

VELA[®] ventilator

Service manual



CardinalHealth

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Revision History

Date	Revision	Pages	Changes
September 2006	A	NA	NA
May 2008	B	2, 10 – 20, 23 – 25, 27, 37, 40 – 42, 44 – 46, 57, 60, 63, 66, 69 – 92	Updated for VELA Coldfire 2
		Throughout the document	Changed VIASYS Healthcare to Cardinal Health and Cardinal Health Respiratory Technologies Changed Vela to VELA
		viii	Updated Intended Use Notice and IEC Classification to remove references to infant ventilation.
		4	Remove “optional” from the first sentence of “Oxygen Blending System.”
		65	Removed the Caution statements regarding non-operational ports.

Warranty

THE VELA ventilator systems are warranted to be free from defects in material and workmanship and to meet the published specifications for two (2) years or 8,000 hours, whichever occurs first. The turbine only is warranted to be free from defects in material or workmanship for five (5) years or 40,000 hours whichever occurs first.

The liability of Cardinal Health (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company will not be liable under this warranty unless (A) the Company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. In no event shall the Company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

The Company warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation of Liabilities

This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of TWO (2) years from date of shipment or 8,000 hours of use, whichever occurs first, with the following exceptions:

1. Components for monitoring of physical variables such as temperature, pressure, or flow are warranted for ninety (90) days from date of receipt.
2. Elastomeric components and other parts or components subject to deterioration, over which the Company has no control, are warranted for sixty (60) days from date of receipt.
3. Internal batteries are warranted for ninety (90) days from the date of receipt.
4. The turbine only is warranted to be free from defects in material or workmanship for five (5) years or 40,000 hours whichever occurs first.

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of the Company.

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Notices

EMC Notice

This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

The ventilator has been tested to conform to the following specifications:

MIL-STD-461D:1993, MIL-STD-462D:1993, EN55011:1991, IEC 1000-4-2:1994, IEC 1000-4-3:1994, IEC 1000-4-4:1994, IEC 1000-4-5:1994, QUASI-STATIC:1993

This ventilator is also designed and manufactured to comply with the safety requirements of IEC 601-1, IEC 601-2-12, CAN/CSA-C22.2 No. 601.1-M90, and UL 2601-1.

MRI Notice

This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.

Do not operate the ventilator in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the ventilator.

Intended Use Notice

The Vela Ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs), who require the following general types of ventilation support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation

The ventilator is suitable for use in institutional and transport settings. It is not intended for use as an emergency medical transport ventilator or for homecare applications.

Regulatory Notice

Federal law restricts the sale of this device except by or on order of a physician.

IEC Classification

Type of Equipment: Medical Equipment, Class 1 type B
Adult/Pediatric Lung Ventilator

Declaration of Conformity Notice

This medical equipment complies with the Medical Device Directive, 93/42/EEC, and the following Technical Standards, to which Conformity is declared:

EN60601-1
EN60601-1-2
ISO 13485-2003

EU Notified Body:

BSI (Reg. No. 0086)

Trade names:

VELA



If you have a question regarding the Declaration of Conformity for this product, please contact Cardinal Health, Respiratory Technologies, at the number given in Appendix A.

Safety Information

Please review the following safety information prior to operating the ventilator. Attempting to operate the ventilator without fully understanding its features and functions may result in unsafe operating conditions.

Warnings and Cautions which are general to the use of the ventilator under all circumstances are included in this section. Some Warnings and Cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

If you have a question regarding the installation, set up, operation, or maintenance of the ventilator, contact VASYS Healthcare Customer Care as shown in Appendix A, Contact & Ordering Information.

Terms

WARNINGS	identify conditions or practices that could result in serious adverse reactions or potential safety hazards.
CAUTIONS	identify conditions or practices that could result in damage to the ventilator or other equipment.
NOTES	identify supplemental information to help you better understand how the ventilator works.

Warnings

Warnings and Cautions appear throughout this manual where they are relevant. The Warnings and Cautions listed here apply generally any time you operate the ventilator.

- The VELA Ventilator is intended for use by a trained practitioner under the direction of a qualified physician.
- When the ventilator is connected to a patient, a trained health care professional should be in attendance at all times to react to an alarm or other indications of a problem.
- Alarm loudness must be set above ambient sound in order to be heard.
- Always have an alternate means of ventilation available whenever the ventilator is in use.
- The operator should not touch the electrical connectors of the ventilator or accessories, and the patient simultaneously.
- Due to possible explosion hazard, the ventilator should not be used in the presence of flammable anesthetics.
- An audible alarm indicates an anomalous condition and should never go unheeded.
- Anti-static or electrically conductive hoses or tubing should not be used within the patient circuit.
- If a mechanical or electrical problem is recognized while running the Operational Verification Tests, or while operating the ventilator, the ventilator must be removed from use and referred to qualified personnel for servicing. Using an inoperative ventilator may result in patient injury.
- When a low gas supply alarm occurs, the oxygen concentration delivered to the patient will differ from that set on the O₂ control setting.
- A source gas failure will change the FIO₂ and may result in patient injury.
- The functioning of this equipment may be adversely affected by the operation of other equipment nearby, such as high frequency surgical (diathermy) equipment, defibrillators, short-wave therapy equipment, "walkie-talkies," or cellular phones.
- Do not block or restrict the Oxygen bleed port located on the instrument back panel. Equipment malfunction may result.

- Electric shock hazard - Do not remove any of the ventilator covers or panels. Refer *all* servicing to an authorized Cardinal Health, Respiratory Technologies, service technician.
- A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. Upon loss of protective ground, all conductive parts including knobs and controls that may appear to be insulated, can render an electric shock. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the ventilator, and make sure the power cord is in good condition.

Cautions

The following cautions apply any time you work with the ventilator.
















- When replacing fuses, ensure that new fuses are of the same type and value as those being replaced. Incorrect fuses can cause damage to the ventilator.
- A battery that is fully drained (i.e. void of any charge) may cause damage to the ventilator and should be replaced.
- All accessory equipment that is connected to the ventilator must comply with CSA/IEC601/UL2601.
- To avoid damage to the equipment, clean the air filter regularly.

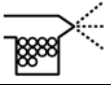



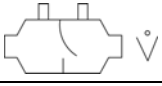

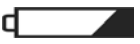
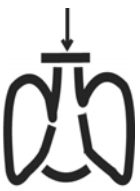


The following cautions apply when cleaning the ventilator or when sterilizing ventilator accessories.

- Do not sterilize the ventilator. The internal components are not compatible with sterilization techniques.
- Do not gas sterilize or steam autoclave tubing adapters or connectors in place. The tubing will, over time, take the shape of the adapter, causing poor connection and possible leaks.
- DO NOT submerge the ventilator or pour cleaning liquids over or into the ventilator.

Equipment Symbols

The following symbols may be referenced on the ventilator or in accompanying documentation

Symbol	Source/Compliance	Meaning
	Symbol #03-02 IEC 60878	Indicates ATTENTION, consult ACCOMPANYING DOCUMENTS
	Symbol #5016 IEC 60417	This symbol indicates a FUSE.
	Symbol #5034 IEC 60417 Symbol #01-36 IEC 60878	This symbol indicates INPUT.
	Symbol #5035 IEC 60417 Symbol #01-37 IEC 60878	This symbol indicates OUTPUT
	Symbol #5019 IEC 60417 Symbol #01-20 IEC 60878	This symbol indicates protective EARTH (ground).
	Symbol #5021 IEC 60417 Symbol # 01-24 IEC 60878	This symbol indicates the EQUIPOTENTIAL connection used to connect various parts of the equipment or of a system to the same potential, not necessarily being the earth (ground) potential (e.g., for local bonding).
	Symbol # 5333 IEC 60417 Symbol #02-03 IEC 60878	This symbol indicates TYPE BH equipment, which indicates equipment that provides a particular degree of protection against electric shock, particularly with regards to allowable leakage current and reliability of the protective earth connection.
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 30878	This symbol indicates the equipment is suitable for alternating current.
	Symbol# 5049 IEC 60417	This Symbol indicates the ON condition for a part of the equipment. When pressed the ventilator will operate from the MAINS voltage (if connected) or internal or external batteries if the battery charge is within operating specifications.
	Symbol #5007 IEC 60417 Symbol #01-01 IEC 60878	Indicates ON (Power)
	Symbol #5008 IEC 60417 Symbol #01-02 IEC 60878	Indicates OFF (Power)
	Symbol #0651 ISO 7000	Horizontal return with line feed. Indicates ACCEPT entered values for a specific field.
	Graphical Symbol in general use internationally for "DO NOT"	This symbol indicates CANCEL. Do not accept entered values. The ventilator continues to operate at previous settings.
	Symbol #5467 IEC 60417	Pressing the button with this symbol will FREEZE the current display.
	Symbol #5569 IEC 60417	This symbol indicates a CONTROL LOCK.

Symbol	Source/Compliance	Meaning
	Cardinal Health symbol	This symbol represents a NEBULIZER.
	Symbol #5319 IEC 60417	This symbol indicates ALARM SILENCE
	Symbol #5307 IEC 60417	This symbol indicates ALARM RESET
	Cardinal Health symbol	Increase OXYGEN
	Cardinal Health symbol	Indicates VARIABLE ORIFICE FLOW SENSOR
	Symbol #5031 IEC 60417	This symbol indicates DIRECT CURRENT (DC)
	Symbol #5546 IEC 60417	This symbol indicates the INTERNAL BATTERY STATUS display
	Cardinal Health symbol	This symbol indicates INSPIRATORY HOLD
	Cardinal Health symbol	This symbol indicates EXPIRATORY HOLD
	Cardinal Health symbol	This symbol indicates MANUAL BREATH

Chapter 1: Introduction

General Instructions

When disassembling or assembling the VELA, refer to the pneumatic schematic, tubing diagram, and the wiring diagram shown in Appendix B and the appropriate schematics and assembly drawings for each assembly. The illustrations shown in this manual are for reference only, current revisions of these diagrams and schematics are available to qualified personnel from Cardinal Health, Respiratory Technologies, Technical Support.

Always take standard ESD precautions when working on VELA ventilator systems.

Ensure the ventilator is disconnected from the AC power supply before performing and repairs or maintenance. When you remove any of the ventilator covers or panels, immediately disconnect the internal battery "Molex" connector (see figure 3.0) before working on the ventilator.

Recommended Tools & Equipment

Note

Before using any test equipment [electronic or pneumatic] for calibration procedures, the accuracy of the instruments must be verified by a testing laboratory. The laboratory master test instruments must be traceable to the NIST (National Institute of Standards Technology) or equivalent.

When variances exist between the indicated and actual values, the calibration curves [provided for each instrument by the testing laboratory] must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage.

Long & short Phillips screwdrivers	
Flat bladed screwdriver	1/8" ID Tubing tee P/N 00358 D (10pk)
¼" Nut Driver	1/8" ID silicone tubing P/N 04029 X (50ft)
5/16" Nut Driver	Adult Test Lung P/N 33754
11/32" Nut Driver	Adult Patient Circuit P/N 10684
Digital Volt Meter	Variable Orifice Flow Sensor assembly P/N 15972
Tack puller or Needle nosed pliers	Valve Body P/N 20005
Diagonal cutters	Tapered nipple P/N 00680
1" and ¾" open ended wrenches	Hex nut P/N 00822
Pressure Manometer (cmH ₂ O and psig)	Regulator P/N 6754

Recommended Maintenance Schedules

Schedules

Every 500 hours, the fan and ambient air filters should be cleaned and replaced if necessary.

Every year, the following preventive maintenance procedure should be performed (see chapter 4 for instructions). This procedure includes:

- Install PM kit P/N 11416
- Perform verification procedures described in Chapter 4
- Calibration of the transducers & solenoids if necessary.

Every 10,000 hours or every two years, whichever occurs sooner, the internal oxygen sensor P/N 16101 and internal batteries P/N 21542 (4 ea) should be replaced.

Maintenance on the VELA should only be carried out by a trained and authorized service technician. Cardinal Health will make available to qualified technicians, service manuals and such items as circuit diagrams, component parts lists, calibration instructions and other information to assist in repair of those parts of the ventilator designated by the manufacturer as repairable items.

The drawings, diagrams and schematics included in this manual are for reference only and may be updated separately from this manual after publication. For current revisions of all documentation, contact Cardinal Health, Respiratory Technologies, Technical Support at the numbers provided in Appendix A.

Chapter 2: Theory of Operation

General Device Description

The VELA Ventilator uses a revolutionary turbine gas delivery system with sophisticated microprocessor control. Its Graphical User Interface provides support for pediatric to adult patients. The VELA can deliver clinically advanced modes of ventilation like Pressure Support, APRV, NPPV and PRVC, and can be powered with an internal battery or AC power for a more extensive patient range.

Pneumatic System Overview

The VELA ventilator pneumatic system is electromechanical and comprises four major subsystems, each containing several components. These systems are the flow delivery system, the exhalation system, the safety system and the inspiratory hold valve. Individual subsystems are discussed in detail below.

Flow Delivery System

This electromechanical system controls all inspiratory flow to the patient. The system delivers flow to satisfy criteria for many breath types, including volume controlled, pressure controlled, pressure supported, APRV, NPPV and PRVC. The system comprises a turbine, differential pressure transducer, 2 auto-zero valves, and an optical encoder speed transducer. When a breath is initiated, the microprocessor controls the speed of the turbine to achieve the required flow rate.

The speed and differential pressure transducer signals function as control inputs to ensure that the proper flow rate is delivered even when backpressure varies. Periodically, the auto zero valves activate to reference both sides of the differential pressure transducer to ambient pressure. The offset is recorded by the microprocessor, and is used as a correction for future pressure measurements. This compensates for long term and temperature drift. Materials exposed to patient gases include compatible plastics, aluminum, and plated steel.

Exhalation System

The exhalation system controls the flow of gas from the patient's lungs during the exhalation phase of a breath. This electromechanical subsystem is made up of an exhalation valve, a flow transducer, a differential pressure transducer, an airway pressure transducer, and three auto zero solenoid valves. During exhalation, the outflow of gases is regulated by the exhalation valve to achieve the set PEEP. The exhalation valve is comprised of an electromagnetic linear actuator operating against a mechanical poppet/seat. The gas flow travels through the flow transducer. The flow transducer is a variable orifice type and creates a differential pressure proportional to flow. This differential pressure is transmitted to the differential pressure transducer, which converts the pressure signal to an electrical signal. The microprocessor uses this signal for flow triggering and to monitor exhaled tidal volume. The airway pressure transducer reads pressure in the exhalation leg of the patient circuit. This signal is used as a feedback signal for controlling PEEP, pressure control, pressure support, and various pressure monitors. Periodically, the auto zero valves activate to reference the differential and airway pressure transducers to ambient pressure. The offset is recorded by the microprocessor, and is used as an offset for future pressure measurements. This compensates for long term and temperature drift. Materials exposed to patient gases include compatible plastics, aluminum, and stainless steel.

Safety System

The mechanical safety system ensures that the patient can breath spontaneously from room air and that the patient pressure is limited to a maximum preset value in the event of a ventilator malfunction. This mechanical system consists of a pressure relief valve and a sub ambient relief valve. In the event of a ventilator malfunction that results in high pressure, the pressure is limited by a relief valve. The relief valve consists of a user-adjustable, spring-loaded poppet acting against a seat.

In the event the ventilator fails to deliver a breath, the patient may inspire spontaneously by drawing room air through the sub ambient relief valve.

Materials exposed to patient gas are aluminum, compatible rubber, and compatible plastics.

Inspiratory Hold Valve

The inspiratory hold valve is an electromechanical solenoid valve. If activated, the inspiratory hold valve blocks flow between the flow delivery system and the patient. This valve is activate during inspiratory hold and maximum inspiratory pressure maneuvers. Materials exposed to patient gases are aluminum and compatible rubber and plastic.

Oxygen Blending System

The oxygen blending system is made up of an O2 inlet transducer, an O2 inlet pressure regulator, seven solenoid valves, five flow orifices, one nebulizer orifice, an inlet filter, and an accumulator. When a breath is initiated, the turbine draws mixed gas from the accumulator. Filtered air is drawn into the accumulator through the filter. Oxygen is supplied to the accumulator through the solenoids and orifices. The microprocessor opens and closes the valves as required to supply the correct amount of oxygen to satisfy the O2 setting and the flow demand. The signal from the O2 inlet pressure transducer is used to compensate delivered O2 for O2 inlet pressure variations. The blender can be used to supply nebulized flow at 100% oxygen. A safety solenoid is used to shut off the flow of oxygen when the ventilator is turned off or has gone inoperative. The O2 inlet pressure regulator helps minimize variations in the oxygen supply. Surfaces exposed to patient gas are constructed from compatible plastics, plated steel, and aluminum.

There is also an oxygen inlet port, which allows for low-flow titration of oxygen into the gas output of this device.

Electronic Overview

The VELA ventilator electronic system is comprised of several subsystems, each containing numerous components. These subsystems are the GUI System, the Power System, the Main Microprocessor System, and the Exhalation and Flow Delivery systems. Individual subsystems are discussed in detail.

User interface module (UIM)

The UIM consists of a 10.4-inch, 800x600 active matrix LCD with an analog resistive touch screen overlay, a back light inverter, a set of membrane key panels, an optical encoder, and the Main System PCB. Software and the touch screen provide a set of context sensitive soft keys. The membrane panel provides a set of hard (permanent) keys for dedicated functions. Selecting the function with a soft key and adjusting the setting using the optical encoder changes a parameter. A parameter is accepted or canceled by pressing the appropriate membrane key.

The UIM performs all ventilator control functions, gas calculations, monitoring and user interface functions. The UIM uses a Graphical User Interface (GUI) via the active matrix SVGA LCD and resistive touch screen to provide system and patient information to the user and to allow the user to modify ventilator settings. The Main System PCB handles all user interface requirements, including updating the active matrix liquid crystal display (LCD), monitoring the membrane keypad, analog resistive touch screen, and optical encoder for activity. The Main System PCB also performs all the input/output functions of the UIM, including RS-232 (GSP and VOXP), printer, video output, and IEEE 1073 Medical Information Bus (MIB).

Liquid Crystal Display

The liquid crystal display (LCD) provides graphical and digital feedback to the clinician. The panel is a 10.4" SVGA, 800x600 pixel, active matrix LCD. The LCD is used to implement the graphical user interface (GUI). It provides all of the adjustable controls and alarms, as well as displays waveforms, loops, digital monitors and alarm status in real time.

Touch Screen

The touch screen is a 10.4" analog resistive overlay on a piece of glass, which is placed over an LCD screen. The touch screen and the LCD together provide a set of software configurable soft keys. The software enables the keys to be context sensitive. The touch screen has a resolution of 1024x1024. Physically, the touch screen consists of two opposing transparent resistive layers separated by insulating spacers. Touching the screen brings the two opposing layers into electrical contact. The Y coordinate is determined by applying a voltage from top to bottom on the top resistive layer. This creates a voltage gradient across this layer. The point of contact forms a voltage divider, which is read by the analog-to-digital converter. The X coordinate is determined by applying a voltage from left to right on the bottom resistive layer. Again this creates a voltage gradient and the point of contact forms a divider, which is read with an analog-to-digital converter.

Membrane Panel

The membrane panel provides a set of permanent dedicated keys, which enable control of ventilator functions. The membrane panel also provides visual display using embedded light emitting diodes (LEDs). The membrane panel consists of membrane switches, which are read by the microprocessor. The switches form a matrix of rows and columns. A key closure causes an interrupt to the microprocessor, which responds by scanning the key matrix to determine which key has been pressed.

Light Emitting Diodes (LED)

Some of the membrane keys require LED's to indicate when the key is active. The LED's are embedded into the membrane panel.

Optical Encoder

The optical encoder is used to modify control settings. A setting is selected by pressing a soft key on the touch screen and then modified by turning the optical encoder (data dial) to change the value. When the encoder is rotated two pulse streams are generated, phase A and B. When the encoder is turned clockwise, phase A leads B by 90 degrees. When the direction is counter clockwise, phase B leads A by 90 degrees. The electronics uses the phase information to drive an up-down counter, which is read by the microprocessor. The optical encoder is not interrupt-driven and therefore must be polled by the microprocessor.

Back Light Inverter

The back light inverter converts 12 VDC into the high frequency AC voltage necessary to power the LCD back light, which is used to illuminate the LCD.

Power System

The Power System conditions and controls electrical energy from the AC line input and the internal batteries. The Power System supplies 24VDC, 8VDC, and 5VDC to the Main System PCB. When energy is available from the AC line, the ventilator operates from this source, and also recharges the internal batteries. When AC line power is not available, the power system draws energy from the internal batteries. The power system uses energy efficient DC-to-DC converter technology to convert energy from the AC line or batteries to appropriate voltages and currents to supply power to ventilator components and systems.

Main System PCB

The Main System PCB is comprised of three Pressure Transducers, an Analog-to-Digital Converter, two Digital-to-Analog Converters, Solenoid Valves, and the Watchdog and Hardware Fault Monitors.

One of the pressure transducers measures the patient circuit pressure. This pressure is an input to the control system. A differential pressure transducer measures the pressure across the turbine. This pressure is also an input to the control system. A second differential pressure transducer is used to measure the flow at the outlet of the exhalation valve. This pressure is also an input to the control system.

Analog to digital converters are used to change the analog pressure signals into measured binary numeric values for use by the microprocessor.

Digital to Analog converters are used to change the binary numeric commands generated by the microprocessor in the control system into analog signals which drive the turbine and exhalation valve.

The microprocessor also performs several repetitive tasks such as generating the refresh signals for the display system, cycling the A-to-D converters through a pattern of measurements from the multiple signal sources, and scanning the control panel for pressed buttons.

Solenoid Valves and Valve Drivers (including the Auto Zero valves) are employed on the Circuit Pressure transducer and on the Turbine Differential Pressure Transducer. These valves allow the control systems software to compensate for long term drift and temperature induced zero shift in the pressure transducers by periodically rechecking the zero pressure readings. Similar solenoid valves are employed in the Oxygen Blending System. The valve drivers for the Auto Zero and Blender valves are similar.

The Main System PCB controls all ventilator functions. All user settings for alarms, controls, ventilation mode, waveform, and monitored data are stored here and are combined with measured pressure, flow, and speed data to cause the ventilator to function. The algorithms, formulae, and control functions which define ventilator behavior are contained in the software program executed by the microprocessor.

The Watchdog Circuit and Hardware Fault

The Watchdog circuit requires the microprocessor to periodically send a signal. If the signal is not received by the Watchdog Circuit then the ventilator will be shut down. When the Watchdog shuts down the CPU it forces the ventilator hardware to a safe state. The Hardware Fault Monitors check the status of the power supplies to the ventilator electronics. If any is out of the safe operating range, the ventilator will shut down and cannot be made to operate until the fault is corrected.

Exhalation System

The electrical portion of the exhalation system is comprised of the Exhalation Valve Driver Circuitry. The driver converts the low voltage signal output by a D-to-A converter into a controlled constant current which energizes the linear solenoid positioner in the exhalation valve.

Flow Delivery System

The electrical portion of the flow delivery system is comprised of a 3 Phase Brushless Motor Driver, and an Optical Speed Transducer.

The 3 Phase Brushless DC Motor Driver converts the low voltage signal output by a D-to-A converter into three controlled currents which energize the three motor phases and cause the motor to create a torque, resulting in motor rotation. The torque generated is a function of current, and therefore of the control voltage from the D-to-A converter. The speed of rotation is monitored by the optical Speed Transducer. The transducer outputs a train of pulses with a frequency proportional to the rotational speed of the motor. This pulse train is a control feedback input to the microprocessor.

Oxygen Blending System

The electrical portion of the oxygen blending system is made up of a safety solenoid, a pressure regulator set to 40 PSI, an O2 Inlet Transducer, five Solenoid Valves, one Nebulizer solenoid, and the driver circuitry for the solenoid valves.

The Oxygen Blender Pressure Transducer measures the system gas pressure after the regulator so that O2 delivery can be compensated for inlet pressure fluctuations.

The Solenoid Valves are energized and deenergized under software control by the Main System microprocessor to supply the correct amount of oxygen to satisfy the current O2 setting and current gas flow demand.

The driver circuitry translates the binary logic signals presented by the microprocessor to larger voltage and currents suitable for energizing the Solenoid Valves.

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Chapter 3: Disassembly and Assembly

General Instructions and Warnings

When performing the procedures in this chapter, refer to the VELA wiring and tubing diagrams. Reference copies of these are located in Appendix B of this manual. Ensure that you follow these safety warnings and precautions:

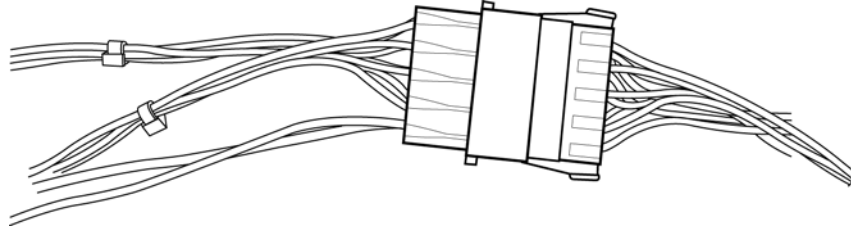


Figure 3.0 Battery Disconnect Molex Connector

WARNING

Always disconnect the main power cable before removing the instrument cover and disconnect the battery once the top cover and battery tray have been removed to prevent injury and/or damage to the VELA Ventilator System (see figure 3.1).

CAUTION

The VELA contains ESD susceptible components. Ensure you are properly grounded through a current-limiting connection before performing any service or maintenance procedures, and store ESD susceptible electrical components in anti-static bags to prevent damage to the components.

Note

When the batteries are disconnected, the system will automatically re-set the battery status memory and will initiate a 30-hour re-charge cycle upon re-connect. If the DC status light is not green after the initial charging period has expired, contact Cardinal Health tech support as described in Appendix A.

Note

The terms left and right refer to a view from the front of the unit looking towards the rear.

Required Tools

Long & short Philips screwdrivers	Digital Volt Meter
Flat bladed screwdriver	Tack puller or Needle nosed pliers
¼" Nut Driver	Diagonal cutters
5/16" Nut Driver	11/32" Nut Driver
7/8" Nut Driver	1" and ¾" open ended wrenches

Disassembly and Reassembly Procedures

To perform a complete disassembly of the unit, follow all of the steps in each *removal* section, in the order presented in this chapter. To reassemble the unit, follow all of the steps in each *Installation* section in reverse, starting with the last component and finishing with the power cable installation instructions.

Power Cable

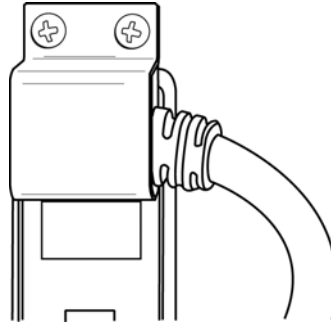


Figure 3.1 Power Cord and Bracket

Removal

1. Remove the (2) Phillips pan-head screws in the top portion of the power cable guard at the rear of the unit (see figure 3.2)
2. Remove the guard and unplug the power cable.

Installation

Follow removal process in reverse order

Top Cover P/N 15893

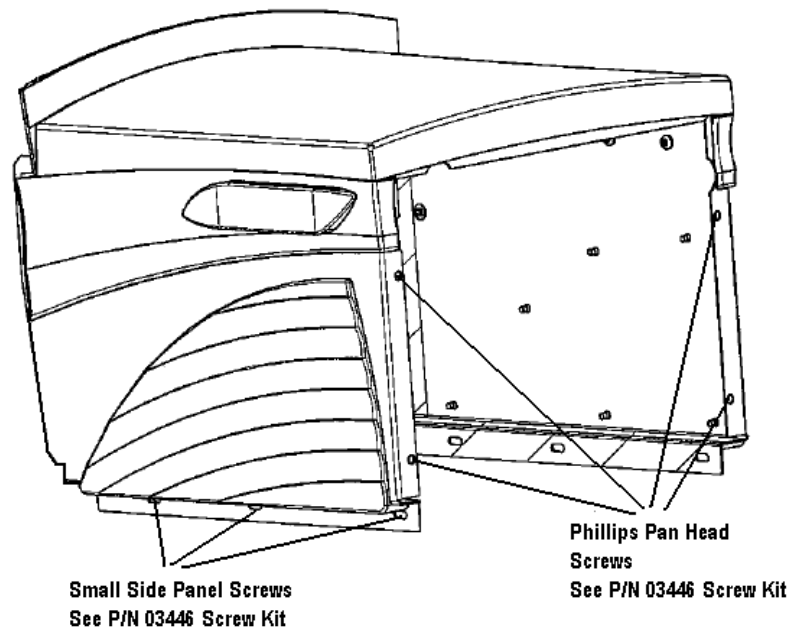


Figure 3.2 Top Cover Assembly

Removal

1. Remove the power cable.
2. Remove the (4) Phillips pan-head screws in the back panel.
3. Remove the (3) screws from the bottom of each side of the ventilator (if present).
- 4.. When all screws have been removed, slide the top cover towards the rear of the unit and lift off.

Installation

Follow removal process in reverse order

Battery Tray P/N 16049 (Reorder P/N 16048)

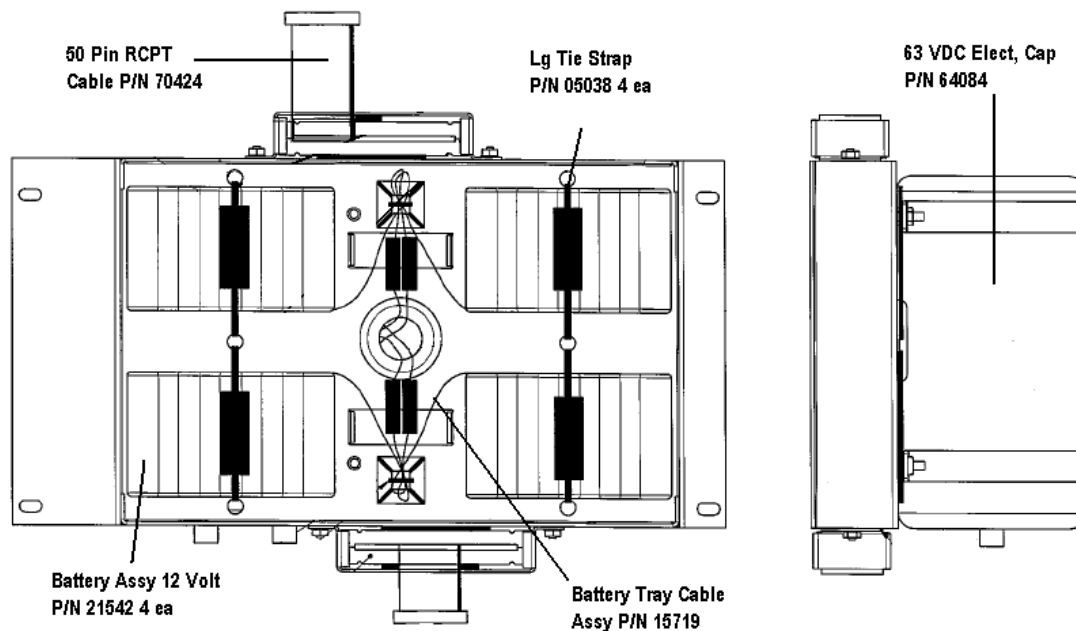


Figure 3.3 Battery Tray assembly

Removal

1. Remove the power cable and top cover.
2. Remove the (4) Phillips pan-head screws in the battery tray.
3. Lift the battery tray out of the unit.
4. Disconnect the batteries from the white Molex DC power connector

Note

When the batteries are disconnected, the system will automatically re-set the battery status memory and will initiate a 30-hour re-charge cycle upon re-connect. If the DC status light is not green after the initial charging period has expired, contact Cardinal Health tech support as described in Appendix A.

Installation

Follow removal process in reverse order

Right Panel Containing the Power PCB P/N 16351A

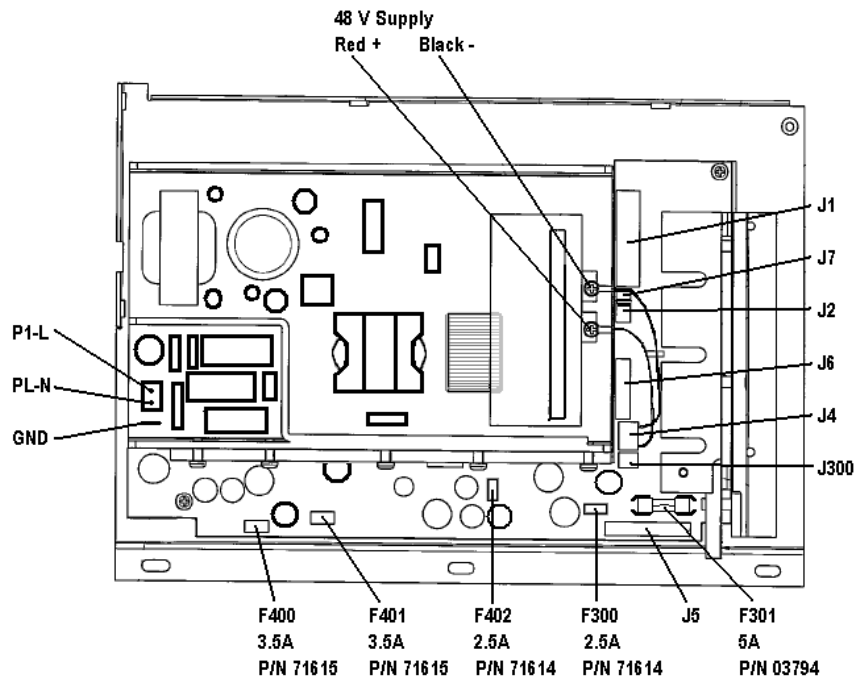


Figure 3.4 Power PCB Assembly

Note

The internal battery fuse is located on the power PCB. See F301 in figure 3.4..

Removal

1. Remove the power cable, top cover, and battery tray.
2. Remove the (2) Phillips countersink screws from the right side of the rear panel.
3. Remove the (1) Phillips countersink screw in the upper front of the right panel.
4. Remove the (1) Phillips pan-head screw in the lower center of the right panel.

Gently lift out the panel and the power PCB. Lay the panel flat and make the following disconnections:

5. On the Power PCBA disconnect the 26 pin ribbon cable at J1
6. On the Power PCBA disconnect the 2 wire (brown/black) connector at J7
7. On the Power PCBA disconnect the 3 wire connector at J2
8. On the Power PCBA disconnect the 10 wire connector at J6
9. On the Power PCBA disconnect the 2 wire (red/black) connector at J300
10. On the Power PCBA disconnect the 2 wire (black/white) connector at P1-L & P1-N
11. On the Power PCBA disconnect the ground wire (green/yellow) spade connector

Installation

Reconnect cables and follow removal process in reverse order

Front Panel P/N 16345A (S/N AHT07499 & Below)

Note: For further details on ordering the replacement front panels and Main PCB see Appendix B

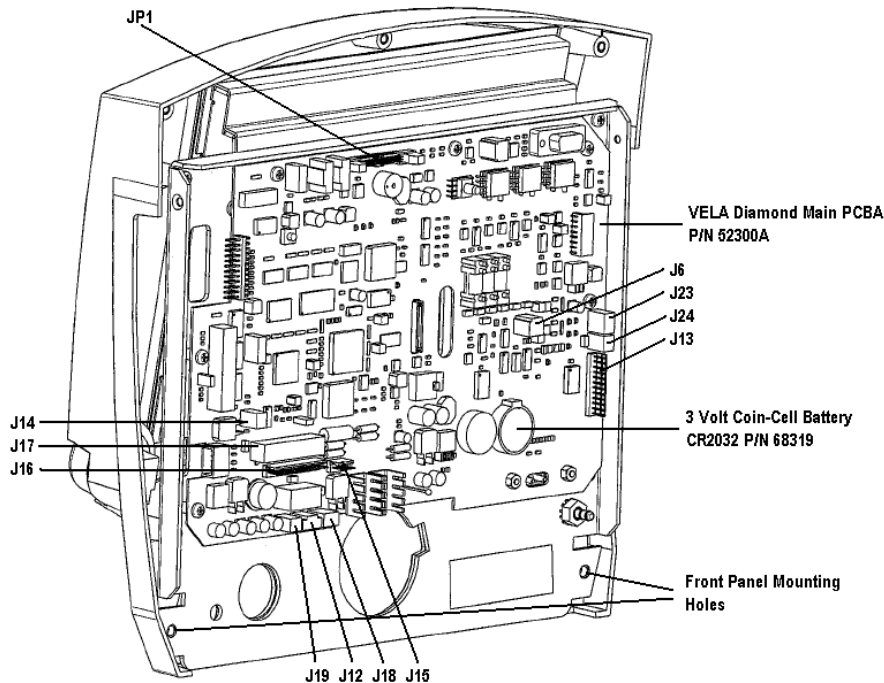


Figure 3.5 Front Panel Assembly

Removal

Remove the power cable, top cover, battery tray, right panel, and left panel.

From the Power PCBA side (Rt side) of the vent remove the following cables and tubing:

1. On the Main PCBA disconnect the 50-pin ribbon cable at JP1
2. On the Main PCBA disconnect the Insp Hold Solenoid cable at J14
3. On the Main PCBA disconnect the Power to Main ribbon cable at J17
4. On the Main PCBA disconnect the Power to Main wire cable at J16
5. On the Main PCBA disconnect the Alarm Loudness cable at J19
6. On the Main PCBA disconnect the O2 Cell cable at J12
7. On the Main PCBA disconnect the Nurse Call cable at J18
8. On the Main PCBA disconnect the Exhalation Valve cable at J15
9. On the Main PCBA disconnect the Gas dryer Tube from the Luer fitting

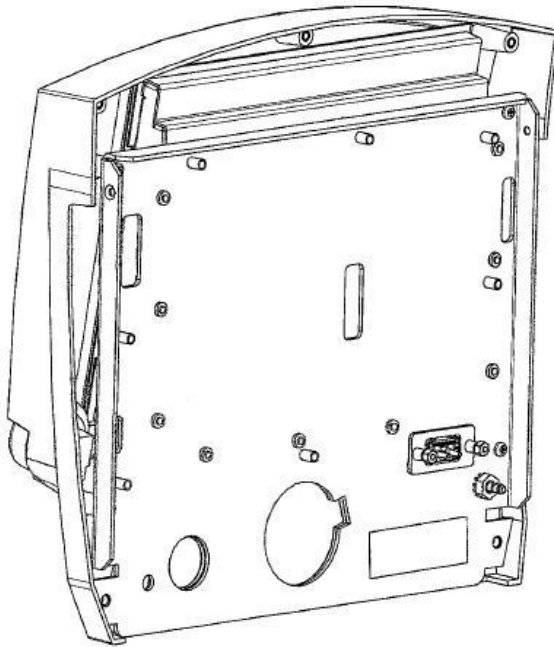
From the Left side of the Vent remove the following cables and tubing:

10. On the Main PCBA disconnect the O2 and Nebulizer Solenoids at J23 & J24
11. On the Main PCBA disconnect the Blender Cable Assy at J13
12. On the Main PCBA disconnect the Turbine Encoder cable at J6
13. On the Main PCBA disconnect the green Nebulizer tube assy
14. On the Main PCBA disconnect the 1/8 & 1/4 ID tubing from the turbine assy
15. Remove the two (2) front panel mounting screws from the back inside corners of the front panel assy.

Installation

Install Front Panel Assy and follow removal process in reverse order.

Front Panel for VELA ColdFire 2 (S/N AHT07500 & Above)



Note

All Front Panels for the ColdFire 2 ventilators (S/N AHT07500 & above) come without the Main PCB assemblies, The Main PCB must be ordered separately.

P/N 16687-0A VELA Basic Front Panel Used for Domestic English Overlay.

P/N 16687-1A VELA Plus Front Panel Used for Domestic English Overlay.

P/N 16687-2A VELA Comprehensive Front Panel Used for Domestic English Overlay.

P/N 16688-0A VELA Basic Front Panel Used for International ICON Overlay.

P/N 16688-1A VELA Plus Front Panel Used for International ICON Overlay.

P/N 16687-2A VELA Comprehensive Front Panel Used for International ICON Overlay.

Main PCB P/N 52300A (S/N AHT07499 & Below)

Main PCB P/N 52850A (S/N AHT07500 & Above)

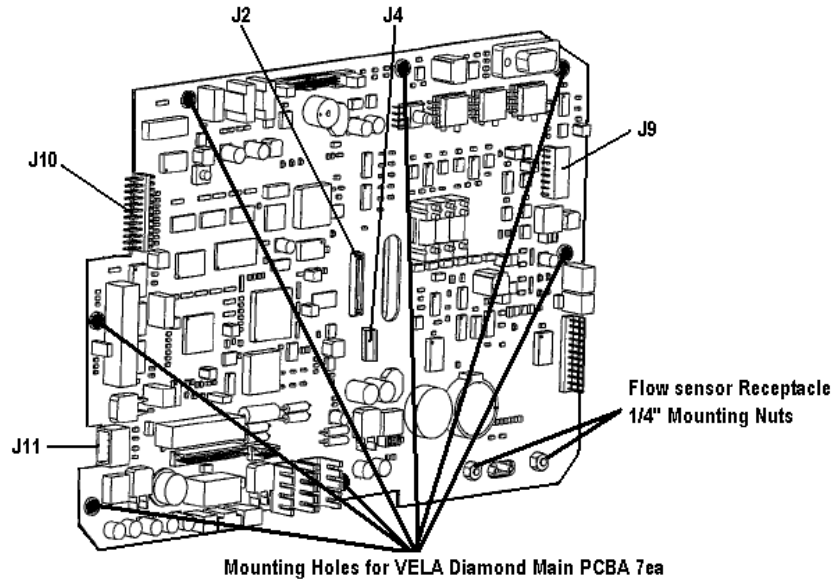


Figure 3.6 Main PCB Assembly

Removal

After removal of the Front Panel Assy, follow the steps below:

1. On the Main PCBA disconnect Soft key control panel flat cable at J10
2. On the Main PCBA disconnect Touch Screen flat cable at J9
3. On the Main PCBA disconnect the LCD 20 pin connector at J2 (center of PCB)
4. On the Main PCBA disconnect the Backlight Inverter cable at J4 (center of PCB)
5. Remove the seven (7) mounting screws securing the Main PCBA to the LCD Panel
6. Remove the two (2) 1/4" nuts securing the Flow Sensor Receptacle
7. Carefully lift the Main PCBA and disconnect the Optic Encoder cable at J11

Note

If you are not replacing the Main PCBA, and you have removed it to access other components do not remove the Pneumatic tubing

If you are replacing the Main PCBA, carefully replace each tube one at a time to ensure proper connection points

Installation

Install Main PCBA and follow removal process in reverse order

Flow Sensor Receptacle assembly P/N 16106

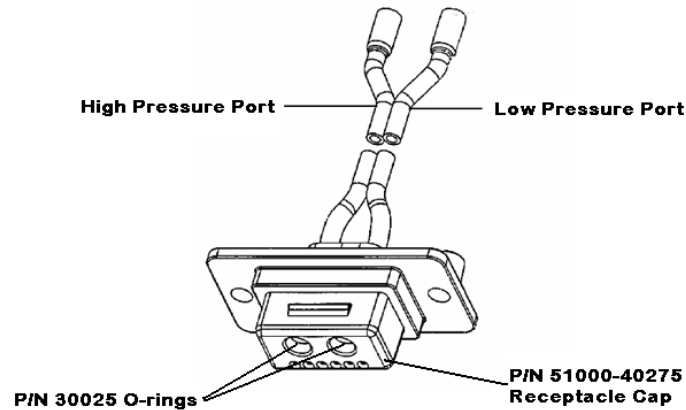


Figure 3.7 Flow Sensor Connector

Removal

After removal of the Front Panel and the Main PCBA the Flow Receptacle is accessible and can be removed by sliding the receptacle off of the threaded studs that are part of the LCD panel.

Installation

Follow removal process in reverse order

Exhalation Valve Assembly P/N 16417A

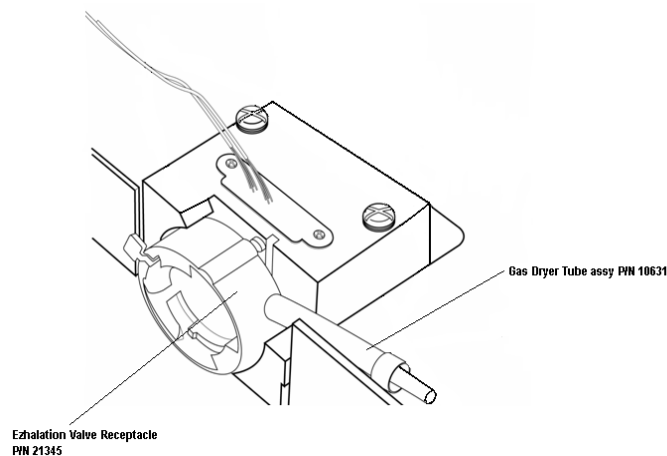


Figure 3.8 Exhalation Valve Assembly

Removal

After removal of the Front Panel Assy, follow the steps below:

1. Remove the two mounting screws securing the Exhalation Valve assy and remove.

Installation

Follow removal process in reverse order

Blender Assembly P/N 16358A

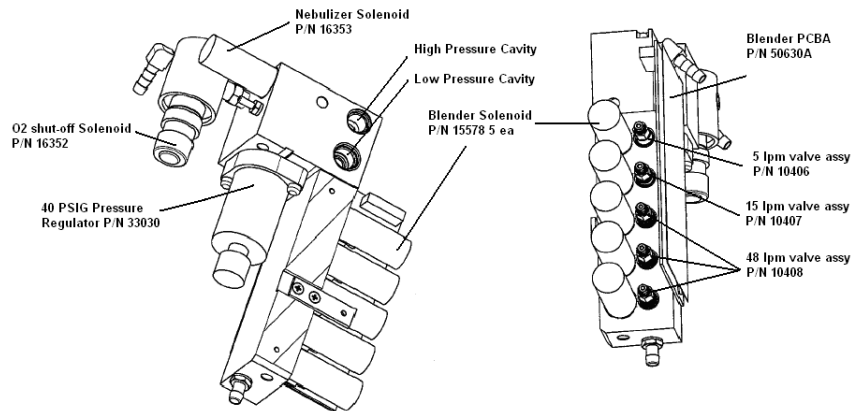


Figure 3.9 Blender assembly

Removal

1. Remove the power cable, top cover, battery tray, and left panel.
2. If the rear panel is installed, remove the high and low pressure oxygen fittings from the rear panel using a 3/4" wrench, noting that the high pressure fitting is located above the low pressure fitting.
3. On the Blender PCBA disconnect the 12 wire connector at J301
4. Remove the bottom strip ambient air inlet filter by pinching and pulling it out
5. Remove (3) Phillips pan-head screws on the right side of the rear panel.
6. Use needle-nosed pliers to disconnect the oxygen diffuser tube as you remove the blender assembly.

Installation

Follow removal process in reverse order

Note

When the blender is replaced or re-installed new screws will be required. These (3) screws, p/n 53002-56206, will be included with all blender assemblies. The screws can be ordered separately.

Turbine and Muffler Assembly P/N 16350 (Turbine reorder P/N 16349A)

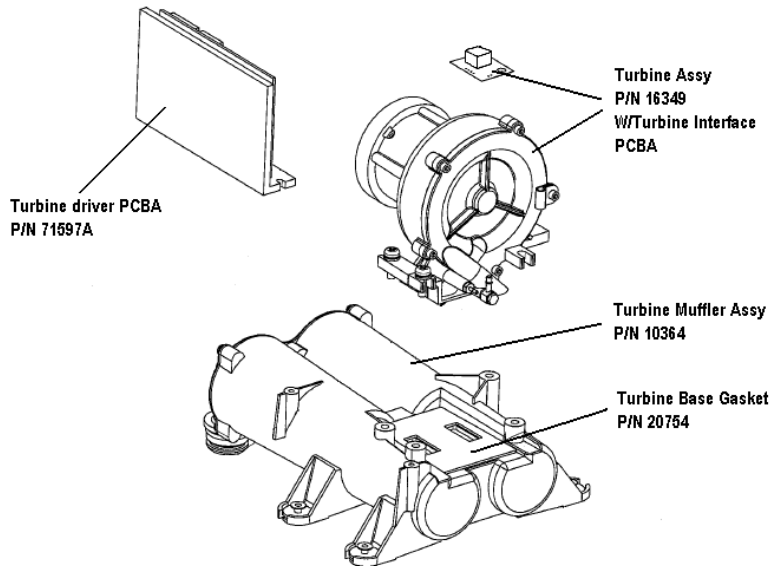


Figure 3.10 Turbine and Muffler Assembly

Removal

1. After the Blender assy has been removed
2. Disconnect the Main Wire Harness connector at P2 on the Turbine Driver PCBA
3. Remove the five (5) mounting screws securing the turbine muffler assy
4. Disconnect the Turbine Encoder Cable from the Main PCBA at J6
5. Lift out the turbine assy carefully.

Installation

Follow removal process in reverse order

Inlet Filter Screen P/N 21575

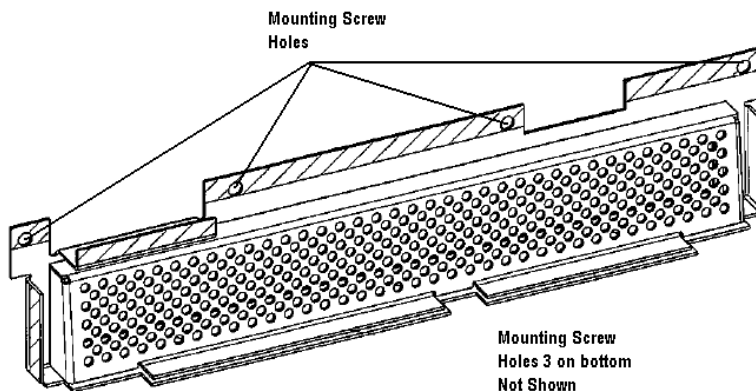


Figure 3.11 Inlet filter screen

Removal

1. Prior to removal of the Back Panel the Inlet Filter Screen must be removed.
2. Remove the seven (7) mounting screws securing the screen to the Manifold base assy

Installation

Follow removal process in reverse order

Oxygen Sensor P/N 16101

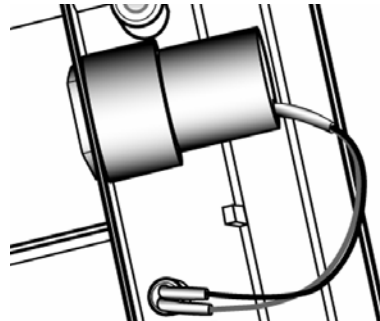


Figure 3.12 O2 Sensor Cell

Removal

After removing the inlet filter screen, you will be able to access the O2 cell.

1. The O2 sensor is visible on the left. Disconnect the O2 cell wire connector from the manifold base.
2. Twist and pull the O2 cell firmly to remove.

Installation

Follow removal process in reverse order

Rear Panel P/N 16346 (S/N AHT07499 & Below)

Rear Panel P/N 16559 (S/N AHT07500 & Above)

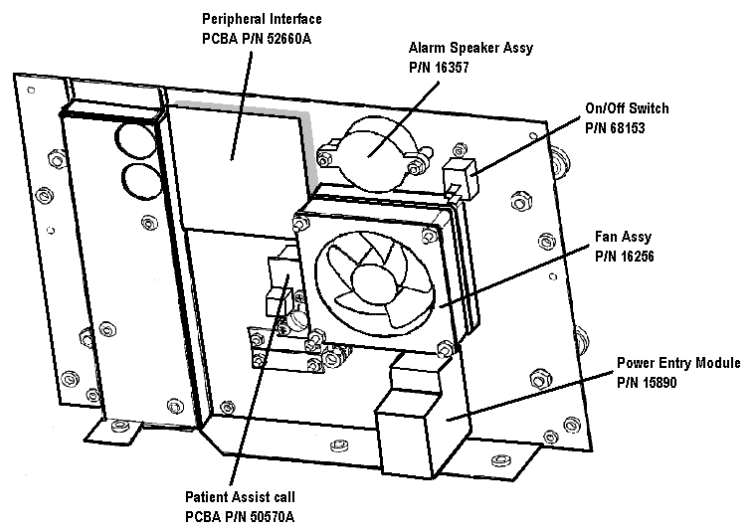


Figure 3.13 Rear Panel assembly

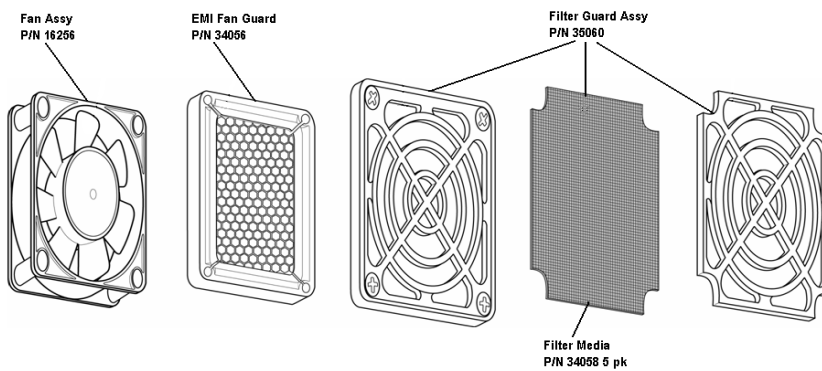
Removal

1. After the Turbine assy has been removed.
2. Disconnect the Remote Alarm cable connector at J2 on the Remote Alarm PCBA
3. Disconnect the Main Power Switch wires (brown/black) from Main Power switch.
2. Turn the unit on its side.
6. Remove (3) Phillips pan-head screws securing the rear panel to the Manifold Base assy.
3. Remove the rear panel from the manifold base.

Installation

Follow removal process in reverse order

Fan and Filter Assembly P/N 16256



Removal

1. With rear panel removed or with rear panel still installed, remove the 4 5/16ths nuts from fan assembly.
2. Slide the fan itself off of the four screws holding them in there place.

Installation

Follow removal process in reverse order.

Manifold Base Assembly P/N 16348

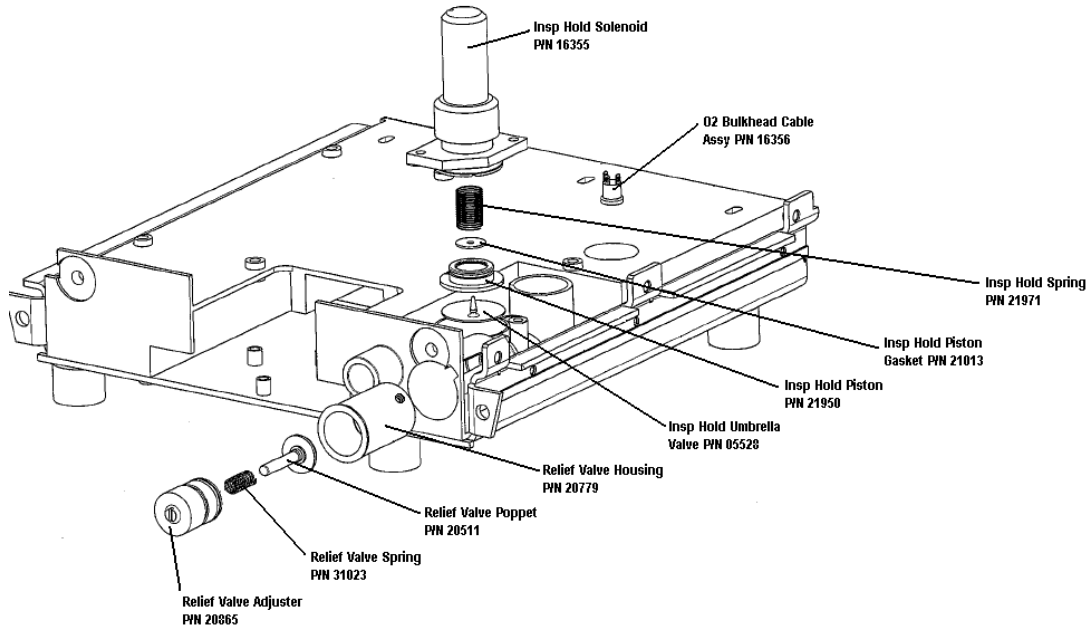


Figure 3.14 Manifold Base Assembly

Note

This manifold base is a complete assembly and can only be ordered as P/N 16348. It will come from the factory completely tested with components as pictured.

CAUTION

Further disassembly of the manifold base is not recommended. If further disassembly is performed there is no guarantee from Cardinal Health that the manifold will function properly

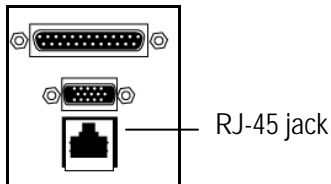
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Chapter 4: Software Download Procedure

Software Download

Follow the instructions below to load new software into the VELA™ ventilator. If you need assistance, contact a Cardinal Health representative.

1. Make sure the VELA Ventilator is powered OFF.
2. Assemble the adaptor, P/N 16392 (9-pin female connector to Ethernet cable adaptor), and Ethernet cable , P/N 70693.
3. Connect the 9-pin end of the adaptor, P/N 16392, to the 9-pin serial communication port connector of the computer being used to download the new software. If a serial communication port is not available on your computer, a USB to 9-pin serial adaptor is required to connect to P/N 16392.
4. Connect one end of the Ethernet cable, P/N 70693, to the RJ-45 jack on the back panel of the VELA Ventilator.



5. Ensure the other end of the Ethernet cable, P/N 70693, is connected to the 9-pin adaptor P/N 16392.
6. If you have the VELA Software Update CD (p/n 63663), insert the CD into the computer CD drive and proceed to step 9, otherwise acquire the VELA software update files from the Cardinal Health FTP site and proceed to the next step.
7. After downloading the VELA software update files from the Cardinal Health FTP site, use My Computer or Windows Explorer to navigate to the location where the files are stored on the computer. There are three files required for the VELA software update. It is important that these three files be in the same folder on the computer.

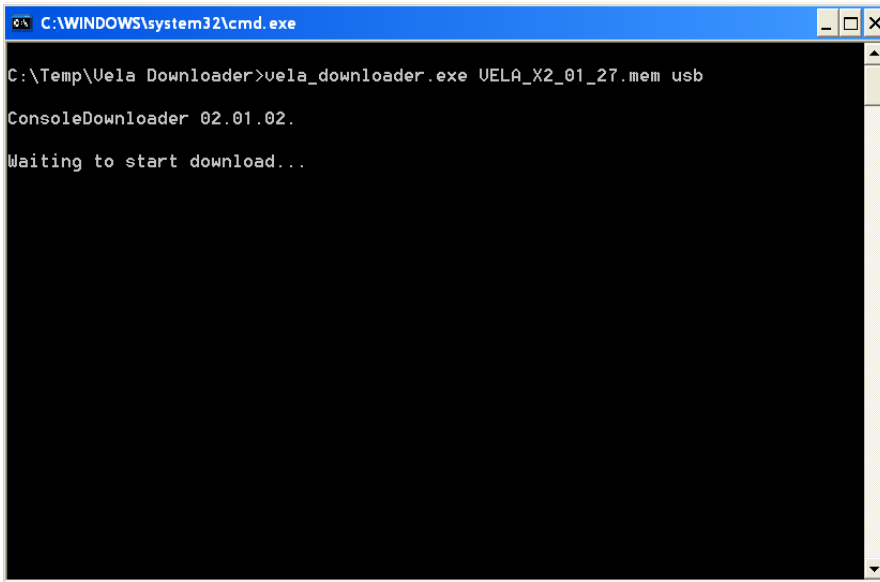
VELA_Downloader.exe

Start_VELA_Download.bat

VELA_XX_XX_XX.mem (where XX_XX_XX represents the Version of the VELA software)

8. Double-click the file *Start_VELA_Download.bat*.

A window similar to the one shown below opens.



```
C:\WINDOWS\system32\cmd.exe
C:\Temp\Ue1a Downloader>vela_downloader.exe UELA_X2_01_27.mem usb
ConsoleDownloader 02.01.02.
Waiting to start download...
```

9. Power ON the VELA ventilator.
10. The following messages will be added to the screen:

Load address:

Start address:

File size (# bytes):

The VELA ventilator then erases the old application software. Once this is completed, the ventilator starts receiving and loading the new application software. This will take approximately 8-9 minutes.

Note

The alarm sounds continuously during this time.

Ventilator Upgrade Procedure

Note

The VELA Ventilator has many modes and functions that can be purchased in addition to the basic configuration the vent is shipped with. These options will be available for purchase initially as well as available any time in the future. This procedure can only be accomplished after the purchase and sales order number have been verified. Technical Support can enable these other features in the ventilator after confirmation of added enhancements.

Chapter 5: One-Year P.M. Procedure

Contents of PM kit P/N 11416

2 ea	03808	Inlet assy O-Ring
2 ea	03895	Duckbill check valve
2 ea	03897	Delrin washer
2 ea	05186	Inlet assy O-Ring
1 ea	05528	Umbrella valve 1 1/4"
2 ea	06804	O2 inlet filters
1 set	10365	Muffler filter core assy.
2 ea	20819	Rear inlet filter
1 pk	33801	Fan filter media (small)
1 pk	34058	Fan filter media (large)
1 ea	21950	Piston , inspiratory valve
1 ea	21971	Compression spring
2 ea	30020	Filter end cap O-Ring
1 ea	31028	Insp check valve cover O-Ring
1 ea	31029	Insp piston O
1 ea	68319	Battery 3V coin cell
1 ea	21013	Inspiratory Valve gasket

General Instructions and Warnings

WARNING

Always disconnect the main power cord before removing the instrument cover and disconnect the battery once the top cover and battery tray have been removed to prevent injury and/or damage to the VELA Ventilator System

CAUTION

The VELA contains ESD susceptible components. Ensure you are properly grounded before performing any service or maintenance procedures and store ESD susceptible electrical components in an anti-static bag to prevent damage to the component.

Note

When the batteries are disconnected, the system will automatically re-set the battery status memory and will initiate a 24-hour re-charge cycle upon re-connect. During this period, the DC status light will remain red for Approximately 2 hours and Amber for 16-18 hours, then it will go to green and continue its trickle charge until complete.

If the charge cycle does not follow this sequence, please contact Cardinal Health technical support for further assistance.

Note

The terms left and right refer to a view from the front of the unit looking towards the rear.

Note

All personnel performing preventive maintenance and product repair must be trained and certified by Cardinal Health to service the product

Required Tools

- Philips screwdrivers
- Flat tip screwdrivers
- Needle nosed pliers
- ¾" Open end wrench

Procedure

Battery Duration Test

Below is a procedure that will identify batteries that need to be replaced as well as reset the Battery Charger Controller. This test procedure will take approximately one hour to complete. The following settings should be used for this test.

Control	Control Setting		Alarm	Alarm Setting
Breath Mode	Pressure A/C		Low Ve	0.1
Rate	80 bpm		High Rate	OFF
Insp Pres	75 cmH2O		Low Ppeak	OFF
Insp Time	0.5 sec		High Ppeak	120
PEEP	5 cmH2O		Apnea Interval	60
Flow Trigger	OFF			
O2	21%			

Battery Check Procedure

1. The vent should be connected to a properly grounded AC source for at least 24 hours prior to executing this procedure.
2. Install a patient circuit and test lung on the VELA.
3. Connect the VELA to a properly grounded AC source. Turn on power to the unit.
4. Set the VELA to the settings shown above.
5. Record the start time of the test.
6. Unplug the vent from the AC source so the vent is now operating on battery.
7. Run the vent for one hour. Any battery alarms should be ignored at this point.
8. If the vent does not run for an entire hour then turn the power switch off, the test is complete. **The batteries should be replaced.** If the vent is still running then proceed.

Note

Cardinal Health recommends that customers perform a Battery Performance Verification Test annually and change the batteries on the VELA at least every two years. Batteries should be changed sooner if deemed necessary in the performance verification testing.

9. If, during the one hour test period, there were alarms and alert messages, the Battery Charge circuit will need to be reset. During the P/M procedure this will be done when the batteries are disconnected. The Battery Charge Controller will be reset when the batteries are disconnected and then reconnected.
10. Turn off the VELA power switch and unplug from the AC source.

Replacing the ambient air filter.

The Ambient Air Filter (P/N 20819) is a high-density foam insert and is located at the rear of the ventilator below the rear panel, it can be accessed by removing seven screws holding the perforated aluminum cover. To remove it, pinch and pull it out of the aluminum cover. The filter will lift out. Replace with a clean filter.

Replacing the fan filter

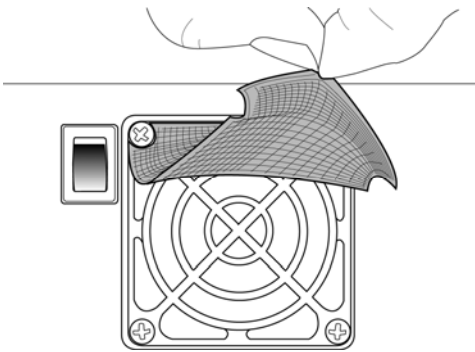


Figure 5.0 Pinch and remove foam fan filter

Pop out the fan filter retaining grid, using a flat tip screwdriver. Pinch & pull out the foam filter (Small filter P/N 33801, Large filter P/N 34058) (see figure 1).

To install a new filter, carefully place the new filter in the fan housing and place the retaining grid back onto the fan housing. Check to make sure there are no creases or folds in the foam filter as this will reduce its efficiency and could allow contaminants into the ventilator body. Push the retaining grid until all four "tabs" click into place.

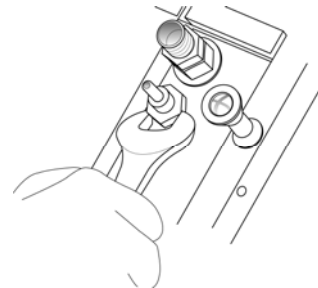


Figure 5.1 Unscrew the low pressure O2 fitting

Replacing the filter, retaining ring & check valve on the low pres O2 fitting

Using a $\frac{3}{4}$ inch open-end wrench, loosen and remove the low-pressure oxygen fitting from the back panel as shown in figure 2.



Remove the white cone filter P/N 06804 and dislodge & remove the white delrin retaining step washer P/N 03897 (use needle nose pliers if needed).

Using needle nose pliers, pull the black duck billed check valve P/N 03895 out.

Figure 5.2 White Delrin retaining step washer and duck billed check valve

To replace, take a new black duck billed check valve P/N 03895 and insert it into the fitting. Tap lightly with the end of a screwdriver to make sure it is seated then place a new delrin retaining step washer P/N 03897 over it with the "lip" facing towards the check valve. Place the new cone filter P/N 06804 onto the delrin washer and push gently until you are sure it has seated correctly. Replace the fitting and tighten down with the $\frac{3}{4}$ inch open-end wrench.

Replacing the filter, retaining ring and check valve on the hi pressure fitting

Using a $\frac{3}{4}$ inch open-end wrench, loosen and remove the threaded high-pressure oxygen fitting (this is a two-piece fitting, remove only the outer threaded retainer fitting). Remove the white cone filter, the white delrin washer & the black duck billed check valve as described above.

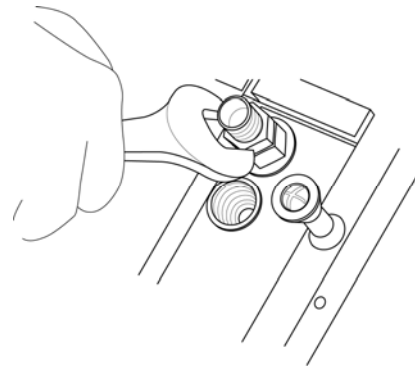


Figure 5.3 Unscrew the high pressure O2 fitting

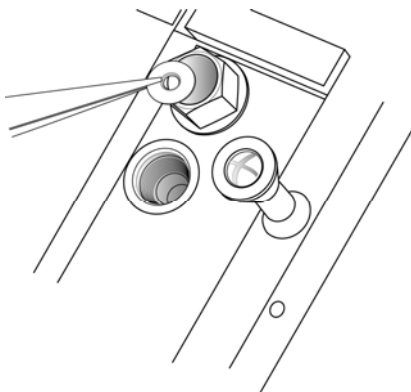


Figure 5.4 Installing the Delrin Washer

Install a new black check valve and make sure it is seated. Install a new white delrin washer with the lip down as shown in figure 5 and described above. Place the cone filter on the delrin washer and push gently to seat. Replace and tighten down the fitting with a $\frac{3}{4}$ inch open-end wrench.

Replacing the muffler and muffler filter assemblies

Note

Always take precautions against static discharge when working with the ventilator. Retain all hardware for re-assembly.

From the back panel, remove the power cord guard by unscrewing the two retaining screws as shown in figure 6. Unplug the power cord.

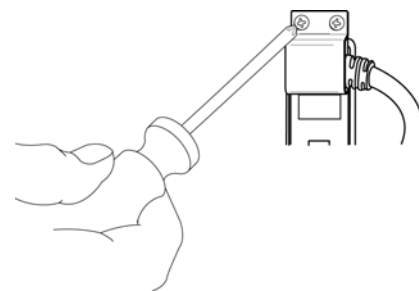


Figure 5.5 Removing the power cord guard

Unscrew the screws holding on the VELA cover. Slide cover towards the rear of the machine and lift off as shown in figure 7.

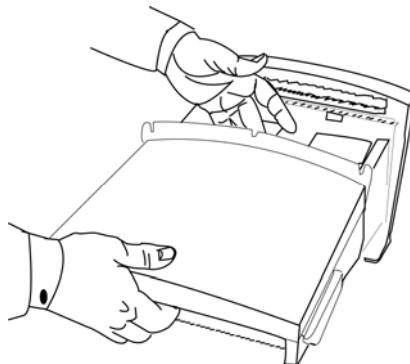


Figure 5.6 Slide cover off towards the rear

Remove the 4 screws securing the battery tray & lift it, and the attached large capacitor assembly out. Lean the battery tray and capacitor assembly against the left side of the VELA while you disconnect the large white Molex DC power connector shown in figure 8. Set the complete assembly aside.

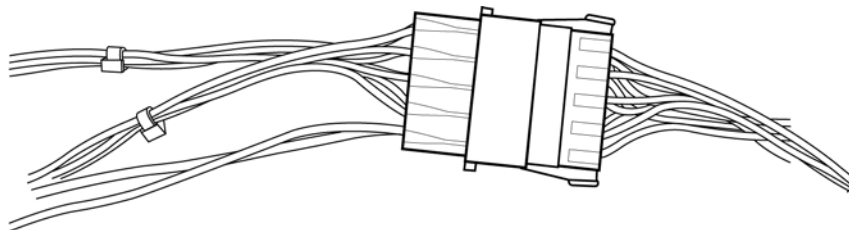


Figure 5.7 Battery Disconnect Molex Connector

Note

When the batteries are disconnected, the system will automatically re-set the Battery Charge Controller and will initiate an 28-hour re-charge cycle upon re-connection. During this period, the DC status light will remain red for approximately 2 hours and amber for 16-18 hours, then it will go to green and continue it's trickle charge until complete.

If the charge cycle does not follow this sequence, please contact Cardinal Health tech support for further assistance.

Remove the right panel. There are two screws securing the panel from the upper right back of the ventilator, one in the front top and three on the bottom edge of the panel.

Pull the panel out from the rear first, then ease it towards the back & tilt out. Lay the assembly flat. The Mufflers are now accessible.

Replacing the muffler/filter assemblies.

To remove & replace the muffler/filter Assemblies P/N 10365, first pull out the two silicone elbows from the muffler assembly end cap P/N 20714.

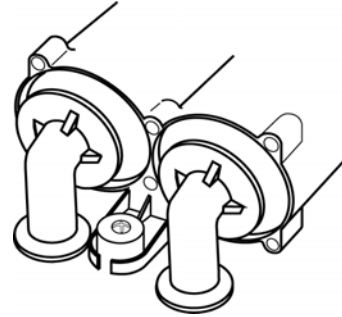


Figure 5.8 Turbine muffler W/ Elbows

Remove the 6 screws on the end cap.
Remove and replace the two black o-rings P/N 30020 on the end cap.

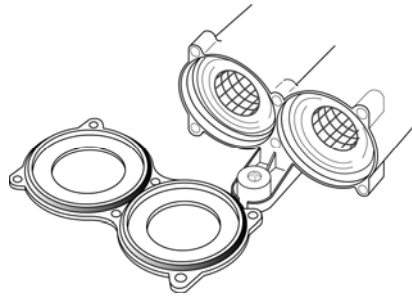


Figure 5.9 Muffler W/ end cap removed

Using needle nose pliers, firmly grasp the metal grid inside the R side muffler housing assy. Pull and remove the filter. Repeat with the left side muffler.

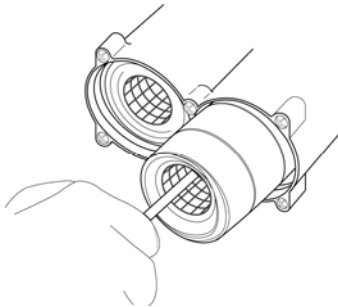
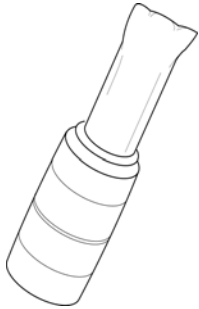


Figure 5.10 Removing the Filter Assembly



You will see that only the Right side muffler has a filter attached, the L side is a muffler only.

Figure 5.11 Filter assembly

To install the new muffler/filter assemblies P/N 10365, push the left side muffler (with no filter) firmly in and make sure it is pushed all the way into the housing. Insert the right side muffler with the filter, ensure that the seam on the filter is horizontal as you install and press home. Replace the Muffler housing end cap with the new O-rings and secure with six screws.

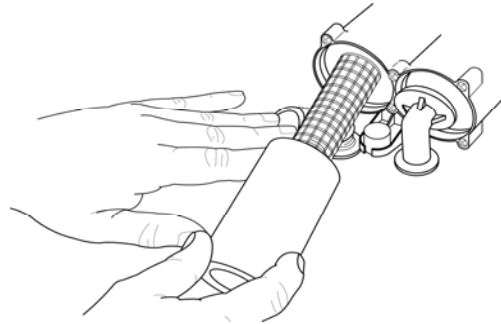
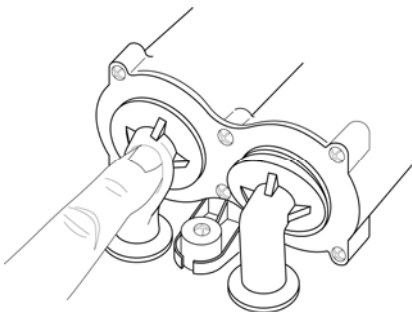


Figure 5.12 Muffler removal



Install the two silicone elbows into the muffler cover and push in the center to make sure they are seated.

Figure 5.13 Installing silicone elbows

Replacing the Inspiratory Check Valve.

1. Remove the inspiratory hold solenoid cable J302 from the Main PCB assy.
2. Remove (2) Phillips pan-head screws and lift out the solenoid. Remove the O-ring from the base mount and replace with new P/N 31028 O-ring.
3. Lift out the spring and check valve assembly and discard.

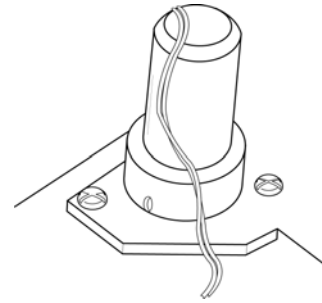


Figure 5.14 Inspiratory Hold Solenoid P/N 10346

4. Install the O-ring P/N 31029 on the new inspiratory piston P/N 21950.
5. Install the 1-1/4" Umbrella valve P/N 05528 into the bottom of the piston using a pair of needle nose pliers to gently pull it through the hole in the piston.
6. Install the silicone rubber washer P/N 21013 inside the piston and feed the nipple of the Umbrella valve through the center of the silicone washer. Use a pair of needle nose pliers and after you have fed the nipple through the center of the washer grasp the nipple and lightly pull on it until the washer can be placed at the base of the piston.
7. Place the inspiratory check valve in the base manifold cavity centering it.
8. Place the spring (P/N 21971) into the center of the check valve (P/N 21950).
9. Slip the solenoid over the spring using the guide in the base of the solenoid and seat into place.

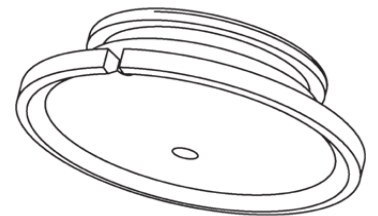


Figure 5.15 Inspiratory piston valve (P/N 21950)

Replacing the 3 volt coin battery on the Video PCB.

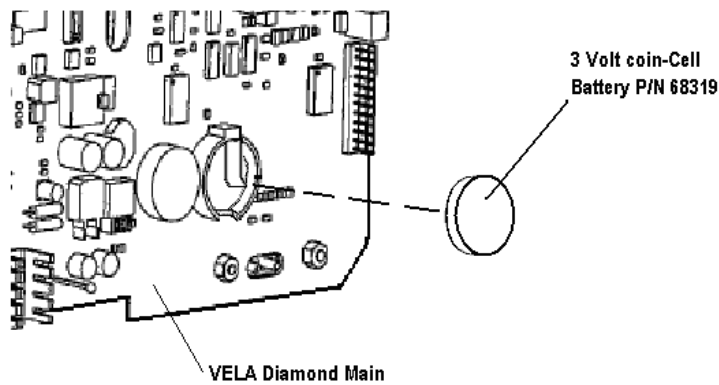


Figure 5.16 Main PCB W/3 volt coin cell location

1. Remove the front panel assembly and lay flat on level surface.
2. Remove 3 volt Coin-Cell, gently slip the old battery out being careful not to stress the holding arm spring.
3. Install new battery with care.
4. Reinstall the front panel assy.
5. Discard the battery in accordance with local laws.

Replacing the left panel w/power PCB and top cover assy.

1. Lean the right panel up to the VELA, slide in the front then push in the rear. Reattach the screws on the rear (2), front (1) and lower edge of the right side (3).
2. To install the battery tray, re-attach the large white Molex connector and make sure it lays between the muffler elbows as you replace the battery tray onto the VELA. This will ensure that there is enough space for the large capacitor attached to the Battery tray. Re-attach the 4 screws holding the battery tray in place. Reconnect the ribbon cable.
3. Slide the cover in place from the rear and push the top front edge home under the lip. Attach the (4) screws on the rear of the cover.
4. Reattach the power cord and re-attach the power cord guard with the two screws.
5. Perform Ventilator OVP and performance test. Chapter 7

Chapter 6: Calibration Procedure

Calibration

Note

All personnel performing preventive maintenance and product repair must be trained and certified by Cardinal Health to service the product

Test Set-up

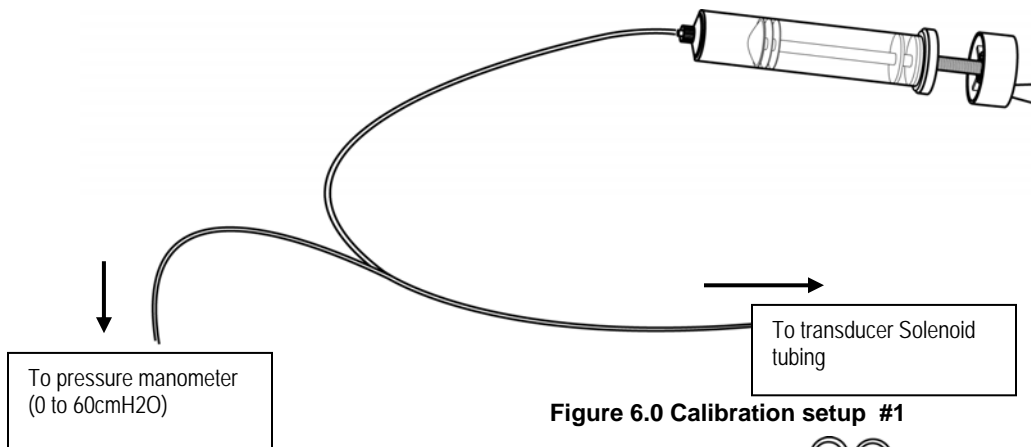


Figure 6.0 Calibration setup #1

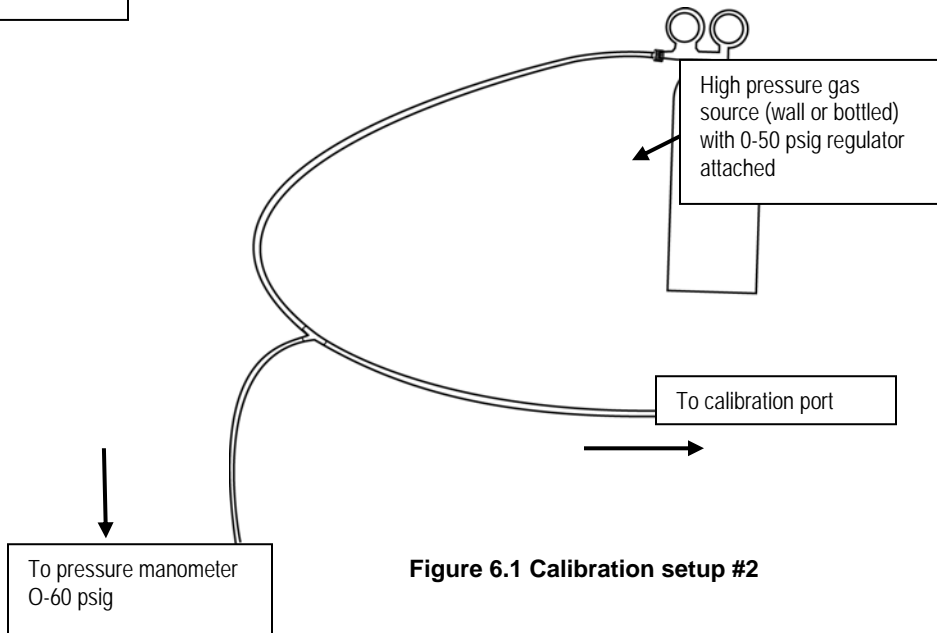


Figure 6.1 Calibration setup #2

Calibration and Test Kit

Note

Before calibrating the internal transducers, run the performance test to confirm that calibration is required. If the ventilator passes the performance tests calibration is not necessary.

Power Up Service Verification Tests

1. Remove the top cover and battery tray.
2. Locate DIP Switch pack at SW900 on top right of the Main PCBA.
3. Place switch #1 in on position and power vent on. See Figure 6.2

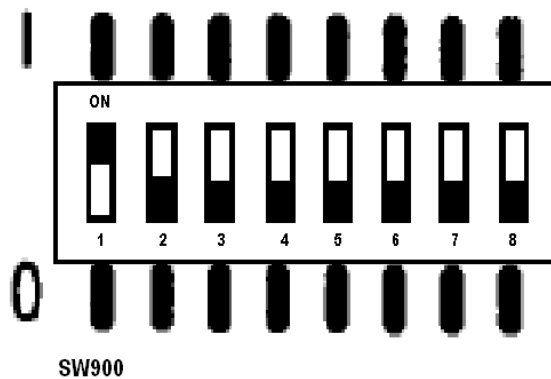


Figure 6.2 DIP Switch Pack (as pictured on PCB)

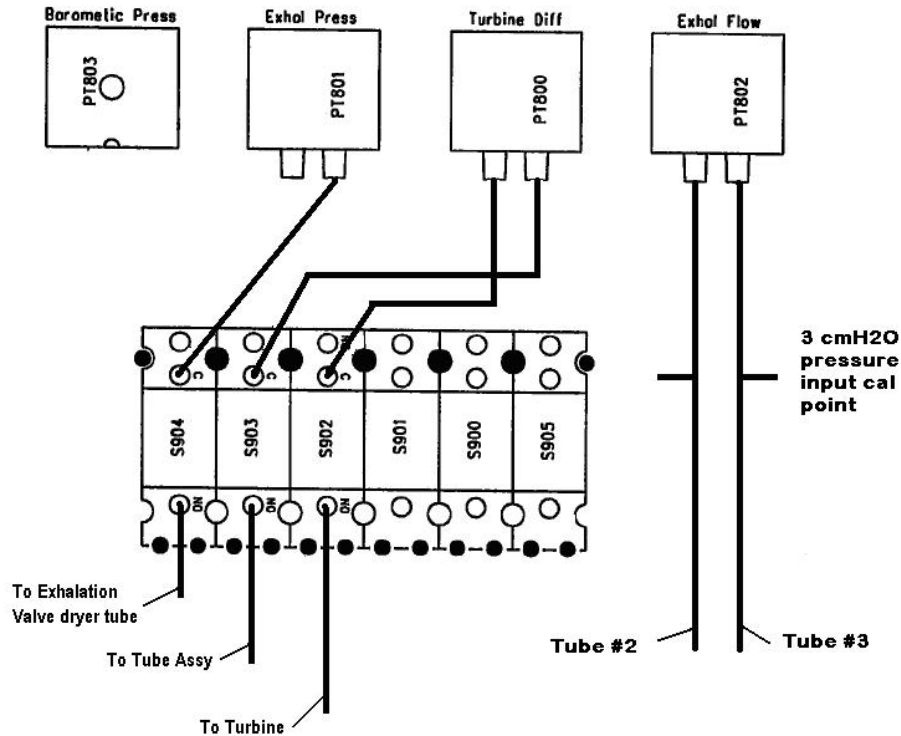


Figure 6.3 Transducer configurations as mounted on main PCB

Gas pressure release for calibration

1. Select Solenoids on SVT Test Screen.
2. Select "O2-0" it will read "ON" exit screen.

Screen Calibration

1. Select Touch Screen Calibration.
2. Using a stylus pen touch all three points as they appear on the screen. Verify calibration passed.
3. If calibration does not pass, repeat calibration process until it does pass.

CAUTION

Do not remove tubing from the transducers or the solenoids mounted below the transducers. Damage may occur to these components if tubing is removed.

Exhalation Pressure Transducer Calibration

1. Follow the tube connected to the bottom port of solenoid S904 and disconnect tubing at the larger side 1/8th end of the luer-lock connector. See figure 6.3
2. Select "EXLPRESS XDCR" on screen.
3. Select "PRESSURE APPLIED" to set the zero pressure reference.

4. Verify "OK" appears next to "0" press.
5. Connect test set-up #1 as shown in figure 6.0.
6. Connect calibration tubing to the tube listed in figure 6.3 labeled "to exhalation valve dryer tube" (S904)
7. Apply 60cmH₂O of pressure to the transducer. Allow pressure to stabilize for 3-4 seconds. Press the "PRESSURE APPLIED" button to confirm the 60cmH₂O span calibration.
8. Verify "O.K." is displayed next to the 60. Select "Save Calibration" to store settings.
9. Reconnect the tubing to the luer-lock connector.

Turbine Pressure Transducer Calibration

1. Follow the tube connected to the bottom port of the solenoid S903 and disconnect the tube at the larger end of the 1/8th end of the tube assembly connector.
2. Select "TURB PRESS XDCR" on screen.
3. Select "PRESSURE APPLIED" to set the zero pressure reference.
4. Verify "OK" appears next to "0" press.
5. Connect test set-up #1 as shown in figure 6.0.
6. Connect calibration tubing to the tube listed in figure 6.3 labeled "to tube assy" (S903)
7. Apply 60 cmH₂O of pressure to the transducer. Allow pressure to stabilize for 3-4 seconds. Press the "PRESSURE APPLIED" button to confirm the 60 cmH₂O span calibration (± 0.6 cmH₂O).
8. Verify "O.K." is displayed next to the 60. Select "Save Calibration" to store settings.
9. Reconnect the tubing to the tube assembly connector.

Exhalation Flow Transducer Calibration

1. Install the flow sensor adaptor to the flow sensor receptacle P/N 51000-40078, provided in the Calibration kit
2. From PT802 follow the tube labeled "High Pressure side of flow sensor receptacle" in figure 6.3 down to the 1/16th tee connector. At the tee connector turn and follow over to the tubing connector and disconnect at the larger 1/8th side of the tubing connector.
3. Select "XFLOW XDCR" on screen.
4. Select "PRESSURE APPLIED" to set the zero pressure reference.
5. Verify "OK" appears next to "0" press.
6. Connect test set-up #1 as shown in figure 6.0.
7. Connect calibration tubing to the tube listed in figure 6.3 labeled "Tube #3" that was disconnected from the tee.
8. Apply 3 cmH₂O of pressure to the transducer. Allow pressure to stabilize for 3–4 seconds. Press the "PRESSURE APPLIED" button to confirm the 3 cmH₂O span calibration (± 0.3 cmH₂O).
9. Verify "O.K." is displayed next to the 3. Select "Save Calibration" to store settings.
10. Reconnect the small tubing to the tee connector it was disconnected from.

O2 Pressure Transducer Calibration

1. Apply 50 PSI to the high pressure O2 inlet on the rear of the ventilator.
2. Select "**O2 PRESS**" (you should hear the gas flow from the front nebulizer port) now turn gas pressure off and disconnect the high pressure gas hose from the high pressure inlet on the rear of the ventilator.
3. Select "**Pressure Applied**" to set a zero pressure reference.
4. Verify "**OK**" appears next to "**0**" press.
5. Connect test setup #2 as shown in figure 6.1 to the front panel nebulizer port and regulate oxygen to 50 PSIG +/- 0.5 PSIG.
6. Select Nebulizer button on right front panel to allow gas to reach the blender internal transducer. Allow pressure to stabilize for 3-4 seconds. Press the "**PRESSURE APPLIED**" button to confirm the 50 PSIG span calibration.
7. Verify "**O.K.**" is displayed next to the "**50**" press. Select "**Save Calibration**" to store settings.
8. Turn off gas supply and disconnect the test setup.

Exhalation Valve Characterization

1. Reconnect the battery tray at this time.
2. Manual pressure relief should be set to maximum position fully clockwise.
3. Select "**Exhale Valve**" on screen.
4. Connect 30" reusable circuit tubing P/N 09531 from the vent output to the exhalation valve body port.
5. Select "Start calibration". This process will take 4-6 minutes
6. Verify calibration passed.

Note

*Before calibrating the FIO2 Monitor verify that the altitude is set correctly and vent has been running for a minimum of 30 minutes to ensure that the sensor is at proper operating temperature.
The FIO2 monitor calibration is located in the UVT screen.*

FiO2 Monitor Calibration

1. Connect 50 PSIG O2 source to the high pressure O2 inlet assembly
2. Enter "Extended Functions" screen and select "Vent Setup"
3. Select "FiO2 Monitor Enable" only if "FiO2 Monitor Disable" is showing
4. Select exit and return to "Extended Functions" screen.
5. Select the "FiO2 monitor Calibration" button and perform a complete calibration of both the ambient and the 100% calibrations. This may take 3-5 minutes each.

Blender FIO2 Calibration

1. Make sure the ventilator is in normal operating mode before adjusting the blender. The switch #1 on the SW900 must be in the "OFF" position.
2. Connect 50 PSIG O2 source to high pressure inlet assembly.
3. Attach a test circuit made of reusable patient tubing with the test lung p/n 33754
4. Power up ventilator and make the following adjustments to settings on front panel.

Set Ventilator parameters as follows:

Mode:	Volume Assist Control
Volume:	500 ml
Peak Flow	60 lpm
Breath Rate	12 bpm
PEEP	5 cmH ₂ O

Adjust all other controls and alarm limits out of range of operation to either "OFF" or min/max settings for alarms.

5. Set the O2 setting for 30% on front control panel and allow reading to settle for 1 minute.
6. On the side of the blender there are five solenoids and five needle valves see Figure 3.9 page 16, using a 3/16's nut driver loosen the top jam nut on the 5 LPM needle valve in the top position of the blender aluminum block. Using a 1/16th inch hex head wrench insert the tip through the hole in the jam nut and adjust the needle to either increase FIO2 value (counter clockwise) or decrease (clockwise) to achieve a reading of 30% +/- 1%. **The adjustment must be made within the first 1.5 Minutes of setting the FIO2 of 30%.**
7. Tighten the Jam nut and allow reading to settle within Specifications.
8. Set the O2 setting for 90% on the front control panel and allow reading to settle for 1 minute.
9. Repeat above procedure, adjusting the 15 LPM needle valve, this valve is the second valve from the top of the blender aluminum block. Adjust it as mentioned above for the monitored value of 90% +/- 1%.
10. After making final adjustments to the blender 5 LPM and 15 LPM needle valves and making sure the needle valve jam nuts are secure. Check all settings of the FIO2 range from 21% to 100%.
10. Check the O2 settings and confirm that accuracy is within +/- 3% through-out the blender range.

Chapter 7: Operational Verification Procedure

1.0 UVT Functions Screen

1. Connect ventilator to a properly grounded A/C electrical outlet.
2. Install diaphragm P/N 16240, Valve Body P/N 20005, and Flow sensor P/N 15972 to the front of the ventilator.
3. Press and hold the "ACCEPT" button on front panel as you turn on the ventilator. Continue to hold the "ACCEPT" button until vent boots-up completely.
4. Select "Patient Removed"

1.1 Select Lamp Test

1. Verify all LED's are flashing, except AC and Charge Status.
2. Verify the Display Monitor "Lamp Test-in Progress-ON/OFF"

1.2 Select Switch Test

1. Press the "ACCEPT" button once "ACCEPT" will be displayed in monitor window
2. Press the following switches and verify the correct name of the switch pressed appears in monitor window.

<u>Switch Activated</u>	<u>Message in Window</u>
ALARM SILENCE	Silence
ALARM RESET	Reset
FREEZE	Freeze
INSP HOLD	INSP Hold
MANUAL BREATH	Manual Breath
EXP HOLD	EXP Hold
NEBULIZER	Nebulizer
100% O2	100% O2
PANEL LOCK	Lock
ACCEPT	Accept
CANCEL	Cancel

1.3 Select Alarm Test

1. Verify Alarm Activates
2. Verify Alarm loudness function
3. Press "Alarm Test" and verify Alarm Deactivates

1.4 Select LCD Test

1. Select "Dim Screen" and verify screen intensity level dims
2. Select "Bright Screen" and verify the screen returns to normal intensity
3. Select "Video Normal" and verify Screen has turned white
4. Select "Video Inverse" and verify the screen returns to normal operation

1.5 Connect Leak Test Circuit to the ventilator and select "Leak Test"

1. Completion of the test takes about 15 seconds
2. Verify test passes.
3. Turn ventilator off.

Note

If any test does not pass, do not continue with performance test. Turn to Chapter 9 "Troubleshooting" section under "UVT Test" Tests and follow the troubleshooting guide for the failed test.

- Disconnect the Leak Test circuit and connect a suitable permanent Patient Test Circuit (*Do not use disposable circuits for testing purposes*) using the Siemens test lung P/N 33754 to continue the "Performance Tests"

2.0 Performance Test

1. Ensure that a 50 PSIG Oxygen gas source is connected to the High Pressure inlet assembly on the rear of the VELA. Connect the VELA power cord to a properly grounded AC outlet.
2. Press and hold the "ACCEPT" button on front panel as you turn on the ventilator. Continue to hold the "ACCEPT" button until vent boots-up completely and you are in the "UVT" screen.
3. Enter the Extended Functions screen and ensure the FiO2 Monitor is "ENABLED".
4. Select the "VENT SETUP" button and select the FiO2 Monitor Calibration button.
5. Select the "Start Ambient Calibration" button and ensure the cal is complete and valid; this can take up to 3-5 minutes to complete.
6. Select the "Start 100% Calibration" button and ensure the cal is complete and valid; this can take up to 3-5 minutes to complete.
7. After FiO2 calibration is successful exit the calibration screen, exit the extended functions screen

Set Ventilator parameters as follows:

Mode:	Volume Assist Control
Volume:	500 ml
Peak Flow	20 lpm
Breath Rate	12 bpm
PEEP	0 cmH ₂ O

8. Adjust all other controls and alarm limits out of range of operation to either "OFF" or min/max settings for alarms. Turn off ventilator.

2.1 Delivered Volume Test

1. Power ventilator on.
2. Press the "MAIN" icon on the top center screen; select the "Extended Functions" button; select the "Vent Setup" button.
3. Select the "Altitude" button (far right of window) and set current locations proper altitude before continuing.

Note

There are many different and varied types of Pressure/Volume measurement devices used in calibration and functional testing. It is not the intention of Cardinal Health to suggest the use of any one particular device over another. Whatever device is used should have the capabilities to measure pressures and volumes accurately.

4. With the ventilator in normal operating mode with parameters set as listed above.
5. Measure the delivered volume from ventilator with Peak Flow of 20 lpm. Results must be within 10% of volume setting, i.e. 500 ml +/- 50 ml
6. Measure the delivered volume from ventilator with Peak Flow of 60 lpm. Results must be the same as mentioned above.
7. Measure the delivered volume from ventilator with Peak Flow of 80 lpm. Results must be the same as mentioned above.

Note

If this test does not pass, do not continue with performance test. Turn to Chapter 9 "Troubleshooting" section under "Delivered Volume Test" and follow the troubleshooting guide for the failed test.

2.2 Monitored Volume Test

Note

Perform this test only after the "Delivered Volume Test" has been completed and the results are acceptable with tolerances provided.

Set Ventilator parameters as follows:

Mode:	Volume Assist Control
Volume:	500 ml
Peak Flow	60 lpm
Breath Rate	12 bpm
PEEP	5 cmH ₂ O

- Adjust all other controls and alarm limits out of range of operation to either "OFF" or min/max settings for alarms.
 1. Allow ventilator to operate at these settings for one minute.

2. Check ventilator monitors for the following results:

Minute Volume	6L +/- 1.2 L
Tidal Volume	500 ml +/- 100 ml
I:E Ratio	1:6.3 +/- 10%
Breath Rate	12 bpm +/- 2 bpm
PIP	Equal to manometer +/- 5 cmH ₂ O
PEEP	5 cmH ₂ O +/- 2 cmH ₂ O
Inspiratory Time	1.15 sec +/- 0.5 sec

Note

If this test does not pass, do not continue with performance test. Turn to Chapter 9 "Troubleshooting" section under "Monitored Volume Test" and follow the troubleshooting guide for the failed test.

2.3 FiO₂ Performance Test

Note

Perform this test only after the "Delivered Volume Test" has been completed and the results are acceptable with tolerances provided.

1. Ensure that a 50 PSIG Oxygen gas source is connected to the High Pressure inlet assembly on the rear of the VELA.
2. Continue to operate ventilator with current settings from monitored volume tests.
3. Select FiO₂ monitor window on left side of screen to read monitored O₂ results.
4. With control setting at 21% the monitored value should read 20-22%.
5. Adjust % O₂ control setting to 30%, the monitored value should read 27-33%.
6. Adjust % O₂ control setting to 60%, the monitored value should read 55-65%.
7. Adjust % O₂ control setting to 90%, the monitored value should read 85-95%.
8. Adjust % O₂ control setting to 100%, the monitored value should read 95-100%.
9. Adjust % O₂ control setting to 21%, the monitored value should read 20-22%.

Note

If this test does not pass, do not continue with performance test. Turn to Chapter 9 "Troubleshooting" section under "FiO₂ Performance Test" and follow the troubleshooting guide for the failed test.

2.4 Battery Performance Tests

Mode	Pressure AC
Breath Rate	80 BPM
Insp Press	75 cmH ₂ O
Insp Time	0.5 sec
PEEP	5 cmH ₂ O

1. Prior to executing the following test perform a battery charge controller reset. To properly reset the charge controller you must disconnect the batteries from the power PCB, after vent cover is removed disconnect one of the battery connectors. Connect AC and power vent up to operation and then power down, reconnect the batteries and follow steps below.
2. The vent should be connected to a properly grounded AC source for at least 24-30 hours after battery charge controller reset.
3. Install a patient circuit and test lung on the VELA.
4. Turn on power to the unit.
5. Set the VELA to the settings shown above.
6. Record the start time of the test.
7. Unplug the vent from the AC source so the vent is now operating on battery.
8. Verify the "On Battery Power" message is displayed on the alarm banner top right.
9. Run the vent for one hour.
10. If the vent does not run for an entire hour then turn the power switch off, the test is complete. **The batteries should be replaced.**

Note

Cardinal Health recommends that customers perform a Battery Performance Verification Test annually and change the batteries on the VELA at least every two years. Batteries should be changed sooner if deemed necessary in the performance verification testing.

11. If the ventilator operated for the one hour period without interruption or alarms the batteries can be considered operational and ready for use.
12. Turn off the VELA power switch and unplug from the AC source.

Note

If this test does not pass, do not continue with performance test. Turn to Chapter 9 "Troubleshooting" section under "Battery Performance Test" and follow the troubleshooting guide for the failed test.

2.5 Touch Screen Calibration

1. Enter the SVT Calibration screen as described in Chapter 6
2. Select Touch Screen Calibration.
3. Using a stylus pen touch all three points as they appear on the screen. Verify calibration passed.
4. If calibration does not pass, repeat calibration process until it does pass.

2.5 Battery Status Verification

1. Charge battery to minimum 80% capacity before returning to service.
2. Verify voltage capacity
3. Access the SVT mode. Access "Transducer Data". Choose "Analog X" any one showing will do. Rotate the control knob until IB (Internal Battery) is selected press accept. Exit screens and return to the wave form screen. In the area just above one of the wave forms that shows what the wave form represents you can touch this and a menu window will appear rotate the control knob until the "Analog X" that you set IB in is selected then press accept. The wave form will now represent a battery capacity. You can see this voltage by pressing the freeze button and the voltage value will appear next to the cursor line, with a green status light this voltage should read above 80% of full charge. The charge scale is 1.0 to 4.0, 1.0 being 0 charge and 4.0 being Fully charged. The formula to find the percent of charge for the VELA internal batteries is;

$$\# - 1.0 \div 3 \times 100 = \% \text{ of charge}$$

$$3.4 - 1.0 = 2.4 \div 3 = 0.8 \times 100 = 80 \% \text{ of full charge capacity}$$

If ventilator passes the UVT and Performance Tests the Ventilator is performing to specifications and may be put into service.

Operational Verification Procedure Checklist

This checklist is for use during the VELA Operational Verification Procedure.

Serial Number Ventilator _____ Hours _____ Date _____

Serial Number Turbine _____

Verification Steps:

Verification Step	Check & Initial
Inspect the ventilator and components for appearance and cleanliness. Confirm the Exhalation valve, diaphragm, and air intake filter and test lungs are correctly installed. Wipe the ventilator clean if needed using a cloth moistened with an approved cleaning solution.	<input type="checkbox"/>
1.0 Enter the User Verification Test (UVT).	<input type="checkbox"/>
1.1 Lamp Test Verification	<input type="checkbox"/>
1.2 Switch Test Verification	<input type="checkbox"/>
1.3 Alarm Test Verification	<input type="checkbox"/>
1.3 Alarm Loudness Verification	<input type="checkbox"/>
1.4 LCD Test Verification	<input type="checkbox"/>
1.5 Leak Test Verification	<input type="checkbox"/>
2.0 Performance Test Set Parameters for Delivered Volume Test	<input type="checkbox"/>
2.1 Step #9 Delivered Volume Test at 20 lpm	<input type="checkbox"/>
2.1 Step #10 Delivered Volume Test at 60 lpm	<input type="checkbox"/>
2.1 Step #11 Delivered Volume Test at 80 lpm	<input type="checkbox"/>
2.2 Monitored Volume Test Adjust Set Parameters for Monitored Test	<input type="checkbox"/>
2.2 Step #2 Monitored Volume Test Verification	<input type="checkbox"/>
2.3 FiO2 Performance Test Parameters for Fio2 monitoring test	<input type="checkbox"/>
2.3 Step #4 Monitored Value @ 21% setting 20-22%	<input type="checkbox"/>

- 2.3 Step #4 Monitored Value @ 30% setting 27-33%
- 2.3 Step #4 Monitored Value @ 60% setting 55-65%
- 2.3 Step #4 Monitored Value @ 90% setting 85-95%
- 2.3 Step #4 Monitored Value @ 100% setting 95-100%
- 2.3 Step #4 Monitored Value @ 21% setting 20%-22
- 2.4 **Battery Performance Test Parameters for Battery Duration Test**
- 2.4 Step #1 Battery Charge Controller Reset
- 2.4 Step #6 Record Start time of test ____:____
- 2.4 Step #8 Verify "On Battery Power" message
- 2.4 Step #10 Battery Performance and Duration Test Verification
- 2.5 Touch Screen calibration
- 2.6 Charge Status Verification

Signature: _____

Procedure Complete

Chapter 8: Troubleshooting/Codes/Messages

UVT Test Troubleshooting

Problem	Possible Cause	Action
Lamp Test has various LED's that do not light during test	Front Control Panel has open traces to lights or damaged LED's	Replace Control Panel P/N 80519 and Overlay P/N 80520-01 English P/N 80520-00 Icons
During Switch Test not all switches activate with indicated nomenclature	Front Control Panel has open traces to switches or damaged switches	Replace Control Panel P/N 80519 and Overlay P/N 80520-01 English 80520-00 Icons
Alarm Test fails to activate	<p>Front Control Panel has open traces to switches or damaged switches.</p> <p>Alarm speaker is not functional.</p>	<p>1. Replace Control Panel P/N 80519 and Overlay P/N 80520-01 English 80520-00 Icons.</p> <p>Check Speaker wires to speaker and main PCB ensure proper connection.</p> <p>Replace Alarm speaker Assy. P/N 16357</p>
Leak Test fails	<ol style="list-style-type: none"> 1. External circuit leaks, wrinkled exhalation diaphragm, valve body damaged. 2. Pressure relief valve not set. 3. Internal tubing leaking. 4. Insp hold solenoid leaking 5. Anti-suffocation check valve leaking or damaged. 6. Manifold base o-rings damaged, or manifold cracked. 	<ol style="list-style-type: none"> 1. Ensure circuit is a reusable permanent type. Turn ventilator off. Remove Valve Body and reseal the diaphragm assy. Inspect and replace valve body if damaged. 2. Adjust relief valve clockwise until seated completely. 3. Check dryer tube luer lock connectors for tightness. 4. On top of Insp Hold Solenoid are two wires press with thumb between these wires during the test. If leak stops call Cardinal Health Technical Support. 5. Pull Turbine outlet boot out of the manifold and look in boot cavity for Check Valve P/N 20651. If missing replace. 6. Remove bottom plate of manifold and remove the red silicone O-ring's. Inspect O-ring grooves for cracks, if found replace manifold assy. P/N 16348.

Delivered Volumes Test Troubleshooting

Problem	Possible Cause	Action
Delivered volumes are out of the 10% specification.	<ol style="list-style-type: none"> Altitude setting is not accurate for location. Transducer has drifted over time. Turbine filters are dirty. Turbine characterization is no longer valid. 	<ol style="list-style-type: none"> Check altitude setting and adjust to current location. Recalibrate the Turbine Differential and Exhalation Pressure Transducer. Check the Turbine filters and replace if necessary P/N 10365. Remove turbine and return to Cardinal Health Service Center for Re-characterization, or replace Turbine P/N 16349.

Monitored Volume Test Troubleshooting

Problem	Possible Cause	Action
Monitored volumes are out of the 20% specification.	<ol style="list-style-type: none"> Altitude setting is not accurate for location. Patient Circuit leaks. Flow Sensor is inaccurate Flow Sensor receptacle is leaking. Flow Sensor receptacle internal tubing is kinked or damaged. Exhalation Flow Transducer has drifted over time. 	<ol style="list-style-type: none"> Check altitude setting and adjust to current location. Correct leaking Patient circuit. Replace Flow Sensor. Sensor receptacle o-rings may be damaged, inspect and replace as needed P/N 30025. Inspect and correct tube routing or kinks causing restricted flow. Re-calibrate Exhalation Flow Transducer.

FiO2 Performance Test Troubleshooting

Problem	Possible Cause	Action
FiO2 Monitor window only reads *** and will not monitor O2%	<ol style="list-style-type: none"> 1. The FiO2 Monitor is not "Enabled" 2. O2 cell has drifted out of cal range. 3. The O2 cell is faulty. 	<ol style="list-style-type: none"> 1. Enable FiO2 monitor in Vent setup screen. See chapter 6 2. Re-calibrate FiO2 monitor see Chapter 6 3. Replace O2 cell P/N 16101
"Check O2 Cal" alarm occurs after 5 minutes of operation	<ol style="list-style-type: none"> 1. O2 cell has drifted out of cal range. 2. The O2 cell is faulty. 3. The delivered Oxygen Blender O2 output is 6% out of range. 	<ol style="list-style-type: none"> 1. Re-calibrate FiO2 monitor see Chapter 6 2. Replace O2 cell P/N 16101 3. Re-calibrate the O2 blender.
"O2 Range Error" alarm occurs after 5 minutes of operation.	<ol style="list-style-type: none"> 1. The delivered Oxygen Blender O2 output is 8% out of range. 	<ol style="list-style-type: none"> 1. Re-calibrate the O2 blender.

Battery Performance Test Troubleshooting

Problem	Possible Cause	Action
Ventilator does not pass the battery performance test.	Battery capacity has diminished and cannot hold a charge.	Replace the batteries P/N 21542
Ventilator DC status light shows green light, but does not run on batteries for more than a short time.	<ol style="list-style-type: none"> 1. Batteries are not holding charge. 2. Battery charge monitor lost its memory. 	<ol style="list-style-type: none"> 1. Check batteries for capacity level. Chapter 9 Q & A 2. Reset Battery Charge Circuit. See Chapter 7 Step 2.4
Ventilator DC status light shows green light when AC is disconnected it runs for short time but gets a "Battery Low" message and it can be cleared by pressing reset, only to return within minutes, vent runs for hours	<ol style="list-style-type: none"> 1. Battery Charge Monitor lost it's memory 	<ol style="list-style-type: none"> 1. Reset Battery Charge Circuit. See Chapter 7 Step 2.4

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Chapter 9: Frequently Asked Questions

Q. How do I check the battery charging circuit?

- A. Access the SVT mode. Access "Transducer Data". Choose "Analog X" any one showing will do. Rotate the control knob until IB (Internal Battery) is selected press accept. Exit screens and return to the wave form screen. In the area just above one of the wave forms that shows what the wave form represents you can touch this and a menu window will appear rotate the control knob until the "Analog X" that you set IB in is selected then press accept. The wave form will now represent a battery capacity. You can see this voltage by pressing the freeze button and the voltage value will appear next to the curser line, with a green status light this voltage should read above 80% of full charge. The charge scale is 1.0 to 4.0, 1.0 being 0 charge and 4.0 being Fully charged. The formula to find the percent of charge for the VELA internal batteries is;

$$\# - 1.0 \div 3 \times 100 = \% \text{ of charge}$$

Example:

$$3.4 - 1.0 = 2.4 \div 3 = 0.8 \times 100 = 80 \% \text{ of full charge capacity}$$

Another way to see if the battery charge is working would be to connect to the internal battery Molex connector on the red and black leads using the voltage meters probes enter the back of the connector on these leads and with the unit connected to AC you should see a slight increase of voltage taking place over time. If you disconnect the AC plug while unit is running on a test lung you will see the battery voltage maintain a very stable reading.

Q. How do I determine if the batteries are good?

- A. Refer to the "Battery Performance Test" in chapter 7. Using the same set-up as mentioned above, with voltage meter probes connected to the back of the Molex connector and ventilator connected to and running with a test lung connected. Check the battery voltage during step #7. The voltage should decrease very slowly during this test. If you detect a very rapid discharge occurring and the batteries are very hot to the touch the batteries have lost their capacity and should be replaced.

Q. How often do I need to change the batteries?

- A. The Nickel Metal Hydride batteries have a life expectancy of 300 to 500 full discharges, however this is a difficult life expectancy to quantify in an amount of time as few customers will often discharge the batteries fully. The life of a battery will depend largely on the exercise of the batteries regularly. It is a good practice to run the ventilator on battery power for 2-4 hours on a regular interval to ensure discharge and recharge. This could be done once or twice a month, if vent is in constant use. The battery care is a very important aspect of preventative maintenance. It is however, recommended that the batteries be replaced every two years.

Q. How do I know the Monitored Volumes are good or bad?

- A. Because the monitored values are calculations based on the Delivered volumes you must first determine if the delivered volumes of the ventilator are accurate before you can know if the monitored values are inaccurate. Follow the "Delivered Volume Test" in chapter 7. This will tell you if the delivered volumes are accurate. If the delivered volumes are good, follow the "Monitored Volume Test" in chapter 7 to determine accuracy of the monitored values.

Q. Why does the O2 Inlet fluctuate so much when my wall pressure is consistent?

- A.** The VELA ventilator does not have a pressurized accumulator like many ventilators do that add a volume of gas to equal out pressures during higher demands of gas flow. With that in mind when the FiO2 settings are set above 21% and a demand by means of a delivered breath is made on the blender, the solenoids will servo open and closed. On higher FiO2 settings you can see a pressure drop occur on the monitored O2 inlet pressures. This is normal and should not be viewed as a problem. The blender has 5 solenoids with 5 fixed orifices that can flow as much as 140 lpm for short periods of time which will drop the inlet (system) pressure readings dramatically. However, the pressure does not remain low. The pressure will fluctuate with every breath and you will be able to see a pressure drop during every inspiration. The Low O2 inlet alarm is triggered when the pressure drops below the low alarm setting which is 35 psig for more than 30 seconds.

Q. How often do I need to change the O2 cell?

- A.** Every 900,000% O2 hours! O2 cell life is stated in "oxygen-percent-hours" The formula is "O2 Concentration (%) x Exposure time (hours)". Once the cell is exposed to ambient air out of its package, it starts clicking off 21 oxygen hours every hour. When it is in use at say 60% you are then using 60 oxygen hours every hour it is used at 60%. So with a life of above 900,000 oxygen hours it averages out to about 2 years of use. The O2 cell industry states this info based on an average setting of about 50% with constant use.

Q. Why does it take so long for the FiO2 alarms "Check O2 Cal" and "O2 Range Error" to alarm?

- A.** The Oxygen blending circuit in the VELA is quite unique in its operation. The blender is microprocessor/software controlled with many variables considered, FiO2 setting, volume, flow, breath rate, FiO2 cell data, etc... to create a firing order or algorithm for the blender solenoids to be able to maintain the accurate O2 concentrations. When you set a FiO2 value on the front panel all of this goes into play. The initial information from the FiO2 setting and variables mentioned above are taken into account, after 90 seconds the processor compares the set value to the monitored value and if the input from the O2 cell monitor is greater than 1% or less than the "Check O2 Cal" table then an adjustment to the algorithm is made to make up the difference in setting versus monitored value. This comparison is accomplished three times and an adjustment will be made to the algorithm each time if necessary for a total of approximately 4 ½ minutes. At this time the processor will open the closed loop of operation and the blender will operate with the last adjusted algorithm. If the FiO2 setting or the altitude setting is changed the whole process will start over.

These alarms will present themselves only after the closed loop of operation has finished its 4 ½ minutes and the specified alarm criteria are met. The "Check O2 Cal" alarm will appear if the monitored O2 is outside the specified range of the set FiO2 continuously for 20 seconds.

Specified ranges for Check O2 Cal alarm, Medium Alarm (Yellow):

O2 setting 21%-60%: +/- 6% O2
7% O2

O2 setting 61%-80%: +/-
O2 setting 81%-100%: +/- 8% O2

Specified ranges for O2 Range Error alarm, High priority alarm (Red):

O2 setting 21%-60%: +/- 10% O2
+/- 11% O2

O2 setting 61%-80%:
O2 setting 81%-100%: +/- 12% O2

Q. Why do I get a "Filter" message?

A. This is a reminder to check the rear inlet fan filter and will appear every 500 hours of operation. The reset can be completed by pressing the reset button twice while the alert message is displayed

Q. Why does the circuit hum between breaths?

A. This is an annoyance and not a critical issue. The inspiratory hold check valve is vibrating. This is more prevalent in disposable circuits as the sound resonates through the thin tubing noticeably louder. The check valve can be repositioned by turning the inspiratory piston ¼ turn.

Q. How do I find the hours of operation on this vent?

A. Enter the "Extended Functions" screen and select the "Date & Time" button. You will find Turbine and Machine hours both listed.

Q. Why do I have event messages in my event log stating "INVALID SERIAL NUMBER"?

A. Due to the redesign of the main pcb from S/N AHT07500 forward, the S/N is stored on the small peripheral pcb mounted on the rear panel. When the battery tray is removed for maintenance or just to move it and you disconnect the communications cable mounted to the battery tray this message will appear when you power up the ventilator with the cable disconnected.

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Chapter 10: Maintenance and Cleaning

Cleaning & Sterilization

The VELA is designed for easy maintenance. All exposed parts of the ventilator are corrosion resistant. To prevent pooling of liquids, there are no flat surfaces on the ventilator body.

CAUTION

DO NOT submerge the ventilator or pour cleaning liquids over, into or onto the ventilator.

Cleaning

Cleaning of External Surfaces

All external surfaces of the ventilator can be wiped clean with a soft cloth using Isopropyl Alcohol

Cleaning of Accessories and Ventilator Parts

Accessories

The following accessories can be cleaned using Klenzyme® :

- The exhalation valve body
- The exhalation flow sensor.
- The exhalation diaphragm

Cleaning Method for the Exhalation Valve Assembly

Remove the Exhalation Valve Assembly for Cleaning

1. Press and hold the release latch on the lower left of the exhalation valve housing.
2. Grasp the exhalation valve body, rotate it counter-clockwise until the alignment slots line up, and then gently pull it free from the housing.
3. Grasp the exhalation valve diaphragm by the center and remove it from the exhalation valve body.
4. Using a clean soft cloth and Isopropyl Alcohol, wipe all exposed surfaces around the exhalation valve housing. Do not allow cleaning fluid to spill into the opening in the exhalation valve housing.

To Clean the Exhalation Valve Body, Flow Sensor and Diaphragm:

1. Soak in Klenzyme solution for 5 minutes. Klenzyme bath may be heated to a maximum of 67 °C (152 °F).
2. Rinse in distilled water. After cleaning the surfaces, make sure all excess cleaning solution is completely removed to prevent residue buildup. Dry with a soft cloth or allow to air dry.

Sterilization

The following accessory parts may be sterilized:

- The exhalation valve body
- The exhalation flow sensor
- The exhalation diaphragm

Method of Sterilization

The preferred method of sterilization is

Steam Sterilization (autoclave), minimum 132° C (270° F) maximum temperature 134 °C (273 °F). It is recommended that the accessories listed above be replaced after 30 cleaning and sterilization cycles.

1. After cleaning the surfaces, make sure all excess cleaning solution is completely removed to prevent residue buildup.
2. Sterilize the exhalation valve body, flow sensor and diaphragm using steam autoclaving within the guidelines stated above.
3. Using a low flow gas source (less than 10 L/min) ensure the differential pressure tubes are free of moisture and debris.
4. To avoid possible damage to elastomeric components, the peak temperature for Cardinal Health accessories should not exceed 275 °F (135 °C) for steam autoclave.
5. Ultrasonic cleaning is not recommended. Liquid sterilizing agents containing more than 2% glutaraldehyde are also not recommended. If such agents must be used, be sure to thoroughly rinse and dry the assembly to prevent residue buildup. Residue buildup in the differential pressure ports can cause inaccurate pressure and volume readings.
6. Prior to replacing the exhalation valve diaphragm, inspect it for excessive wear. If signs of damage are found, obtain a new diaphragm.
7. Insert the diaphragm. Hold it by the center and set it into the exhalation valve-housing receptacle. Gently tap around the perimeter until the diaphragm is firmly seated.
8. Line up the tabs of the exhalation valve body with the alignment slots on the exhalation valve housing. Gently push the exhalation valve body into place and rotate it clockwise until the release latch pops out. The exhalation valve body 'clicks' into place.
9. Gently pull on the exhalation valve body to make sure it is securely attached to the ventilator.

Other Accessories

For all other accessories purchased for use with your VELA Ventilator, but not supplied by Cardinal Health, follow the manufacturer's recommendations for cleaning or sterilization.

Recommended Periodic Maintenance

Cardinal Health is committed to product support. If you have any questions concerning your ventilator's operation or maintenance contact your product support representative as shown in Appendix A, Contact Information.

Every 500 hours, the air intake filter should be checked and cleaned if necessary. A reminder message is displayed on the front panel at 500 hour increments. To clear this message, press the Accept Key. To clean the filter, remove it from its recess and immerse in warm soapy water. Rinse thoroughly and dry thoroughly before replacing in the ventilator.

Preventive maintenance should be performed on your VELA ventilator yearly. Call the applicable number given in Appendix A to arrange for a qualified service technician to perform this.

WARNING

Electric shock hazard - Do not remove any of the ventilator covers or panels. Refer *all* servicing to an authorized Cardinal Health service technician.

The one-year maintenance includes the following.

Kit P/N 11416 consists of the Replacement of:

- The Rear Air Inlet Filter
- The Oxygen Inlet Filter
- The Turbine Muffler Filter Cores and O-rings
- The Fan Filter
- The Video 3 volt coin cell

At this time the following maintenance is performed:

- Removal & replacement of the above items
- Calibration if required
- Verification Testing to confirm the ventilator is functioning within optimum parameters.

Note

VELA Maintenance should only be performed by a trained and authorized service technician. Cardinal Health will make available to qualified technicians, service manuals, which include such items as circuit diagrams, component parts lists, calibration instructions and other information to assist in repair of those parts of the ventilator designated by the manufacturer as repairable items.

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Chapter 11: Specifications

Oxygen Supply

High Pressure Connector

Pressure Range:	40 to 85 psig	(Supply Oxygen)
Temperature:	10 to 40° C (50 to 104° F)	
Humidity:	Dew Point of gas should be 1.7° C (3° F) below the ambient temperature (minimum)	
Minimum Flow:	80 LPM at 20 psig	
Inlet Fitting:	CGA DISS-type body, No. 1240	

Low Pressure Connector

Pressure Range:	0 to 0.5 psig	(Supply Oxygen)
Maximum Flow:	80 LPM	
Inlet Fitting:	¼ inch tapered	

Electrical Supply

AC Power Supply

The ventilator operates within specification when connected to the following AC power supplies:

Nominal	Voltage Range	Frequency Range
100 VAC	(85 to 110 VAC)	47 to 65 Hz
120 VAC	(102 to 132 VAC)	55 to 65 Hz
230 VAC	(196 TO 253 VAC)	47 to 65 Hz
240 VAC	(204 TO 264 VAC)	47 to 65 Hz

DC Power Supply

The ventilator can also operate from a 48 VDC power source (internal battery).

Internal Battery:

The ventilator operates within specification for approximately 6 hours with a fresh, fully charged battery under moderate load. Maximum charge time for a full charge is 8 to 12 hours.

Data Input / Output

Analog Inputs

The ventilator provides up to 8 programmable channels for analog signal inputs. Each channel shall be scalable for the input ranges specified.

Ranges:	0 to 1 VDC
	0 to 5 VDC
	0 to 10 VDC
Resolution:	0.25 mV (for 0 to 1 VDC)
	1.37 mV (for 0 to 5 VDC)
	2.5 mV (for 0 to 10 VDC)

Analog Outputs

The ventilator provides 4 signals at the analog output connector:

1. Airway Pressure, P_{AW} :

Range:	-60 to 140 cmH ₂ O
Scale:	1 cmH ₂ O/25 mV
Accuracy:	± 50 mV or ± 5% of reading, whichever is greater
Zero Offset:	1.5 VDC at 0 cmH ₂ O

2. Flow

Inspiratory/Expiratory:

When selected, the ventilator provides a continuous analog voltage representative of inspiratory flow minus expiratory flow.

Range:	-100 to 200 LPM (Adult)
Scale Factor:	1 LPM / 10 mV (Adult)
	1 LPM / 25 mV (Pediatric)
	1 LPM / 50 mV (Neonate)
Accuracy:	± 10% of reading or ± 30 mV, whichever is greater
Zero Offset:	3.0 VDC at 0 LPM

Machine:

When selected the ventilator provides a continuous analog voltage representative of machine delivered flow.

Range:	0 to 200 LPM (Adult)
Scale Factor:	1 LPM / 25 mV (Adult)
	1 LPM / 50 mV (Pediatric)
	1 LPM / 100 mV (Neonate)
Accuracy:	± 10% of reading or ± 30 mV, whichever is greater
Zero Offset:	None

3. Volume:

Range:	-1.00 to 4.00 L	(Adult)
Scale Factor:	1 L / V	(Adult)
	1 mL / 5 mV	(Pediatric)
	1 mL / 10 mV	(Neonate)
Accuracy:	± 10% of reading or ± 30 mV, whichever is greater	
Zero Offset:	1.000 VDC	

4. Breath Phase

The ventilator provides a continuous analog voltage representative of breath phase (Inspiration = 5 VDC, Expiration = 0 VDC).

Digital Communication

The ventilator is constructed with one RS-232 port for bi-directional communication of data.

CAUTION

This is a non-operational port. Do not make connection.

Printer

The ventilator is constructed with a standard 25-pin female Centronics parallel printer port.

Remote Nurse Call

The ventilator has a modular jack configured to interface with external systems that are either wired for normally open (N.O., close on alarm) or normally closed (N.C., open on alarm) signals.

Video Output

The ventilator is constructed with a video output connector.

Atmospheric & Environmental Specifications

Temperature and Humidity

Storage

Temperature: -20 to 60° C (-4 to 140° F)

Humidity: 10 to 95% RH non-condensing

Operating

Temperature 5 to 40° C (41 to 104° F)

Humidity 15 to 95% RH non-condensing

Barometric Pressure

760 to 545 mmHg

Physical Dimensions

Overall Size

13" W x 14.5" D x 12" H

Weight

≤ 38 lbs.

Appendix A: Contact and Ordering Information

How to Call for Service

To get help with any of the preventive maintenance routines, or to request service for your ventilator, contact Cardinal Health, Respiratory Technologies, at the following numbers:

Technical and Clinical Support

Hours: 6:30 AM to 4:30 PM (Pacific Time) Monday through Friday
Phone: (800) 231-2466 (From within the U.S. only) or (714) 283-2228
Fax: (714) 283- 8471

After-hours service:

Phone: (800)231-2466 (From within the U.S. only)
Fax: (714) 283-8473 or (714) 283-8419

To obtain VELA Ventilator parts contact customer service at:

Hours: 7:00 Am to 4:30 PM (Pacific Time)
Monday through Friday
Phone: (800) 328-4139 (From within the U.S. only)
(714) 283-2228
Fax: (714) 283-8473 or (714) 283-8419

Online service for warranty replacements parts can be found at cardinalhealth.com

Select "Warranty Form" from the choices on the left of the screen.

Cardinal Health Customer Care Help line

Hours: 24 hours, seven days a week
Phone: From within the U.S. only: (800) 934-2473 or (800) 231-2466 or (800) 520-4368
Fax: (714) 283-8473 or (714) 283-8419

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Appendix B: Reordering Instructions

(For front panels S/N AHT07499 and below)

The VELA series ventilator has had three different platforms since it's release in 2002.

VELA T-2, VELA CF-1 & VELA CF-2

The major differences between the three platforms is seen in the Front Panels. VELA T-2 used a modified Main PCB from the T-Bird series ventilators, and a separate video PCB. When we went to the VELA CF platform we had a new Main PCB that incorporated it's own Video capabilities with FiO2 monitoring as well. This was a solid PCB that would allow the ventilator to have external software downloads with minimal down time waiting for parts to be shipped. Our software updates and upgrades are obtainable through our Website.

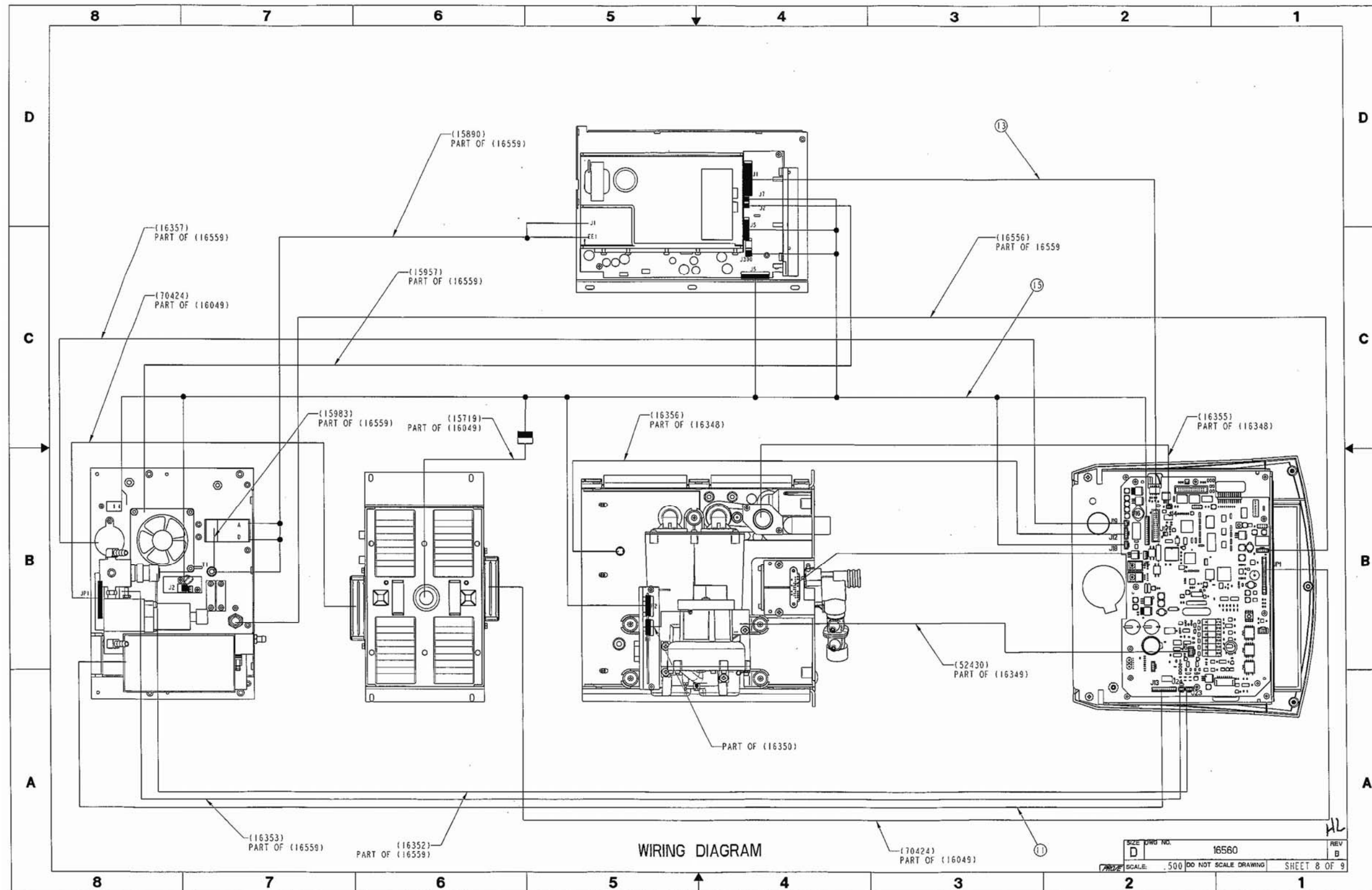
Our first run of Cold Fire processors worked well, but unfortunately certain components used on this PCB were no longer manufactured in a similar package and so we had to redesign the PCB completely. During this time also other capabilities were required for the growth of the VELA Ventilator series and these new features were then introduced into the new design. With the release of Cold Fire 2 there was a need to change the P/N's of the Front Panel and the Main PCB's which is evident in the Disassembly/reassembly section of this manual.

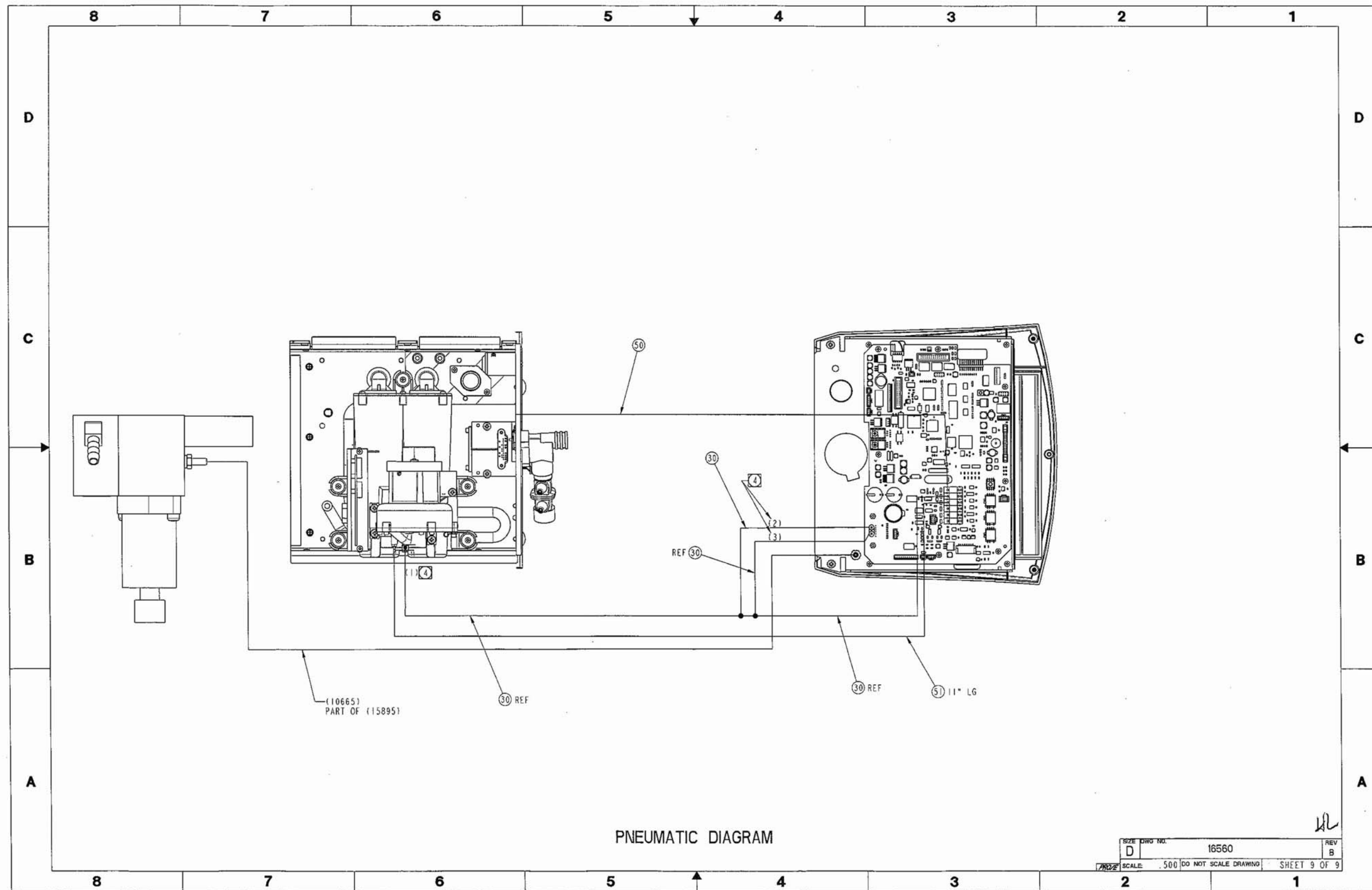
We have a limited amount of the Cold Fire 1 Front Panels P/N 16345A & J available. When these are no longer available, kit P/N 82850K Main PCB will replace them. This kit will include the Turbine EEPROM, as the existing EEPROM on the Cold Fire 1 Turbines are not forward compatible with the Cold Fire 2 processor.

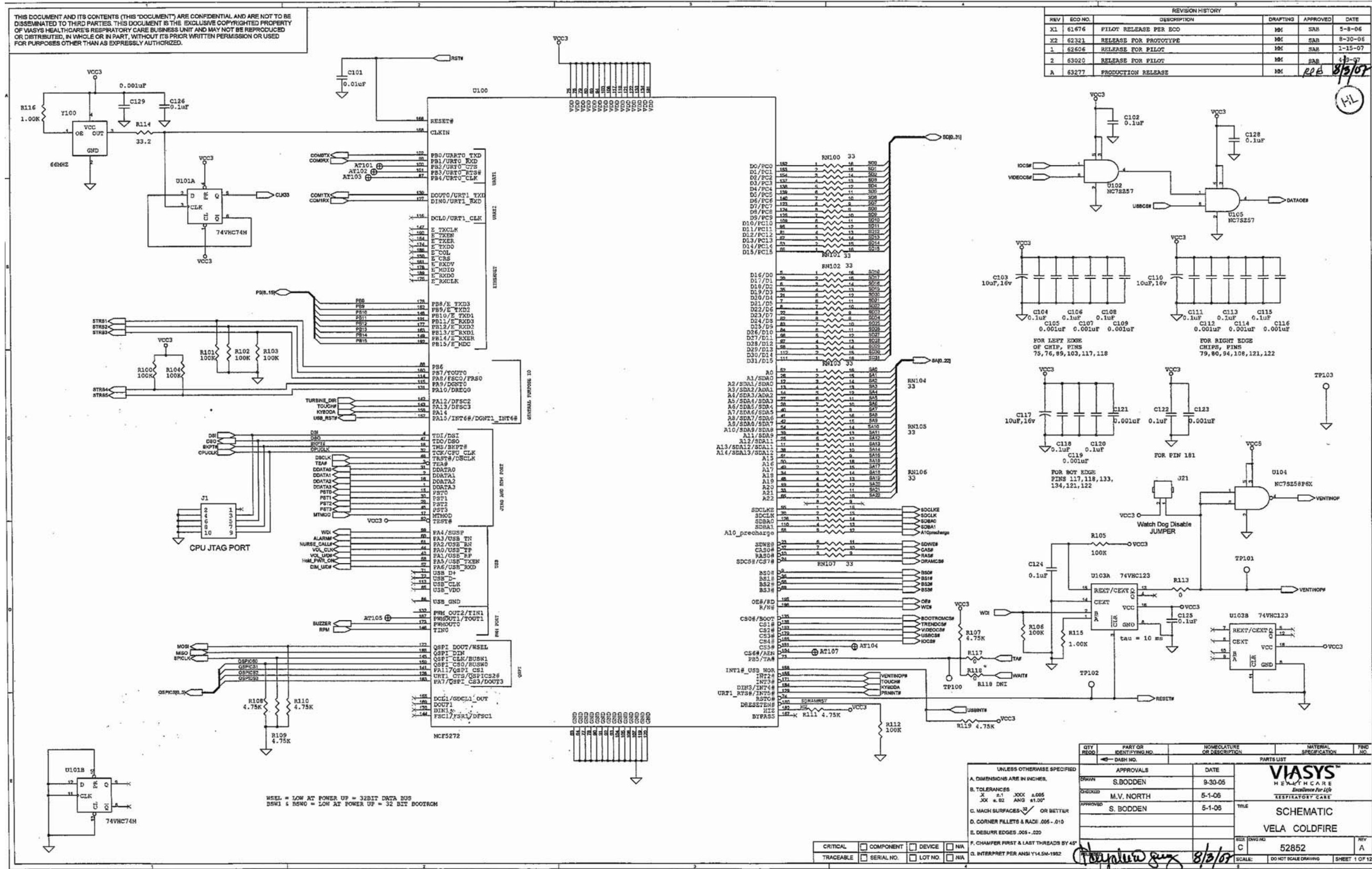
When ordering the kit the S/N of the ventilator and the turbine will need to be provided. The factory will then reprogram the new turbine EEPROM with the stored characteristics from the original turbine file.

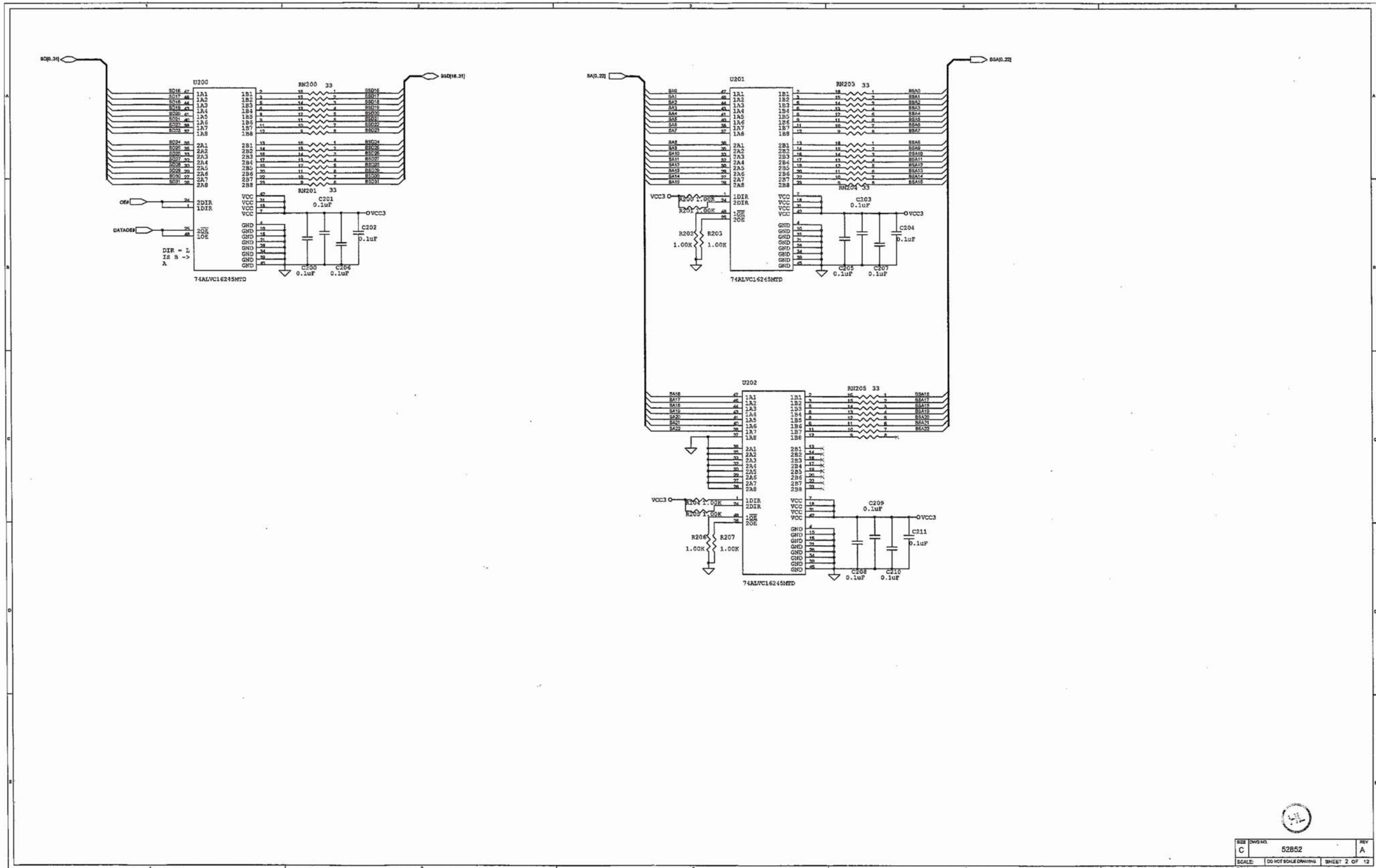
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Appendix C: Schematics & Diagrams

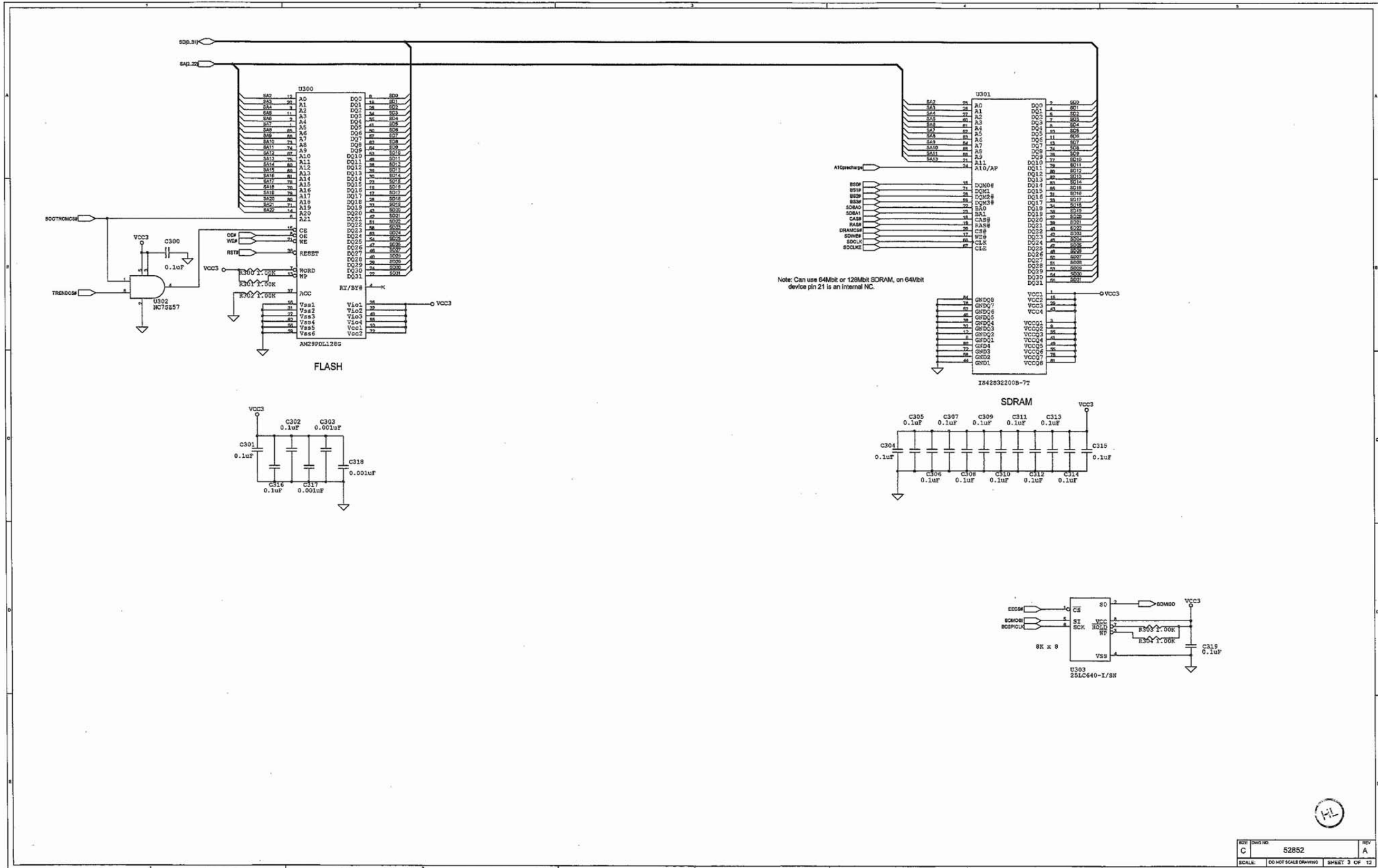




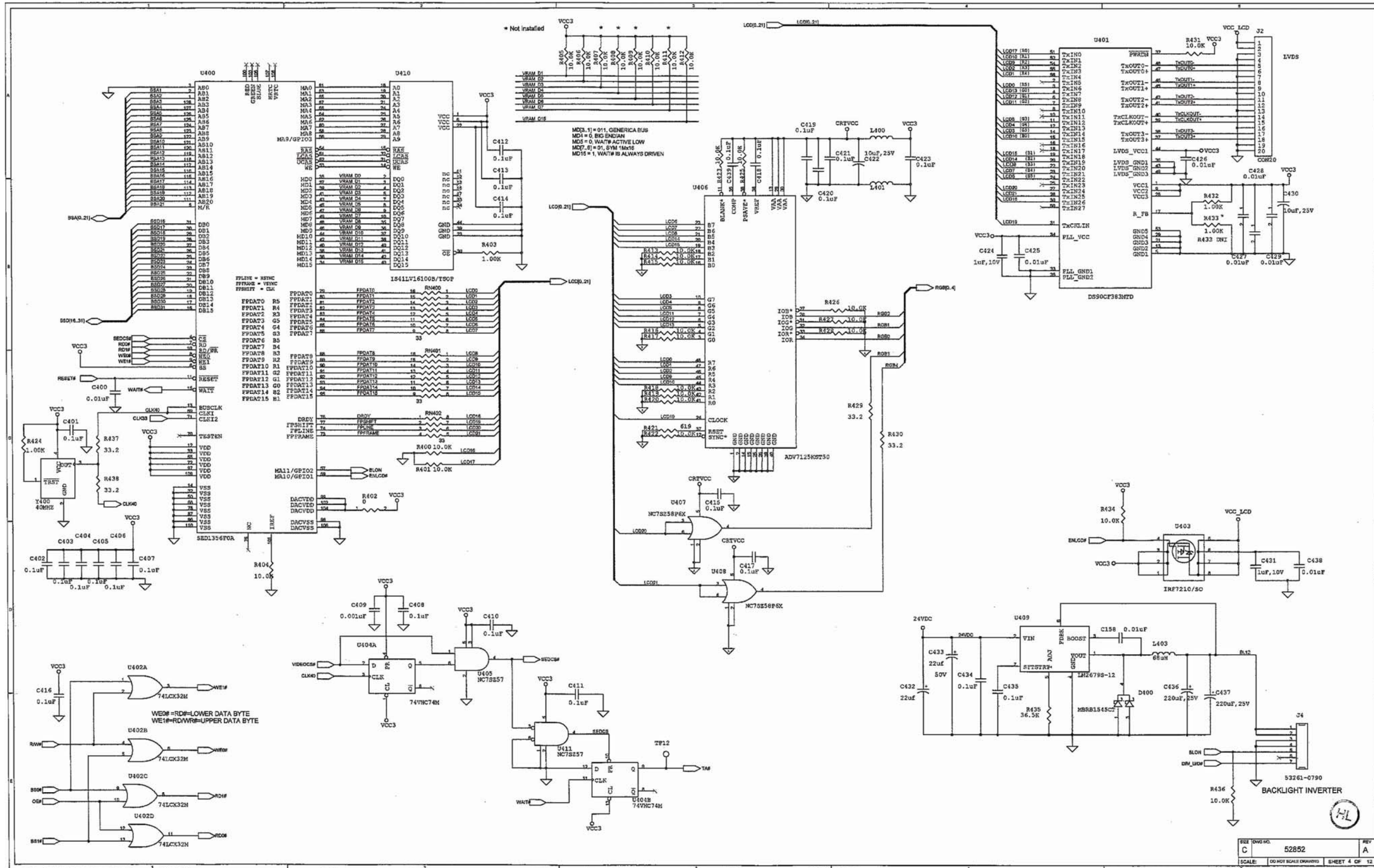




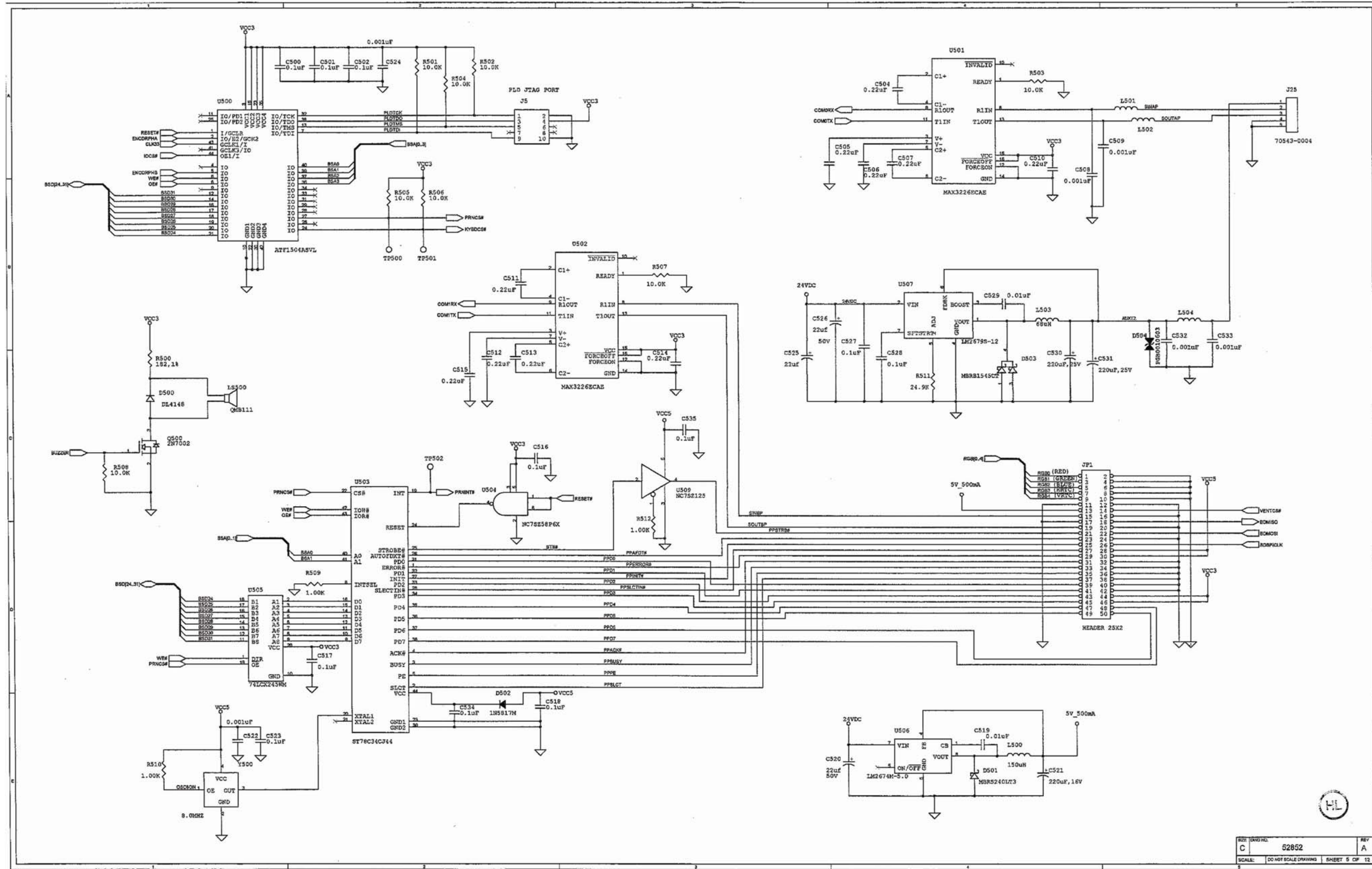
SIZE	DWG NO.	REV
C	52852	A
SCALE: DO NOT SCALE DRAWING SHEET 2 OF 12		



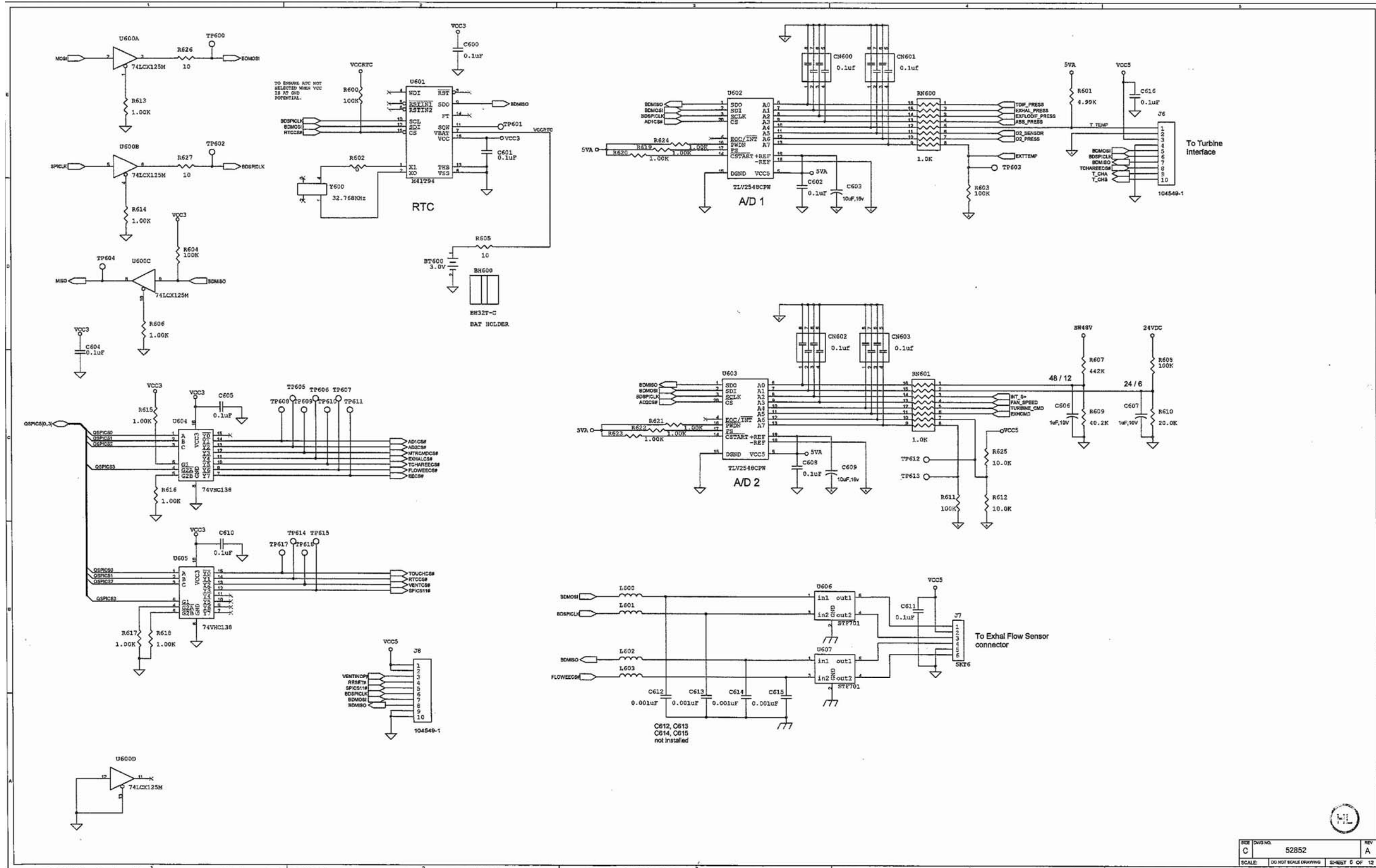
REV	52852	REV	A
C		SCALE	DO NOT SCALE DRAWING
		SHEET	3 OF 12



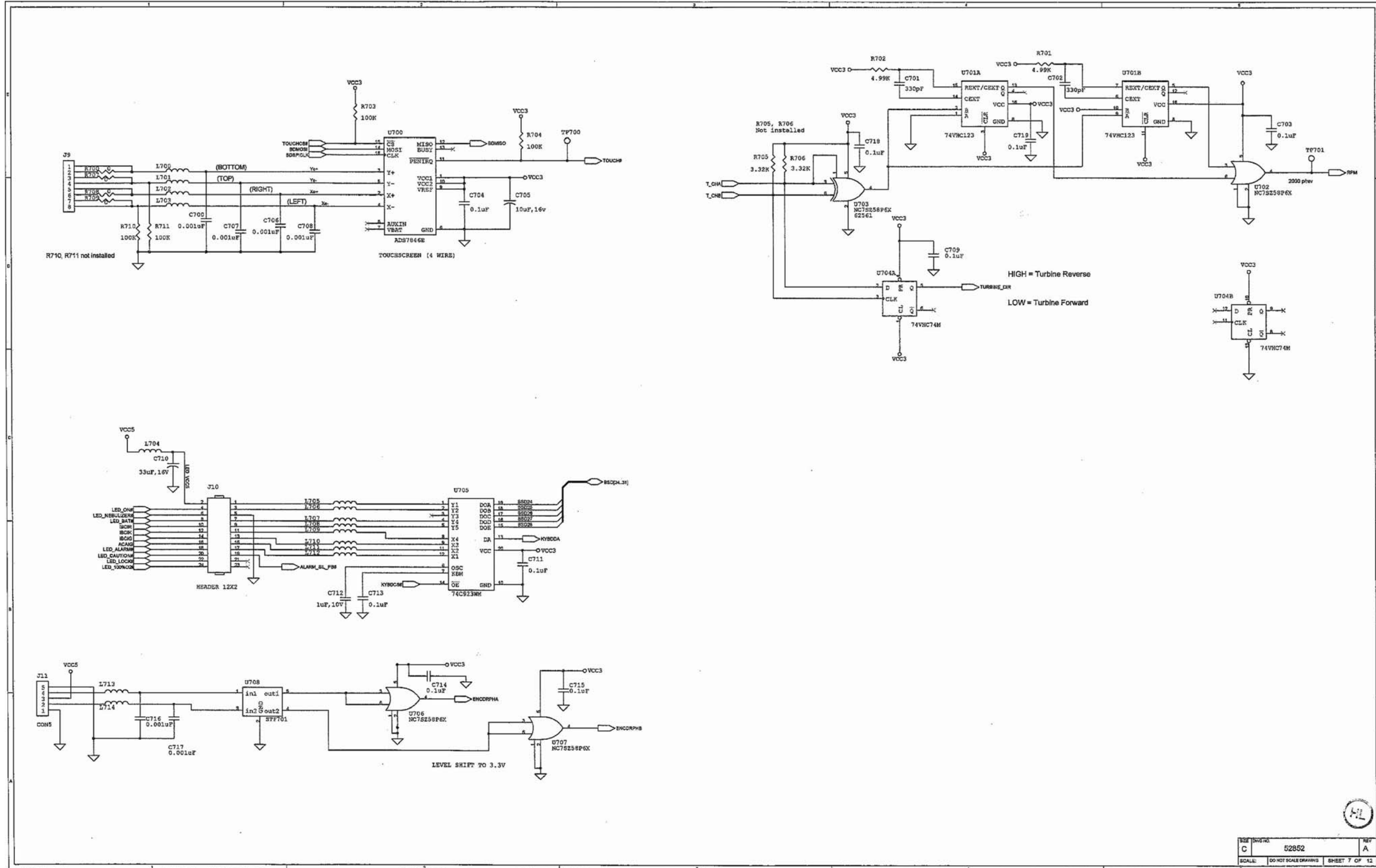
REV	52852	REV
C		A
SCALE: DO NOT SCALE DRAWING SHEET 4 OF 12		



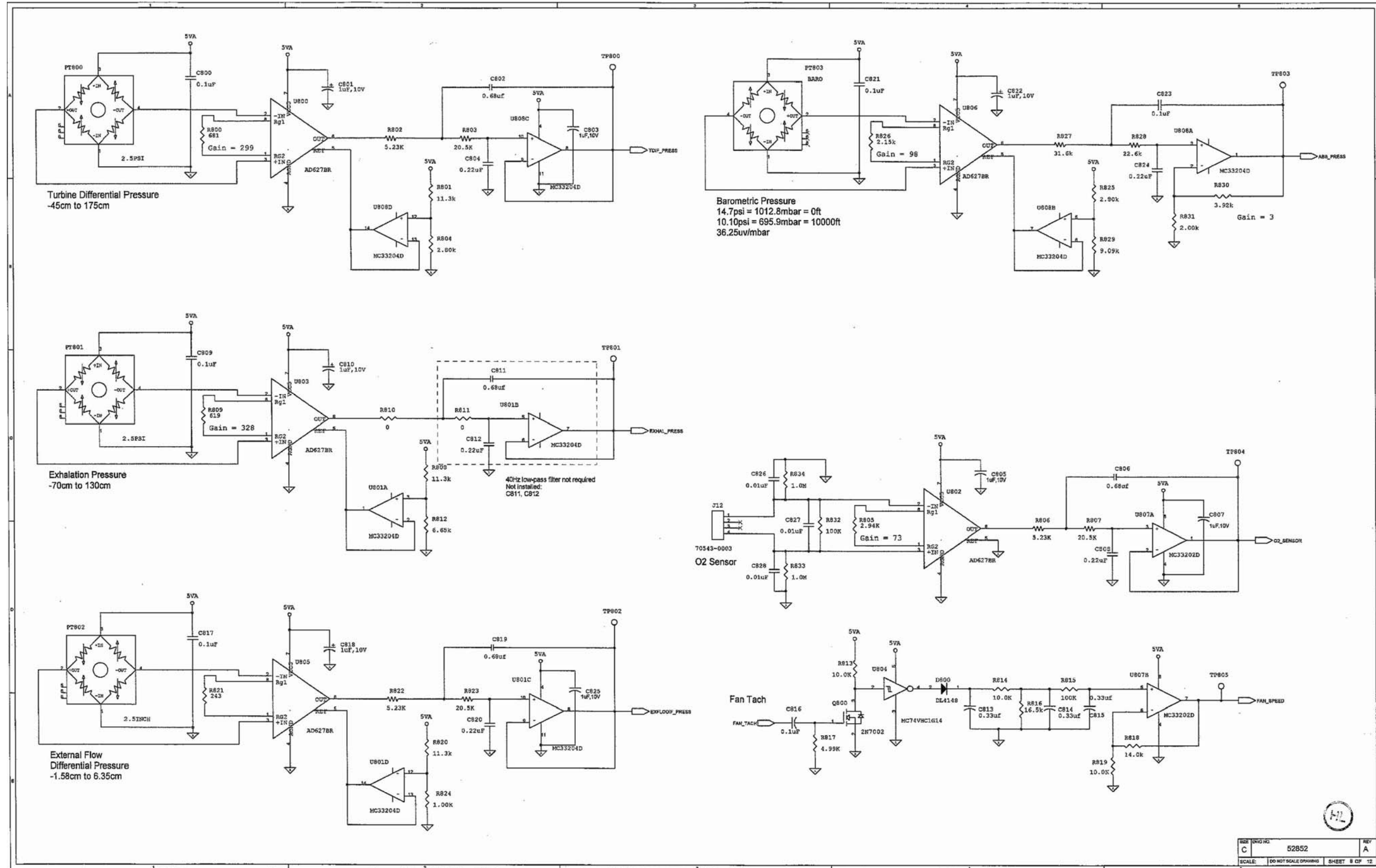
REV	A
DRAWING NO.	52852
SCALE	DO NOT SCALE DRAWING
SHEET	5 OF 12



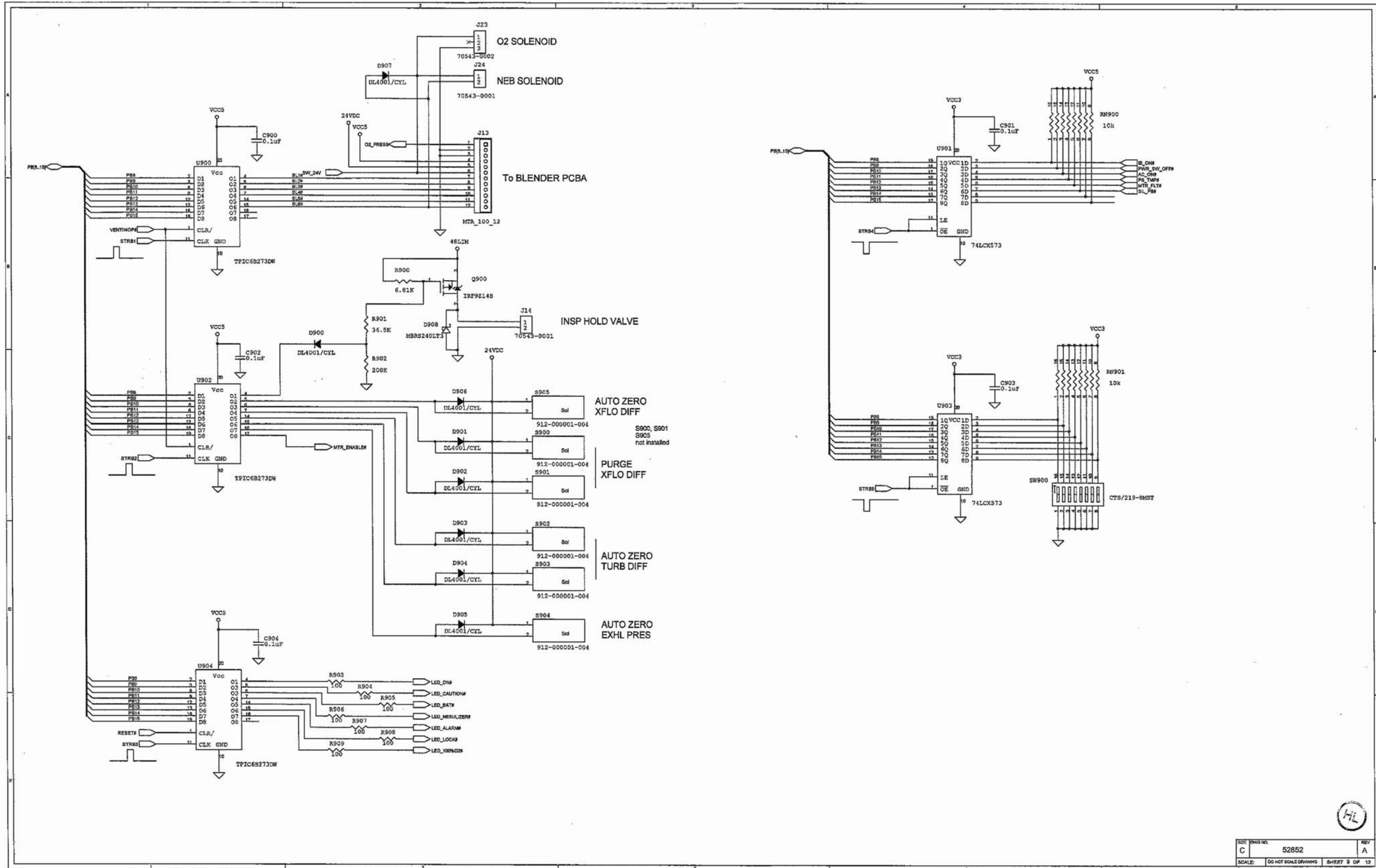
SIZE	DWG NO.	REV
C	52852	A
SCALE: DO NOT SCALE DRAWING		SHEET 6 OF 12



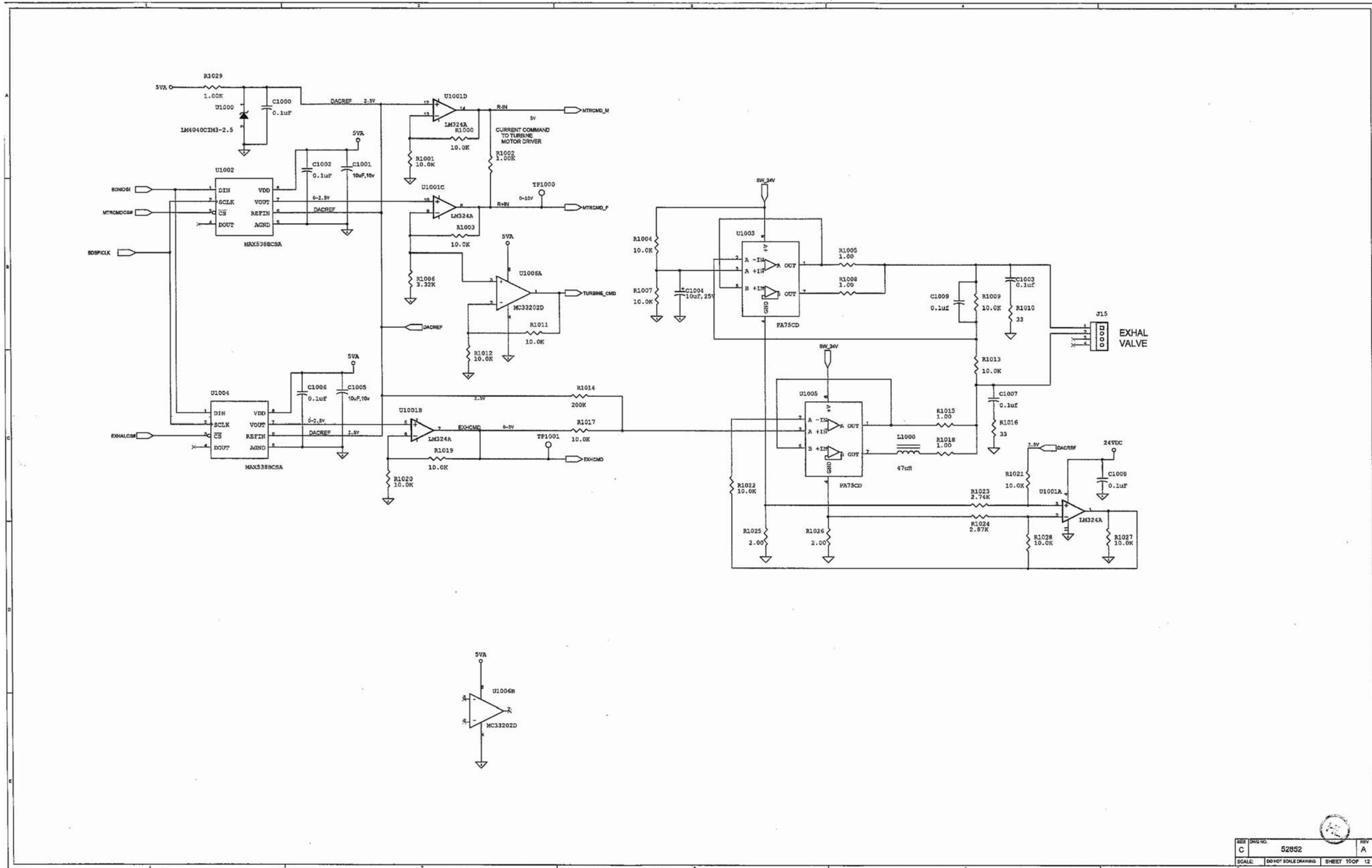
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C	52852	A
SCALE:	DO NOT SCALE DRAWING	SHEET 7 OF 12

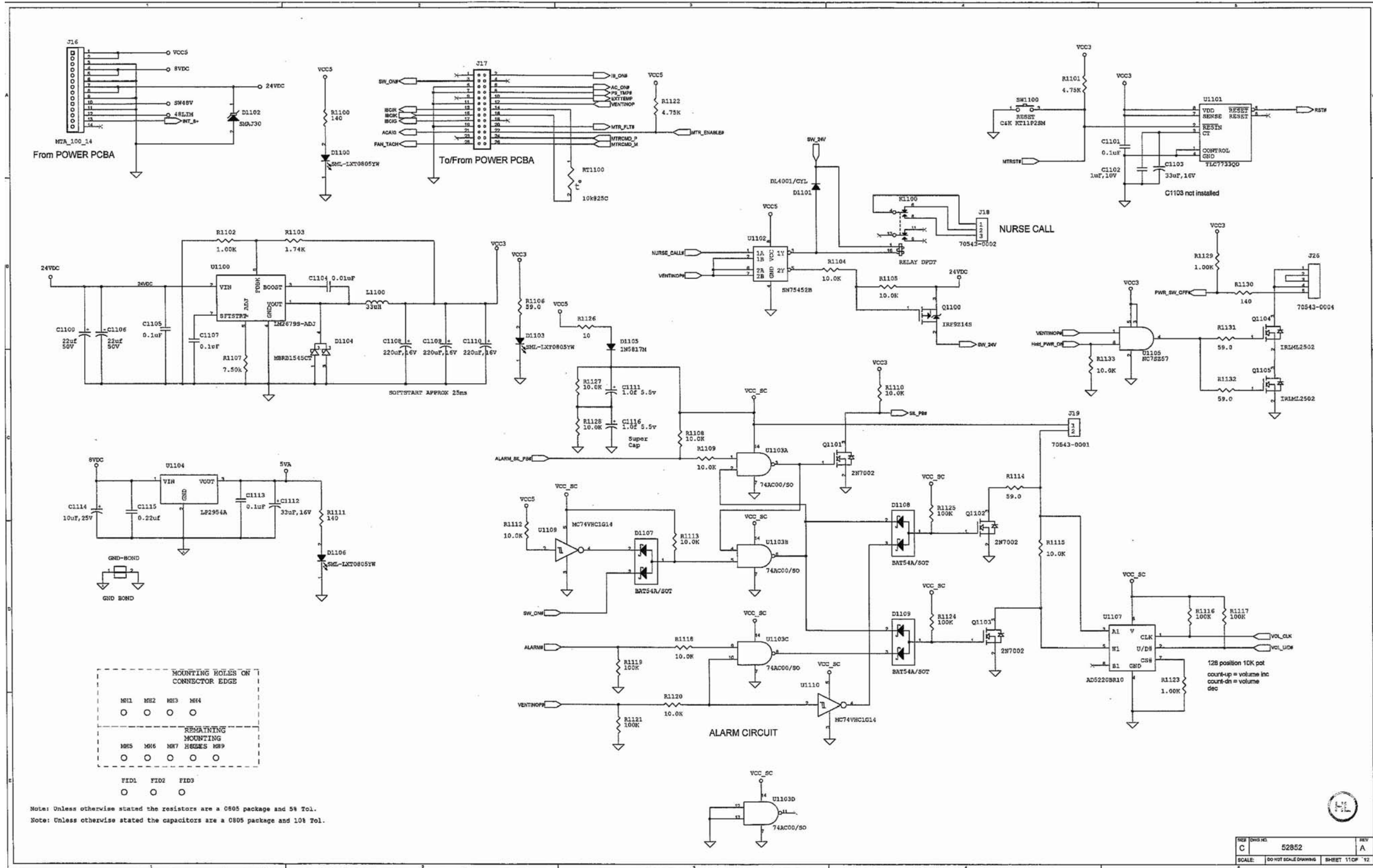


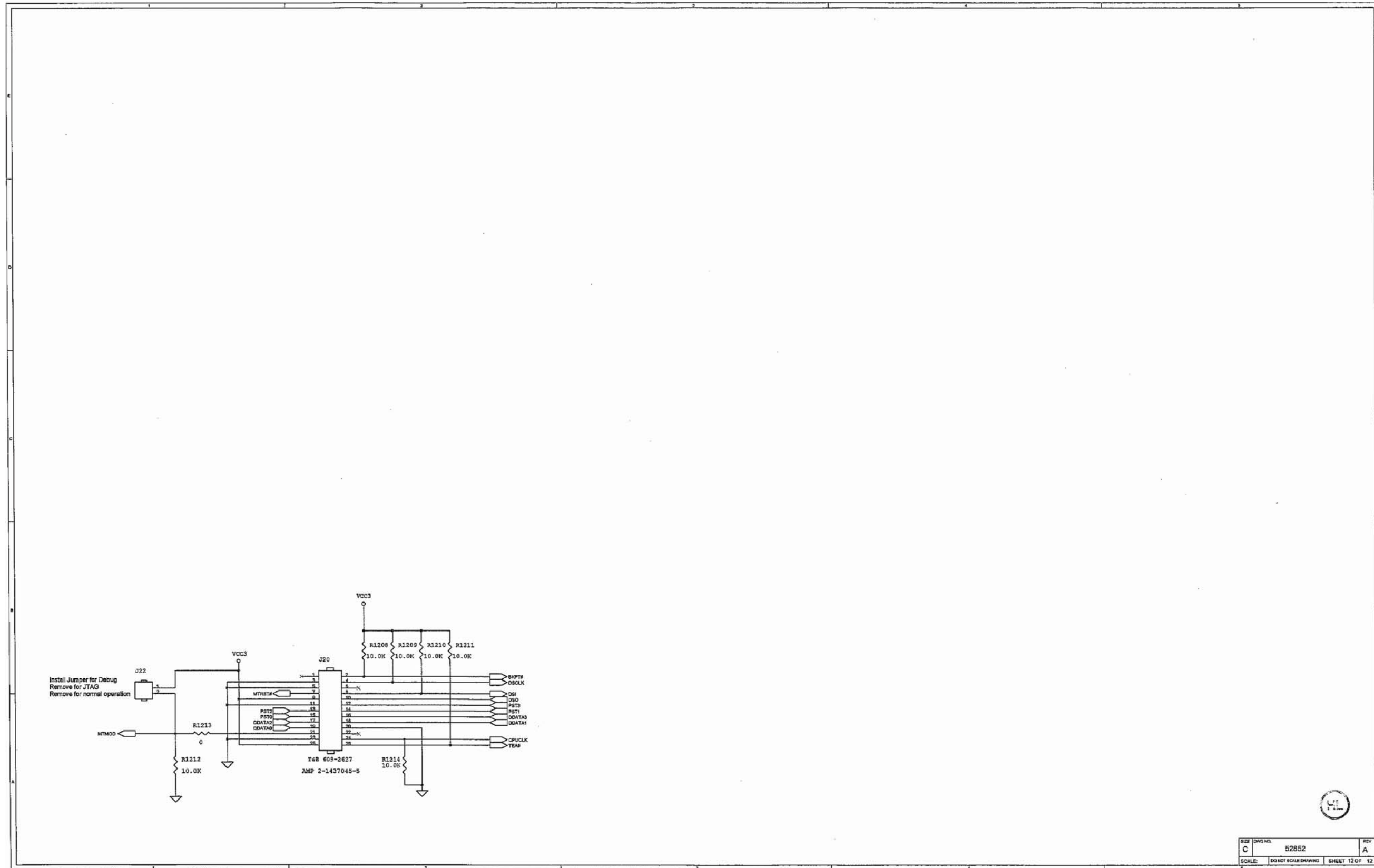
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C		A
SCALE:	DO NOT SCALE DRAWING	SHEET 8 OF 12

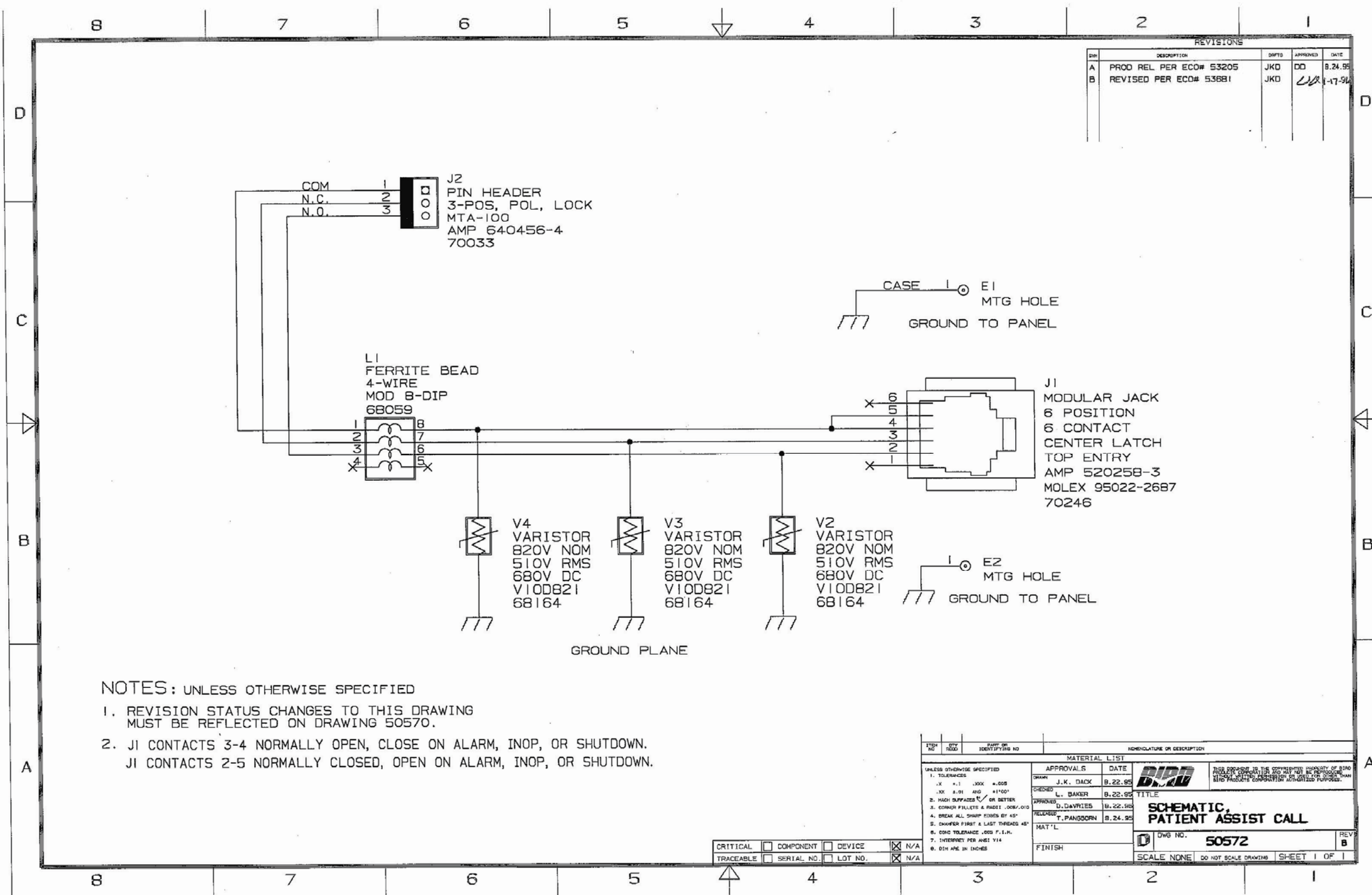


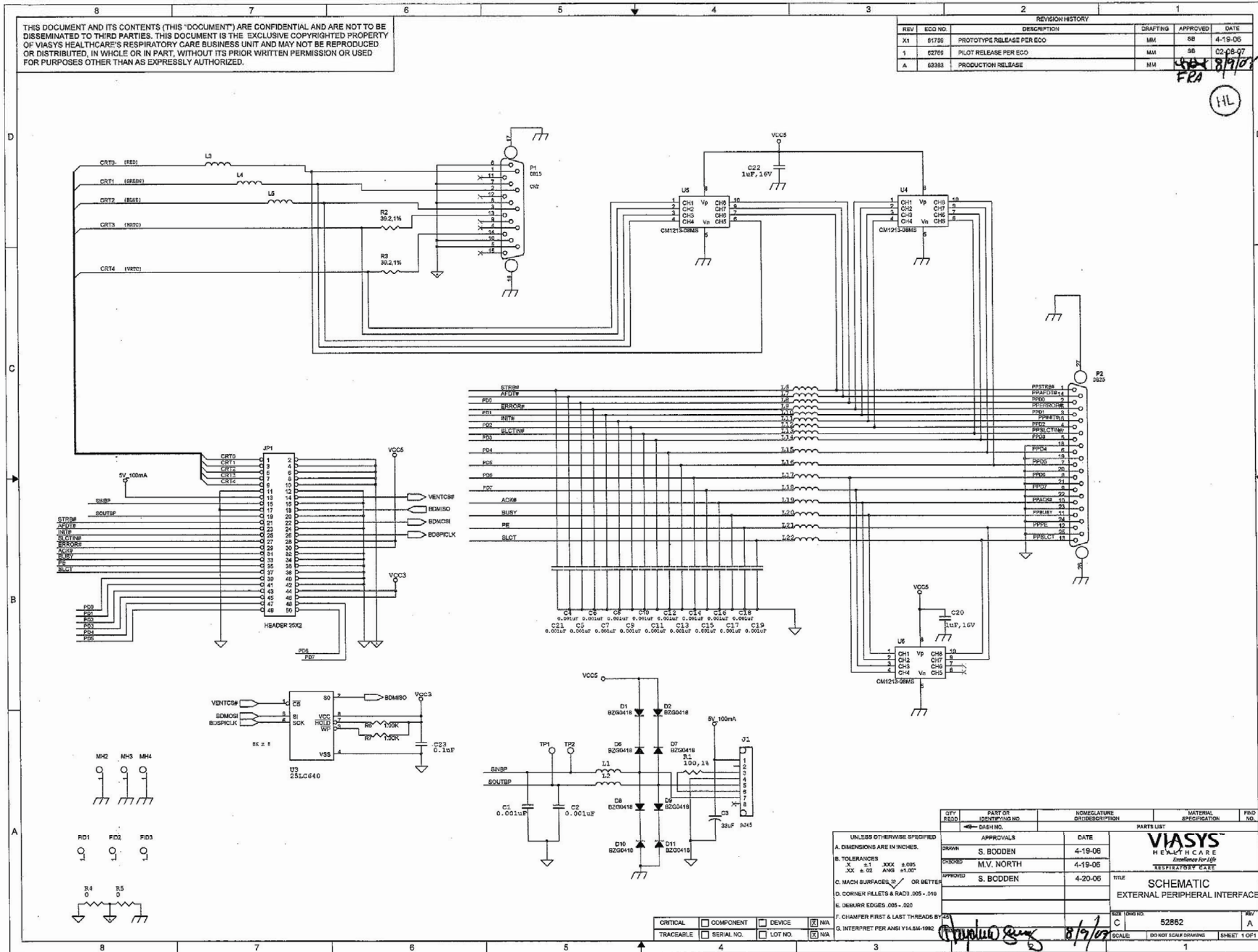
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52852	
C	
SCALE:	DO NOT SCALE DRAWING
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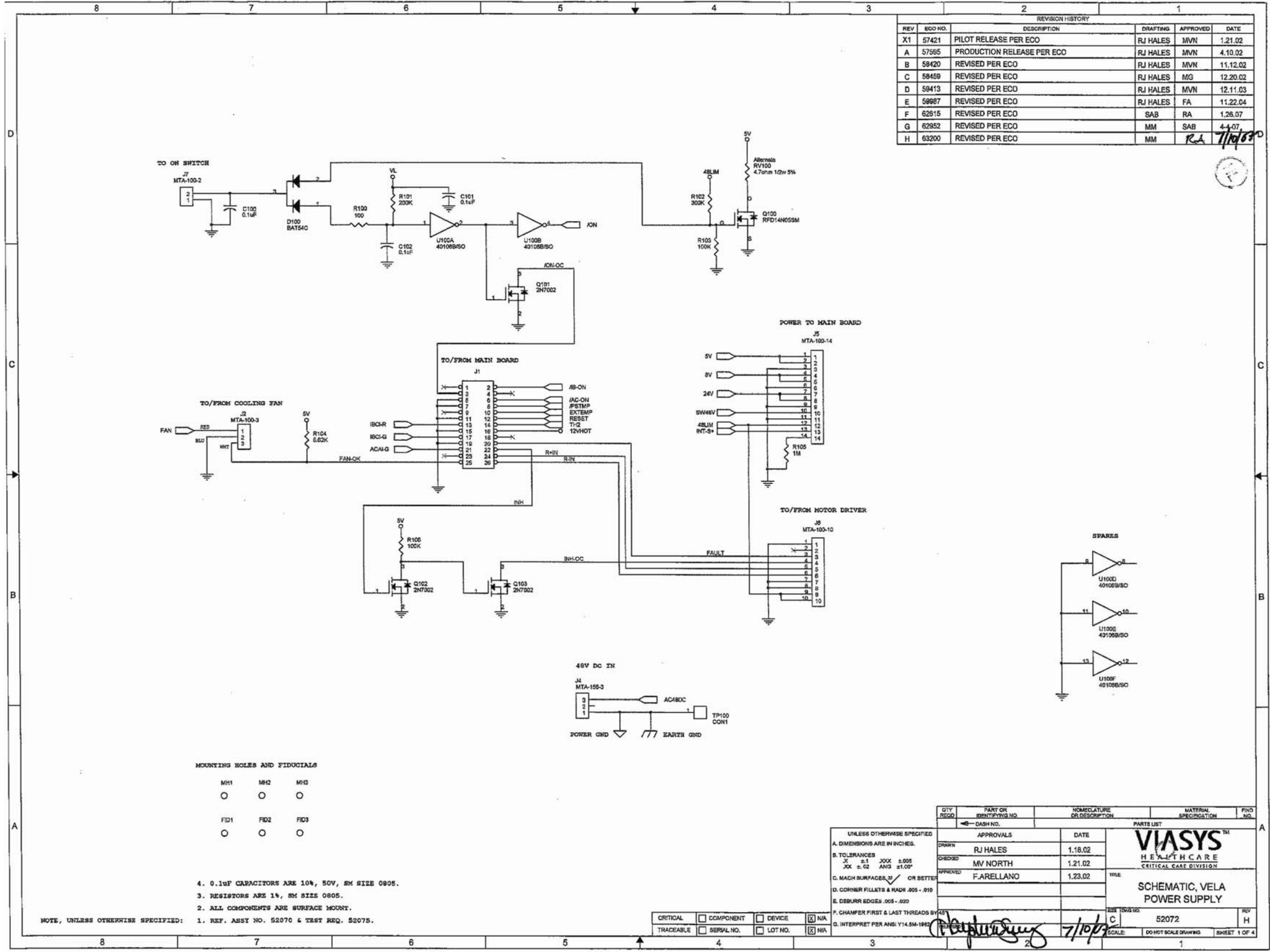


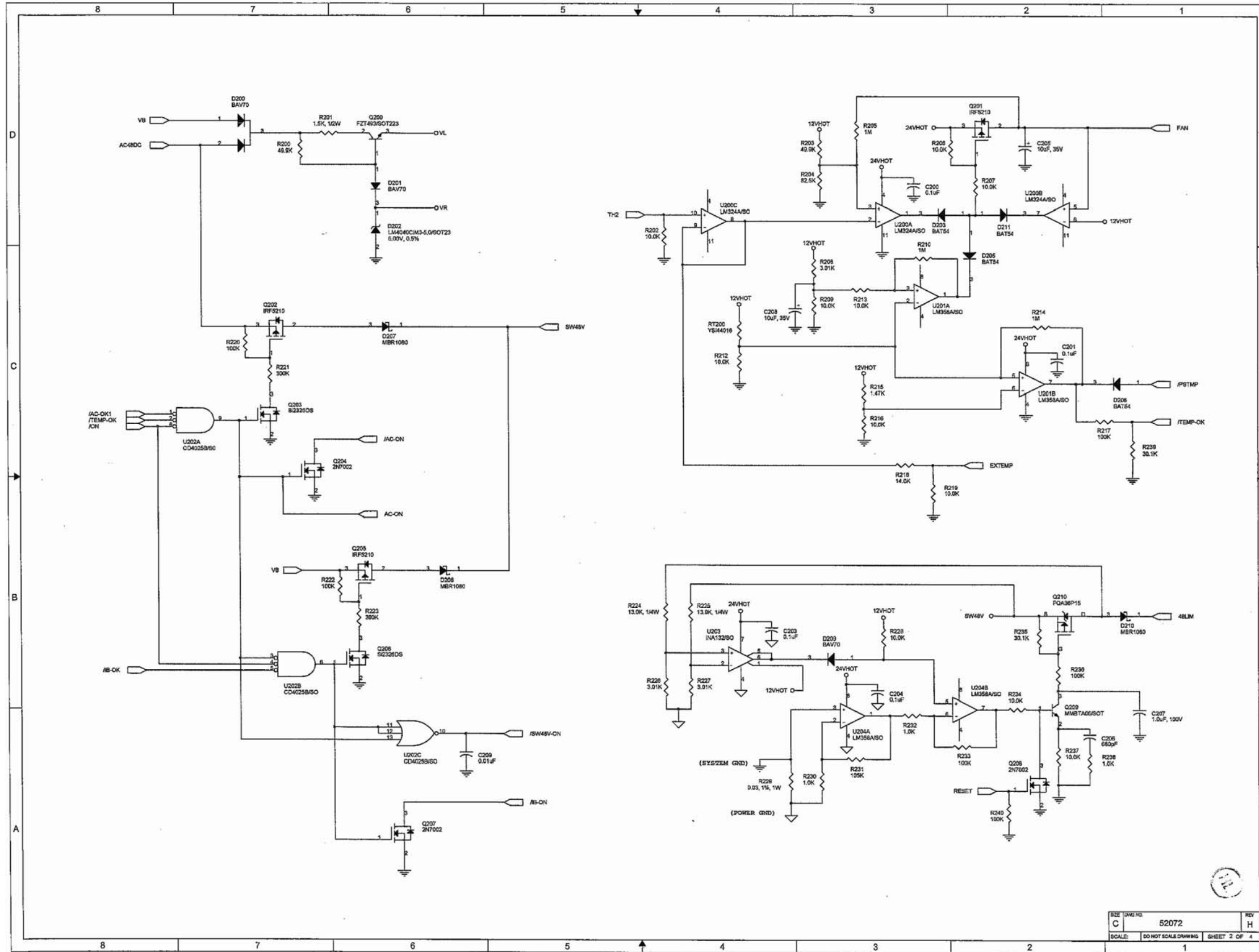


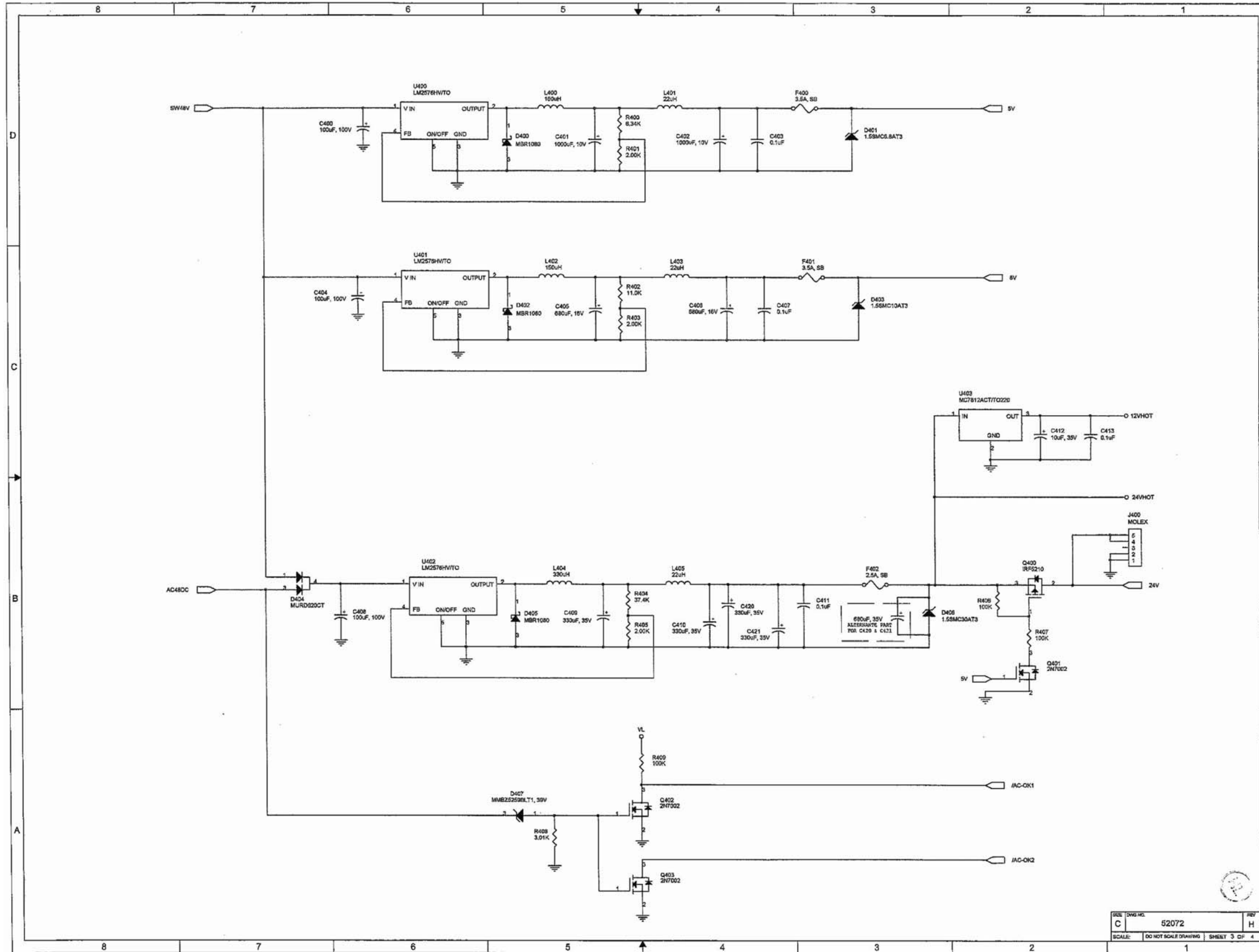




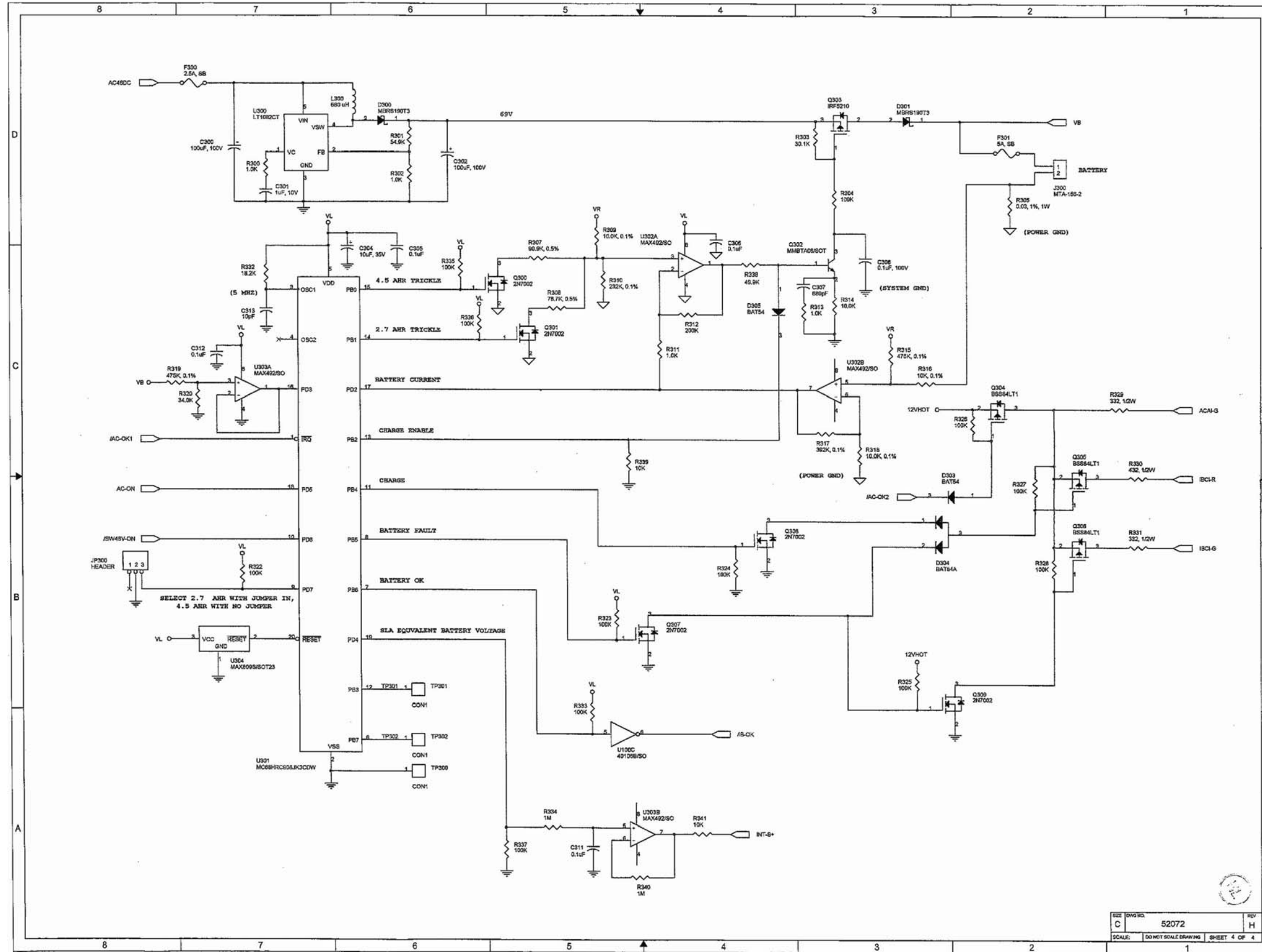


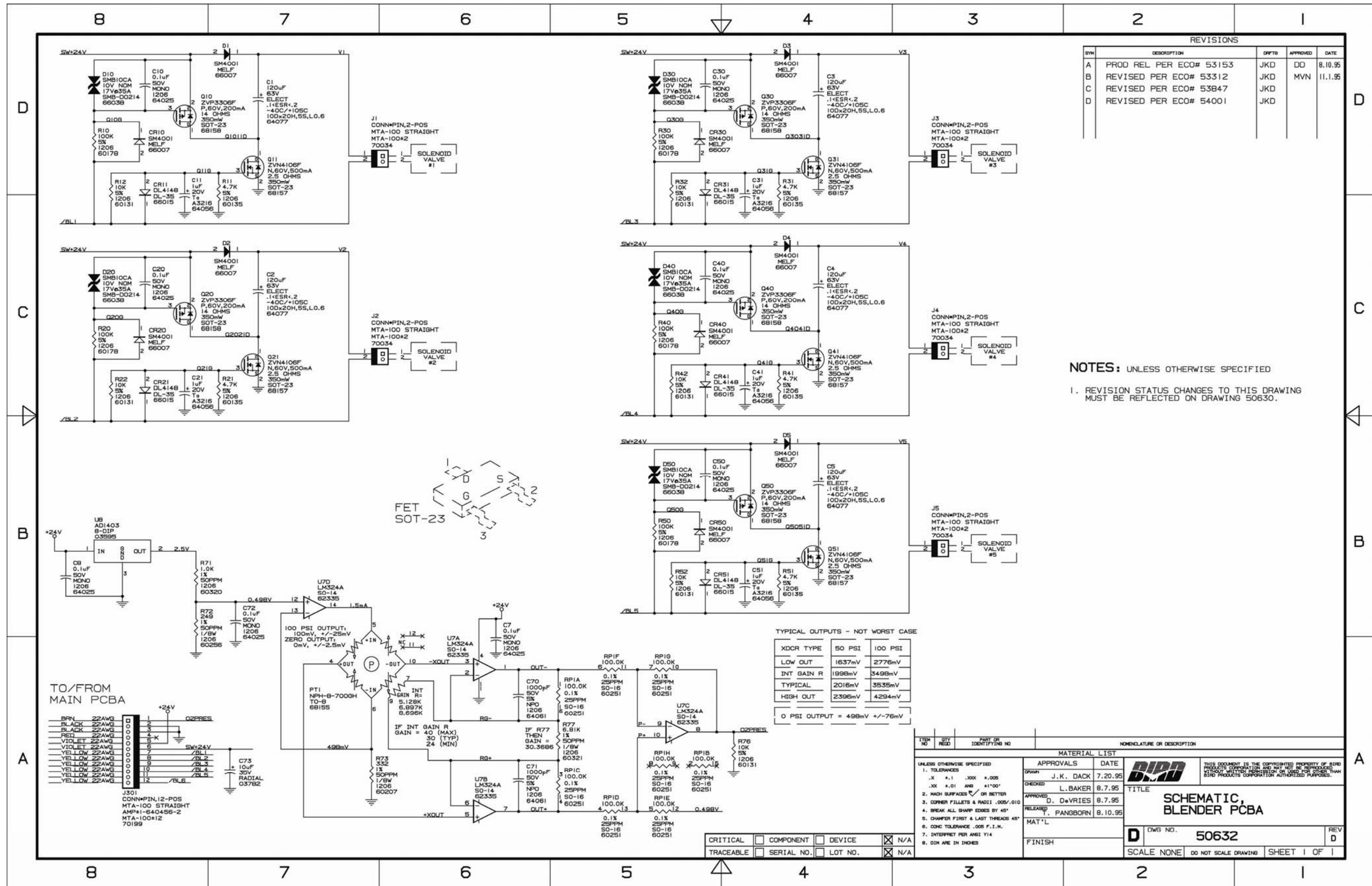


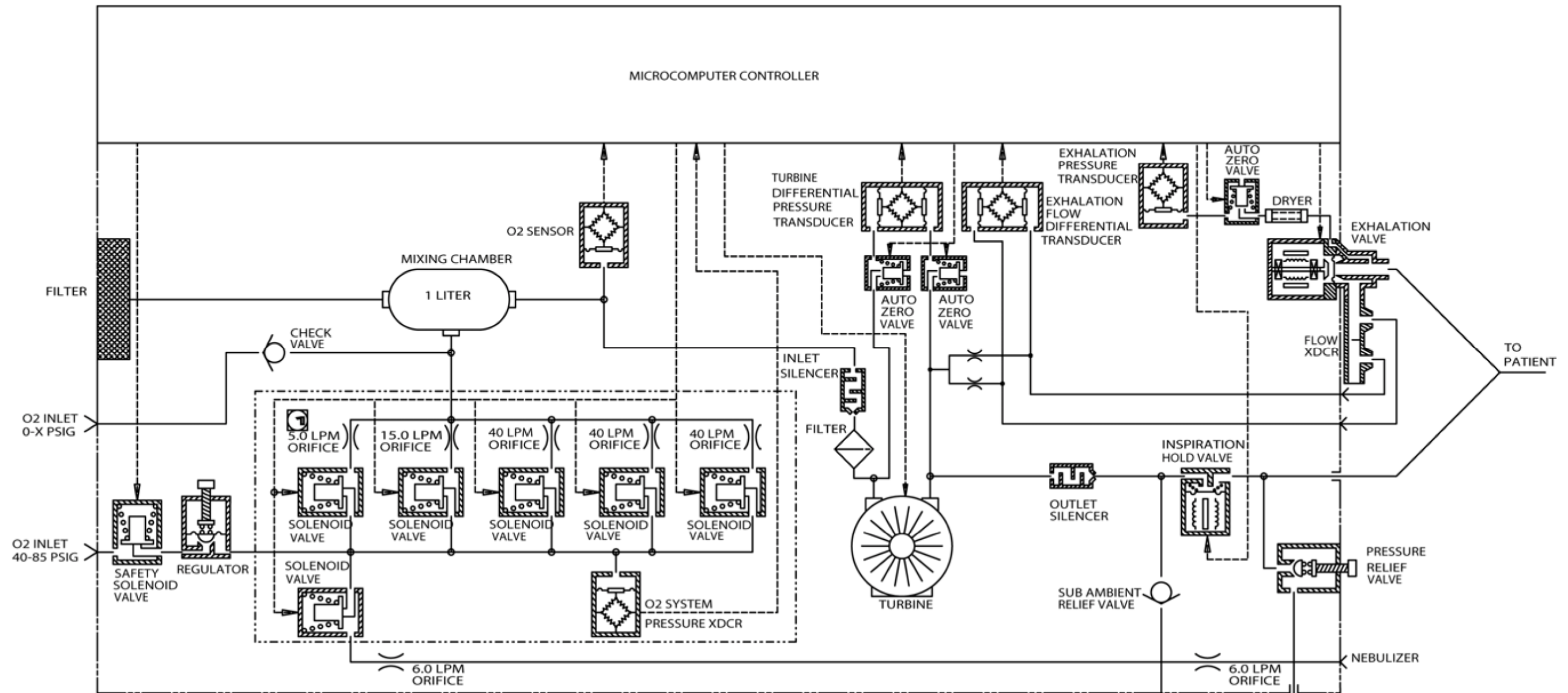




REV	52072	REV
C		H
SCALE	DO NOT SCALE DRAWING	SHEET 3 OF 4







NOTE: UNLESS OTHERWISE SPECIFIED.

ALL OXYGEN FLOWS CALIBRATED AT 40 PSIG
INLET PRESSURE.

SCHEMATIC, PNEUMATIC SYSTEM - VELA

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