADM™ is operating on internal power.
	Anesthetic Canister Level (SEVO)
	Anesthetic Canister Level (ISO)

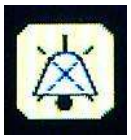
Icon /Text	Explanation
	Type of Anesthetic (yellow and SEVO = sevoflurane; purple and ISO = isoflurane)
	Alarm Status The icon at left indicates that the audio of all alarms has been *temporarily* muted (dashed X) for a period of two (2) minutes.

Table 4: Info Screen Icons – Top Left

NOTE: *Alarms are muted by pressing the [MUTE/ENTER] key (the key on top of the device and closest to the back, or farthest from the user when facing the device). One press will mute the alarm(s) for two minutes (and display a dashed X through the bell).*

NOTE: *The exception to the above is the Purge Limit Exceeded Fault alarm, which is reset by turning the device OFF and then ON again.*

Device Status Area

The area in the top right quadrant of the screen provides information about the status of MADM™.

Figure 11: Device Status Area

In the Figure above, MADM™ is showing four alarms / errors (and that no anesthetic is being delivered).These are accompanied by numbers that indicate what area of the system is experiencing the problem and which correspond to picture areas on the screen where the numbers are replicated.

The four alarms / errors are also color- and symbol-coded to indicate the severity of the alarm / error. The following table explains the alarm color and symbol coding.

Symbol	Description	Alarm Level
	Red Circle	High
	Solid Amber Square	Medium
	Empty Amber Square	Low

Table 5: Alarm Symbols & Color Coding

Other messages that could be displayed in the same place are shown in the following table.

Message	Explanation
<not available>	Indeterminate state. Communication has been lost with Algorithm processor.
Stopped	MADM™ is ready to be used.
Stopping	MADM™ is preparing to stop.
Priming	Anesthetic is being introduced into the system to be supplied to the patient.
Standby	The system has been supplied with anesthetic and is ready to begin delivering it to the patient.
Delivering	MADM™ is supplying anesthetic to the patient. The pumps delivering air and anesthetic are ON. If isoflurane is being delivered, the heater used to evaporate the anesthetic is targeted to 65°C. If sevoflurane is being delivered, the heater used to evaporate the anesthetic is targeted to 75°C. (***NOTE:*** *A counter showing minutes and seconds is also displayed beneath this message.*)
Purging	The system is purging itself. When the anesthetic type is being changed (from ISO to SEVO, or vice versa), the system automatically purges itself.

Patient Information Display Area

The remainder of the screen is primarily given over to the display of patient information taken from the patient sensor near the patient's mouth.

Figure 12: Patient Information Display Area – System Delivering

WARNING! IF THE PATIENT INFORMATION DISPLAY AREA INDICATES THAT A SENSOR OR SENSORS ARE OUT OF CALIBRATION, DO NOT ADJUST THE ANESTHETIC DIAL SETTING.

The following table explains the various display areas.

Display Area	Info Displayed
FIA SET	**Fractional Inspiratory Anesthetic Setting** – The concentration of anesthetic that the user is setting to be delivered to the patient. A maximum limit of **3.5%** is set for isoflurane and **5.0%** for sevoflurane.
FIA	**Fractional Inspiratory Anesthetic** – The concentration of inspired anesthetic being delivered to the patient measured by the patient sensor near the mouth. ISO values are shown in purple. SEVO values are shown in yellow. Measured as a percentage.
FETA	**Fractional End Tidal Anesthetic** – The concentration of expired anesthetic being vented by the patient at the end of a breath out and measured by the patient sensor near the mouth.
RR	**Respiratory Rate** – Measured in B/M (Breaths per Minute)
PI CO2	**Partial Pressure Inspired of CO2** – The amount of CO_2 inhaled by the patient and measured in mmHg. Measured by the patient sensor near the mouth.
PET CO2	**Partial Pressure End Tidal of CO2** – The concentration of expired CO_2 being vented by the patient at the end of a breath out and measured by the patient sensor near the mouth.
VE	**Minute Ventilation** – Total volume of gas supplied to the patient in one minute (measured in liters per minute).
FCA	**Fractional Concentration in Circuit of Anesthetic** – The average concentration of anesthetic seen at the gas inlet.

Display Area	Info Displayed
MAC	**Minimum Alveolar Concentration –** The concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

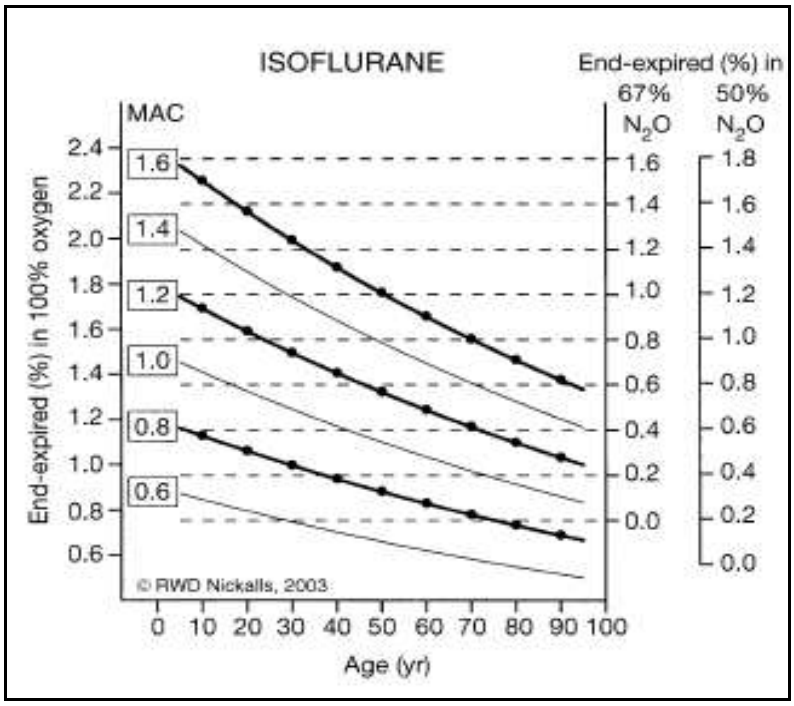
Table 6: Patient Info Display

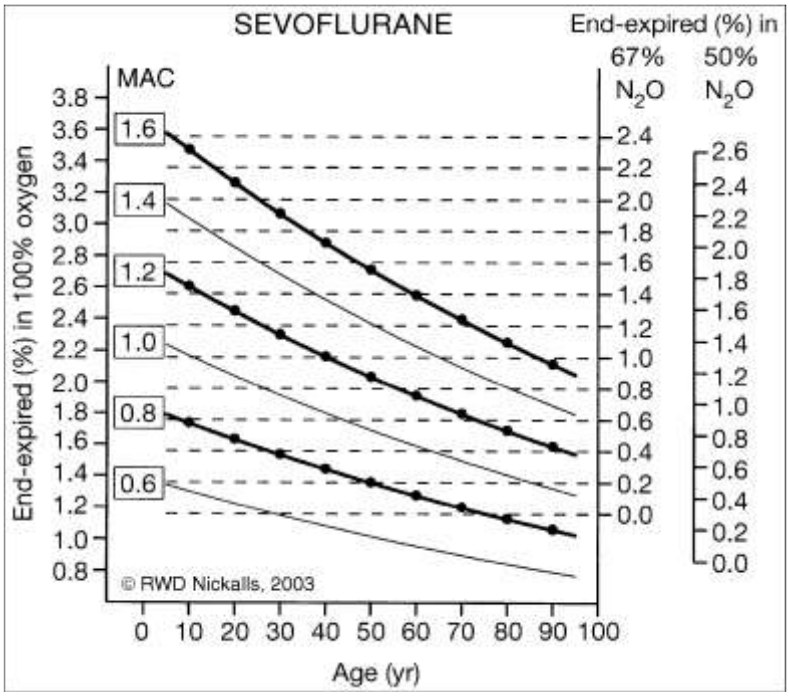
MAC Calculation and Display

MAC is defined as the concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

Dependence of MAC on Age and Agent Type

The dependence of MAC on age and agent type is shown below.*





*MAC dependence on age and N_2O% for males reproduced from *British Journal of Anaesthesia 91 (2): 170±4 (2003)*.

Value of MAC

The value of MAC is the combined effect of all anesthetic agents in the system. The effect varies with the physiology of the patient and the altitude. The MAC value displayed on MADM™ is adjusted for altitude and is calculated only on isoflurane and sevoflurane in the system. If any of halothane, enflurane, desflurane, or N_2O are detected, the MAC value cannot computed. Below is the basic equation for MAC for a 40 year-old adult patient at sea level.

$$MAC = \frac{Iso_{ET\%}}{1.15\%} + \frac{Sevo_{ET\%}}{2.05\%}$$ [Source: ISO 80601-2-55:2011(E)]

Uncompensated, the MAC value will vary at altitude. Since the effect of anesthetic agents is dependent on partial pressure, and not volume percent, the above expression can alternatively be expressed as:

$$MAC = \frac{Iso_{ET\%}}{1.15\%} \cdot \frac{101.325}{101.325} + \frac{Sevo_{ET\%}}{2.05\%} \cdot \frac{101.325}{101.325}, \\ = \frac{Iso_{pp}}{1.165} + \frac{Sevo_{pp}}{2.077}$$

… where the pp subscript denotes partial pressure of the anesthetic agent.

So, the altitude-adjust MAC based on the volume percent readings is governed by the following equation:

$$MAC = \left(\frac{Iso_{ET\%}}{1.165} + \frac{Sevo_{ET\%}}{2.077} \right) \cdot P_{baro}$$, where P_{baro} is the barometric pressure.

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6. MADM™ Specifications

Model Number

The documentation in this manual is for MADM™ model number 124641.

Physical Specifications

Property	Specification
Unit Weight	2.4 kg (5.25 lbs) w/ anesthetic canister empty
Width	21 cm (8.3 in)
Height	17.3 cm (6.8 in) including feet
Depth	9 cm (3.5 in) top 12.5 cm (4.9 in) bottom
Exterior Housing Material	ABS plastic
Volume at Minimum Fill Level	12.5 ml minimum
Volume at Maximum Fill Level	100 ml maximum
Total Capacity	125 ml
Mouth Sensor Weight	25 g
Leak Rate	<200ml/min @ >55 LPM flow
Effect of Tilting up to 30 degrees	None

MADM™ Electrical Specifications

Property	Specification
Input Voltage	24 VDC
Input Current	3.0 A

Power Supply Electrical Specifications

Property	Specification
Input Voltage	100–240 VAC Nominal
Input Frequency	50–60 Hz
Input Current	<1.6 A rms
Inrush Current	<37A at 230 VAC cold start
Zero Load Power Consumption	<0.5 W
Earth Leakage Current (Typical)	<80 µA @ 132 VAC @ 60 Hz <100 µA @ 264 VAC @ 60 Hz
Patient Leakage Current	<40 µA @ 132 VAC @ 60 Hz <50 µA @ 264 VAC @ 60 Hz
Output Voltage	24.0 V
Output Current	3.0 A

Property	Specification
Peak Current	3.6 A
Power	72 W max
Total Regulation	±5%
Typical Efficiency	91%

Performance Specifications

Property	Specification
Time from startup to anesthetic agent detection	10s, full specification in 60s
Delivered Vapor Accuracy	+30% and -20% of dial setting or +7.5%/-5% of maximum agent setting.
Time from start-up to anesthetic delivery	<60s
Detection Threshold for a single halogenated agent	0.15%. When concentration has passed the threshold, concentrations will be reported even below the threshold.
Detection Threshold for multiple halogenated agents in a gas mixture	0.2%. When concentration has passed the threshold, concentrations will be reported even below the threshold.
Respirator Rate for which end-tidal gas readings remain accurate	0–150 BPM
Range of IE ratio for which end-tidal gas readings remain accurate	2:1 to 1:3
High Priority Alarm Sound Pressure Level (at one meter)	47.2 dB
High Priority Alarm A-Weighted Background Sound Level	26.8 dB
Medium Priority Alarm Sound Pressure Level (at one meter)	46.3 dB
Medium Priority Alarm A-Weighted Background Sound Level	26.8 dB
Peak Flow	60 LPM
Ventilator Flow Range	0.2 to 60 LPM
Maximum Average Flow at maximum dial setting in opened circuit	15 LPM (ISO), 10LPM (SEVO)
Maximum Average Flow at maximum dial setting in closed circuit	15 LPM (ISO), 15 LPM (SEVO)
Maximum Minute Ventilation for Open-Circuit use at Max ISO Setting	15 LPM
Maximum Minute Ventilation for Open-Circuit use at Max SEVO Setting	10 LPM
Maximum concentration at 15LPM in opened circuit	3.5% ISO, 3.5% SEVO
Delivery Range	0-3.5% (ISO), 0-5% (SEVO)
Minimum Flow	0.2LPM
Accuracy	+30%, -20% of dial setting

Property	Specification
Electrical Source Displayed	Yes
Time to concentration	<30s
CO2 Range and Accuracy	0-15 vol% +/-0.2vol%+2% of reading
N2O Range and Accuracy	Alarm only
HAL Range and Accuracy	Alarm only
ISO Range and Accuracy	0-8 vol% +/-0.15vol%+5% of reading
ENF Range and Accuracy	Alarm only
SEV Range and Accuracy	0-10 vol% +/-0.15vol%+5% of reading
DES Range and Accuracy	Alarm only
Rise Time (CO2)	<90ms
Rise Time (N2O)	<300ms
Rise Time (Anesthetics)	<300ms
Total system Response Time	<1s
Respiratory Rate	0-150bp, +/-1bpm

O_2 Effect on Gas Readings

The table below shows the typical effect if using SetO2 value 50 vol% (default for MADM™).

O_2 Concentration in Gas Mix	**Effect on Gas Reading (% Relative)**	**Displayed Value if True Concentration is 5.0 vol% CO_2**
21 vol%	2.76	4.9
50 vol%	0.00	5.0
70 vol%	-1.91	5.1
95 vol%	-4.29	5.2

Compatible Ventilator Specifications

MADM™ has been validated to meets its specifications when used with open circuit ventilators such as the Impact Eagle (K931473) and circle system ventilators such as the Narkomed 2B (K86447) for the ventilation conditions shown below.

Property	Specification
Ventilator Flow Range	0.2-60 LPM
Maximum Minute Ventilation for Open-Circuit use at Max ISO Setting	15 LPM
Maximum Minute Ventilation for Open-Circuit use at Max SEVO Setting	10 LPM
Ventilator Respiratory Rate	1-40 BPM
Respirator Rate for which end-tidal gas readings remain accurate	0–150 BPM
Range of IE ratio for which end-tidal gas readings remain accurate	1:1 to 1:3

Property	Specification
Fresh Gas Flow	2 to 8, Opened Circuit (Where FGF matches Ventilation)

About Performance Graphs and Tables

All data is acquired at an input flow rate of 10 LPM and 100% oxygen unless otherwise stated.

Effects of Output at Varied Altitudes and Sub Atmospheric Pressure.

The MADM™ vaporizer is calibrated in percent v/v, and the calibration is not affected by ambient pressure changes within the operating range specified.

Effects of Ambient Temperature

MADM™ is not significantly affected by temperature variations and meets its operating accuracy specifications, within the operating range specified.

Effects of Back Pressure and Resistance

MADM™ is not significantly affected by back pressure or airway resistance and meets its operating accuracy specifications across the ranges experienced in a ventilator breathing circuit (up to 50 cmH_2O).

Effects of Carrier Gas Composition

MADM™ is not significantly affected by changes in carrier gas composition for carrier gas comprising 10–100% oxygen (opened or circle system) and 0–80% nitrous (in a circle system) and meets its operating accuracy specifications.

Effects of Ventilator Characteristics

MADM™ meets its operating accuracy when inserted into a manual resuscitating bag circuit, a flow-through circuit and a circle circuit ventilator. MADM™ has been tested with respiratory rates from 0 to 40 BOM, IE ratios from 2:1 to 1:3, and Tidal Volumes up to 1L. MADM™ is capable of achieving maximum target concentrations of ISO only at fresh gas flows up to 15 LPM and at 10 LPM for SEVO.

Environmental Specifications

Variable	Storage Condition	Operating Condition
Altitude	NA	0–10,000 ft
Temperature	–20°C to 50°C (–4°F to 122°F)	10°C to 40°C (50°F to 104°F)
Relative Humidity	15% to 95% (non-condensing).	15% to 95% (non-condensing).

Table 7: Device Environmental Specifications

Standards Compliance

MADM™ complies with the standards listed below.

STANDARD #	DESCRIPTION
IEC 60601-1	Medical Electrical Equipment (Ed 3.1, 2012), General Requirements for basic safety and essential performance.
IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Ed 3.0 2007)

STANDARD #	DESCRIPTION
IEC 60601-1-8	Medical Electrical Equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (Ed 2.1 2012)
ISO 80601-2-13	Medical Electrical Equipment – Part 2: Particular Requirements for the safety and essential performance of anaesthetic systems (Ed 1.0 2011)
ISO 80601-2-55	Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors (2011)

CAUTION! OPERATION OF MADM™ OUTSIDE OF SPECIFIED LIMITS MAY CAUSE INACCURATE RESULTS.

EMC (Electromagnetic Compatibility) Statements

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	MADM™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	MADM™ is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** MADM™ is intended for use by healthcare professionals only. MADM™ may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating MADM™ or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 8: EMC Immunity Tests

MADM™ is intended for use in the electromagnetic environment specified below. The customer or the user of MADM™ should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 Kv contact ±8 Kv air	±6 Kv contact ±8 Kv air with documented necessary	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 Kv for power supply lines ±1 Kv for input/output lines	±2 Kv for power supply lines ±1 Kv for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 610004-5	±1 Kv line(s) to line(s) ±2 Kv line(s) to earth	±1 Kv line(s) to line(s) ±2 Kv line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles No anomalies <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. End user shall ensure charged batteries are installed in the equipment.
Power frequency (50 Hz) magnetic field IEC 61000-48	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9: EMC Immunity Tests

7. MADM™ Components and Connections

Figure 13: Front Controls

Front Controls	
Label	**Control**
A	Anesthetic Canister Release Button

Figure 14: Top Controls

Top Controls	
Label	**Connection**
A	[MUTE/ENTER] Key
B	[X] Key
C	Anesthesia Percentage Knob
D	Anesthesia Percentage Knob Release / Lock Button
E	LED Status Indicators

Figure 15: Left Side Connections

Left Side Connections	
Label	**Connection**
A	Gas Outlet
B	Anesthetic and CO_2 Sensor Connection

Figure 16: Right Side Connections

Right Side Connections	
Label	**Connection**
A	Gas Inlet

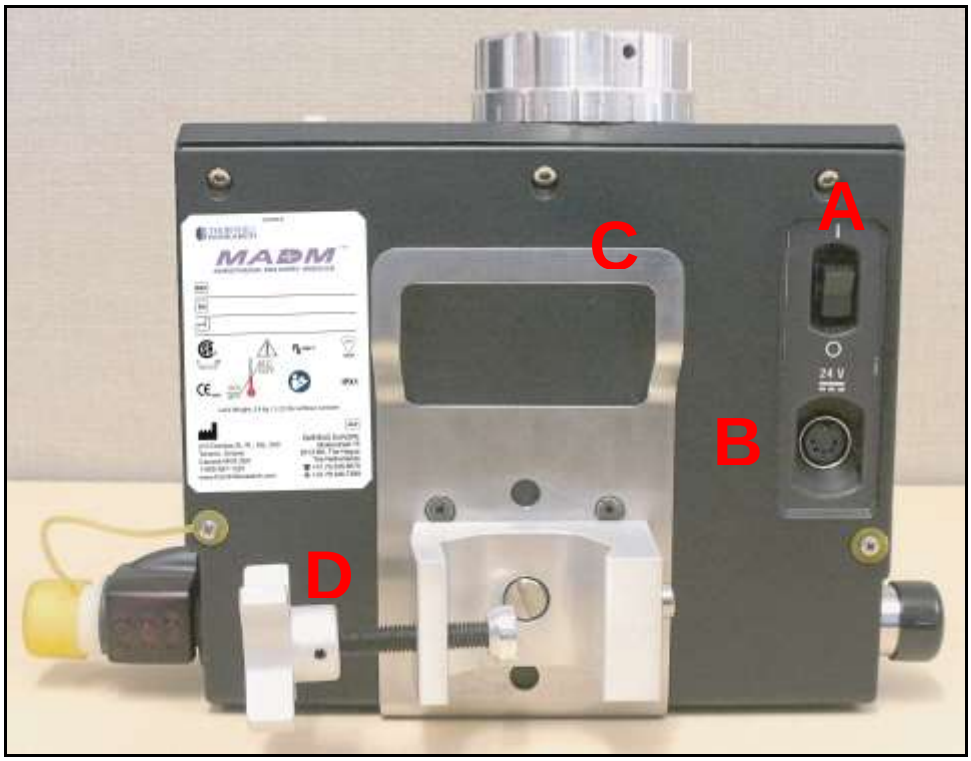

Figure 17: Rear Controls and Connections

Rear Controls and Connections	
Label	**Connection**
A	On / Off Switch
B	Power Connection
C	Handle
D	Clamp

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8. The MADM™ Battery Base and Battery

Overview

The MADM™ battery base, with its various parts labeled, is shown in the two Figures below.
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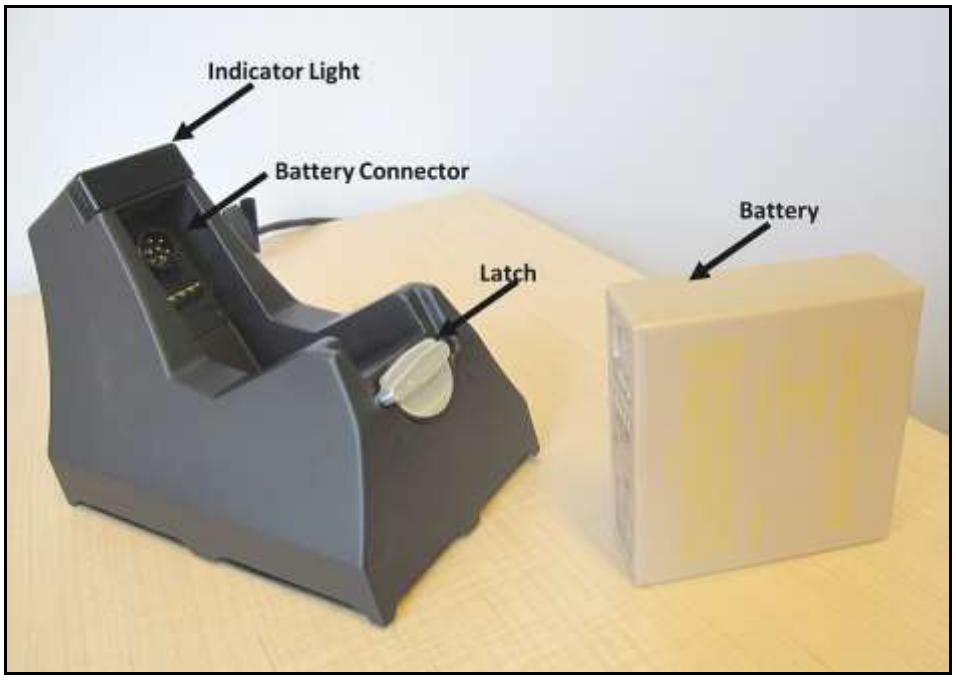

Figure 18: MADM™ Battery Base & Battery

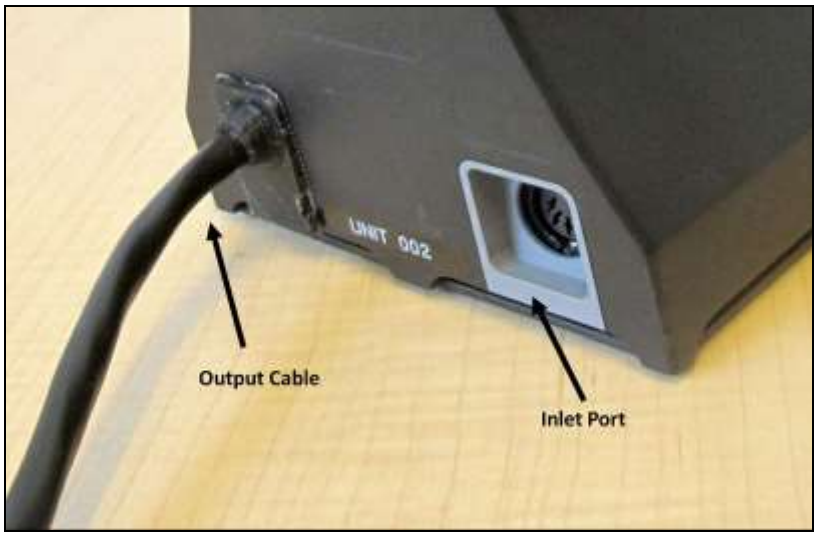

Figure 19: MADM™ Battery Base Rear View

Using the Battery Base

To use the MADM™ Battery Base:

1. Insert a battery pack into the battery base and align the battery connector on the Battery Base to the Connector on the battery.

NOTE: *Use only the Bent-Tronics BT-70757G battery with MADM™.*

2. Rotate the latch to lock the Battery Base in place.
3. Attach the MADM™ power supply to the inlet port of the Battery Base.
4. Connect the output cable of the Battery Base to MADM™.
5. Monitor the Indicator Light to confirm the charging and discharging status as per the table below.

Battery Base LED State	Explanation
5 Green LEDs	Battery is Charging, Full charge
4 Green LEDs	Battery is Charging, 80% charge
3 Green LEDs	Battery is Charging, 60% charge
2 Green LEDs	Battery is Charging, 40% charge
1 Green LED	Battery is Charging, 20% charge
5 Red LEDs	Battery is Discharging, Full charge
4 Red LEDs	Battery is Discharging, 80% charge
3 Red LEDs	Battery is Discharging, 60% charge
2 Red LEDs	Battery is Discharging, 40% charge
1 Red LED	Battery is Discharging, 20% charge
Single Red LED on Right of Indicator	Battery is outside of temperature specification, is not charging, or discharging.

Table 10: Battery Charging Status Indicators

Battery and Battery Base Maintenance

The MADM™ Battery Base can only be serviced by qualified service personnel. However batteries should be regularly inspected for physical damage such as cracks, holes and leaks. If any of these are discovered the battery should not be used. It should be replaced and the damaged battery discarded in accordance with local disposal regulations.

WARNING! DO NOT USE OR CHARGE A DAMAGED BATTERY.

The external surface of the Battery Base can be cleaned using standard cleaning agents, excluding oxidizing agents. The Battery Base can be wiped clean with one of the following:

- Isopropyl Alcohol
- Chlorine Compounds*****
    - Maximum Concentration: 1:10

*****_These compounds are diluted by volume in water._

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9. Setup, Filling and Draining Instructions

Setup Overview

MADM™ can be used in three different configurations:

1. Open circuit with ventilator
2. Open circuit with resuscitation bag
3. Closed circuit (circle circuit) with ventilator

The first configuration vents the exhaled gas. The second configuration recirculates the exhaled gas and, consequently, less anesthetic is used.

Anesthetic from MADM™ is delivered to the patient either via a breathing mask that covers the patient's mouth or, if the patient is intubated, via a tracheal tube inserted into the patient's airway via the mouth.

NOTE: *MADM™ has been designed to attach to 22 mm ID (inside diameter) airway tubing.*

Open Circuit with Ventilator

Assembly Diagram

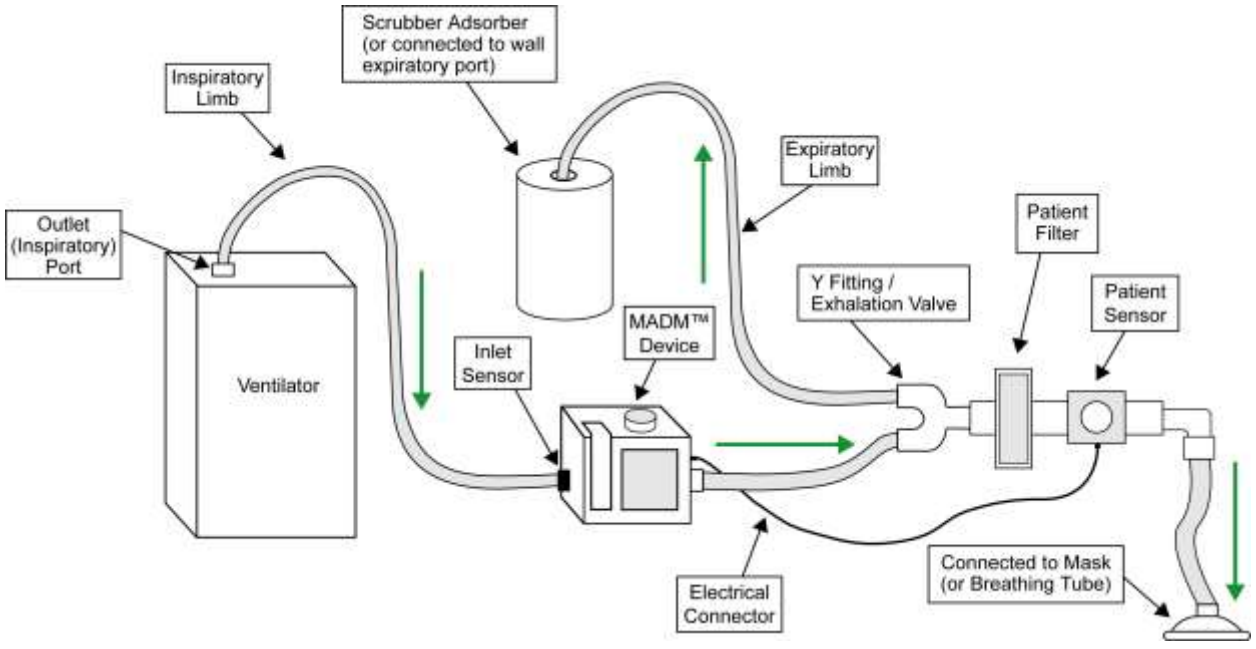

Figure 20: Open Circuit with Ventilator Assembly Diagram

NOTE: *Green arrows in diagram above indicate direction of air flow.*

Steps

1. Calibrate MADM™. For information on calibration, see *Calibration* on *page 60*.
2. Attach the fitting with the *patient sensor* to the input / supply end of the tracheal tube connected to the patient.
3. Attach the opposite end of the patient-sensor fitting to one end of the *patient filter*.
4. Attach the other end of the patient filter to the patient port of the *"Y" fitting / exhalation valve*.
5. Attach the inspiratory port of the "Y" fitting \ exhalation valve to a *connection tube* which will serve as the inspiratory limb.
6. Attach the other end of the inspiratory limb connection tube to the *outlet port* on the left side of MADM™ (use adapter fittings, if necessary).
7. Attach the remaining end of the "Y" fitting / exhalation valve to a *connection tube* which will serve as the expiratory limb.
8. Attach the other end of the expiratory limb connection tube to either an activated charcoal *adsorption filter can* or a *wall connection* used for the removal of waste anesthetic gases (use adapter fittings, if necessary).
9. Attach the ventilator to the inlet port of MADM™ using the necessary connection tube and any fittings needed.
10. If it is not already connected, attach the *electrical connector* on the end of the cable attached to the patient sensor to its matching *pin connection* on the left side of MADM™.

NOTE: *MADM™ must be calibrated before being used. For information on calibration, see Calibration on page 60.*

Open Circuit with Resuscitation Bag

Assembly Diagram

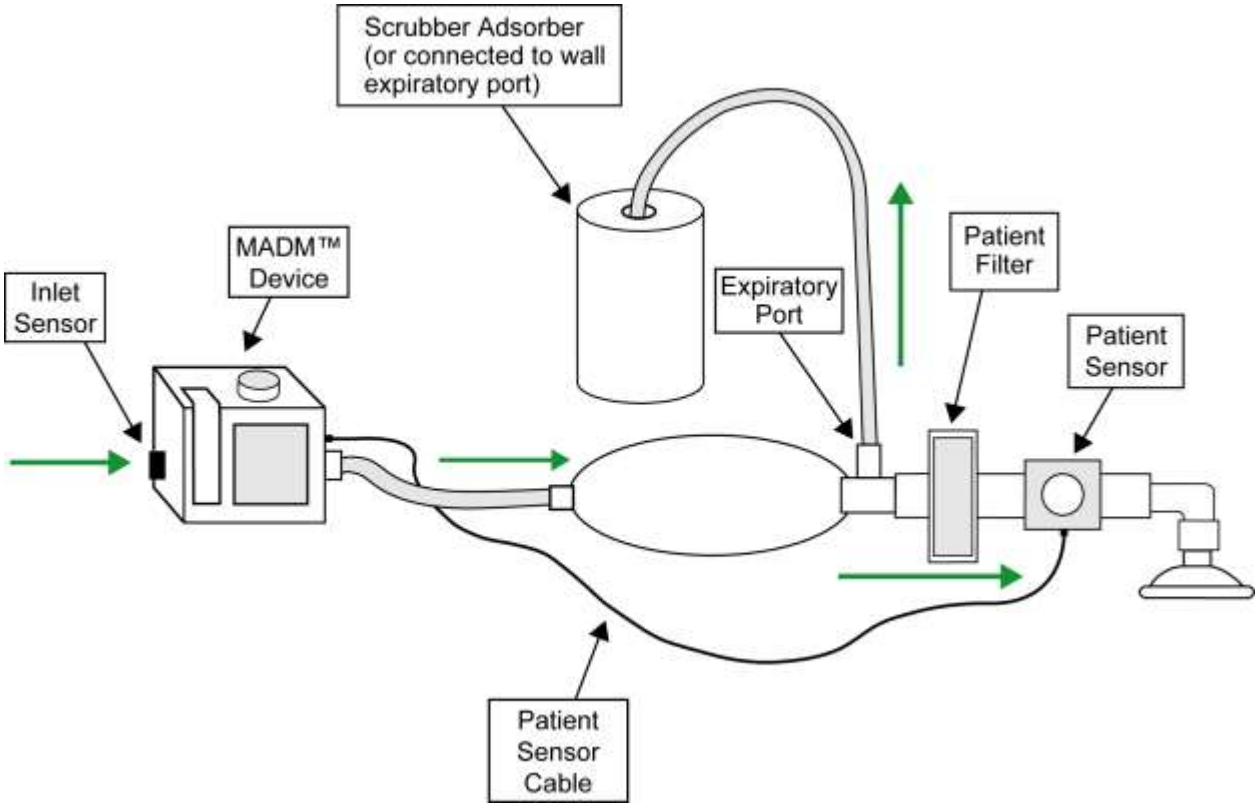

Figure 21: Open Circuit with Resuscitation Bag

Steps

1. Attach the fitting with the *patient sensor* to the input / supply end of the tracheal tube or mask connected to the patient.
2. Attach the opposite end of the fitting to the exit port of the *resuscitation bag*.
3. Attach the inlet port of the *resuscitation bag* to the tube which will connect it to the outlet port on MADM™ (use an adapter fitting, if necessary).
4. If supplying additional oxygen, attach the outlet port of an *O_2 bag* to the inlet port of MADM™. Then attach the device supplying oxygen to the O_2 inlet (the smaller L-shaped inlet) of the *O2 bag*. Lastly, attach an expiratory and inspiratory relief valve to the large inlet port of the *O_2 bag*.
5. If not supplying additional oxygen, leave the inlet port of MADM™ accessible to ambient air (make sure the opening is not occluded).

NOTE: *Attaching a connection tube to the inlet port of MADM™ will provide a less turbulent, more laminar flow of air.*

6. Attach one end of another connection tube to the *exhalation port* on the fitting connected to the outlet port of the resuscitation bag.
7. Attach the other end of the exhalation-port connection tube to either an activated charcoal *adsorption filter can* or a *wall connection* used for the removal of waste anesthetic gases.

8. Attach the *electrical connector* on the end of the cable attached to the patient sensor to its matching *pin connection* on the left side of the MADM™ device.

NOTE: *MADM™ must be calibrated before being used. For information on calibration, see* Calibration on page 60*.*

Closed Circuit with Ventilator

Assembly Diagram

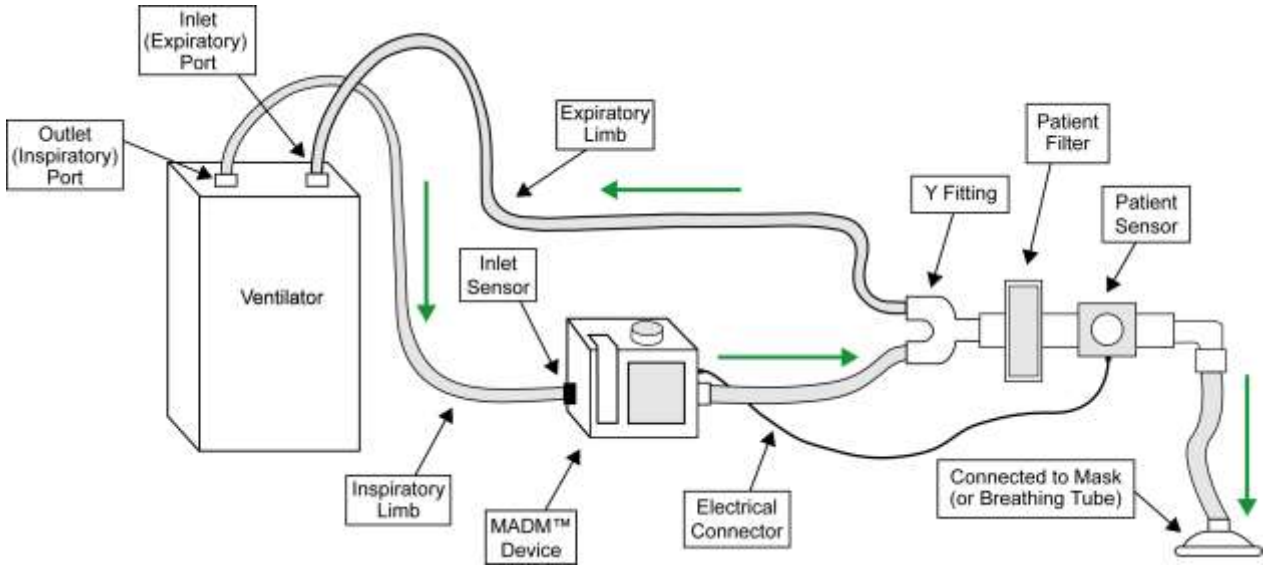

Figure 22: Closed Circuit with Ventilator Assembly Diagram

NOTE: *Green arrows in diagram above indicate direction of air flow.*

Follow the previous steps for an open circuit. When you reach *Step 8*, attach the output end of the expiratory limb connection tube to the input for the expiratory limb connection on the ventilator (rather than to a filter can or wall outlet).

Anesthetic Canister Filling Instructions

NOTE: *The maximum capacity of the anesthetic canister is 100 ml.*

NOTE: *The anesthetic canisters should only be filled with anesthetic for immediate delivery by MADM™. Anesthetic should not be stored in the anesthetic canisters, and unused anesthetic should be drained from the canisters after they are ejected from MADM™.*

NOTE: *MADM™ canisters should only be filled with agent-specific filling systems which comply with ISO 5360.*

To fill or refill the anesthetic canister that is part of MADM™, follow the instructions below:

1. Remove the canister by pressing the *release button* below it on MADM™ and lifting the canister out.
2. Locate the *refill door* on the front of the canister near the top.

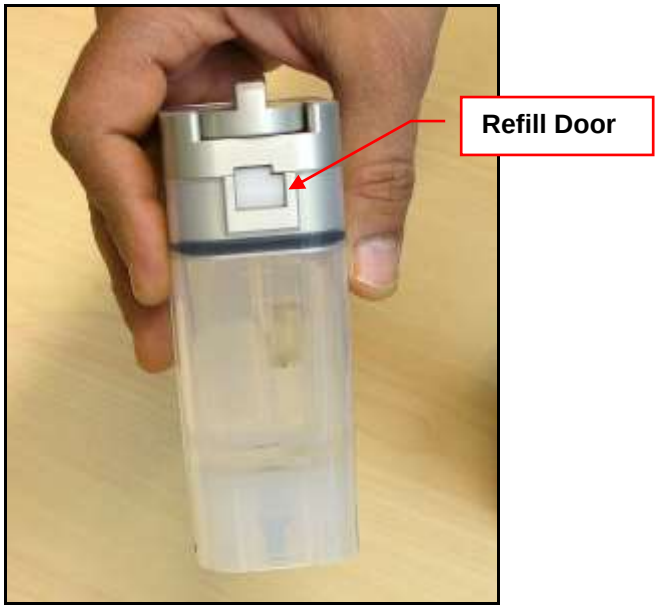

Figure 23: Refill Door

3. Turn the knob above the door *counterclockwise* to release the pressure on the door so that it can be pushed open.
4. Attach the refill gooseneck connector to the anesthesia bottle by fitting the interlocking matching connectors together and screwing down the circular collar on the gooseneck.

NOTE: *Matching interlocking collars are present on both the gooseneck and the anesthesia bottle. The collars are also colour-coded: purple for isoflurane and yellow for sevoflurane.*

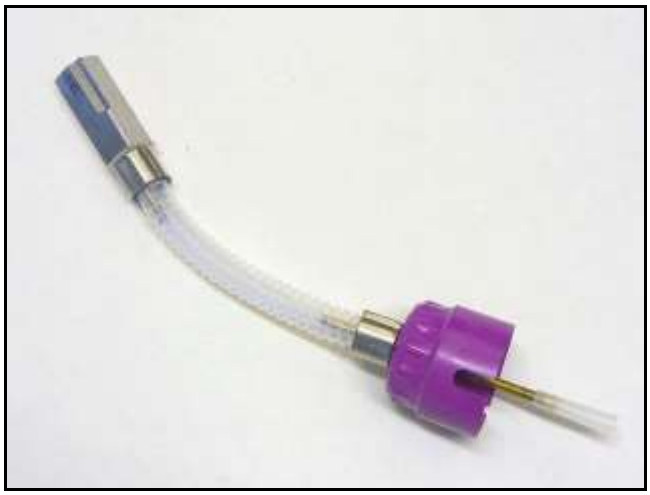

Figure 24: Refill Gooseneck Connector

Figure 25: Anesthesia Bottle with Collar

Figure 26: Bottle with Gooseneck Attached

5. Insert the rectangular fitting on the end of the gooseneck into the door of the canister and secure it there by turning the knob above clockwise until the rectangular fitting feels firmly clamped.

Figure 27: Gooseneck Fitted to Canister

6. Raise the bottle above the canister input and allow the anesthetic to flow into canister until the desired amount is reached.
7. Lower the bottle and allow the residual anesthetic in the gooseneck to flow back into the bottle.
8. Turn the screw on the top of the canister counterclockwise to loosen the door, withdraw the gooseneck fitting, then turn then screw on top of the canister clockwise until it locks.
9. Reinsert the canister vertically from the top of MADM™ into its slot. Be sure to align the indentations on the side of the canister with their matching extrusions on either side of the slot.
10. When the canister is correctly seated, press it down firmly until it snaps into place.

CAUTION! DURING DISCONNECTION OF THE MALE ADAPTER FROM THE VAPORIZER, AND THE BOTTLE ADAPTER FROM THE BOTTLE, SMALL AMOUNTS OF ANESTHETIC AGENT WILL ESCAPE TO THE ENVIRONMENT.

NOTE: *If you are trying to determine the liquid level remaining in the canister, it is easier to see the level clearly when MADM™ is turned on.*

Anesthetic Canister Draining Instructions

Anesthetic should not be left in the MADM™ canister once a procedure is completed. It should be drained from the canister and returned to the anesthesia bottle.

Figure 28: Residual Anesthetic Should Be Drained

To drain the anesthetic canister that is part of MADM™, follow the instructions below:

1. Attach the end of the gooseneck connector to the anesthesia bottle by fitting the interlocking matching connectors together and screwing down the circular collar on the gooseneck.

Figure 29: Bottle with Gooseneck Attached

2. Remove the canister from MADM™ by pressing the *release button* below it and lifting the canister out.
3. Locate the *refill door* on the front of the canister near the top.
4. Turn the knob above the door *counterclockwise* to release the pressure on the door so that it can be pushed open.

Figure 30: Turn Knob Counterclockwise to Release

5. Insert the rectangular fitting on the end of the gooseneck into the door of the canister and secure it there by turning the knob above it clockwise until the rectangular fitting feels firmly clamped.

Figure 31: Insert the Rectangular Fitting

Figure 32: Turn Knob Clockwise to Secure

6. Raise the canister above the bottle input and allow the anesthetic to flow into the bottle until the canister is empty.

Figure 33: Raise Canister Above Bottle

7. Lower the canister and allow any remaining anesthetic in the gooseneck to flow back into the bottle.
8. Turn the screw on the top of the canister counterclockwise to loosen the door, withdraw the gooseneck fitting, then turn then screw on top of the canister clockwise until it locks.
9. Reinsert the canister vertically from the top of MADM™ into its slot. Be sure to align the indentations on the side of the canister with their matching extrusions on either side of the slot.
10. When the canister is correctly seated, press it down firmly until it snaps into place.
11. Remove the gooseneck connector from the anesthesia bottle by unscrewing the circular collar on the gooseneck and separating the interlocking matching connectors of the gooseneck and the bottle.
12. Tightly recap the anesthesia bottle.

10. Using MADM™

Calibration

Before MADM™ is used, it should be calibrated. Specifically, calibration must be done of its two internal sensors (for flow and anesthetic concentration) and its external patient sensor (for anesthetic concentration and CO_2). Therefore, the patient sensor should be connected to the control unit when calibration is being performed.

NOTE: *If MADM™ has been recently used prior to calibration, any residual anesthetic remaining in the device must be flushed out. Flushing should be done with air.*

NOTE: *The alarm "Unsupported Agent Detected" may appear beside the MAC value if MADM™ has not been thoroughly flushed out after a previous use. If this alarm appears, MADM™ should be flushed with air and recalibrated.*

NOTE: *The alarm "Unsupported Agent Detected" may also appear if the adapter has been replaced in the patient sensor even though MADM™ has been thoroughly flushed out. In this case, pressing and holding the [MUTE / ENTER] key for five (5) seconds at the calibration screen will force calibration to be initiated.*

NOTE: *The Operator should be within arm's reach of MADM™ throughout the procedure and be able to view the display without obstruction.*

Steps

1. Connect the patient sensor to the control unit by fitting its cable connector into the pin connection on the left side of MADM™.
2. Place end caps over the input and output ports on the right and left sides of MADM™. Remove the inlet sensor from the device.
3. Turn on MADM™ using the toggle switch on the back in the top left corner.
4. Wait for MADM™ to warm up. During warm up, the alarm LEDs cycle through a sequence of green, amber, and red repeatedly. All three alarm LEDs (red, amber and green) display as solid when the device has finished warming up and is ready for calibration.
5. When you are prompted on screen, press the [MUTE / ENTER] key (the key farthest from the user on the top of MADM™).
6. As calibration is being done, the red and green LEDs on top of the control unit will toggle. The yellow LED will remain solidly lit.
7. The green LED will blink slowly after calibration has been completed (or if it is skipped).
8. Reinstall the inlet sensor.

NOTE: *If the calibration does not complete successfully, or is skipped, the reason may be that there is residual anesthetic in the system, or that the patient sensor is not connected. Address these issues and try again.*

Running MADM™

NOTE: *It is recommended that a biophysical monitoring device be used to measure and monitor a patient's vital signs while the patient is connected to MADM™.*

After MADM™ has been successfully calibrated, follow the steps below to begin using the device.

WARNING! ALWAYS HAVE A BACKUP METHOD OF DELIVERING ANESTHETIC TO THE PATIENT AVAILABLE.

CAUTION! MADM™ IS TO BE USED WITH AN ANESTHETIC GAS SCAVENGING TRANSFER AND RECEIVING SYSTEM IN ACCORDANCE WITH ISO/IEC 80601-2-13.

Steps

1. Insert the anesthetic canister into its slot in MADM™ and press it down firmly until it snaps into place.
2. Make sure that all circuit connections (either open or closed) are in place.
3. Press in and hold the *Release / Lock Button* on the circular knob on the top of MADM™ that controls flow concentration.
4. Turn the Flow Concentration Knob *counterclockwise* to the desired percent concentration.

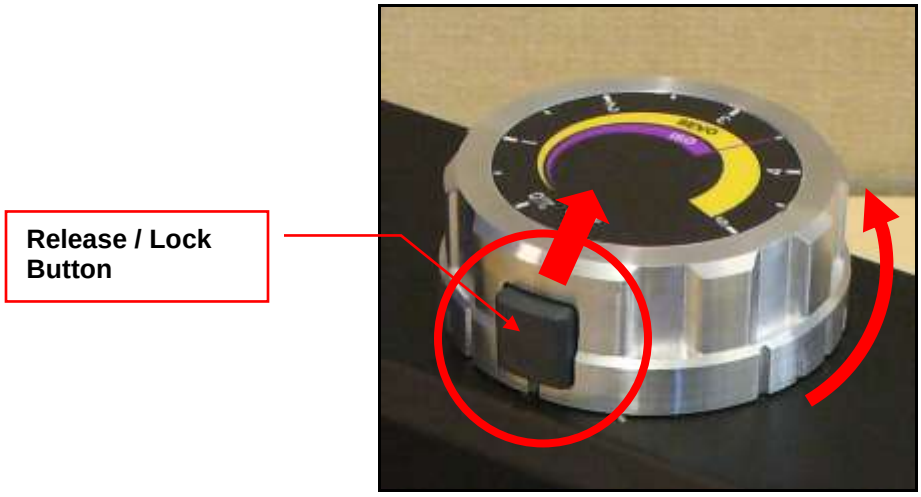

Figure 34: Flow Concentration Knob

Running

When a full anesthetic canister is inserted into MADM™, and the device is turned on, the screen will indicate that it is in *Standby* mode; i.e., that the system has been supplied with anesthetic and is ready to begin delivering it to the patient.

When the *Flow Concentration Knob* is set to a percentage, the screen will first display a message that the system is *Priming*; i.e., that anesthetic is being introduced into the system to be supplied to the patient.

Once *Priming* is complete, the screen will then display a message that the system is *Delivering*; i.e., that it is supplying anesthetic to the patient. A counter showing running time in minutes and seconds will also be displayed beneath this message.

Anesthetic concentration can be adjusted throughout the procedure by turning the *Flow Concentration Knob* to the desired value. MADM™ can be set to "idle" (delivering no anesthetic but still primed and ready to deliver) by turning the knob to the area between 0% and OFF.

NOTE: *More anesthetic may be needed to increase the anesthetic dosage at higher altitudes (compared to sea level).*

Turning Off

To turn the *Flow Concentration Knob* to the OFF position, the *Release / Lock Button* must be pressed again.

LEDs

A blue LED is used to indicate that MADM™ is in an Active state. Three other LEDs indicate when the system is in one of these other states: Warming Up, Finished Warming Up, Calibration in Progress, Calibration Completed, Normal, Warning, and Error. The system's overall status, audio alarm, and alarm LED state are defined by the active alarm condition with the highest severity.

LED State	Explanation	Alarm Priority / Audio Tone Sequence
LEDs cycle through a sequence of GREEN, AMBER, and RED repeatedly.	The system is **warming up**.	Not Applicable
GREEN, AMBER, and RED LEDs display solidly lit.	The system has **finished warming up**.	Not Applicable
RED and GREEN LEDs on top of the control unit toggle. The YELLOW LED remains solidly lit.	Calibration is **in progress**.	Not Applicable
GREEN – Flashing (slowly)	Calibration of the system has been **completed**. At this point, *the MADM™ alarm system takes control of the alarm LEDs* and indicates the alarm level of the system. If there are no alarms, the green LED becomes solidly lit.	Not Applicable
GREEN – Solid	The system is in a **Normal** state; i.e., safe and good working order. (***NOTE:*** *No audio alarm is present.*)	Not Applicable
BLUE – Solid	The system is in an **Active** state and will deliver anesthetic as needed to reach the desired inspired anesthetic setpoint (FiA SET).The system may not actually be delivering anesthetic if the recycled anesthetic percentage (FcA) is larger than the current FiA setpoint (FiA Set).	Not Applicable
AMBER – Solidly lit	The system is in a **Caution** state. Operator awareness is required.	Low priority alarm / Tone sequence off

LED State	Explanation	Alarm Priority / Audio Tone Sequence
AMBER – Flashing (slowly) (blink rate = 1 Hz, 50% duty cycle)	The system is in a **MEDIUM** priority state. The system delivers anesthetic and attempts to maintain target inspired concentration. (***NOTE**: A slow-pulsed audio alarm is present.*)	Medium priority alarm / Three notes of equal, medium length and ascending pitch: C–D–G (alarm can be muted for up to 120 seconds). When measured with a microphone at a distance of one (1) meter, the sound pressure level of the Medium Priority alarm is 46.3 dB. (This was measured with an A-weighted background level of 26.8 dB which included any information signal or extraneous noise.)
RED – Flashing (quickly) (blink rate = 2.5 Hz, 50% duty cycle)	The system is in a **HIGH** priority alarm state. It is not delivering anesthetic and will not run. (***NOTE:** A fast-pulsed audio alarm is present.*)	High priority alarm / Three short notes of ascending pitch followed by two long notes of ascending pitch: C– D–G followed by C–D. When measured with a microphone at a distance of one (1) meter, the sound pressure level of the Medium Priority alarm is 47.2 dB. (This was measured with an A-weighted background level of 26.8 dB which included any information signal or extraneous noise.)

Replacing Inlet and Mouth Sensor

When the *Patient or Inlet Sensor: Replace Adapter* message is displayed, the operator should replace the indicated adapter.

Steps

1. Ensure a replacement adapter is available.
2. Remove the adapter that needs replacement from the circuit and reconnect the circuit.
3. Replacer the adapter with a new adapter and replace in the circuit.

CAUTION! REMOVAL OF THE PATIENT SENSOR OR INLET SENSOR FROM THE CIRCUIT TO REPLACE THE ADAPTER WILL RESULT IN MADM™ DISCONTINUING THE DELIVERY OF ANESTHETIC. THIS SHOULD ONLY DONE AT THE POINT IN THE OPERATION WHERE ANESTHETIC DELIVERY CAN BE DISCONTINUED FOR 30 SECONDS OR MORE.

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11. Alarms

Alarm Description

There are three alarm priorities: low, medium and high. In the low and medium priority alarm conditions, the system can still deliver anesthetic, but the user should take some action to resolve the low and medium alarm conditions. For high-priority alarms, delivery of anesthetic is not possible due to a physical condition or an unsafe condition for the patient. For warnings, an amber LED blinks and sound is generated in sync with the blinking. For errors, a red LED blinks and sound is generated in sync with the blinking. The buzzer complies with IEC60601-1-8 2012 2.1b requirements for multitones and loudness.

Highest Alarm Priority	LED	Audio Tone Sequence
No alarms	Green only	Off
Low	Solid Amber only	Off
Medium	Amber only (blink rate = 1 Hz, 50% duty cycle)	C-D-G (can be muted for up to 120s)
High	Red only (blink rate = 2.5 Hz, 50% duty cycle)	C-D-G – C-D (can be muted for up to 120s)

Table 11: Alarm Description

NOTE: *To mute all alarms temporarily (120 seconds), press the [MUTE/ENTER] key (the key on top of the device and closest to the back) once. To mute all alarms permanently (120 seconds), press and hold the [MUTE/ENTER] key for five (5) seconds.*

NOTE: *There are no operator-adjustable alarms. See the table in the following section, Alarm Causes and Corrections on page 66, for all pre-set alarm limits. No change in these pre-set limits occurs after power loss.*

WARNING! SOUND PRESSURE LEVELS OF AUDITORY ALARM SIGNAL THAT ARE LESS THAN AMBIENT LEVELS CAN IMPEDE OPERATOR RECOGNITION OF ALARM CONDITIONS.

Safety Interlock

When an error condition occurs, or in the absence of a positive determination that no errors are present, MADM™ initiates a safety interlock preventing the device from delivering anesthetic. This interlock involves preventing the solenoids from opening to allow anesthetic to move from the canister to the system, disabling the heater, and prohibiting the anesthetic delivery pump from operating.

Verification of the Alarm System

The alarm system should be verified prior to each case. The alarm system can be verified by disconnecting the Anesthetic and CO_2 sensor from MADM™ or ejecting the canister. Both of these actions will cause a high priority alarm, including an audio signal and flashing LEDs. These indicators will be active until the alarm-generating condition or conditions are resolved.

Alarm Causes and Corrections

The following table lists all error and warning alarms displayed by MADM™, their possible cause(s) and suggests the action(s) to be taken to correct them.

***NOTE:** If an alarm or message persists after all suggested actions have been taken, return MADM™ to Thornhill Research Inc. for servicing.*

***NOTE:** If there is discrepancy between the alarm state displayed on the screen and the alarm state as reported by the LEDs, the alarm state report displayed by the LEDs should be considered accurate, and device operation should be discontinued as soon as possible.*

Table 12: Alarm Causes and Corrections

Alarm Message	Location	Cause	Delay	Action
HIGH PRIORITY ALARMS				
1. Internal Fault 1 (*Error Code*)	Device-[6]	Unspecified internal device fault detected.	< 5s	Return device for servicing.
2. Internal Fault 2 (*Error Code*)	Device-[6]	Unspecified internal device fault detected.	< 5s	Return device for servicing.
3. Device Tilted > 30˚	Device-[6]	Device tilted at angle exceeding 30˚ from normal.	< 5s	Place device on a flat surface. (If message persists, return device for servicing.)
4. Critical SEVO% At Mouth (> 5.5%)	FIA SEVO Display – [10]	Concentration of SEVO at patient sensor too high.	1 breath	• Reduce device anesthetic delivery set point. • Purge patient circuit with fresh gas.
5. Critical ISO% At Mouth (> 4.0%)	FIA ISO Display – [9]	Concentration of ISO at patient sensor too high.	1 breath	• Reduce device anesthetic delivery set point. • Purge patient circuit with fresh gas.
6. Unsupported Agent Detected	MAC Display [13]	Anesthetic agent other than SEVO and ISO detected by device.	1 breath	• Purge patient circuit with fresh gas and recalibrate. • Replace patient circuit.
7. Patient Sensor Fault (*Error Code*)	Patient Sensor –[5]	Patient sensor fault detected by device.	< 5s	• Power cycle the device. • Retry calibration. • Try another sensor.
8. Patient Sensor: Adapter Missing	Patient Sensor –[5]	Patient circuit adapter on patient sensor missing.	< 5s	Replace sensor adapter.
9. Patient Sensor: Unsupported Model	Patient Sensor –[5]	Patient sensor model not supported.	< 5s	Replace patient sensor with model approved for use MADM™.
10. Unrecognized Canister Type	Canister – [3]	Anesthetic gas canister not recognized by device.	< 5s	• Remove agent canister from device and reinstall. • Remove agent canister and reinstall a different canister.

Alarm Message	Location	Cause	Delay	Action
11. Apnea Detected	Patient Sensor –[5]	Patient breathing not detected.	20s	• Ensure device, including patient sensor, is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks. • Clinical intervention required.
12. Airway Tubes Backwards	Ventilator-[8]	Ventilator connected to device backwards.	1 breath	Disconnect ventilator tubes from device and connect tubes as indicated on device or in manual.
13. Inlet Sensor Fault (*Error Code*)	Inlet Sensor-[7]	Inlet sensor fault detected by device.	< 5s	• Power cycle the device. • Retry calibration. • Return device for servicing.
14. Inlet Sensor: Adapter Missing	Inlet Sensor-[7]	Patient circuit adapter on inlet sensor missing.	< 5s	Replace sensor adapter.
15. Inlet Sensor: Unsupported Model	Inlet Sensor-[7]	Inlet sensor model not supported.	< 5s	Return device for servicing.
16. Inlet Sensor: Cal Failed	Inlet Sensor-[7]	Calibration of inlet sensor failed.	< 5s	• Power cycle the device. • Retry calibration.
17. Patient Sensor: Cal Failed	Patient Sensor –[5]	Calibration of patient sensor failed.	< 5s	• Power cycle the device. • Retry calibration.
18. Flow Sensor Fault	Device-[6]	Flow sensor fault detected by device.	< 5s	• Power cycle the device. • Retry calibration.
19. Patient Sensor: Disconnected	Patient Sensor –[5]	Patient sensor disconnected from device.	< 5s	• Fully disconnect and reconnect the patient sensor to the device. • Fully disconnect the patient sensor and reconnect a different patient sensor.
20. Inlet Sensor: Disconnected	Inlet Sensor-[7]	Inlet sensor disconnected from device.	< 5s	Return device for servicing.
21. Patient Sensor: Fault - Try Re-Cal	Patient Sensor –[5]	Patient sensor fault detected by device.	< 5s	• Power cycle the device. • Retry calibration.
22. Inlet Sensor: Fault - Try Re-Cal	Inlet Sensor-[7]	Inlet sensor fault detected by device.	< 5s	• Power cycle the device. • Retry calibration.

Alarm Message	Location	Cause	Delay	Action
23. FIA exceeds FIA set (High Priority)	FIA ISO Display [9] or SEVO Display – [10]	Concentration of anesthetic agent at patient sensor too high (> 0.5% absolute or > 25% of target, whichever is greater).	1 breath for steady state 45s after a decrease in dial setting	• Reduce device anesthetic delivery set point. • Purge patient circuit with fresh gas. • Return device for servicing.
24. Canister Not Detected	Canister-[3]	Anesthetic agent canister not detected by MADM™.	< 5s	• Fully install anesthetic agent canister into MADM™. • Remove agent canister and reinstall a different canister.
25. Patient Sensor: Replace Adapter	Patient Sensor –[5]	Patient circuit adapter on patient sensor is dirty or broken.	< 5s	Replace sensor adapter.
26. Inlet Sensor: Replace Adapter	Inlet Sensor-[7]	Patient circuit adapter on inlet sensor is dirty or broken.	< 5s	Replace sensor adapter.
27. Internal Battery Level Critically Low	Battery-[1]	Device internal battery is insufficient to continue delivery.	< 5s	• Plug device into wall. • Return device for servicing.
28. Purge Limit Exceeded	Device-[6]	Internal reservoir of anesthetic has been exceeded.	< 5s	• Return device for servicing.
29. Vent Waveform Not Detected	Ventilator-[8]	Ventilation waveform not detected.	< 5s	• Ensure device, is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks. • Ensure Ventilator is on, or patient is being ventilated through MADM™.
MEDIUM PRIORITY ALARMS				
1. Agent Underdelivery	FIA ISO Display [9] or SEVO Display – [10]	FIA of Canister Anesthetic Agent Type is below dial setpoint by ≥ 0.2% absolute and 20% relative for at least one minute.	1 breath	• Reduce device anesthetic delivery set point. • Ensure device, including patient sensor, is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks.

Alarm Message	Location	Cause	Delay	Action
2. FIA Exceeds FIA Set (Medium Priority)	FIA ISO Display [9] or SEVO Display – [10]	Concentration of anesthetic agent at patient sensor too high (> 0.2% absolute and 15% relative to setpoint.	1 breath	• Reduce device anesthetic delivery set point. • Purge patient circuit with fresh gas. • Return device for servicing.
3. Detected Agent Mismatch for Canister	Patient Sensor –[5]	Anesthetic agent detected by device does not match agent canister.	1 breath	• Purge patient circuit with fresh gas. • Replace patient circuit. • Remove agent canister from device and reinstall. • Remove agent canister and reinstall a different canister.
4. Device In Expiratory Limb	Ventilator-[8]	Device has detected unscrubbed exhaled gas which indicates it is placed in the expiratory limb.	45s	• Install device in inspiratory limb. • Ensure scrubber is installed in circle system.
5. Patient Sensor: Re-Cal Reqd	Patient Sensor –[5	Patient sensor requires calibration.	< 5s	• Power cycle the device. • Retry calibration.
6. Agent Level in Canister Low	Canister-[3]	Anesthetic agent level in canister low.	< 5s	Refill or replace anesthetic agent canister.
7. Inlet Sensor: Re-Cal Reqd	Inlet Sensor-[7]	Inlet sensor requires calibration.	< 5s	• Power cycle the device. • Retry calibration.
8. Max Delivery Rate (3000 µL/min) Exceeded	Device-[6]	Minute ventilation measured by device exceeds upper alarm limit.	60s	• Reduce Fresh Gas flow, ventilation rate, or target anesthetic level.
9. Backup Battery Failure	Battery-[1]	Failure detected with device battery.	< 5s	Return device for servicing.
10. Internal Battery Level Low	Battery-[1]	Device battery charge level is low.	< 5s	Connect wall power to power device and charge battery.
11. Patient Sensor: Unspec Acc	Patient Sensor –[5]	Potential inaccurate measurement from patient sensor.	< 5s	• Replace sensor adapter. • Power cycle the device. • Re-calibrate. • Return device for servicing.
12. Inlet Sensor Unspec Acc	Inlet Sensor-[7]	Potential inaccurate measurement from patient sensor.	< 5s	• Replace sensor adapter. • Power cycle The device. • Re-calibrate • Return device for servicing.
LOW PRIORITY ALARMS				
1. Both SEVO and ISO Detected	Patient Sensor –[5]	Device detects both SEVO and ISO in patient circuit in quantities above 0.15%.	1 breath	• Purge patient circuit with fresh gas. • Replace patient circuit.
2. On Battery Pwr: Need Wall	Plug-[20	Device is not connected to wall power.	< 5s	Connect wall power to device.

Alarm Message	Location	Cause	Delay	Action
3. Internal Fault, Service Soon (%d)	Device-[6]	Unspecified internal device fault detected.	< 5s	• Power cycle the device. • Return device for servicing.
4. Internal Tilt Sensor Fault	Device-[6]	Failure detected with device tilt sensor. Device may not detect and alarm if tilted.	< 5s	Return device for servicing.
5. Inlet/Flow Sensors: Cal Skipped	Inlet Sensor-[7]	Inlet and flow sensor calibration has been skipped by user.	< 5s	• Power cycle the device. • Retry calibration.
6. Patient Sensor: Cal Skipped	Patient Sensor –[5]	Patient sensor calibration has been skipped by user OR patient sensor has been disconnected and reconnected.	< 5s	• Connect patient sensor to device. • Power cycle the device. • Retry calibration.
7. Flow Sensor: Using Default Cal	Device-[6]	Flow sensor has not been calibrated.	< 5s	• Power cycle the device. • Retry calibration.
8. Dial Beyond Maximum Allowable	FIA Set-[14]	Device dial is set beyond that maximum safe concentration for the agent detected in the canister.	< 5s	Turn dial down to allowable setting.
9. N2O Detected	MAC Display [13]	N2O detected in circuit.	< 5s	• Information only, N2O not included in MAX calculation. • To eliminate N2O flush circuit.
10. Dial Setting May Be inaccurate	FIA Set-[14]	Potential misalignment of dial.	< 5s	• Use displayed dial setting on GUI. • Return device for servicing.

12. Servicing and Maintenance

Servicing and Maintenance While Connected to the Patient

With the exception of replacement of inlet and airway sensor adapters, and filling the anesthetic canister, no other maintenance or servicing may be performed while the device is connected to a patient.

Routine Inspection and Maintenance

The Startup tests should be performed prior to connecting each patient. In addition, a monthly inspection and test can be performed as follows:

1. Visual inspection including the agent specific filling system.
2. Disconnect wall plug and confirm device operates on battery power; reconnect plug and confirm device operates on wall power
3. Attach six (6) feet of tubing, connect flow from oxygen source, set dial to 1% and measure output concentration and flow
4. To measure the output gas concentration, attach the mouth sensor to the end of the tubing.
5. Confirm that the flow displayed on MADM™ corresponds to the flow on the gas source.
6. After 30 seconds, confirm that the anesthetic concentration displayed is within 10% of that set by the dial.

System Maintenance

MADM™ is designed for easy maintenance. MADM™ should be serviced after every six (6) months of use or after every 12 months of storage.

MADM™ can only be serviced by qualified service personnel.

With the exception of replacing airway adapters, no maintenance or servicing should be conducted on MADM™ when it is being used on a patient.

System Cleaning

The external body of the system can be cleaned using standard cleaning agents, excluding oxidizing agents. It is recommended that the external metal surfaces be wiped down with isopropyl alcohol during routine maintenance.

External surfaces of MADM™ can be wiped clean with one of the following:

- Isopropyl Alcohol
- Chlorine Compounds*****
    - Maximum Concentration: 1:10

*****_These compounds are diluted by volume in water._

In the event that the device becomes contaminated by direct exposure to exhaled gas without protection of a patient filter, the following components need to be replaced by qualified service personnel according to the MADM™ service manual:

- Homogenizer
- Flow sensor

In addition, all single-use patient components must be replaced.

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13. Index