Quality Manual

Authorized by: _____

1.0 Scope

The scope of the quality assurance system encompasses the entire organization and is mandatory. The baseline specification for the quality assurance system established and maintained by Analytical Industries, Inc. shall reflect the more stringent requirements as set forth by ISO 13485:2003 (Health Canada) and ISO 9001:2008, but in any event the baseline must satisfy both standards.

Assure equipment and protective systems intended and independently certified for use in potentially explosive atmospheres comply with Annex II of ATEX Directive 94/9/EC and EN 13980.

2.0 Reference

Analytical Industries, Inc. is engaged in the design, manufacture, and distribution of electrochemical gas sensors and gas analyzers that have worldwide application. In general, the purpose of these products is either monitoring a manufacturing process or personnel safety.

Analytical Industries, Inc. was incorporated in the state of Nevada in 1993. The shares of the company's common stock are owned entirely by three individuals who serve as directors, officers, and are actively involved in operating the company. In 1995, the company established a business unit doing business under the name Advanced Instruments, Inc. for the purpose of creating a separate identity to market to industrial end users.

Gas sensors and related accessories are marketed directly to OEM customers in a variety of markets. Replacement gas sensors for the medical market are sold through a network of distributors. A business unit known as Advanced Instruments, Inc. has been established along with a separate network of representatives and distributors to exclusively market the company's line of gas analyzers, replacement sensors, and related accessories to the industrial market.

End users of the company's products include a wide variety of industrial processes as described in the Advanced Instruments, Inc. product brochure: environmental monitoring of processes and testing of automotive emissions, personnel safety, anesthesia and respiratory therapy segments of the medical field.

The majority of these end users are larger organizations placing emphasis on quality and reliability issues for a number of reasons: international standards, legislated requirements, pressure to increase profits and legal liability issues. Feedback from end users is obtained through direct interface and constitutes the primary source of input for product design.

3.0 Terms & Definitions

For purposes of this quality manual, the terms and definitions of ISO 13485:2003 and ISO 9001:2008 apply. The term "organization" replaces "supplier" used in ISO 9001:1994 and refers to the entity to which the new standard ISO 9001:2008 applies. Also, the term "supplier" now replaces the term "subcontractor". Wherever the term "product" appears, it can also mean "service".

Reference: Quality Assurance – Standards binder

4.0 Quality Management System

4.1 General Requirements

The outline of the quality manual is based on the more stringent requirements as set forth by ISO 13485:2003 (Health Canada) and ISO 9001:2008, but in any event the outline must satisfy both standards. These general standards provide an overview to the elements of the quality system in place to ensure product conformance to specified requirements. In addition the following shall apply:

- FDA - Federal Register/Vol. 16 No. 195/October 7, 1996/Rules and Regulations
- ISO 21647:2004 / EN 12598:1999 / ISO 7767:1997
  (Oxygen monitors for patient breathing mixtures – Particular requirements)

- European Union: Medical Device Directive 93/42/EEC, Annex II as amended by 2007/47/EC
- ISO 9001:2008

- Health Canada: Medical Device Regulations, F-27/ SOR-98-282
- ISO 13485:2003

- ATEX Directive 93/9/EC Safety Requirements for Electrical Equipment in Explosive Atmospheres for:
  Gas Group II 2 G Ex d IIB or Ex d IIB+H2 T6 or T5 (explosion proof analyzers)
  Gas Group II 2 G Ex d [ib] ib IIB T4 and Group II 2 G Ex ia IIB T4 (intrinsically safe transmitters)
  Gas Group II 2 G Ex ib IIB T4 (intrinsically safe portable analyzers)

- EN 13980 Potentially Explosive Atmospheres Application of Quality Systems

A Device Master Record or Technical File (DMR/TF) shall be established and maintained that contains product specifications including complete manufacturing and quality assurance procedures for each type of device.

The organization must inform the appropriate regulatory

Reference: P-1065 Regulatory Reporting

4.2 Documentation Requirements

4.2.1 General

Information the organization requires to ensure the effective planning, operation and control of its processes shall be documented in a formal quality system and controlled in such a manner as to comply with the appropriate requirements.

The organization shall demonstrate its fulfillment of the obligations imposed in 4.1 by ensuring that the products concerned meet the provisions of the standards that apply to them. The organization must affix the CE marking accompanied by the identification number of the notified body and draw up a declaration of conformity which must cover the devices manufactured identified by product name, code or other unambiguous reference.

The organization must prepare and make the following technical documentation available, either through the organization or its authorized representative, to the national authorities for inspection for a period ending at least five years after the last product has been manufactured.

- Declaration of Conformity
- EC type-examination certificates and their additions
- General description of the product and its intended use(s), including indicating whether the device or any accessories are intended to transport and store substances intended to administer or remove medicines, body liquids or other substances from the body and contain phthalates, carcinogens or other reproductive toxics.
- Design drawings, calculations, diagrams, etc. with necessary explanations
- Risk analysis results and underlying standard(s)

- Statement indicating if the device is sterile, and if applicable a description of methods used and a validation report
- Statement indicating whether the device incorporates a substance or human blood derivative requiring a safety assessment
- Statement indicating whether the device is for single use to be included in the Instructions for Use also and factors know to the organization that could pose a risk if the device were to be re-used
- Results of design calculations and tests carried out including proof of compliance to essential requirements if the indications for use include connection to another device
- Design solutions must conform to generally acknowledged state of the art safety principles
- Clinical evaluation, or where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and due substantiation of performance evaluation, bench testing, pre-clinical or simulated clinical evaluation.
- Labeling and where appropriate Instructions for Use

Reference: Quality Manual, Appendix D Declaration of Conformity
Certifications (separate binder)
P-1081 Instructions for Use, AII 2000 Series Analyzers
P-1032 Product Identification, Labeling, Storage and Preservation
P-1007 Design Control

4.2.1.1 Documentation Requirements

To define the methods for good documentation practices, completing printed forms legibly and avoiding errors, omissions and ambiguities with respect to written documents.

Reference: P-1092 Documentation Requirements

4.2.2 Quality Manual

The outline of the quality manual is derived from ISO 13485:2003 and ISO 9001:2008 general standard and provides an overview to the elements of the quality system in place to ensure product conformance to specified requirements including the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

The quality assurance system shall assure equipment and protective systems intended and independently certified for use in potentially explosive atmospheres comply with Annex II of ATEX Directive 94/9/EC and EN 13980.

4.2.3 Control of Documents

A list of controlled documents and quality records shall be maintained, their distribution controlled and reviewed, updated and re-approved as necessary or at a minimum every three (3) years. The documents shall have a control page, be reviewed and approved prior to issue, made available at appropriate locations, subsequent changes reviewed and approved by the same group that performed the original approval.

Documents issued for fabrication and/or assembly of component parts are to be destroyed following completion of the job. Changes to controlled documents shall be obviously identified either by yellow highlight, a written description (formal CAPA/ECO) or annotated (to include initial and dated).

Documents shall reflect where practical date, revision level, and the nature of change and authorization. Documents of external origin shall be identified, marked as to reference the related internal document(s) and otherwise be treated in the same manner as documents generated internally. Change logs shall be maintained. Derivations from controlled documents shall not be authorized unless specifically approved. To prevent unauthorized copying, copies of controlled documents shall be stamped with a red 'authorized' stamp to readily identify them. Copies without the red authorized stamp or any stamp shall be destroyed immediately.

Formal CAPA (corrective and preventative action)/ECO request forms, documentation and archiving shall be limited to significant change requests. The head of Design shall be authorized to designate, approve, and implement minor changes including but not limited to clarifications, modifications for special one of a kind orders, typographical errors, etc. based on informal discussions, sketches, red line notes, etc. In all cases, obsolete documents shall be so marked and removed from points of use. Similarly, Department heads shall be authorized to conduct and document at their discretion targeted training reinforcement based on individual instances generated by the Returned Material Assessments and Device History Record.

Reference: Quality Manual Appendix C, Controlled Documents / Quality Records (formerly P-1052)
P-1008 Document Control
P-1009 CAPA/ECO Form
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1058 Device History Record Sensors
P-1073 Device History Record Analyzers
P-1080 Equipment Intended for Use in Potentially Explosive Atmospheres

4.2.4 Control of Records
For maximum efficiency, a concerted effort has been made to organize the document flow to accumulate and store related records together in a practical location to facilitate reference and retrieval. Where appropriate, quality records shall provide evidence of conformity to the requirements of the standards specified and remain legible. The individual department heads shall be responsible for the storage, protection, retrieval and retention of quality records.

Quality records shall be retained for a period of at least the lifetime of the device plus 10 years but not less than any retention period specified by relevant regulatory requirements. Under no circumstances shall correction fluid be used on any company document. Line out the error, provide a written justification for the change, initial and date.

Reference: Quality Manual Appendix C, Controlled Documents / Quality Records (formerly P-1052)

5.0 Management Responsibility

5.1 Management Commitment
The scope of the quality assurance system encompasses the entire organization and is mandatory. The baseline specification for the quality assurance system established and maintained by Analytical Industries, Inc. shall reflect the higher of the requirements set forth by ISO 13485:2003 and ISO 9001:2008 and MDD 93/42/EEC as amended by 2007/47/EC. At present, only section 8.5.1 of ISO 9001:2008 presents a requirement exceeding that of ISO 13485:2003.

The quality assurance system shall assure equipment and protective systems intended and independently certified for use in potentially explosive atmospheres comply with Annex II of ATEX Directive 94/9/EC and EN 13980.

5.2 Customer Focus
Except for inquiries and orders for a standard product with generic terms, inquiries and orders for non-standard products shall be reviewed by the head of Marketing to ensure the requirements are adequately defined, interface with other disciplines as necessary to confirm the company's capability to meet the requirements with minimal risk and resolve any differences promptly with the end user.

Increasing pressure from end users for quality products at lower prices coupled with an increase in the number of new manufacturers has made competition very keen. The design criteria must be flexible enough to amortize development costs over several applications. Similarly, the criterion for human resources emphasizes versatility over specialization to achieve the efficiency necessary to respond timely to market demand. As a result, the strategy for securing and maintaining a competitive advantage requires designs based on end user feedback and minimizing overhead costs.

Reference: P-1006 Contract Review
P-1023 Order Entry
P-1025 Application Data Sheet
P-1035 Order Processing and Invoicing
P-1036 Order Processing and Invoicing (Navy Contract)
P-1037 Analyzer Specification binder
P-1038 Verbal Order Form
P-1041 Returned Material Assessment Sensor

P-1042 Returned Material Assessment Analyzer
P-1043 Product Complaint & Recall
P-1057 Oxygen Cleaning
P-1059 Complaint Record
P-1064 Order Processing Documentation
P-1080 Equipment Intended for Use in Potentially Explosive Atmospheres

5.3 Quality Policy

The quality policy found in Appendix A summarizes Management's position and recognition of the importance of quality in the overall strategy for growth.

5.4 Quality Planning

5.4.1 Quality Objectives

The objective of the quality assurance system is to demonstrate the organization's ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and, to enhance customer satisfaction through effective application and continual improvement of processes within the system.

The measure of improvement is expected to be a minimum 5% improvement annually. The quality objectives shall be communicated through the Quality Policy and measurable using the information tools specifically identified as Key Data by P-1069

5.4.2 Quality Management System Planning

The quality system shall be revised to ensure the compliance of future products with shall reflect the higher of the requirements set forth by ISO 13485:2003, ISO 9001:2008 and MDD 93/42/EEC as amended by 2007/47/EC.

At present, only section 8.5.1 of ISO 9001:2008 presents a requirement exceeding that of ISO 13485:2003. With respect to medical devices to be CE marked, ISO 21647:2004 / EN 12598:1999 / ISO 7767:1997 shall be the standard for testing devices.

The quality assurance system shall assure equipment and protective systems intended and independently certified for use in potentially explosive atmospheres comply with Annex II of ATEX Directive 94/9/EC and EN 13980.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The organization chart demonstrates that the quality function is responsible to the top management of the corporation. Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Quality is responsible for developing an efficient and effective quality system to preclude product nonconformity, document and quality problems, implement cost effective solution, control further processing until the corrective action is verified, and enhance the company's competitive position in the market. Top management shall ensure the personnel assigned quality responsibilities to manage, perform and verify have the authority and independence necessary to perform these tasks.

Reference: Appendix B, Organizational Chart

5.5.2 Management Representative

Administration of the quality assurance system is the responsibility of Patrick J. Prindible, Vice President.

5.5.3 Internal Communication

The management representative is responsible for communicating the organization's policy and posting it throughout the facility. Similarly, information accumulated from customer feedback, management analysis reports and management review input (including third party audits) shall be communicated within the organization to achieve the stated objectives - demonstrating the organization's ability to consistently provide product and the assurance of conformity to applicable customer

and regulatory requirements, and, enhancing customer satisfaction through effective application and continual improvement of processes within the system.

Reference: Quality Manual Appendix A, Quality Policy
Quality Manual Appendix B, Organization Chart
P-1020 Internal Quality Assessment
P-1050 Management Review
P-1069 Key Data

5.6 Management Review

5.6.1 General

The quality assurance system shall be assessed annually during the fourth quarter of the year to assess its continuing adequacy, effectiveness for the environment existing at the time, opportunities for improvement and impact of changes to the quality management system. The review will be conducted by a committee comprised of at least the managing principals and other key personnel they may designate. The responsible Quality Representative or his designee shall document the results of the results of the annual meeting to demonstrate that the quality system is effective.

5.6.2 Review Input

The input to the management review shall include but not limited to information on:

- Findings of third party audits
- Findings of Internal Assessments
- Customer feedback
- Returned Material Assessment Reports (process performance)
- Analysis of scrap (product conformity)
- Status of corrective action implementation
- Statistical techniques and scrap analysis
- Changes in approved vendors
- Findings from previous Management Reviews
- Impact of Changes on QA System
- Review risk analysis for possible impact
- Recommendations for improvement
- Impact of new or revised regulatory requirements
- Analysis and assessment (whether objectives are being met) of information generated by Key Data reports, P-1069.

Reference: P-1050 Management Review

5.6.3 Review Output

The output from the management review shall include any decisions implemented in the form of new or revised procedures related to:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product(s) based on customer feedback and/or regulatory requirements
- Resource needs

6.0 Resource Management

6.1 Provision of Resources

The current environment in the growth of Analytical Industries, Inc. does not provide the resources or justify personnel dedicated solely to the verification and administration of quality functions. Alternately top management is actively involved in the establishment and maintenance of the quality assurance system.

6.2 Human Resources

To establish awareness of the quality assurance system, minimum standard operation procedures shall require employees to possess basic reading, writing, mathematical, and communicational skills in the English language. Where necessary the requisite vocational or advanced degree education shall be required as determined by the appropriate department head. The use of an apprenticeship or on-the-job training approach to train qualified personnel in the proper technique shall be the primary method of training given the unique proprietary operations impacting the quality of product supplied. Employees shall receive specific training with respect to individual procedures. Department heads shall be responsible for maintaining an appropriate record of this training. Department heads shall be authorized to conduct and document at their discretion targeted training reinforcement based on individual instances generated by the Returned Material Assessments and Device History Record.

Reference: P-1039 Training Documentation Form

6.3 Infrastructure

The organization shall provide the necessary work space, equipment (both hardware and software) and supporting services to facilitate the execution of the quality management system. Preventative maintenance programs shall be established on critical machinery and in particular those used for production of medical devices and their components. All preventative maintenance programs shall comply that recommended by the manufacturer's instruction manual. The appropriate Dept. Head is responsible for documenting the preventative maintenance

6.4 Work Environment

To maintain awareness of the quality assurance system, minimum standard operating procedure shall require employees to perform tasks in accordance with drawings and/or procedures and require supervisors to provide a valid example of the quality expected of the employee. Statistical techniques shall be established, maintained and reviewed by management to assure their effectiveness. Further, any indication of non-conformance shall be immediately brought to the attention of the appropriate supervisor(s) and be resolved or removed before resuming the task.

7.0 Product Realization

7.1 Planning

The organization shall develop the processes needed for product realization and ensure the compliance of future products with other processes and applicable quality standards, refer to section 4.1. Reference: P-1060 Company Processes

7.2 Customer Related Processes

Qualified organizational and technical resources shall interface as necessary to qualify the design input and intended use, determine action assignments, review preliminary design output, quality system requirements, final design output, and ancillary requirements (manual, spare parts lists, delivery, regulatory, statutory, etc.).

These resources shall be responsible for documenting necessary information including assignments, prelim design output, red line changes, final design output and verification data necessary to validate the design input. Department heads are responsible for establishing and maintaining files for their respective documentation to ensure it can be readily retrieved for future reference.

Reference: P-1006 Contract Review
P-1023 Order Entry
P-1025 Application Data Sheet
P-1035 Order Processing and Invoicing
P-1036 Order Processing and Invoicing (Navy Contract)
P-1037 Analyzer Specification binder
P-1038 Verbal Order Form
P-1045 Remittance Checks and Accounts Receivable
P-1046 Remittance Wire Transfers
P-1047 Remittance Credit Card

7.3 Design and Development

Exclusion: Non-standard products that constitute in the judgment of the head of Design a one-of-a-kind modification to a proven design required to meet specific end user requirements.

The devices as identified in Section 1.5 Declaration of Conformity have been designed and manufactured in such a way that when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or safety of the users or other persons.

Conformity with essential requirements shall be demonstrated by verifying the performance of the device under normal conditions, bench testing, pre-clinical and simulated clinical evaluations and determining that undesirable malfunctions constitute minimal risk to patients and users.

Devices incorporating software, the software must be validated according to the state of the art taking into account the development lifecycle, risk management, validation and verification.

The procedures governing the development and/or modification of new products shall be controlled and documented as to functional and performance specifications, component requirements, risk analysis, verification and validation (assess using appropriate quality standard) of the product design to ensure that the intended customer, regulatory and quality specifications are met. The design of new products shall require the appointment of an appropriate project manager who is responsible for developing an overall plan and recording formal documented reviews at appropriate stages.

Reference: P-1007 Design Control
P-1037 Analyzer Specification binder
P-1048 Risk Analysis
P-1049 Risk Analysis Form
P-1051 Design Plan and Review
P-1010 Purchasing
P-1080 Equipment Intended for Use in Potentially Explosive Atmospheres

7.4 Purchasing

The procurement of materials and services shall conform to specified requirements as determined by authorized Design and Engineering personnel. Deviations require authorization from the group that issued the original specification. Evaluation of and designation of approved vendors shall be based on their ability to meet required specifications as determined by experience, evaluation of specifications and/or samples and testing as appropriate.

Where the design, manufacture and testing of products or key components is carried out by a third party, the quality system shall describe the extent of control and methods of monitoring applied to the third party to ensure the products conform to the standards and requirements specified herein.

Approved purchase data and vendors shall be identified as active in computer files, the access to which shall be limited.
Incoming components and materials shall be subject to visual inspection, physical count, physical condition and agreement of company and manufacturer part numbers. Fabricated components shall be inspected by qualified personnel for compliance with purchasing documents including dimensional drawings. The receipt of said components and materials shall be verified to and documented in the Purchase Order Log. The components and materials shall be segregated until satisfactory inspection is completed. Manufacturing personnel shall not remove the components or materials until they are inspected and released to production.

Nonconforming material shall be identified, segregated, and removed from the facility as soon as possible. Verification of purchases product by the end user shall not impact the requirements of the quality system.

Reference: P-1010 Purchasing
P-1012 Receiving and Inspection
P-1056 Vendor Approval / Evaluation
P-1010 Purchase Order & Inventory Item No.
P-1012 Vendor Assessment
P-1070 Purchase Order Log

P-1080 Equipment Intended for Use in Potentially Explosive Atmospheres

7.5 Production and Service

7.5.1 Control of Production and Service Provision

To establish awareness of the quality assurance system, minimum standard operation procedures shall require employees to possess basic reading, writing, mathematical, and communicational skills in the English language. Where necessary the requisite vocational or advanced degree education shall be required as determined by the appropriate department head. Employees shall receive specific training with respect to individual procedures.

Department heads shall be responsible for maintaining an appropriate record of this training. Department heads shall be authorized to conduct and document at their discretion targeted training reinforcement based on individual instances generated by the Returned Material Assessments and Device History Record.

Installation, operating, maintenance, servicing, and qualifying procedures shall be established as necessary for each product. Employees shall receive specific training with respect to individual procedures. Department heads shall be responsible for maintaining an appropriate record of this training.

Reference: P-1039 Training Documentation Form
P-1001 Weighing Lead
P-1002 Leak Test Oxygen Sensors
P-1003 Soldering PCB
P-1004 Preparation of Leak Test Solution
P-1005 Assembly Procedure PSR-11-33-N, PSR-11-33-NM
P-1014 Installing Sensing Membrane Clamp
P-1018 Installing Sensor into Housing
P-1022 Sensor Specifications and Configurations
P-1026 Sintering Lead
P-1027 Staking Lead Anode
P-1028 Sealing Back Membrane
P-1029 Sealing Sensing Membrane
P-1030 Testing the Output of Sensors
P-1031 Soldering of PCB on Sensors
P-1033 Cleaning Cathodes
P-1034 Cleaning Pins and Ribbon
P-1044 Preparation of Electrolyte Solution
P-1055 Pressure Test Tolerance
P-1057 Oxygen Cleaning
P-1058 Device History Record Sensors
P-1066 Assemble Sample System
P-1067 Contract Private Label CE
P-1073 Device History Record Analyzers
P-1080 Equipment Intended for Use in Potentially Explosive Atmospheres

7.5.1.2.1 Cleanliness of Product and Contamination Control

This section is not applicable at this time.

7.5.1.2.2 Installation Activities

This section is not applicable at this time.

7.5.1.3 Particular Requirements for Sterile Medical Devices

This section is not applicable at this time.

7.5.2 Validation of Processes for Production and Service Provision

The product design provides for verifying the output of production and service processes by subsequent monitoring and/or measurement. In the event the resulting output cannot be monitored or measured the organization shall provide employees

with specific training as described above.

The organization shall provide the necessary work space, equipment (both hardware and software) and supporting services to facilitate the execution of the quality management system. Preventative maintenance programs shall be established on critical machinery and in particular those used for production of medical devices and their components. All preventative maintenance programs shall comply that recommended by the manufacturer's instruction manual. The appropriate Dept. Head is responsible for documenting the preventative maintenance.

Reference: P-1013 In-Process Inspection
P-1015 Quality Control Certification (Analyzer Instruction Manual)
P-1040 Statistical Techniques
P-1053 Preventive Maintenance
P-1054 Preventive Maintenance Form

7.5.2.2 Particular Requirements for Sterile Medical Devices
The devices are not required to be sterile in normal indications for use.

Reference: P-1081 Instructions for Use

7.5.3 Identification and Traceability
Procedures shall be established to identify and provide traceability of in-process production. With respect to sensors, a Device History Record shall be issued for each lot and travel with the product throughout the manufacturing process.

Sensor Department supervisors shall ensure the Device History Record properly identifies the product and is documented to record pertinent information such as target quantity, employee sign-offs and accept/fail/scrap quantities of critical operations, batch(es) finishing processes, labeling specimens to avoid mix-ups, final testing, serialization and final sign-off releasing the product for sale. Analyzer Department supervisors shall ensure that component sub-assemblies and/or final assemblies are produced in accordance with approved drawings. Further, final assemblies shall be identified, serialized and tested in accordance with established test procedures.

Analyzer Department supervisors shall ensure Quality Control Certification documents evidence conformity, e.g. initial and date, with established criteria, serialization and final sign-off releasing product for sale. Copies shall be retained by the department supervisor and sales administration with the original going to the customer as section 2 of the Owner's Manual that accompanies every analyzer.

Product and medical devices received from the field for repair, refurbishing or warranty claim shall be tagged and identified appropriately to clearly distinguish it from normal production. The returned material shall be segregated from normal production in a clearly marked area. The appropriate Department Head or his designate shall prepare a documented assessment report for each return. The identification of inspection and test status shall be maintained as necessary during the manufacturing process.

Reference: P-1011 Product Traceability
P-1015 Quality Control Certification (Analyzer Instruction Manual)
P-1058 Device History Record Sensors
P-1064 Order Processing Documentation
P-1073 Device History Record Analyzers

7.5.3.2.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices
This section is not applicable at this time.

7.5.4 Customer Property
Not applicable to the normal manufacturing process.

7.5.5 Preservation of Product
The organization's processes shall preserve the conformity of the product and related components during internal processing and delivery to the intended destination. Preservation shall include but is not limited to identification, handling, packaging, storage and protection.

Medical Device Directive 93/42/EEC Annex II as amended by 2007/47/EC: CE marking of conformity must appear in a visible, legible and indelible form on the device where practical and appropriate, on the instructions for use and where applicable on sales packaging. It shall be accompanied by the identification number of the notified body.

Since the manufacturer does not have a registered place of business in the EC, our name and address along with the name and address of our authorized representative in the European Community shall appear on the label, or outer packaging of the device, or instructions for use.

Reference: P-1032 Product Identification, Labeling, Storage and Preservation

7.6 Control of Monitoring and Measuring Devices

The heads of Manufacturing and Engineering shall be responsible for determining the appropriate inspection and test equipment necessary to ensure product quality. Further, they shall develop procedures to ensure the equipment is controlled, calibrated as necessary, maintained, and that the intended users are trained to use the equipment correctly.

In the event that equipment is found to be out of tolerance upon routine calibration or recommended checks a documented formal review of the effect of the out of tolerance condition on product shipped, completed inventory and work in process shall be conducted.

Reference: P-1016 Inspection, Measuring and Test Equipment
P-1068 Weigh Scale Calibration Record

8.0 Measurement, Analysis and Improvement

8.1 General

The organization shall implement appropriate methods, including statistical techniques, for the monitoring, measurement, analysis and improvements needed to demonstrate conformity of the product, ensure conformity of the quality management system and to continually improve the effectiveness of the quality management system.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As a means of assessing the performance of the quality management system, the organization shall monitor information (8.4) to determine whether the organization has met customer requirements.

Reference: P-1043 Product Complaint & Recall
P-1059 Complaint Record
P-1069 Key Data

8.2.2 Internal Audit

Internal quality assessments based on the standards identified by the 4.1 Quality System Requirements shall be conducted annually during the third quarter. At the discretion of the head of Quality, internal quality assessments may be conducted more frequently on the basis of importance or need for improvement. The assessment procedure shall provide for verification that corrective action was effective. The quality assessment shall assure equipment and protective systems intended and independently certified for use in potentially explosive atmospheres comply with Annex II of ATEX Directive 94/9/EC and EN 13980.

Reference: P-1020 Internal Quality Assessment

8.2.3 Monitoring and Measurement of Processes

The appropriate department head shall be responsible for developing sampling methods to assure the best possible product

quality. Further, the methods established shall be incorporated into the individual process control procedures. Variables such as operator experience, quality of equipment, tool wear and complexity of design may dictate the testing of every nth item to assure consistency. The adequacy and the effectiveness of statistical techniques and processes (as evidenced by the key indicators established by 8.4) shall be assessed at least annually in conjunction with the Management Review.

Reference: P-1015 Quality Control Certification (Analyzer Instruction Manual)
P-1030 Testing the Output of Sensors
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1058 Device History Record Sensors
P-1012 Vendor Assessment
P-1069 Key Data
P-1073 Device History Record Analyzers

8.2.4 Monitoring and Measurement of Product
The procedures established to identify and provide traceability of in-process production (7.5.3) shall include documented evidence of conformity with acceptance criteria, record the individual authorizing release of product for sale and retention of these quality records (4.2.4).

Reference: P-1015 Quality Control Certification (Analyzer Instruction Manual)
P-1030 Testing the Output of Sensors
P-1058 Device History Record Sensors
P-1064 Order Processing Documentation
P-1073 Device History Record Analyzers

8.3 Control of Nonconforming Product

Any indication of non-conformance shall be immediately brought to the attention of the appropriate supervisor(s) and be resolved or removed before resuming the task. Nonconforming product removed from the manufacturing process shall be clearly identified and segregated in the designated area of the storeroom. The appropriate department heads shall review and effect a timely disposition including any corrective action required.

Nonconforming product (analyzers and sensors) approved for rework by the aforementioned review shall be subject to the original test criteria. Compliance with the original test criteria shall constitute satisfactory evidence that there are no potential adverse affects from the rework. Sensor rework is limited to a second heat seal and/or replacing the circuit board, otherwise they are to be scrapped. Analyzers may be reworked in accordance with accepted troubleshooting techniques including component replacement. Failed components shall be scrapped.

Reference: P-1012 Receiving Inspection
P-1017 Control of Non-Conforming Product & Review
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1043 Product Complaint & Recall
P-1059 Complaint Record

8.4 Analysis of Data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and identify opportunities where improvements can be made. Sources include data generated by compliance records, processes and other relevant sources.

The organization shall institute, maintain and document a periodic quarterly review of feedback from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action, including notifying the competent authorities of any malfunction or deterioration in the performance of a device or inadequacy in the instructions for use which might lead to or might have led to the death of a patient or serious deterioration in the state of health or a systematic recall of devices.

Analysis of Sales/Shipments:
- Territory
- Sales Reps/Distributors
- Major Customers
- On-time Delivery
- RMA Turnaround Time
- Analysis of Quotations Issued – Success Rate, Reason for Losing Order, Repeat Business
- Feedback from independent sales reps/distributors and customers

Analysis of Non-Conforming Material:
- Device History Records
- Returned Material Assessment Reports – Sensors
- Returned Material Assessment Reports - Analyzers

Vendor Evaluation - Quality System, Product Quality, Accuracy, On-time Delivery

Reference: P-1012 Receiving Inspection
P-1013 In-Process Inspection
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1043 Product Complaint & Recall
P-1058 Device History Record Sensors
P-1064 Order Processing Documentation
P-1065 Vendor Approval / Evaluation
P-1069 Key Data
P-1070 Purchase Order Log
P-1073 Device History Record Analyzers

8.5 Improvement

8.5.1 Continual Improvement

The objective of the quality assurance system is two-fold: a) to demonstrate the organization's ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and, b) aims to enhance customer satisfaction through effective application and continual improvement of processes within the system.
Information accumulated from customer feedback, management analysis reports and management review input (including third party audits) shall be communicated within the organization to achieve the stated objectives - demonstrating the organization's ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and, enhancing customer satisfaction through effective application and continual improvement of processes within the system.

Reference: P-1015 Quality Control Certification (Analyzer Instruction Manual)
P-1030 Testing the Output of Sensors
P-1058 Device History Record Sensors
P-1069 Key Data
P-1073 Device History Record Analyzers

8.5.2 Corrective Action

Use of corrective action process is not limited to deviations from procedures, nonconforming product or internal quality audits. Opportunities for improvement shall be accorded the same degree of investigative analysis, documentation, determination and implementation of conclusions.

Where deemed necessary by feedback from the marketplace, competent authorities, customer complaints or the assessment of returned material, procedures shall be established to provide customers with an advisory notice or conduct a product recall at the discretion of the company.

With respect to medical products, all complaints as defined by §820.3 of the FDA Federal Register shall be recorded as required by §820.198 of the FDA Federal Register, issued a reference number and provided to the reporting party.

Formal CAPA/ECO request forms shall be limited to significant events. The appropriate department heads shall verify and sign-

off on the CAPA/ECO form that the change is effective. The appropriate Department heads shall be authorized to designate, approve, and implement minor changes including but not limited to clarifications, modifications for special one of a kind orders, typographical errors, etc. based on informal discussions, sketches, red line notes, etc. Similarly, Department heads shall be authorized to conduct and document at their discretion targeted training reinforcement based on individual instances generated by the Returned Material Assessments and Device History Record.

Medical device vigilance reporting and recall procedures shall be established (reference MEDDEV 2.12-1 rev 4) with respect to what to report, format, content and timescales.

Reference: P-1017 Control of Non-Conforming Product & Review
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1043 Product Complaint & Recall
P-1058 Device History Record Sensors
P-1064 Order Processing Documentation
P-1069 Key Data
P-1070 Purchase Order Log
P-1073 Device History Record Analyzers

8.5.3 Preventive Action

The organization shall make a concerted effort to identify and eliminate potential nonconformities in order to prevent a repeat. These efforts shall be documented using the CAPA/ECO procedure and form.

Reference: P-1017 Control of Non-Conforming Product & Review
P-1041 Returned Material Assessment Sensor
P-1042 Returned Material Assessment Analyzer
P-1043 Product Complaint & Recall
P-1058 Device History Record Sensors
P-1064 Order Processing Documentation
P-1069 Key Data
P-1070 Purchase Order Log
P-1073 Device History Record Analyzers