System Design Specification

Open Source Ventilator Electronic System

Velocity Team

Nadim Conti

Electronics System Design & coordination on behalf of the Open Source Ventilator - Open Lung Velocity team

GitLab - @nadimconti
Email - osv@nadimconti.com

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Last update: 17 April 2020 Version 1.2

TO DO

Changelog

Legenda

version: what's new (update date)

- ***0.1**: first release, document created from the guideline specifications*
- *0.2: updated usage notes and specific parameters in the motor section (30-March-2020)*
- *0.3: added panel dimensions and fixed alarm board section (31-March-2020)*
- *0.4: specified powers supply unit section (1-April-2020)*
- *0.5: polishing here and there (2-April-2020)*
- *0.6: adding board dimensions (3-April-2020)*
- *0.7: adding suggested PSU and flow sensors part numbers (4-April-2020)*
- ***0.8**: adding information on Alarm module, creating alarm module flow chart , adding information on stepper motors used in Concept 13 (5-April-2020)*
- *0.9: adding info on General Purpose Inputs, need to be able to read up to 4x limit switches.*
- *0.10 Adding note on stepper motor encoders requirements and usage (6-April-2020)*
- *0.11 correct connectors PN on power board, Update power module LDO PN (7-April-2020)*
- ***0.12** Update alarm module casing considerations, different buzzers, LEDs/lights and dimensions. Fix watchdog time window on alarm module to 300ms. Add pinout definition on Motor Control Board. Uploaded alarm module dimensions and pinout. Moved module dimension specs in their respective section. Removed panelization image to avoid confusion.*
- ***0.13**: adding motherboard dimensions and specifications, corrected MCU selection statement. Abandoning ESP32 to stay only on one architecture, added protection fuse PN, alarm sound control via I2C PN (8-April-2020)*
- *0.13.2: add table of contents and polishing (9-April-2020)*
- *0.14: updating motor control board dimensions and new pinout, adding power board dimensions and pinout (11-April-2020)*
- *0.15: updating pressure sensor selection and part numbers (12-April-2020)*
- *0.16: adding User Interface flow chart and user interface module dimensions, adding component on SMD placement only on one side of the PCB as preferred layout (14-April-2020)*
- ***1.0: Integrate the guideline specification,** Update control loop block diagram, add comments on Motor Control loop and Physiological Control Loop, updated BOM max budget and considerations, specified IEC requirements for the PSU and reviewed example part numbers (15-April-2020)*
- ***1.1: Complete revision and polishing,** add power module dimension and pinout, add 3D MODEL of the ES assembly**, adding power supply board rail generation tree, adding motor***

board new dimensions, adding note on pins going to MCU from motor control board , *add user interface definitions, add user interface development tools comment, add Useful links section at the end of the document,Update motherboard dimensions and Power board placement* ***(16-April-2020)***

- ***1.2: Introduced the Electronics System Design Safety Related Directives section, added pressure sensor calculations, flow chart diagrams updated and corrected (17-April-2020)***

TO DO

1.

Usage Notes

This document is a **system design specification** for the **electronic system** design planned to be used in the Open Source Ventilator project and related.

This document covers both a guideline to a well structured **design and the Velocity Team Implementation, studied to be pneumatic mechanics agnostic.**

IF YOU WANT TO COLLABORATE PLEASE CONTACT THE COORDINATOR TO BETTER DISTRIBUTE THE EFFORTS!

This document shall be used as a reference to participate in the OSV & OSV-Velocity team design and to understand the working principles of the Electronic Control System.

The here detailed system is designed to work with the Mechanical Concept 13, but, as it is modular and mechanical concept agnostic oriented, given that compatibility must be verified, it can also be used by all the other mechanical concepts.

This document is not final and is being updated as the design process progresses-

This document provides definitive system specifications for the electronics system developed by the velocity team, **based on the guidelines in itself contained**. **These guidelines are derived from user requirements and user experience feedback on the OSV concepts as well as on existing ventilators.**

Disclaimer

The design guidelines, attached documents and other materials ("Material") contained and linked on this document are intended to facilitate the design of an electronics system controller for a prototype reproducible medical device to be used, if required, during the Covid-19 pandemic or similar emergency situations. The Material is not itself a medical device. The Material has not been tested and has not been approved for use in humans or animals by any regulatory authority of any country.

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Any ventilator system that has not been approved by a competent medical device regulatory authority may not deliver to the user the ability to properly monitor and control tidal volume, inspiratory pressure, inspiratory: expiratory ratio, heart rate, nor provide the user with the ability to monitor and control positive-end expiratory pressure (PEEP), peak inspiratory pressure (PIP) or to adapt to individual patient requirements. Inability to monitor and/or control any of these factors can cause death or serious permanent injury.

The disclaimer of warranties and limitation of liability provided above shall be interpreted in a manner that, to the extent possible, most closely approximates an absolute disclaimer and waiver of all liability.

System Introduction

The goal of the Electronics System can be summarized as:

To be able to monitor the respiratory status of a patient, and provide ventilation support or control as defined by the user via a user interface

Note: User: medical figure responsible for setting and monitoring the ventilation of a patient

The system monitors sensors and controls an electrical actuator to provide mechanical movement for the ventilation. Senses feedback on the movement itself, in addition to the control of the parameters defined in this document, derived via electromechanical sensor readings and calculations.

The system provides visual and auditory alarms in case certain monitored readings are outside the preferred range selected by the user.

The system provides all of this while maintaining a reduced BOM price to ease manufacturing and leaves room for changes on the controlled actuator.

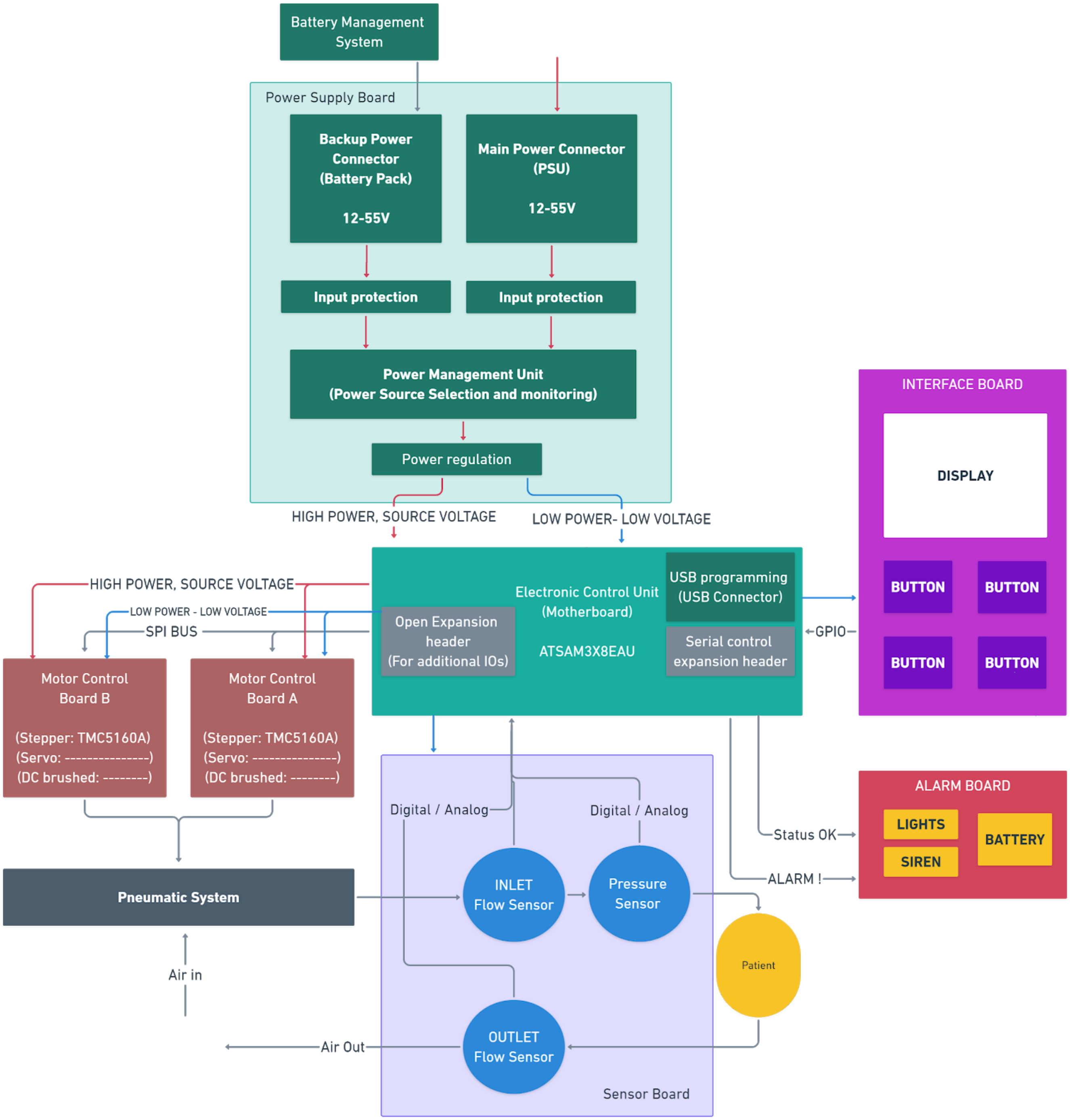
The system provides a redundant power supply line selection, with main and backup line, enabling hot swap operations.

The system uses open source firmware and hardware as much as possible to enable rapid prototyping, testing, and firmware development.

Links and further information

1. The OSV Electronic System is responsible for the control, operation and user interface for the Open Lung project (https://gitlab.com/open-source-ventilator/OpenLung/-/tree/master)
2. The OSV Electronic System is being developed by the OSV-Velocity Team
3. Communications between team members are held in the slack group: osv-velocityteam.slack.com
4. Task management and synchronization is controlled in the Trello board: https://trello.com/b/VwPQonmK. *To request access to the Trello board, use the contacts provided in the cover page of this document.*
5. The Whimsical interactive block diagram (seen in the next chapter) can be reached here: https://whimsical.com/SYkDG1o1GHBbhKQFqAbXPB

Block diagram



The electronic system block diagram is shown.

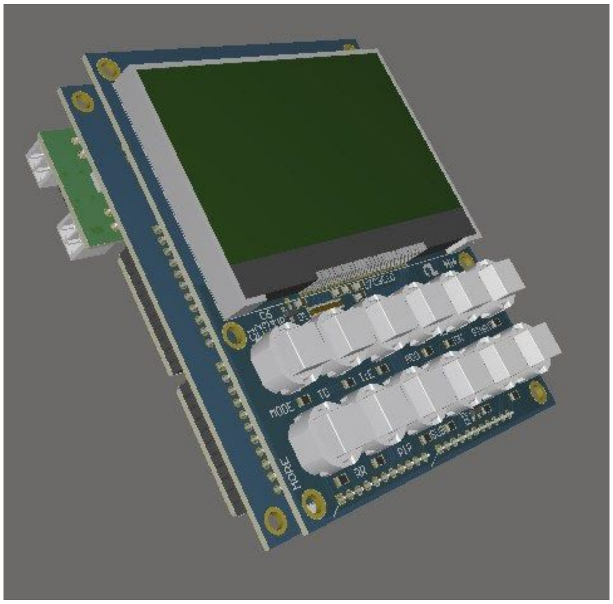
The block diagram includes all the mandatory components that the electronic system must have to properly reach its goal.

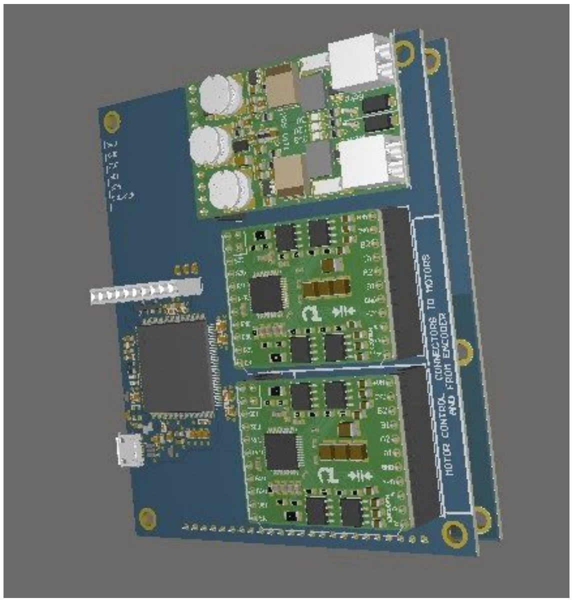
The Velocity team OSV Electronics system is a rigid PCB multiboard approach that tackles the OSV BMV (Bag-Mask-Ventilator) control problem with modularity and ease of access-modifications in mind.

Blocks unrelated to the electronics are not included in the block diagram.

The pneumatic system and patient blocks are shown only for reference as the system, at least in its hardware architecture, is patient and pneumatic system agnostic.

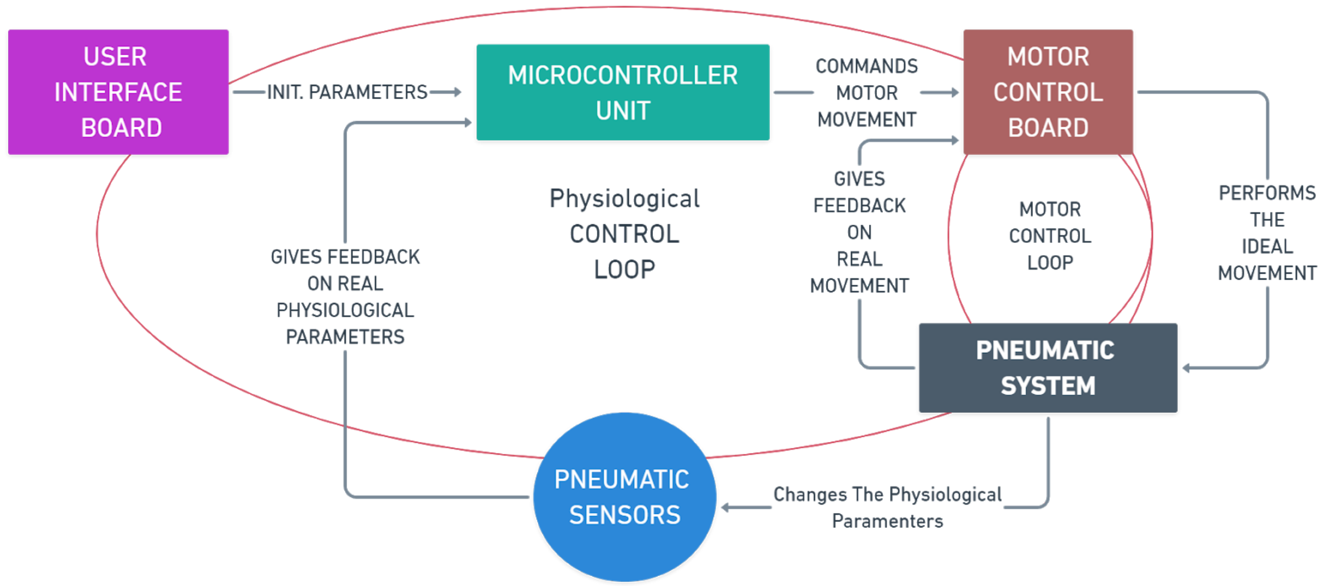
Blocks are coloured to highlight different areas of development.





Modular Electronics System Approach. On the left the User Interface panel side Can be seen. On the right the motor control, power supply input, and microcontroller units are shown.

Control Loop

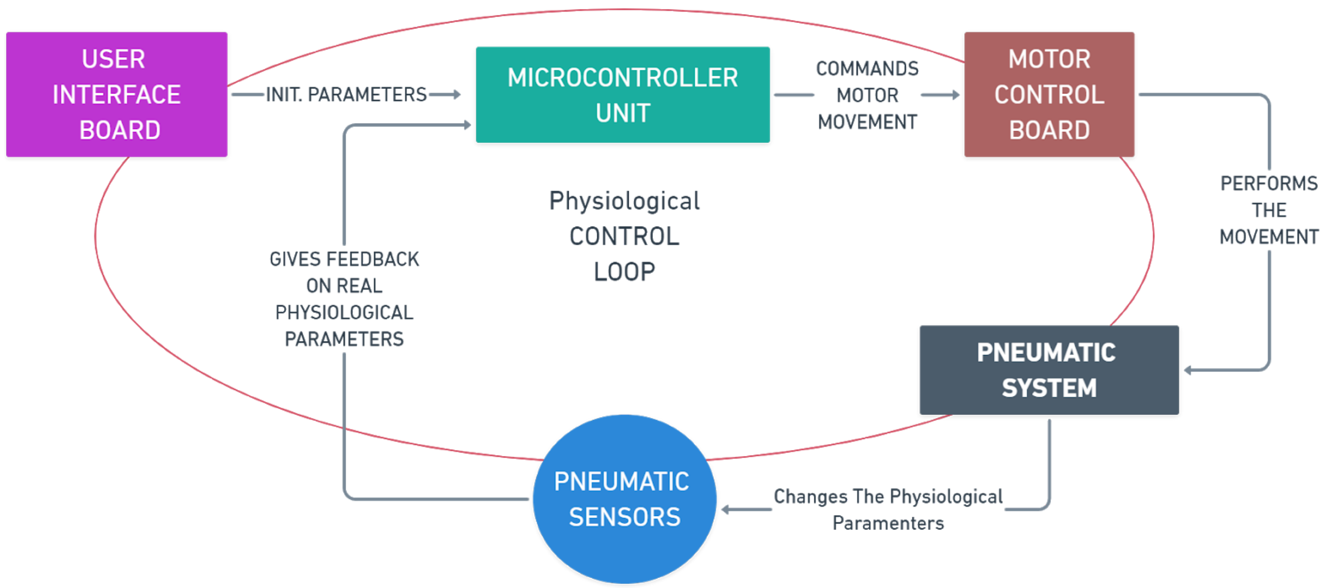


The feedback control system is what defines the system behaviour and needs. It is characterized by two control loops, an inner one taking care of the motor behaviour, and an external one taking care of the physiological response. To avoid stability problems, the inner control loop must be much faster than the outer one, possibly by being completely hardwired with no code handling it on the microcontroller unit (MCU).

Motor Control Loop Guideline and Overview

1. A Pneumatic System movement/variation is needed as computed by the MCU.
2. The MCU commands the motor control board to perform the movement
3. The Motor control board drives the pneumatic system by performing the movement requested by the MCU (or the correction after point 6).
4. The pneumatic system (motor position-movement) is changed by the Motor Control board.
5. The Motor control board senses the motor movement and checks that it is consistent with the original intention
6. If the movement is not consistent, the motor control board corrects the operation. Loop to 3.
7. If the movement is consistent, the motor control board acknowledges the MCU. Loop to 1.

Physiological Control Loop Guideline and Overview



1. The User (Responsible Medical Personnel) sets a MODE of operation, pressure, and volume data in the input/output interface
2. The Interface communicates all the data to start the ventilation to the MCU.
3. The MCU computes the sequence of movements to be done by the motor control board to achieve the desired behaviour, based on pre-calibrated reference variables.
4. The MCU activates motion of the pneumatic system by issuing commands to the Motor Control Board.
5. The Motor control commands the Pneumatic system accordingly.
6. The pneumatic system is altered and starts providing ventilation to the patient.
7. The sensors connected to the pneumatic circuit provide feedback on the current physiological parameters.
8. The MCU reads the sensors and computes if the system is following the pre-computed trajectory.
9. The MCU computes the correction (if needed) to keep the system on trajectory and goes to step 4.
10. **Interrupt: if new commands are being issued by the Input/Output panel, the MCU computes the new trajectory to be executed at the next breathing cycle**

General Electronics requirements

The final PCBA (Printed Circuit Board Assembly) must satisfy all the following requirements, therefore all the components included in the BOM (Bill Of Materials) must match or exceed them. Both the PCB stackup and all the components included in the BOM must be lead-free and RoHS-compliant.

Environmental requirements

Operating Temperature:	-10℃ to 70℃
Transport / Storage Temperature:	-20℃ to 80℃
Operating Humidity:	15% to 95% (non condensing)
Operating Altitude:	-170 to 3000 m
Mean Time Between Failures (MTBF):	10000 hours*

**Absolute minimum requirement for all the components placed on the electronics boards. This is not an indication of the MTBF of the whole Electronics System, but a guideline for component selection.*

Cost

Final BOM cost (PCBA components) for 1000 units is being evaluated. Components should be selected to match availability for a 1000 unit volume production.

Boards size and integration

Board outline dimensions allow for efficient panelization in 10"x12” ca. panels (25x30cm).

PCB Layout Directives

PCB Layout must follow IPC Class 2 design rules (Dedicated service electronics), to achieve a good quality and long life cycle. **IPC Class 3 directives are preferred** (High-reliability electronics), to achieve a fail proof quality and very long life cycle.

PCB Layout rules should follow the recommended technical capability of the PCB manufacturer and assembler as, in example, explained at the following link: https://circuithub.com/capabilities

PCB stackup should not exceed 4 Layers. Routing should be done with absolute minimum details as 150um/150um/300um for copper clearance, minimum copper detail and minimum hole diameter to keep the manufacturing price low and production timelines short.

Every component connected to a power plane should have thermal reliefs to help with hand soldering.

All the SMD components **should** be placed only on one side of the board. It is allowed to place THT connectors on the opposite side. The number of different SMT/THT components should be minimized. Silk screen should clearly define each component and their respective polarity.

PCB Manufacturing Directives

PCB Manufacturing should be done in as few layers as possible without compromising on performance (EMI) and reliability. The multilayer rigid FR-4 substrate should have the following properties:

1. **Conductor material :** must be Cu, either Rolled Annealed (RA) or Electro Deposited (ED).

2. **Surface finish: ENIG** to improve assembly yield and therefore lower the final total PCBA (Printed Circuit Board Assembly) cost.

3. **Core material critical properties:**
    a. FR4 TG130-140 or greater as by E-2/105 DSC
    b. Flammability rating equal or exceeding V-0 as by UL94
    c. Dielectric breakdown greater than 40kV (preferred 60kV) as by D-48/50+D-0.5/23
    d. Moisture Absorption lower than 0.35 as by D-24/23
    e. Surface resistivity greater than 10^5 MOhm as by C-96/35/90
    f. Volume resistivity greater than 10^5 MOhm-cm as by C-96/35/90

PCB Assembly Directives

PCB Assembly should follow IPC-A-610 (Acceptability of Electronics Assemblies) Class 2 or above, to guarantee a good reliability of the final assembly.

The PCB BOM should avoid using THT (Through Hole Technology) parts.

SMD (Surface Mount Device) Components smaller than 0603 imperial (1608 metric) should also be avoided to enable easy emergency repairs and hand assembly processes, this is not a mandatory requirement as certain power integrity related components could have the technical need to be smaller.

BGA packages shall not be used, as well as any package with pitch below 0.5mm.

Schematic Design Directives

The schematic design should be written by following the convention of only one functional block per page. Pages must follow the A4 (or A3) landscape standard and feature the name of the engineer/designer drawing the page in consideration. The designer should also include one or two ways to contact him or her, preferably a GitLab account / Slack and email.

The various schematic pages should then be linked together via a schematic block diagram and dedicated page.

In each schematic page, a title and brief description of the page must be included to improve clarity of the final work.

In each page, nets proprietary to the page *(that do not need connection to any other pages)* and nets that do require connection to other pages must be clearly highlighted to avoid schematic and integration errors.

Every component should clearly state its identifier (i.e. C12, R25, IC2), value (10R, 4u7F, 1mH), and if possible the full manufacturer part number, manufacturer name is a plus to be shown on the schematic.

Suppliers part numbers (PN) should not be used in the schematic, but can be provided in the component information together with the manufacturer PN.

Note: providing contact identification is necessary to be able to track design choices and contact whoever already worked on a system part prior to starting a new iteration or upgrade.
Contacts save time.

Electronics System Design Safety Related Directives

- **WIRELESS COMMUNICATION**

  Over The Air firmware upgrade for any module of the electronics system shall not be possible. If wireless communication capability is chosen to be implemented, the wireless unit must feature a hardware switch that, once triggered, completely removes power to the wireless communication element. Therefore, MCUs with integrated wireless must not be used. This requirement is necessary to limit ICT safety issues in a life-critical medical device. Remote hacking must be prevented.

- **FIRMWARE AND MICROCONTROLLERS**

  Firmware must be minimized in its presence. A non microcontroller oriented approach must be followed wherever possible. State machines and logic structures or integrated circuits, especially if approved for critical applications, must be preferred. This requirement is necessary to limit the load on firmware certification and validation.

- **CONTROL STRUCTURE**

  The electronics control system must operate in a close loop. Open loop control approaches shall not be pursued as to measure the physiological parameters of the patient is a fundamental requirement of the final application.

Specific Electronics requirements

Power Supply Unit

The Power Supply Unit (PSU) block is responsible for converting AC main voltages to DC low voltages usable by the Electronic System (ES) here detailed. The PSU is not included as a design module in this document as it is not designed by the team.

The ES therefore does not include AC-DC conversion and galvanic isolation from the main supply, that must be provided by the PSU.

*Note: The electronic system can accept 2 voltage sources at the same time, one designated as **primary unit**, and a second (optionally installable, but not mandatory to have for the correct functioning of the ES) designated as **backup unit**.*

PSU Technical Requirements:

1. **Certification:** IEC 60601-1
2. **Conducted Emissions:** EN55011 (CISPR11) Class B
3. **Radiated Emissions:** EN55011 (CISPR11) Class B
4. **RF field susceptibility:** EN61000-4-3, Level 4
5. **Conducted susceptibility:** EN61000-4-6, Level 3
6. **Magnetic field immunity:** EN61000-4-8, Level 4
7. **Voltage dip, interruption:** EN61000-4-11
8. **Input Voltage:** 90 - 240VAC
9. **Input Frequency:** 50 - 60Hz
10. **Isolation Voltage:** 4kV or higher
11. **Output Voltage:** 48 Volt (nominal)
12. **Minimum Nominal Power Output (MNPO) *:** 240W
    Note: convection only, without forced airflow

Compatible Power Supplies:

- *RPS-400-48-C*
  MEAN-WELL
  IEC60601-1 (OK)
  AC/DC CONVERTER 48V 254W (400W WITH FORCED AIRFLOW).
  https://www.digikey.com/product-detail/en/mean-well-usa-inc/RPS-400-48-C/1866-4063-ND/7706074

- *CFM351M*
  CINCON
  IEC60601-1 (OK)
  AC/DC CONVERTER 48V 240W (350WWITH 10CFM AIRFLOW) MEDICAL POWER SUPPLY WITH PFC
  https://www.cincon.com/productdownload/SPEC-CFM351M-V18.pdf

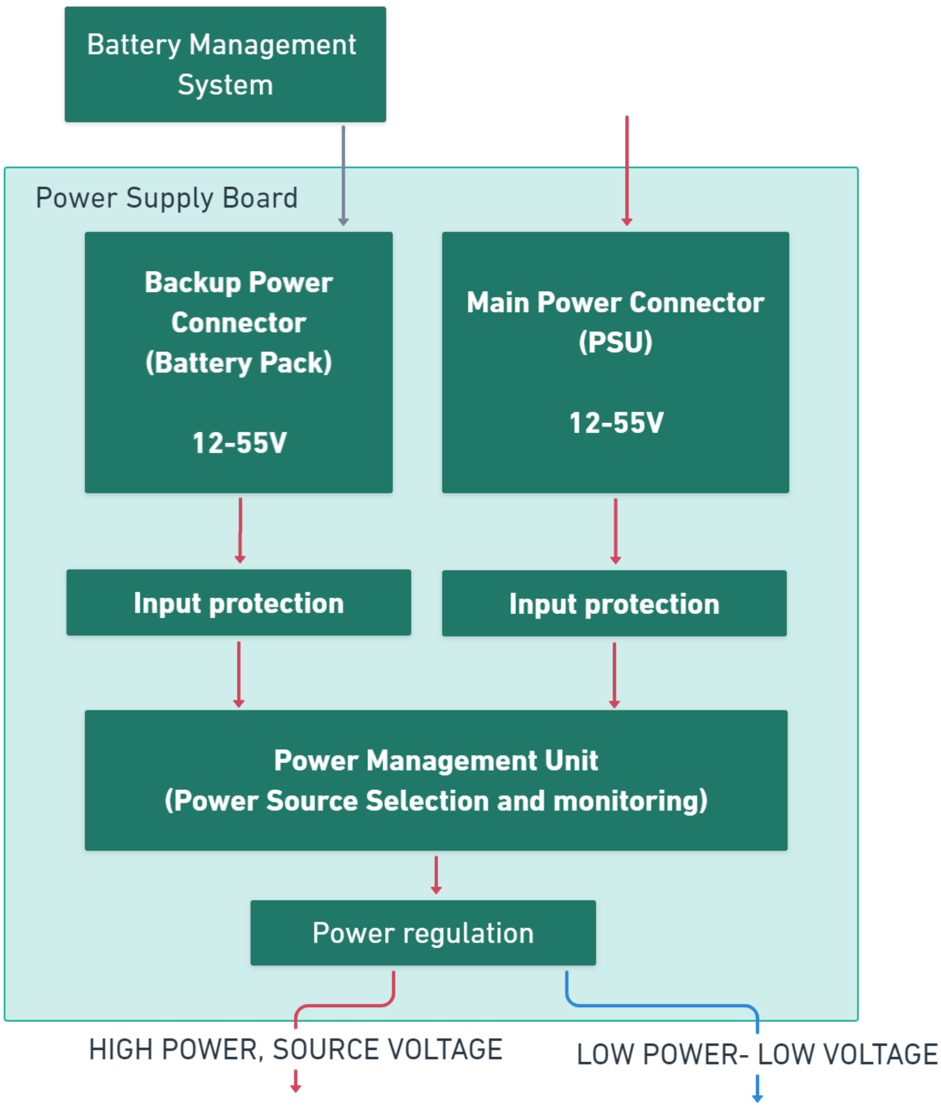
Backup Battery Pack Unit

If a battery pack is chosen to be used with the ES, either as primary or backup PSU, the battery pack must integrate all the required battery-related safety circuits including, but not only, undervoltage detection, thermal protection, cell voltage equilibration (for multi cell packs) and charging circuit.

Note: if a Backup Battery Pack is used as a backup PSU, and the charging circuit of the battery pack is connected to the primary PSU, the primary PSU power ratings must follow the relation:

$$MNPO_{(with\_battery\_pack)} = MNPO + (Max\_Charging\_circuit\_required\_power)$$

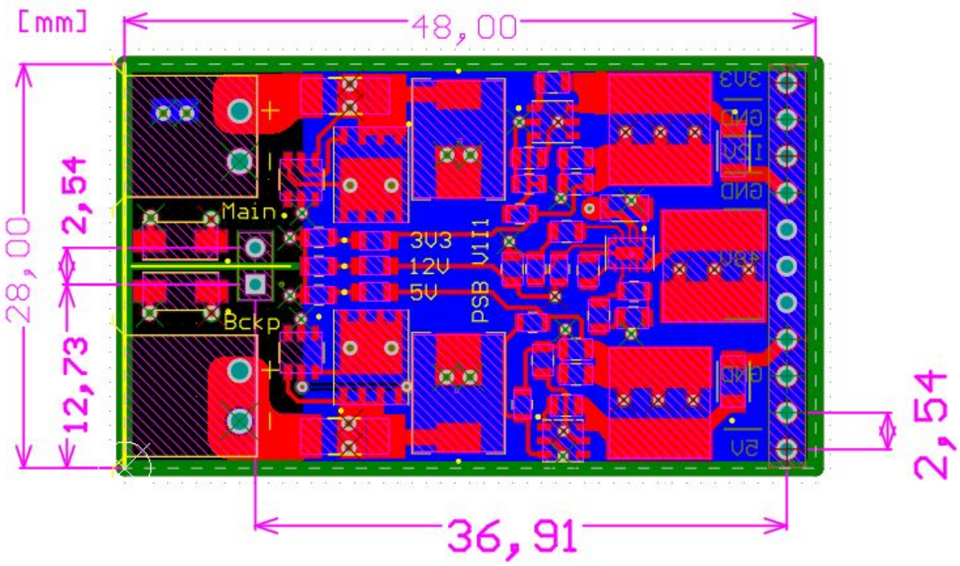
Power Supply Board



The Power Supply Board (PSB) is the block responsible for all the functional elements included in the image above. The board can be partially or totally included into a PSU external to the ES. If the PSB is designed into the ES, it must provide two separated input connectors at the nominal voltage and power rating, input protections, power regulation and the power source selection/monitoring.

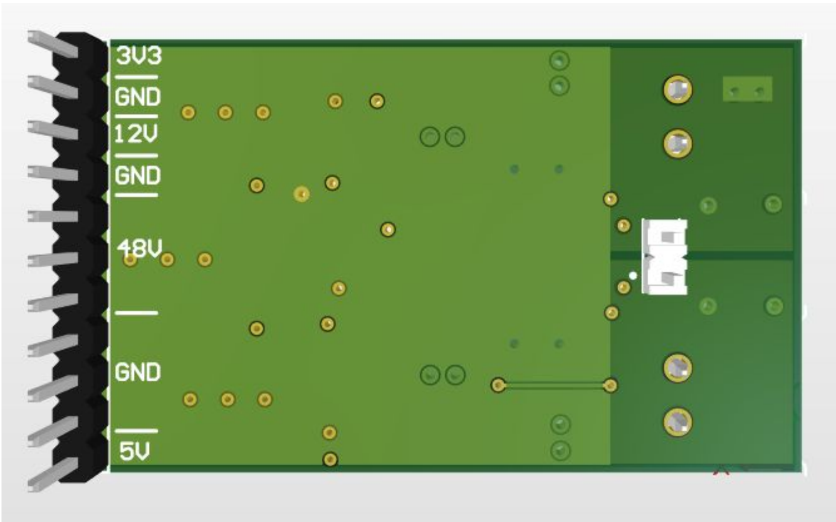
If the PSB is designed to be manufactured on the ES, it should be done on a single PSB that follows all the guidelines explained in the previous pages. Dimensions of the board, inclusive of all the power management sections, but the PSU block, are here presented.Its footprint includes the Power Connectors, input protection, power rail regulation and UPS (OR-ing) features.

Power Supply Board Dimensions and Pinout



Board dimensions, top view. Two connectors are provided on the bottom layer. One 2POS for mechanical support, and a 11POS 2.54 mm header for power connectivity to the motherboard.

Board suggested pinout, bottom layer view. In BLACK the connectivity header and in white the mechanical support one.



Power Supply Connectors on PSB/Motherboard

The connectors handling power delivery from the PSU unit to the motherboard/PSB (depending of the first module that interfaces with the PSU) must comply with the following requirements.

Technical Requirements (equal or exceeding)**:**

1. **Flammability rating:** UL94 V-0
2. **Maximum Contact Resistance:** 20 mOhm
3. **Absolute Minimum Voltage Rating (Operation Voltage):** 200 VAC
4. **Dielectric Withstanding Voltage (UL1059-12):** 1.5KV (60Hz, 1 minute)
5. **Surge voltage (IEC60947-1) :** equal or exceeding 2kV

Notes:

Power Supply connectors should leave ease of adaptation and repurposing. A standard terminal block header 2POS is suggested.

Each connector must have a mechanical polarization to avoid user-induced damage to the electronics components at first boot after assembly *(i.e. if the connector is pin-symmetric, it must be very difficult to plug it in the orientation opposite to the right one via asymmetric housings).*

Each power input, both main and backup, should have their own separated connection area (connectors) clearly distinguished on the silk screen of the PCB.

A backup connection for each power supply is welcome. Preferred backup connector is a 5mm barrel jack to be able to use commercially available PSUs (Power Supply Units) in case the need arises.

Connectors part numbers for reference:

1. *Preferred power connector:*
   MOLEX PN: 0395021002
   (TERM BLOCK HDR 2POS 90DEG 3.5MM)
   https://www.digikey.it/product-detail/it/molex/0395021002/WM7770-ND/1280621

2. *Preferred power connector mating:*
   MOLEX PN: 0395005002
   (TERM BLOCK PLUG 2POS STR 3.5MM)
   https://www.digikey.it/product-detail/it/molex/0395005002/WM23176-ND/2735117

3. *Alternative:*
   TE Connectivity AMP Connectors
   PN: 1776275-2
   TERM BLK 2POS SIDE ENT 3.5MM PCB
   https://www.digikey.it/product-detail/it/te-connectivity-amp-connectors/1776275-2/A98036-ND/1826899

   Note: the alternative connector can be placed instead of the MOLEX. This at volume productions will save on assembly cost as less tooling is needed, and save on BOM cost. The TE component is not suggested as a preferred choice as uncontrolled torque on its screws can lead to irreversible PCBA damage.

Important design consideration: for safety reasons, the primary and secondary power block shall not be connected if not via the power selection module.

Input Protection

The Input Protection block provides safety features to the power delivery network reaching the internal components. The input protection components are placed as near as possible to the power input connectors and in no exception are shared between the two PSU inputs, therefore there must be two power input protection circuits, one for the primary input, and one for the backup.

Input Protection Requirements:

Note: nominal input power supply line is at 48V

1. **Over voltage protection:** must engage at 56V (Absolute Max. voltage input + 12% ca.)

2. **Surge voltage protection:** up to or exceeding 1.5kW* of maximum dissipated power, **must engage at 58V (Absolute Max. voltage input + 20%)**
   **Note: via Transient Voltage Suppression (TVS) devices with ratings exceeding 1.5kW.*

3. **Overcurrent protection:** must engage at 6.3A or lower if needed*

   Note: depending on maximum expected current consumption. Can be done via resettable fuses or fast blow fuses.* ***Overcurrent protection, if non resettable, must be implemented using anti-blast packages.*

Note: the layout and schematic of the power input protection MUST allow change of the here detailed required technical values *(i.e. from 6.3A overcurrent protection to 4A or 5A)* ***by means of component swap only (change of Part Number in BOM).***
A structure of the input protection block that would require change in the layout to vary these values shall not be pursued.

Important design consideration: for safety reasons, the primary and secondary power block shall not be connected if not via the power selection module.

Part numbers for reference:

- **Fuse (non resettable):**
  Bourns Inc.
  SF-2410FP630W-2
  FUSE BRD 6.3A 125VAC/125DC 2410
  https://www.digikey.it/product-detail/it/bourns-inc/SF-2410FP630W-2/SF-2410FP630W-2CT-ND/8619429

- **Fuse (non resettable) substitute:**
  Littelfuse Inc.
  2410SFV6.30FM/125-2
  FUSE BOARD MOUNT 6.3A 125VAC/VDC
  https://www.digikey.it/product-detail/it/littelfuse-inc/2410SFV6-30FM-125-2/2410SFV6-30FM-125-2CT-ND/2766080

- **Surge Voltage protection:**
  Bourns
  SMCJ58CA
  TVS DIODE 58VWM 93.6VC SMC
  https://www.digikey.it/product-detail/en/SMCJ58CA/SMCJ58CABCT-ND/2254308

- **Over Voltage protection:**
  ON Semiconductor
  1SMA5943BT3G
  Diodes Zener 56V 1.5W
  https://www.digikey.it/product-detail/en/on-semiconductor/1SMA5943BT3G/1SMA5943BT3GOSTR-ND/147475

Power Management Unit

The PMU ensures that voltage levels are as expected, current is under control, and manages the joining of primary and backup power chains with, if possible, priority over the primary connection.

Note: in the PMU the two power rails are joined together.

Requirements:

1. **Providing a one way current flow, from the input protection block to the power regulator. Current must not flow backwards in any circumstance.**

2. **Being simple and modular (so that if the backup power chain is not populated, the module can operate accordingly).**
   Note: the simplest example of a PMU are two couples of two diodes, with in each couple their cathodes connected together, representing the output stage of the PMU, and anodes connected to the power regulator stages.

Part numbers for reference:

- **OR-Ing (Power Supply Selection):**
  TI National Semiconductors
  LM5050MK-2/NOPB
  IC OR CTRLR N+1 6SOT
  https://www.digikey.it/product-detail/en/texas-instruments/LM5050MK-2-NOPB/LM5050MK-2-NOPBTR-ND/2508265

Important design consideration: for safety reasons, the primary and secondary power block shall not be connected if not via the power selection module.

Power Regulation

The power regulation unit provides voltage levels regulation for the electronics component on the ES.

The power regulation unit operates without knowledge of the power source, therefore its nominal voltage input is the output of the power management unit.

The power regulation block allows for two distinguished power domains to enter the ES, one dedicated to power only uses (i.e. only powering the motor), and the other with 3 power rails going to the electronic control only (i.e. powering the Micro Controller Unit (MCU), User input and output interface, sensors, etc..). This allows for noise isolation between the two domains and avoids power delivery network issues that could affect the control operation of the ES.

The two separated domains are obtained by splitting the power input into two before starting any regulation process. The Power planes should then be kept separated across the whole ES system and be connected at one point only: in the PSB.

Requirements (Power Rail):

1. **48V 4A**
   Note: must provide enough power to the motor control unit.

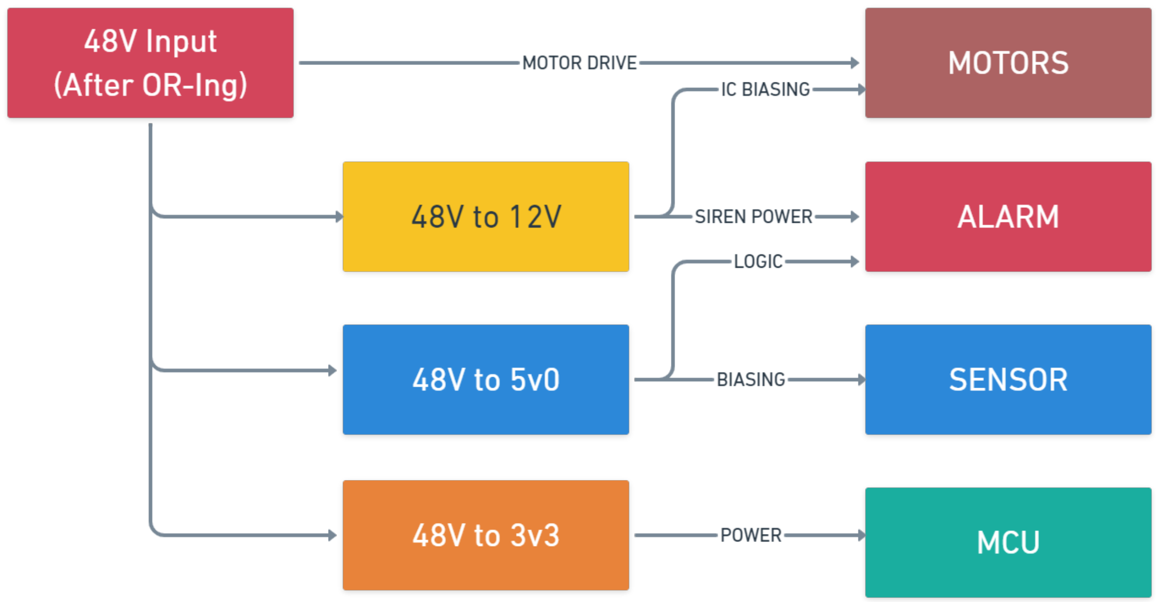
2. **Must provide a low loop inductance (design best practices)**
   Note: to lower EMI (ElectroMagnetic Interference), current and voltage spikes in the network.

Requirements (Control Rail):

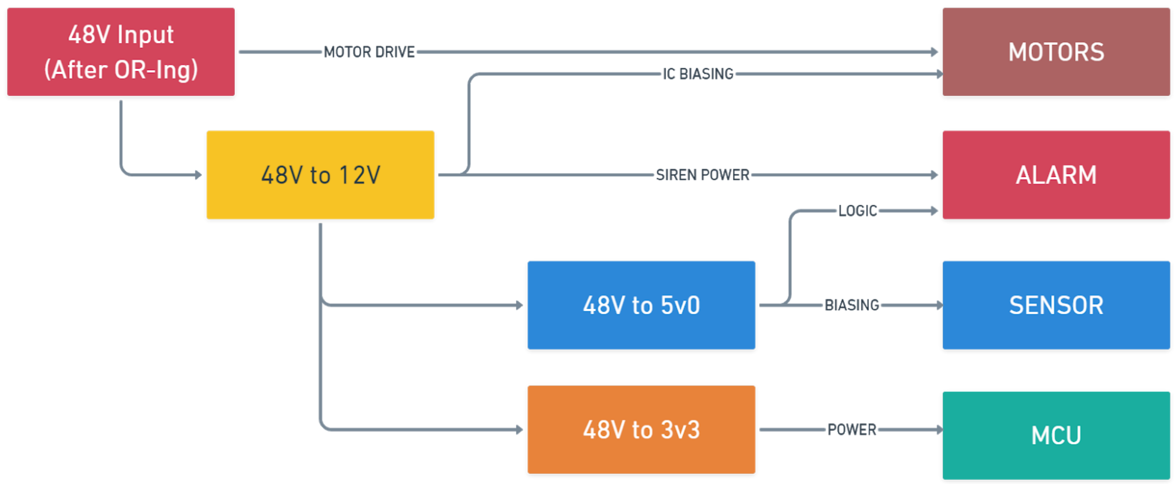
1. **5V 0.5A rail (A)**
   Note: Must provide enough power to control all the electronics on board
2. **3v3 0.5A rail (B)**
   Note: Must provide enough power to control all the electronics on board
3. ***12v 0.1A (C)***
   Note: added to provide enough power to sirens on the alarm module and motor control IC
4. **Voltage ripple below 20 mVpp**
5. **Output Capacitance 30uF or higher** (or according to selected integrated circuit)
   Note: must provide enough bulk decoupling capacitance to avoid charge depletion in the circuit and ensure correct operation of the regulation module

The Control Rail power generation tree can be of the two following kinds. Depending on the chosen structure, the current and power ratings of each regulator must be changed accordingly:

- 48V to 12V regulator, 48V to 5V regulator, 48V to 3v3 Regulator



- 48V to 12V regulator, 12V to 5V regulator, 12V to 3v3 Regulator



Part Numbers for reference:

- **3v3 and 5v rail generation from 12V:**

  Texas Instruments
  LMR14010ADDCR
  IC REG BUCK ADJ 1A TSOT23-6
  https://www.digikey.it/product-detail/it/texas-instruments/LMR14010ADDCR/296-49761-1-ND/9462675

- **3v3, 5V, 12V rail generation from 48V:**
  Maxim
  MAX17502EATB+T
  IC REG BUCK 1A
  https://datasheets.maximintegrated.com/en/ds/MAX17502.pdf

Electronics Control Unit (Motherboard)

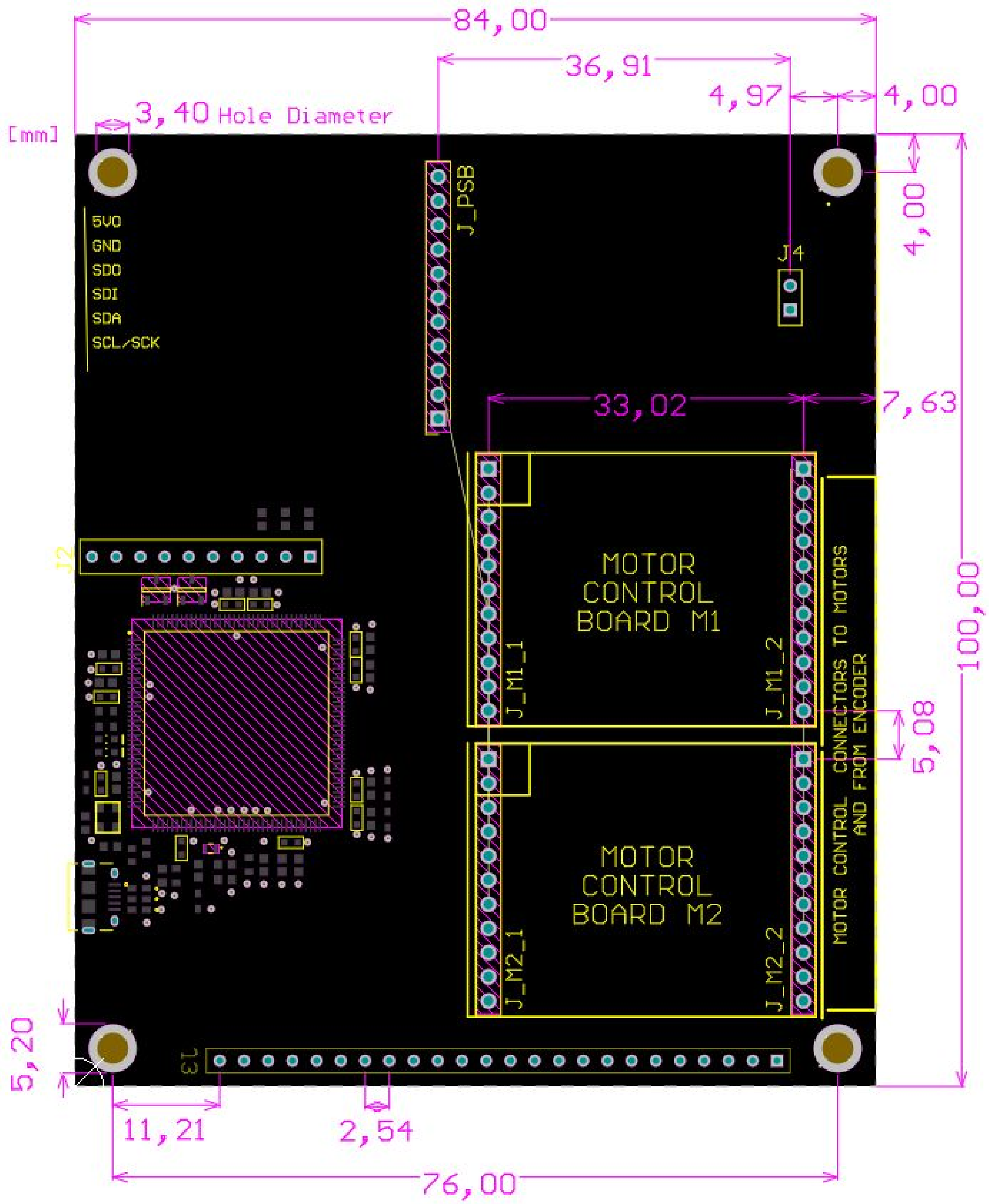
The Electronic Control Unit (ECU) is the block responsible for the overall control of the system and the internal interconnection of sensors and actuators.

The ECU is based on a microcontroller to enable simple dedicated firmware development and high performance. Any MCU is welcome as long as it can satisfy all the following technical requirements.

Technical details:

1. The MCU can be programmed via a micro-USB (or USB-C) connector with no additional external hardware required other than the USB cable itself.
2. The MCU supports firmware upload and upgrade via the **Arduino IDE, impersonating an ARDUINO IDE compatible MCU, or via an easy to access and mainstream MCU Programming IDE.**
   Note: This enables rapid firmware development and universal, well documented access.
3. The MCU communicates with the Motor Control Unit chipsets via SPI, and provides / reads all the signals related to the unit as detailed in the relative section.
4. The MCU monitors all the sensors detailed in the **sensor** section. The monitoring can be done via ADC sampling, I2C interrogation, or SPI communication. The communication protocol is set in the firmware, therefore the MCU should support all the here mentioned connections.
5. The MCU must take user input as detailed in the **user interface** and **IO Panel** section.
6. The MCU must send to the IO panel all the information that the user requires to be shown via SERIAL UART communication.
7. The MCU must be able to trigger alarms as required in the **alarm** section, supporting all the signals and required timings.
8. The MCU should be able to be interrupted by the GPIOs going to the user interface connector without compromising the effectiveness of the pneumatic system action.
9. The MCU should not require a complex external BOM to function.

Motherboard dimensions and pinout



Note: the electronics module positioning on the motherboard can vary. The image serves the sole purpose of highlighting space constraints and a guideline for modules positioning in the first modular prototype of the ES.

Layout consideration: *If the motherboard is designed on a 2 layer stackup, it is possible to route the signals coming from the modules across the whole surface area**. If the chosen stackup is a 4 Layer one, it is MANDATORY in the motherboard layout NOT TO DRAW ANYTHING inside the area covered by the electronics modules**. This is necessary as, in case the first round of multi-PCB assembly works, the electronics modules will be integrated into the motherboard exactly where they are.*

Part Numbers for reference:

- Microchip Technology
  ATSAM3X8EA-AU
  IC MCU 32BIT 512KB FLASH 144LQFP
  https://www.digikey.com/product-detail/en/microchip-technology/ATSAM3X8EA-AU/ATSAM3X8EA-AU-ND/3128687

  Note: this is the preferred MCU as it is the same used in the Arduino Due board

- Microchip Technology
  ATSAM3S4BA-AU
  IC MCU 32BIT 256KB FLASH 64LQFP
  https://www.digikey.com/product-detail/en/microchip-technology/ATSAM3S4BA-AU/ATSAM3S4BA-AU-ND/2238266

  Note: cheaper alternative (almost half the price of the preferred option). It is slightly slower than the first two MCUs.
  It needs a check to be sure it is fully compatible with many arduino functions.

- ST Microelectronics
  STM32H750VBT6
  IC MCU 32BIT 128KB FLASH 100LQFP
  https://www.digikey.com/product-detail/en/stmicroelectronics/STM32H750VBT6/497-18110-ND/9453371

  Note: much faster than the first two MCUs, similar price.

Motor Control

The Motor control block is responsible for the correct operation of the electrical motor connected to the system. Two motor control blocks, although identical, will be needed to be able to drive the two motors present in the system. Driving two motors from a single driver is strongly discouraged.

The block operates autonomously from the ECU to save lines of code on the MCU, and offer a higher performance reliability and immunity over the chosen MCU firmware.

Motor specifications:

- Part Number: STP-MTR-17048D
- Frame: NEMA 17
- IP: 40
- Phase Current: 2A
- Step Angle: 1.8°
- Steps/revolution: 200
- Link: https://www.automationdirect.com/adc/shopping/catalog/motion_control/stepper_systems/dual_shaft_and_encoder_stepper_motors/stp-mtr-17048d

Motor Driver Technical requirements (equal or exceeding):

1. **Load supply Voltage Range:** 12 - 48V
   Note: *to guarantee a high torque at high rotations per minute on the stepper motor it is suggested to keep the power supply voltage as close as possible to 48V.*
   Note: *considerable BOM cost savings can be achieved by reducing the motor voltage needs below 36Volts.*

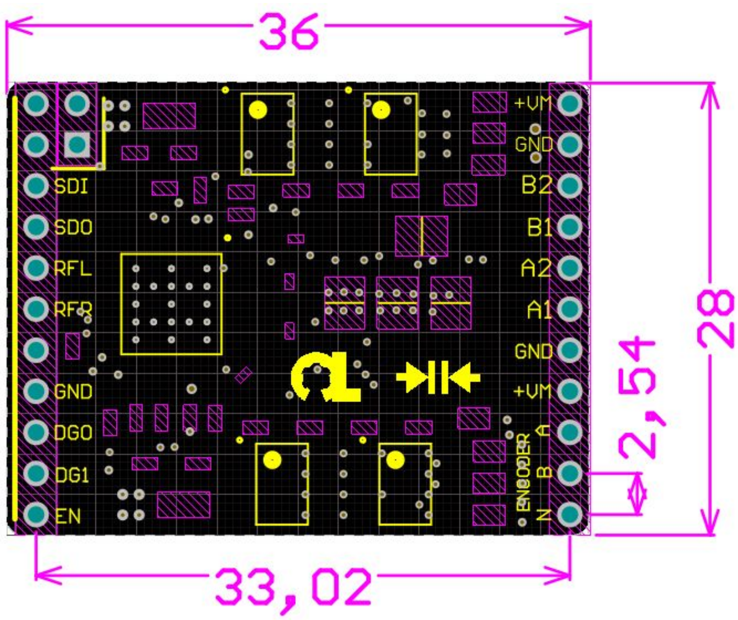
2. **Logic Supply Voltage Range:** 3 - 12V
3. **Maximum drive current per phase: +/-** 2.5A
   Note: this allows for different stepper motor to be used, including NEMA 17 and NEMA 23 types
4. **Step resolution:** 1, ½, (¼)
5. **Control procedure:** direction, step, resolution (as a bare minimum), SPI/I2C protocol is preferred
6. **Autonomous operation from the MCU is preferred**
7. **Autonomous correction of movement with integrated encoder reading is preferred**
8. **Reset / Enable pins must be present to enable fast shut down of movement from the MCU**

Motor Control Board Signals

The current Motor Control Board’s signals summary is here presented. It should be noted that the amount of signals directed towards the MCU is reduced to the SPI bus and 3 GPIOs.

- VCC_IO: 5v0 input
- CSN: SPI Chip Select Pin **(TO MCU)**
  Note: ACTIVE LOW
- SCK, SDI, SDO: SPI Interface to the microcontroller **(TO MCU)**
  Note: Check maximum SCK frequency according to IC Motor Driver Datasheet
- DRV_ENN: Driver Enable **(TO MCU)**
  Note: ACTIVE LOW
- ENCA, ENCB, ENCN: Encoder readings (Incremental)
- A1, A2 Motor Phase A terminals
- B1, B2: Motor Phase B terminals
- VS: 48v input
- DIAG0/DIAG1: Diagnostic Output **(TO MCU)**
  Note: connected to GPIO pin on MCU via pull-down mosfet to provide over voltage protection.
- CLK_16: Driver Clock
  Note: can be pulled to GND if running with clock already on the motor board
- REFL: Left End Stop input
  Note: provides direct connection to limit switches
- REFR: Right End Stop Input
  Note: provides direct connection to limit switches

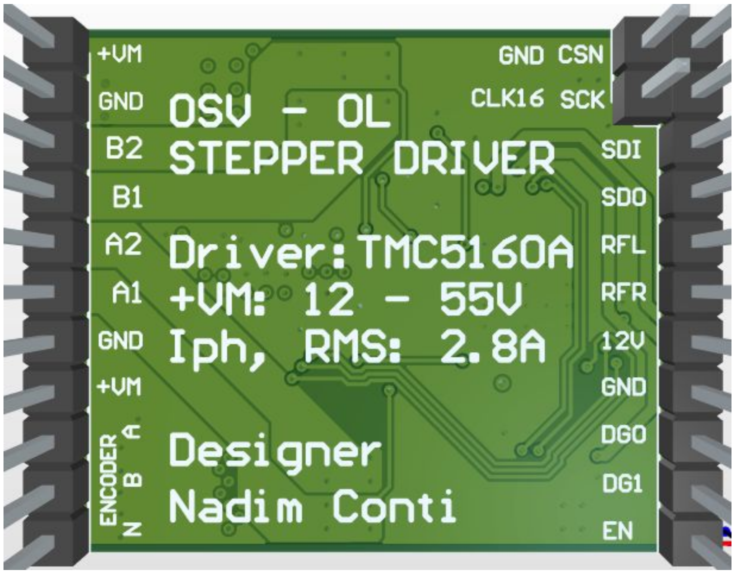
Motor Control Board Dimensions and pinout



Note:
36 mm x 28 mm maximum dimension
(Dimensions are FIXED)

11 POS MALE HEADER 0.1" per side, both are used. One goes to the MCU (the one with 2 additional pins for external CLK16), and the other to the motor bay.

The dimensions are such that, if needed, the board can be integrated in a bigger PCB to be mounted right on a NEMA 17 stepper motor or similar footprint electrical motors.



Sensors

The sensor block takes care of closing the control loop opened by the MCU. Sensors are responsible for the correct readout of volume and pressure transferred into and out of the patient's lungs.

Required sensors:

1. **2x temperature sensor in the Motor Control Area (strongly suggested)**
   Note: to monitor the temperature of the two motor controllers and warn the user of high temperatures and possible imminent thermal damage to the electronics.

2. **1x humidity sensor on board**
   Note: to compute condensation risk

3. **1x temperature sensor in a thermally stable area of the PCB**
   Note: to be used as a reference for the sensor in the Motor Control Area ad compute condensation risk

4. **2x Air Flow (differential pressure) and 1/2x pressure sensors in the pneumatic area**
   Note: to monitor air pressure in the lungs and airflow, important to compute delivered volume and to trigger the respiratory cycle when the thoracic cage muscles start to contract.

5. **1x Temperature sensor in the pneumatic area**
   Note: to monitor air temperature flowing to the patient.

6. **1x Humidity sensor in the pneumatic area**
   Note: to monitor air relative humidity flowing to the patient

Note: the here specified requirements are extracted from technical datasheets of various professional ventilators. (I.e: https://event-medical.com/media/site/document/ML-0178L.pdf), and user experience needs.
These requirements should not be taken as an Absolutely Mandatory set of performances to have for the correct operation of a ventilator, but are suggested guidelines to maintain an elevated standard of quality in the final system.

Technical requirements (equal or exceeding):

1) **Temperature Readings:**
   a) **Range:** -10°C to 100°C
   b) **Accuracy:** 1% of FSR (Full Scale Range)
   c) **Resolution:** 0.1°C
   d) **Maximum Sampling Rate:** 10Hz
      Note: required for motor control temperature monitoring
      Note: required to monitor humidifier working status in inhaled air and exhaled humidity to be used as flow metering compensation

2) **Relative Humidity Readings:**
   a) **Range:** 5 to 95% RH
   b) **Accuracy:** 5% of FSR (Full Scale Range) [preferred 2%]
   c) **Resolution:** 1% (RH)
   d) **Maximum Sampling Rate:** 0.2Hz
      Note: required to monitor humidifier working status in inhaled air and exhaled humidity to be used as flow metering compensation

3) **Pressure Readings:**
   a) **Maximum pressure:** 100 cmH20 (9.80665 kPa)
      Note: required for peak pressure reading
   b) **Minimum pressure:** 1 cmH20 (0.0980665 kPa)
      Note: required for PEEP pressure reading
   c) **Resolution:** 0.1 cmH20 (0.00980665 kPa)
      Note: required for breath pressure triggering
   d) **Absolute Accuracy:** 0.5 cmH20 (0.04903325)
      Note: required for breath pressure triggering and PEEP feedback
   e) **Maximum Sampling Rate:** 0.15 ksps (150Hz)

4) **Volume Readings:**
   a) **Maximum Computed Volume Range:** 100 - 1999 mL (cm^3)
      Note: required for tidal volume monitoring
   b) **Computed Result Resolution:** 1 mL (cm^3)
      Note: required for lung compliance monitoring
   c) **Computed Absolute Accuracy:** 5 mL
      Note: required for lung compliance monitoring

5) **Flow Rate Readings:**

a) **Maximum Flow Rate Detection Range:** 1 - 200 Lpm (liters per minute)
Note: required for spontaneous breath triggering with flow triggering, if no flow triggering is implemented, range can be reduced to 1 - 120 Lpm.

b) **Flow Rate Resolution:** 0.5 Lpm
Note: required for spontaneous breath triggering with flow triggering, if no flow triggering is implemented, resolution can be 1 Lpm

c) ***Flow Rate Absolute Accuracy:*** *5 Lpm*

Pressure Sensor Requirements Analysis

In this section the analysis of an existing ventilator design is carried out to evaluate the pressure resolution needs of a medical ventilator.

The inspected design uses the same part number for Internal and proximal pressures related to the respiration of the patient.

The pressure sensor being used in the inspected design is a differential sensor used for gauge measurements. This means that the sensor will read the pressure difference between the inside of the lungs and external air pressure.

The sensor used in this existing design is an analog output one, with the following characteristics::

- Output range: 0.5 - 4.5 V
- LSB: 3mV
- Pressure maximum range: 1 PSI (70,307 cmH2O)

As the output excursion is 4.5 - 0.5 = 4V, and a lower LSB threshold is specified, it means that we will have a maximum set of discrete values on the output pin of the sensor, this amount is:

- 4V / 0.3mV = 1333 ca. LSBs (11 bit)

If we divide the maximum pressure range by the maximum number of discrete values, we obtain the absolute maximum resolution (finer detail) as:

- 70.307 cmH20 / 1333 = **0,0527 cmH20**

Therefore, to match this analized medical ventilator design in its best case scenario operation, the ES should have a comparable pressure resolution (at least to do pressure triggering).

The part numbers highlighted in the following section have resolutions comparable to the one calculated here..

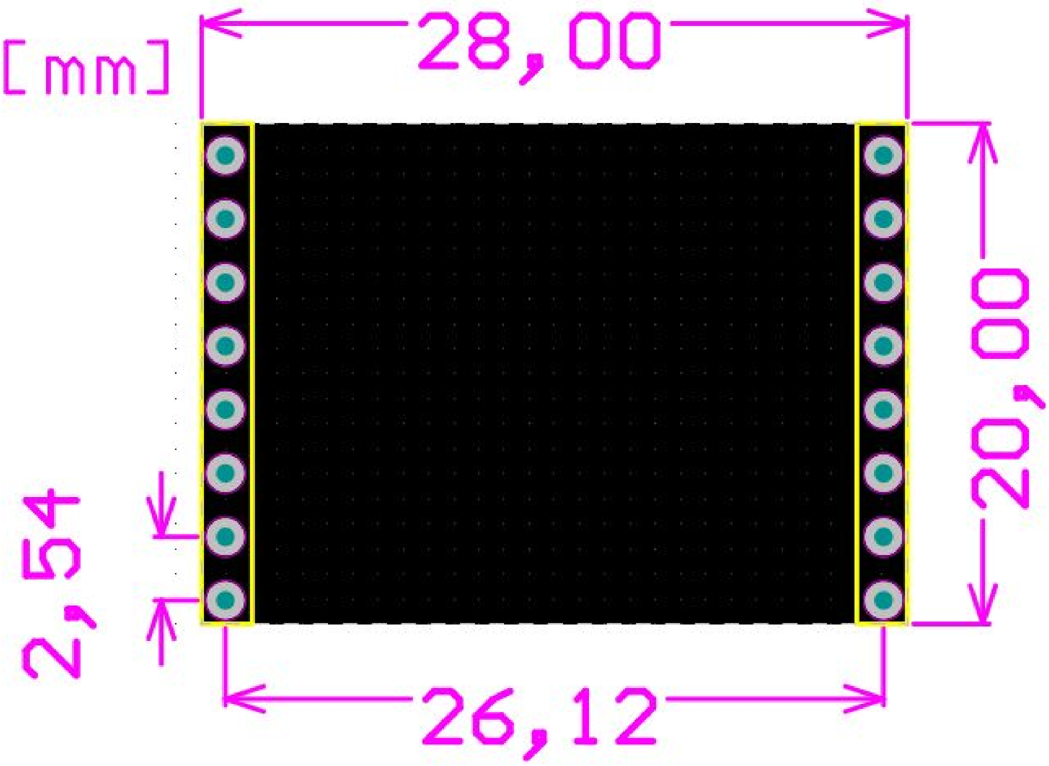
Sensors Part Numbers for reference:

- **Temperature:** Thermistors from Shibaura or Tewa
- **Humidity:** Honeywell HIH-4000/6000/6100 SeriesHIH-7000/8000
- **Pressure and Temperature:** TE Connectivity MS4525DO-SS(or TP) differential **
  Note: range between 1 and 5 psi to be used as gauge sensor for pressure measurements into the lungs, compensated for air pressure.
- **Absolute Pressure:** TE Connectivity MS4525DO-SS(or TP) absolute **
  Note: to measure ambient pressure, range MAX limit between 30 and 100 PSI
- **REFERENCE FLOW SENSORS:**
  - Sensirion SFM3000 (Inhaling phase) / Sensirion SFM3200 (exhaling phase, can be cleaned)
  - Sensirion SDP3x (i.e. SDP31-500PA in bypass configuration)
- **Flow Measurement:** SMI (Silicon Microstructures, Inc.) SM6391-BCC **
  Note: Any range, the lowest the better
- **Pressure:** SMI (Silicon Microstructures, Inc.) SM5331-BCC **
  Note: pressure range between 1 and 2.49 PSI is preferred, 0.8 is accepted
- **Flow and pressure:** Honeywell TruStability, HSC Series, ABP series (less reliable ?)
  - https://sensing.honeywell.com/honeywell-sensing-basic-board-mount-pressure-abp-series-datasheet-32305128.pdf

** **IMPORTANT Mechanical Note:** Sensor Ports accept 3/32" I.D. tubing (or 2.4 mm I.D. tubing).

CalculationSensor Board Dimensions

- 20 mm x 28 mm * 8 POS MALE HEADER 0.1” per side



*Note: * Board dimensions can vary.*

It is suggested to use only one connector side instead of two

The here highlighted board can include all the respiratory related sensors.

- 2x Flow

- 2x Pressure

- 1x Temperature (can be integrated in one of the previous)

- 1x RH (can be integrated in one of the previous)

Visual & Acoustic Alarm board

The Visual and acoustic alarm board must, in case the need arises, convey a sense of urgency (with different levels of priority) and the need of user intervention.

As the code written for the ES must be minimized, the alarm board should be designed without the use of Microcontrollers.

Hardware considerations:

- The visual means used to notice the user of a warning or emergency alarm must be separated. No RGB or dual color lighting is allowed. Warning alarm lights are yellow, Emergency alarm lights are red.

- The auditory means used to notice the user of a warning or emergency alarm must be separated (different). Therefore, the Warning alarm must have its own part number, different from the emergency one.

- The sound frequency of the warning and emergency alarm must have a frequency difference of at least 1 KHz. The frequency of both alarms must be lower than 4 KHz.

- The emergency alarm, when firing, must fire both sirens/buzzers at a low ON-OFF period. The emergency ON-OFF period must be lower than the one used in the highest Warning Level (see alarms levels in the next section).

  Note: this helps in conveying urgency to the user and avoid the possibility of having a single siren failure.

- The casing surface plane is considered to be parallel to the surface of the PCB, therefore Sirens/buzzers must be selected in such a way that the sound firing hole is vertical, opposite to the part piece facing the PCB (not edge firing). The same consideration applies to the visual counterpart.

User intervention requests should be conveyed on 4 different levels, 3 warning and one emergency level:

1. **Warning Level:** the alarm board must visually and acoustically signal that user intervention is needed with different degrees of urgency.

   Note: This will happen every time a value reading does not match the set reading by the user or every time there's something in the system that the user must acknowledge.

   Note: A certain margin of error is allowed for the system to operate correctly and avoid triggering false positive alarms. The Warning margin is set by the user at the system startup, this is defined in the user interface block.

   Warning levels:

   a. **LOW PRIORITY:** Yellow Lights on and blinking at a slow frequency, buzzer on and playing at slow beep rates.
   b. **MEDIUM PRIORITY:** Yellow Lights on and blinking at medium frequency, buzzer on and playing at medium beep rates.
   c. **HIGH PRIORITY:** Yellow lights on and blinking at high frequency, buzzer on and playing at high beep rates.

   Note: the ***acoustic alarm sound level can be set by the user via the user interface, and it is common for all the warning levels.***

2. **Emergency Level:** the alarm board must visually and acoustically signal that **immediate user intervention is needed and cannot be postponed**.

   Note: This will happen when either any critical threshold is crossed, ***or if the motherboard does not acknowledge the alarm board to be working inside the pre-defined Watchdog time window)****. Therefore, as this could happen even during a total power failure, the alarm board section that controls the EMERGENCY LEVEL,* ***must function on its own power source, separated from the main power source on the ES.***

Emergency level:

a. **Very visible red lights being turned on and blinking**
b. **Acoustic alarm with loudness 90 dB SPL @50cm or exceeding**
   Note: Respironics V60 Ventilator from Philips offers up to 95dB

Note: it is suggested to provide a way for the emergency level acoustic alarm sound pressure to be modified independently from the warning level sound settings. In case this cannot be achieved, the emergency level sound pressure must be set at its maximum sound pressure.

Technical requirements:

- **Watchdog Absolute maximum Timer Window:** 300ms

- **Warning visual:**
  - **Minimum luminous Intensity:** 200 mcd
  - **Minimum viewing angle (x-axis):** 100 deg
  - **Minimum viewing angle (y-axis):** 40 deg
  - **Operating Temperatures:** -20 / +80°C
  - **Minimum lens diameter:** 5 mm
    Note: more than one light source can be used in parallel to increase the emitting area. At least 2 light sources are suggested to be used.

- **Emergency visual:**
  - **Minimum luminous Intensity:** 1000 mcd
  - **Minimum viewing angle:** 100 deg
  - **Minimum viewing angle (y-axis):** 40 deg
  - **Operating Temperatures:** -20 / +80°C
  - **Minimum lens diameter:** 5 mm
    Note: more than one light source can be used in parallel to increase the emitting area. At least 2 light sources are suggested to be used.

- **Warning & Emergency auditory:**
  - **Sound Pressure Level (SPL):** 90dB @50 cm
  - **Operating Temperatures:** -20 / +80°C
  - **Moisture Sensitivity Level (MSL):** 1 (Unlimited)

Alarm module components under scrutiny:

- ***Emergency sound alarm:***
  Mallory Sonalert Products Inc.
  MCP320B2Q
  https://www.digikey.it/product-detail/it/mallory-sonalert-products-inc/MCP320B2Q/458-1059-ND/969786

- ***Emergency sound alarm:***
  Mallory Sonalert Products Inc.
  MAS803Q
  https://www.digikey.it/product-detail/it/mallory-sonalert-products-inc/MAS803Q/458-1257-ND/1957907

- ***Emergency LIGHT alarm:***
  Cree Inc.
  C5SMF-RJE-CT0W0BB2
  https://www.mouser.it/ProductDetail/Cree-Inc/C5SMF-RJE-CT0W0BB2

- ***Warning LIGHT alarm:***
  Lumex
  SSL-LX507DT3SYT
  https://www.mouser.it/ProductDetail/Lumex/SSL-LX507DT3SYT

- ***Sound Pressure level control:***
  Texas Instruments
  TPL0401A-10QDCKRQ1
  Digital Potentiometer ICs Automotive 128-Taps Single-Channel Digital Potentiometer With I2C Interface 6-SC70 -40 to 125
  https://www.mouser.it/ProductDetail/Texas-Instruments/TPL0401A-10QDCKRQ1

  Note: this component must be integrated into an amplifier circuit to work as intended.

Alarm board pinout signals:

1. **(input) WARNING_ALARM_0:** bit zero of the WARNING ALARM level selection
2. **(input) WARNING_ALARM_1:** bit one of the WARNING ALARM level selection

   Combinations of the first two signals (**WARNING_ALARM_0,WARNING_ALARM_1)**:

   a. 0,0: NO WARNING
   b. 0,1. WARNING Low Priority
   c. 1,0: WARNING Medium Priority
   d. 1,1: WARNING High Priority

3. **(input) WARNING_MUTE:** if activated, it mutes the WARNING ALARM, but does not block visual alarms *(i.e. mutes sounds, but does not stop lights from turning on and does not affect the emergency alarm)*

4. **(input) SYSTEM_OK:** periodic signal from MCU indicating that MCU is still operational, it is the watchdog timer keepalive signal, needs to be triggered at each watchdog window when the emergency level alarm is armed

   Note: It is a logic pulse issued by the microcode of the main microcontroller. Two consecutive "system OK" signals must not happen further apart in time than a watchdog time window. ***The alarm unit must signal an EMERGENCY ALARM in case the SYSTEM_OK signal is not being received by the end of the watchdog time window.***

5. **(input) EMERGENCY_NOW:** signal to start the emergency alarm immediately without waiting for the watchdog timer window to elapse

6. **(input) MONITOR_STATUS:** signal to arm-disarm the emergency alarm section.

   Note: this is a signal issued by the MCU to the alarm unit to state that the ventilation operation is about to start or stop.

   Note: If the start of ventilation is signalled, the emergency alarm board is ARMED, therefore ***any malfunctioning on the SYSTEM_OK signal from now on will be signalled as an EMERGENCY ALARM.***

*Note: if the halt of a ventilation (as during liberation/weaning) is signalled, the emergency board is DISARMED, therefore, **any malfunctioning on the good-state pin from now on will be ignored.***

7. **(input) MONITOR_STATUS_CLK:** monitor_status clock signal to latch state in the emergency alarm section

8. **I2C SDA/SCL:** used to increase-decrease the warning alarm sound level pressure.

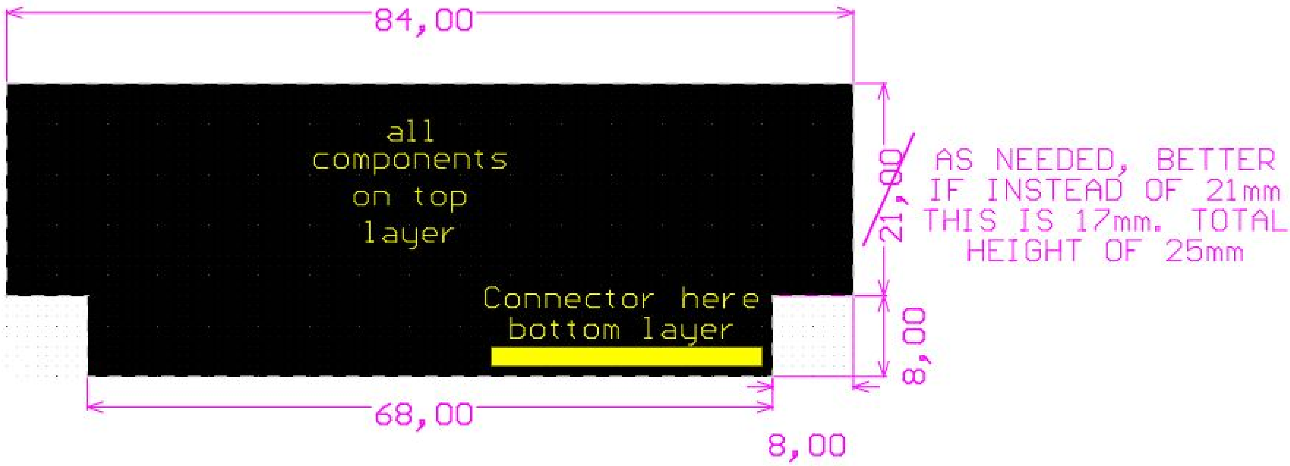
9. **+5V, +3v3, +12v, GND:** used to power the alarm module

The **emergency block functions out of a backup battery** (C2032 coin cells are acceptable), and can be isolated from all the other components on the system with a galvanic isolation of 2kV or higher.

The **emergency block backup battery must guarantee a 5 minute runtime with the alarm fully engaged in EMERGENCY alarm after a standby period of 2 weeks.**

The emergency block **must** be activated right before starting the ventilation, and asserted at a set frequency by the MCU to communicate a good system state. The Emergency block is then de-asserted at shutdown or during patient liberation (weaning).

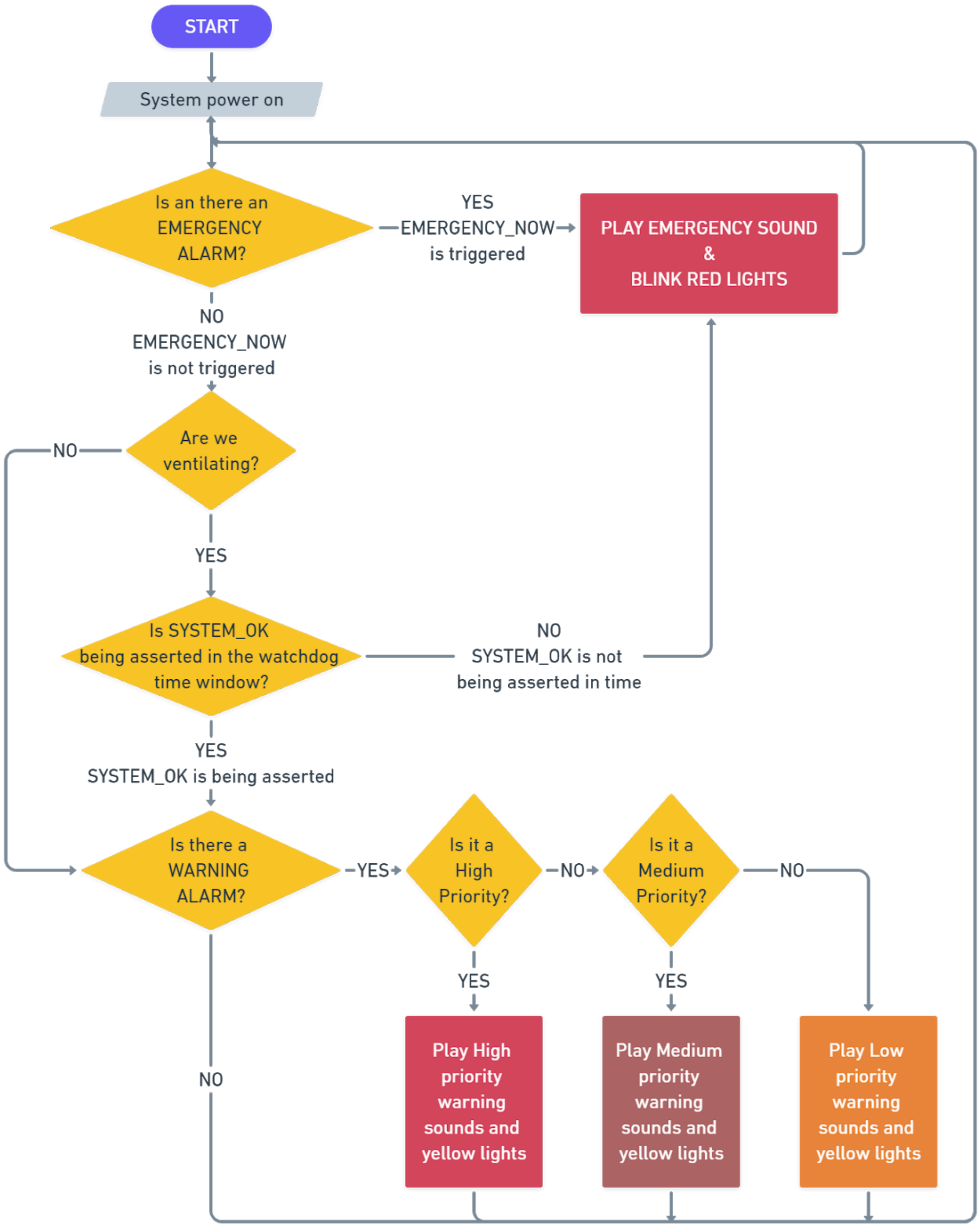
Alarm Board Pinout and dimensions



Note:

- 84 x 25 mm (25mm as PCB height, this could be increased if needed).
- 12 POS MALE HEADER 0.1” on the opposite side of the PCB in respect to the SMD components
- Visual and Acoustic signalling components must be placed on the PCB face shown in the picture, shining the light or playing the sound towards the user (camera view).

Alarm Board Flow Chart



User Interface (Input / Output)

The user, or Input/Output, interface (UI), is the unit responsible for the communication with users.

Via the UI, users should be able to set all the required important parameters for the correct operation of the system, read the real response of the machine-patient system and set all the threshold levels that must trigger the warning alarm. Some ability of emergency alarm tweaking should be given.

The UI should clearly display all the required values on a screen and provide the possibility of showing graphs and trends. The UI should clearly display the current battery charge level.

The UI block should be designed so that, depending on the available budget, a variety of displays can be selected during the assembly phase. This can be achieved with an SPI interface going from the MCU motherboard to the UI module.

The user control input electronics should follow the feedback from the USERs. A mechanical push button array is preferred to any kind of touchscreen. Knobs should be avoided.

IMPORTANT NOTE:

The User interface module shall not result in a change of control settings when accidentally placed in an abnormal position.

IMPORTANT NOTE:

The user interface module shall not, under any circumstance and in every point of the module, have a surface temperature above 43°C when operating in standard environment conditions as specified in IEC 60601-1. This will be verified in standard laboratory conditions.

IMPORTANT NOTE:

Under normal conditions, the touch current from or between parts of the ES and the UI shall not exceed 100uA (Leakage current from accessible outer surfaces of the overall ventilator system) as specified in IEC 60601-1. This will be verified in standard laboratory conditions.

User Interface Mockup

The mockup presented to medical doctors and approved for usage is here shown. The development of user interfaces should start from this mockup and evaluate expansion or removal of the buttons.
The display should, as a bare minimum, show the selected and real time value of the user settings.
If possible, the display should also show the waveform of Flow, Pressure and Volume on a linear scale.

Every user interface implementation MUST integrate in its design anti-ESD diodes. Diodes MUST comply with IEC 61000-4-2 LEVEL 4 rating.

Part numbers for reference:

- IC DRIVER
  FTDI 815
  SPI to LCD interface
  https://www.ftdichip.com/Products/ICs/BT815_6.html

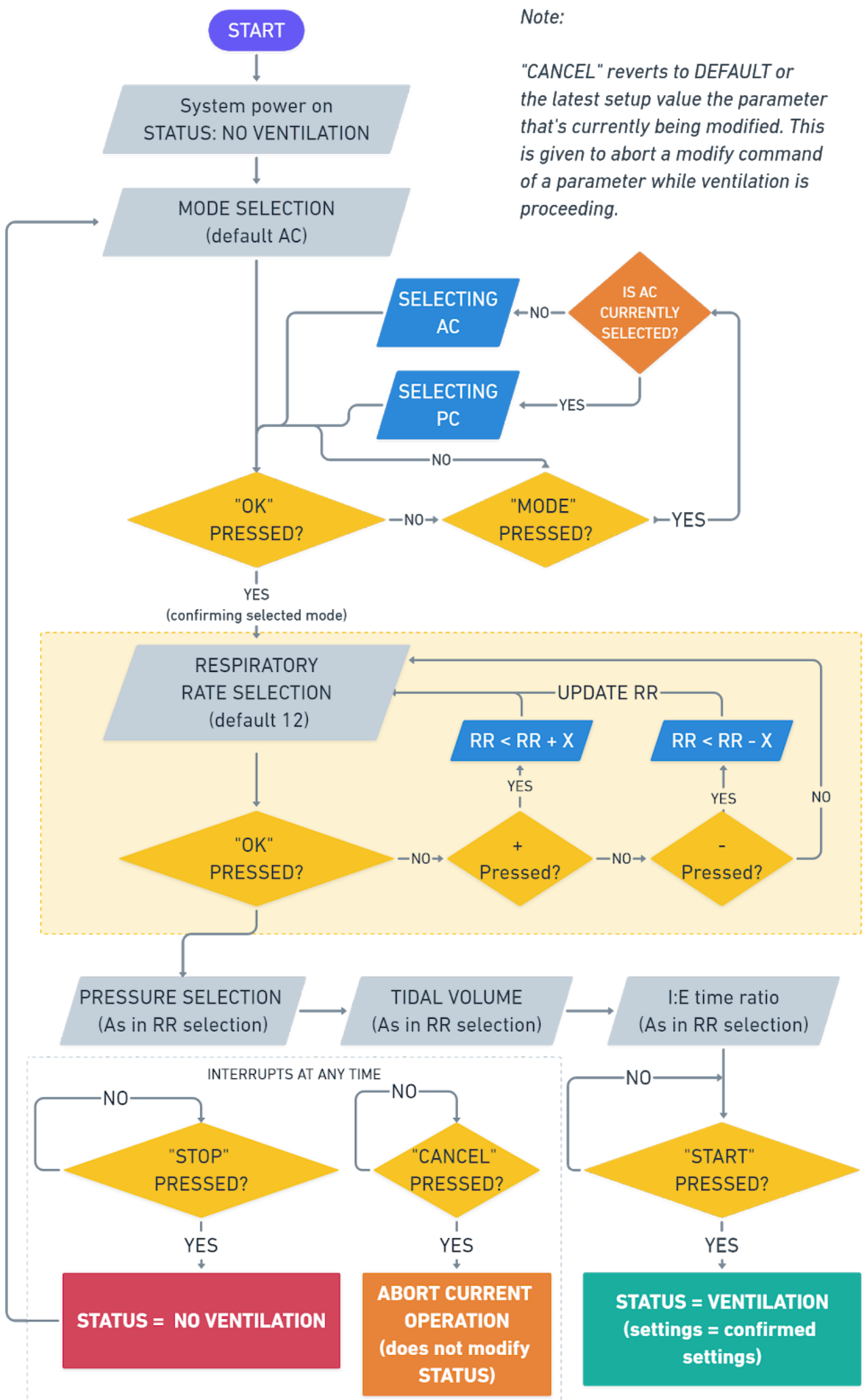
- Tianma Micro-electronics Co
  TM043NDH02-40 - 4.3” LCD
  https://www.arrow.com/it-it/products/tm043ndh02-40/tianma-micro-electronics-co

- Displaytech
  64128M FC BW-3
  DISPLAY LCD 128X64 TRANSFL
  https://www.digikey.it/product-detail/it/displaytech/64128M-FC-BW-3/1756-1041-ND/6650335

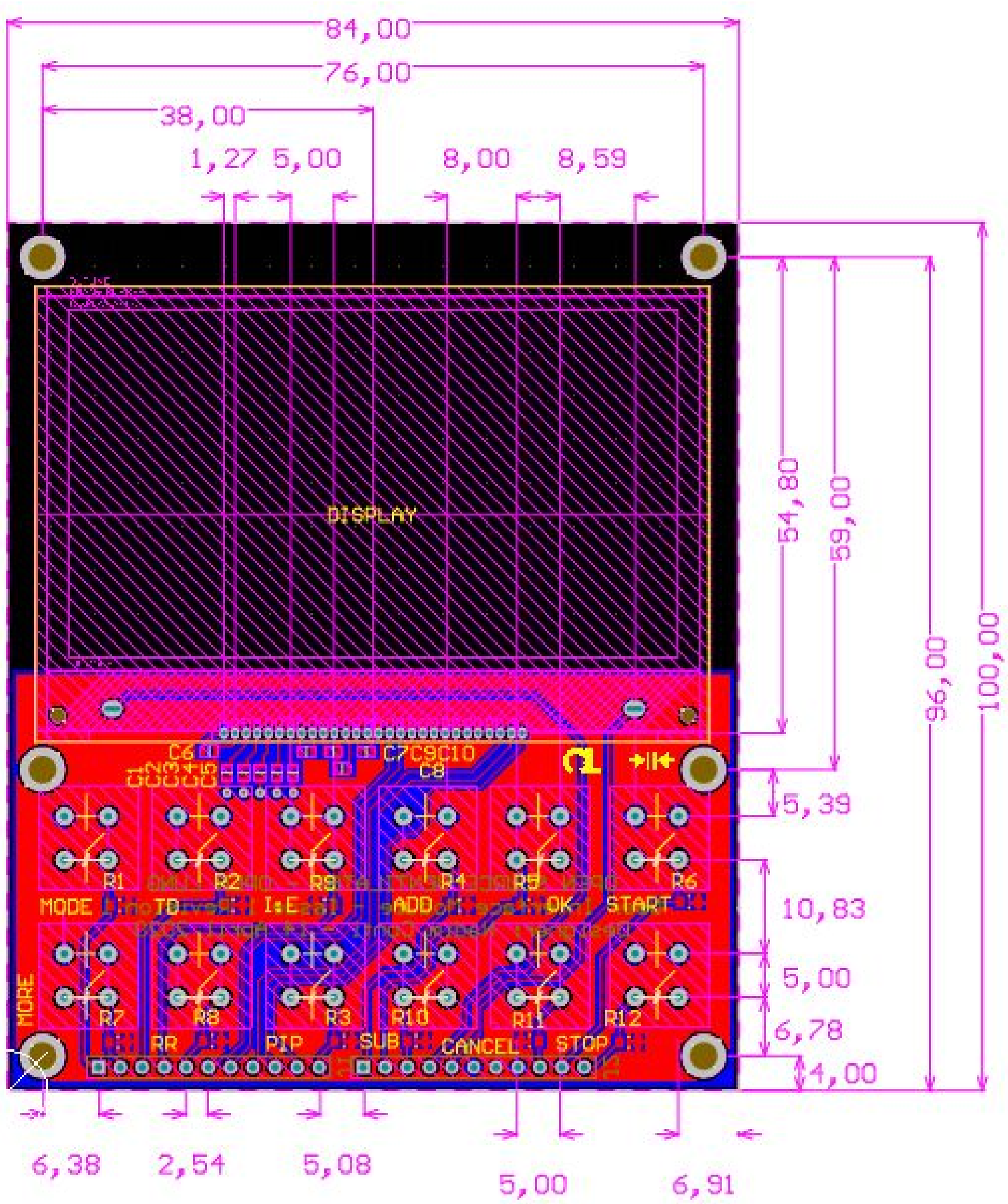
Current User Interface Module:

https://gitlab.com/open-source-ventilator/ventilator/OpenLung/-/tree/master/control-electronics/Electronic-Modules/User_Interface/Rev1_OSV-UserInterface-Velocity-Team

User Interface Flow Chart

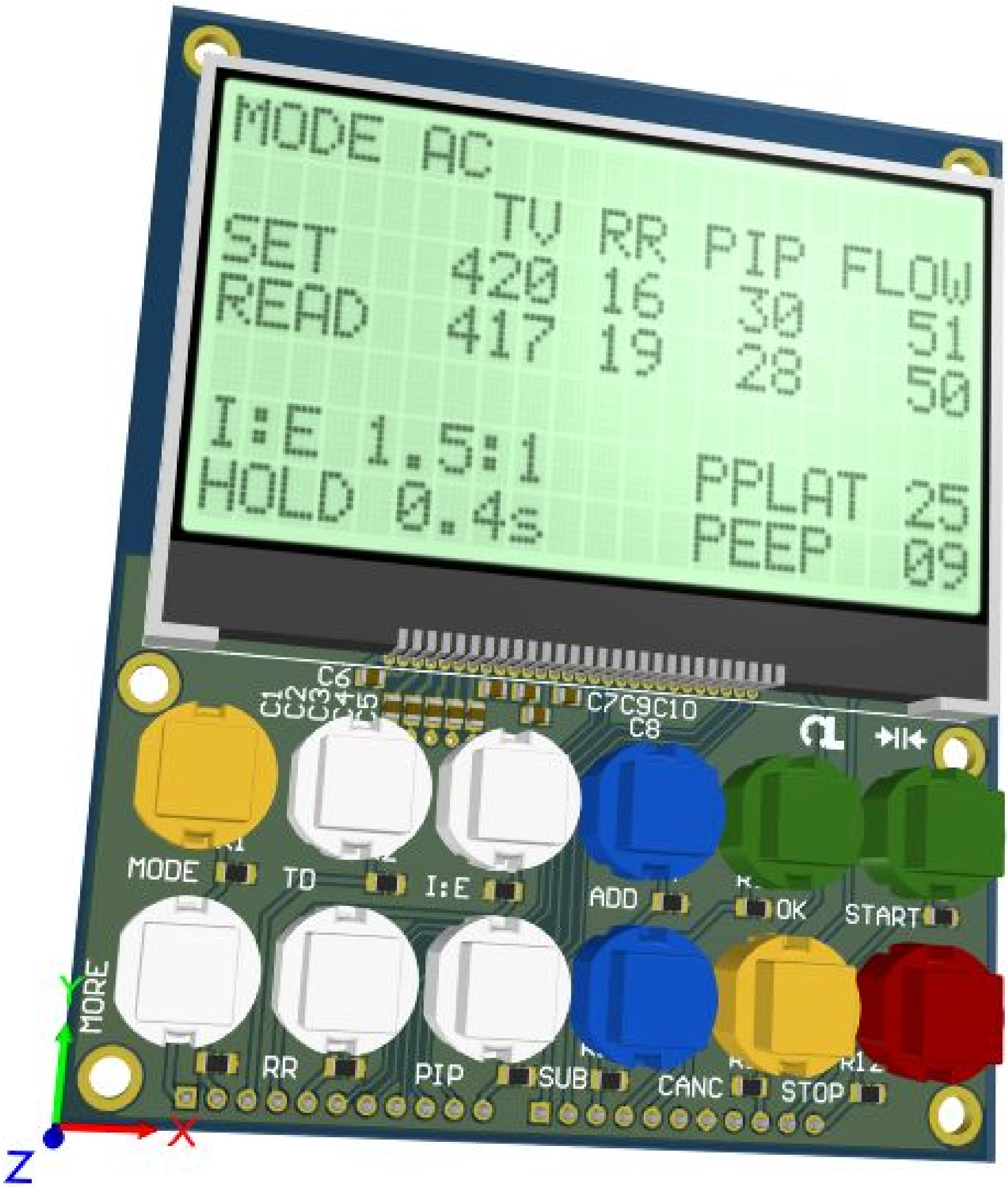


User Interface Module Dimensions (Rev.1.1)



The image here shown highlights all the necessary dimensions of the OSV-Velocity team user interface implementation. The dimensions are a general guideline for the development of other user interfaces and should be followed as closely as possible in the design of new modules.

User Interface Module 3D Rendering (Rev.1.1)



Expansion Serial/USB interface

The system should be equipped with one or more external USB - Serial interfaces for future expansion of the ES (not critical).

Expansion General Purpose Output interface

The GPOI (General Purpose Output Interface) is responsible for providing output pins that can be used to interface the system with electronics loads, valves and external alarm or signalling systems. Outputs should be protected and avoid direct connection to the MCU.

Expansion General Purpose Input Interface

The GPII (General Purpose Input Interface) is responsible for providing input pins that can be used to interface the system with external interfaces (i.e. buttons, switches).

Inputs should be protected and avoid direct connection to the MCU.

General Purpose Input Interface signals:

- **4x Limit switches**

  Note: This requirement comes from the Concept 13 use case scenario. Two limit switches are the bare minimum to establish safe range maximum travel. 4 are only necessary if redundancy is implemented in concept 13.

  Note: Concept 13 is designed with the two arms of the jaws mechanism that are mechanically geared (Linked) together. As this will only fall out of sync in the event of a fatal mechanical failure, and as the control loop system already receives feedback from the pressure and flow sensors, the two additional limit switches can be omitted.

- **1 or 2 Motor Encoders (if not already included in the motor control board)**

  Note: Encoders are not strictly needed for the feedback loop as it closes with the pressure and flow sensors. Anyhow they can be a great indication of mechanical stress and wear on the gears and to ***trigger a pre-emptive alarm before the system actually fails with the ventilation ongoing.***

Useful links for the system development

- **Open source C-library for graphics:** https://littlevgl.com/
- **Useful tool for graphic interface development:** https://www.touchgfx.com/
- **State Machine generation:** https://www.state-machine.com