

1.0 SCOPE

A one-way RF data communications system that will notify a personal computer when message is received from a Legacy Pump. This system will have two parts: a transmitter and a receiver. The transmitter accepts a data string from a Legacy pump and transmits the data. The receiver demodulates the transmitted RF signal and forwards it to a personal computer.

2.0 DOCUMENT CITATIONS

IEC 61000-4-2 (1995) Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 2: Electrostatic Discharge immunity test. Basic EMC Publication.

47 CFR 15 Radio Frequency Devices

IPC-A-600 Acceptability of Printed Circuit Boards

IPC-D-300 Printed Board Dimensions and Tolerances

IPC-6012 Qualification and Performance Specification for Rigid Printed Boards

IPC-D-949 Design Standards for Rigid Multilayer Printed Boards

IPC-SM-840 Qualification and Performance of Permanent Polymer Coating (Solder mask) for Printed Boards

IPC-S-815 General Requirements for Soldering Electronic Interconnections

IPC-A-610 Acceptability of Electronic Assemblies

SDI PQ-044 Electrostatic Sensitive Material: Definitions, Handling, and Protection

3.0 FUNCTIONAL REQUIREMENTS

3.1. Cable

See drawing for specifications.

4.0 ELECTRICAL REQUIREMENTS

4.1. Power Source

4.1.1. Power Source

The Legacy pump will provide power for this device. The data out signal provides power for the transmitter. Voltage range of the peak of the data signal to be greater than 2.9volts, and less than 3.5 volts.

4.2. Current Consumption

4.2.1. Power Source for Pump Circuit

The maximum current consumption less than 20mA.

4.3. Operating Frequency

417.900 MHz Minimum, 418.100 MHz Maximum

5.0 PHYSICAL REQUIREMENTS

5.1. Dimensional

See drawings for device dimensions.

5.2. Weight

The device's weight is less than 75g.

5.3. Impact Resistance

This device shall be capable of withstanding a minimum of 3 drops, in any orientation, from 1 meter onto a hardwood board 5mm thick and a density greater than 700 kg/m without loss of functionality.

5.4. Water Resistance

The Transmitter offers a degree of protection against potential safety hazards caused by the ingress of fluids. The system is classified as "splash-proof".

5.5. Cable(s) Pull Strength

The connectors shall be capable of withstanding a 7-lb minimum pull force between the housing and connector for ten (10) seconds without damage.

5.6. Connector Durability

The device shall meet the requirements of this specification following 2,000 connection/disconnection cycles of the pump interface connector.

6.0 ENVIRONMENTAL

6.1. Operating Environment

- Temperature: 2°C (35.6°F) to 40°C (104°F)
- Humidity: 90% relative humidity maximum, non-condensing.
- Atmospheric Pressure: 70 kPa (10.2 PSI or 10,000 feet above sea level) to 106 kPa (15.4 PSI).

6.2. Storage Environment

- Temperature: -20°C (-4°F) to 60°C (140°F)
- Humidity: 90% relative humidity maximum, non-condensing
- Atmospheric Pressure: 70 kPa (10.2 PSI or 10,000 feet above sea level) to 106 kPa (15.4 PSI).

6.3. Electrostatic Discharge (ESD) Susceptibility

When subjected to electro-static discharges per IEC 61000-4-2 (1995), the device shall not produce an unsafe condition. Test levels for this product are $\pm 2\text{kV}$ and $\pm 4\text{kV}$ for current injection, and $\pm 2\text{kV}$, $\pm 4\text{kV}$ and $\pm 8\text{kV}$ for air discharge. An unsafe condition shall be any condition caused by ESD that results in a violation of a minimum safety requirement of the device as specified in the safety analysis for the device.

6.4. Emissions

The device shall meet the requirements of this specification for 47 CFR 15 – Radio Frequency Devices. FCC Part 15 Subpart C Section 15.231.

(Insert Chart here)

6.6 6.6.4 Chemical Resistance

The exterior surfaces of the device shall not exhibit mechanical deformation and the device shall meet all functional requirements of this specification when wiped with a cloth dampened with the ingredients found in common germicides and disinfectants when these solutions are mixed according to the manufacturers recommendations for cleaning delicate instruments. The chemicals that the device shall be resistant to include (distilled water shall be used as the diluent):

Distilled Water

Sodium Hypochlorite Solution, USP (Bleach)

Defined as a 10% solution that is diluted to a final concentration of 1:100 (1.0%) for use as a disinfectant.

Chlorox Bleach (5.25% solution) can be used as a source, if diluted to a final concentration of 1:100 (1.0%).

Isopropyl Alcohol, USP (99% solution)

Alcohol, USP (93%)

Glutaral Concentrate, USP (Cidex 7)

Defined as a 50% solution that is diluted to a final concentration of 1:50 (2%) for use as a disinfectant.

Cidex 7 (2% solution) can be used as a source without further dilution.

Benzalkonium Chloride Concentrate (Zephiran)

Defined as a 17% solution that is diluted to a final concentration of 1:750 (0.13%) for use as a disinfectant.

Zephiran concentrate (17% solution) can be used as a source, if diluted to a final concentration of 1:750 (0.13%).

70% Chlorohexidine 1 oz. per gallon.

Soapy water

Defined as a solution that is diluted to a final concentration of 1:40 for use as a general cleaning solution.

Any commonly used liquid detergent can be used as a source, if diluted to a final concentration of 1:40.

n-Alkyl (68%C12, 32%C14)dimethyl ethylbenzyl ammonium chloride

n-Alkyl (60%C14, 32%C16, 5%C12, 5% C18)dimethyl benzyl ammonium chloride

PDI, Super Sani-cloth (Manufacturer, Product)

Disobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride
Isopropanol

MadaCide, Mada Medical

6.6.5 Sterilization

The device shall not be required to withstand any form of sterilization other than these stated in the chemical resistance section of this document.

7.0 BILL OF MATERIALS

source		Desc	
Electromark	BUD Plastibox	#PS11521	Transmitter Enclosure
DAL Machine, Inc		Custom	Secondary Machining, Transmitter Enclosure
Mn Wire and cable		71-0314	Cable, Wireless Transmitter, SIMS Deltec #71-0314
Electromark	BUD Plastibox	#PG1172	BUD #PG1172 Gasket
Pensar		71-0316	Transmitter Board

Pensar			Shipping Bag
Pensar			Shipping Carton
Pensar			Shipping Carton label
Pensar			IFU
Pensar			Device Label
Arden Fasteners			#4X5/16" Lg, Type 25, Self Tapping Screw

8.0 TEST REQUIREMENTS

8.1. In-Circuit Test

This section defines the requirements for an in-circuit test.

8.1.1. Sampling

100% of production shall have been tested and documented as passed the in-circuit test requirements of this specification.

8.1.2. Marking/Reporting

All PWA assemblies which are tested per these requirements and pass shall be marked with a permanent ink or paint mark indicating test acceptance.

8.1.3. Applied Voltage

Unless otherwise indicated, all tests in this specification shall be performed at the voltages specified in this specification.

8.2. Baseline Tests

Baseline tests shall be performed which encompass the following requirements:

8.2.1. Shorts/Opens

All nodal connections shall be learned and tested for shorts and opens.

8.2.2. Capacitors

Test all capacitors for value within their specification.

NOTE: Some circuit nodes may include more than one component in parallel. In this situation, the node will be tested for a value equal to the sum of all the parallel component values.

8.2.3. Resistors

Test all resistors for value within their specification.

NOTE: Some circuit nodes may include more than one component in parallel. In this situation, the node will be tested for a value equal to the sum of all the parallel component values.

8.2.4. Diodes

Standard in-circuit test shall be used on these devices.

8.2.5. ICs – U1

Program this device with the program specified on the PWA BOM.
Programming can be before assembly, or after assembly - through the programming port on the PWA.
Standard in-circuit test.

8.3. Communication Test

The test shall be a functional test performed to verify functionality.

9.0 PRINTED CIRCUIT BOARD

Requirements outlined in this specification supersede those outlined in published reference documents.

9.1. Physical Requirements

9.1.1. Classification

The classification of the following categories for the PCB shall be in accordance with the indicated IPC standards:

Design	Class C IPC-D-949
Performance	Class 2 IPC-6012
Dimensioning	Class B IPC-D-300 Type 1

9.1.1.1. Dimensions and Tolerances

Parts shall meet the dimensional requirements of the applicable SDI drawing and IPC-D-300 as detailed herein, with the SDI document superseding.

9.1.1.2. PCB lay-Out

1 oz. copper weight all layers

9.1.1.3. PCB Construction

Two layers as detailed in drawings.

9.1.1.4. Soldermask

“LPI” (Liquid Photo Imagable) soldermask per IPC-SM-84, type B, class 3, both sides green transparent with max

misregistration to be .003, over bare copper. All exposed copper areas, both sides, to be tin lead coated using hot air leveling process to yield .0003 minimum. Vendor must modify soldermask artwork to remove any slivers that are .004 or less between fine pitched lands.

9.1.1.5. Silkscreen

Both sides as required using white epoxy ink. Vendor must modify silkscreen artwork to remove white epoxy ink from exposed metal..

9.1.1.6. Annular Ring

Minimum annular ring around plated through holes to be .002".

9.1.1.7. Copper Plating

Minimum copper plate in all holes to be .001".

9.1.1.8. Conductive Pattern Finish

63/37 tin lead with a thickness of .0001"-.0008" on plated through holes and non-solder masked areas. Tin can deviate 50 to 70%.

9.1.1.9. Materials

Materials used in the manufacture of the PCB shall comply with the requirements of IPC-D-949. Base material shall be FR4.

9.1.1.10. Marking Inks

Marking inks used shall meet the requirements of IPC-D-949.

9.1.2. Chemical Requirements

PCBs must be able to withstand fluxes, cleaning solvents, soldering and coatings used in the manufacture thereof or later manufacturing processes as specified in IPC-D-949.

9.1.3. Cleanliness Requirements

Parts shall meet the requirements for ionic and organic contamination as specified in IPC-ML-950.

9.1.4. Performance

The PCBs shall meet the requirements as specified in IPC-ML-950 and IPC-SM-840.

9.1.5. Workmanship

The PCBs shall meet the workmanship, visual, and dimensional requirements as specified in IPC-D-300, IPC-A-600 and IPC-ML-950.

9.1.6. Bow and Twist

The PCBs shall meet the requirements of IPC-D-300 and IPC-A-600.

9.2. Dimensional

As specified on drawings.

9.3. Markings

For circuit board markings, see In-circuit Test section.

9.4. Cleanliness

The material shall not exhibit observable embedded foreign material and loose particles or fibers. Visual inspection shall be by the unaided eye (having original or restored 20/20 vision) at approximately 18 inches.

9.5. Workmanship

PWAs shall meet the applicable sections of the IPC publications ANSI/IPC-S-815B and IPC-A-610B, for Class 3 devices.

9.0 PACKAGING AND LABELING

9.1 Device Label

Label shall be supplied by TBD.

Labels shall be clean and legible and not have damage such as frayed edges, holes or tears, and discoloration.

9.1.1 Artwork

SDI part number: TBD

Artwork shall be supplied by SIMS Deltec at time of order.

9.1.2 Material and Dimensions

Substrate: T5 4 mil polyester, bright white

Adhesive: AB 2 mil Acrylic, Hi-temperature

Laminate: UU9 Coating, Clear, Hi-temperature

Dimensions: Length TBD ± 0.016 inch
Width TBD ± 0.008 inch
Thickness TBD ± 0.001 inch

9.2 Packaging Instructions

TBD

10.0 SHIPMENT PACKAGING AND CONFIGURATION

10.1 Packaging Configuration

10.1.1 Packaging shall be adequate to provide protection from damage and contamination from expected handling, transit, and storage.

10.2 Shipment Identification

10.2.1 Each shipping carton shall have adequate identification to positively identify the parts to the respective purchase order.

10.2.3 The final assembly shall have a lot code stamped (using permanent ink) on the exterior and interior of the enclosure (see drawing for location). The lot number will be supplied by SDI at the time of order.

11.0 QUALITY ASSURANCE REQUIREMENTS

11.1 Acceptance Criteria

SIMS Deltec, Inc. (SDI) may, at its discretion, perform any inspection, tests, or audits to assure the manufacturer's compliance with the documents specified by the Bill of Documents for this part(s).

11.2 Traceability

The manufacturer shall maintain a manufacturing process history by recording and retaining lot numbers of the items supplied, and lot number traceability of the raw materials used to manufacture them. This information shall be available for a minimum of five (5) years on request by SDI or until the manufacturer is notified otherwise.

11.3 Notification/Approval of Change

Prior to producing or shipping product, the supplier is required to notify a Purchasing Agent of SDI to obtain written approval for material, process or tooling changes that are discrepant to the documentation specified by the Bill of Documents.

11.4 Certification

The supplier shall provide a certification with each lot shipped which specifies that the articles shipped meet the requirements of this specification and accompanying documentation. The certification shall be printed on suppliers company letterhead. As a minimum, the certification shall contain the following information:

- Date
- Purchase Order Number
- SIMS Deltec Part Number
- Description of Articles Shipped
- Quantity Shipped
- Signature and Title of Appropriate QA Personnel

- 11.4.1 Certification shall also include a statement that 100% of the devices in the lot shipped have been tested and have passed the Test Requirements outlined in this specification. Test data shall be available upon request.
- 11.4.2 Supplier may contact a Purchasing Agent of SDI to obtain information for preparing an appropriate certification.