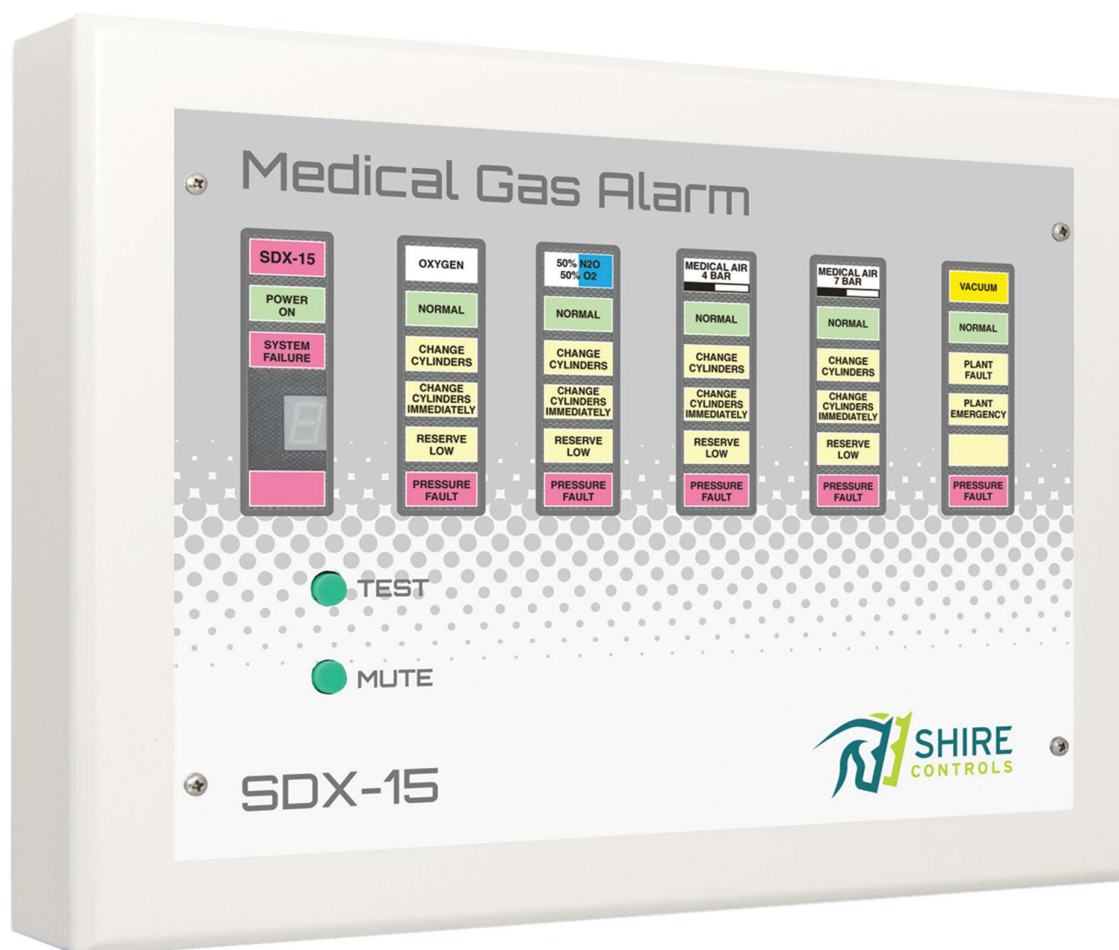


SDX-15 Plant Alarm for Piped Medical Gases





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1. Introduction

The SDX-15 plant alarm system is designed to monitor the status of gas sources for piped medical gas systems. The SDX-15 will act as a stand-alone alarm or operate as a repeater to another SDX-15 alarm within 500 meters, using a 2-core screened cable

The SDX-15 Medical Gas Alarm system has been developed according to the requirements of Medical Gas Plant Alarms as defined in DH & DSS HTM02-01 and C11 model standard, fully meeting the requirements of these documents.

The SDX-15 alarm system can monitor up to 15 gas sources within a medical piped gas system. Each SDX-15 alarm can monitor up to 5 gases at one time. Each SDX-15 plant alarm enables monitoring of up to 3 duty status conditions for gas types such as VIE, Plant & Manifolds, with a 4th condition available for a secondary supply (i.e. reserve manifold).

For larger systems a second panel should be added alongside the first to monitor up to 10 gases (i.e. 2 x 5 gas) and similarly for the largest systems a third panel should be used enabling monitoring of the full 15 gases (i.e. 3 x 5 gas).

Each gas has a green “Normal”, yellow 1st/2nd/3rd Intermediate warning levels and a red “Pressure Fault” LED. The panel also has a green “Power On” LED and a red “System Fault” LED, together with a mutable audible alarm.

Emphasis is placed on reliability and flexibility, enabling an economic system to be installed and expanded as required. The manufacturers guarantee the availability of electrically compatible equipment for system expansion for a minimum of 10 years from the date of supply of the original system. The SDX-15 is fully back compatible.

A full range of accessories (i.e. transmitters, interfaces, etc.) are available, allowing the system to be shaped to the requirements of each system.

2. Safety-Related Information

2.1. Intended Purpose:

Shire Controls Ltd. Plant Alarm is intended to monitor the status of gas sources for hospital system piped medical gases. The alarm is designed to monitor up to 5 gases via locally mounted SDX transmitters from volt-free contacts integral with the gas source (plant or manifold).

Alarms can be mounted in twin and triple sets so up to 15no Gases can be monitored on a system from a single point (i.e. Telephone Switch-Room or Estates).

2.2. Intended User group:

The device is intended to alert operators including technical and clinical staff of abnormal operating gas source status.

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. Plant 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 SDX15 Plant 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.

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.

Avoid using the Plant Alarm (or associated transmitters) in an environment where there is a risk of explosion.

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

The SDX-15 Plant Alarm is a multiplexed medical gas alarm system designed to monitor up to 15 gas services at the plant room level and monitors and signals abnormal operating conditions of piped medical gas sources (e.g. VIE, manifold, or plant), including supply failure, reserve fault, or pressure anomaly. It is used by clinical or technical staff to initiate timely responses to gas system faults. 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.

Structural Components and Materials

1. Alarm Enclosure and Mounting

Flush or Surface Mount metal enclosures with knockout entries (bottom or rear entry)

Flush Mount Dimensions: 295 mm × 225 mm × 55 mm (W × H × D)

Back Box: M1016, Mild Steel, 1.2 mm: Powder-coated Green

Surface Mount Dimensions: 324 mm × 251 mm × 53 mm (W × H × D)

Back Box: M1019, Mild Steel, 1 mm: Powder-coated White

Common To Both Flush & Surface

Bezel: M1010, Mild Steel 1mm: 330x257x25mm (WxHxD) Powder-coated White

Fascia Plate: M1057, Aluminium 1.5 mm, 274 mm x 182 mm (WxH)

Hinge: M1276, Mild Steel

2. PCB Assemblies and Terminals

Control PCB: SDX15 C. Provides LED indication, muting, alarm status logic, and user interface (Configurable up to 5 gases per panel)

Indicators: LEDs (Green Normal, Yellow Intermediate, Red Pressure Fault)

Front Controls: Test & Mute, with internally accessible Lockout buttons

Audio: Integrated speaker for 2-tone HTM02-compatible audible output

Power Supply PCB: 230Vac input, AC/DC power conversion, battery charger, relay outputs.

Data Terminals: Dual 4 mm² terminals for 2-core signal (marked 1 & 2), earth stud for screen termination

Relay Output: Volt-free common fault relay, de-energized under fault

Power Supply and Backup

Input: 230 Vac, 50/60 Hz, fused at 3 A

Internal Fuse Protection: 250 mA ceramic and 1.6 A glass fuses

Central / Repeater Mode

Battery Modes: “B” Full / “M” System Fault + Audible only (HTM02 mode)

3. Electrical Safety Cover:

Protective Mains Cover: Acrylic 3mm', 20×40×40 mm, light grey and non-conductive.

4. Battery:

12 V, 2.1 Ah sealed lead-acid, up to 8 hours backup depending on mode

5. Transmitters (Internal and Remote)

Internal transmitters (1–4 gas services) mount inside SDX-15 alarm

Remote transmitters (e.g. SDXRTX & RTX1) mounted near plant equipment

Plant to Alarm Interface: for external gas plants, includes visual LEDs and relay outputs

Termination boards (56k or 1k8 resistors as appropriate) support line monitoring

6. Interfaces and Extensions

Computer Interface: Volt-free relay outputs (4 conditions per service, 0.5 A 24 V dc)

The SDX15 Plant 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, medical-grade materials including steel, brass, 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 SDX-15 Plant Alarm is designed for manual operation via the Test & Mute pushbuttons. Hence it is envisaged that the operator is able to visually monitor from within 900mm.

The inherent design includes Red/Yellow/Green indicator LED's and the use of gas colour recognition within the title bar of each gas window, which ensures that the alarm can be monitored comfortably from 3-4 meters away.

Consideration should be made for the 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

The SDX15 Plant Alarm

- Surface mounting
Mount the enclosure with Knockout cable entry holes at the back & bottom as per diagram to rear of this manual (fig 6: surface mounting).
- Flush mounting
Mount the enclosure with Knockout cable entry holes on the bottom edge as per diagram to rear of this manual (fig 7: flush mounting).
- For Both mounting types –
 - Fit the back box in the wall so that the front edge is from 2 to 15 mm lower than the finished wall surface.
 - When the wall is finished (plastered and painted), attach the bezel to the back box, using the 4no M3 x 25mm countersunk screws (flush) or 4no M3 x 10mm (surface) provided, with the hinge mounting to the left.
 - Connect the earth lead on the bezel to the adjacent M4 stud in the box.
 - Take the battery from the packing & stand it on end, in the right-hand end of the box, with the negative (Black) terminal at the top and facing to the left.
 - Connect the red & black leads to the red & black battery terminals (OBSERVE POLARITY)
 - Fit the 4no corners of the Power Supply PCB to the left set of 4no PCB fixings clips, locate & push gently until the clips locate.
 - Fit M4x6 Pan Head Screw (with BX35 Copper Crinkle Washer) through Power Supply PCB, just left of 'Live' terminal.
 - Locate the Control PCB & Fascia Plate Assembly to the Hinge, gently ease the hinge ends apart and locate (top & bottom) into the P-clips in reverse of the PCB.
 - After connection of 230vac & data cables (and earthing ALL data cable screened), close the fascia onto the back box assembly and secure with 4no M3x6 Pan-head screws through fascia plate.



WARNING

The SDX-15 Plant 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. Connecting



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).

Connect signalling devices (i.e., pressure switches) with screened cable, SWA or single core cable in steel conduit or trunking.

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

For cable entry, bring the cables into the box as shown on the drawings:

- Fig 7 Flush Mounting
- Fig 6 Surface Mounting.

The SDX15 Alarm is to transmit/receive data directly from SDX15 Transmitters and to other SDX15 Plant Alarms. A 2-core screened cable, minimum 0.5mm square CSA, is required between the Central alarm panel in a 24-hour monitored location (i.e. Telephone Switch Room or Estates) and ALL other SDX15 alarm system equipment (Alarms, Transmitter, Interfaces and Plant To Alarm Transmitters).

**WARNING**

This equipment is not suitable for 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 Supply

Remove the "Warning", by loosening the 2no M3 pozi-drive screws on the cover to reveal the mains terminals. Connect Live, Neutral and Earth from an essential supply to L, N & E.

Replace the "Warning" Cover, making a cut-out in the side to allow the cable to pass.

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

Battery

Connect the 12V battery on the right of the back box with terminals at the TOP & facing LEFT, with Negative (Black) terminal at the top, to avoid possible damage to the PCBs. Note: Connect the red & black leads to the red & black terminals (red to red and black to black) and OBSERVE POLARITY.

Connect signalling transmitters, interfaces, etc devices with screened cable, SWA or single core cable in steel conduit or trunking.

Cable Types

Use only the following types of cable for wiring the alarm system:

- SWA
- Overall screened cable
- Single core cable in steel conduit. Must not contain any other cables.

A minimum cable size of 0.5 sq.mm is recommended to ensure a 500-meter continuity of signals between components (Alarms or Transmitters) of the system.

**WARNING**

Solid cable such as telephone cable should NOT be used.

Data Signals

Install cable, observing cable entry areas as shown on the mounting instructions in this manual.

Before connecting cabling on any panels, check continuity of cores and earth (or screen), and insulation between cores and to earth.

The SDX-15 Alarm is designed to transmit & receive system status on a 2-core data bus. The alarm also displays this status in the form of LEDs on the Control board. Transmitters are used to read

analogue signals from volt-free relays at gas sources and then transmit these signals on the 2-core data bus to the SDX-15 Plant Alarms.

At the Alarm connect the 2-core screened cable into the terminals marked '1' & '2' on the power supply board.

Note: Remember to keep the same polarity of cores at the alarm and the transmitter (i.e. other end of the cable).

Note: Remember to earth the screen onto the M4 earth stud on the back of the back box.

A Common Fault Relay output is provided, The relay out terminals are clearly marked and have continuity when all conditions are at normal. The Relay operates (i.e. Open Circuit), when there is:

- A Gas Condition Fault Present
- System Fault (Wiring/Line Monitoring Fault) is Present
- Under Battery Back Up – Loss of Mains Supply 230Vac

Where a Repeater/Repeater Alarm is required, the 2-core data cable can simple be extended to the repeater Alarm.

Note: there are 2no '1' & 2no '2' 4mm sq. terminals to ensure that multiple cable runs can be made from here.

Transmitters

Transmitters introduce signals from gas sources, such as VIE, Plant or Manifold, onto the multiplexed signal bus.

They also monitor the wiring between the plant contacts and the transmitter terminals via termination boards mounted in or near the plant, checking for short or open circuits of the cable.

Here is a brief description of the range of transmitters available for the SDX-15 Plant Alarm System (separate data sheets are available for these products).



WARNING

Important. Ensure that each condition is only transmitted from one location although other conditions on the service may be transmitted from other transmitters.

Any service can be displayed on any alarm panel by selecting the channel on which the service is transmitted using the rotary switch for the appropriate column on the alarm.

INTERNAL TRANSMITTERS (ITX)

Internal transmitters are available as 1, 2, 3 or 4 service units and are mounted, 1 per SDX-15 Plant Alarm, in the alarm panel enclosure. If a fault is detected on the contact lines, an alarm condition is transmitted for the condition relating to the faulty line, and a system fault visual and audible alarm will appear on this panel.

Each service on the system is allocated a channel when the system is initially set up. The alarm contacts on the plant or manifold are connected via the termination board to a service on the transmitter as follows:

- | | |
|---|---------------------------|
| C | Common |
| 1 | First condition |
| 2 | Second condition |
| 3 | Third condition (Reserve) |
| 4 | Pressure fault |

This service is then set to the channel for this service with the rotary switch. For example, if Oxygen is allocated channel 1, this plant could be connected to service A terminals on the transmitter, which would then be set to channel 1.

Any condition not transmitted from this transmitter must be terminated with a 56k resistor to set the condition to normal if the condition is not to be used (or with a 1k8 resistor if the condition is to be transmitted from another transmitter).

Note: If a resistor is fitted, the condition must NOT be connected to the termination board.

Note: Failure to do this will create a "System Fault" (open circuit) resulting in the condition staying at fault and the System Fault lamp flashing.

Resistor codes:

- 1k8 brown, grey, red silver, gold or red
- 56k green blue, orange silver, gold or red

For medical applications which require cable monitoring, a termination board (supplied with the panel) must be mounted in or by the contact source (plant or pressure switches) for each service. (The termination boards supplied can be mounted in boxes if required). The contact source should be connected to the "PLANT" terminals on this board, and the alarm terminals are connected to the "ALARM" terminals (see Transmitters section).

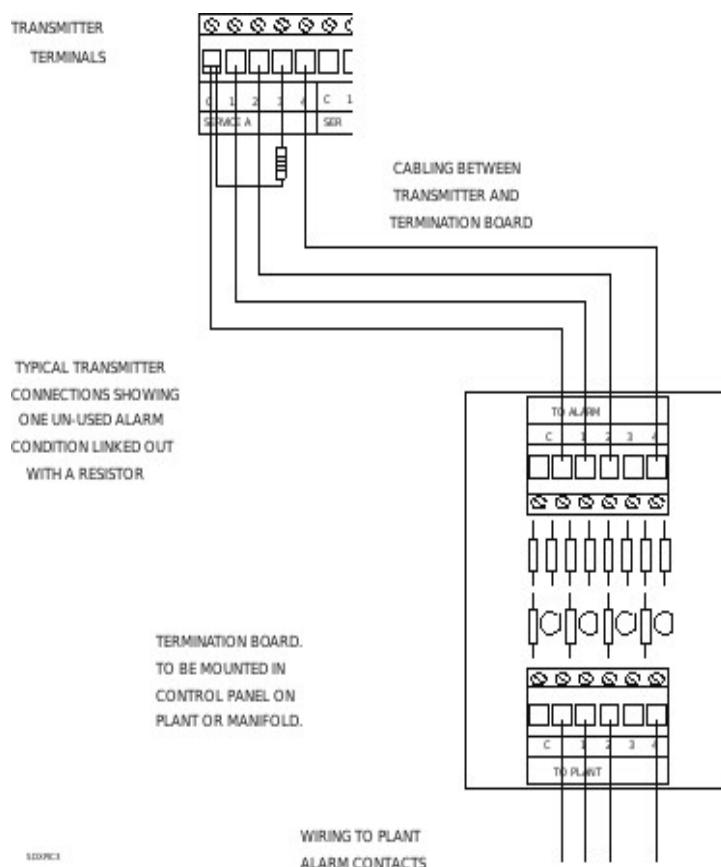


Figure 1: Internal transmitter connection

Internal transmitters are powered by the alarm panel power supply or the reserve battery in the event of a power failure. Should the power remain off for long enough to discharge the battery, all conditions transmitted from this transmitter will show on other alarm panels as gas fault conditions (i.e. not system fault).

REMOTE TRANSMITTERS (RTX).

The Remote transmitter is a self-contained unit, used where indication of the alarm condition is not required locally, e.g. when a manifold or plant has an integral plant to alarm interface, and are available as 1, 2, 3 or 4 service units.

The services are selected, as in the alarm panel, with a rotary switch. However, the remote transmitter has only one switch for up to 4 services. This switch is set to the first service required and the other services will follow in sequence. e.g. if the switch on a 3-service transmitter is set to channel 2 then the services transmitted will be channels 2, 3 & 4.

Connection to the plant (or manifold) is identical to the internal transmitter above.

A 230Vac, 50/60 Hertz supply is required, which is connected under the mains terminal cover. The 2 core inter-panel wiring is connected to signal terminals 1 & 2. The cable screen must be connected to the 'S' terminal.

Refer to the instruction sheet supplied with the transmitter.

RTX1 TRANSMITTER

Again, the RTX1 is a self-contained transmitter, used where indication of the alarm condition is not required locally and is available as a single channel variation only.

These transmitters are often factory fitted by Plant or Manifold Controller manufacturers within the same housing as the contact sources, hence the board is designed to be used **WITHOUT** termination boards.

Again, the service channel is selected with a rotary switch and the connection to the plant (or manifold) is similar to the internal transmitter, only there is no requirement for the Termination Board.

A 230Vac, 50/60 Hertz supply is required.



WARNING

Note. This is the only item on the SDX-15 system which does not include a mains termination cover as it is intended to be installed within the manufacturer's plant. Note the warning label on the outside of the box.

The 2 core inter-panel wiring is connected to signal terminals 1 & 2. The cable screen must be connected to an earth point or to the circuit earth.

Refer to the instruction sheet supplied with the transmitter.

COMPUTER INTERFACES.

Computer Interfaces are available which will give volt-free contact outputs intended for interfacing with other site-based systems. These relays are typically closed when the corresponding condition is at normal. The relays are grouped in blocks of four, giving four conditions per channel. The rating of the relay contacts is 0.5amp, 24V dc resistive.

NOTE. Each SDX-15 central or repeater alarm has an integral common alarm relay fitted as standard. This relay opens when any alarm condition or fault occurs on the panel and is similarly rated.

The services are selected, as in the alarm panel, with a rotary switch. However, the computer interface has only one switch for up to 5 services. This switch is set to the first service required and the other services will follow in sequence. e.g. if the switch on a 5-service interface is set to channel 2 then the services detected will be channels 2, 3, 4, 5 & 6.

The computer interface is a self-contained unit, supplied as a 5-service unit.

A 230Vac, 50/60 Hertz supply is required, which is connected to terminals under the mains terminal cover.

The 2 core inter-panel wiring is connected to signal terminals 1 & 2. The cable screen must be connected to the 'S' terminal

Refer to the instruction sheet supplied with the Interface.

PLANT TO ALARM INTERFACE.

The plant to alarm interface is a low cost means of complying with the C11 & HTM02-01 requirements for indication of alarm status in plant or manifold room. It is mounted in a clear fronted polycarbonate enclosure protected to IP65, making it weatherproof and suitable for use in VIE compound etc. with no further protection.

The SDX Plant To Alarm Interface consists of the following outputs:

1no Power On Block LED (Green)

1no Normal Block LED (Green)

3no Intermediate Alarm Condition Block LEDs (Yellow)

1no Priority Alarm Condition Block LED (Red)

1no System Fault Block LED (Red)

4no Volt-free Relays (closed under normal conditions), for connection to other site systems, BMS systems etc.

The Plant To Alarm interface is a one gas transmitter, connected to the plant & set to the required channel in the same way as a standard transmitter.

Again, A 230Vac, 50/60 Hertz supply is required, which is connected under the mains terminal cover.

The 2 core inter-panel wiring is connected to signal terminals 1 & 2.

Note: The cable screen must be connected to the 'S' terminal.

The service channel is selected with a rotary switch and the connection to the plant (or manifold) is similar to the internal transmitter.

A battery reserve to power the system failure lamp and the transmitter in the event of power failure.

Note. Being a basic indicator, the plant to alarm interface has no audible alarm or test facility.

Refer to the instruction sheet supplied with the plant to alarm interface for further details.

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 CM & C	Audible Output (2-Tone)	Comment
Normal	On	Off	Off	Closed	No	
Mute-Test (With Alarm at Normal)	On	Flashing	Flashing	Closed	Yes	Gas Condition Green Normal's All On
Gas Fault	On	Off	Specific 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	Gas Condition Green Normal's All On
System Fault (Loss Of Line Monitoring)	On	Flashing	Off	Open	Yes	Temporary Mute Only can be used
Gas Fault & System Fault (Loss Of Line Monitoring)	On	Flashing	Specific Condition Flashing	Open	Yes	Temporary Mute Only can be used
Loss Of Mains Battery Jumper On M	Off	Flashing	Off	Open	Yes	Gas Conditions Not Supported/Monitored Temporary Mute Only can be used
Loss Of Mains Battery Jumper On B	Off	Flashing	Supports With Current Status	Open	Yes	Gas Conditions & Normal's Supported. Temporary Mute Only can be used

7. Battery

Select the required mode of battery operation with the Battery Mode Selector. With the red jumper across the centre & bottom pins (marked B) full battery reserve is provided for all Gas Conditions, System Fault and Audible Warning.

With the jumper across the centre & top pins (marked M), HTM02 mode is in operation (only supporting system fault and audible warnings for maximum battery life).

The battery reserve enables the system to remain in operation for up to 8 hours with only the lamps on the panel affected by the power failure out of operation, or for 4 hours if the panel is set for full backup.

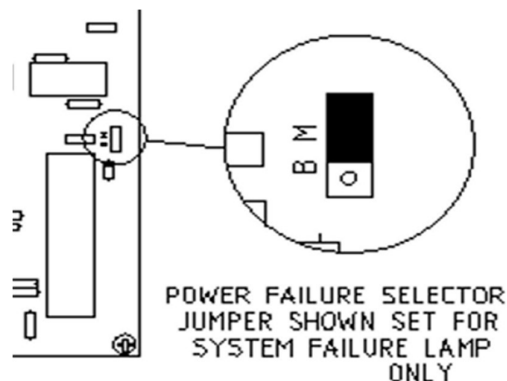


Figure 2: Mode of Operation and Typical Area Alarm Installation.

The Battery is a 12v 2.1ah Lead Acid type and should be mounted on the right-hand side of the Power Supply PCB with terminals at the top and facing left.

Note: This will reduce any risk of damage if the battery is moved while disconnected.

INSTALL & SET-UP THE LED CONTROL BOARD.



WARNING

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

Connect the ribbon cable from the Power Supply to the 26way socket on the back of the Control Board.

Note: It is keyed to prevent incorrect connection.

Locate the hinge ends to the centre right copper P clips (top & bottom) on the rear of the board.

Set the rotary switch behind each Gas Channel window to the corresponding channel that has been used for that gas's transmitter.

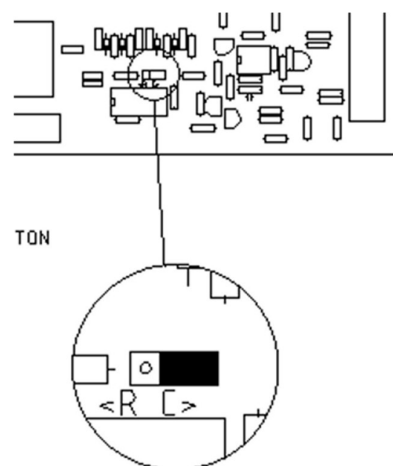
Set the Central-Repeater Jumper

For the designated Central Alarm panel (located in a 24-hour operated area, such as estates office or telephone switch room), set the red jumper across the centre & right pins (marked C).

For all other Alarms, set the red jumper across the centre & left pins (marked R).

Set the volume control to the required level, by holding in the mute button until a permanent audible is heard. Then by rotating a small terminal screwdriver in the component marked VOLUME, on the reverse of the board, until suitable.

Locate the fascia plate over the front of the Control PCB and push through the 5no spacer clips until they click. One in each corner and one in the centre.



CENTRAL/REPEATER SELECTOR JUMPER
SHOWN AS CENTRAL

**Figure 3: Mode of Operation and
Typical Area Alarm Installation**

System Concept

Set the alarm panel at the central location as a central as described above and ensure that all other panels have the jumper to R. Set the power failure mode as required using the jumper adjacent to the ribbon cable connector.

Allocate a channel for each service and enter the name of the service on the log sheet at the back of this manual in the "Gas Service" column. It may be useful to allocate the services in the order in which they appear on the central panel, although this is not necessary.

Go to each transmitter and interface and set the rotary switch for each service to the channel allocated to that service on the log sheet.

Set the rotary switches on all Alarm panels to the corresponding gas channel allocations.

Note: If a column is not required (e.g. if a spare service has been installed for future use), set the rotary switch to F which switches off that column

Set the four audible switches for each service as required (switch number 1 is condition 1, the first lamp below normal. If a switch is on, the audible for that condition will operate, otherwise it will never sound).

Switch on the power to all panels, transmitters etc. and connect the battery described above, observing polarity. The system should now be operational.

**WARNING**

When satisfied that all conditions operate correctly, anti-confusion tests must be carried out by creating alarm conditions on each service in turn and confirming that each panel on which the service is displayed operates correctly.

8. Priority Signals

All normal conditions are represented by Green LEDs (Power On if 230Vac is present & Normal when neither fault on a gas is present).

All intermediate fault warnings are represented by Yellow Flashing LEDs.

- Loss of one means of maintaining gas pressure.
- Loss of all means of maintaining gas pressure.
- Reserve Supply fault.

All fault conditions are represented by flashing Red LEDs.

- A System Fault is displayed if there is a cable fault or mains loss.
- Pressure Fault Gas warnings are displayed if the pressure is out of range.

9. Operation

The system must consist of a single central panel, which should be mounted in an area occupied 24 hours a day. Select the number, location and size (number of services to be displayed) of alarm panel according to the site and system design requirement.

Select the location and size of transmitters.

- Use internal transmitter if an alarm panel is in the same room as the plant, or
- Use remote transmitter if no additional local indication is required.
- Remember that a plant to alarm interface is a cost-effective way to provide a one service repeater with internal transmitter for locations where local indication only is required.
- With more than one service, a repeater with transmitter is more economical.
- The distance between the plant and the transmitter should be kept to a minimum, max. 100 meters.
- See Transmitter section if conditions of a service are to be transmitted from more than one location.
- Transmitters are supplied with termination boards, which must be mounted in or adjacent to the plant.
- Select Computer interfaces as required.

The SDX-15 Medical Gas Alarm system is a multiplexed system using the MEDCON data transmission standard, a pulse width modulated signal, on 2 core inter-panel wiring, capable of displaying up to 15 services, each consisting of up to 4 fault conditions (plus normal). Any service

may be split into four individual displays to be used to bring signals, such as the common alarm output from Area alarms to a central point.

Signals from plant or other monitored equipment are fed into the system via transmitters located adjacent to the equipment. A complete service can be transmitted from one transmitter or, if required, the service can be transmitted from multiple transmitters (i.e. ERM for plant located remotely to the plant). The services are displayed on each panel as required; the service being selected by a rotary switch for each service within the panel.

When all conditions and the power supply are at normal, only the “Power On” and “Normal” lamps energize. If any transmitter signal contact opens, the appropriate “Normal” lamp goes out, the appropriate Gas Fault condition LED will flash, and the audible will sound if selected by a 4-way DIL switch for that service within the panel (these are always set as ON upon dispatch).

Operating the Mute switch on a repeater panel will silence the audible on that panel, whilst on the central panel this will both silence the audible on the central panel and convert the flashing condition LED to steady on all panels (see stabilizing mute). If the condition remains, the audible will re-trigger, on all Alarms requiring re-muting every 15 minutes.

If a condition is to be in an alarm condition for a prolonged period (e.g. for pipeline maintenance) the re-trigger can be prevented by silencing the audible with the Lockout button (see Permanent mute) within the panel (large flat white push-button on the rear of the LED board. The audible will not then sound for that condition of that service until it has returned to normal and then back to alarm condition.

A volume control is fitted within the panel. Typically, the volume is set at half level but can be adjusted by inserting a 3mm terminal screwdriver and rotating.

A loudspeaker is used for the audible rather than a buzzer, to give a mellow 2-tone sound which, whilst drawing attention to the alarm condition, can be tolerated by staff otherwise occupied.

The operation of the test button on the front of the panel will cause the normal lamps to illuminate, the alarm conditions to flash, the system fault lamp to flash and the audible to sound. Any fault condition which is locked out will not flash, showing at a glance if a condition has returned to normal operation. A seven-segment display below the system fault lamp will also illuminate, showing which system fault, if any, is present (Power failure, data transmission failure, flashing circuit failure or contact line fault – see testing).

In the event of power failure, if the battery mode is set to M mode, only the “System Fault” lamp and the audible will operate, otherwise operation in B mode is as follows: When the power fails, the “Power On” lamp will go out, the “System Fault” lamp will flash, and the audible will sound. All other lamps will continue to function normally. The battery reserve enables the system to remain in operation for a minimum of 4 hours.

A fault on the data bus on a unit used as a Repeater (for example, failure of the master or its power supply or damage to the cabling) will cause the “System Fault” lamp to flash, all “High” & “Low” lamps to flash and the audible to sound.

If any gas or system fault is present, the Common Fault Relay output relay will be de-energised, only re-energising when all gases and power are at normal.

All that is required for routine operation is for staff to mute the audible alarm on alarm panels in their areas as required, taking any action required by the nature of the service fault. The audible will resound periodically as long as the service fault remains, requiring re-muting.



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 pressing the Mute button 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) or Lockout

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

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

A system fault cannot be locked out.

c. Mute (Stabilizing) or Central

If an alarm condition is muted from the designated central alarm, pressing the mute button will stop the flashing Yellow & Red gas condition and change it to a permanently lit condition. Also, this action will then stabilize any gas fault conditions on ALL Plant alarms on the system.

Note: Any other gas conditions present at this time, if muted or not, will also be stabilized. The stabilizing mute cannot be cancelled until the gas fault condition(s) are cleared.



WARNING

Where over 5 Gases are displayed at the Central location (i.e. more than one panel is present). Connect the remote 'common', 'mute' & 'test' terminals on power supply, to similar terminals in the adjacent alarm(s). This ensures that the designated central panel is always muted when any of the alarms are muted, thus activating the stabilizing mute operation.

d. Testing

Periodically operate the Test button. Hold in until

- All Red Gas Condition LEDs flash,
- The “System Fault” flashes (opposite timing to the Gas Condition flashing),
- All Green LEDs show continuously,
- The 2-tone audible sounds,
- Gas conditions which are locked out will be steady-On.

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 until.

- The audible sounds,
- The “System Fault” flashes.

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

Notes:

Provided that the battery in the panel under the test is sound and fully charged, no other panel will be affected by this test.

Any remote audible connected to the alarm panel under test will sound.

No panels will operate if the central panel is not functioning. In this case, all repeater panels will show an Incoming Signal (number 1) on the system fault display when the test button is pushed. This will also happen if the inter-panel wiring is reversed at any panel, or the wiring is short circuited. Disconnect each panel in turn until the fault clears. If it does not, check for short circuits.

If a Contact Line fault (number 4) is indicated this indicate that a n Internal Transmitter is fitting inside the SDX Alarm. Check that:

- Resistors are fitted in all unused conditions on the internal transmitter,
- Termination boards are fitted correctly,
- Cabling between termination board and transmitter is not short or open circuit.

If a Power Failure (number 2) is indicated, check:

- 230Vac supply to the panel,
- 250v 250ma Ceramic Fuse on power supply is OK,
- 24v 1.6ma Glass Fuse on power supply is OK.

FAULT FINDING

Professionally installed, the SDX-15 alarm system will give many years of trouble-free service. Experience shows that the majority of problems are due to incorrect connection or poor workmanship during installation. Problems with intermittent faults are usually due to screens not connected to earth, badly made connections or water-filled junction boxes.

Most problems will be identified by the system fault indicator below the system fault lamp, which will illuminate when the test button is pressed. See System Fault below) to decode these numbers.

If no lamps show when the test button is pressed, check that the power supply is present on the panel and that the battery is not discharged. (a discharged battery will take about 72 hours to fully recharge).

Flashing circuit has failed.

Fit a service exchange or replacement SDX-15 control PCB.

Incoming Signal fault.

If this fault is present on all panels on the system, using an analogue voltmeter (10-volt DC range), measure the voltage across terminals 1 & 2 on the central panel. If no voltage is present, disconnect the signal wiring from terminals 1&2 on the central panel and repeat the test. If a voltage of between about 2-8 volts is now present, then a short circuit exists on the signal wiring, or a repeater panel has been wired with the signal wires reversed (check the polarity of the wiring with the meter with the signal wires disconnected from the repeater. Number 1 should be positive).

Reconnect the central panel and disconnect each part of the signal wiring until the fault clears. The last part of the wiring to be disconnected has the fault on it.

If no voltage was present at the central panel after disconnecting the signal wires, first ensure that the panel is set to be central. If it is then fit a service exchange board (Remember. A board can be “borrowed” from another, less critical, location and used to keep the more essential part of a system running).

If the system fault only appears on one section of the system, look for a broken wire or loose terminal between the section with the system fault and the rest of the system.

Contact Line fault.

This indicates that the wiring between the transmitter in the alarm panel showing the system fault, and the termination board is open or short circuit.

A service fault will be shown at the same time. This fault (or faults) indicates which cable has the problem with it. e.g. if a panel is showing a number 4 system fault and say, pressure fault on nitrous oxide, the cable connected to condition 4 on the nitrous oxide service on the transmitter is broken or shorted to common or earth.

Note: Unused inputs to transmitters must be connected to common with a resistor to prevent a system fault (see Transmitter section).

Summary of System Faults (seven segment display)

- 0. No fault
- 1. Incoming signal fault
- 2. Power failure
- 3. Incoming signal and power faults
- 4. Contact line fault
- 5. Contact line and incoming signal faults
- 6. Contact line and power faults
- 7. Contact line, power & incoming signal faults
- 8. Flashing circuit failed
- 9. Flashing circuit & incoming signal faults

e. Clinical Benefits

The Plant 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 Plant Alarm used as instructed aims to indicate normal functioning of gas sources within the Medical Gas Pipeline System by means of visual indicators on the alarm panel
- The Plant 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.

f. Disposal

This product must be disposed of in accordance with national regulations.
The unit does not contain any hazardous substances.

g. Technical distance

- **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 90% RH, non-condensing
- Atmospheric Pressure Range: Tested between 860 mbar and 1010 mbar.

- **Operating Data**

Operating voltage: 230vac

Power Consumption: 18va

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

Fuse: 5x20mm 250ma (Slow Blow) Ceramic

- **Display Unit**

Status display of pressure ratios: None Displayed

Pressure display: Red LED Denote Pressure warning received from a Plant Contacts (By others)

Maximum Pressure: Pressure Levels are set at the pressure switches as part of the system installation.

- **Relay Module**

A Common Fault Relay is incorporated within the Power Supply 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 1-5 Gases (Gas Fault, Gas Emergency, Reserve Fault & Pressure Fault)

Transmitters With or Without Line Monitored Data Inputs

Medical (15 Minute Audible reset) Operation

Indoor use

Continuous (equipment may be left switched on indefinitely)

- **Risk Classification**

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

h. 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

i. Fault Troubleshooting

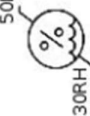
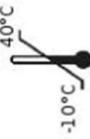
Fault	Cause	Remedy
Alarm does not switch on	No 230vac connected	Check site supply to fused spur adjacent to alarm.
	Check the round 5mm green led in centre of pcb.	If off, 1.6a glass fuse may have failed. Replace fuse.
	Recheck the round 5mm green led in centre of pcb.	If off, 250ma ceramic fuse has blown. If this repeats call Shire Controls for assistance.
Alarm Condition Does not switch On when Gas level is out of Operating Range	Plant Contact incorrect or set incorrectly	Remove wiring to Transmitter Termination PCB check for Visual/Audible indication.
	If after removing wiring to CLH terminals, alarm does not respond.	PCB may have been damaged or noise present on system, Call Shire Controls for assistance.
Alarm Condition Does not switch Off when Gas level is in Normal Operating Range	Plant Contact incorrect or set incorrectly	Check wiring to Transmitter Termination PCB, replace with 56K resists C-x and check for Normal conditions.
	If after replacing wiring with 56K resistors to CLH terminals, 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	Retest for another gas condition to see if the audible is working correctly.
	If 2 nd test produced different outcome, original fault may have been permanently muted from 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 Alarm earth stud.	Call Shire Controls for assistance.
	Battery may have exceeded it life cycle.	Check for date code on heat stamp of top of battery.
	If battery code is OK, is battery still sound	Check DC voltage across terminals (should be 12-12.5v)

Battery Back Up not functioning.	If battery is OK, check jumper link on power supply	Is jumper is fitted between middle-top or middle-bottom pins
	If no jumper is fitted, fit jumper link to middle-right pins and test	If jumper is fitted, pcb may be damaged, call Shire Controls for assistance
Intermittent faults on same conditions	May be due to broken cables between pressure switches & end of line PCB	Check cabling between these points.
	Faulty plant contact.	Check operation of contact switch.
Intermittent faults on different conditions	Are these faults lasting for 3-4 seconds before changing/clearing	Check all data cables are screened & Earthed at Both ends.
	Faults still persist after cabling screened check	PCB or ribbon connectors may be damaged, call Shire Controls for assistance.

j. 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)

k. UDI-DI & UDI-PI Label

 SDX15 Plant Alarm Medical Gas Alarm		Model No. ?????	
			
			
QTY: 999999		Shire Controls Ltd. Studio 3 Channocks Farm, Gilston, Harlow Essex CM20 2RL United Kingdom http://shiremedical.co.uk/	
		2023-12-06	
999999		506108026999999	
999999		2023-12-06	
999999		999999	

I. Alarm Variations

Description	Part Number	Supplier
1 Gas SDX15 Alarms (Flush)	sdx1f	Shire Controls Ltd
2 Gas SDX15 Alarms (Flush)	sdx2f	Shire Controls Ltd
3 Gas SDX15 Alarms (Flush)	sdx3f	Shire Controls Ltd
4 Gas SDX15 Alarms (Flush)	sdx4f	Shire Controls Ltd
5 Gas SDX15 Alarms (Flush)	sdx5f	Shire Controls Ltd
1 Gas SDX15 Alarms (Surface)	sdx1s	Shire Controls Ltd
2 Gas SDX15 Alarms (Surface)	sdx2s	Shire Controls Ltd
3 Gas SDX15 Alarms (Surface)	sdx3s	Shire Controls Ltd
4 Gas SDX15 Alarms (Surface)	sdx4s	Shire Controls Ltd
5 Gas SDX15 Alarms (Surface)	sdx5s	Shire Controls Ltd
Transmitters & Interfaces		
1 Gas Internal Transmitter PCB	itx1	Shire Controls Ltd
2 Gas Internal Transmitter PCB	itx2	Shire Controls Ltd
3 Gas Internal Transmitter PCB	itx3	Shire Controls Ltd
4 Gas Internal Transmitter PCB	itx4	Shire Controls Ltd
1 Gas Remote Transmitter in GW44208	sdxrtx1	Shire Controls Ltd
2 Gas Remote Transmitter in GW44208	sdxrtx2	Shire Controls Ltd
3 Gas Remote Transmitter in GW44208	sdxrtx3	Shire Controls Ltd
4 Gas Remote Transmitter in GW44208	sdxrtx4	Shire Controls Ltd
RTX1 Transmitter In GW44206	rtx1	Shire Controls Ltd
Plant To Alarm Interface	pa	Shire Controls Ltd
5 Gas SDX Computer Interface in GW 44208	sdxc15	Shire Controls Ltd

m. Alarm Spares

Description	Part Number	Supplier
Surface box	sdxbxs	Shire Controls Ltd
Flush Box	sdxbxf	Shire Controls Ltd
Bezel	sdxbez	Shire Controls Ltd
Front Plate+Membrane	sdxpasy	Shire Controls Ltd
Blanking Plate	sh963	Shire Controls Ltd
SDXRTX box	sdxrtxbox	Shire Controls Ltd
SD/SDX Adapter Plate Set	sh825	Shire Controls Ltd
Weather Proof Box	sh700	Shire Controls Ltd
1 Gas SDX15 Control Boards	sdx1control	Shire Controls Ltd
2 Gas SDX15 Control Boards	sdx2control	Shire Controls Ltd
3 Gas SDX15 Control Boards	sdx3control	Shire Controls Ltd
4 Gas SDX15 Control Boards	sdx4control	Shire Controls Ltd
5 Gas SDX15 Control Boards	sdx5control	Shire Controls Ltd
Power Supply	sdxpower	Shire Controls Ltd
1 Gas Termination Boards	TB4	Shire Controls Ltd
1 Gas Remote Transmitter PCB	sdxrtx1control	Shire Controls Ltd
2 Gas Remote Transmitter PCB	sdxrtx2control	Shire Controls Ltd
3 Gas Remote Transmitter PCB	sdxrtx3control	Shire Controls Ltd
4 Gas Remote Transmitter PCB	sdxrtx4control	Shire Controls Ltd
5 Gas SDX15 Computer Interface PCB	sdxcipretest	Shire Controls Ltd
RTX1 Board Only	rtx1pcb	Shire Controls Ltd
RTX1 PCB & Mounting Plate	rtx1 pcb & rtx1 plate	Shire Controls Ltd
Plant To Alarm Interface Control PCB	pacontrolpcb	Shire Controls Ltd
Plant To Alarm Power Board	papowerpcb	Shire Controls Ltd



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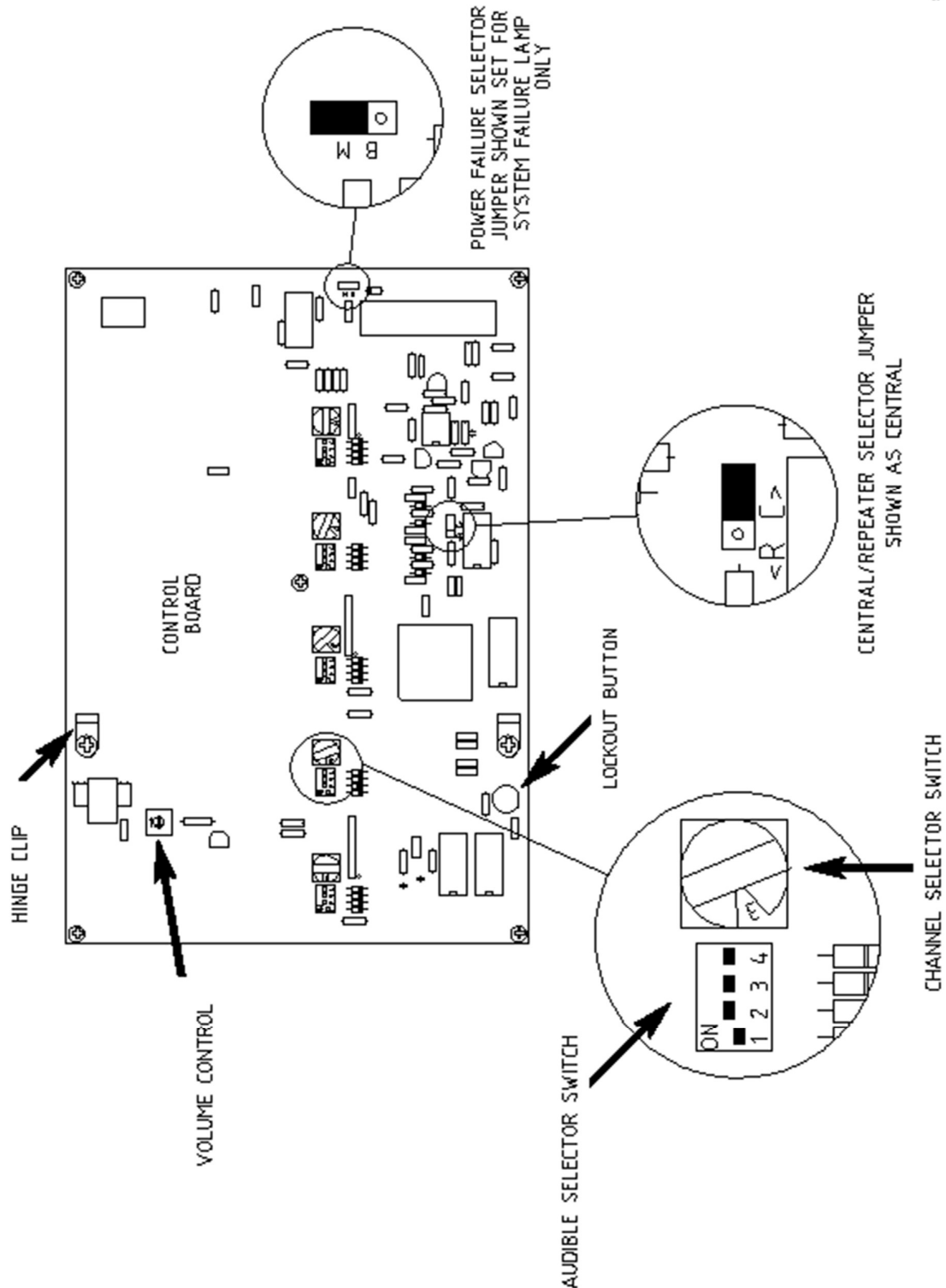
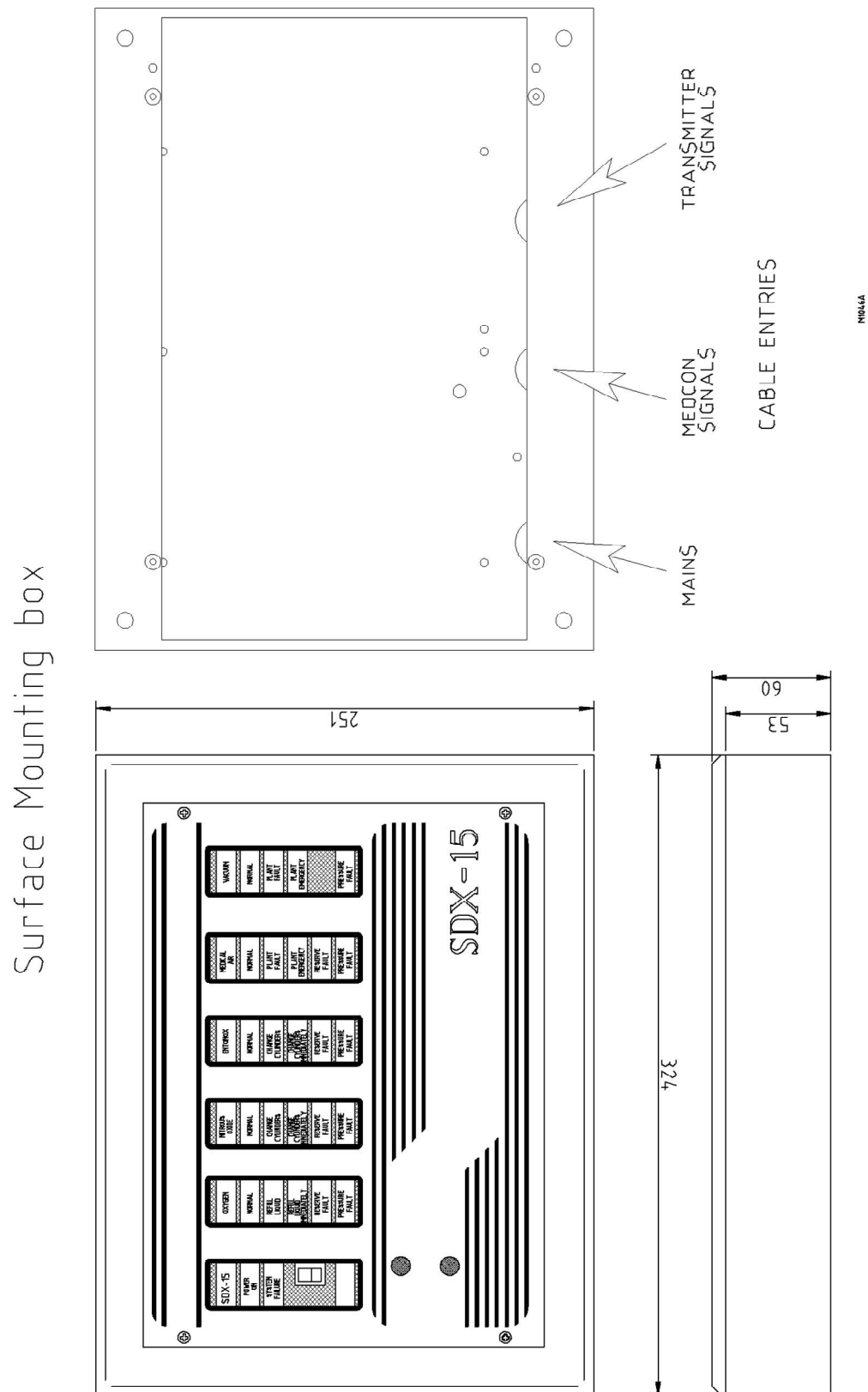


Figure 5: Mode of Operation and Typical Alarm Installation





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n. Regulatory Standards

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

EN60601-1-2 4th Edition 2015

Emissions Standard for Medical Equipment

EN55011, Class A 2016

Emissions Standard for ISM Equipment

EN60601-1-2 4th Edition 2015

Immunity Standard for Medical Equipment

EN61000-4-2 2009 ESD Requirements

EN61000-4-3 2006 + A1 + A2 Radiated Susceptibility

EN61000-4-4 2016 Electrical Fast Transient Burst Requirement

EN61000-4-5 2017 Surges Requirements

EN61000-4-6 2014 Conducted Susceptibility

EN61000-4-8 2012 Magnetic Field Immunity

EN61000-4-11 2017 Voltage Dips and Interruptions

History

- 1 For Production
- 1.1 Updating of Spare Lists & Product Variations, Maintenance, Environment, Symbols, Labelling, & Structural