Huntleigh HEALTHCARE

SERVICE MANUAL

Dopplex®
Fetal Assist

Service Agreements

Periodic inspection and preventative maintenance are essential to ensure continued effective operation. Contact the Company or its approved agents or distributors for further information on service contracts.

DIAGNOSTIC Products Division

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1. General Information

1.1 Introduction

The *Dopplex® Assist* range of modular medical systems is a new generation of medical devices designed to meet the demands of healthcare providers worldwide.

This service manual provides the technical information required for repair and maintenance of the Huntleigh Healthcare Fetal Assist.

Using it's modular approach, the *Dopplex® Fetal Assist* provides the user with a compact, flexible, functional solution. System flexibility allows the user to connect application specific modules to the host.

1.2 System Components

The Dopplex Assist is modular in format, requiring that several components are assembled before a particular procedure can be undertaken.

Host Unit	This is a handheld core system powered from rechargeable batteries, or via a mains adaptor. It includes a graphic display and connectivity and data storage/management.
Application Module	This is a rectangular 'box', (approx. 180* 140* 20mm), which contains all the necessary electronics and software to perform the specified function.
Patient Applied Parts (Transducers)	These items produce the signals that are analysed by the Dopplex Assist system. They plug into the Module via 9 pin connectors.
Battery Pack	The batteries are housed in a unit that fits into the Host. The design of the case is such that the Battery Pack can only be inserted in one way.
Power Adaptor	This unit allows the Host/Module combination to be powered from mains electricity supply. The batteries can also be recharged from the output of this unit, during, or independent of, patient assessments. The output is regulated, and the complete power adaptor meets the safety requirements of EN60601-1. The output of the power adaptor is fitted with a unique connector that is specific for use with the Dopplex Assist system.
Docking Station	This accessory allows the Host/Module combination, (together with the battery pack), to be used as a desktop unit. The unit is held at a convenient angle for viewing the displayed results. The preferred option is for the power adaptor to be connected to the Docking Station. In this configuration, an external printer and audio speakers are available.

Host Unit

Several elements are brought together in this unit. They are described below:

Element	Location	Function
Touch Screen	Front Face	Displays information useful to the clinician such as patient information, results of procedures etc.
Membrane Keypad	Front Face	Can be used to input information in addition to using the Touch Screen.
Headphone and Serial Port Sockets	Right Hand Edge	A headphone socket is provided for the clinician to listen to procedures if required. A mono loudspeaker is also included for audio presentations. A serial input/output port for connection to an external keyboard or mouse is also provided.
PCMCIA Port	Top Edge	This permits connection from an external telephone/LAN network to be made to the Dopplex Assist so that information gathered can be downloaded to a central location. The Fax/modem cards are manufactured to comply with EN60950.
Smart Card Reader	Right Hand Edge	For the indirect entry of patient data.
IrDA Port	Right Hand Edge	Provides wireless printing capability

1.3 Servicing Policy

Due to the nature of static-sensitive surface-mount technology, specialised equipment and training is required when working on the surface mounted components used within this product.

For this reason, circuit diagrams are not included in this manual. Block diagrams and fault finding sections are included to make fault finding to modular or leaded component level possible.

Units within the warranty period must not be dismantled and should be returned to Huntleigh Healthcare, Diagnostic Products Division for repair. Any units returned showing signs of tampering or accidental damage will not be covered under the warranty.

Caution!

To reduce the risk of electric shock, do not remove the cover or back. Refer servicing to qualified service personnel.

Only trained service technicians should perform all unit repairs.

Voltages dangerous to life exist in this unit. Take care when servicing the power supply and display assembly.

1.4 Acoustic Safety

Continuous wave Doppler ultrasound instruments such as the ASSIST have been used extensively for medical diagnosis in the United States for over 25 years. Throughout this period, there have been no reports of adverse effects to patients or instrument operators at the acoustic intensities recommended for diagnostic use. Despite this highly favourable safety experience, available data is not conclusive and the possibility remains that unwanted biological effects might be identified in the future.

Authorities therefore recommend that ultrasound procedures be performed in accordance with the "ALARA" principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable. With the ASSIST RANGE, the transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

1.5 Product Description

The Dopplex Assist range of modular systems is designed to fulfil a multitude of application areas using a single 'host' unit and selecting the relevant module to provide the required functionality.

The host unit comprises

- High resolution ½ VGA colour graphic display complete with touch screen for data entry
- Internal rechargeable battery providing up to 4 hours use
- Internal memory for storage of patient record
- PCMCIA slot for expansion of memory or addition of modem/network card
- Smartcard reader allowing direct patient data entry

Fetal Module

By fitting the fetal module, the Assist becomes a handheld obstetric assessment unit incorporating full fetal monitoring (CTG) capability, utilising a selection of transducers.

The *Fetal Assist* can also be connected to a colour printer to allow high quality printouts of the fetal test.

1.6 Antistatic Handling, Electro Static Discharge (ESD)

The *Fetal Assist* range uses Electrostatic Discharge Sensitive Devices (ESD's) in its manufacture. The damage they suffer when handled incorrectly may be catastrophic. More often and potentially even worse, the damage may be partial or latent, seriously impairing the reliability of the unit.
Due to the nature of the components used within the Assist, special precautions must be taken to avoid damage to the circuitry. Static damage may not be immediately evident but could cause premature failure.
The Assist must only be dismantled and serviced within an ESD protected area (EPA) as defined by CECC00015 (published by CENELEC) to avoid damage to the assemblies.

1.7 Construction

The Host unit comprises five PCB's, the main PCB, docking station connector, Smartcard reader, bulkhead and LCD backlight PCB's.

The fetal module consists of one main PCB.

All electromechanical and through hole components are serviceable using standard tools and soldering techniques, provided that anti-static precautions are always taken.

Recommended servicing is limited to replacement of assemblies detailed in this manual.

2. Quality Reliability and Safety

2.1 General Safety

This equipment has been manufactured using quality components and designed to operate safely and with reliability. Huntleigh Healthcare Limited can accept responsibility only if the following conditions are observed.

The equipment is used in accordance with the instructions for use provided by Huntleigh Healthcare.

The equipment is used in a building whose electrical installations conform to the standards specified by the country in which the building is situated.

If the integrity of the protective earth conductor arrangement is in doubt, the equipment should be operated from its internal electrical power source.

All modifications and repairs to the equipment are carried out by service engineers, agents or hospital technicians authorised by Huntleigh Healthcare Limited.

The Fetal Assist and its transducers are designed to high standards of performance, reliability and safety.

Functional and safety checks should always be made after carrying out any repairs or dismantling the equipment.

It is recommended that regular inspections are to be made to check the integrity of the unit, and to ensure cables are not showing any signs of wear or noise when flexed.

Note	The following are descriptions of general hazards and unsafe practices that could result in death, severe injury or product damage. Specific warnings and cautions not appearing in this section are found throughout the manual.
Possible Fire or Explosion	A possible explosion hazard exists if used in the presence of flammable anaesthetics. Explosion or fire can result.
Possible Electrical Hazard	**Do not** operate the equipment using damaged cables and wires, or loose snap fittings, which may cause interference or loss of signal. **Do** perform frequent electrical and visual inspections on cables and wires.
Possible Equipment Damage	**Do not** immerse any portion of the instrument in water. Fluid spills may damage the instrument's electrical components. **Do not** sterilise this product. Sterilisation environments can cause severe damage. **Do not** autoclave or gas sterilise accessories unless manufacturer instructions clearly approve it.
Possible Safety Risk	**Do not** substitute accessories. Use only recommended accessories listed in this manual. Substitution may cause the instrument to work improperly. The correct accessories are shielded to prevent conductive parts of the electrodes contacting other conductive parts or earth.

Do not use this equipment in the presence of flammable gases.

Do not immerse any part of the equipment in any liquids.

Do not use solvent cleaner on any part of the system.

Do not use high temperature sterilising or E-beam / gamma sterilisation processes.

This product contains sensitive electronics; strong radio frequency fields could interfere with the operation of the system. In the event where this occurs, we suggest that the source of interference is identified and the equipment is used 'out of range'.

If any doubt exists concerning the use of this equipment, an alternative method should be used.

2.2 Safety Testing

Using suitable safety test equipment, refer to the following guidelines;

2.3 Power Adaptor

Earth Leakage Test

Maximum allowable leakage current :	100 μA Limit
Enclosure Leakage Current :	100 μA Limit

Fetal Assist Unit

Patient Leakage :	<10 μA DC
	<100 μA AC
Protection :	Class 1
Safety Standard :	EN60601-1, UL2601-1

Insulation Test

Mains to Case :	> 200 M

Breakdown Test

Apply 1500Vac to the mains connector, connecting the low voltage probe to the "EARTH" terminal. Firstly test the "LIVE" terminal and then the "NEUTRAL" for 60 seconds each. No breakdowns should occur.

The output from the power adaptor is double insulated from its supply. The third pin from the adaptor is earthed but this is a functional earth and not a safety earth.

2.4 Assist Host and Docking Station

Due to the fact that these are powered from an isolated supply, testing of these units is not necessary.
If you require any assistance with safety testing your Huntleigh Diagnostics equipment, contact Huntleigh Diagnostics. For the UK refer to the Health Equipment Information Document No 95 - Code Of Practice or IEC 601 Standards For Acceptance Testing Of Medical Equipment.
The following safety summary should be read before operating or carrying out any of the procedures described in this manual:

2.5 Cleaning

Ensure the system is switched off and disconnected from the mains supply.

Main Unit / Screen	If required, this can be wiped with a soft cloth dampened with a mild detergent, avoiding the connectors. Do not allow any fluid to seep into the connectors. Do not allow any fluid to seep into the unit. Ensure the unit is completely dry before reconnecting to the mains.
 *Do NOT immerse connectors*	

Disinfection	Transducers Only. To assist with disinfection, wipe the transducers with a soft cloth dampened with sodium hypochlorite 1000ppm, and wipe dry. Please be sure to check your local infection control policies or equipment cleaning procedures.
Check your local infection control policies or equipment cleaning procedures.	

Caution

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system as permanent damage will result.

2.6 Preventative Maintenance

The Huntleigh Diagnostics *Fetal Assist* is designed for a minimum amount of maintenance. To support the high standard of performance and safety, the safety and functional checks should be carried out as part of a regular maintenance routine.

Periodic inspection and preventative maintenance are essential to ensure continued effective operation. Contact the Company or its approved agents or distributors for further information on service contracts.

Refer to the user manual for details of connection of cables and accessories, and also for the correct setting of controls which may have been altered during maintenance.

No attempt should be made to service the unit unless adequate workshop facilities and suitable staff are available.

2.7 CE marking

This equipment carries a CE mark but this is only fully valid if it is used in conjunction with cables and other accessories approved by Huntleigh Healthcare Limited.

All rework procedures detailed in this service manual must be strictly adhered to, to ensure continuing compliance with EC Directive 93/42/EEC.

Any rework routine carried out outside the scope of this manual may result in the equipment no longer meeting this specification and the rework organisation will be responsible for this non-conformance.

3. Specifications

3.1 EN60601-1 classification

Type of protection against electric shock.	Class 1 (when operated via the supplied PSU) / internally powered.
Degree of protection against electric shock	Type B applied part 
Mode of operation.	Continuous
Degree of protection against water ingress	IPX0
Degree of Safety in Presence of Flammable Gases:	Not suitable for use in the presence of flammable gases.

3.2 General

Regulatory Compliance	Complies with:	EN60601-1: 1990; EN60601-1-2 : 1993 UL2601-1

3.3 Environmental

Operating Temperature	+10°C to +30°C
Storage Temperature	-10°C to +40°C
Relative Humidity	90% (non condensing)
Atmospheric Pressure	700mb - 1060mb

3.4 Physical

System		*Module*
2" (50mm) x 10" (250mm) x 6" (150mm)	*Size* (HxWxD)	¾" (18mm) x 7" (175mm) x 5.4" (135mm)
3.5 lb (1.6Kg) (including battery)	*Weight*	2 ½ oz. (325g)

Docking Station	
Size (HxWxD)	5" (127mm) x 11" (279mm) x 10.2" (258mm)

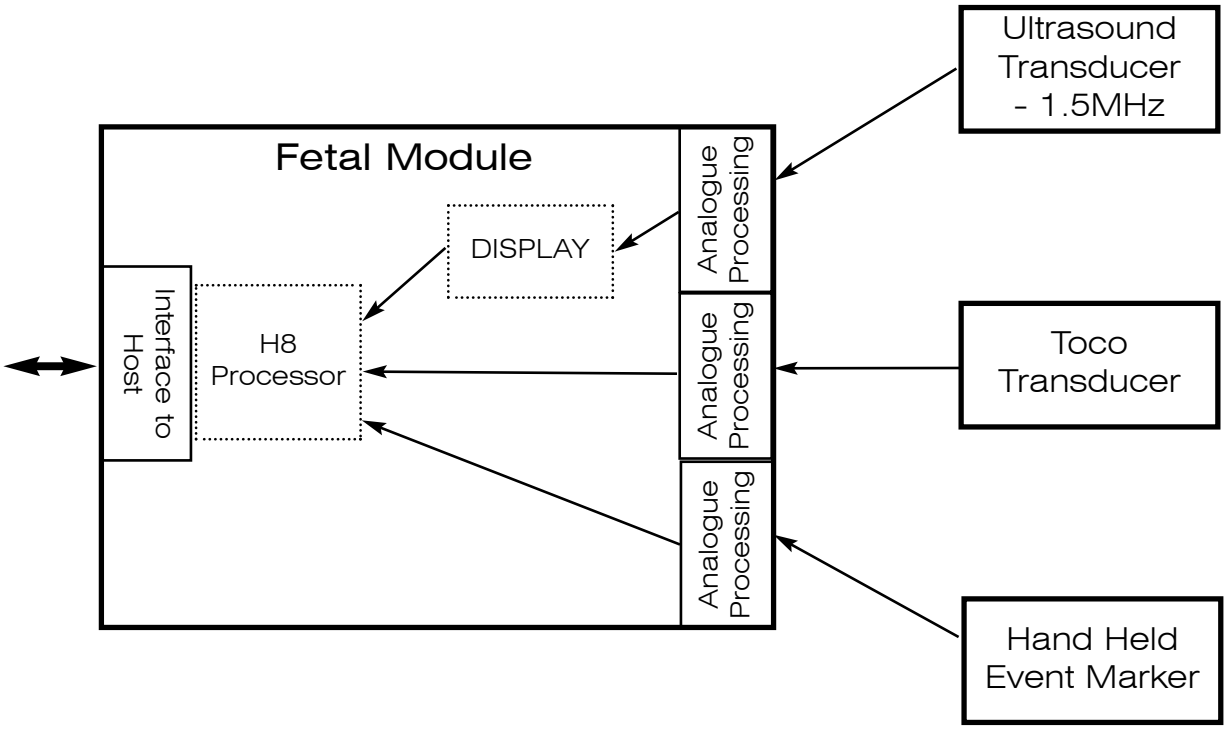
4. Technical Description

4.1 The Doppler Principle

The *Fetal Assist* uses the Doppler principle for non-invasive monitoring of Fetal Heart Rate and Fetal movement.

The Doppler principle states that if a signal is transmitted at a fixed frequency and is reflected by a moving body, the frequency of the received signal will be shifted. An increase in frequency results if the reflector is moving towards the transmitter/receiver, and a decrease results if moving away from the transmitter/receiver. The amount of frequency shift is proportional to the velocity of the reflector relative to the transmitter/receiver.

In the Dopplex range, a fixed frequency ultrasonic signal is transmitted from the transducer into the body. This is reflected from, for example, movement of the fetal heart. The signal is reflected from this and is received by the transducer. Due to this movement, a frequency shift results, which is proportional to the velocity of movement.



4.2 Doppler Audio Processing

The Dopplex Assist ultrasound transducer contains a transmitter and receiver. In use, the transducer sends out a pulsed ultrasonic signal, generated by the piezo-ceramic transmitter crystals.

This signal is scattered by blood cells or any other "interface" such as skin, muscle layers, organs, walls of vessels etc. A small proportion of the scattered signal will be reflected back and detected by the receiver.

By demodulating the received signal (removing the high frequency carrier) the Doppler shifted component (i.e. the difference between the transmitted and received signals) can be produced. With typical target velocities found in the human body, this Doppler shift signal falls within the audio frequency range. It can therefore simply be amplified and heard through a loudspeaker. It is important to remember that the sound you hear is an artificial sound, the frequency (pitch) of which is proportional to the velocity of the moving target.

Please Note: This is not the actual sound of the Fetal Heart.

5. Main PCB Circuit Description

5.1 Introduction

The PMA Host's main PCB is a PC-based single board computer that uses the AMD ELAN SC400 as its main processor. It is used as part of hand held multi-purpose medical devices. The board is to be used to record, display and communicate medical data that has been pre-processed by a connected module. The connected module will determine the nature and functionality of the complete device.

5.2 Overview of Circuit Functionality

The overall circuit is controlled by the ELAN SC400; a single chip embedded 486-based micro-controller. Additional functionality has been added externally to this chip in the form of Ultra I/O, Display controller, touch screen controller, Power supplies, DRAM, Flash memory, EPROM, Dual port ram, external micro-controller, reset circuitry, Audio amplifier and various support circuitry. The circuit supports various operating systems including, QNX, Windows95, MSDOS etc.

5.3 The AMD SC400 Micro Controller

The Elan SC400 is a 32 bit low voltage (2.7V -3.3V) AM486 CPU with a complete set of PC/AT compatible peripherals, and in addition, power management features for increased battery life. The Elan SC400 uses the industry standard 486 instruction set; therefore software written for x86 architecture is compatible with the ELAN SC400 micro-controller.

The AM486 CPU core, which is of a fully static design that, can be operated at frequencies up to 100MHz. It also contains an 8Kbyte write-back cache for enhanced performance by reducing bus traffic.

The ELAN SC400 has internal configuration registers that are used to configure the micro-controllers internal features. These registers use a pointer index scheme and most can be accessed writing the register index to I/O port 22h and then reading or writing data to I/O port 23h.

5.4 CPU Clocks

The Elan SC400 uses an on chip crystal oscillator circuit that requires only one external 32KHz crystal connected to X32IN and X32OUT pins. This is used to generate all other clock frequencies, needed by the micro-controller. This is done by the use of four Phase-locked loop circuits with dedicated external loop filters, consisting of two capacitors and a resistor.

5.5 ROM/FLASH Interface

The micro-controller has three glue-less burst-mode ROM/FLASH active low chip selects, that allows a mixture of ROM and FLASH memory to be added with no external control logic. Each chip select area can be individually configured to use 8/16/32bit ROM/FLASH devices up to 64Mbytes. These areas may be individually write-protected to protect code in flash devices.

ROMCS0# and ROMCS1# have direct mapping to external pins, unlike ROMCS2# which has to be redirected to any of the GPIO_CS 0-14 pins.

The PMA uses ROMCS0# as the EPROM area and ROMCS1# and ROMCS2# as FLASH memory banks.

5.6 DRAM Controller

The SC400 has an integrated DRAM controller that provides all the signals necessary to support DRAM's gluelessly. Internal registers are provided to select the type, operating mode and refresh rate. It supports the following features: -

- 3.3V Fast page mode or EDO 70ns DRAM's
- Extended and self refresh modes
- Page mode reads and writes
- Symmetrical and asymmetrical DRAM support

5.7 SC400 Functions Used by the PMA Main PCB

The PMA circuit uses the following functions in its design: -

- Internal DMA control is available only.
- Uses 7 of the eight external interrupts (PIRQ1-7)
- Internal programmable interval timers are all available.
- The internal Real Time Clock is used.
- The PC/AT support features including speaker output.
- The serial port and IrDA port are both available for use but only one can be used at any one time. (The SC400 serial port is the systems COM1 at address 3F8h. It is used as the docking station/module programming serial port and is 5V TTL level only)
- PCCARD socket one is used only.
- GPIO's are used where available.
- The boundary scan interface is available to use for test purposes only.
- VESA-Local bus is being used
- ISA bus is being used
- DRAM interface is being used.
- Graphics interface
- Parallel port.
- Keypad matrix support
- External DMA
- External interrupt PIRQ0
- PC Card-socket 2.

5.7.1 PC-Card Socket 1 (PCMCIA port)

The SC400's integrated PC-Card controller is PCMCIA2.1 compliant. Although capable of supporting two card sockets, this circuit only utilises one socket and uses the extra pins as GPIO ports. The socket is capable of DMA transfer from PC-Card to system DRAM.

The PCMCIA card socket is to be used for the addition of extra memory with the use of SRAM or FLASH memory cards; it is also to support "Card" modems in order to transmit data over a telephone line.

In addition to this the socket card be used to boot the system when used in conjunction with the configuration pins described above. This will allow the programming of the on board flash array from the PC-Card socket.

5.8 FLASH Memory

The PCB contains a flash memory array that consists of 4 x 2Mbyte or 4 x 4Mbyte AMD flash memory. This gives a total of 8/16Mbytes of flash that is used as a solid state disk. It is to be used as a storage medium for the QNX image, temporary storage of the application software and user files etc.

The FLASH memory is a form of EEPROM that contains embedded algorithms to erase and program the internal memory. As well as being able to read internal status registers, for the current status of the flash memory, there is an external RDY/BSY# line. This gives a hardware indication of whether the flash memory is busy erasing/programming the flash array, or ready for the next command. There is also an external reset pin that puts the flash memory into read access mode.

The flash memory is arranged in either 32x or 64x, 64K sectors, depending on which device is fitted. These sectors can be individually or group erased, or the whole chip can be erase at once. (Individual address can not be erased).

5.9 Battery Level Comparator

The MAX924 (U36) is a quad comparator circuit for monitoring the battery voltage level so the SC400 can implement hardware power management features. It is powered from the 3.3V power supply rail in order not to overpower the battery level inputs of the SC400. The device outputs a 1.182V reference, which is produced by an internal band-gap reference diode. This is then potentially divided to produce the four reference levels for the four comparators. These reference levels for the negative inputs of the four comparators are A = 1.047V, B = 997mV, C = 818mV and D = 798mV. A proportion (0.116 * battery voltage) of the battery level is then feed to the positive inputs of these comparators. When the positive input falls below a comparators negative input reference the output of that comparator goes logic low (0V). As a comparators positive input increases above the negative input reference the output of that particular comparator goes high (3.3V). These comparators produce logic low output levels for the following battery voltage levels. A = 9.05V, B = 8.62V, C = 7.07V and D = 6.9V.

5.10 On/Off Detect Circuit

When the on/off button is pressed on the front panel the raw battery voltage is fed to the base of Q5 via the diode D24 and the R96, R93 potential divider this turns the transistor on and pulls the gates of a dual FET (U42) to ground. This switches the FET (U42) on switching the battery voltage through to the power supplies. Once out of reset the sc400 micro-controller holds the CPU_ON_HOLD signal high, this in turn holds the transistor Q5 on via the second diode in D24. When the on/off button is pressed the Transistor Q6 is switched on sending a low-level pulse to the micro-controllers CPU_ON_OFF_DETECT input. When the button is not being pressed the transistor Q6 is off holding the CPU_ON_OFF_DETECT high (3.3V). (Note the transistor is not activated when the CPU_ON_HOLD signal is active because of the reversed biased diode.) When the SC400 micro-controller receives the CPU_ON_OFF_DETECT low signal it should proceed to power down and release the CPU_ON_HOLD signal. This in turn will switch off transistor Q5 and the Gates of U42 are pulled high via R117 to switch of the FET (U42), thus removing the power from the power supplies.

5.11 Clock Ladder

A 7.3728MHz crystal (XM2 or X3 which ever is fitted) is used to produce 3 of the PCB's clock frequencies. They are divided down using to d-type flip-flops to produce 3.6864MHz for the AVR micro-controller and CODEC circuit, and 1.8432MHz for the touch screen controller. The master 7.3728Mhz clock signal is for the A/D converter of the CODEC circuit.

This clock ladder can be switched on/off via the 1.8MHz_OFF# signal. The resistor R100 and capacitor C136 filter the clock signal to reduce EMC emissions from this source.

5.12 Docking Power and Detect Circuit

The power from the docking station comes in on the contacts JP14, JP15 this is then fed to the battery via the diode (D35). D35 also prevents false triggering of the docking detect signal when the power supply is plugged in to the battery.

When power is present between the contacts JP14, JP15 this turns on the transistor Q10, which in turn pulls the DOCKED# signal low, signalling to the rest of the circuit the docking station is present. When no power is connected to JP14, JP15 the transistor is off and the signal can be pulled high signalling the docking station is not present.

5.13 VR Micro-controller

The AVR is an 8bit micro-controller its main job is to release the SC400 from slow, time intensive, single line communication protocols. It communicates with the battery gas gauge IC (in the battery pack) via a single line protocol at a maximum bit rate of 333bit/s. The AVR also communicates with a temperature sensor via a one-wire protocol. The data from these two sources is then transmitted via UART at a 9600baud rate, to the SC400 on COM3 (this is UART 2 on the Ultra I/O.)

The AVR also monitors the battery voltage level via an internal comparator circuit. The reference for this comparator is set at 2.2V via the potential divider across the 3.3V supply. The battery voltage level is then potentially divided to give battery voltage * 0.166. If the battery voltage is more than 13.2V it triggers the internal comparator. This comparator output used in conjunction with the charge status bit of the gas gauge can then be used to detect whether a power supply is present. The result of this monitoring means that the ACPWR pin can be used to indicate there is a power supply plug in to the SC400 power management inputs.

A temperature sensor is used to measure the temperature of the unit in order to compensate for contrast and brightness drift due to temperature. This device can be programmed to convert the temperature in a 9-12bit resolution over the range -55ºC to 125ºC. The temperature sensor has a 64 bit unique serial number that can also be used to identify the PCB. The communication with this device is through a 1-wire serial interface.

Provision has been provided that the AVR software can be updated via the SC400 application software. This is done via the integral SPI interface and holding the AVR in reset. The AVR is clocked from the 3.6864MHz clock this is a baud rate frequency clock that produces 0% error in UART baud rate. The inverters U40C-F are used to convert the 3.3V signals to 5V signals for the ULTRA I/O chip.

The AVR also illuminates the power on LED on the front panel this is so the LED can be 'immediately' turned on as power is applied it also allows for future LED flashing to indicate suspend mode.

5.14 Dual Port RAM Interface

The dual port RAM is the main communication interface between the host unit and the module. It consists of an 8K x 8 static RAM and two-access ports to permit independent high speed, read and writes to the RAM. The dual port RAM provides 8 additional addresses for semaphores; to allow either processor to claim privilege over the other processor for functions defined by the software designer.

Each side has an interrupt output that can be used to indicate that and data is available this is done by one port writing to address 1FFEh this sets the interrupt output on the other port. The interrupt output is then released when the receiving port reads address 1FFEh.

The two bus switches are used to protect the dual port ram so the module may be hot swap safely. Until the module has been fully powered up the MODULE_READY# signal hold the bus switch off. This prevents any signals being shorted to ground while the module is switched off. When the MODULE_READY# signal goes low the all the switches turn on and the signals can pass as normal.

5.15 Ultra I/O

An Ultra I/O chip is used to expand the SC400 features by adding two UARTS, a hard-disk controller, additional I/O ports, mouse and keyboard interfaces. It also contains a floppy disk drive controller, a Real Time clock, a parallel port, and an intelligent automatic power management controller and is also ISA plug and play standard (V1.0a) compatible register set.

The Ultra I/O chip is connected to the 5V supply rail and is therefore connected to the 5V-system bus. All I/O addresses are qualified with AEN, as there is no other address on this bus that should conflict with this device so this has been pulled low permanently.

The SC400 communicates with the Ultra I/O chip through a series of read write registers. These registers are accessed through programmed I/O. (DMA transfers with this device are not possible with the current circuit arrangement.) The registers are all 8bit, with exception of the IDE data register at port 1F0h, which is 16bit. The port addresses of these registers are shown in the table below.

The Ultra I/O chip is clocked at 14.31818MHz by a crystal (XM1 or XM3) which is controlled from the SC400 via the 14MHz_OFF# signal. It outputs this clock signal via its CLKO1-14 pin and is then potentially divided to give a 3.3V clock source for the Graphics Controller.

5.16 Parallel Port

The Ultra I/O has a parallel printer port this has been used by the PMA for additional I/O lines. These functions are listed in the table 8 along with their alternative functions.

Ultra I/O Parallel port usage

Pin No.	Signal Name	Description	Alternative Function
138	AUDIO_MODE	Audio Amp Control line	Parallel Port Data-bit 0
137	AUDIO_MUTE	Audio Amp Control line	Parallel Port Data-bit 1
136	AUDIO_SHUTDOWN	Audio Amp Control line	Parallel Port Data-bit 2
135	VPP_ENABLE PCMCIA	Vpp-enable	Parallel Port Data-bit 3
134	SMRESET	Smart card reset	Parallel Port Data-bit 4
133	SMCS1	Smart-Card Chip Select	Parallel Port Data-bit 5
132	SMCS2	Smart-card Chip Select	Parallel Port Data-bit 6

Pin No.	Signal Name	Description	Alternative Function
131	SMCS3	Smart-card Chip Select	Parallel Port Data-bit 7
129	SMWP	Smart card write protect	Printer Acknowledge
128	SMDETECT	Smart card detect	Printer Busy
127	UNUSED	N/A	Printer Paper End
126	UNUSED	N/A	Printer Select
144	UNUSED	N/A	Printer Strobe
143	SRESET#	AVR Programming	Printer Auto Line Feed
142	MISO	AVR Programming	Printer Error
141	MOSI	AVR Programming	Printer initialise
140	SCK	AVR Programming	Printer Selected

5.17 Serial Ports

The Ultra I/O chip has two 16550A compatible UART's. The base address of which can be set during configuration mode. The PMA sets these addresses to 2F8h and 3E8h for the PCB's COM2 and COM3 respectively, in software

5.18 32KHz Oscillator

The 32Khz oscillator is used for triggering the watchdog circuit. During the initial boot up the IPL/BIOS does not trigger the watchdog. With the additional circuitry described below, this clock triggers the watchdog. A link (LK10) is used to select between constant triggering of the watchdog (Pads 2 and 3 soldered together for development purposes) or switched out after 30secs (pads 1 and 2 soldered together normal position).

There is also a link (LK11) present to allow this clock to be connected to the display controller. This enable self refresh of the display DRAM during standby mode of the display controller. With out this the display controller cannot refresh DRAMS during standby mode.

5.19 RESET and Watch Dog Circuit

The Reset circuit is controlled by a MAX706. This monitors the 3.3V supply rail and keeps reset asserted when it falls below 3.08V. It releases the reset after 200ms after the supply rises above this threshold. The IC also has a built in watchdog that needs to be toggled before an internal timer reaches 1.6secs. The watchdog output is pulled low when this timeout period is reached but it does not cause a reset, therefore the watchdog output is shorted to the manual reset input (MR).

The 555 timer is used in mono-stable mode in order to inhibit the watchdog for 30secs during boot up. This is to allow time for QNX to run the application, which will then trigger the watchdog accordingly. A NAND logic is used to divert either the 32Khz clock or the SC400 watchdog trigger output to the Watchdog input on the MAX706 according to the state of the 555 Timer output.

5.20 Graphics Controller

The 65550 is a 64-bit high performance multi-media flat panel / CRT GUI accelerator controller. The 64-bit graphics accelerator engine has functions for Bit Block Transfer (BitBLT), hardware cursor, and other functions intensively used in Graphical User Interfaces (GUIs). The 65550 controller is fully compatible with VGA at the register level.

The 65550 implements independent multimedia-capture and display systems on-chip, although this is not utilised on the PMA

The 65550 supports a wide variety of monochrome and colour LCD panels. For monochrome panels, up to 64 gray scales are supported. Up to 4096 different colours can be displayed on passive STN LCD's and up to 16M colours on 24-bit active matrix (e.g. TFT) LCD's.

Along with the LCD panel support the 65550 can drive an RGB monitor simultaneously. RGB outputs are available pin 57, 58, and 60 along with the necessary VSYNC and HSYNC on pins 64, and 65. The RGB outputs need to be pulled down with 75R resistor in order to produce the required impedance of the line of 37.5R (this is because the resistor is in parallel with the monitors 75R)

Due to the need for simultaneous display at ½ VGA on LCD and full VGA on monitor the connection for the LCD output pins are P0-4 and P8-11 and the LCD display driver set up for Dual scan 16bit mode. This has the effect of showing only the top half of the full VGA screen on the LCD while masking the rest (because the low half data never gets to the LCD). The other flat panel signals are: -

- SHFCLK - shift clock used to clock one byte of data to the display
- LP - line pulse to indicate end of data line
- FLM - FRAME LATCH PULSE to indicate end of one screen display
- M - Modulation signal to modulate dc signal to prevent premature aging of the liquid crystal from dc voltages. (can cause shadowing if set incorrectly)

5.21 Memory Addressing

An extensive set of registers control the graphics system. These registers are a combination of registers defined by the Video Graphics Array (VGA) standard, and others that support graphics modes that have colour depths, resolutions, and hardware acceleration features that go well beyond the original VGA standard. Some of the registers are directly accessible at various I/O addresses. They may be read-only or write-only, and some must be read from and written to at different I/O addresses. Most of the other registers are accessed through a sub-addressing arrangement. The index of the desired register is written to an index register, and then the desired register may be read from or written to through a data port. Almost all of these sub-addressed registers are both readable and write-able. Still other registers are directly accessible at various memory addresses, and here too, almost all of these registers are both readable and write-able.

Part of the VGA standard requires the VGA graphics system to take the place of either the IBM Monochrome Display and Printer Adaptor (either MDPA or MDA) or the IBM Colour Graphics Adaptor (CGA). The MDA has registers at I/O addresses 3B4-3B5 and 3BA, and a character buffer (not a frame buffer -- the MDA is a text-only device) within the memory address range of B0000-B7FFF.

5.22 Contrast and Brightness Control

The contrast and brightness of the touch screen are adjusted by two digital potentiometers. The digital pots are configured to use up and down inputs by connecting them to a tri-stated port during power up. This is to allow full control by software over the position of the wiper. By incrementing or decrementing the wiper 64 times, puts the wiper either at the top or bottom of the range accordingly. This places it in a known position where it can keep track of any adjustments, so as to indicate the setting on screen.

The power supply sequencing of the LCD display and backlight can be fully controlled by the 65550 timing registers. The backlight has an additional on off control signal generated by the SC400 as a power saving feature.

5.23 Touch Screen Controller

The touch screen control is used to calculate the position of a 'pen' or finger on the resistive touch screen and to send this information to the SC400 via serial or parallel format. In order to read the XY co-ordinates of the current position, it first applies a current drive to the x plane resistive film and read the voltage present on the Y-plane film. It reads this voltage with internal 10 bit A-to-D's, to get the X co-ordinate. It will then calculate the Y co-ordinate in a similar manner by applying current drive to the Y-plane and reading the voltage on the x plane. The touch screen controller can sample the position 200 times a second with a 1.8432MHz clock attached.

The chip detects if the 'pen' is in contact with the touch screen and flagged on the PEN_OFF pin (0V pen is touching screen, 5V is not touching the screen). When new data is available for reading from the parallel output buffers, the NEW_DATA pin is pulled low. Any new data that is available is sent via the serial port immediately.
The parallel interface uses three control lines to fetch the data, COEN which is the chip enable line X_SELECT which is used to address X or Y data and BHE to address the upper or lower byte of the 10bit data. When X_SELECT is 0 the Y-data is accessed, when X_SELECT is 1 the X-data is accessed. The 10bit data is formatted for data transfer with the BHE signal.

5.24 Key Pad Interface

The keypad interface is 4 by 4 matrix of rows and columns, allowing up to 16 keys to be matrixed. They are read and written to by the Ultra I/O GPIO pins 15-24. The 4 columns are strobed low individually and read back on the rows, the key pressed can be calculated by knowing which column was strobed and which row had been pulled low by that column.

5.25 Touch Screen Controller

Module left and right audio signals are pre-filtered via an IC prior to a Power Amplifier. The bandwidth is 72Hz to 19.5KHz and has a unity gain over this range. The Capacitors C165 and C163 add high pass filter stage with internal 20kW resistors with a roll off at 80Hz.
The mono beep in from the SC400 is added to each of these channels prior to the internal volume control stage.

A DC signal level, on the DCVOL input adjusts the internal volume control. This is externally produced by the digital potentiometer, controlled by the SC400. The digital pot is set up in the same manner as described for the backlight and contrast above, and is controlled by the SC400 GPIO.

Control of the Line/HP and speaker outputs is achieved by the state of the shutdown, mode, mute and HP-sense inputs of the LM4834

Additional external circuitry was added to muted the line outs to the base station when the headphones are plugged in without affecting the headphone volume. Stripping the AC component off the headphone signal, and comparing the DC level to a known DC reference of 2.5V does this. The comparator gets the 2.5V reference from the resistor divider R104 + R89. With the headphones removed the sockets internal switch pulls the positive input of the comparator to ground, this causes the output of the comparator to remain low and thus allowing the MAX324, an analogue switch, to remain in its normally closed position. When the headphones are plugged in the AC signal is removed by the C30, R85 low-pass filter with a roll-off of 1Hz. This causes the output of the comparator to go high, opening the analogue switch and therefore muting the Lineout signals.

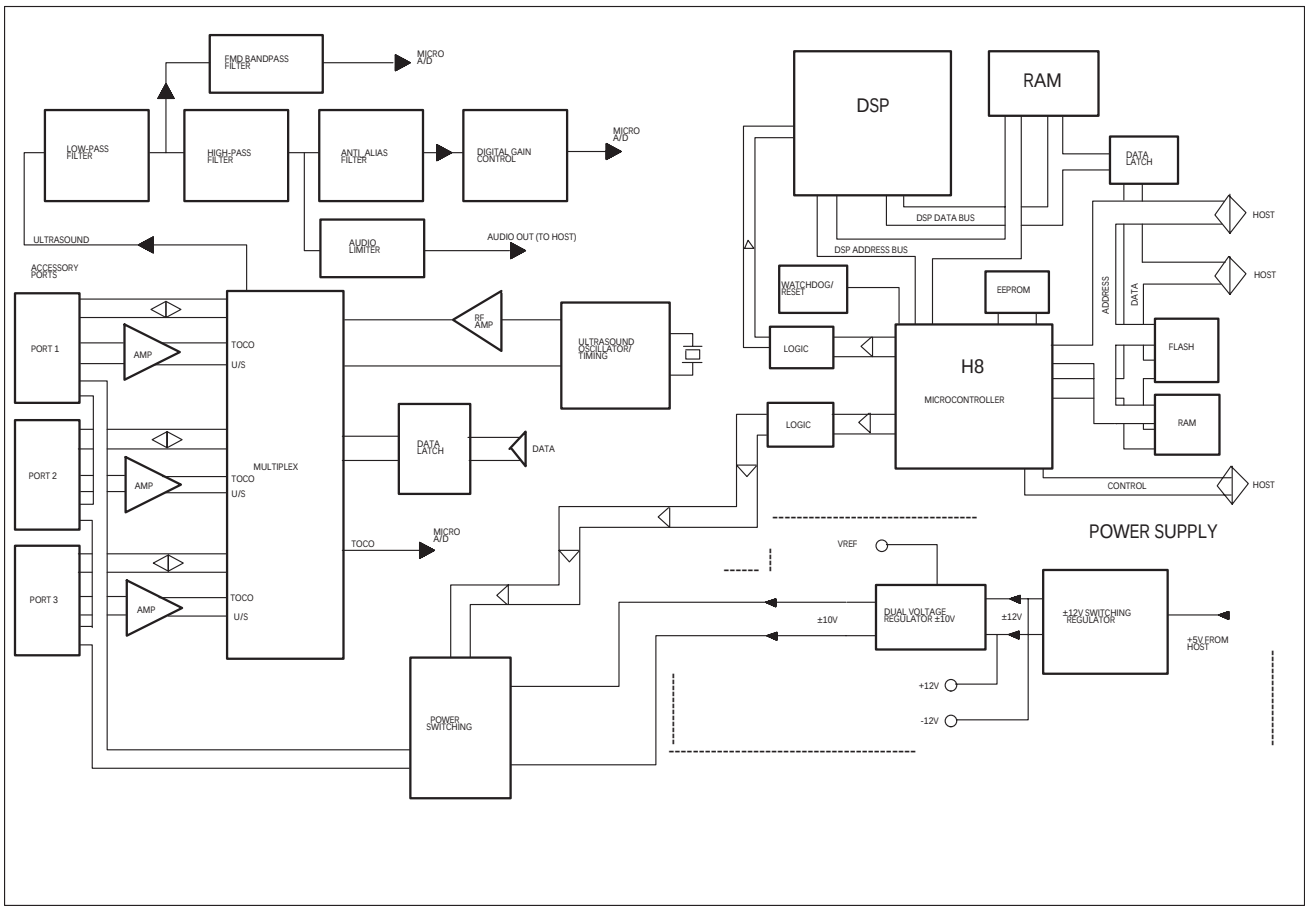
The logic contained in U15 is used to mute the internal speaker of the PMA unit when either the headphones or base station is attached.

6. Fetal Assist overview

The circuit design has been implemented in the form of a hybrid of conventional analogue circuits, a DSP, and a microcontroller system. The microcontroller establishes a digital communications link with the Host unit, controls switching of the various analogue circuit blocks, controls the operation of the DSP IC, and fulfils a number of other functions.

The Fetal Assist has been split up into several sections as shown below for clarity.

Obstetric Module Block Diagram



6.1 Microcontroller section

6.1.1 3048 microcontroller

The obstetric module co-processor is a Hitachi 3048H device with 128K internal Flash memory. It communicates with the host embedded 486 processor via a bespoke 44 way inter-connection scheme which maps an 8K dual port RAM on the host into the address space of the H8 co-processor.

The H8 works in tandem with an Analog Devices Digital Signal processor, ADSP2105.

Intrinsic functions of the H8/3048F

The device runs at 9.8304MHz in mode 6 from an external crystal (X1) to give a linear addressing range of 16Mbytes with external data and address bus. The data bus in all address ranges in fixed at 8 bit. The embedded firmware is programmed into the internal flash of the H8 using the intrinsic boot facility of the device via serial port SC1 in conjunction with Hitachi flash download and programming software running on a PC Host. The code segment is similarly limited to 128kbyte . The code size at present is typically about 40kbytes.

Microcontroller section details

External flash in the form of a 29F016 holds the application software for the host. This is uploaded to the host 486 via a software protocol upon demand. The H8 otherwise makes no use of this device beyond the facility to read, program and erase it as a result of explicit instructions issued by the host.

External RAM is provided as a 128K 68128 device for optional storage of data or 'C' compiler variables. At present the link map for the IAR 'C' compiler used to generate the embedded code has been organised such that only internal RAM is used and the 68128 RAM may be omitted. This restricts the obstetrics co-processor software to a 4Kbyte limit for the data segment.

H8/3048 memory map

Address range	CS line	Function
0x000000-1FFFFF	CS0	128Kb internal ROM including vectors
0x200000-3FFFFF	CS1	29F016 chip select (2Mb Application Software)
0x400000-401FFF	CS2	Not used
0x600000-6001FF	CS3	DSP data write (data)
0x800000-9FFFFF	CS4	DSP interface logic strobe (control)
0xA00000-BFFFFF	CS5	68128 128k RAM CS (not used at present)
0xC00000-DFFFFF	CS6	analogue multiplexer latch clock
0xE00000-E01FFFF	CS7	8K DPRAM data
0xE02000-E02007	CS7	8 x DPRAM semaphore
0xFFEF10-FFFF00		4kb internal RAM
0xFFFF1C-FFFFFF		Special function registers (internal)

Chip selects CS0-7 are automatically asserted by the H8 when the current access address falls within the ranges defined in its bus control registers. Memory areas marked as not used are not available to the co-processor software as the pins are reserved for other purposes

Microcontroller functionality

The H8 microcontroller section embodies the following functions :-

(a) Non-volatile data storage :-

Up to 4k bytes of data can be stored in a 24C32 I2C type serial EEPROM. This device is driven by software algorithms using port lines PB.1 and PB.2. The internal synchronous serial interface of the H8 is not used. The obstetrics application does not currently require non-volatile data storage.

(b) DSP program download

The ADSP2105 runs a DSP algorithm to process the Doppler signal from the ultrasound probe. This DSP code is embedded within the H8 program memory at a fixed address within the H8 flash programming operation. The DSP code sections required are :-

- MEM.A20 checks DSP presence, located at 1FE00
- FHRUS.A20 performs fetal heart rate determination, located at 1D600
- USECG.A20 improved heart rate algorithm, located at 1E000

The H8 uploads this code to the DSP chip at start-up by asserting P4.7 to generate an interrupt to the ADSP2105. From this point the code transfer to the DSP memory takes place over a parallel link comprising 8 bit latch (U8 a 74HC374) in conjunction with handshaking implemented as Bus Grant from the DSP (read as data bit 15 by the H8) and a Bus Request from the H8 generated by writing to the HC374 latch.

(c) DSP bidirectional data interface

When running its signal processing algorithm, the DSP will continually output its results to the H8 and accept update commands for the AGC control and the basal signal threshold required. This is performed synchronously over a serial link using the SCI0 module of the H8. The system clock for the DSP is generated by the H8 as its PHI (system clock out) pin running at 9.8304MHz. The serial data transfer clock is synthesised by the ADSP2105 which connects directly to the SCIO SCLK in of the H8.

(d) US signal level determination

The integrated level of signal from the ultrasound transducer is measured by an internal 10 bit analogue to digital converter (AN0). This value is processed by the H8 over a finite time period and reported back to the DSP over the serial link.

(e) Toco signal input

The filtered output from the Toco transducer is read as analogue input AN1. This gives a 10 bit resolution. A buffering arrangement within the H8 firmware averages this reading.

(f) AGC and FMD

The H8 periodically samples the values of the AGC and filtered fetal Doppler signals. These are fed back into the DSP algorithm for adaptive processing. This technique is used as the ADSP2105 does not possess its own internal A/D conversion sections.

(g) Accessory (probe) identification

The H8 reads the data contained within the identification component located within the connector of an attached probe to determine the combination and position of attached probes. Each probe has a DS2430 single wire EEPROM pre-configured to hold its accessory type and Assist module category. Based on this information, which is read every 100msec, the H8 will configure the module hardware to match the probe arrangement. Each ID is read on pins PB.5 to PB.3 respectively. Each ID read operation requires approximately 3msec to complete.

(h) Hardware multiplexing

The 'plug and play' feature of the obstetrics module permits an ultrasound, toco or event marker transducer to be inserted into any of the accessory connection ports. The hardware will only permit one of each type of probe to be present at any given time although duplicate types may be attached without causing hardware problems. The H8 uses the detected ID information to select the appropriate routing channels through analogue multiplexers . These are controlled by static signals latched into a 74HC273 chip by writing to address C0000.

(i) Dual Port RAM

By writing and reading the semaphore area of the host DP RAM the H8 implements a parallel data transfer interface with the host 486 which has intrinsic handshaking. In host control mode, the H8 firmware responds to commands issued by the host 486 which allow it to download its own application code as well as gain access to the other hardware facilities of the module. Upon receipt of a 'Run' command, the H8 executes the fetal monitor code loop which periodically stuffs four bytes into fixed locations of the Dual Port RAM. These are recovered by the host 486 (without data handshake) as required, to implement the end user obstetric function application.

6.1.2 Watchdog

The internal watchdog feature of the H8 is used to cause a program restart if the code execution goes awry. To further ensure correct software operation a microprocessor supervisor chip, (a MAX823 device), holds the co-processor in reset if the voltage rail is unstable and also serves as a second watchdog source for enhanced security. This latter device is periodically strobed by pin P6.0 of the H8. The MAX823 has been selected to give a longer time-out period than the internal watchdog and also to remain in tri-state during reset such that the H8 may implement its boot code load without the watchdog perpetually resetting the device.

6.1.3 H8/3048H resource assignments

Timer 0	TIOCA0	Periodic interrupt 1msec
Timer 1	TIOCA1	not used
Timer 3	TIOCA3	not used
Timer 2	TIOCA2	not used
A/D 0		US_FECG signal
A/D 1		TOCO signal
A/D 2		AGC raw signal
A/D 3		FMD filtered signal
A/D4		not used
IRQ2		reserved for DP RAM (not used at present)
IRQ0		reserved for 29F016 programming (not used at present)
Serial Chan 1	SC1	UART : Boot loader (auto-detect baud rate)
Serial Chan 0	SC0	Synchronous : DSP communications interface

6.1.4 On-chip Flash programming voltage

The H8/3048 uses the +12V supply derived by the obstetric module as its on-chip memory programming supply. This is switched by Q4 and Q20 in response to a control line VPPENABLE at the 44 way host connector being asserted high by external programming equipment. The programming interface will normally have an RS232 interface to a host PC. When the H8 is brought out of reset via RESETDRV going low at the 44 way host connector, the H8 will automatically enter boot mode and expect to first receive a small loader program from the host PC on serial channel 1. This boot loader will subsequently pull down a more sophisticated program which will take an S record file from the host and program the internal H8 flash.

6.2 Power supply

6.2.1 Switching regulator

A single voltage power supply of 5V is provided to the module by the host. This is used directly for the digital circuits, and is converted to ±12V and ±10V to power the analogue circuits. The step-up to ±12V is achieved by a dual PWM current mode DC to DC convertor. This IC controls two MOSFET, which are switched on every cycle, at a rate of 200KHz. Both switches are turned off when the current through the inductors exceeds a threshold value. Energy stored in the inductors is routed to, and stored in four capacitors. The output voltages are fed back for comparison with the on-chip reference (pin 7). High surge currents on initial switch-on are limited by the action of C26, which is connected to the soft-start pin of U3. Output noise content is reduced by the low-pass filters formed by a series of resistor/capacitor configurations.

6.2.2 ±10V linear regulator

This circuit, based around dual op-amp U4 produces a fixed ±10V low noise supply of power for driving connected transducers. Two independent 2.5V references (VREF) are used to control the output voltages. U4 reaches equilibrium only when the feedback voltages on it's non-inverting inputs are equal to those on it's inverting inputs (the reference voltages). Current is controlled by varying the base current of Q2 and Q5. Short circuit protection is provided by RT1 and RT2, which allow up to 100mA(RT2) and 200mA(RT1) to flow continuously. If the output current exceeds this value, the devices heat up and enter a high resistance state, thus lowering the current to a safe value. Power, or the load must be removed for the output to revert back to normal. The two low-pass filters R4/C14 and R13/C19 reduce the reference noise which would otherwise degrade the noise content of the output. Capacitors C11 and C18 are necessary to prevent instability.

6.2.3 5V_ANA supply

A 5V supply for various analogue circuits on the module is derived from the VCC rail via the filter R1/ C4&C5.

6.2.4 Transducer power switching

To conserve power, the dc supply to the transducers is switched off when the transducers are inactive, by the microcontroller. Three independent switching lines "CH1_POWER to CH3_POWER" control the switch state of six series MOSFETs. Each pair of MOSFETs is switched on by one of these lines, as it changes from low to high. When the MOSFETs are on, ±10V dc is fed to pins 1 and 2 of the transducer connectors JP3 - JP5.

6.3 Signal processing

6.3.1 Input multiplexing

The module incorporates a useful feature referred to as "plug and play", which means that any suitable transducer can be connected to any of the three input ports. The module will identify the connected transducer, and configure the interface circuits appropriately.

Signal switching is achieved by multiplexers. The multiplexers are controlled from the data bus via octal D-type flip flop.

An instrumentation amplifier is provided for each of the three transducer ports. This amplifier actually has two output stages; one for toco and one for ultrasound operation, depending on the connected transducer. The toco output stage incorporates a small positive offset to ensure that negative transducer offsets do not result in 'dead bands' near zero. R140 ensures that the inputs are not left floating with no transducer connected.

6.3.2 Ultrasound low pass filters

The ultrasound output from the multiplexers first passes through a buffer, and low pass filter . This is a two pole Butterworth type, with a -3dB frequency at 1KHz. This feeds another low pass filter, which has 8 poles, and a -3dB frequency of 720Hz. This heavy filtering is needed to remove the unwanted 3.2KHz tone present on the Doppler ultrasound signal, caused by the pulsed operation of the transducer.

6.3.3 FMD bandpass filter

The signal output from the low pass filter above (6.3.2) contains low frequency signal components produced by fetal/maternal movement (FMD signals) in addition to those produced by the beating of the fetal heart. The bandpass filter incorporating a pair of Op-Amps has a passband of 10Hz to 50Hz designed to match that of the FMD signals. The filter output is fed to the A/D convertor from storage capacitor C98. This output is biased to +1.25V dc to optimise the dynamic range of the signal to that of the A/D converter.

6.3.4 High pass filter

A four pole high pass Butterworth filter with a -3dB point at 115Hz. It's purpose is to reject signals produced by movement, and pass signals produced by beating of the fetal heart.

6.3.5 Audio amplifier / limiter

The fetal Doppler signals passed by the high pass filter are fed to this amplifier which has a mid-band gain of around 3.3 (10dB). This amplifier exhibits a limiting behaviour if the signal amplitude exceeds around 2.8Vpp. The output from this amplifier is fed to the Host power amplifier to drive the speaker.

6.3.6 Anti-alias filter

An 8-pole Butterworth switched capacitor filter, whose cutoff frequency is programmed by the value of C113. With C113 = 820pF, the -3dB frequency is approximately 400Hz. This device is operated from a single +10V supply, so the input and output signals are biassed to +5V to allow linear operation.

6.3.7 Digital gain control

This circuit section allows the microcontroller to adjust the voltage gain applied to the Doppler ultrasound signal so that it's amplitude can be regulated. This continuous gain adjustment is essential due to the continually varying amplitude of the signal.

A dual 8-bit Digital to Analogue converter (DAC). Unusually, the signal is fed into the reference inputs (instead of a voltage reference). A DAC configured in this way will act as a variable potentiometer, and can therefore be used to control gain.

The circuit is unusual in another way, as two DACs are used to control the amplitude of only one signal. This was done to overcome a glitch problem which exists when only one DAC is used. The glitches will occur because of the DC bias applied to the signal. That is, every time the DAC is adjusted, the DC bias will also change. This produces the troublesome transient.

To overcome this, the second DAC is fed with the same DC bias as the signal, but with no signal on it (REF1). The same digital value is written to both DACs simultaneously. So, the outputs of the DACs will be:

DAC1 output = k (signal + bias)

DAC2 output = k (bias)

(where k is the potentiometer attenuation)

Therefore, if the output signals are subtracted, the result will be k(signal). This subtraction is achieved by a conventional difference amplifier. The signal at this point is referred to 0V. So that the signal can be fed into the A/D convertor, it's bias is shifted to +1.25VDC. Diodes serve to protect the A/D input should the signal venture outside the range 0 to +2.5V. U28B produces a buffered +1.25V bias in conjunction with R26 & R132.

6.3.8 AGC raw

So that the gain control can respond quickly to large changes of signal amplitude, a non-regulated version of the signal is fed in to another A/D channel. To avoid overdriving the A/D converter, this signal is heavily attenuated. A diode protects the A/D input should the raw signal venture outside the range 0 to +2.5V.

6.3.9 Ultrasound oscillator / timing

A single invertor CMOS gate is configured as a conventional oscillator, with the operating frequency set by Y4 to 6MHz. This clock signal is fed into a programmable logic device (PLD). This PLD is programmed with a file which configures internal circuits to perform the intended functions. In this case, the PLD produces timing waveforms to control the transmitter and receiver of the ultrasound transducer. J2 is a standard interface connector for the PLD, used once only, for initial programming. The PLD produces two output signals:

- 1.5MHz carrier (square wave)
- Transmit gate signal (Pulse train, prf = 3.2KHz)

(a) 1.5MHz carrier

The output from the PLD is first passed through an RLC filter which extracts the fundamental frequency. This of course, is a sine wave at 1.5MHz. This is amplified by a special video (high frequency) op-amp. This amplifier has a low output impedance, essential to drive the ultrasound transducer via a 75 ohm cable.

(b) Transmit gate

The transmit gate signal present on pin 37 of the PLD is inverted and fed to the ultrasound transducer where it controls the on/off state of the transmitter. Note that the pull-up resistor for Q7 collector is located on the transducer.

6.3.10 ESD Protection

Two different types of protection device are used to protect the electronics against electrostatic discharge (ESD):

- Varistors (eg D19)
- Blocking diodes (eg ESD7)

Generally, varistors are used on most lines, except where their significant capacitance would result in unacceptable loading, in which case, the blocking diode type is used.

7. Transducers & Accessories

7.1 Ultrasound Transducer - US1 TOCO

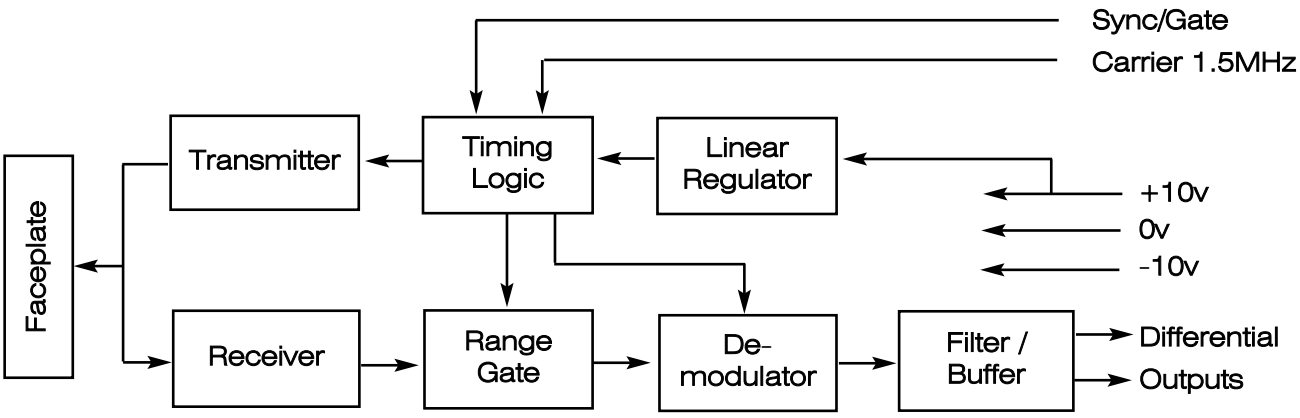
Please Note: Waterproof transducers must be returned to Huntleigh Healthcare Service Dept.

The ultrasound transducer is a 7 circular crystal array with integral drive electronics. The crystals are all energised to transmit a burst tone of ultrasound at 1.5MHz. They are then all configured as listening devices to receive reflected signal.

The transducer signal includes all the drive and timing electronics and generates audio bandwidth signals representing the Doppler shift in the ultrasound signal that has been reflected from moving objects in the uterus.

Ultrasound					
Device	Transmitter Frequency (MHz)	Acoustic Output		Pulse Repetition rate (kHz)	Output beam dimension (cm^2)
		$I_{spta.3}$ (mW/cm2)	$I_{sata.3}$ (mW/cm2)		
1.5MHz Fetal Transducer	1.5 1%	6.31	4.27	3.2	0.785 per crystal
510(k) Limits		94	20		

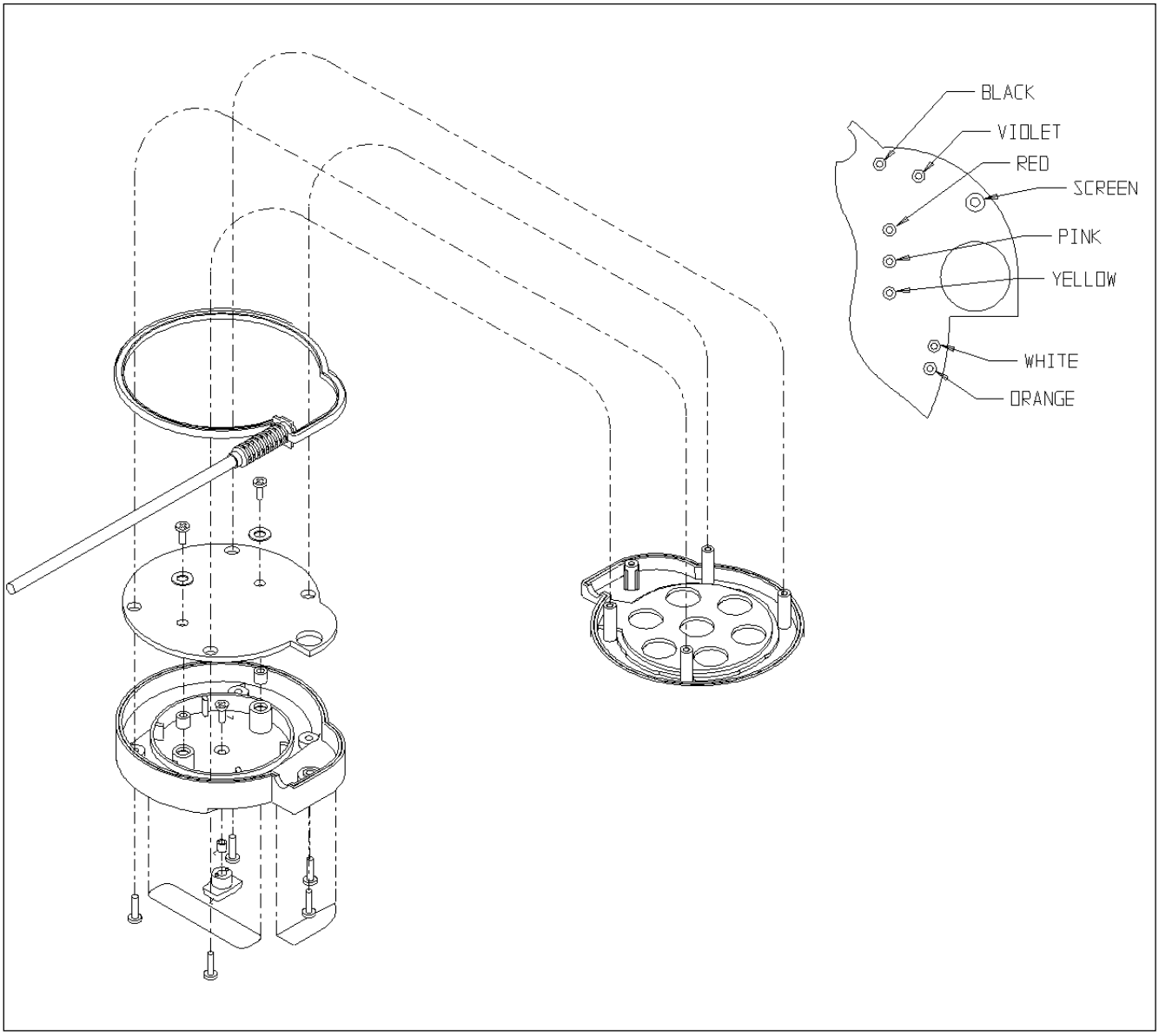
7.1.1 Ultrasound Transducer Functional Block Diagram



7.1.2 Ultrasound Transducer Key Parameters

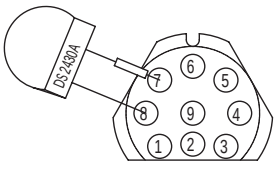
Parameter	Specification
Bandwidth	105Hz to 620Hz, +0, -3dB
Ultrasound Transducer Gain	72dB typical, from 5.7 ohm source impedance
Ultrasound Transducer Isolation	Provides isolation type B to EN60601-1. All necessary electrical isolation is assumed to be provided by the main unit. This assembly contains low voltage circuits only.

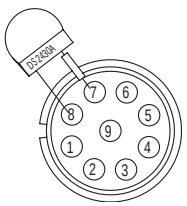
7.1.3 Ultrasound Transducer Construction



7.1.4 Ultrasound Transducer Connector

Ultrasound transducer is configured with a keyed 9 pin HYPERTAC or REDEL plug and is colour coded red.



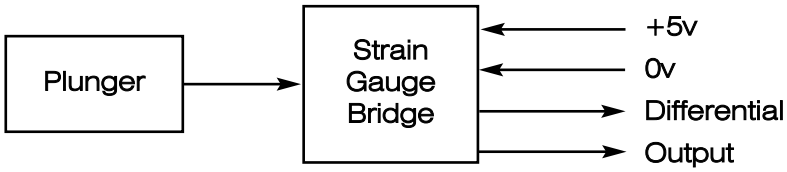


Pin	Description
1	Screen
2	TX1 - Transmit sync/gate input - pulled high for tdr detect
3	+10v supply input - typical 65mA
4	-10v supply input - typical 15mA
5	-US White
6	Ultrasound signal output
7	ID Chip
8	Black ID Chip
9	Carrier input (1.5MHz)

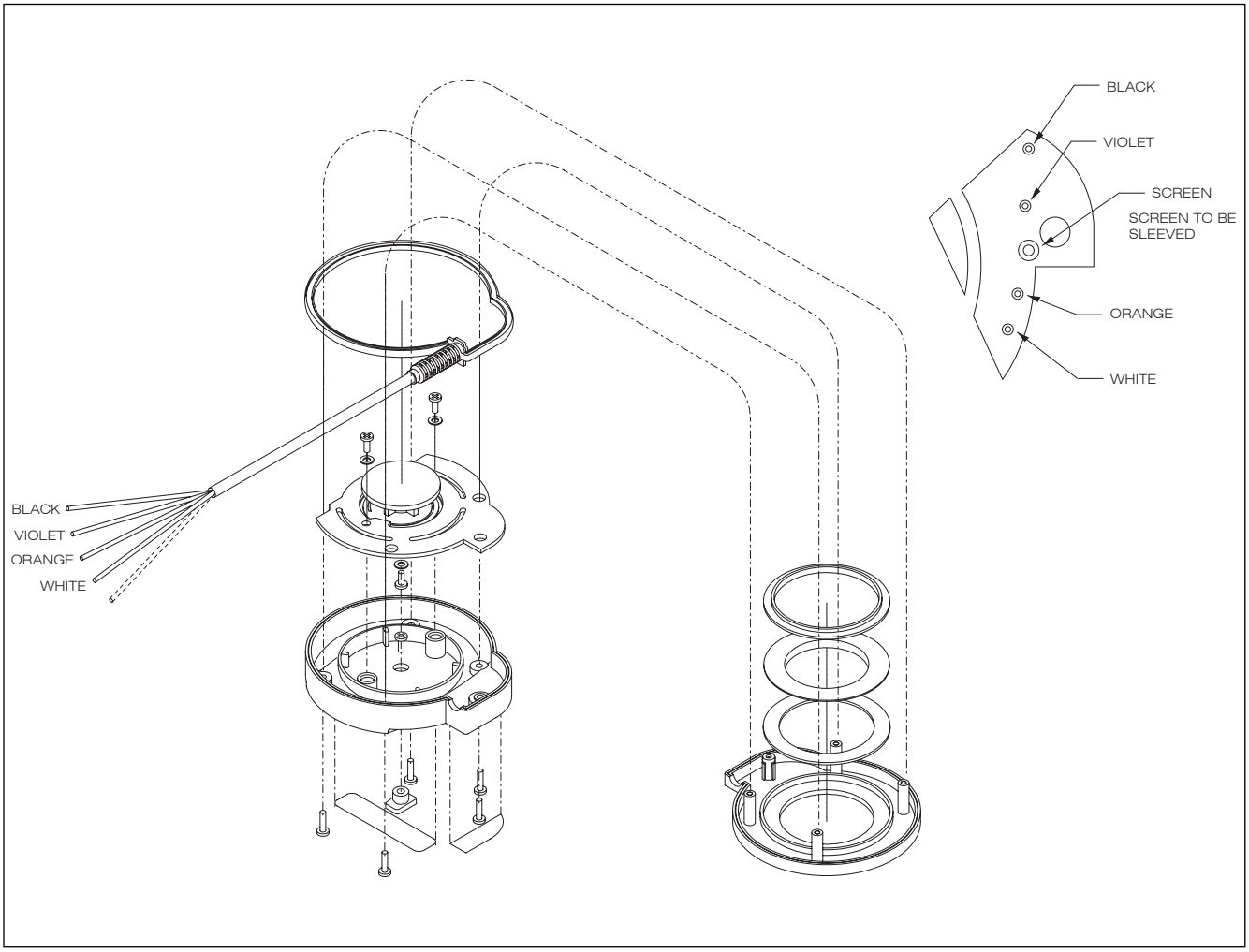
7.2 Toco Transducer - CT1

Parameter	Specification
Toco Load range	0 to 300g
Toco Output sensitivity	8.1 mV/V for 100g load
Toco Zero balance	5mV to 15mV positive
Toco Isolation	Provides isolation type B to EN60601-1. All necessary electrical isolation is provided by the main unit. This assembly contains low voltage circuits only.
Toco Cable	As ultrasound transducer - US1.

7.2.1 Toco Functional Block Diagram

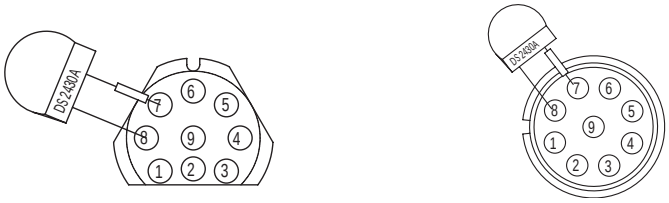


7.2.2 Toco Construction



7.2.3 Toco Connector

External contractions transducer is configured with a keyed 9 pin HYPERTAC or REDEL plug and is colour coded blue.



View from rear of plug

Pin	Wire
1	SCREEN
2	N/A
3	ORANGE
4	N/A
5	WHITE
6	VIOLET
7	ID CHIP
8	BLACK/ID CHIP
9	N/A

8. Docking Station

This is a polyurethene moulding that is designed to hold the Dopplex Assist at a convenient angle so that procedures can be completed with the unit mounted in a suitable level surface, such as a desktop.

The Docking Station houses additional electronics together with two loudspeakers. This permits the production of stereo sound and also an output to an external printer.

Several elements are brought together in this unit. They are described below:

Element	Location	Function
Power Input Socket	Lower Back Face	Accepts input from the power adaptor. In this configuration, and when the Host unit is locked in position, the Docking Station can separately feed an external printer and produce stereo audio output from the twin inbuilt speakers. The signals for these functions being transferred from the Host unit via spring loaded contacts. The exposed contacts on the bottom rail of the Docking Station, which mate with the Host unit, are isolated when the Host unit is not located.
Printer Output Port	Lower Back Face	This 25 way D-type connector is only powered when the Docking Station is directly powered from the power adaptor.
VGA Output	Lower Back Face	This 9 way connector is provided for a possible future expansion to a VGA output.
Accessory Holder		For the convenient storage of gels, transducers etc.

8.1 Desktop Operation - Power fed through the Docking Station

Note: In this configuration, the Host and the Module are located in the Docking Station, leaving the user with both hands free. The system is powered from the Power Adaptor, the input being connected to the rear of the Docking Station.

Please Note: This is the Preferred Mode of Operation

a. The power from the Power Adaptor is routed through the Docking Station to power the Host and Module. This input is protected by an in-line fuse and a relay.

The power is fed to the Host unit via 2 pins located on the lower edge of the Docking Station. These pins are isolated when the Host is not located in the docking station.

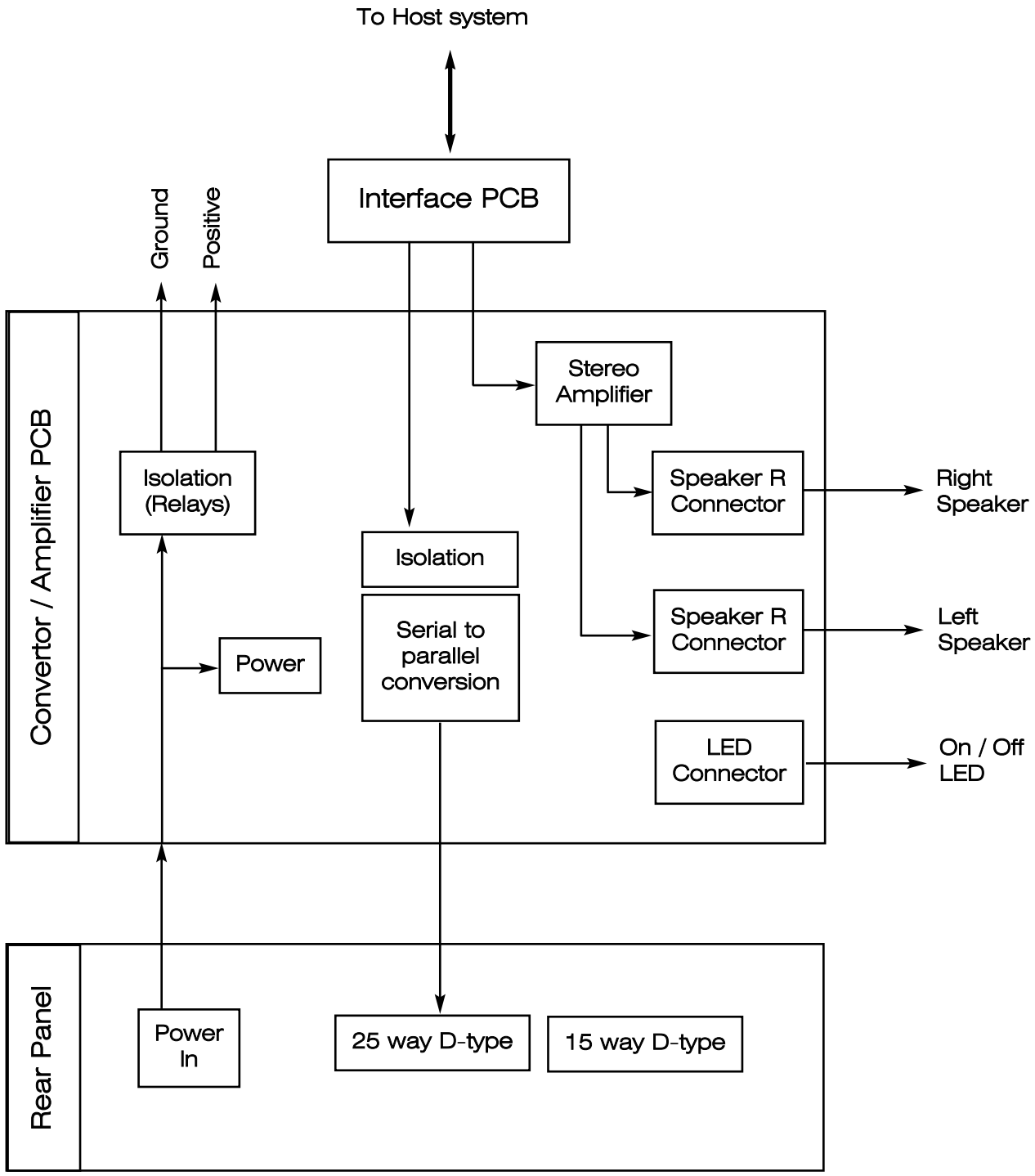
b. Hardcopy printouts are available if a conventional parallel printer is connected to the printer port located to the rear of the Docking Station.

The printer port is isolated from the circuitry of the Docking Station to 1500V ac and complies with the 4mm and 2.5mm creepage and clearance requirements of EN60601.

Stereo loudspeakers are fitted within the Docking Station for optimum audio presentation.

c. It is possible for the Host to be located in the Docking Station, without a Battery Pack being inserted. In this situation, there is no access to the internal circuitry of the Host.

8.2 Docking Station Block Diagram



9. Mains Adaptor/Battery Pack Specification

9.1 Mains Adaptor

9.1.1 Introduction

This specification applies to the mains adaptor for use with the Battery Pack system and its range of modules and accessories. It is of universal input switching type, compatible with all international supplies of power.

9.1.2 Mains Input

Input Voltage Range	90 - 264 VAC inclusive
Input Frequency Range	50 - 60 Hz inclusive
Indication	Green lamp to indicate mains ON

9.1.3 DC Output

Output Voltage	15V DC ± 5%, (except when in current limit mode)
Output Current	Zero - 2A, current regulated at between 2.0A min & 2.4A max.
Output Ripple Content	< 100m Vpp
Operating Efficiency	> 80% at load current of 2A

9.1.4 Safety / Isolation

Standards	to meet EN60601-1 :1993 and UL2601-14 Class I
Leakage Current (between mains input and DC output)	Less than 100μA RMS in normal conditions, and 500μA RMS in single fault conditions, as defined in and measured according to EN60601-1 : 1993
Earth Leakage Current (via mains outlet earth pin)	Less than 0.5mA RMS normal condition and 1mA RMS single fault condition (EN60601-1 table 4, Type BF, general)
Dielectric Strength	Greater than 4KV AC RMS, measured according to EN60601-1:1993, between primary and secondary circuits.

9.1.5 Operating Environment

Ambient Temperature	0 °C to +40 °C
Ambient Humidity	Maximum RH 90%, non-condensing

9.1.6 Storage Environment

Storage Temperature	-40 °C to +70 °C

9.1.7 Electromagnetic Compatibility

Emissions	Radiated / conducted	To comply with EN55011 : 1998
	Harmonics	To comply with EN61000-3-2, Class D

9.2 Battery Pack

9.2.1 Introduction

There are no accessible conductive parts on the Battery Pack or Power Adaptor. The rechargeable batteries within the Battery Pack are NiMH.

The pack is provided with an LED to indicate when the Battery Pack is being fast charged. It also indicates when the pack is self checking prior to fast charging. The actual level of charge in the Battery Pack is shown on a bar graph in the Host display when in use.

Battery trickle charging is automatically instigated when the power adaptor is being used. The user needs to take no action to commence the trickle charging procedure. To initiate fast charging, the user has to remove, and then re-insert, the jack plug from the power adaptor. This triggers the automatic system self checks and, if necessary, fast charging will commence.

The battery pack is provided with a resettable thermal fuse to prevent the battery pack overheating during charge or short circuit occurances.

There is also a resettable overcurrent fuse to prevent excess current flow, in case of a short circuit in either the battery pack or Host units.

If the resettable protection devices are tripped, they are automatically reset after unplugging the power supply and allowing the battery pack to cool in ambient temperature.

The battery pack is capable of controlling its own fast charge regime, and also indicates the current charge mode via an integral LED. It monitors its current charge capacity and can communicate this to the host unit via a single line. Safety devices are included for temperature and overload currents.

The battery pack provides two external connectors to a DC socket (Hypertronics 3 way D01), and an AMP 5 way battery pack connector. The pin outs are as follows:-

Socket	Pin 1	Pin2	Pin3	Pin4	Pin5
D01-3	GND	15V DC	TBD	-	-
AMP	Vout	Vin	DQ Line	GND	GND

9.2.2 Cell Type

Rechargeable NiMH cells are to be used as they are less toxic than the NiCad cells. The chosen batteries are 400mAhr 4/3A type.

9.2.3 Battery Discharge

The battery pack is to be used to provide power to the Host unit, in portable use, including the module and transducers.

Discharge time

The battery pack is capable of supplying the PMA Host and Module for 4 hours continuously before recharge is necessary.

9.2.4 Desktop Operation - Power fed through the Battery Pack

Note: In this configuration, the Host and the Module are located in the Docking Station, leaving the user with both hands free. The system is powered from the Power adaptor, with the input connected to the Battery Pack. Alternatively, the system could be run from the charged Battery Pack when in this configuration.

Please Note: This is Not the Preferred Mode of Operation

a. The power from the Power Adaptor is routed through the Battery Pack to drive the Host and Module, but it is not fed to the Docking Station.

b. In this configuration, printer and stereo outputs are disabled.

10. Electrostatic Discharge (ESD) Precautions

10.1 What is Static Electricity?

Static electricity is generated when two materials move against one another. The voltage generated depends on the materials generating the electricity, the speed of movement, humidity and rate of discharge. All man made materials generate static, such as plastic coffee cups, plastic bags, binders and folders, all of which are likely to be within the working area.

Activity	10-20% Relative Humidity
Walking across carpet	35,000 Volts
Walking across vinyl floor	12,000 Volts
Working at bench	6,000 Volts
Plastic folder	7,000 Volts
Poly bag lifted from bench	20,000 Volts
Foam padded work chair	18,000 Volts

Protective Measures

To protect devices (ESDs) from the unwanted effects of ESD, two key measures must be taken to minimise the possibility of damage.

1. All sensitive devices and assemblies must be handled in an ESD Protected Area (EPA).

2. All sensitive devices and assemblies must be transported in a protected state.

11. Servicing Procedures

Fault finding described is only intended to identify boards, modules and major components that need to be replaced. This document is not intended as a full diagnostic tool because many of the boards are multi layered and may not be adequately repaired in the field and must be returned to Huntleigh Healthcare Service Department.

Due to the complexity of the product and the use of surface mount technology, the electronic circuitry is not serviceable without specialised training and equipment.
The repairs detailed in this manual are therefore limited to replacement of certain parts.
Fault finding is limited to checking for the presence or absence of signals around suspect components using an oscilloscope or multimeter.
Repairs should only be undertaken by suitably skilled service personnel.

This equipment contains static sensitive devices. Precautions must be taken to avoid static damage to the circuitry.
Due to the high density tracking and small size of components, extreme care in handling the PCB's must be taken at all times.
When soldering, take care to ensure the minimum heat is applied to the boards and components for the minimum time necessary to ensure high quality joints. Inspect the area around the repairs for solder splashes and bridges.

11.1 Unit dismantling

Caution: Ensure that mains supply is removed and the unit turned off before opening.

1. Remove the battery (ACC100)
2. Invert the unit and place on a smooth surface.
3. Remove the Fetal Module by pressing down in the centre release button .Slide the module back from the connector and lift.
4. Remove the 6 case securing screws.
5. Lift the case from the rear and at the same time break the seal of the sticky pad within the battery chamber.
6. Be very careful when separating the cases; the smartcard PCB will be attached to the main PCB via a ribbon cable.
7. Remove the Battery Clip.

11.2 Removal of the Host PCB

1. Disconnect the keypad and smartcard ribbon cables.
2. Disconnect the 4 pin power supply and 2 pin speaker sockets.
3. Lift the main PCB slightly out of its setting and remove the Bulkhead PCB.
4. Disconnect the LCD Module ribbon cable and the Touchscreen ribbon cable.
5. Turn the Main PCB over and disconnect the 2 pin connector to the battery.
6. The Main PCB is now disconnected.
7. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.3 Removal of the Touch Screen and LCD Module

1. Remove the Blue Bezel moulding.
2. Unscrew the 6 screws that hold down the metalwork covering the LCD Module.
3. Remove the metalwork and then the foam pad.
4. Disconnect the LCD Ribbon cable.
5. Disconnect the Blue wire Pin 2 and Pink wire Pin 1 from the invertor board.
6. The LCD Module can now be lifted free of the case.
7. On removal of the LCD Module, easy access is available to the Touch screen.
8. Touch calibration is required after touch screen replacement.
9. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.4 Invertor PCB Removal

1. Disconnect the Pink wire Pin 1 and Blue wire Pin 2 from the invertor board.
2. Disconnect the 4 pin power supply socket.
3. Unscrew the 3 screws holding the PCB in place.
4. Invertor PCB can now be removed.
5. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.5 Speaker Removal

1. Disconnect the 2 pin socket from the Main PCB.
2. Unscrew the 3 screws that secure the speaker clamping plate.
3. Remove the speaker spacer.
4. The speaker can now be removed from the case.
5. Check the integrity of the gasket after removing the speaker.
6. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.6 Removal of the Keypad

1. Remove the Main PCB as detailed above.
2. Remove the Invertor PCB.
3. The keypad can now be removed.
4. Flip the unit over and peel back the sticky pad.
5. On refitting a new keypad, ensure that the surface is free from any grease and dirt.
6. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.7 Fetal Module

1. Remove the fetal module from the host by pressing down on the centre release button.
2. Slide the module back from the connector and lift.
3. Invert the module and place it onto a smooth surface.
4. Remove the 4 securing screws and lift the back case off.
5. *Please Note! The back case may be stuck on the metal shielding on the module PCB.*
6. Replacement in the reverse order of the removals procedure, taking note of the procedures described.

11.8 ACT3/AUS3 (Ultrasound) Transducer Dismantling

1. Remove the 5 screws from the rear of the transducer (one under label). Invert case assembly and lift the top clear. Care should be taken not to lift the seal clear at this stage.

11.9 Re-assembly of ACT3/AUS3 (Ultrasound) Transducer

1. Ensure the seal is located in the case before fitting transducer top, and that the seal assembly is fitted correctly.
2. Fit transducer top and tighten screws to 20 cNm. Replace label.

Water resistance of Ultrasound transducers can only be ensured if the units are returned to Huntleigh Healthcare Ltd, Diagnostic Products Division for refurbishment.

11.10 Strain Gauge Assembly Removal

1. Remove case top as detailed in 11.8, and de-solder the grey cable from the termination PCB. De-solder the strain gauge wires from the PCB.
2. Remove 2 securing screws from the strain gauge PCB and lift clear from the assembly.

11.11 Strain Gauge Assembly Refitting

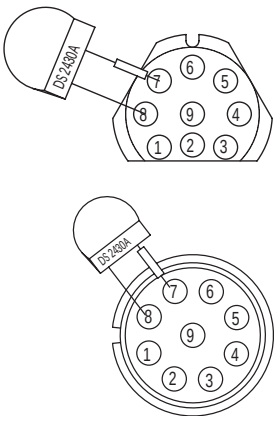
1. Fit the strain gauge assembly noting orientation.
2. Solder the wires to the termination PCB and tighten the screws to 40 cNm. Solder the connector cable to termination PCB. Align transducer as detailed in 11.12.

11.12 ACT3 Transducer Alignment

Equipment required

a). Power Supply b). Digital Volt Meter c). Weight - 1 x 100gm

1. Remove case top as detailed in 11.8.
2. Set up power supply voltage to 5.00d.c. +/-0.05V.



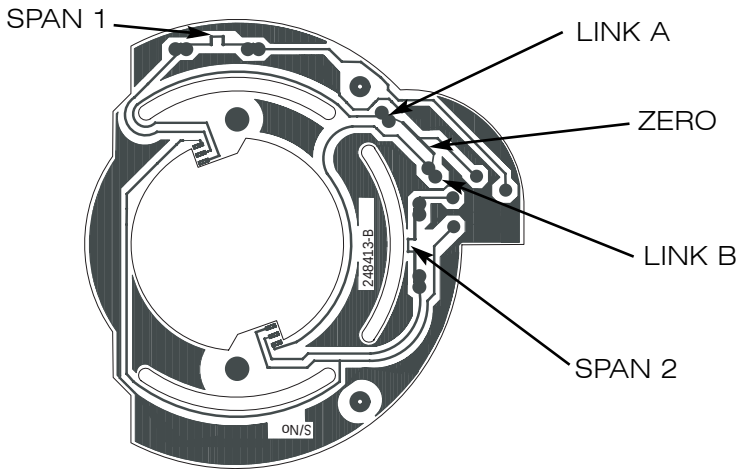
View from rear of plug

Table 1

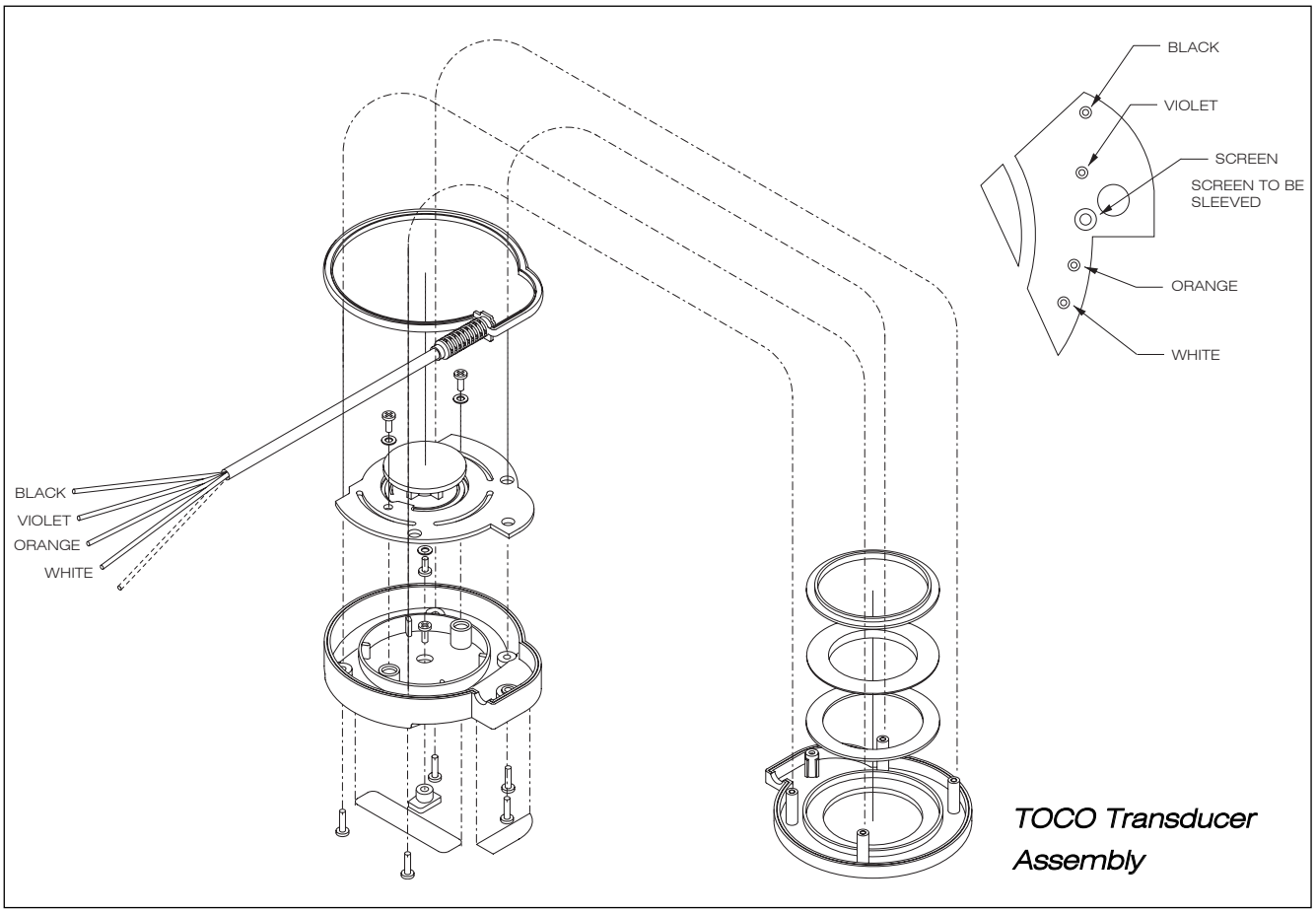
Pin	Wire
1	SCREEN
2	N/A
3	ORANGE
4	N/A
5	WHITE
6	VIOLET
7	ID CHIP
8	BLACK/ID CHIP
9	N/A

Pin	Connection
1	SCREEN
2	N/A
3	5V SUPPLY
4	N/A
5	- VE O/P DIFFERENTIAL
6	+ VE O/P DIFFERENTIAL
7	ID CHIP
8	BLACK ID CHIP
9	N/A

3. Connect transducer to power supply and DVM as shown in Table 1, (previous page).
4. Turn transducer so that the strain is uppermost.



5. Apply power to the strain gauge and allow 1 minute to settle. Use a TOCO socket, connected as shown above, to supply strain gauge and read values.
6. DVM should read zero +13 to +23mV.
   If the offset is positive, check that link 'A' is cut and link 'B' intact. Replace 'Zero' resistor with a new value as required to bring the offset within specification. If the offset is negative, check that link 'A' is intact and link 'B' is cut.
   Repair cut link with tinned copper wire as required.
7. Place 100g weight on the strain gauge button. Observe the DVM.
   DVM should read 38.9 - 42.1mV.

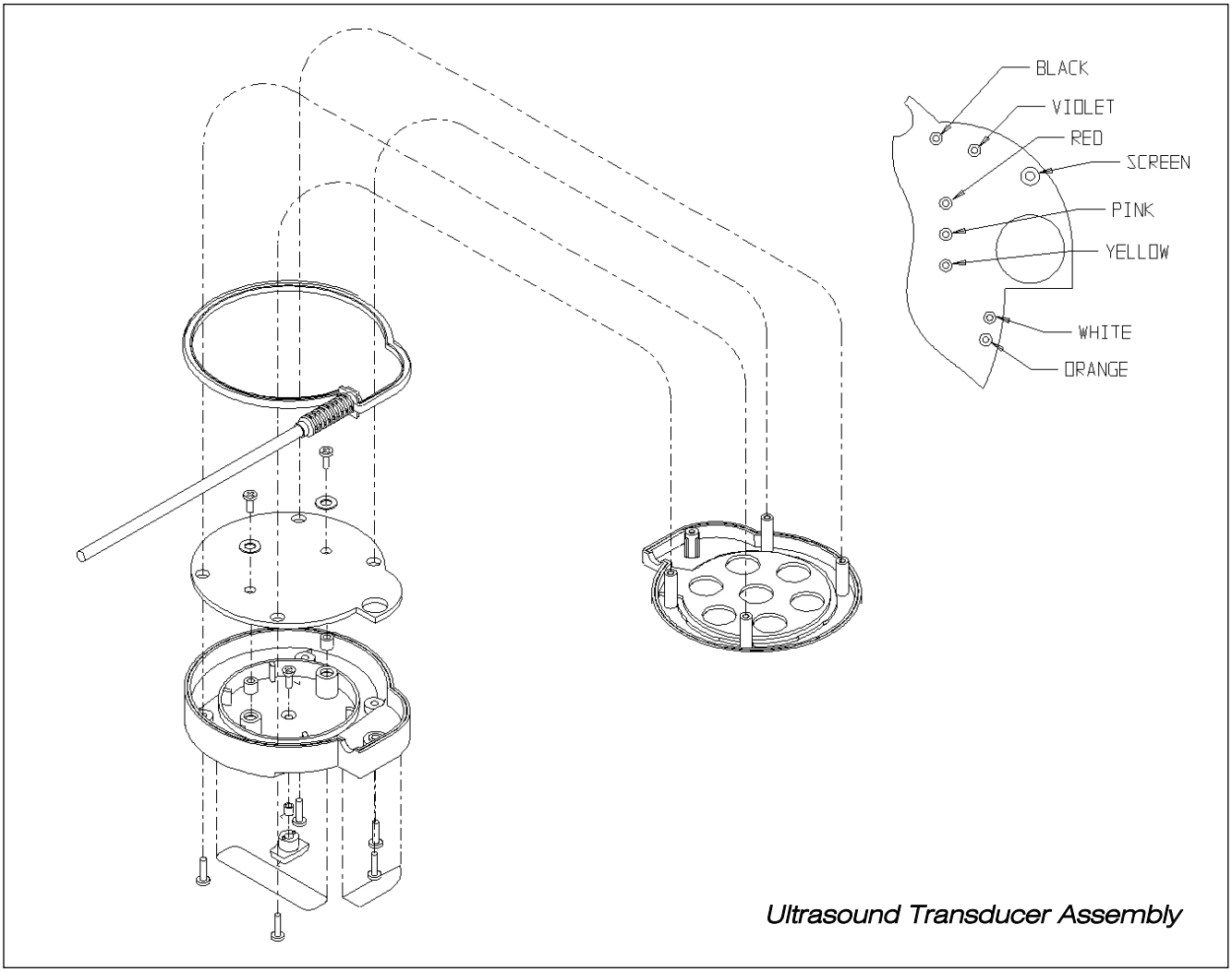


TOCO Transducer Assembly

8. Change the value of the span resistors and repeat until within specification. Both span resistors should be of the same value.
   If the sensitivity is low, decrease the value of both resistors.
   Allow the resistors to cool before repeating the process.
9. Assemble the transducer as detailed in 11.9 and check zero value is +5 to +15mV when assembled.

11.13 Replacing the Transducer Cable

1. Remove the case top as detailed in 11.8 and de-solder cable from PCB.
2. Unscrew the back of the plug and pull insert free. De-solder wires and remove the plug from the cable



Ultrasound Transducer Assembly

3. Fit plug shroud to cable and attach collet. Solder wires to the plug as shown in the configuration above.
   Apply threadlock to plug body and tighten the assembly.
4. Assemble the transducer as detailed in 11.9.

Water resistance of Ultrasound transducers can only be ensured if the units are returned to Huntleigh Healthcare Ltd, Diagnostic Products Division for refurbishment.

12. Ordering Spare Parts

Due to developments improving the product, over the years, certain spare parts may not be readily interchangeable between early and late production units. Always quote the serial number of the unit and date of purchase, if known.

Items returned for replacement under warranty should be labelled with the unit type, serial number, date of purchase, if known and written details of the symptoms and fault found.

Orders of spare parts may be sent by post, telex, fax or telephone to Huntleigh Healthcare approved agents or distributors.

Recommended Spare Parts

Number of units to be maintained		1	5	10
Description	Part No.			
Battery Pack	ACC100	-	1	2
Main Adaptor	ACC105	-	1	2
Bulkhead PCB	708061	-	1	1
Host Main PCB	708057	-	1	1
Packing Pad (Battery Clamp)	708348	-	1	2
LCD Module	LM7M632	-	1	2
LCD Ribbon Cable	708356-1	-	2	3
Touch Screen	708322	1	2	4
Keypad	708310	1	2	3
Invertor PCB	CXA-K0505-VJL	-	1	1
8 Ω Speaker	5LYDM50A-8	-	1	2
Speaker Gasket	708323-2	-	1	2
Speaker Spacer	708349-A	-	1	2
Speaker Clamping Plate	708405-B	-	1	1
Battery Clip	708312-D	-	1	1
Redel Loom Assembly	709091-1	-	1	2
Hypertac Loom Assembly	709055	-	1	2

Recommendation for Battery Pack (ACC100)

It is recommended that a battery pack be replaced every 2½ years.

13. Fault Finding / Trouble shooting

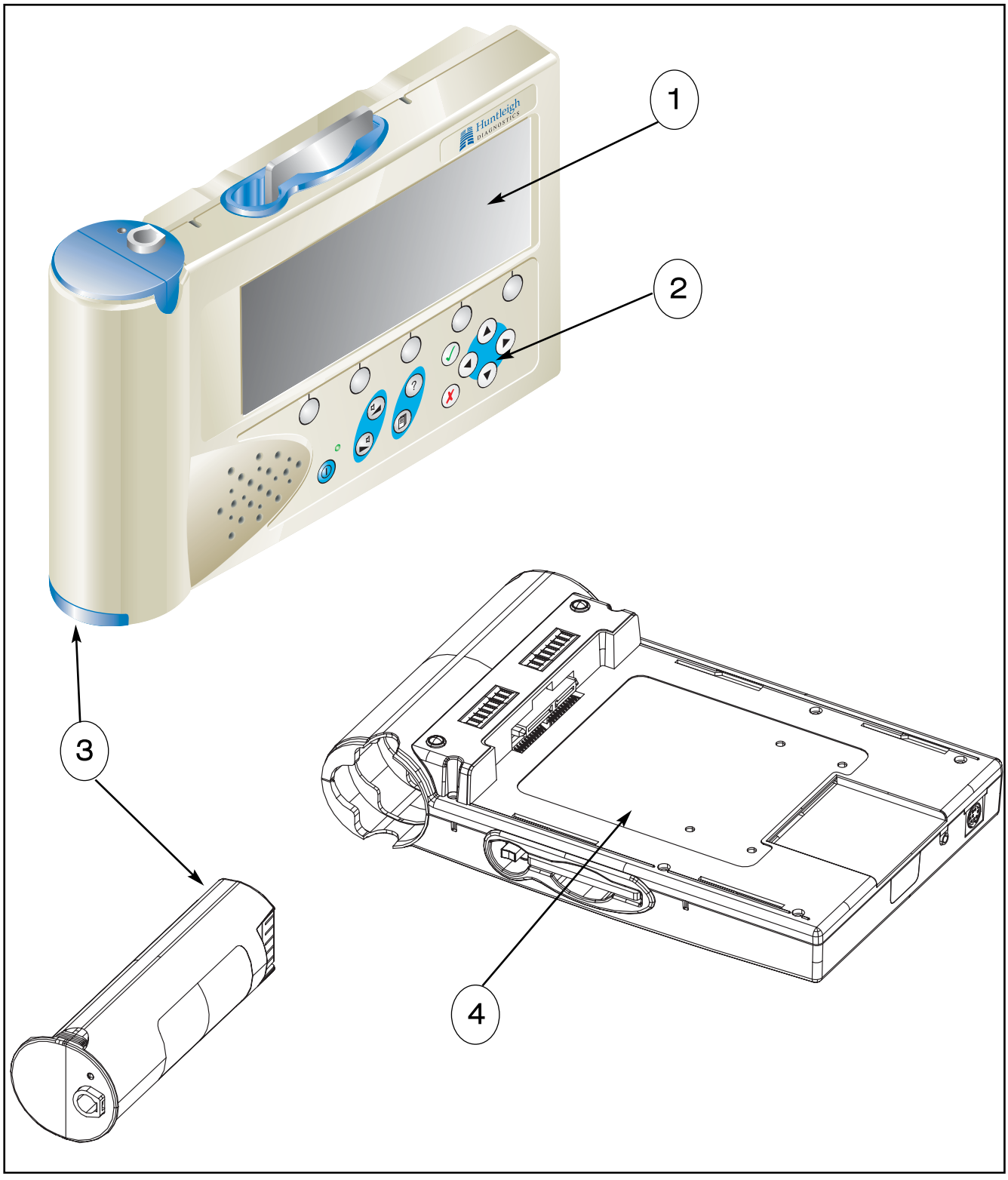
Symptom	Possible Cause
Unit will not switch on	Check that the battery is fully charged and that the mains adaptor is working correctly; (green light is illuminated) During charging, the Amber LED on top of the battery will pulse. Keypad (Touch panel) may be inoperative and require replacing.
The unit switches on but No information on the LCD	Connect VGA lead to the unit to drive an external monitor. If the monitor receives information, the LCD module may need replacing
Touchscreen Inoperative	Re-calibrate touchscreen as described in the Inspection and test procedures. Replace touchscreen.
Vertical Lines appear on the LCD module	Replace LCD Module Ribbon Cable
Unit will not print via Docking Station	Ensure that the printer settings are correctly adhered to, as the user manual. Faulty Bulkhead PCB. Replace as required.
No Audio	Check the operator settings; replace speaker.
Locking Up	Low Battery voltage, check for latest software.
Inoperative	Failure to complete an upgrade due to low capacity battery.
Wrong Time & Date	Older module may require internal battery to be replaced.

Problem	Cause	Solution
Unit displays incorrect time & date	Internal clock incorrectly set	Reset clock
Unit will not switch ON	Discharged battery pack	Recharge battery
	Membrane panel or touch screen does not respond to key presses.	Refer to service department.
Unable to record UA	TOCO baseline set too high / low	Zero baseline
Unable to zero baseline	Defective TOCO transducer	Replace transducer
Ultrasound Probe		
Poor signal	Doppler probe incorrectly positioned.	Reposition probe, check angle
	Insufficient gel.	Apply gel.
	Fetus moved or transducer incorrectly positioned.	Reposition the transducer and adjust belts.
No signal	Damaged probe	Replace probe.
	Damaged cable	Replace cable
No audio signal	Incorrect volume setting	Increase volume setting
	Transducer not connected	Connect transducer - Audio only enabled in *trace mode*.
	Defective ultrasound transducer	Replace transducer

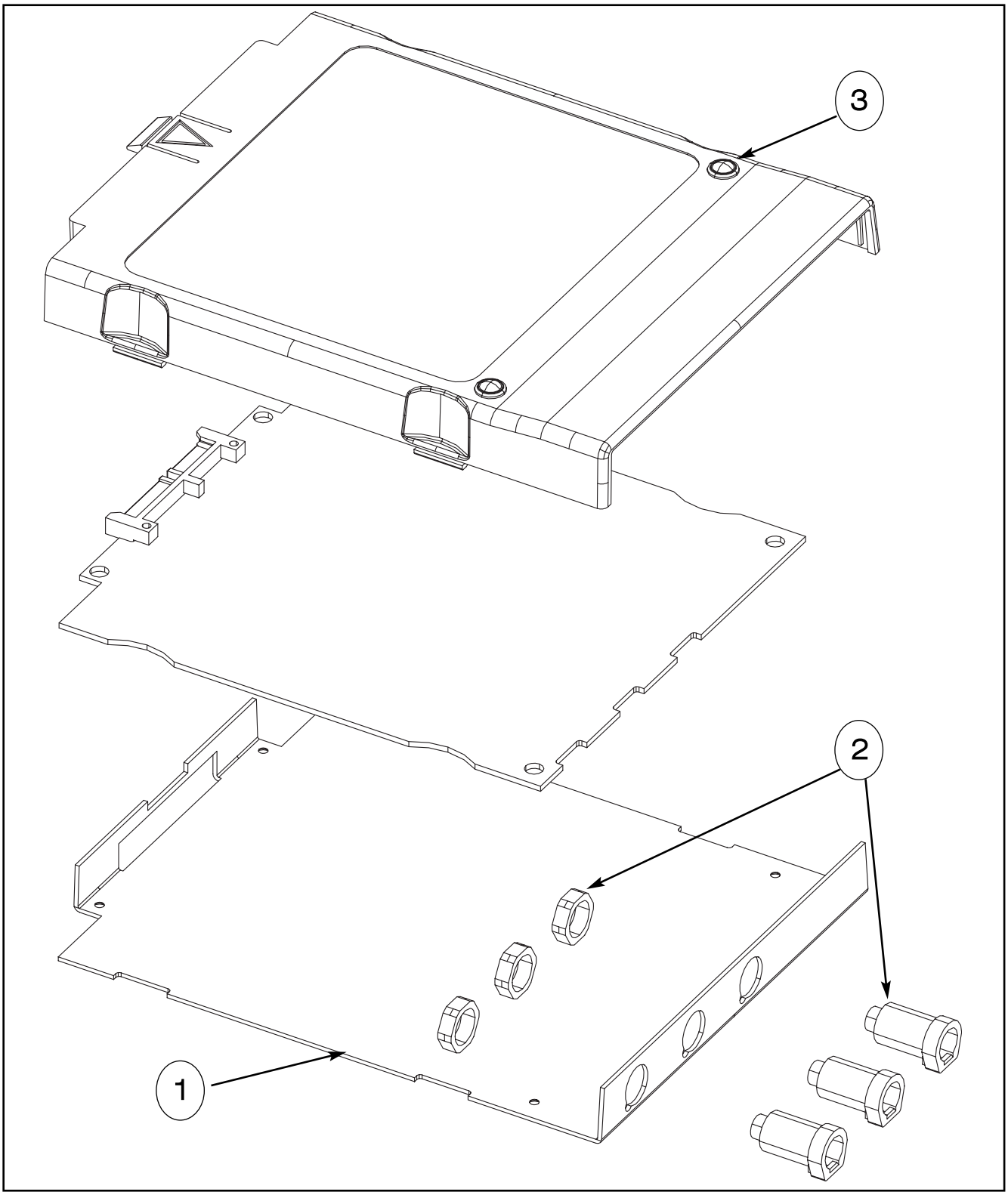
Problem	Cause	Solution
Printing Applications		
Unable to print trace	No printer set up	Configure printer
	No printer drivers set up	Load drivers
	No printer connected	Connect printer
	Remote monitoring enabled	Disable in set-up screen
	Printer 'off line'	Refer to printer user manual
	Printer out of paper	Load paper
	Unable to print via docking station	Ensure unit is correctly docked & that mains power is applied to the docking station (not to the unit)
Data Transfer Applications		
Unable to send trace	Telephone Number incorrectly set	Re-configure telephone number
	Faulty modem card	Replace modem card
	Faulty modem cable	Replace modem cable
	No modem connected / set up	Configure modem
	Problem hospital end	Contact hospital

If trouble persists, consult your service centre or Huntleigh Healthcare using the contact details at the rear of this manual.

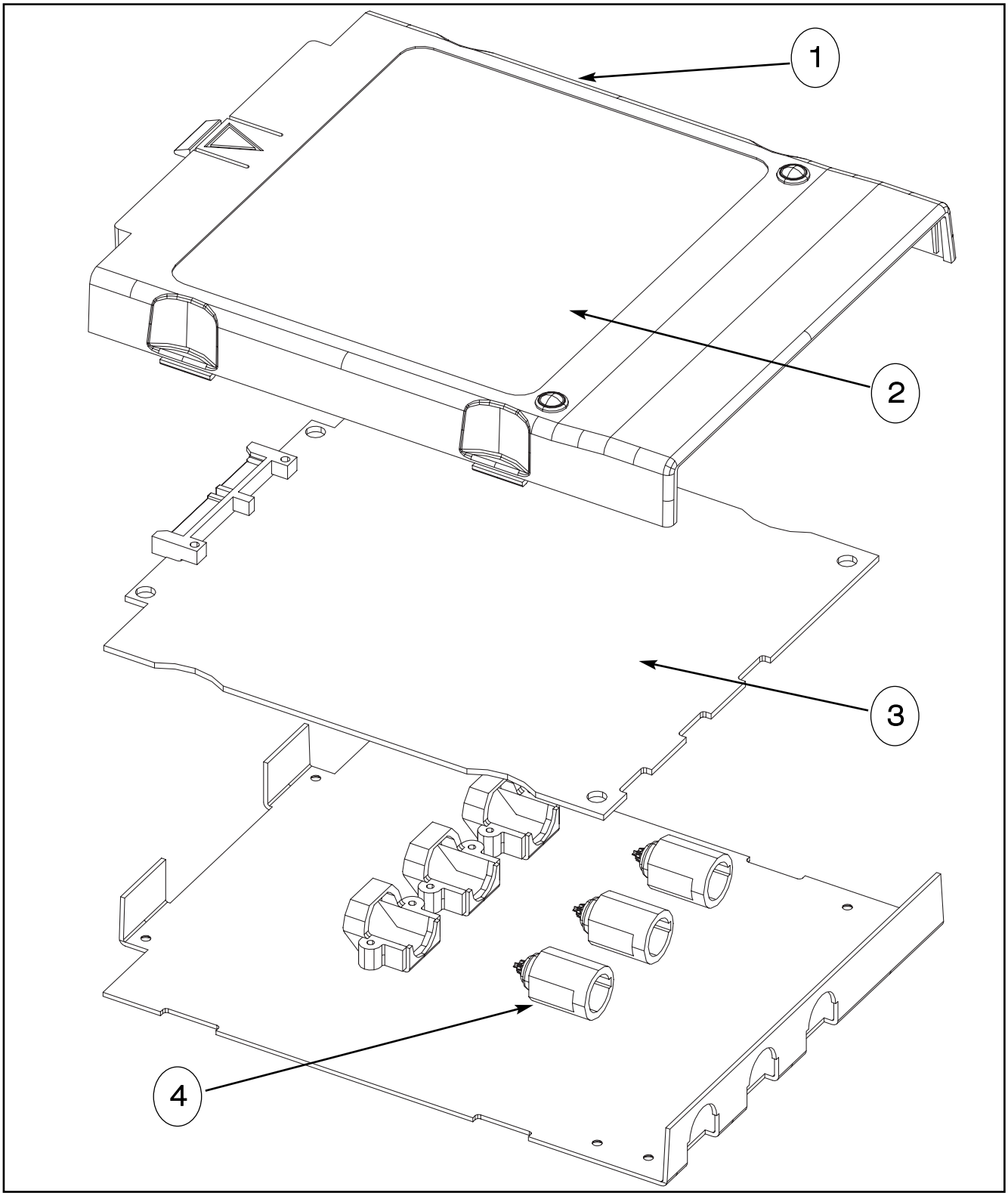
14. Modular Diagrams



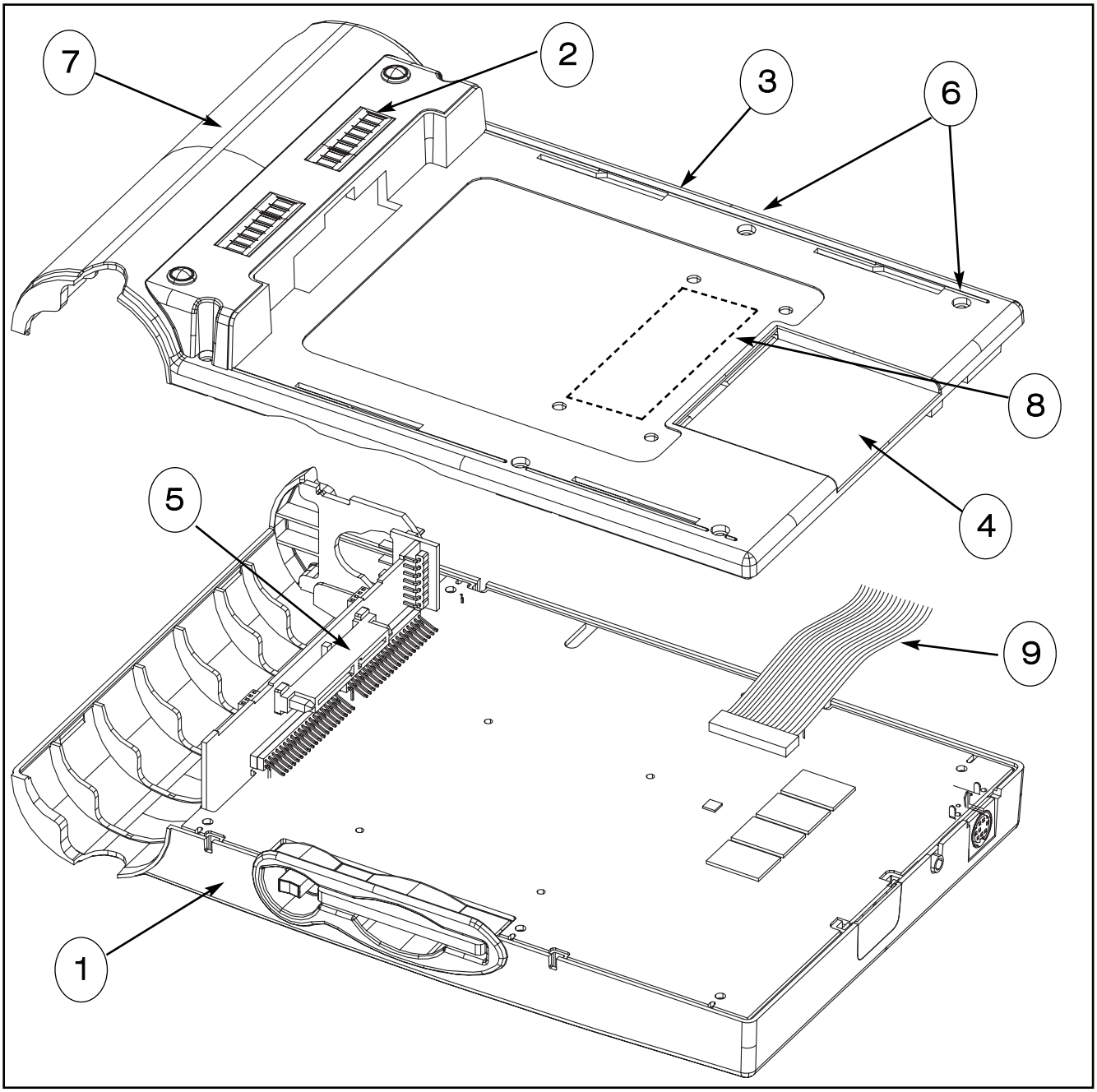
No.	Description	Part No.
1	TOUCH SCREEN	708322-2
2	KEYPAD	708310-1
3	BATTERY	ACC100
4	HOST REAR PANEL LABEL (USA) HOST REAR PANEL LABEL (REST OF THE WORLD)	708452-B 708446-1



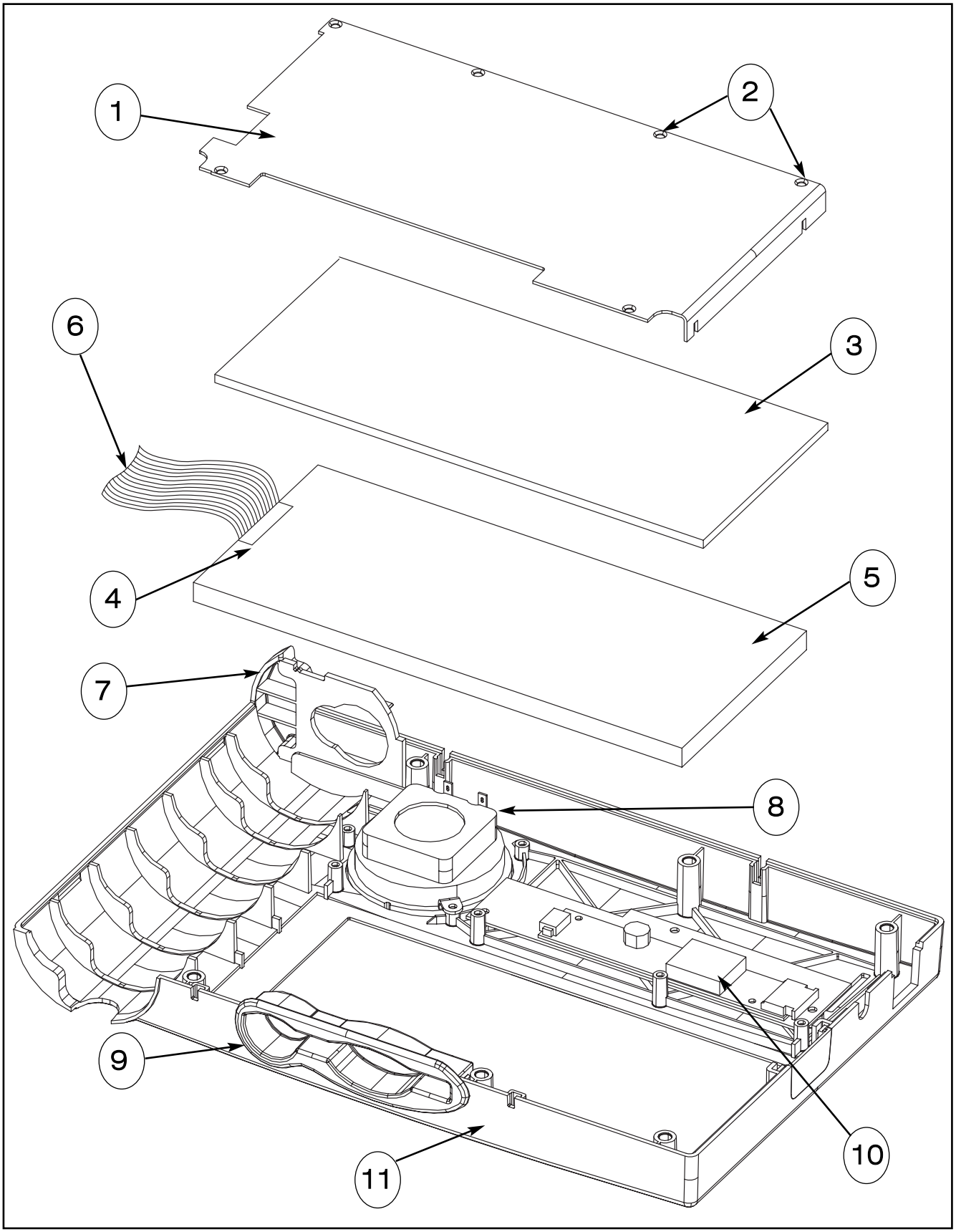
No.	Description	Part No.
1	CONNECTOR PANEL	710414 / VAS-2
	CONNECTOR PANEL	710414 / VPPG-2
	CONNECTOR PANEL	710414 / DOP-2
	CONNECTOR PANEL	710414 / COR-2
	CONNECTOR PANEL	710414 / OBS -2
2	HYPERTAC LOOM ASSY	709055
3	RUBBER FOOT (CLEAR)	P2644



No.	Description	Part No.
1	MODULE MOULDING	708314-1
2	MODULE REAR PANEL LABEL (USA)	709333-B
	MODULE REAR PANEL LABEL (REST OF THE WORLD)	708401-C
3	MODULE PCB - VAS	710052
	MODULE PCB - CAM	710129
	MODULE PCB - FETAL	709052
4	REDEL LOOM ASSY	709091-1

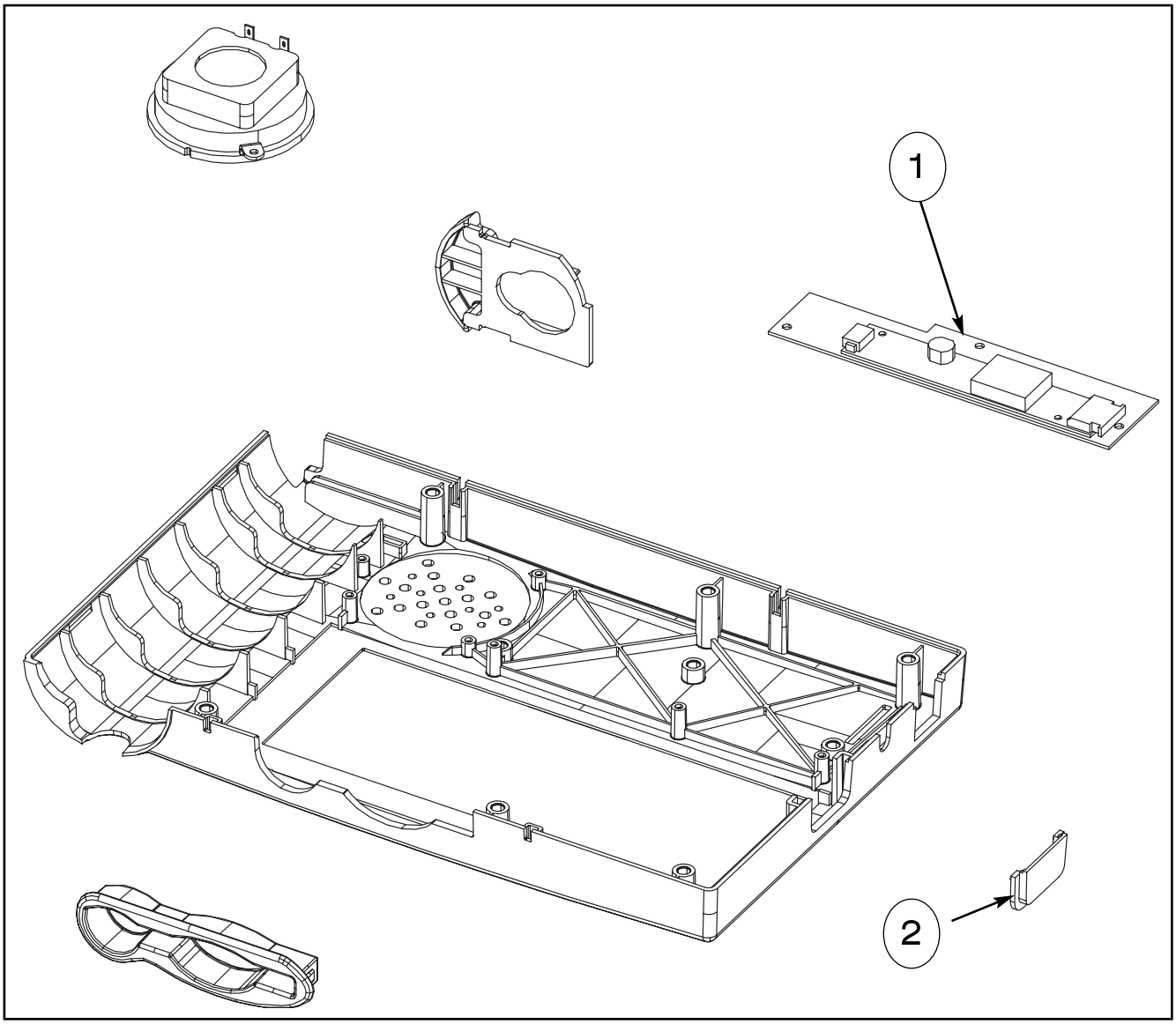


No.	Description	Part No.
1	FRONT CASE (NON SCREENED) FRONT CASE (SCREENED)	708302/B-2 708055
2	CONTACT PCB ASSY	708066
3	HOST REAR INSULATOR	708436-A
4	HOST REAR CASE INSULATION LABEL	708466-1
5	HOST BULKHEAD CONNECTOR INSULATION INSULATION LABEL (USA ONLY)	708478-1
6	CASE SCREWS (x 6)	M5 x 12-POZI-PA
7	REAR CASE (NON-SCREENED) REAR CASE (SCREENED)	708303 708065
8	PMA SMART CARD PCB ASSY	708067
9	FLAT FLEXI CABLE 80mm	FFC100A16/0070

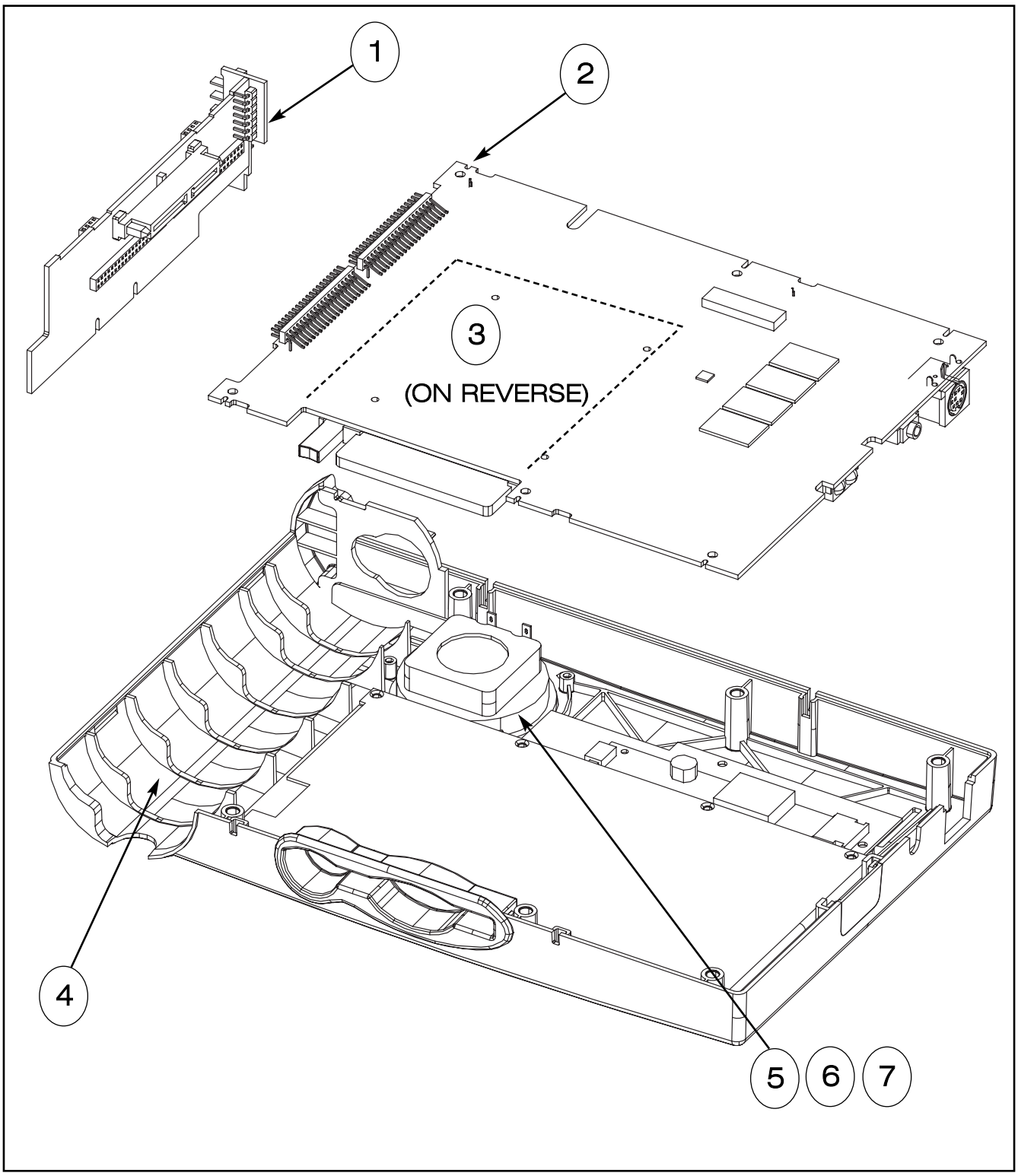


No.	Description	Part No.
1	METAL PLATE	708316-D
2	LCD PLATE SCREWS (x 6)	WN1413-KB22X8Z
3	FOAM PAD	708347-A
4	BERRILIUM FINGER	55EU102226

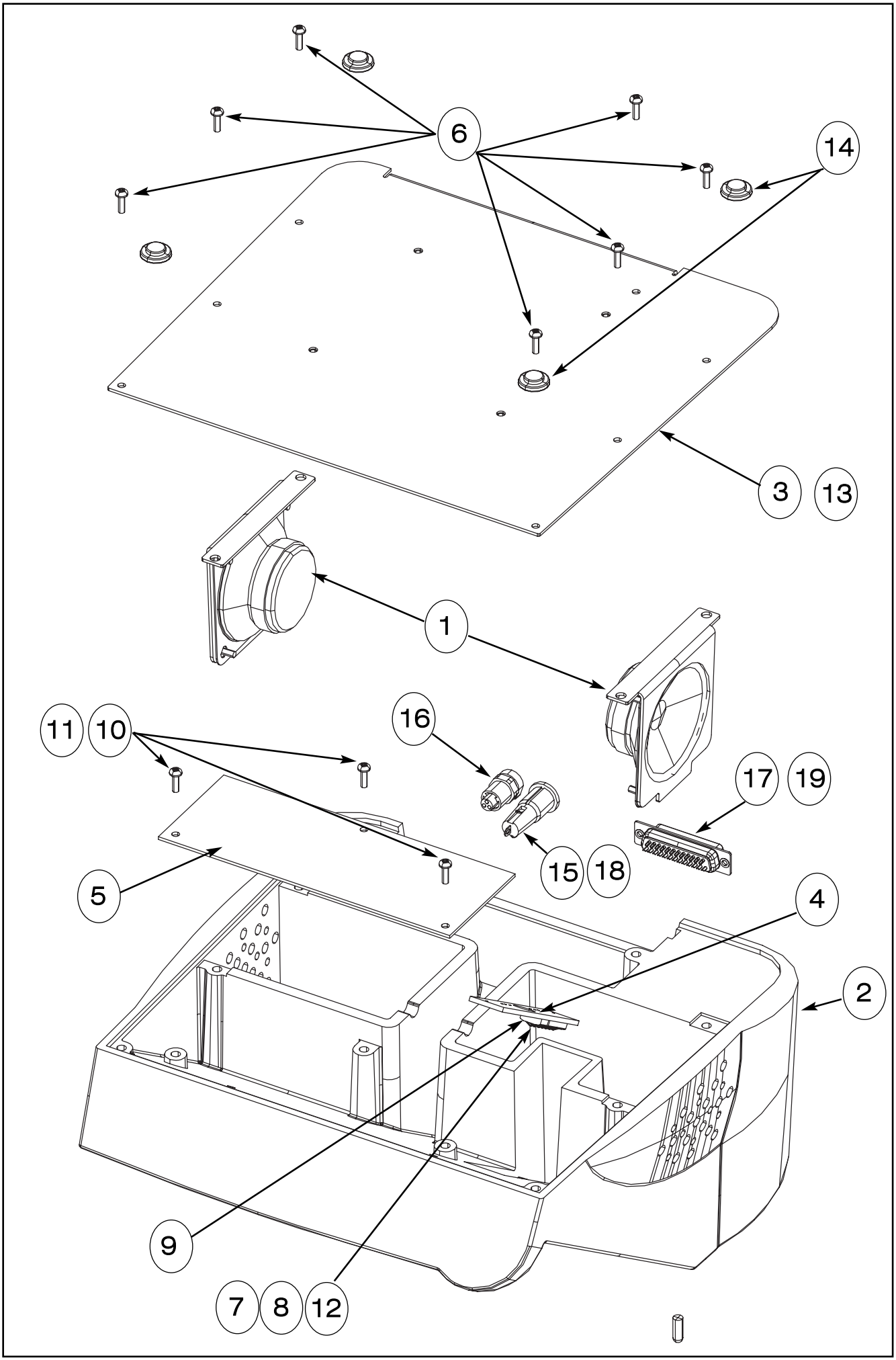
No.	Description	Part No.
5	LCD MODULE	LM7M632
6	RIBBON CABLE	708356-1
7	BATTERY CLIP	708312-D
8	8Ω SPEAKER	SLYDM50-8
9	BEZEL MOULDING	708313-1
10	VJL INVERTOR PCB	CXA-K0505
11	REAR CASE (NON SCREENED) REAR CASE (SCREENED)	708303-A 708464-2



No.	Description	Part No.
1	INVERTOR LEAD ASSY	708351-A
2	IRDA WINDOW	708311-C



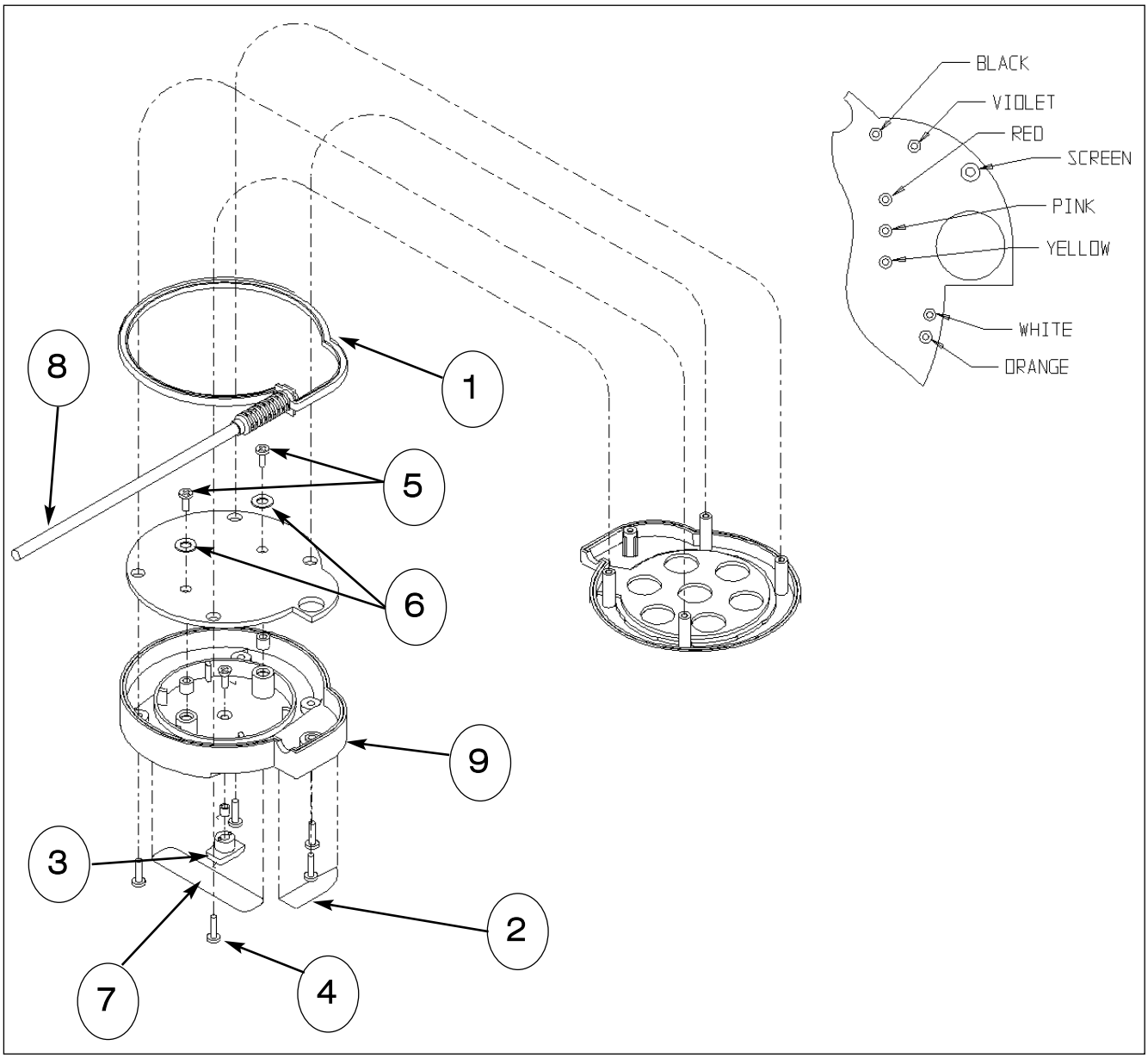
No.	Description	Part No.
1	BULKHEAD PCB	708061
2	MAIN PCB	708057
3	INSULATION LABEL (PC-CARD)	708414-1
4	PAKCEL PAD	708348-A
5	SPEAKER GASKET	708323-2
6	SPEAKER SPACER	708349-A
7	CLAMPING PLATE	708405-B



No.	Description	Part No.
1	SPEAKER ASSEMBLY	708075
2	DOCKING STATION ASSEMBLY	708076
3	BASEPLATE ASSEMBLY	708077
4	PMA INTERFACE PCB	708078
5	CONVERTER/AMPLIFIER PCB	708079
6	SCREW POZI PAN HEAD BZP&CP (x 7)	M3X8-POZI-PAN
7	SCREW POZI PAN HEAD BZP&CP	M3X4-POZI-PAN
8	INTERFACE PCB MOUNTING BLOCK	708422-A
9	DOCKING STATION INTERFACE CABLE	708423-A
10	SCREW POZI PAN HEAD BZP&CP (x 3)	M3X6-POZI-PAN
11	M3 NYLON WASHER (x 3)	M3-WASHER-N
12	WASHER, CRINKLE	M3-WASHER-C
13	BASE PLATE	708325-1
14	TOP HAT BUMB ON FEET (x 4)	SJ6115
15	FUSE HOLDER	T0340RD
16	PANEL MOUNT CONNECTOR ASSEMBLY	708099
17	D-TYPE SCREWLOCK ASSY FEMALE 8mm	814-023
18	3.15A 20 mm FUSE, T-TYPE	S505-3.15
19	DOCKING STATION 26 WAY CABLE ASSY	708098

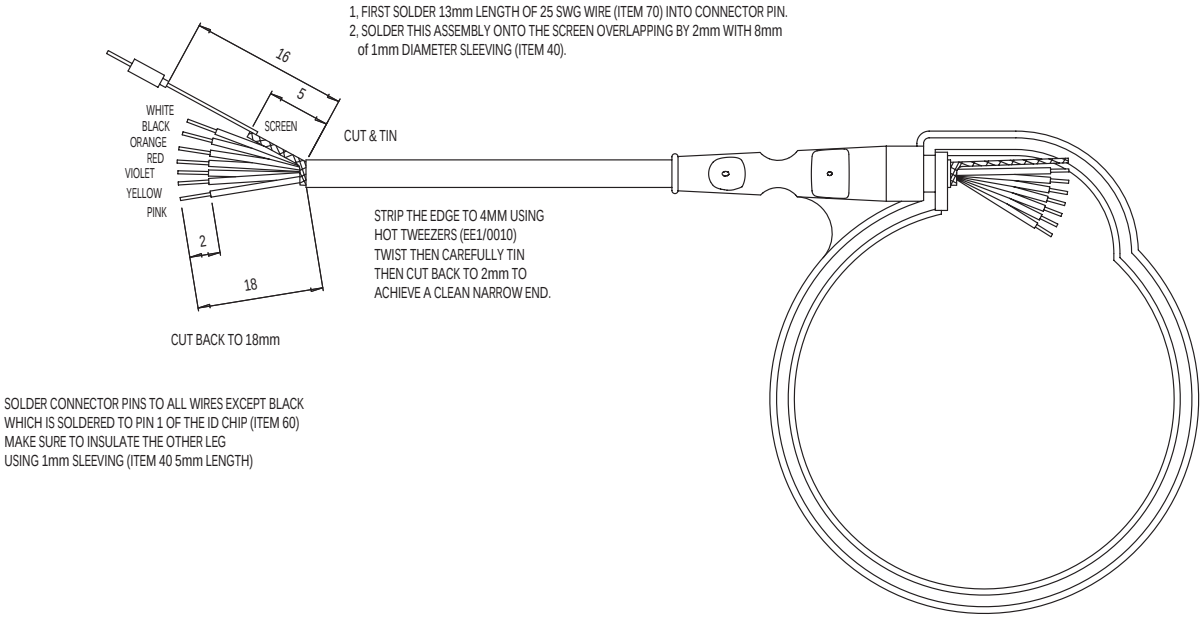
15. Transducer / Cable Assemblies

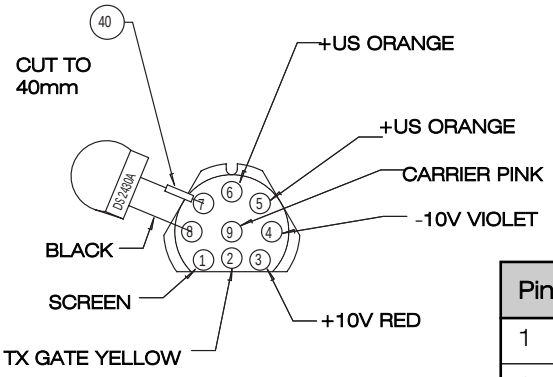
15.1 AUS3 Ultrasound Transducer Assembly

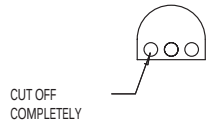


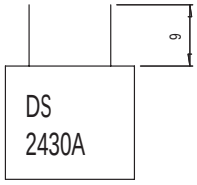
No.	Description	Part No.
1	CABLE ASSEMBLY (REDEL CONNECTOR) CABLE ASSEMBLY (HYPERTAC CONNECTOR)	709088 709059
2	AUS LABEL	709307-A
3	AUS3 BUTTON	674408
4	SELF TAP SCREW (X 5)	WN1412-KB22-8
5	POZIPAN SCREW	M2.5 X 6 - POZI - PAN
6	M2.5 - WASHER	M2.5 - WASHER - 5
7	SERIAL NUMBER LABEL	709309-1
8	CABLE	614339-3
9	TDR TOP MOULD (DARK GREY) TDR TOP MOULD (PALE GREY)	614078-DG-2 614078-PG-2

AUS 3 Cable Assembly (Hypertac)

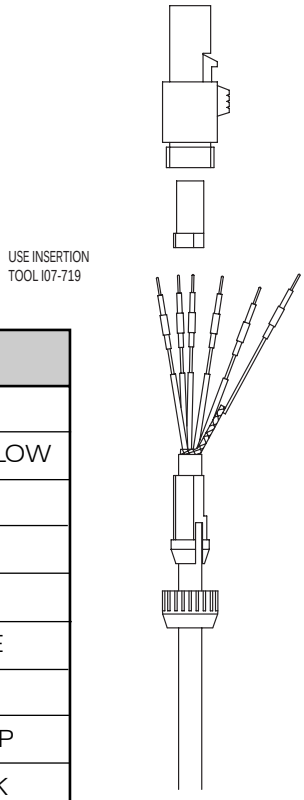






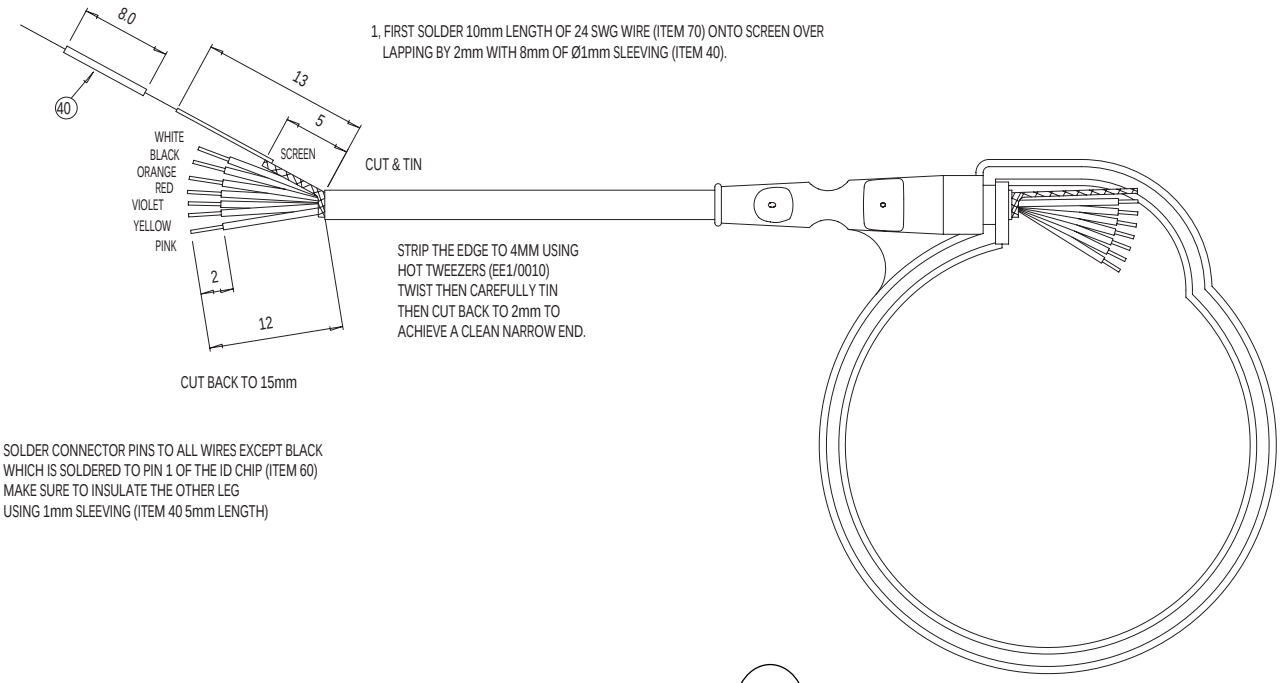


Pin	Wire
1	SCREEN
2	TX GATE YELLOW
3	+10V RED
4	-10V VIOLET
5	-US WHITE
6	+US ORANGE
7	ID CHIP
8	BLACK/ID CHIP
9	CARRIER PINK

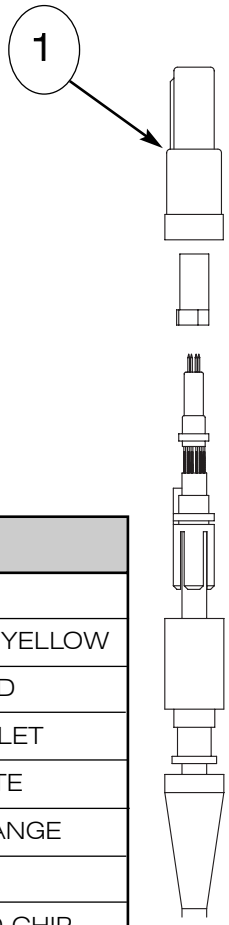


No.	Description	Part No.
1	HYPERTAC CONNECTOR	D01PB904MSUTH

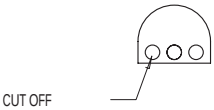
AUS 3 Cable Assembly (Redel)



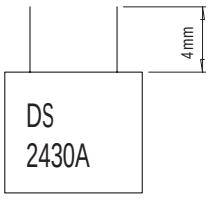
SOLDER CONNECTOR PINS TO ALL WIRES EXCEPT BLACK WHICH IS SOLDERED TO PIN 1 OF THE ID CHIP (ITEM 60) MAKE SURE TO INSULATE THE OTHER LEG USING 1mm SLEEVING (ITEM 40 5mm LENGTH)



CUTTING ID CHIP LEG



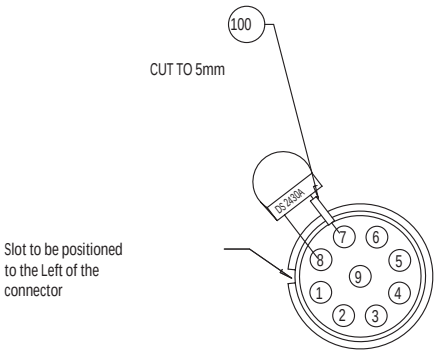
REMAINING LEG LENGTHS



ASSEMBLY INSTRUCTIONS

1, SLIDE STRAIN RELIEF, COLLET NUT AND COLLET ONTO CABLE.
2, CUT BACK CABLE (15mm) TO EXPOSE WIRES. CUT OFF THE PINK, RED AND YELLOW WIRES AND THEN STRIP THE REMAINING WIRE BY 5mm.
3, SOLDER 13mm LENGTH OF 24 SWG WIRE (ITEM 70) ONTO SCREEN OVER LAPPING BY 2mm WITH 8mm OF 1mm DIAMETER SLEEVING (ITEM 40).
4, TIN WIRES AND CUT OFF 3mm.
5, SOLDER ID CHIP TO PLUG ENSURING TO INSULATE PIN 7 LEG WITH SYNEL FIRST AS SHOWN.
6, SOLDER WIRES FROM CABLE TO PLUG AS SHOWN, STARTING WITH THE BLACK WIRE (ATTACHING TO EXPOSED LEG OF ID CHIP) AND THEN INSULATING ALL OTHER WIRES BEFORE SOLDERING.

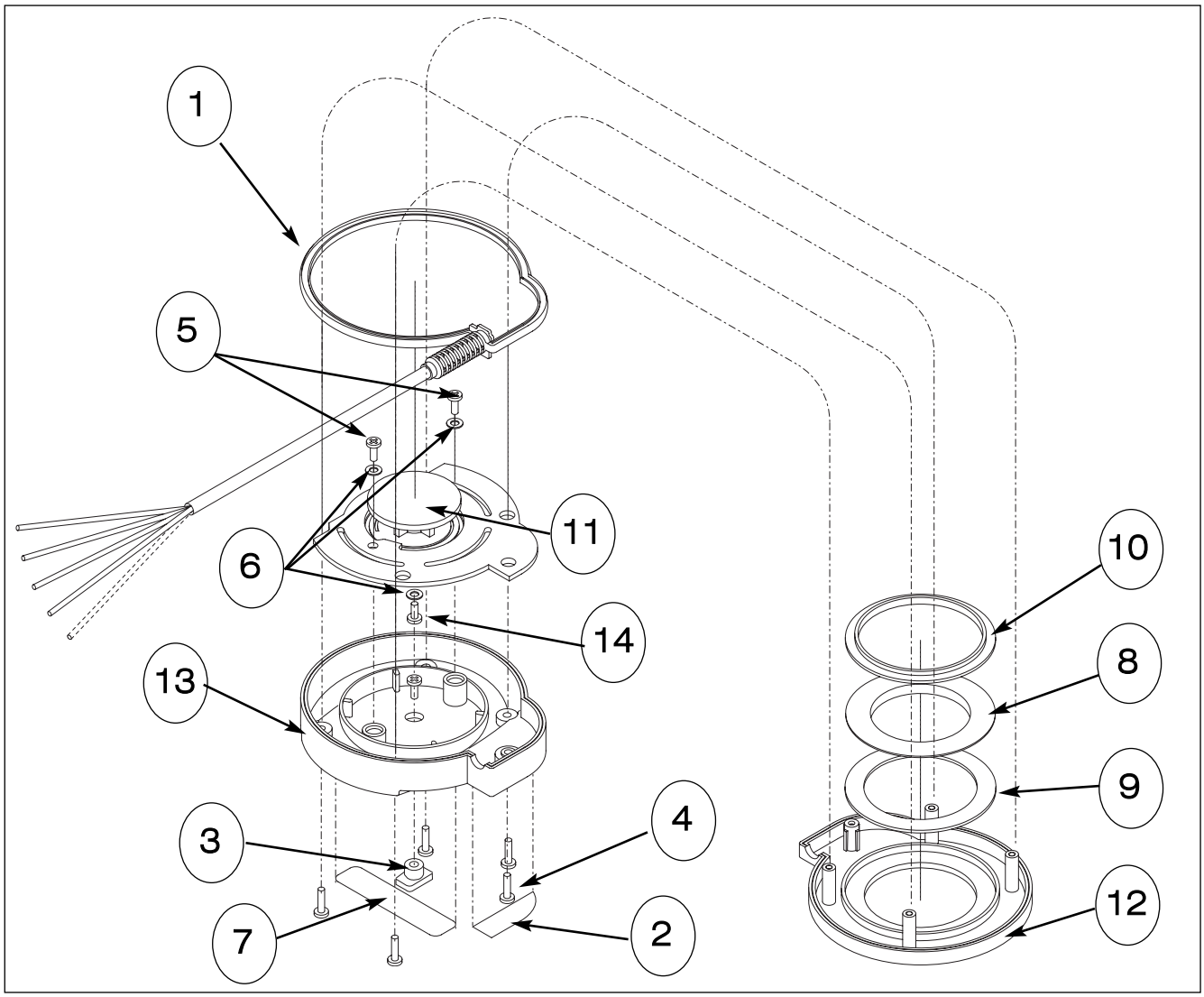
CONNECTOR WIRING



Pin	Wire
1	SCREEN
2	TX GATE YELLOW
3	+10V RED
4	-10V VIOLET
5	-US WHITE
6	+US ORANGE
7	ID CHIP
8	BLACK/ID CHIP
9	CARRIER PINK

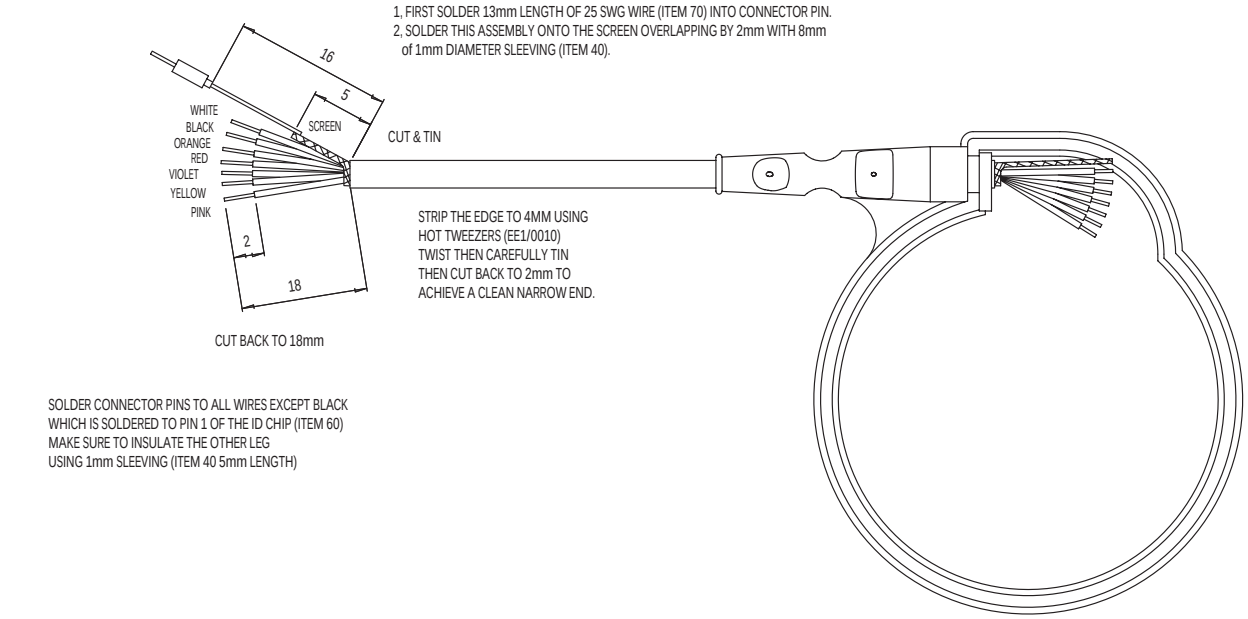
No.	Description	Part No.
1	REDEL CONNECTOR	PAGMOGGLAC52NZ

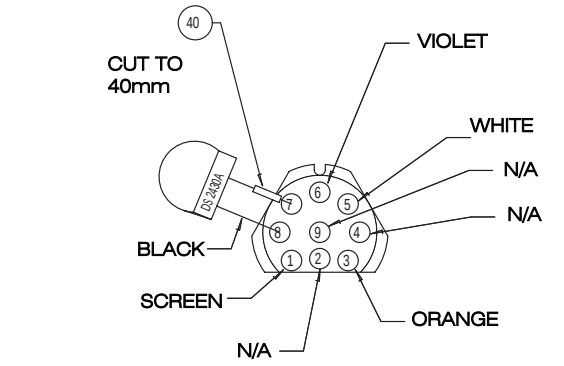
15.2 ACT 3 Transducer Assembly

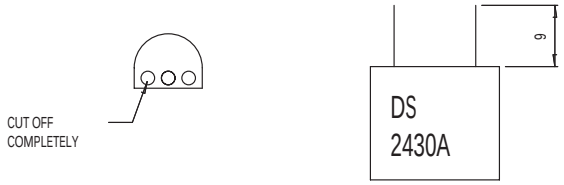


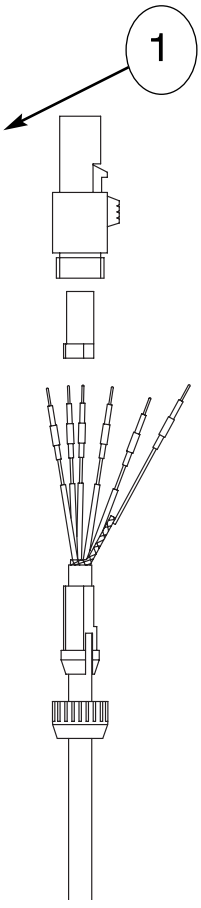
No.	Description	Part No.
1	CABLE ASSEMBLY (REDEL CONNECTOR) CABLE ASSEMBLY (HYPERTAC CONNECTOR)	709086 709062
2	ACT3 LABEL	709308-A
3	ACT3 BUTTON BLUE	674408
4	SELF TAP SCREW (X 5)	WN1412-KB22-8
5	POZIPAN SCREW	M2.5 X 6 - POZI - PAN
6	M2.5 - WASHER	M2.5 - WASHER - 5
7	SERIAL NUMBER LABEL	709310-1
8	BOOT	1211-8
9	SEALING GASKET	1208
10	TRANSDUCER SPACER	1209-2
11	ACT3 BUTTON	1210
12	TDR BOTTOM MOULD (DARK GREY) TDR BOTTOM MOULD (PALE GREY)	248301/DG/1-7 248301/PG/1-7
13	TDR TOP MOULD (DARK GREY) TDR TOP MOULD (PALE GREY)	248300/DG/IN-9 248300/PG/IN-9
14	SELF TAP SCREW	WN1412-KB25-8R0

ACT 3 Cable Assembly (Hypertac)





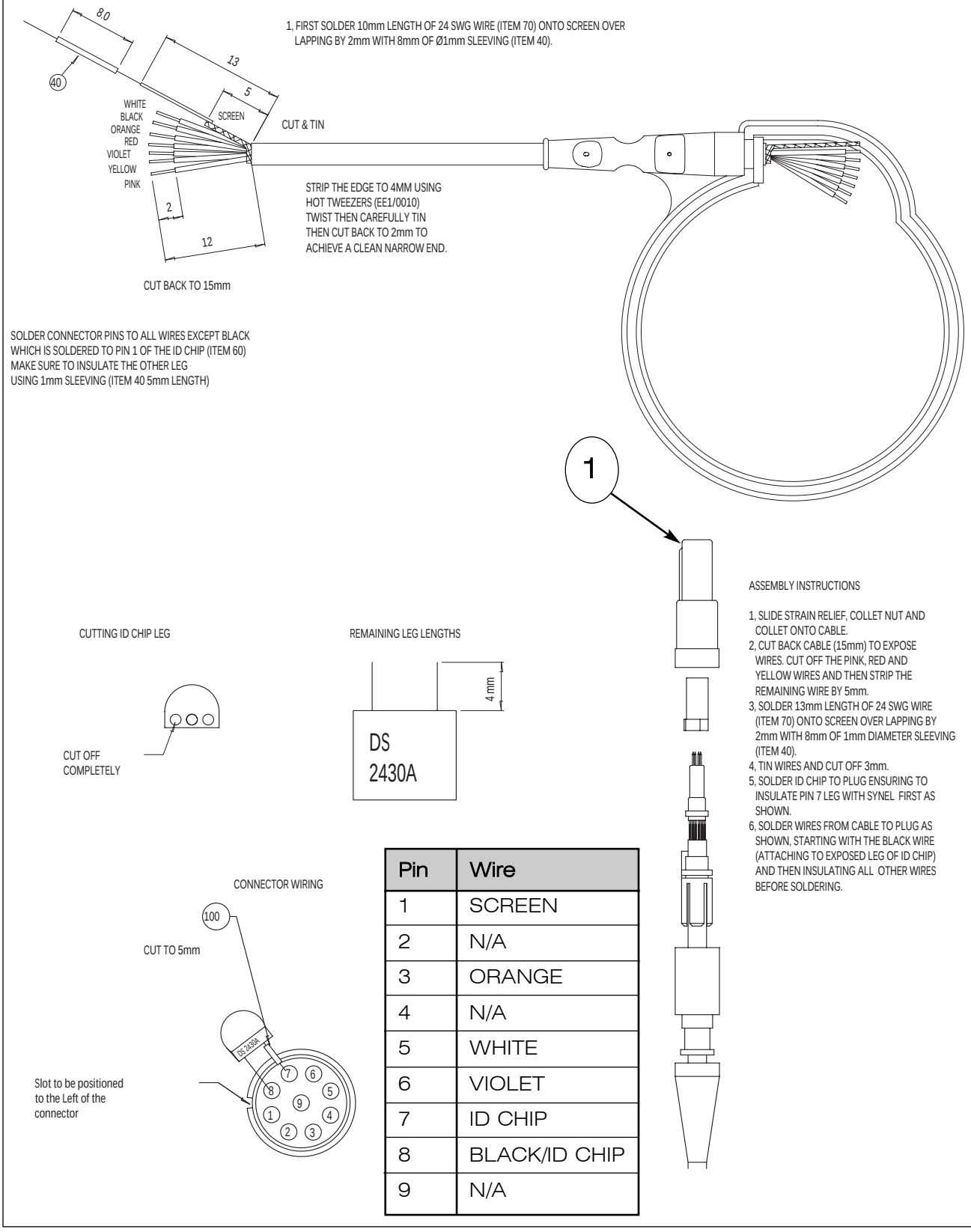




Pin	Wire
1	SCREEN
2	N/A
3	ORANGE
4	N/A
5	WHITE
6	VIOLET
7	ID CHIP
8	BLACK/ID CHIP
9	N/A

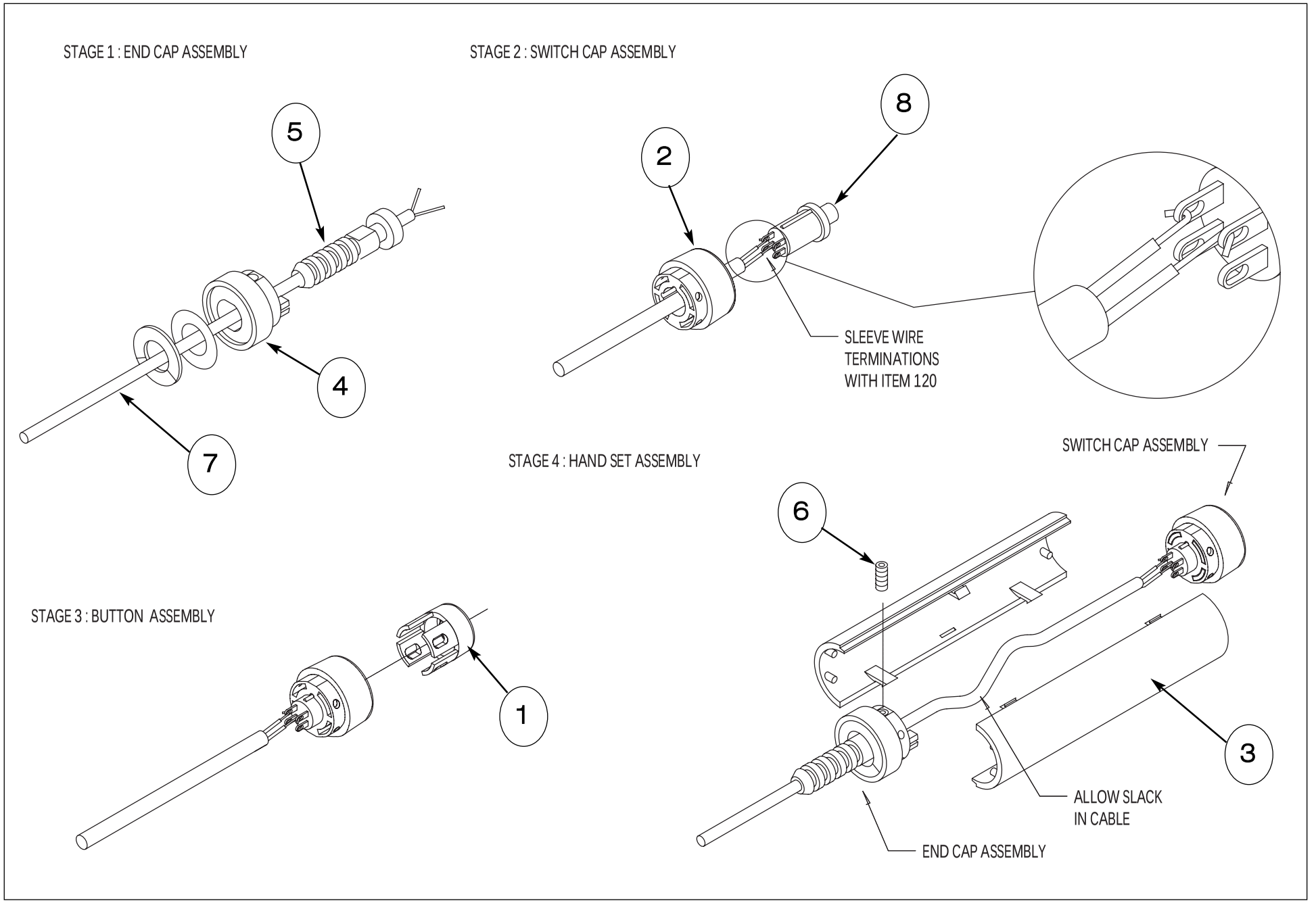
No.	Description	Part No.
1	HYPERTAC CONNECTOR	D01PB904MSUTH

ACT 3 Cable Assembly (Redel)



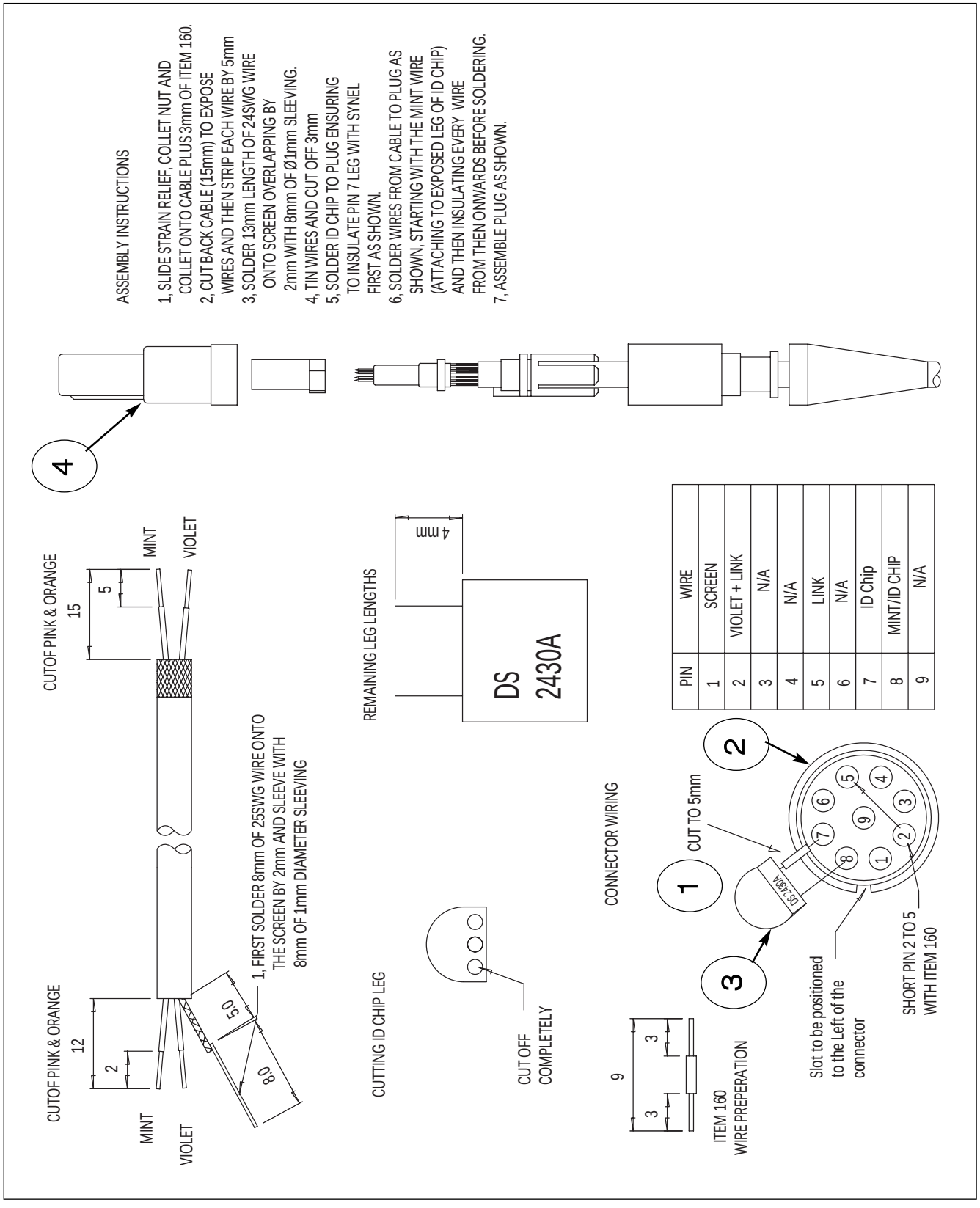
Pin	Wire
1	SCREEN
2	N/A
3	ORANGE
4	N/A
5	WHITE
6	VIOLET
7	ID CHIP
8	BLACK/ID CHIP
9	N/A

No.	Description	Part No.
1	REDEL CONNECTOR	PAGMOGGLAC52NZ



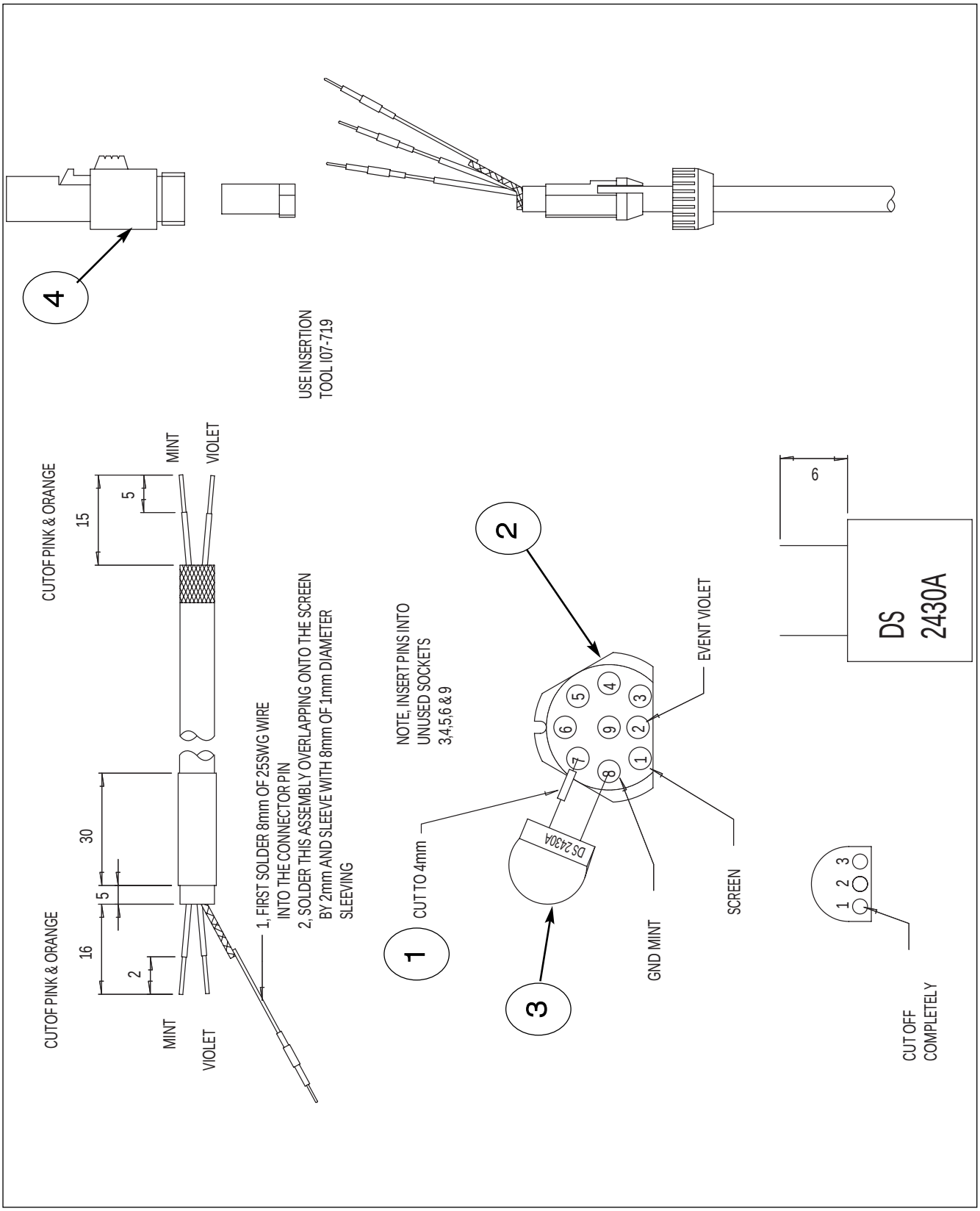
No.	Description	Part No.
1	EVENT MARKER BUTTON	248323-4
2	EVENT MARKER TOP	248324-2
3	PROBE CASE HALF	6AE114-2
4	END CAP - DARK GREY	6AE115/DG-6
5	CABLE GROMMET	6AE113-2
6	GRUB SCREW	M3X6 - GRUB
7	CABLE EVENT MARKER	248388-5
8	MINIATURE SWITCH	0041.8841.6106

AEM3 Cable Assembly (Redel)



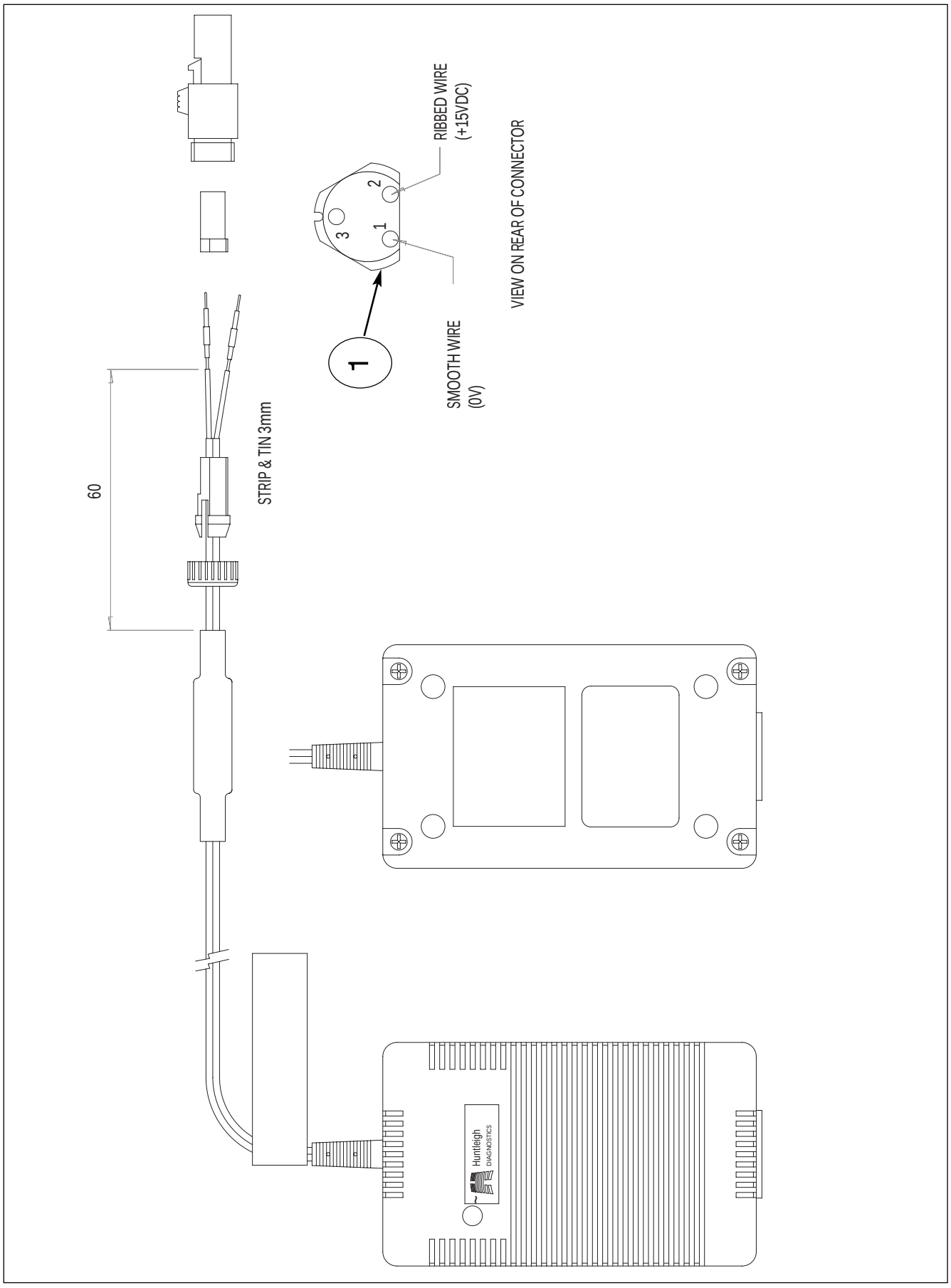
No.	Description	Part No.
1	SILICONE RUBBER 1MM SLEEVING	399-394
2	CABLE ASSEMBLY (REDEL CONNECTOR)	PAGM09GLAC39NZ
3	256 BIT EEPROM	DS2430A
4	REDEL CONNECTOR	PAGMOGGLAC52NZ

AEM3 Cable Assembly (Hypertac)



No.	Description	Part No.
1	SILICONE RUBBER 1MM SLEEVING	399-39
2	CABLE ASSEMBLY (HYPERTAC CONNECTOR)	D01PB904MSUTH
3	256 BIT EEPROM	DS2430A
4	HYPERTAC CONNECTOR	D01PB904MSUTH

15.4 Mains Power Adaptor Assembly



No.	Description	Part No.
1	MAINS ADAPTOR HYPERTAC CONNECTOR	D01P306MST

16.0 Fetal Functional Inspection & Test Procedure

16.1 SOAK TEST

Connect all transducers to unit and plug in power block to operate from mains power.
Turn unit ON and leave in main start-up screen. Run unit for 24 hours.
Indicate TIME ON and TIME OFF on DHR.

16.2 POST SOAK TEST

1. TIME AND DATE SETTINGS

Press the button, to turn Unit On.

When main screen comes up you are asked if the time and date are correct.

Press the green tick for YES'

Press the red cross for NO '

To adjust the time.

After pressing the Red cross you will be presented with UP/DOWN arrows to allow the time and date to be changed.

When date and time are correct, exit by pressing the key

2. SOFTWARE VERSION

When back in main screen check software version displayed on screen.

Please contact Huntleigh Healthcare Ltd, Diagnostic Products Division, Service Dept., for current software status.

3. TOUCHSCREEN CALIBRATION/SMART CARD CHECK

Press the key. This brings up the User-Setup screen.

Press the key below the icon showing

Enter Access Code *5315*. When done press the key.

In the Assist Upgrade Facility screen press the top right key below the icon showing a hand.

In the calibration screen, the target appears top left-hand corner. Use the point of a ballpoint pen and touch the centre of the target and repeat as target moves around the screen, (see on screen instructions).

When complete press the key twice to return to the main start screen.

Then turn unit OFF.

Then turn unit ON.

From now on use softkeys/keypad to select options not touchscreen, except where necessary.

3.1 Then press the key.

Enter Password ' 1351. When entered press the key. Press the key.

Use touch screen to ensure unit is correctly calibrated. Use the touch-screen to select keys and observe the correct numeral or digit is displayed when chosen on the screen. If after calibration touch-screen does not correctly identify a key-press Fail the unit.

Press the key when test complete.

3.2 Insert smartcard. Press key. "Reading Smartcard' displayed, then 'Patient Details Not Found' box displayed. Press key.

Type in the following: - '0' (zero). Press the key, then press the key . This returns you to the patient information screen. Press the key. The Trace Review screen will appear, check that the surname and hospital ref. are correct ('backup' & '0'). Press the key 3 times, this will return you to the main screen. Remove the smartcard.

3.3 To verify the information has been saved, press the key , this will take you to the QWERTY screen, again select and confirm the backup file is present. Press the key twice, this will return you to the main screen.

4. BATTERY INDICATOR

The Battery level indicator should be GREEN in colour. No RED areas will be showing. If they are, investigate fault.

5. USER SETTINGS

Press the key.

5.1 Adjust the Brightness using the touch-screen scroll bars in the Power-Up settings.

5.2 Adjust the Contrast using the touch-screen scroll bars in the Power-Up settings. (The LCD screen should respond to the input).

Set Chart Settings to 1cm/min and scale to 50-210bpm.

Press the key.

Use the touch-screen to enter phone number: - _ _ _ _ _ _ _ _ _ _ to your receiving station, if applicable, or Centrale.

To exit this screen press

5.3 Press the key. A red bar will appear bottom centre of screen. Pressing this key a number of times will scroll between Contrast/Brightness and Volume.

Select Brightness,

Using the Volume UP/DOWN keys the red bar should increase/decrease in response to the control. Also the LCD display will darken/brighten.

5.4 Press the key, and select Contrast.

Using the Volume UP/DOWN keys the red bar should increase/decrease in response to the control. Also the LCD display will darken/brighten.

6. TRANSDUCERS.

Plug all three transducers into the sockets provided on the module. (This can be done with the Host ON or OFF).

From the main screen press the key. This brings up the Charting screen. Press the key. This will then change to

6.1. Press the key. This zeroes the TOCO. Depress the TOCO (ACT3) transducer to simulate a Uterus contraction. The Chart will show the TOCO trace corresponding to the user input.

6.2. Depress the Event (AEM3)marker. A BLUE mark should appear on the Chart.

6.3. Stroke the Ultrasound (AUS3) transducer to simulate a foetal heartbeat. A trace should appear and the bpm counter should show the foetal heart rate. Whilst stroking the AUS3 transducer adjust the volume level. Check that the audio quality is good and there are no unusual noises. Also check for speaker rattle

Repeat steps 6.1-6.3 testing each transducer in each port.

6.4 Plug in a set of Stereo headphones. Again stroke the AUS3 transducer, listen for sound in both the left and right ear-pieces. Check that loudspeaker is muted.

Press the key. A blue window will be displayed, press the key twice, this will return you to the main screen.

6.5 ENTERING HOST/MODULE DETAILS

Press the key. In the Surname or Ref window type the last five digits of the Host serial number.

For example H43-99. Press the key

A blue window will then appear, Press the key.

The patient information screen will then appear. With the SURNAME box highlighted.

Press the key.

Type in the Host and Module number, for example H43-99M33-00. Press the key. This returns you to the patient information screen. Press the key twice, this will return you to the main screen.

7. TEST TRACE

Starting the trace: -

From main screen place unit into charting mode by pressing the key.

Press the, key, this will then change to , this shows the trace is running.

IMPORTANT: - At this stage the TOCO must be zeroed.

Press the ACT3 zero button , ensure the ACT3 trace settles at the 20% line when the button is pressed

Stroke the AUS3 transducer to simulate the Fetal Heart Rate.

When the trace has finished: -

Press the, key. You will next be presented with a blue dialogue box. Press the key.

In the next screen press the key.

The Module and Host number will now appear in the Patient column. Press the key twice.

Return to main screen by pressing the key.

8. SENDING TRACE TO CENTRALE

Ensure the PC is switched ON and the Centrale software is running.

Insert the PCMCIA Modem into slot in Assist Host.

Ensure unit is in Main start-up screen.

Ensure Password (1351) has been entered. If not follow procedure outlined in section 3.1.

Press the key. In the top right-most corner of the touch-screen is now displayed a symbol.

Select this symbol on the screen. A file register is then brought up. The Patient name column will contain the Host and Module number entered earlier in the test,

for example H43-99M33-00.

Select this by pressing the key. The Patient detail screen will then be displayed.

Again press the key.

On the next screen press the key.

The unit will now send the trace via the modem to the Centrale receiving station. The unit will display that the transmission is complete.

When complete press the key three times to return to main screen.

9. DOCKING STATION TEST .

9.1 Connect Docking Station to printer.

9.2 Dock Assist onto Docking Station.

9.3 Insert Hypertak connector from power adaptor to Docking Station. The Green LED on the Docking station will illuminate.

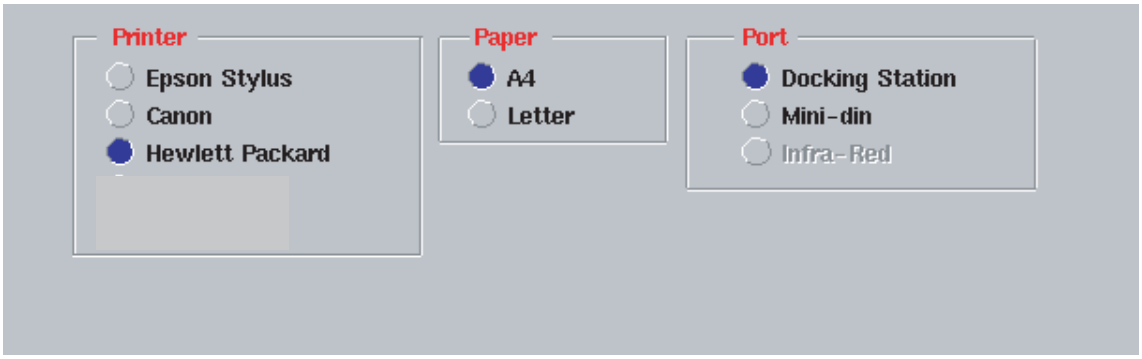
9.4 Ensure the orange LED on the Assist Battery is illuminated. If not FAIL the unit.

9.5 Turn the Assist ON. Enter password as in section 3.1.

9.6 Press the tool bar. You will now be in the Power Up settings screen.

9.7 Press the printer bar . You will now be in the Printer settings screen.

9.8 Ensure the printer settings are as shown opposite: -



9.9 When correct press the key twice.

9.10 When back in main screen press the key. In the next screen press the key.

In the next screen select required trace to print. Press the key. In the next screen press the key.

The next screen shows trace date, and type. Press the key.

9.11 The trace now loads and is presented in the charting screen.

To print the trace press the key.

10. MINI-DIN TEST

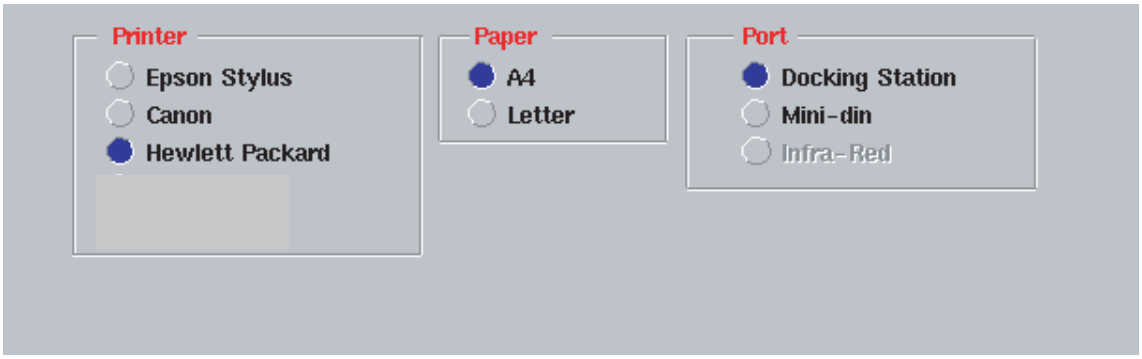
Connect Serial - Parallel converter to Mini-Din Socket and printer.

10.1 Turn the Assist ON. Enter password as in section 3.1.

10.2 Press the tool bar. You will now be in the Power Up settings screen.

10.3 Press the printer bar . You will now be in the Printer settings screen.

10.4 Ensure the printer settings are as shown below: -



10.5 When correct press the key twice.

10.6 When back in main screen press the key. In the next screen press the key.

In the next screen select required trace to print. Press the key. In the next screen press the key.

The next screen shows trace date, and type. Press the key.

10.7 The trace now loads and is presented in the charting screen.

To print the trace press the key.

11. VGA TEST

Plug the VGA adaptor into the MINI-DIN socket on the side of the ASSIST. Connect the other end of the adaptor to the cable of VGA monitor . Turn the Assist ON. The VGA monitor will simultaneously display what is on the LCD display of the ASSIST. If not fail the unit

12. COSMETIC

Check quality of fit of all mouldings.

Check quality and fit of all labels.

Check that battery catch operates smoothly, and battery case and slot are correctly assembled

17.0 Field Software Upgrades For Fetal Assist

1. EQUIPMENT REQUIRED

- Smartcard
- PCMCIA Memory card containing software upgrade
- Assist unit
- Power adaptor

Hospital / Clinic / Dept	:	_ _ _ _ _ _ _ _ _ _ _ _ _ _
Host serial number	:	_ _ _ _ _ _ _ _ _ _ _ _ _ _
Module serial number	:	_ _ _ _ _ _ _ _ _ _ _ _ _ _
Original software version	:	_ _ _ _ _ _ _ _ _ _
New software version	:	_ _ _ _ _ _ _ _ _ _
Installer's name/position	:	_ _ _ _ _ _ _ _ _ _ _ _ _ _
		_ _ _ _ _ _ _ _ _ _ _ _ _ _
Signature	_ _ _ _ _ _ _ _ _	Date : _ _ / _ _ / _ _

2. PROCEDURE

Ensure battery is fully charged or plug into mains.
(ensure battery starts charging)
Ensure there is NO PCMCIA card connected and switch ON unit.
Press  to confirm Time/Date are correct.
Press  which displays the 'QWERTY' screen.
Insert the Smartcard as shown  . 'Reading Smartcard' then 'Upgrade Complete' messages will be displayed.
Turn the unit off and remove smartcard.
Switch On unit again. Press  if prompted to confirm Time/Date are correct.
Press  to go into set-up menu. Press  for advanced options.
Enter PIN code 5315 and press 
Install the PCMCIA ATA card (32MB Kingmax or 32MB Pretec) and **WAIT FOR TEN SECONDS.**
Press  on the touchscreen selecting update via PCMCIA card.
The first stage of the update will be quick (<10 seconds).
When the first stage of the update is complete, follow the on screen messages or wait for the messages to clear.
Turn the Assist off, then back on. **LEAVE THE PCMCIA CARD IN AT ALL TIMES!**
The second stage of the update (installing QNX & Host Executive) will commence, with some initial textual diagnostics in a window on the LCD and then a pause whilst nothing appears to happen. **DO WAIT!**
When the second stage is complete (approx 5-8 mins), it will prompt you to re-calibrate the touch screen. Go around the screen with a pen or similar object in the usual way.
The 3rd stage will commence automatically after the touch screen has been calibrated.
The 3rd stage will program the latest application software into the module. A progress bar will indicate progress (takes around 15-20 minutes). Assist should automatically turn off after update is complete.
Remove PCMCIA card and turn Assist on.
Set the time & date. Re-calibrate the touch screen again. Check appropriate revision of firmware is installed.

3. FUNCTIONAL TESTS

Check all functions before commissioning. Ensure patient files can be stored and retrieved successfully.

4. DOCUMENTATION

Please enter the details required, and sign and date this form, then return it, together with the PCMCIA memory card and Smartcard to :
Service Dept, Huntleigh Healthcare Ltd, 35, Portmanmoor Road, Cardiff CF24 5HN.

18.0 Warranty & Service

Huntleigh Healthcare's standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

USA Warranty only

a) HUNTLEIGH HEALTHCARE INC. HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES (INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND ANY AGREEMENTS, REPRESENTATIONS, AFFIRMATIONS, OR WARRANTIES, WHETHER ORAL OR WRITTEN, MADE BY ANY AGENT, EMPLOYEE OR REPRESENTATIVE OF HUNTLEIGH HEALTHCARE INC., UNLESS SPECIFICALLY SET FORTH IN THIS PARAGRAPH. HUNTLEIGH HEALTHCARE INC. SHALL NOT BE LIABLE FOR BREACH OF CONTRACT ARISING FROM ANY DEFECT IN MATERIAL OR WORKMANSHIP OF THE GOODS. ALL LEGISLATION RELATING TO EXPRESS AND IMPLIED WARRANTIES OR OTHER OBLIGATIONS ON THE PART OF HUNTLEIGH HEALTHCARE INC. THAT MAY BE LAWFULLY EXCLUDED ARE HEREBY EXCLUDED.

b) Notwithstanding the foregoing, Huntleigh Healthcare Inc.'s sole warranty is that the Goods shall be free from defects in material and workmanship for a period, of twenty four (24) months for the Fetal Assist and twelve (12) months for the transducers, following delivery of such Goods to the original purchaser; provided that the Goods were used in an appropriate and reasonable manner during such period and provided further that Huntleigh Healthcare Inc. shall in no event be liable to Customer for defective Goods if: (i) the Goods are damaged in the course of shipping; (ii) any defect is caused wholly or to any material extent by Customer's negligence, misuse, failure to use the Goods properly or use of the Goods in conjunction with any accessory not approved for use with the Goods by Huntleigh Healthcare Inc.; (iii) the Goods are damaged as a result of improper maintenance, failure to follow manufacturer's instructions, including without limitation those on washing and cleaning, or failure to follow necessary routine maintenance procedures; or (iv) the Goods are altered, repaired or dismantled other than with manufacturer's written authorisation using its approved procedures or by any party other than manufacturer's properly qualified and trained technicians.

c) Customer must provide written notice to Huntleigh Healthcare Inc. within said period, twenty four (24) months for unit or twelve (12) months for transducers, of any defect in the Goods. Upon Huntleigh Healthcare Inc.'s written request, Customer must return such Goods adequately packed (in their original packing) and fully insured to Huntleigh Healthcare Inc.'s place of business and shall be responsible for all shipping costs incurred therein. Customer's exclusive remedy and Huntleigh Healthcare Inc.'s exclusive liability for any claim for loss, damage or destruction resulting from any defects in materials and workmanship shall be limited to repair, service, adjustment or replacement (at Huntleigh Healthcare Inc.'s option) of any nonconforming or defective Goods. Huntleigh Healthcare Inc. will have a reasonable time to repair, service or replace such Goods. Any Goods returned to Huntleigh Healthcare Inc. which are found not to be defective in breach of the warranty in Subsection (b) above, shall be returned to Customer in the manner described in this subsection.

d) IN NO EVENT SHALL HUNTLEIGH HEALTHCARE INC. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING BUT NOT LIMITED TO ECONOMIC LOSS, LOSS OF PROFITS OR SPECIAL DAMAGES) ARISING OUT OF OR INCURRED BY CUSTOMER IN CONNECTION WITH THE PURCHASE OF HUNTLEIGH HEALTHCARE INC.'S GOODS EVEN IF HUNTLEIGH HEALTHCARE INC. HAS BEEN ADVISED OR HAS KNOWLEDGE OF THE POSSIBILITY OR EXTENT OF SUCH DAMAGES SUFFERED OR INCURRED BY CUSTOMER OR ANY END USER AS A RESULT OF OR IN CONNECTION WITH ANY BREACH OF THESE TERMS AND CONDITIONS BY HUNTLEIGH HEALTHCARE INC. OR ANY TORT (INCLUDING BUT NOT LIMITED TO STRICT LIABILITY OR NEGLIGENCE) COMMITTED BY HUNTLEIGH HEALTHCARE INC., ITS AGENTS OR REPRESENTATIVES IN CONNECTION WITH THESE TERMS AND CONDITIONS OR ANY CONTRACT WITH CUSTOMER FOR THE SUPPLY OF GOODS.

e) Customer shall not create, directly or indirectly, any warranty obligations on the part of Huntleigh Healthcare Inc. to the customers of Customer, and in particular, without limiting the foregoing, Customer agrees not to pass on to its customers any warranties beyond or in addition to those given by Huntleigh Healthcare Inc. to Customer hereunder. Where the Customer is a dealer in the Goods, it shall be responsible for the labour cost of all repairs and Huntleigh Healthcare Inc. shall be responsible for providing all repair parts during said twelve (12) month warranty period. The dealer shall provide written verification of warranty repairs including the original invoice number, date of purchase, description of repairs, name of its customer and date of sale to such customer.
f) Customer shall be deemed to have full knowledge of the nature and properties of the Goods ordered and of any hazards they involve and the proper treatment, storage and handling thereof. Any technical advice furnished by Huntleigh Healthcare Inc. or its representatives or agents is given only on the basis that it is followed at the Customer's own risk

Service Returns

If for any reason the Assist has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department - Assist'
- For further details, refer to NHS document HSG(93)26 - UK only

Service Address:

Customer Care Department.
Huntleigh Healthcare Ltd,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

USA Only

Service Department.
Huntleigh Healthcare Inc.
40 Christopher Way
Eatontown, NJ 07724-3327
Tel: (800) 223-1218

Tel: +44 (0)29 20496793 - Service (24hr answer machine)
Tel: +44 (0)29 20485885
Fax: +44 (0)29 20492520
Email: sales@huntleigh-diagnostics.co.uk
service@huntleigh-diagnostics.co.uk
Or your local supplier.

CAUTION
In the unlikely event that you need to return this product, please adopt local decontamination procedures and provide documentation outlining the products status.
Please ensure that this documentation is accessible without having to open the package.
No product return will be accepted without first obtaining a Return Goods Authorisation number from a Huntleigh customer service agent. Display the RGA number prominently on the side of the box; this will insure proper servicing of your product. Huntleigh Healthcare Ltd. reserves the right to return unopened any shipment not complying with this requirement.

MANUFACTURED & DISTRIBUTED
IN THE UK BY:

Huntleigh Healthcare Ltd
Diagnostic Products Division
Cardiff CF24 5HN UK
Tel: +44 (0) 29 2048 5885
Fax: +44 (0) 29 2049 2520

Email: sales@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.co.uk

DISTRIBUTED IN THE USA BY:

Huntleigh Healthcare Inc
40 Christopher Way
Eatontown
New Jersey 07724-3327
Tel: (800) 223-1218
Fax: (732) 578-9889

DISTRIBUTED IN GERMANY BY:

Huntleigh GmbH
Im Hülsenfeld 19
40721 Hilden
Germany
Tel: 00 492 103 971100
Fax: 00 492 103 971180

DISTRIBUTED IN AUSTRALIA BY:

Huntleigh Healthcare Pty Ltd
PO BOX 330
Hamilton Hill
Western Australia 6963
Tel: 00 618 9337 4111
Fax: 00 618 9337 9077

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Medical Devices Directive 93/42/EEC

Manufactured in the UK by Huntleigh Healthcare Diagnostic Products Division. As part of the ongoing development programme, the company reserves the right to modify specifications and materials of the Assist® range without notice.