

Manawa Ora User Guide

Revision History

Version	Date	Author(s)
v0.1	01/04/20	JH, RC, JJ, MO

Contact Details

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Warranty

There are no warranties expressed or implied.

Manawa Ora shall not be liable for loss of profits, loss of use, consequential damages, or any other claim based on breach of warranty. Manawa Ora liability for damages of any kind shall be limited to the purchase price of the defective unit.

Notices

- The Manawa Ora ventilator complies with XXX. It does however use and radiate radio frequency energy.
- The function of this machine may be adversely affected by the operation of other nearby equipment, such as high frequency surgical diathermy equipment, short-wave therapy equipment, defibrillators, or MRI equipment.
- The Manawa Ora ventilator may emit and receive electromagnetic interference. Avoidance of this exposure is recommended whenever possible.
- The Manawa Ora ventilator is not suitable for use in shielded magnetic scanners.

Notice To Operators

Unsafe Operation - Operating the Manawa Ora ventilator without a complete and thorough understanding of its attributes is unsafe and may cause harm to the patient. It is important that this

manual be read and understood in its entirety before operating the ventilator.

Warnings and Cautions Section - *Read the section on Warnings and Cautions carefully before operating the Manawa Ora ventilator.*

Use and Maintenance - *Any questions regarding installing, operating, or maintaining the Manawa Ora ventilator, should be directed to a certified Manawa Ora service technician or Manawa Ora.*

Contents

1 Introduction

This Operator's Manual contains detailed information and instructions which when adhered to ensure the safe and effective set up, use and simple maintenance of the Manawa Ora ventilator.

This manual is designed for use by Respiratory Therapists or other qualified and trained personnel under the direction of a physician and in accordance with applicable state laws and regulations. It contains the following:

- Ventilator Overview
- Installation and Checkout
- Using the Controls and Indicators
- Monitored Data
- Ventilator Alarms
- Extended Features
- Ventilator Checkout tests
- Operating Procedure
- Troubleshooting
- Cleaning, Disinfecting and Sterilizing
- Set Up / Maintenance
- Power and Battery Operation

WARNINGS

Untrained Personnel Only properly trained personnel should operate the ventilator. The Manawa Ora ventilator is a restricted medical device designed for use by Respiratory Therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable laws and regulations.

Leak Testing the Patient Breathing Circuit The patient circuit must be leak tested before connection to the patient. In addition, correct operation of the ventilator alarm, displays and controls should also be checked. Harm to the patient or ineffective ventilation may result from failure to leak test the patient breathing circuit before connection to a patient.

Adjustable and Critical Alarms For safety purposes, all adjustable alarms and all critical alarms must be checked to insure proper operation.

Alarms Function Verification All alarms must be verified as functioning properly on a daily basis. If any alarm malfunctions, immediately contact Manawa Ora.

Patient Monitoring Patients who are dependent on a ventilator should be constantly monitored by qualified personnel. Such personnel should be prepared to address equipment malfunctions and circumstances where equipment becomes inoperative. An alternative method of ventilation should be available for all patients dependent on the ventilator, and qualified personnel should be fully familiar with emergency ventilation procedures.

Alternative Ventilation It is recommended that an alternative means of ventilating the patient be available at all times and that all ventilator operators be fully familiar with emergency ventilation procedures.

Fire or Explosion Operation of the Manawa Ora ventilator in the presence of flammable gases could cause a fire or explosion. Under no circumstances is the ventilator to be operated when explosive gases are present. The presence of nitrous oxide or flammable anesthetics presents a danger to the patient and operator.

Patient Breathing Circuit Disconnection Inadvertent disconnection of the patient from the patient breathing circuit can be dangerous.

Cautions

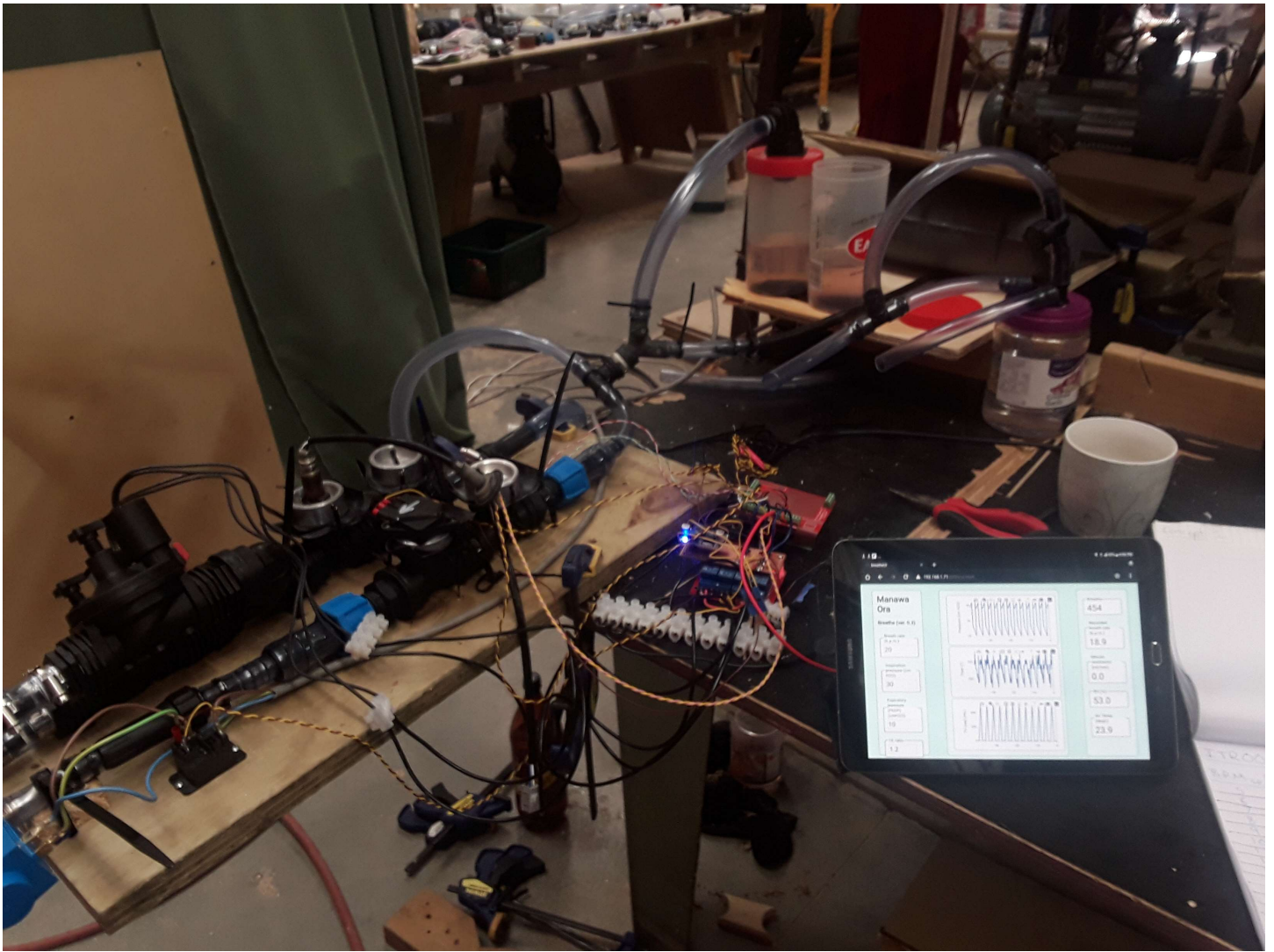
2 Ventilator Overview

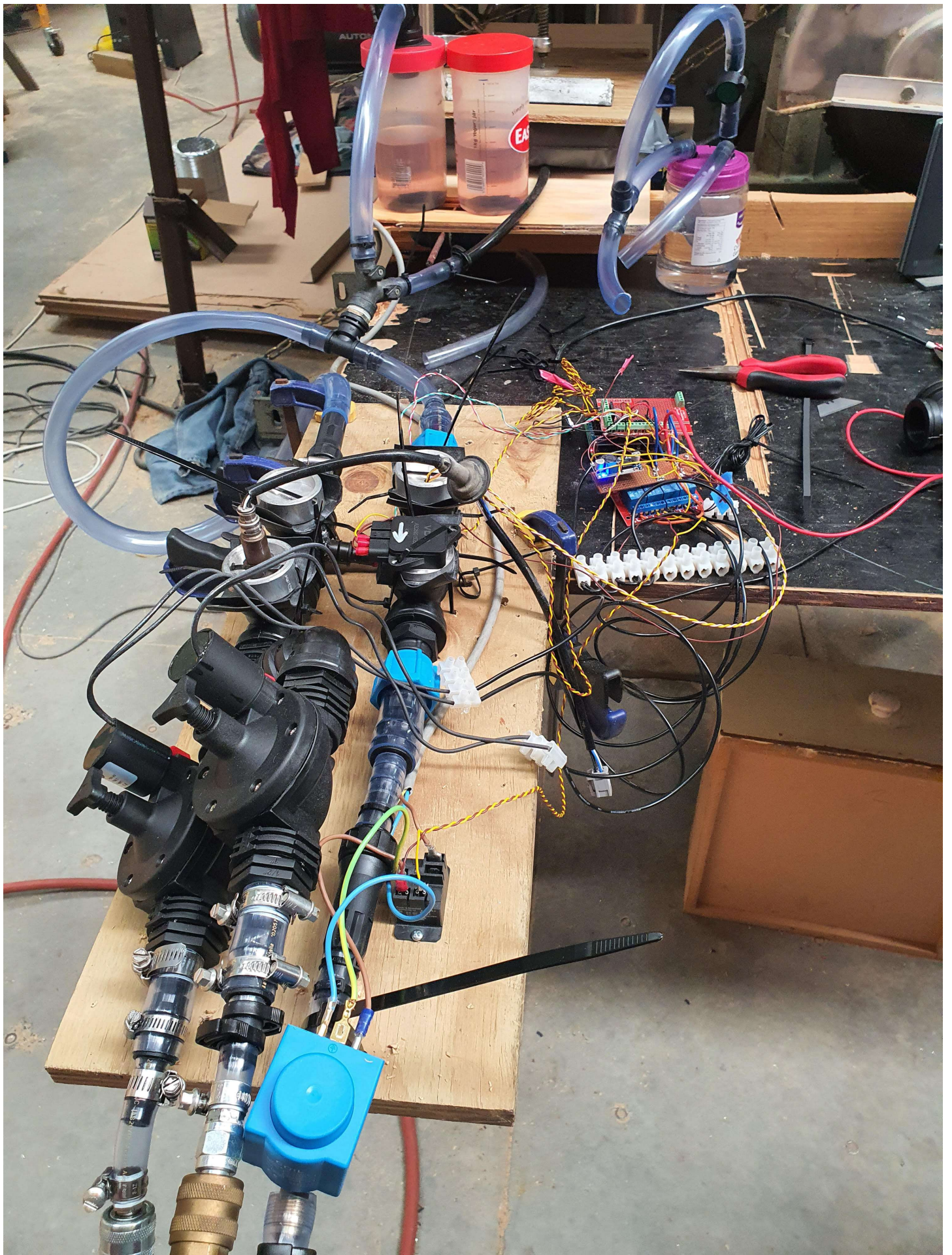
The Manawa Ora ventilator system consists of:

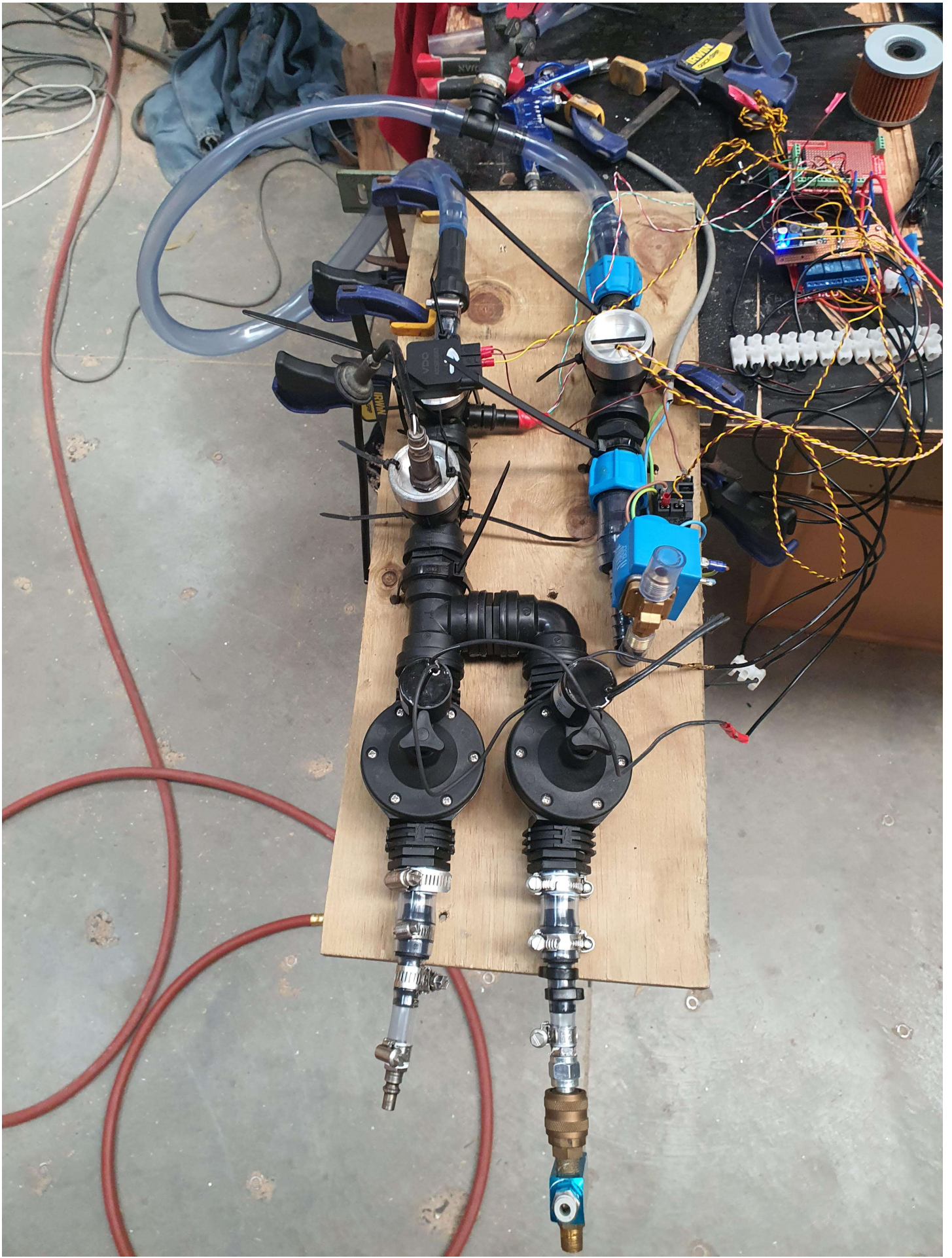
1. Main ventilator unit containing sensors and valves
2. A single board computer control unit
3. User interface screen

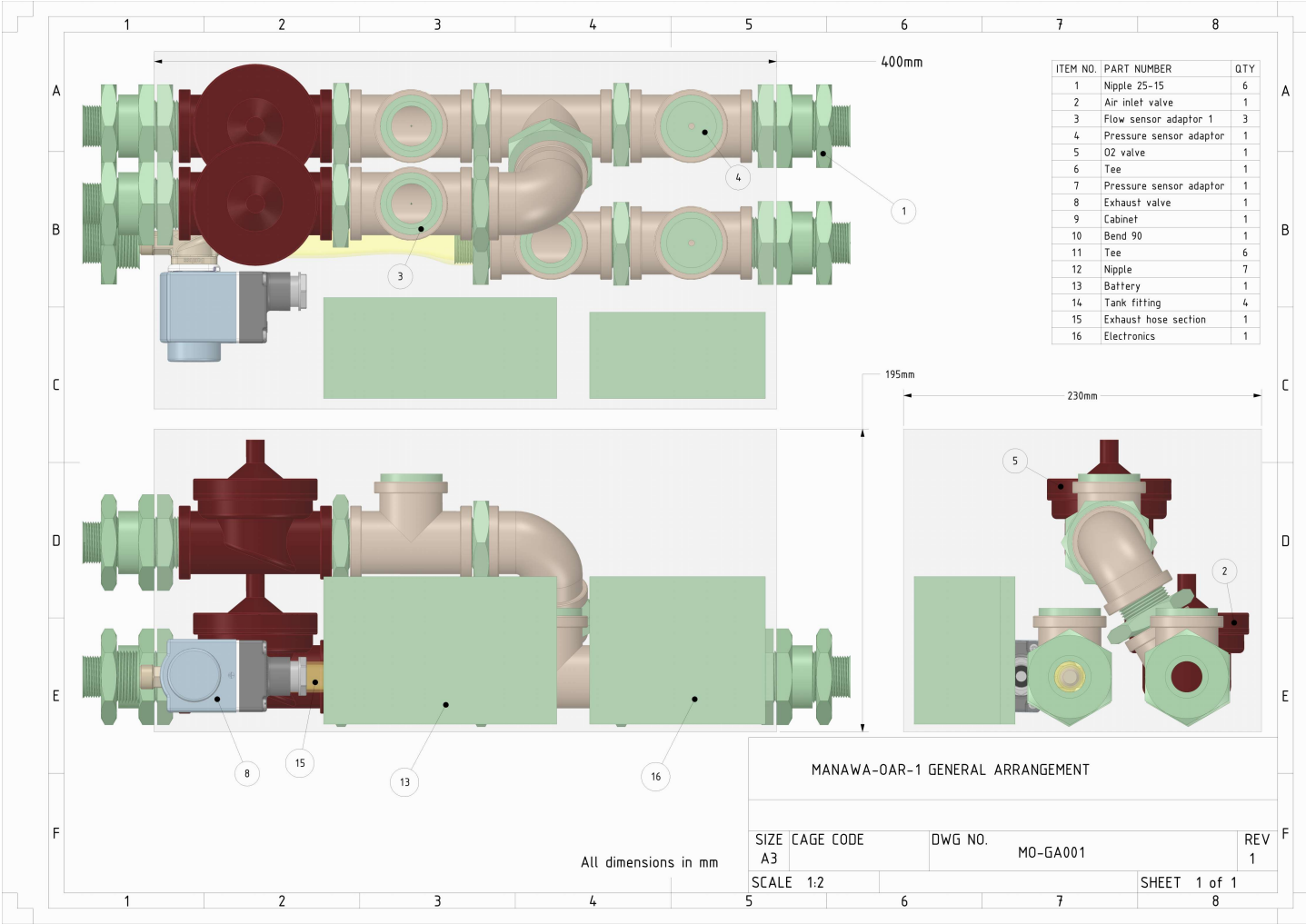
The ventilator system has the following features:

- Low cost unit constructed from readily available parts in small lightweight package
- Controllable from any device with a web browser (computer, tablet, phone, etc) secured via serial number and password. More than one ventilator can be monitored and controlled from a single display.
- Pressure Control ventilation mode
- Optional triggering based on patient inhalation attempt
- Oxygen enrichment based on a High-Pressure Oxygen source
- Monitors for FiO₂
- Real time displays of patient circuit pressure, flow and tidal volume
- Can be operated from AC, internal battery and external DC power sources





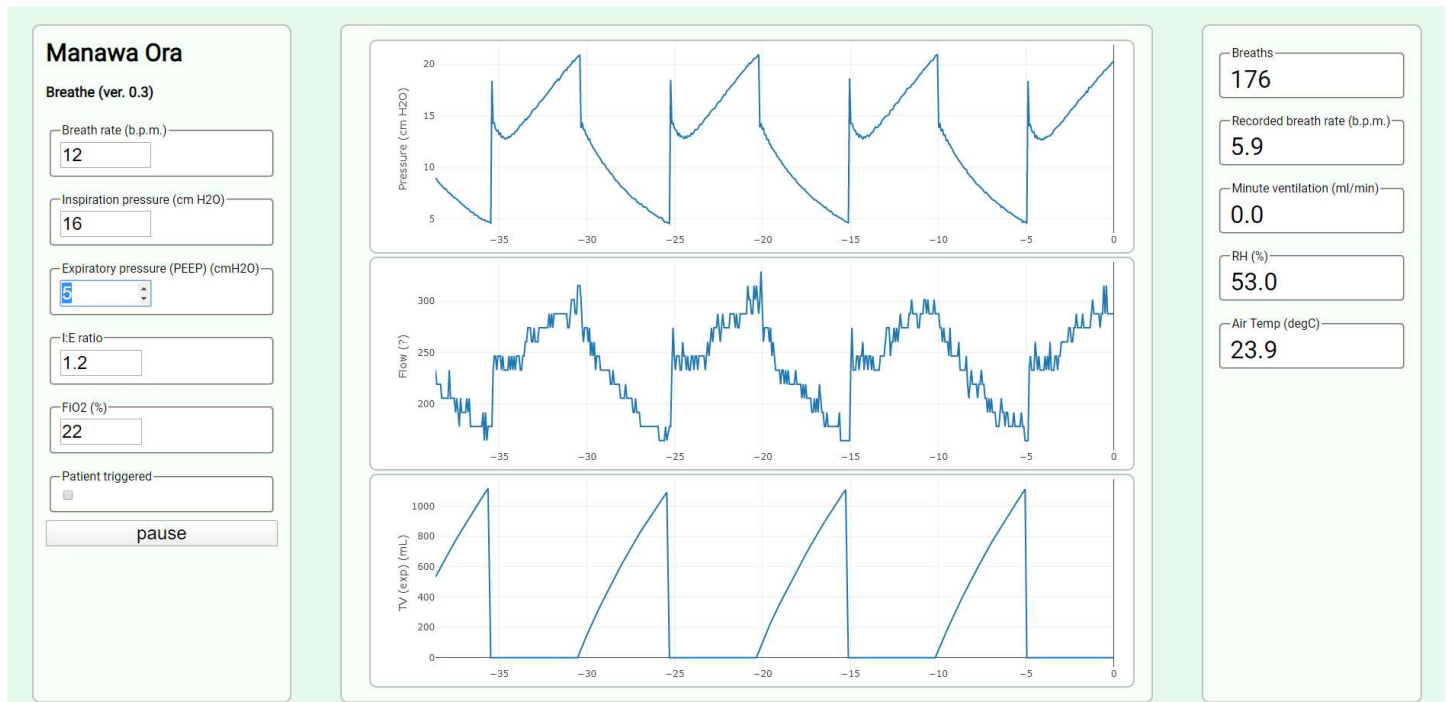




3 Breath Types

4 Ventilation Modes

5 Using the Controls and Indicators



Ventilator Alarms

Ventilator Checkout Tests

Operating Procedure

Start the breathe app on the Raspberry pi.

```
1. $ python3 breathe.py
```

When `breathe` is started the flow meter configuration can be optionally supplied using the `--flow-meters` option, e.g. if both inhalation and exhalation flow meters are installed use:

```
1. $ python3 breathe.py --flow-meters=IE
```

Cleaning, Disinfecting and Sterilizing

Do not immerse.

Remove solenoids and sensors from the ventilator. Autoclave ventialto as usual.

Wipe solenoids and sensors down with appropriate sterilising solution.

Troubleshooting

Symptoms	Potential Causes	Operator Actions
xxx	yyy	zzz

Appendix A - Ventilator Specifications

Appendix B - Set Up / Maintenance

Appendix C - Installation and Checkout
