

SAX-D Area Alarm for Piped Medical Gases





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1. Introduction

The SAX-D area alarm panel is designed to monitor pipeline pressures. The SAX-D will function as a stand-alone Alarm or can be configured to operate as a repeater to another SAX-D alarm display, within 100 meters, using a 1mm 4-core cable.

The SAX-D alarm is designed to monitor specific gas pressures (or vacuum) on up to 6 gases, via 4-20ma transducers mounted in the pipeline, downstream from the final Area Valve Service Unit (AVSU).

The pressure readings are used to provide Green (Normal) or Red (High or Low Pressure) LED visual warnings. The alarms also have Green (Power On) LED and a Red (System Fault) LED, together with a mutable audible alarm.

Each gas is assigned a 1.7inch OLED display, which includes the following:

- Gas Description and,
- Gas Colour Band and,
- Green “Normal” Status or,
- Red “High Pressure” Status or,
- Yellow “Pressure Drop” Status or,
- Red “Low Pressure” Status

Each Display unit includes:

- Monitoring for up-to 3 gases
 - (where 4-6 gases are required) the displays can work in a twin arrangement.
- Separate green twin LED “Power On” status
- Separate red twin LED “System Fault” status
- Mutable audible alarm with volume control

The Encoder/Transmitter provides connection to:

- 12vdc supply via incoming 230vac power supply
 - (separate 3amp spur required)
- Up-to 4x3Gas Alarm Displays (further Displays can be connected using SAXD Booster)
- Volt-Free Common Fault relay
- Modbus2 interface
- SAX Bus interface.
 - Here the alarm can transmit data to existing SAX-6 alarms and Interfaces, which can then remain in service as analogue repeaters.

2. Safety-Related Information

2.1. Intended Purpose:

Shire Controls Ltd. Area Alarm is intended to monitor the pressure in area gas supply pipelines. The Device is designed to monitor up to 6 gases using 4-20ma 1-16 Bar Pressure Transducers or -1-0 Bar Vacuum Transducers mounted in the pipeline.

2.2. Intended User group:

The device is intended to alert operators including technical and clinical staff of abnormal operating pressures downstream from the Area Valve Service Unit.

2.3. Target Patient Group:

Not applicable as device does not diagnose, treat, prevent, cure or mitigate any diseases. It is used in maintaining normal operating conditions of the Medical Gas Pipeline Systems.

2.4. Indications and Contraindications:

Not applicable. Shire Controls Ltd. Area Alarms are not intended to be used by patients as the Device does not directly diagnose, treat, or monitor any medical conditions.

2.5. Environment of use

The SAXD Area Alarm has been designed and validated for use in controlled indoor hospital environments and complies with the environmental requirements set forth under both EU MDR 2017/745 and UK MDR 2002 regulations.

The environmental tolerances are suitable for typical clinical installations and comply with IEC 60601-1 requirements under expected transport and use conditions.

The device housing is unsealed; therefore, it must be installed in dry, climate-controlled interiors as per HTM 02-01. Risk management activities have confirmed that no unacceptable environmental risks exist under the validated conditions.

2.6. Structural (EU MDR – Annex II, Section 1.1)

The SAXD Display Alarm is a compact medical gas alarm designed for integration into medical pipeline alarm systems to monitor pipeline pressures of up to six medical gases downstream from Area Valve Service Units (AVSUs), using 4-20ma pressure transducers. It comprises mechanical and electronic subassemblies enclosed in wall- or surface-mounted housings. All materials and structural components have been selected to comply with requirements of HTM 02-01, ISO 7396-1, and IEC 60601-1 for electrical and structural safety.

The SAXD Area Alarm is used to visually indicate the status of 3 or 6 gas channels and is available in 2-gang flush & surface, and 3/6 gas SAX6-adaptor fascia and SA6 fascia plate variants. The SAXD Display Alarm complies with EU MDR 2017/745 and is built using mechanically robust and electrically safe materials for hospital environments.

Structural Components and Materials

1. Display Enclosure Variants

Flush Mount (Twin Socket Box)

- Dimensions: 146 mm × 87 mm × 55 mm (W × H × D)
- Weight: 0.407 kg
- Box: SH634, 1 mm steel
- Bezel: M2027, 1.5 mm steel
- Battery Plate: M2028, 1.5 mm aluminium
- OLED Spacer: M2029, 1.5 mm acrylic

Surface Mount (Twin Socket Box)

- Dimensions: 146 mm × 87 mm × 45 mm
- Weight: 0.334 kg
- Box: SH415 (material: not specified, typically steel or ABS)
- Bezel: M2027, 1.5 mm steel
- Battery Plate: M2028, 1.5 mm aluminium
- OLED Spacer: M2029, 2 mm acrylic

SAX6 Adaptor Plate Mounting

- Dimensions: 240 mm × 194 mm × 45 mm
- Weight: 0.786 kg
- Adaptor Plate:
 - M2031 (3 Gas) or
 - M2025 (6 Gas), both in 1.5 mm steel
- Battery Plate: M2028, 1.5 mm aluminium
- OLED Spacer: M2029, 1.5 mm acrylic

SA6 Fascia Plate Mounting

- Dimensions: 274 mm × 164 mm × 45 mm
- Weight: 0.676 kg
- Adaptor Plate:
 - M2024 (3 Gas) or
 - M2026 (6 Gas), both in 1.5 mm aluminium
- Battery Plate: M2028, 1.5 mm aluminium
- OLED Spacer: M2029, 1.5 mm acrylic

2. PCB Assembly

- Display PCB: Drives OLED display, controls visual indication logic for 3 or 6 gas channels.
 - Encoder PCB: Drives SAXD displays (up to 4no 3gas Display PCBs max), Bluetooth (set-up and maintenance) App, Transducer inputs (6no max), Modbus, SAX6 & Common Fault Relay Outputs
3. Power Backup
- Battery Pack: SH983 – 6-cell, GP60AAAHT6B6Z, 7.2 V, 600 mAh Ni-MH battery
 - Mounted internally behind display assembly.
 - Mounted within encoder on side wall of enclosure.
 - Supplied with 2-way Molex-style connector.
 - Designed for periodic maintenance and safe replacement.

4. Electrical Safety

The encoder is powered by a 230 Vac mains supply. The connection is made via a 2-piece unpluggable terminal header for safe service disconnection.

Protection Class: Class I (with protective earth, when used with a mains-powered system)

The SAXD Area Alarm has been designed and constructed to eliminate or reduce mechanical hazards in accordance with IEC 60601-1 Clause 9. All accessible mechanical parts are free of sharp edges and constructed from robust materials including steel and acrylic. Enclosures and structural components (e.g., bezels, back boxes, and mounting hardware) are securely fixed and mechanically stable to prevent crushing, impact, shearing, or instability during normal use, maintenance, or foreseeable misuse.

3. Operator

The SAX-D Area Alarm is designed for manual operation via the Test/Mute push-button. Hence it is envisaged that the operator is able to visually monitor from within 90cm or arms-length.

The inherent colour coded design includes Red/Yellow/Green indication and the use of gas colour recognition within the title bar of each gas OLED, which ensures that the alarm can be monitored comfortably from 3-4 metres away.

Consideration should be made for final location, in accordance with the latest HTM guidelines, prior to installation.



Note: When you see this symbol, the associated text refers to something which may cause damage or danger.

4. Mounting

To install the Display unit (flush or surface):

- Remove the fixing screws from the fascia.
 - SAXD 3 Gas in 2 Gand Box – 2no M3.5 screws
 - SAX6- Retro Fit Plate – 2no M3x25 screws
 - SA6 Rerto-Fit – 4no M3x6 screws

Note: The Display printed circuit board (PCB) is integral to the fascia plate assembly and can be placed safely.

- Drill the back box and mount.
 - Up-to 2no separate cable entries should also be drilled at this point for data In and Data Out cables.
 - For SAX6 & SA6 Variations refer to SAX6 & SA6 IFUs for box mounting (if required).
- Select which gases are to be displayed via the 4-way DIL switch on the reverse side of the PCB.

- Switch 4 is set DOWN (Gas channels 1-3) or UP (Gas channels 4-6)
- Switch 3 is set DOWN (3 Gas display) or UP (6 Gas Twin Display)

Note: Where Twin Displays are used, both should be set to the Up position

- Switches 1 & 2 are not used at this point.
- Connect the battery via the 2-way white Molex socket, on to the twin Molex pins on reverse side of PCB (repeat for 2nd display for 6 gas variations) and press the white push-button marked 'Battery' on reverse of PCB.
 - This provides a manual start up so that the volume level can be set.
- Set the volume control to the required level. Activate the audible by covering the Mute-Test window with your finger until the audible sound, use a small 2mm terminal screwdriver in the volume pre-set and rotate as appropriate.
 - Clockwise to Increase volume & Anti-clockwise to decrease volume.
- The fascia can then be temporarily replaced via the fixing screws until cabling is ready for termination (see 'Connection' Section under CABLING in this manual).

The Encoder (and Booster) is provided in a surface mount plastic (Techno polymer) box.

- Unscrew 4no screws and remove the lid.
- Unscrew 3no self-tapper screws and remove the mounting plate assembly.
 - This plate holds the PCB, fused mains input and power supply.
- Drill through rear of box via suggested mounting points and securely fix.
- Use pre-drilled cable entry holes for the following:
 - 1no for 230vac supply
 - 1no for Display unit 4-core connection output
 - 1no for each Pressure/Vacuum transducer (6 max)

Note: 1no per gas monitored

- 1no for Common Fault Relay (optional)
- 1no for SAX6 Bus Interface (optional)
- 1no for Modbus2 Interface (optional)

- Replace the mounting plate assembly with the 3no self-tapper screws.
- Connect the 230vac to the fused input terminal.
- Connect the pressure transducer input and Display unit output via marked pluggable terminals.
- Connect the battery via the 2-way white Molex socket, on to the twin Molex pins on centre of PCB.

**WARNING**

The SAX-D Area alarm is designed and built in accordance with HTM 02-01 and ISO 7396-1 regulations. Persons undertaking installation (or maintenance) should be trained in work of this nature. The “PERMIT TO WORK” procedure must be adhered to for all installations once commissioned.

Read and become familiar with the contents of this manual before installing (or maintaining) this device.

- Before the device is handed over to the operator, the proper functioning of the system must be proven as part of the acceptance tests for the completely installed system. This verifies compliance with national regulations.
- Equipment must be approved before commissioning the system and after installing the components.
- If the test fails, these medical devices must NOT be put into service.
- An improperly mounted device may compromise the safety of patient care and endanger the user.
- **DO NOT USE OIL OR GREASE** on any parts in contact with medical gases for any reason. This could lead to an **EXPLOSION**.

5. Mounting

**WARNING**

Always ensure that you are in contact with earth when handling electronic components to avoid damage by static discharges.

All cable screens must be connected at both ends. Continuity must be maintained through any junction boxes. A minimum of 20mm clearance must be maintained between the alarm system cabling and any other cables (including the 230Vac to the alarm system).

FAILURE TO CARRY OUT THESE INSTRUCTIONS MAY CAUSE INTERMITTENT FAULTS AND INVALIDATES THE DECLARATION OF CONFORMITY RELATING TO THIS ALARM

This equipment is not suitable for a connection to an IT power system. A readily accessible means of disconnecting the supply must be provided. The maximum prospective fault current must not exceed 1500 amps.

Mains 230Vac Supply (Encoder)

Bring the supply into the pre-drilled mounting hole (on right side of Encoder box) and terminate Live, Earth and Neutral to the fused terminal marked L, N & E.

The supply required is 230Vac, 50/60 Hz, fused at 3 amp.

The Display output from the encoder can drive up to 4no 3Gas Displays and should ALWAYS be connected in parallel. Note: There should then only be 1no Display output can connected from the Encoder. This cable should comprise 4-core cable, minimum 1.0 square mm CSA, between the Encoder and the first display.

If the panel is to receive data directly from pressure transducers, a 2-core cable, minimum 0.5 square mm CSA, is required between each transducer and the Encoder.

If the panel is to be connected to existing SAX-6 alarms, a 2-core screened cable, minimum 0.5 square mm CSA, is required between the Encoder and the existing SAX-6 Alarms (of SAX Computer Interface).

If the panel is to interface via the Modbus2 output, a 3-core screened cable, minimum 0.5 square mm CSA, is required between the Encoder and the other system.

Displays

The Display output from the encoder should comprise 4-core cable, minimum 0.5 square mm CSA, between the Encoder and the first display. A similar cable output to the second display should be used (where required).

Battery (Both Encoder & Displays)

Connect the 7.2V battery (6 x AAA) complete with cable and 2 Way Molex Connector to 2-way Molex header on PCB marked "Battery".

Input Data Signals

All terminal for the Display and Encoder is a plug-socket format and can be unplugged for easy connection, by pulling the terminals away from the PCB mounted socket.

At the Transmitter/Encoder, connect:

- Live, Earth & Neutral to the fused input terminal connections on mounting plate.
- Check connection from the 12vdc output should be factory fitted to the 12v + and - terminals on the PCB.
- 4-core cable into the 4-way Display terminal block and plug-in.

Note: Check +, -, A and B cores match the connections used in the Display.

- 2-way connection for each Transducer input onto terminals marked Gas + and -.

Note: Check Transducers manual for correct cores or colours.

- Optional 2-core connection (marked SAX Bus B C) to existing SAX-6 alarms which are to work as analogue repeaters from this Encoder box.
- Optional 3-core connection (marked MODBUS A B and GND) to provide interface to other site-based system.
- A Common Fault Relay output is provided, which incorporates fail-safe operation. The Relay terminals are clearly marked and have continuity when all conditions are at normal. The Relay operates when there is:
 - Any High- or Low-Pressure Gas Condition Fault Present
 - System Fault (Wiring/Line Monitoring Fault) is Present
 - Under Battery Back Up – Loss of Mains Supply 230Vac

At the Display,

- Connect the 4-core cable into the 4-way terminal block.

Note: Check +, -, A and B cores match the connections used in the Transmitter.

Where a Repeater/Repeater Alarm is required, the inter-Display wiring is repeated to the new displays up to a maximum of 4no displays within a 100metre network.

Setting Up (At the Encoder)

- Enable the Bluetooth device via the 4-way DIL switch on the PCB.
Note: Set switch 1 to ON (Enabled – recommended) or OFF (Disabled).
Note: Switches 2,3 & 4 are not used at this point.
- Other Gas Settings, Descriptions, Switching Levels and more, are set via BLE application.
- Access to this application and available commands are detailed in Appendix A of manual.
- Replace the Encoder lid via 4 fixing screws.

Setting Up (At the Display),

- This has already been covered in this manual. The Display should be ready to operate.
- Replace the Display fascia and secure 2xM3.5 fixing screws tightly.

Note: The following 3 pages support diagrams for this section.

Transmitter/Encoder Unit

Below is a drawing of the PCB, highlighting the location of input terminals for pressure transducers, 230vac, switches and pushbuttons required for setting-up and installation of the Alarm Transmitter Unit.

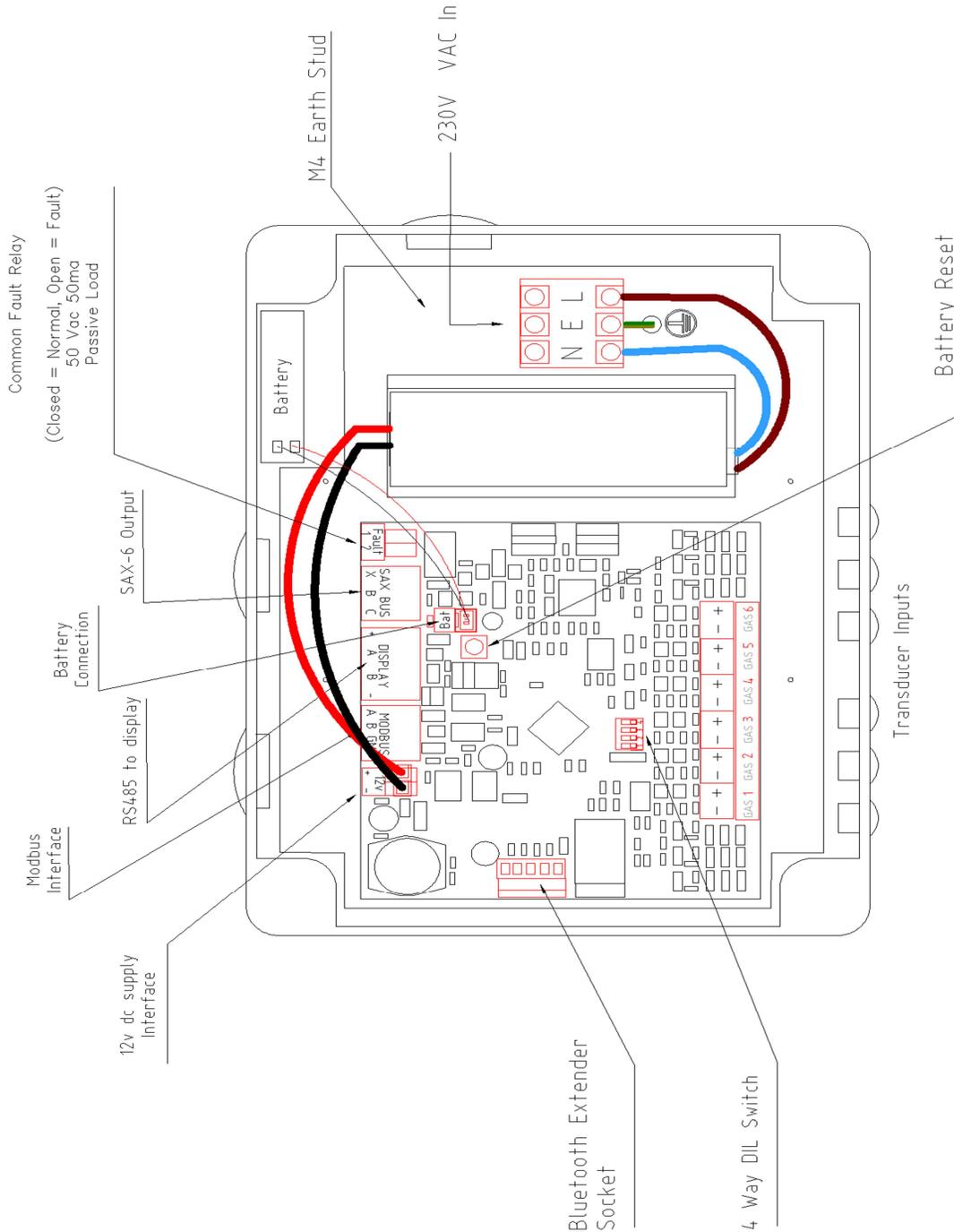


Figure 1: Encoder Mode Of Operation & Typical Connection Detail

Booster Unit

Below is a drawing of the SAXD-EXT-001 PCB, highlighting the location of 230vac connection, RS485 display input terminals and outputs terminals required for setting-up and installation of the Booster (Extension) Unit.

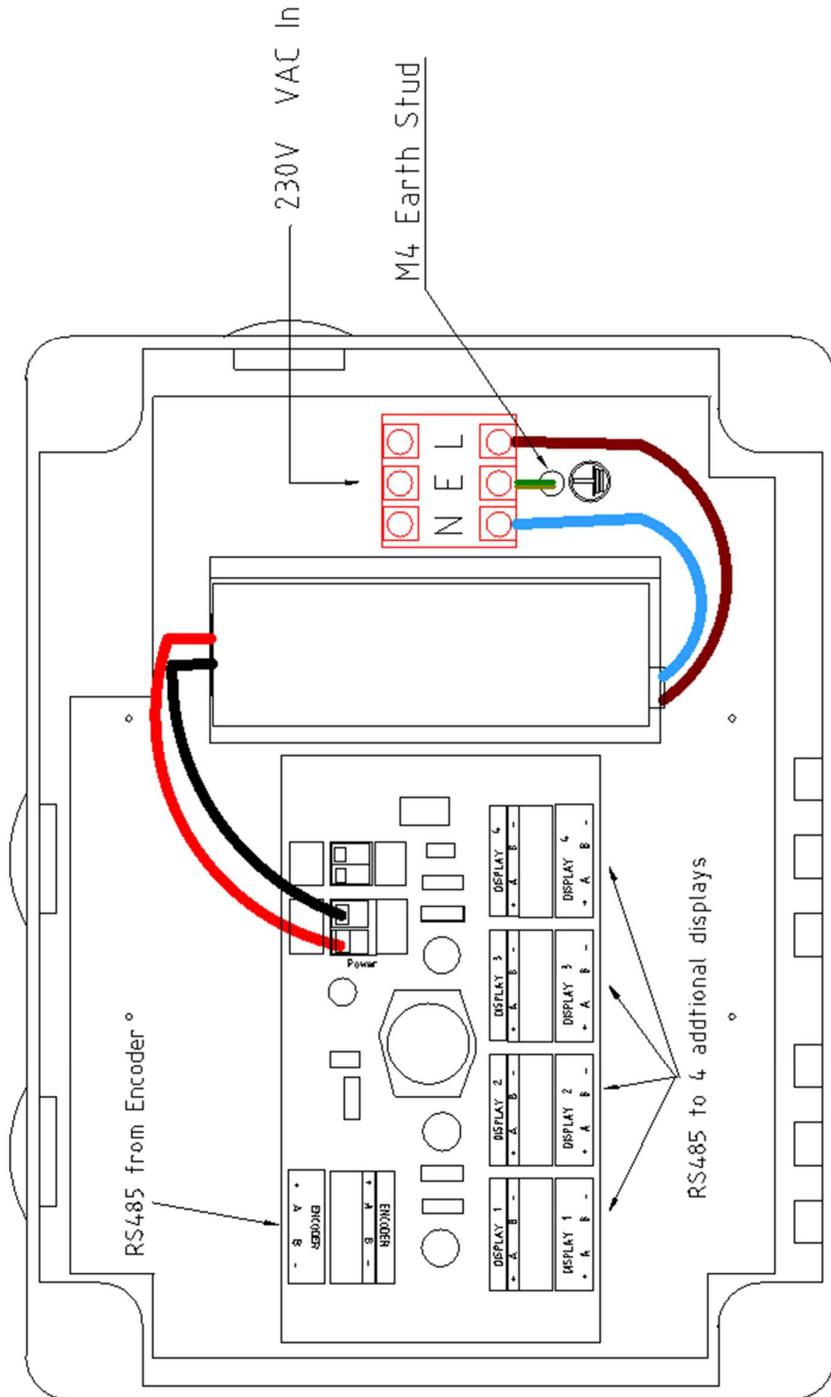


Figure 2: Booster Unit Typical Connection Detail

SAX6 55mm Flush Back Box Assembly for Alternative Transmitter/Encoder Unit Setup

Below is a drawing of the PCB, highlighting the location of all input terminals, 230vac, switches and pushbuttons required for setting-up and installation of the SAXD Encoder within an SAX6 Flush Back Box, to enable Encoder & Display within single flush housing.

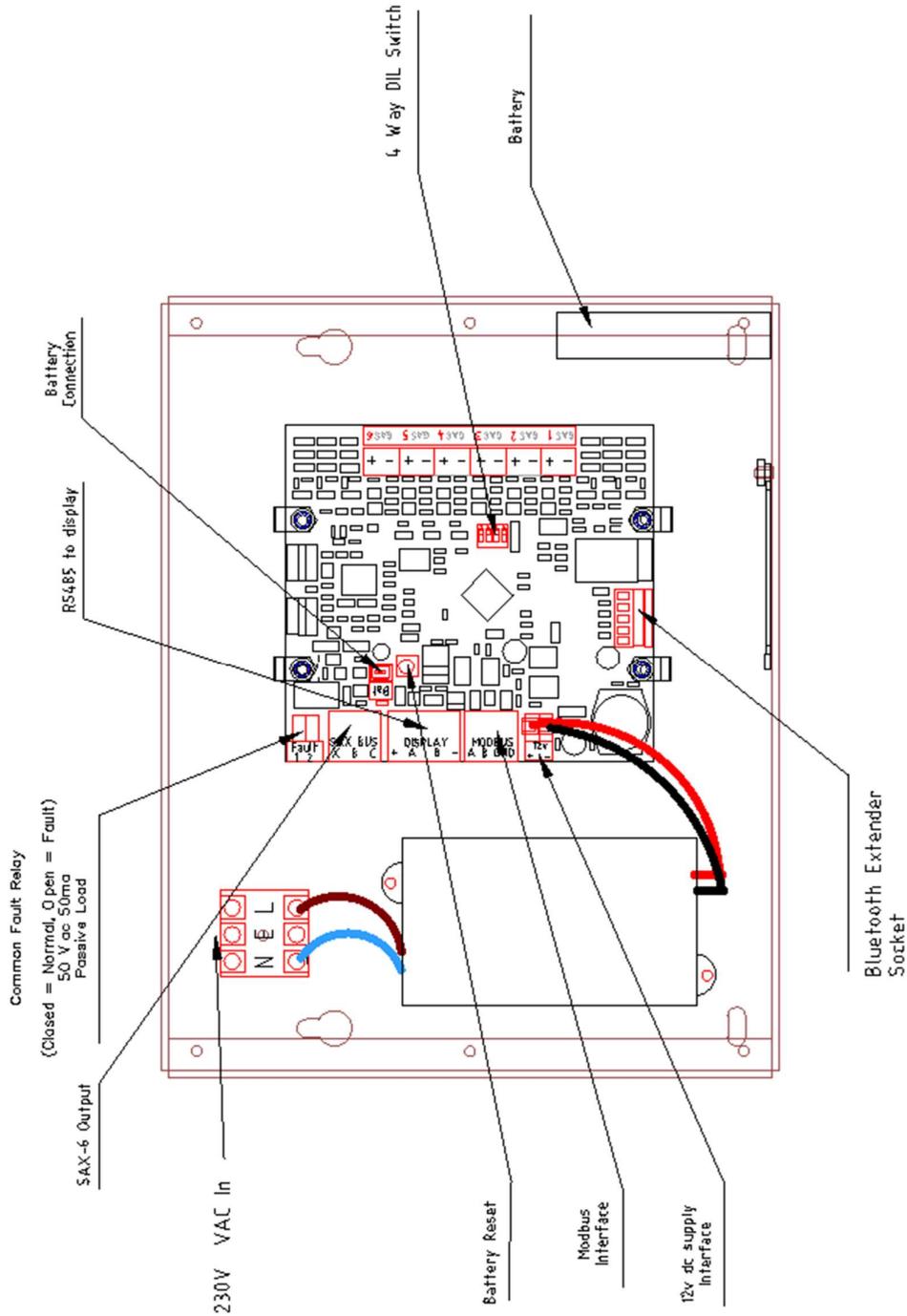


Figure 3: Encoder In SAX6 Flush Box Typical Connection Detail

SAX6 55mm Surface Back Box Assembly for Alternative Transmitter/Encoder Unit Setup

Below is a drawing of the PCB, highlighting the location of all input terminals, 230vac, switches and pushbuttons required for setting-up and installation of the SAXD Encoder within an SAX6 Surface Back Box, to enable Encoder & Display within single surface mounted enclosure.

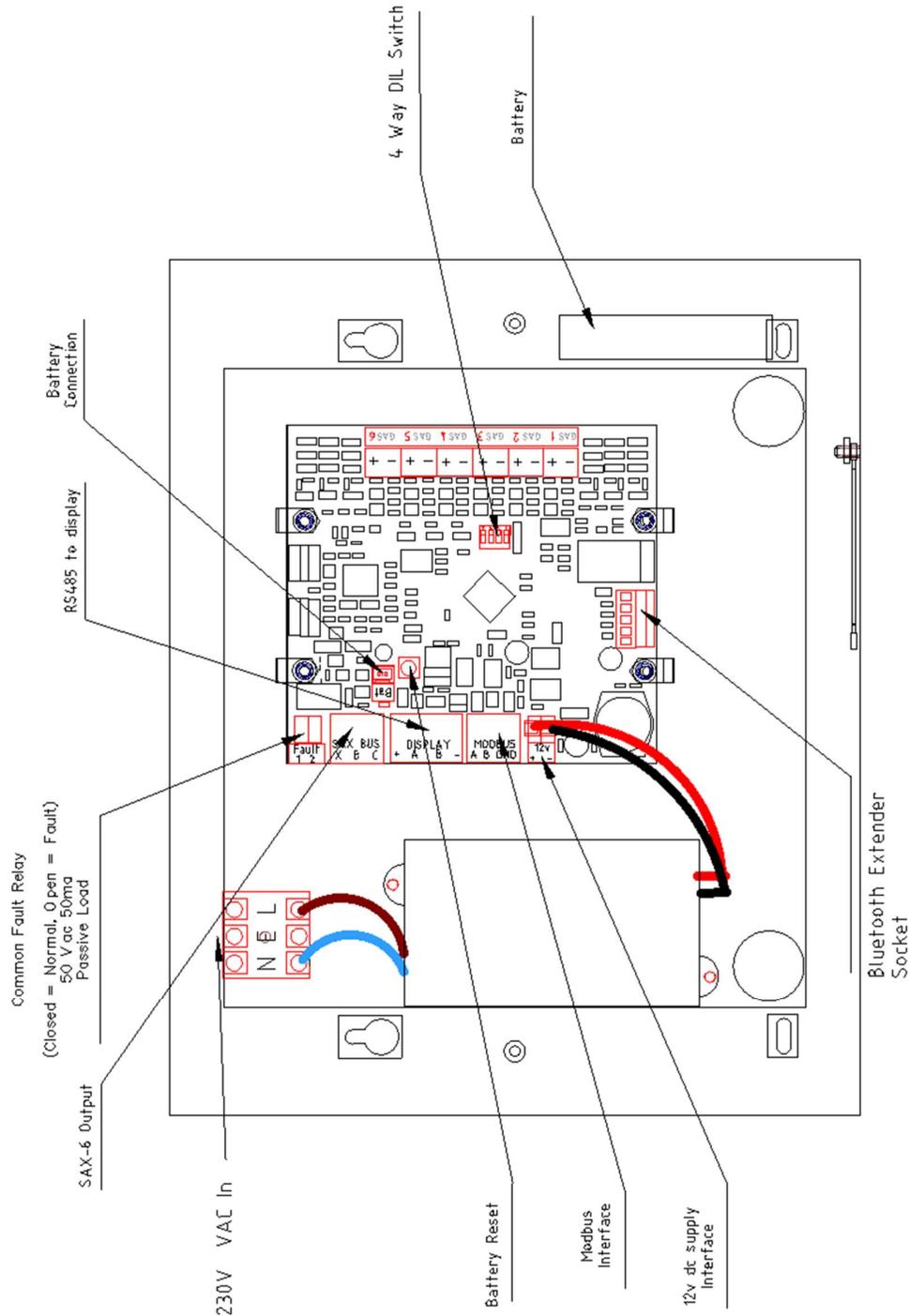


Figure 4: Encoder In SAX6 Surface Box Typical Connection Detail

Display Unit (Single 1-3 Gas Set Up)

Below is a drawing of the reverse of the printed circuit board (PCB), highlighting the location of switches, pushbuttons and connections required for setting-up and installation of the Display Unit.

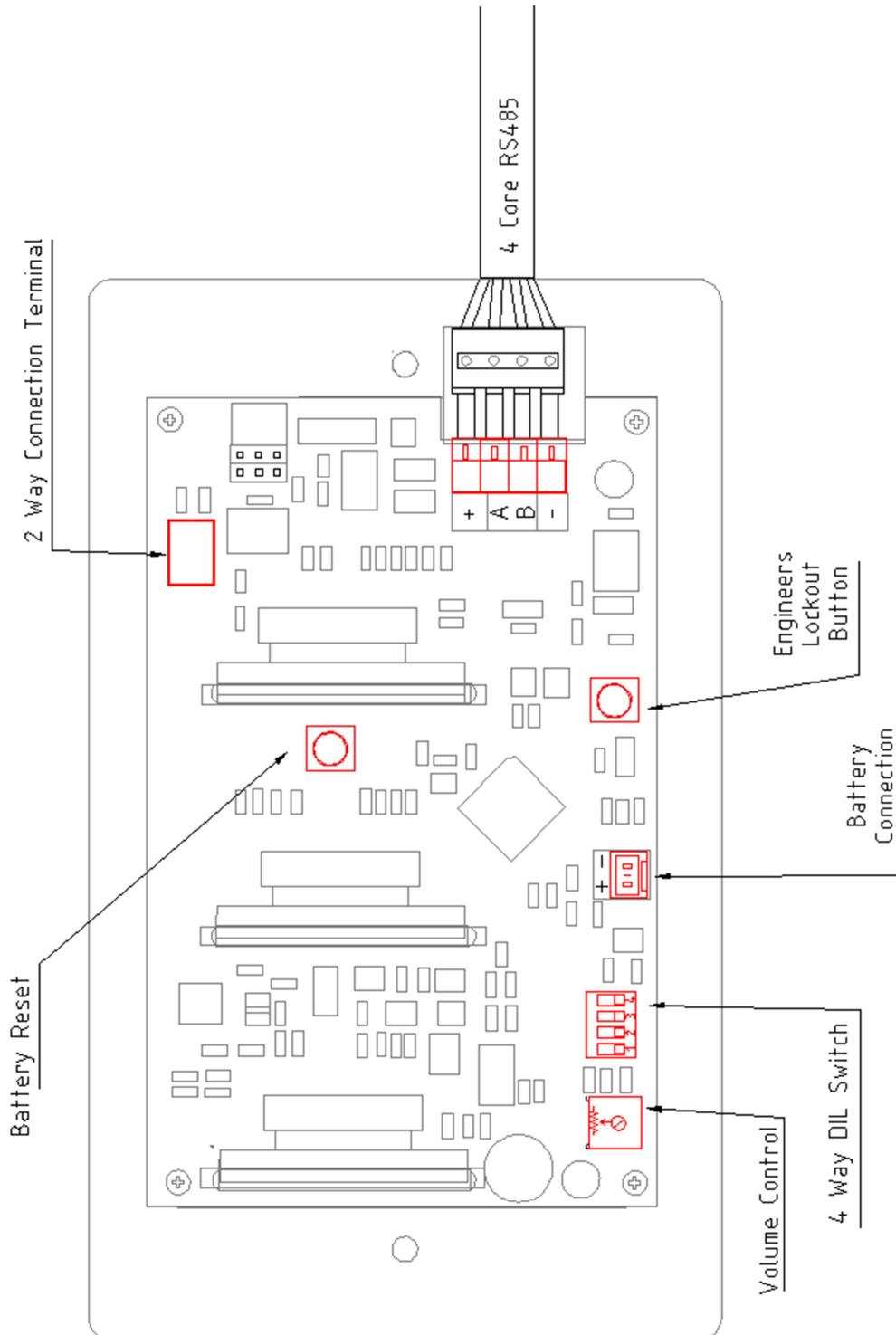


Figure 5: Single Display Mode Of Operation & Typical Connection Detail

Twin Display Unit (4-6 Gases)

Below is a drawing of the reverse of the printed circuit boards, highlighting the interconnection between Display Units and the Encoder. All switches, pushbuttons & connectors are similar to that shown for 1-3 Gas set up.

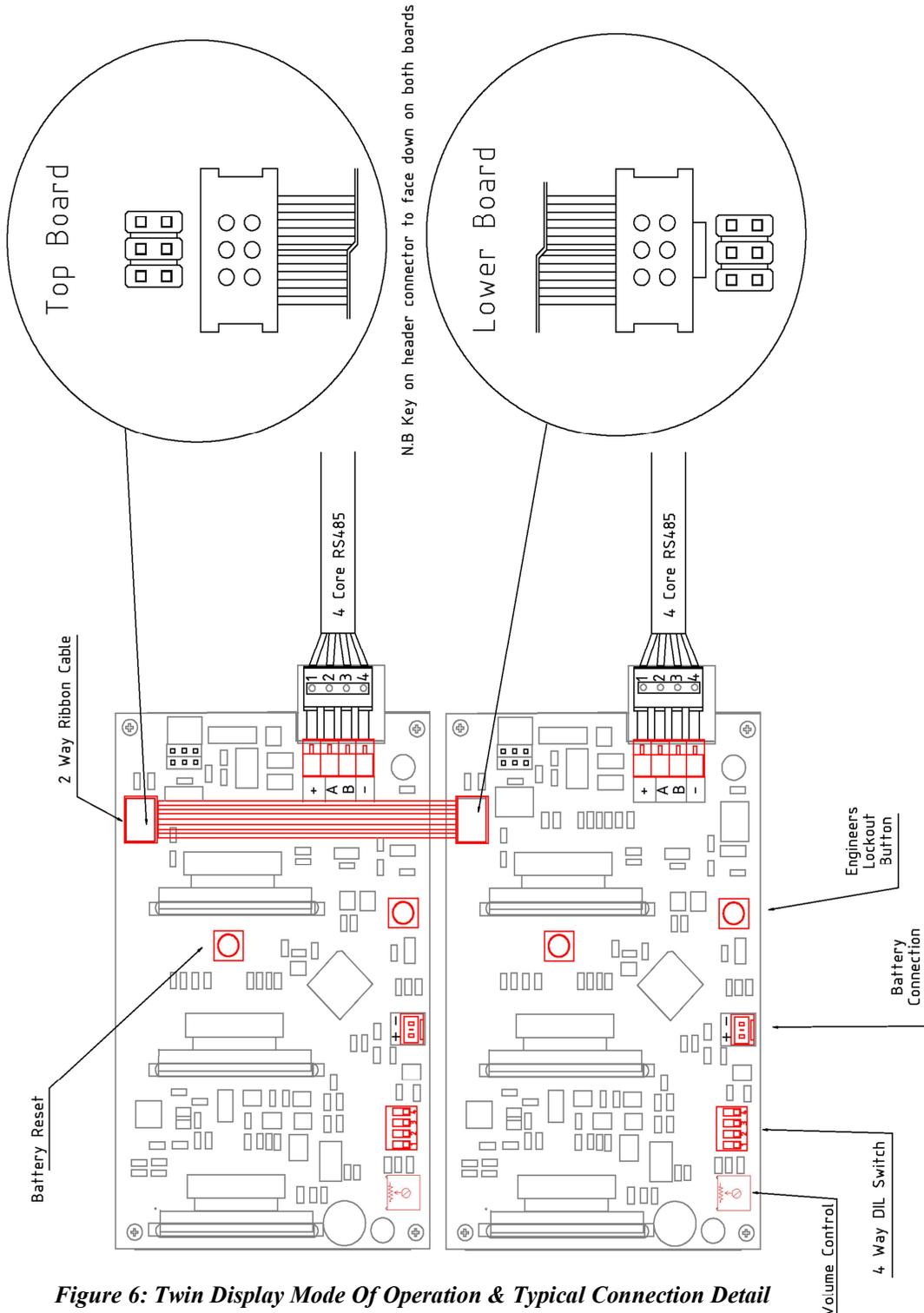


Figure 6: Twin Display Mode Of Operation & Typical Connection Detail

6. Display Unit

This section outlines the display components and their corresponding conditions during use and in case of an alarm.

Alarm Condition	Power On LED	System Fault LED	Red Gas Condition LED	Relay Output	Audible Output (2-Tone)	Comment
Normal	On	Off	Off	Closed	No	
Mute-Test (With Alarm at Normal)	On	Flashing	Flashing, Red-Black	Closed	Yes	Gas Condition Green Normal's All On
Gas Fault	On	Off	Gas Condition Flashing	Open	Yes	Temporary & Permanent Mute can be used
Mute-Test (With Gas Fault Present)	On	Flashing	On* (If Permanent Muted) or Flashing	Open	Yes	For Gas Conditions at Normal, Green OLED's on
System Fault (Loss Of Input Line Monitoring)	On	Flashing	OLED "Loss of Data" & flashing	Open	Yes	Temporary Mute Only can be used
Gas Fault & System Fault (Loss Of Input Line Monitoring)	On	Flashing	1xOLED "Loss of Data" 1 OLED flashing	Open	Yes	Temporary Mute Only can be used
Encoder Loss of Mains	Off	Flashing	Gas Conditions Monitored	Open	Yes	Temporary Mute Only can be used.
Encoder Loss of Mains & Battery	Off	Flashing	3xOLEDs "Loss of Data" & flashing	Open	Yes	Temporary Mute Only can be used
Encoder Display 4-core bus disconnected	Off	Flashing	3xOLEDs "Loss of Data" & flashing	Closed	Yes	Temporary Mute Only can be used

7. Battery (Encoder & Display)

The 600mah 7.2v (6 x AAA) NIMH battery pack should be mounted on the reverse side of the Display PCB assembly, on the rear Protective PCB plate. The battery comes with:

- Pre-fitted 2-way Molex connector, which should be plugged into the Molex header on the PCB.
- Prior to 230vac mains being available, press the Battery Test button on the relevant PCB to start.

8. Priority Signals

All fault conditions are represented by flashing Red LEDs. A System Fault is displayed if there is a cable fault or mains loss. Gas warnings are displayed if the pressure is out of range.

All normal conditions are represented by Green LEDs:

- “Power On” if 230vac is present.
- “Normal” when no fault on a gas is present.
 - (i.e. gas operating within desired pressure range).

High Priority fault conditions are represented by flashing Red LEDs. When:

- A “System Fault” is displayed if there is:
 - Any data cable fault between: -
 - Transducers and the Alarm Transmitter.
 - The Alarm Encoder/Transmitter and the Display.
- Loss of 230vac detected and battery backup is activated.
- A High gas level warning is displayed individually for each gas if:
 - The gas pressure rises above the maximum pre-set operating range.
- A Low gas level warning is displayed individually for each gas if:
 - The gas pressure falls below the minimum pre-set operating range.

Note: All high priority conditions are accompanied by an audible warning, which can be manually suspended for a 15-minute period from the Mute/Test button integral to each Display Unit.

Medium Priority level fault conditions are reported by flashing Yellow LEDs. When:

- Pressure drops on a specific gas but is still within operational guidelines.

Note: All medium level warnings are accompanied by an alternating beep audible warning, which can be manually stopped from the Mute/Test button integral to each Display Unit.

9. Operation

When a pressure transducer reports a pressure level between the pre-set High Pressure and Pressure Drop switching levels, the bottom half of the gas OLED display will show NORMAL and have a solid GREEN background.

When a High or Low Pressure is reported, the bottom half of the appropriate gas OLED screen will show HIGH or LOW PRESSURE and flash Red/Black with a two-tone audible. Operating the mute button will silence the audible. If the alarm condition remains, the audible will re-trigger after a nominal 15-minute period.

If the 2-core cable from a transducer to the Encoder unit has been damaged the bottom half of the appropriate gas OLED screen will flash to show FAULT O/C or FAULT S/C and flash Red/Black with a two-tone audible. Additionally, the 'System Fault' Twin LEDs will Flash. Operating the mute button will silence the audible. If the alarm condition remains, the audible will re-trigger after a nominal 15-minute period

When Pressure has dropped just below the NORMAL range, the bottom half of the appropriate gas OLED screen will show PRESSURE DROP with a flashing Yellow with an alternating beep audible. Operating the mute button will silence the audible permanently or until a further gas condition occurs or the same gas continues to drop into LOW PRESSURE range as described above.

If an alarm condition is present for an extended period, the alarm condition can be permanently muted. Here, remove the Display unit fascia while the alarm condition is present and operate the white lockout push-button on the reverse of the PCB. You can check which alarm conditions are locked out by covering the Mute/Test switch until the alarm reverts to Test Mode. Here the following will happen

- a Gas in NORMAL will flash Red/Green
- Gas In HIGH or LOW will Show Red Background
- a Gas in Fault S/C or O/C will show Red Background
- a Gas in Pressure Drop will flash Red/Green

Also, the

- POWER ON twin Led will remain On
- SYSTEM FAULT twin Led will Pulse/flash
- Two-Tone Audible will sound

During normal operation when 230vac is present, the POWER ON twin Led will be ON. During power failure, the internal batteries will run the alarm. The POWER ON twin LEDs will switch off and the SYSTEM FAULT twin LEDs flash, whilst a two-tone audible will sound. If the 230vac supply remains off for a longer period, the display will show the message FAULT DATA ERROR once the Encoder battery has become exhausted.

Whilst all gas conditions can be muted or locked out via the engineer's button. ALL SYSTEM FAULTS will re-trigger the audible within 15 minutes – this function cannot be disabled as it forms a minimum requirement of the HTM.

To prolong the life of the OLED screens, when all gases are at NORMAL and SYSTEM FAULT is NOT present, the screens will be dimmed to a sleep mode. The sleep mode should not operate when any FAULT error is present.

Failure of the Data line on a receiving signal from the Encoder or (in the case of a Master/Repeater system) another Display unit will create a “System Fault” warning, an audible warning and all OLEDs will report Singal Fault Data Error.

If any gas or system fault is present, the Common Fault Relay output relay in the Encoder will be de-energised (open circuit across 2-way terminal), only re-energising when all gases and power are at normal.



WARNING

Inadequately installing a device could jeopardize patient safety and put the user at risk. Prior to handing over the device to the operator, it is essential to confirm that the system functions correctly through an acceptance test, ensuring adherence to national standards.

- **Prior to system deployment and following component installation, the equipment must undergo approval.**
- **In the event of a test failure, medical devices must NOT be utilized.**

a. Muting (Temporary)

The audible is muted by operating the Mute/Testbutton then releasing. The audible will then stop.

The audible will re-trigger after a nominal 15 minutes. It can then be re-muted.

b. Muting (Permanent) & Lockout

If an alarm condition is to be in fault condition for a prolonged period, the audible on this condition can be permanently muted from the white push button on the centre rear of the Display PCB.

Note: Any other conditions present at this time, whether muted or not, will also be locked out. The lockout can be verified by operating the Mute/Test button. Lamps for conditions which are locked out will flash RED & steady. The lockout condition is cancelled as soon as the condition returns to normal.

A system fault cannot be locked out.

c. Testing

Periodically operate the Mute/Test button. Hold in until

- All Gas Condition OLEDs flash RED-BLACK,
 - The “System Fault” flashes (opposite timing to the Gas Condition flashing)
- All Green OLEDs show continuously
- Audible sounds.
- Any Red alarm LEDs for conditions which are locked out will be RED.

Release the button. After a short delay, all conditions should return to normal operation and the audible should stop.

Periodically switch off the mains supply.

- Lamps should operate as described earlier.
- After a short delay, the audible should sound and the “System Fault” lamp should flash

When the mains supply is switched back on, all conditions should return to normal operation.

d. Clinical Benefits

The Area Alarm is crucial for hospital pipeline systems. A properly functioning Medical Gas Pipeline System avoids any delay in treatment. The claims of Shire Controls Ltd. Area Alarm include:

- The Area Alarm used as instructed aims to indicate normal functioning of the Medical Gas Pipeline System by means of visual indicators on the alarm panel
- The Area Alarm helps to inform the user by providing visual and audible emergency alarms that abnormal conditions have occurred which may require immediate action by the user or clinical staff or Medical Gas Pipeline System (MGPS) operator.

e. Disposal

This product must be disposed of in accordance with national regulations.

The unit does not contain any hazardous substances.

f. Technical Data

- **Environmental Conditions**

The device meets the following operational and storage environmental limits:

- Operating Temperature: -10°C to $+40^{\circ}\text{C}$
- Storage Temperature: -10°C to $+50^{\circ}\text{C}$
- Operating and Storage Humidity: 10% to 85% RH, non-condensing
- Atmospheric Pressure Range: Tested between 860 mbar and 1060 mbar

- **Operating Data**

Operating voltage: 230vac

Power Consumption: 35watts

Protection Class: Class 1 (Mains supplied equipment using protected earth).

Fuse: 5x20mm 500ma (Slow Blow)

- **Display Unit**

Status display of pressure ratios:

- 0 to 16 Bar for Pressured Gases
- -1 to 0 Bar for Vacuum (mmHG)

Pressure display:

Red LED: High- or Low-Pressure warning received from a Pressure Transducer (By others)

Yellow LED: Pressure Drop warning received from a Pressure Transducer (By others)

Green LED: Normal level detected received from a Pressure Transducer (By others)

Maximum Pressure: Pressure Levels are set within the design of the MGPS (By others).

Transducers typically operate within 0-16 Bar Range.

- **Relay Module**

A Common Fault Relay is incorporated within the Encoder/Transmitter PCB of the Alarm
At Normal 'Relay' Terminals have continuity

When a Fault is present 'Relay' Terminals are Open Circuit

Relay Contacts are Volt-free and are rated at 0.5amp for 110Vac & 1-amp 24Vdc
(minimum)

Environmental Transport and Storage Conditions

All products are separately packaged and stored in controlled conditions.

- **Modes Of Operation**

Set For 1-6 Gases (High, Low & Pressure Drop detection with specific pressure)

With Line Monitored Data Inputs from Transducers

Medical (No 15 Minute Audible reset) Operation

All parameters can be adjusted by the client via Bluetooth APP (Appendix A).

Indoor use

Continuous (equipment may be switched on indefinitely)

- **Risk Classification**

Class IIb as per the Annex VIII Classification Rules under Rule 9 of EU MDR 2017/745

g. Maintenance

Recommended cleaning method:

- Use a soft, anti-static brush to remove loose dust particles.
- Wipe surfaces with a lint-free, non-abrasive cloth lightly moistened with Isopropyl Alcohol (IPA), 70–90% concentration.
- Ensure all visible marks or debris are removed.
- Allow the surface to air-dry fully or wipe until dry before packaging or installation.

Justification: Providing detailed cleaning instructions ensures consistent product presentation and reduces the risk of residue or debris interfering with product operation or user perception of quality.

h. Fault Troubleshooting

Fault	Cause	Remedy
Alarm does not switch on	No 230vac connected to Encoder	Check site supplies to fused spur adjacent to alarm.
	No 12vdc output from Encoder Power Supply module.	Check to see on 3no Green Pin LEDs for the dc voltages lines are lit on PCB.
	Check 500ma (Slow Blow) fuse (mounted in Live terminal for LNE connection.	Replace fuse or Call Shire Controls for assistance.
Alarm Condition Does not switch on when Gas level is out of Operating Range	Pressure Transducer Incorrect/Faulty	Remove 2-core input connection and check that the Channel OLED screen report Signal Fault O/C.
	If after removing transducer input wiring, OLED Does not report Fault.	PCB may have been damaged, Call Shire Controls for assistance.
Alarm Condition Does not switch Off when Gas level is in Normal Operating Range	Pressure Transducer Incorrect/Faulty	Remove wiring to transducer and fit 1K5 ¼ watt resistor across input terminals and check for Normal condition.
	If after replacing wiring with 1K5 resistors, the alarm does not respond.	PCB may have been damaged, Call Shire Controls for assistance.

Audible not sounding with visual warning	Possible damaged speaker/audible circuit	Press & hold Mute/Test button and check audible sounds
	If audible sounds when tested, possible external interference	Press & hold Mute/Test button and check that visual warning flashes or is lit steady.
	Visual condition is permanently lit under test function	Temporarily swap transducer input with another transducer input to see if the audible is working correctly on other channel.
	If the 2nd test produced different outcomes, the original fault may have been permanently muted from the Lockout button.	If the 2nd test produced the same outcome, there may be interference from external sources.
	Check for correct earthing of ALL screened data cables on Encoder earth stud.	Call Shire Controls for assistance.
Battery Back Up not functioning.	Battery may have exceeded it life cycle.	Check for date code on side of battery.
	If the battery code is OK, is battery still sound	Check DC voltage across terminals (should be 7.0-7.2v)
	On Encoder, if battery is OK, remove 12vdc connector from PCB, make sure the battery on plugged into the 2-way Molex and press battery reset pushbutton on PCB.	Check to see on 3no Green Pin LEDs for the dc voltages lines are lit. If Pin LEDs are not lit, PCB may be damaged, call Shire Controls for assistance
	On Display, if battery is OK, remove 4-way Display connector from PCB, make sure the battery on plugged into the 2-way Molex and press battery reset pushbutton on PCB.	Check that All 3xOLED displays Signal Fault Data Error. If OLEDs are not lit, PCB may be damaged, call Shire Controls for assistance
Intermittent faults on same conditions	May be due to broken cables between transducer & Encoder PCB	Check cabling between these points.
	Faulty pressure transducer.	Change Transducer with another similar device.

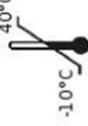
i. Symbol

Symbol	Explanation
	Medical Device
	Do not use it if the package is damaged and consult the instructions for use
	Humidity Limitation
	Keep Away from Sunlight
	Non-Sterile
	Keep Dry
	Caution
	Fragile
	Storage Temperature
	Manufacturer
	Date of Manufacture
	Serial Number
	Observe the Instructions for use
	UKCA Marking
	CE Marking European Union directives & regulations (including (EU) 2017/745 MDR)



INSTRUCTIONS FOR USE
Shire Controls Ltd. SAX-D Area Alarms

j. UDI-DI & Udi-PI Label

 <p>SAXD Area Alarm Medical Gas Alarm</p>		<p>?????</p> <p># Model No. ??????</p>	
			
	<p>QTY: 999999</p> <p>SN 999999</p>	<p>Shire Controls Ltd. Studio 3 Channocks Farm, Gilston, Harlow Essex CM20 2RL United Kingdom</p> <p>http://shiremedical.co.uk/</p>	<p>2023-12-06</p>
<p>(01) 506108026999999</p> <p>(11) 2023-12-06</p> <p>(21) 999999</p>			

k. Alarm Variations & Spares

Description Of Alarm Variations	Part Number	Supplier
SAXD 3Gas in 2 Gang Box (Flush)	saxd3f	Shire Controls Ltd
SAXD 3Gas in 2 Gang Box (Surface)	saxd3s	Shire Controls Ltd
SAXD 3Gas in SA6 Fascia Plate	saxd3sa6	Shire Controls Ltd
SAXD 6Gas in SA6 Fascia Plate	saxd6sa6	Shire Controls Ltd
SAXD 3Gas in SAX Bezel (No Back Box)	saxd3saxf	Shire Controls Ltd
SAXD 6Gas in SAX Bezel (No Back Box)	saxd6saxf	Shire Controls Ltd
SAXD 3Gas in SAX (Surface Box)	saxd3saxs	Shire Controls Ltd
SAXD 6Gas in SAX (Surface Box)	saxd6saxs	Shire Controls Ltd
SAXD Encoder	saxdpow	Shire Controls Ltd
SAXD Booster	saxdboo	Shire Controls Ltd
SAX6 Flush Back Box for Encoder	Saxdbox55f	Shire Controls Ltd
SAX6 Surface Backbox for Encoder	Saxdbox55s	Shire Controls Ltd
Description Of Spare	Part Number	Supplier
Encoder PCB	sh965	Shire Controls Ltd
Transducer For Pressured Gas 1 to 16 Bar (incl Oxygen)	tdoxy	Shire Controls Ltd
Transducer For Vacuum 0 to -1 Bar	tdvac	Shire Controls Ltd

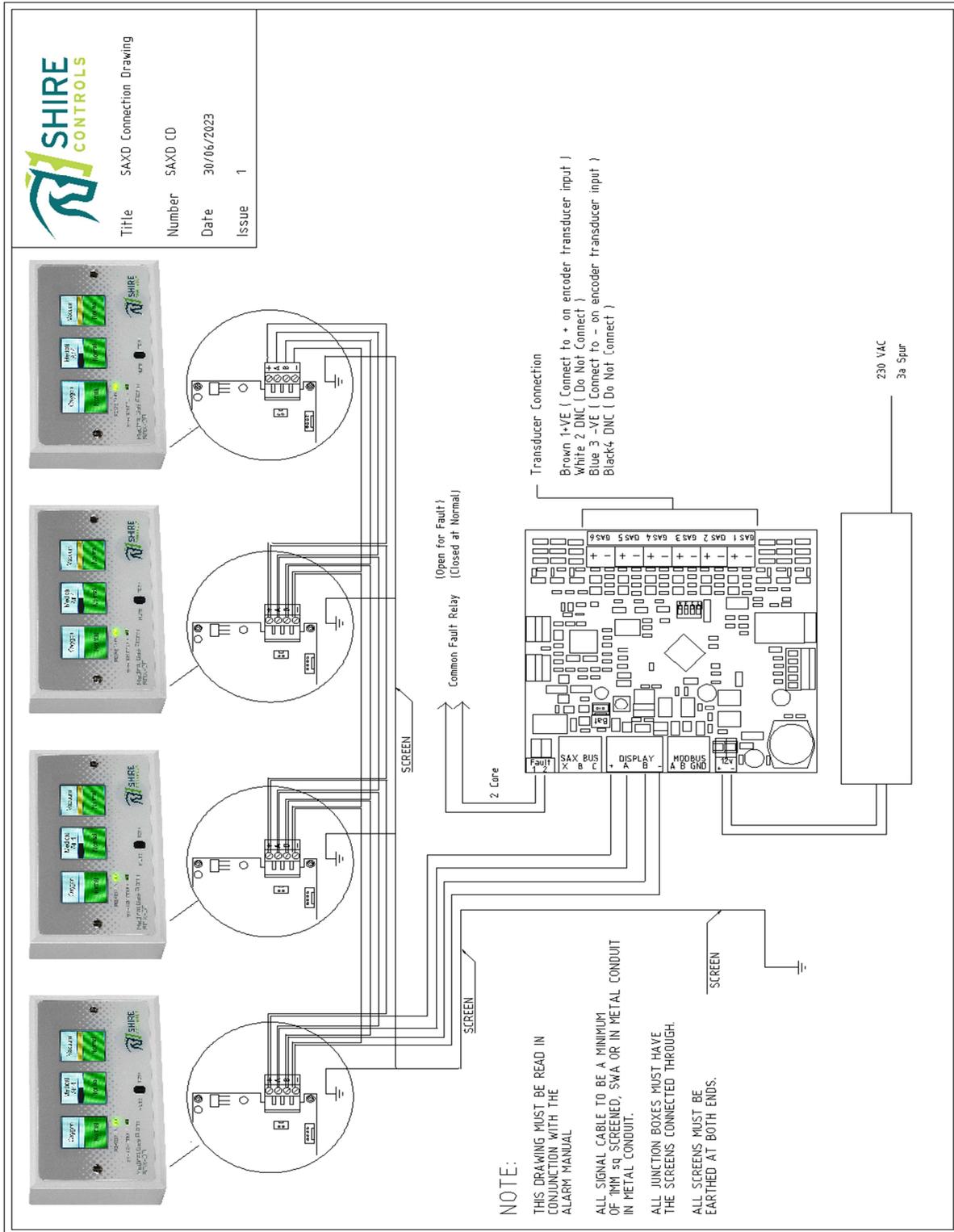


Figure 7: SAXD Typical Alarm Installation



Product Data Sheet

GW44207

44 CE Range

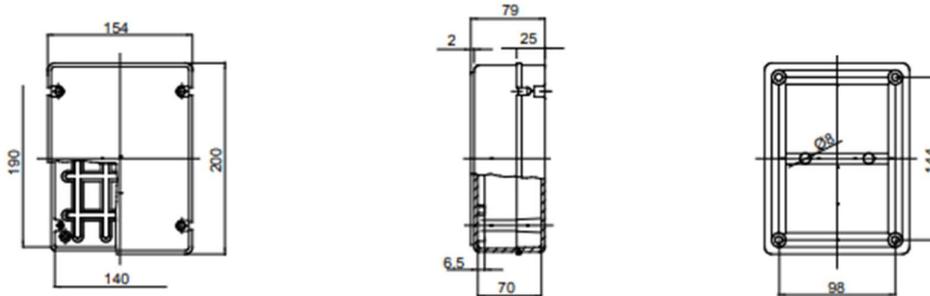


Range 44 CE - Surface-mounting watertight junction boxes in compliance with EN 60670-1 (CEI 23-48) and IEC 60670-22 (CEI 23-94) and made in high-performance technopolymers. The range includes versions with protection degree IP44, IP55, IP56 with smooth walls or with quick entry cable glands and different type of covers: blind / transparent, deep/plain, press-on/screw (in plastic, also 1/4 turn, or in metal). Available in different self-extinguishing materials (up to GWT 960 °C). Suitable for ordinary junctions, for special uses, and for industrial uses.

Insulation class	II (according to IEC 61140 standards)	Colour	Grey RAL 7035
IP degree	IP56	Material	Technopolymer GWPLAST 75
Mechanical resistance	IK08	Internal dim. LxHxD (mm)	190x140x70
Max Ø holes possible	37 mm	Lid screws (no. and type)	4 insul. sealable hinged
Application	Ordinary junctions	Glow Wire Test	650 °C
Lid	Plain screwed	Operating temperature	-25 +60 °C
Type of material	Halogen-free in compliance with EN 60754-2	Electroood	02211
Thermo-pressure with ball	85 °C	Torque screws tightening	1.8 Newton/meter
Walls	Smooth	Accessories for insulation restoring	GW44621, GW44622

BEHAVIOUR WITH CHEMICAL AND ATMOSPHERIC AGENTS										
Saline solution	Acids		Bases		Solvents				Mineral oil	UV rays
	Concentrated	Diluted	Concentrated	Diluted	Hexane	Benzol	Acetone	Alcohol		
Resistant	Limited resistance	Resistant	Resistant	Resistant	Limited resistance	Not resistant	Not resistant	Limited resistance	Limited resistance	Limited resistance

DIMENSIONAL



TECHNICAL SYMBOLOGY



STANDARDS/APPROVALS



Figure 8: Encoder Enclosure

m. Regulatory Standards

To which this declaration relates is in conformity with the following standards:

Emissions Standard for Medical Equipment

EN60601-1-2, 4th Edition Professional Healthcare Environments

Emissions Standard (ERM) for radio equipment

EN 301 489-1

Conducted Emissions AC Port

EN55011, Class A

Conducted Emissions Discontinuous Disturbance

EN55011, Class A / EN 55014

Radiated Emissions

EN55011, Class A

Immunity Standard for Medical Equipment

EN60601-1-2, 4th Edition Professional Healthcare Environments

Immunity Standard (ERM) for radio equipment

ETSI EN 301 489-1

Electrostatic Discharge EN61000-4-2

Radiated Immunity EN61000-4-3

Fast Transient Bursts EN61000-4-4

Surges EN61000-4-5

Conducted Immunity EN61000-4-6

Magnetic Field Immunity EN61000-4-8

Voltage Dips EN61000-4-11

Voltage Interruptions EN61000-4-11

History

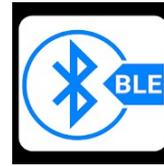
- 1.0 Issued for Production
 - Suitable for Software - Encoder V208 & Display V007
 - Suitable for Software - Encoder V303 & Display V007 (40% Sleep Mode)
- 1.1 Issued for lower-level Sleep Mode & Updates on Transducers
 - Suitable for Software - Encoder V003RC003 & Display V002RC010 (10% Sleep Mode)
- 1.2 Suitable for Software - Encoder V003RC100 & Display V003RC002
 - Suitable for PCBs - Encoder V003_B & Display V002RC000
 - Updating of Variation & Spare, Maintenance, Environment, Symbols, Labelling, & Structural
- 1.3 Issued for Inclusion of SAXD Booster
 - Also for Inclusion of SAX6 55mm (Flush/Surface) Back Boxes For Encoder Housing

10. Appendix A (Bluetooth BLE Application)

Download The App

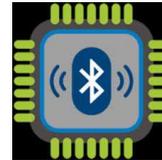
Android

From *Google Play Store* download and the Install “BLE Terminal” by “mightyIT.”



Apple

From *App Store* download and the Install BLE Terminal HM-10.



Connect To Bluetooth

1. Check that LED1 on the encoder PCB is pulsing a single flash (this shows that the Bluetooth link is available and currently disconnected).
2. Ensure Bluetooth is enabled from your mobile device.
3. Open the App.
4. Scan for devices (see fig A).
 - a. You should find device name Shire_SAX_xxxx and select.
5. Check that LED1 now pulses with a double flash (this confirms connection).
6. You should have a message saying “connected” “password” (see fig B).
7. Terminal screen will open as per figure opposite.
8. For Apple ISO Only
 - a. just below the black terminal window press the blue button marked.
 - i. 'selected xxxxxxxx'.
 - b. From the menu selection menu select.
 - i. Characteristic Notify Write WriteWithoutResponse (see fig C).
9. Enter the default password “studio3” (see fig D).
 - a. If all is working you will get message saying, “Welcome to Shire SAX Command Line Interface” (fig E).

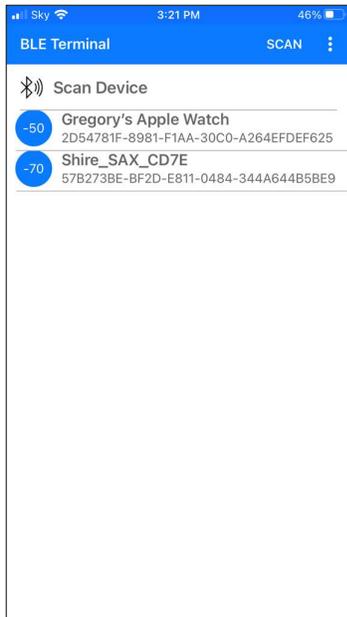


Fig A

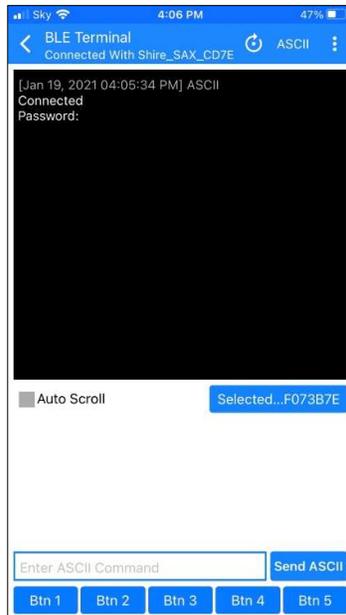


Fig B

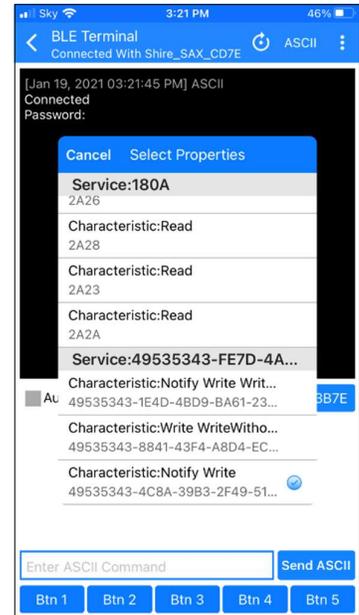


Fig C

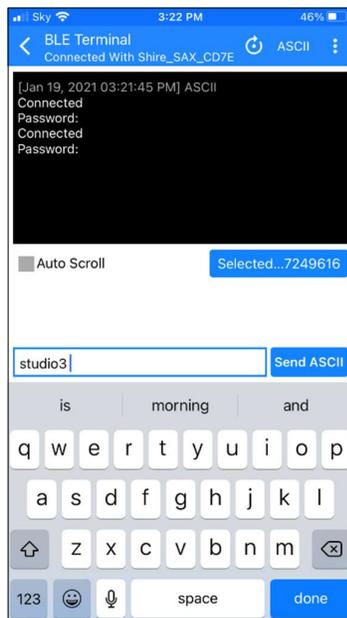


Fig D

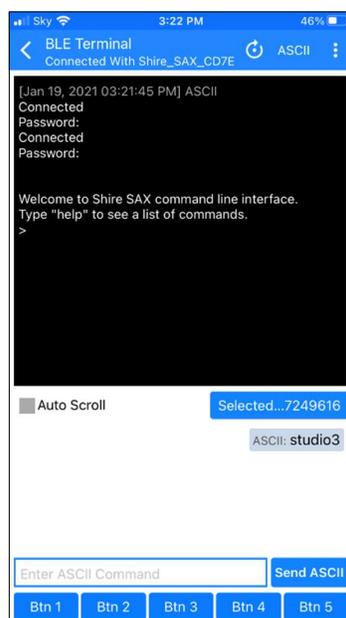


Fig E

You are now ready to write to the Alarm System from your mobile device as per table below.

Option

There are short-cut buttons provided at the bottom of the screen. Hold down 'Btn1' and type 'studio3' in the pop-up window that follows. This means that whenever you need to pair with the device, 'Btn1' will log in from the password prompt.

Command List

Typing 'gashelp' will produce a list of available instructions for gas settings. The command structure, description and useful notes are listed in the table below:

Gas the command we want to work on the gas parameters.
 Number(x) the gas channel we want to address ('1' to '6' or 'a' for all)
 setting the setting you want to change.
 parameter attached to the setting (not always needed)

Gas settings		
Gas Commands	example	description
Change text strings		
Name	Gas x Name Oxygen	Change gas name text string to 'oxygen'
Normal	Gas x normal Normal	Change normal text string to 'normal'
High	Gas x High high\npressure	Change high pressure text string to 'high pressure'
Drop	Gas x drops pressure\ndrop	Change pressure drop text string to 'pressure drop'
Low	Gas x Low low\npressure	Change low pressure text string to 'low pressure'
Fault	Gas x Fault fault	Change fault text string to 'fault'
Change alarm pressures		
Hi_set	Gas x Hi_set 8.4	Set gas x to go into hi pressure alarm above 8.4 bar
Pd_Set	Gas x pd_set 7.8	Set gas x to go into pressure drop alarm below 7.6 bar
Lo_set	Gas x Lo_set7.6	Set gas x to go into lo pressure alarm below 7.6 bar
Other Settings		
List	Gas x list	Display settings for gas x
on	Gas x on	Enable gas x
off	Gas x off	Disable gas x
Press_on	Gas x Press_on	gas x display pressure
Press_off	Gas x Press_off	gas x does not display pressure
Press_al	Gas x Press_al	Display pressure only when in alarm / warning
Press_eng	Gas x Press_eng	Display pressure only when test button pressed
Type	Gas x type CO2	Gas x load default settings for gas type. USER, O2, N2O, ENT, MA_4, MA_7, SA_7, VAC, N2, CO2, BOT_230 or BOT_250
units	Units' psi	Set units Bar,mmHg,PSI,other?
Cal	Gas 6 cal 760 Gas 1 cal 4.15	Force the encoder to update the reading calibration point
Atm	Gas 6 atm 0	Force the encoder to update the Atmosphere (zero) calibration point

Typing 'help' will produce a list of available instructions for general settings. The command structure, description and useful notes are listed in the table below:

Commands		
Command User	example	Description
Help	Help	List commands (Customer)
Gas	gas x list	See Gas settings table
Tone	Tone 1	Change tone '0' or '1' of '2'
mute	Mute 10	Sets mute timer to 10 minutes. 0 = no mute timeout
logout	Logout	Logout of the console
logouttime	Logouttime 15	Sets auto logout time to 15 min
password	Password TheNewPW *	Change the login password
modbus	Modbus address baud	Sets Modbus address to 1-127. Baud rate 0,1,2,3 0 = 9600 1 = 19200 2 = 38400 3 = 115200
location	location Ward\s10	Sets location to Ward 10 The \s denotes a space
Settings	settings	List system settings
logtime	Logtime 15	Sets the max, min log time to 15-minute intervals
logdump	Logdump	List the log data (see note)
logclear	Logclear *	Clears the log data
Factory	Factory *	Reset to factory defaults
Reboot	Reboot *	Reboots the encoder

Note: Logdump Function

The Encoder can record the maximum and minimum value of all 6-gas pressure over a variable amount of time. The default is 5 minutes. A total of 640 records can be stored giving.

For a 5-minute interval, 640 records = 53.3 Hours (2.2 days)

This is a lot of data to download (6 max + 6 min, times 640 = 7680 data points).

11. Appendix B (Modbus Protocol)

Modbus Settings for software versions V002_RC206 onwards

Modbus type: RTU RS485
 Baud Rate: Selectable 9600, 19200 38400, 115200 baud (see modbus command)
 Data bits: 8
 Stop bits: 1 stop bits.
 Flow control: No
 Scan rate/Timeout: 1000ms

Modbus functions implemented.

Read continuous block of holding register (0x03)

Reading an address above 69 will produce an error.

Function	address	data
Condition Status	0 + gas	0 = OFF, 1 = Pressure NORMAL, 2 = Pressure HIGH, 3 = Pressure LOW, 4 = P_FAULT , (Not Used, replaced with OC and SC) 5 = Transducer OC, 6 = Transducer SC, 7 = C_FAULT , (Not Used) 8 = Pressure Drop 9 = Error (end marker, should never see this)
Current Gas pressure	10 + gas	Gas pressure reading. Integers, see units
Set point to go into high alarm	20 + gas	Gas high alarm setpoint. Integers, see units
Set point to go into Pressure Drop alarm	30 + gas	Gas Pressure Drop setpoint. Integers, see units
Set point to go into low alarm	40 + gas	Gas low alarm setpoint. Integers, see units
Gas type	50 + gas	0 = O2, 1 = N2O, 2 = ENT, 3 = MA_4, 4 = MA_7, 5 = SA_7, 6 = VAC, 7 = N2, 8 = CO2 9 = USER,
Gas Units	60 + gas	0 = BAR, 1 = mmHg, 2 = PSI, 3 = LPM,

Gas offset range 0-5.

i.e. gas 3 pressures = address 12

Gas pressure = 418

If gas units = 000 then Bar so, divide by 100. Pressure/100 = 4.18 Bar

If gas units = 100 then mmHg so, divide by 1. Pressure/1 = 418 mmHg

If gas units = 200 then PSI so, divide by 1. Pressure/1 = 418 PSI

If gas units = 300 then NON so, divide by 1. Pressure/1 = 418

Test ModBus:

1. Install QModMaster <https://sourceforge.net/projects/qmodmaster/> software on windows PC.
2. Connect serial/RS485 bus to PC and ModBus connector on the Encoder PCB.
3. Find the com port that windows have set up for the RS485 port (Run Device manager and look for (COM & LPT))

The screenshot shows the Modbus Master software interface. The 'Function Code' is set to 'Read Holding Registers (0x03)' and the 'Format' is 'Decimal'. The 'Start Address' is 0 and the 'Number of Registers' is 70. The data table below shows the following values:

1	1	1	1	1	1	0	0	0	0
380	425	580	400	405	620	0	0	0	0
480	480	800	480	480	800	0	0	0	0
370	370	300	370	370	300	0	0	0	0
340	340	270	340	340	270	0	0	0	0
0	3	6	8	2	6	0	0	0	0
0	0	1	0	0	1	0	0	0	0

Annotations in the image include:

- Red arrows pointing to 'Function Code' and 'Start Address' fields.
- A red arrow pointing to the 'Number of Registers' field, labeled 'Number of registers to be read'.
- Red arrows pointing to the first, sixth, and seventh columns of the data table, labeled 'Gas 1', 'Gas 6', and 'Gas 7,8,9,10 Not Implemented' respectively.
- Red text labels on the left side of the table: 'Gas Status', 'Current Pressure', 'Hi Alarm Pressure', 'PD Alarm Pressure', 'Low Alarm Pressure', 'Gas Type', and 'Gas Units'.

NOTE
On earlier software versions Gas Type and Gas Units were combined into one location.

12. Appendix C (Transducers)

Transducers

The Pressure transducers are all set up as 4-20ma 16bar (0Bar = 4ma, 16Bar=20ma)

The Vacuum transducers are all set up as 4-20ma -1bar (0mmHg = 20ma, 760mmHg=4ma)

Recommended With

- Wika 16 Bar: MG-1 46994706 & 43692206
- Kavlico 16 Bar: PTE5000-016-1-B-1-C
- Bob BE1AS-G-6-X-2-C4-P1
 - Pin 1 = +Vcc
 - Pin 2 = Input

- Wika Vac -1 to 0 Bar:A-10 13409701
- Gems Vac -1 to 0 Bar: 3300 B 000P V 01 E 0 00
- Kavlico Vac: P1A-30G-1-b-01—C

- Scatergood PN: RKT4-07/2M
- 4-20ma cable M12F-A-STR 4P 0RA.PVC LEAD 2M

Other Wise All Connections

Brown	1	+Vcc (Connect to + on encoder transducer input)
White	2	DNC (Do Not Connect)
Blue	3	-VE (Connect to - on encoder transducer input)
Black	4	DNC (Do Not Connect)