

Endure Medical, Inc.
Quality System Manual
ISO 9001:2000
&
ISO 13485:2003



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Endure Medical, Inc. Quality System Manual

Table of Contents

Section	Topic	Page #
i	Quality Policy	i
0	Introduction	1
	Eight Quality Management Principles	1
	Process Approach	2
	Effective Date of the QMS	2
1	Scope of the Quality Management System	2
2	Normative References	3
3	Terms and Definitions	3
4	Quality Management System	3
	Process Interrelationships & Requirements	3
	Quality Management System Documentation	5
5	Management Responsibility	8
	Management Commitment	8
	Customer Focus	9
	Quality Policy (see p. 5, 4.2.1.2.a)	9
	Planning	9
	Responsibility, Authority and Communication	10
	Management Review	11
6	Resource Management	12
	Provision of Resources	12
	Human Resources	12
	Infrastructure	13
	Work Environment	13
7	Product Realization	14
	Planning of Product Realization	14
	Customer Related Process	14
	Design Control	15
	Purchasing	18
	Production and Service Provision	20
	Control of Monitoring and Measuring Devices	24
8	Measurement, Analysis and Improvement	24
	Plan for Implementation	24
	Monitoring and Measurement	25
	Control of Non-Conforming Product	26
	Analysis of Data	27
	Improvement	27
9	Revision Record	29

Endure Medical, Inc.

Quality System Manual

0. Introduction

While not a specified requirement of ISO 9001:2000 or ISO 13485:2003, the eight fundamental quality management principles identified in ISO 9001 and ISO 9004 form the basis for a quality management system. Thus, these eight principles and how they affect Endure Medical, Inc. are addressed as follows:

0.1.1 Customer Focus

Endure Medical, Inc. is a customer focused organization, as evidenced by our Quality Policy and as practiced in daily operations. We use customer feedback and attention to customer needs as the basis for our operations.

0.1.2 Leadership

The Executive Team insures that the work environment is one in which our people can effectively perform their jobs. Our approach is that as we serve our employees by helping them be more effective on their jobs, they will in turn be more productive and more customer-oriented. The Management Review Process, daily reporting processes and job responsibilities insure that we provide positive leadership to our organization.

0.1.3 Involvement of People

As a small organization all of our people must be involved in the processes at an appropriate level according to each one's abilities. We encourage independent thinking, individual responsibility at all levels and provide the freedom for employees to bring their ideas and improvements to the leaders of the company. Teamwork is a must for us to be successful.

0.1.4 Process Approach

Endure operations are processed focused. The basic product realization processes involve purchasing used medical microscopes and re-furbishing them for sale; and assembling new medical microscope assemblies from purchased and/or manufactured components. At the upper management level, the management processes are defined and implemented according to our quality management system documentation. Verification processes are implemented to monitor process and product performance, to ensure we are meeting customer requirements and to provide a basis for continual improvement.

0.1.5 Systems Approach to Management

The Quality Management System at Endure Medical consists of interrelated processes that must be managed as an entire system. These processes are

depicted in our flow charts and process descriptions procedures. The Management Review process is used to insure that we focus on our entire system.

0.1.6 Continual Improvement

Continual Improvement is a part of our quality policy and is vital to our long-term success as a company. We use verification steps as well as employee-initiated corrective and preventive actions as an integral part of improving our quality management system.

0.1.7 Factual Approach to Decision Making

Information from our processes is utilized in decision making. A system of quality objectives has been identified to help us be more effective in goal setting, factually monitoring performance and decision making for day to day operations as well as long range planning.

0.1.8 Mutually Beneficial Supplier Relationships

At Endure we intend to be in business for the long term and realize the importance of building and maintaining relationships with those whom we conduct business.

0.2 Process Approach

The process approach at Endure focuses on the basic product realization processes and their inter-relationships as well as the pre-production and post-production processes. These are all described in more detail in section 4.0 of this manual and in a series of flow charts that describe our processes.

0.3 Effective Date of Quality Management System

The ISO 9001:2000 and ISO 13485:2003 Quality Management System became effective on September 25, 2007.

1. Scope of the Endure Medical Quality Management System

1.1 The scope of the Endure Quality Management System ISO 9001 and ISO 13485 QMS includes the processes for sales, assembling new, re-furbishing used, installing and servicing surgical microscopes. **The ISO 13485 requirements are indicated by bold type like this.**

1.2 Exclusions

Clause 7.3 Design is not a part of the current QMS; clause 7.3 is left in the QMS documents for future use if we need to add design to our system at a later date. Clause 7.5.2, there are no processes that require validation.

***Clauses 7.5.1.3 and 7.5.2.2, there are no requirements for sterilization
Clause 7.5.3.2.2, the products of Endure Medical are not active implantable nor implantable devices.***

2. There are no additional normative references to other standards.

2.1 All applicable regulations must be met by Endure's management systems.

3. Terms and Definitions as they relate specifically to Endure Medical, Inc.

Customers are those for whom we provide services and products. Customers include both end users and/or dealers.

Vendors are those who provide products and services to us.

Organization generally refers to Endure, however in some specific cases it may only apply to a specific situation or location in a particular Standard Operating Procedure.

Product is used at Endure to refer to those products re-furbished or assembled at our facility as well as installation and servicing on site.

New Product generally refers to products that are not re-furbished.

Technical Team refers to the technical employees of Endure Medical.

Executive Team refers to the President and VP of Sales and VP of Finance.

4. Quality Management System

4.1 General Requirements

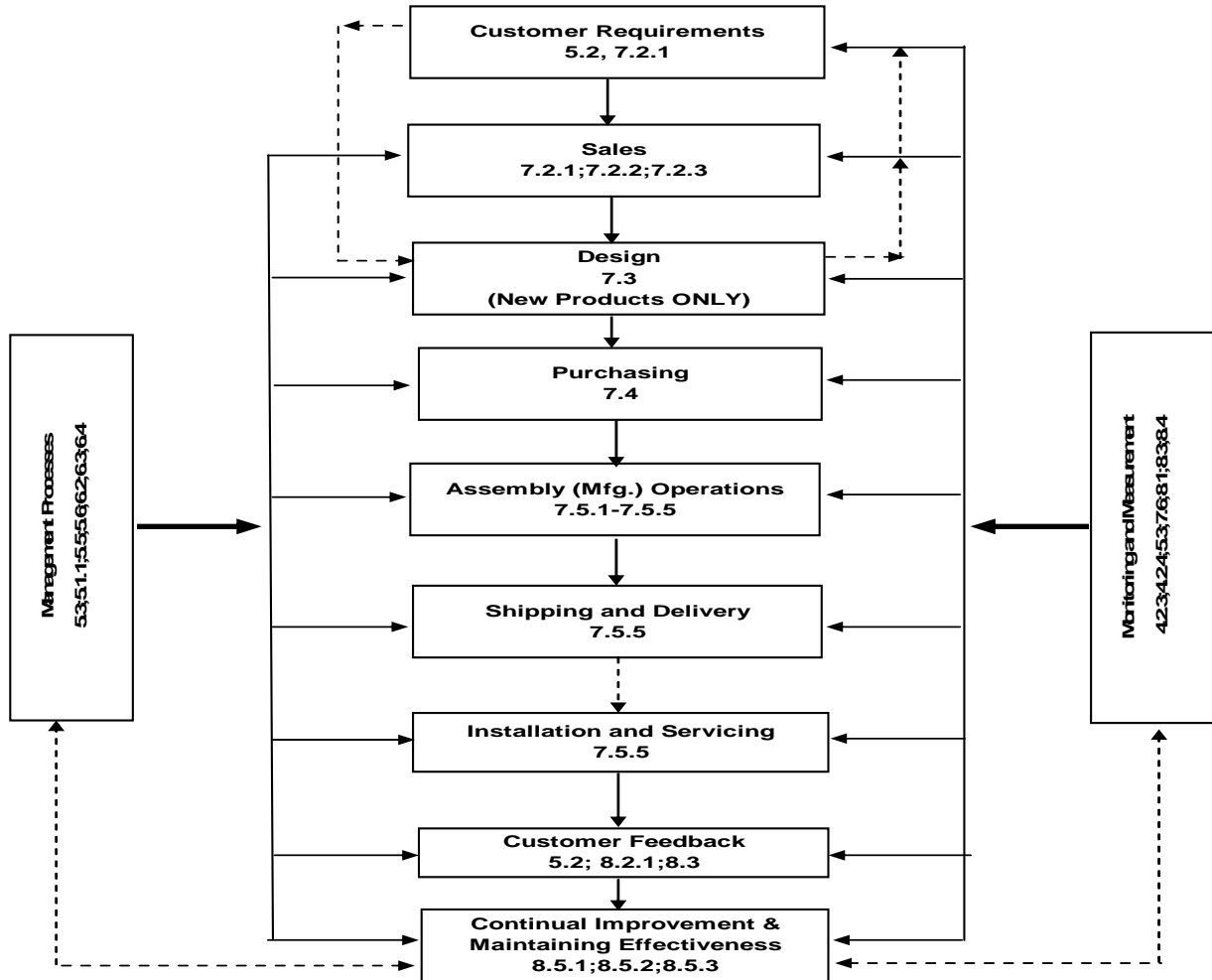
a) The processes at Endure and their interrelationships are identified as follows:

Endure Medical, Inc. Interrelationship of QMS Processes

Process Flow Chart:

The High level sequence and interaction of processes to manufacture products to the requirements of our customers; and to control, monitor and measure those processes is shown in the following chart.

Endure Medical High Level Process Sequence and Interrelationships



b) We use this flow chart as a tool to identify and determine the inter-relationships and sequences among the QMS processes at Endure. Additionally, we use a series of flow charts maintained in the relevant SOP's.

c) The criteria and methods to ensure operation and control of these processes are described in the SOP's in the Quality Management System. The effectiveness of these processes is monitored with specific monitoring and measuring criteria, our verification processes and management reviews.

d) Endure is committed to providing the necessary resources, leadership, training, and facilities that are consistent with the organization's commitment to quality and quality policy. Resources are identified through the contract review and management review processes. Information is managed via daily

internal communications and generally this is by one-on-one conversations between supervisors and workers.

e) Processes are controlled, monitored, measured and analyzed as depicted in the flow charts and various quality system procedures.

f) *Using the process approach we implement the actions necessary to control processes in order to achieve planned results, maintain the effectiveness of the processes and continually improve our processes while meeting customer requirements.*

Optical repairs which are beyond the technical capabilities of Endure Medical for re-furnished microscopes are outsourced to a sole source provider who has been qualified. Purchase orders with the technical requirements and verification upon delivery to Endure are the primary means of controlling this outsourced process. When machining or cable assemblies are outsourced they are controlled via purchase requirements and incoming inspection. Certain calibrations may be outsourced and properly controlled through the purchasing process and quality control reviews of results.

4.2 Quality Management System Documentation

4.2.1 General

The Endure quality system is described in this manual and is intended to conform to ISO-9001:2000 and ISO 13485:2003. The system is designed to insure customer requirements are consistently met or exceeded and that continual improvement is practiced. The Endure Medical, Inc. QMS is designed and implemented around our product realization processes.

4.2.1.1 The Endure Medical QMS became effective September 25, 2007.

4.2.1.2

The Quality Policy is established by management and reviewed during Management Review meetings. Quality goals are established relative to the policy and the policy is reviewed with employees by their supervisors. Understanding of the policy is verified during Internal Audits of the Quality System. The effectiveness of the quality policy is verified during internal audits, reviewed during Management Review, and by measuring results relative to our goals and objectives.

a) *Quality Policy: It is the intent of Endure Medical for the end user to be completely satisfied and ready to do more business with our company. We are committed to:*

- ***Meeting customer and regulatory requirements;***
- ***Satisfying our customers;***

- ***Maintaining the effectiveness of our QMS and,***
- ***Continually improving the processes of our QMS.***

Specific goals and objectives are established using this policy as a framework. The effectiveness of this policy is measured through Management Review of the policy and related quality objectives; and Internal Audits. Quality objectives include customer complaints, Warranty issues; quality monitors; on-time deliveries and safety record. These are a part of the management review process.

b) The Endure Medical Quality System Manual is a controlled document that requires the approval of the President when changes are made. It describes the Quality Management System at Endure and conforms to the requirements of ISO 9001:2000 and ISO 13485:2003. Exclusions are noted in the appropriate location in the manual. Procedures are referenced throughout the manual as appropriate.

c) The procedures required by ISO 9001:2000 and/or ISO 13485 are referenced in the appropriate section of the Quality System Manual. Endure uses a system of controlled documents that includes the Quality Manual, Standard Operating Procedures, Checklists, Work Instructions and Forms.

d) Other documents needed by the organization for effective management of the quality system processes are primarily published references and materials for the specific types of medical microscopes we re-furbish and/or assemble.

e) Quality Records are identified in the Quality Records Procedure SOP-424P001 which defines the procedures for maintaining, filing and disposing of all quality related records, and the record retention schedule. It is the intent of Endure management to be in full compliance with all regulations regarding record retention.

f) When other documents may be specified by national or regional regulations they will be added to the QMS documentation.

A device file is maintained for each type of product we assemble. The device file is also the customer file. This file contains the identifying information, product specifications, quality system requirements and define the processes used in the assembly of these products.

4.2.2 Quality System Manual

a) The ***scope of the quality management system*** and quality system manual is defined in 1.1 and 4.2.1 of this manual. The exclusions noted have been reviewed and approved by management as evidenced by this approved manual.

b) Procedures are in the form of Standard Operating Procedures (SOP's) and Work Instructions, which may be in the form of checklists; and are controlled documents that provide the necessary level of detail for trained personnel to perform their jobs. Additionally, there are controlled forms and customer supplied specifications to aid in the performance of certain specified tasks. These may be maintained in hard copy or electronically. Procedures are also addressed in 4.2.1 above.

c) Description of the Sequence and Interaction of Processes is via the flow charts and process descriptions in 4.1 of this manual and in reference SOP's within the Quality System. The entire process approach at Endure Medical is depicted in 4.1 of this manual and specific flow charts within procedures.

The structure of the documentation is outlined in the appropriate sections of this manual and in SOP 423P001.

4.2.3 Control of Documents

a-g) Document control for Endure' Quality System documentation is defined in SOP 423P001 and covers the requirements in 4.2.3 (a-g) of ISO 9001:2000 and ISO 13485:2003. It provides for ***review and approval for adequacy prior to use***, use, legibility, accessibility and revision of quality system documentation.

The referenced procedure also includes the requirements for approving changes to documents and the retention of obsolete documents as specified in ISO 13485.

The Quality System Manual, SOP Manual, Checklists and Forms are the primary quality system documents. The master list is maintained by the ISO Management Representative. The quality system documentation is a part of the Management review process.

These documents may be in hard copies or electronic format.

External Documents:

Control of external documents is defined in SOP-423P001.

4.2.4 Control of Quality Records

a-g) The control of quality records is accomplished through SOP-424P001 and as referenced in 4.2.1 (e) above in this manual.

The referenced procedure also includes the specific requirements concerning records retention for the lifetime of the devices and not less than two years from the date of product release.

5. Management Responsibility

5.1 Management Commitment and evidence of commitment

a) Endure's management is committed to **developing**, establishing, implementing and **maintaining the effectiveness** of a quality management system that conforms to the requirements of ISO 9001:2000 and ISO 13485:2003 as evidenced by the quality system documentation. The management commitment and involvement is evidenced by the corrective and preventive action systems, continual improvement of the quality system, management reviews, resource reviews and internal audit reviews that require management involvement and signatures as appropriate. The quality policy and goals include appropriate environmental and regulatory issues which are communicated to employees, as appropriate, and evaluated via internal audits and reviews by management.

b) Management establishes the quality policy and reviews it for effectiveness during management reviews. The policy stated in this manual and approved by the President of Endure is evidence of this.

c) Quality Objectives are an integral part of the Quality Management System at Endure. They are established during the 4th quarter of each calendar year for the following year and documented appropriately. These objectives are reported on and results evaluated through our Management Review process and other meetings of the Executive Team. The Executive Team may revise goals as necessary based upon results. The effectiveness of the quality policy is evaluated as stated in 4.2.1.2.a of this manual.

d) The Quality System Reviews and evaluation of effectiveness are accomplished primarily through the Management Review Process which is described in SOP-560P001. The Executive Team reviews the entire Quality System at least annually for **effectiveness** and to identify opportunities for Continual Improvement.

Management review includes, at least annually, a review of the quality policy, objectives, continual improvement actions, customer satisfaction, corrective and preventive action and internal audits.

e) Management conducts Resource Reviews during Management Review meetings and other meetings of the management team. Endure is committed to providing the necessary resources, infrastructure, facilities, leadership, training, and facilities that are consistent with the organization's commitment to quality.

Resource needs are identified through the management review process and other meetings of the Executive Team. These reviews include organizational issues and infrastructure issues such as facilities, capabilities, training needs and any other resources that may be needed to keep our commitments to our customers, employees and regulatory compliance.

5.2 Customer Focus

The Vice President Endure Medical Engineering is responsible to see that customer requirements are **determined** prior to beginning work on an order and that **requirements are met**. These requirements are identified through customer supplied specifications, industry standards and conversations and meetings with our customers prior to contracts being issued and approved. The basic requirement is to insure our capability to meet the customer's requirements.

The Contract Review process is defined in 7.2 of this manual and includes the system for handling amendments to contracts or orders.

Records of Contract Review are the approved quotes that have been converted into sales orders and scheduled into production.

5.3 Quality Policy

a-e) The quality policy is determined to be appropriate to our organization by the evaluation of its effectiveness. The quality policy includes our commitment to **complying with (meeting) customer requirements**, to **maintain the effectiveness** of the quality system and to continually improve the system. It is reviewed, communicated and verified for understanding as stated in 4.2.1 and 5.1.c of this manual. The policy provides the framework for establishing and reviewing quality objectives. The effectiveness and continuing suitability of the policy is determined by results relative to our objectives, internal audits and management reviews (see 4.2.1.2a).

5.4 Planning

5.4.1 Quality Objectives are established by management and include relevant product requirements at the appropriate level of operations. These are addressed in detail in 4.2.1 and 5.1.c of this manual. These sections include provisions for measurement and review. Also, our system of Quality Objectives is a significant part of the review and evaluation of meeting our quality and other business goals.

5.4.2 QMS Planning is a function of the Endure management team and is accomplished primarily in management reviews. Our system of

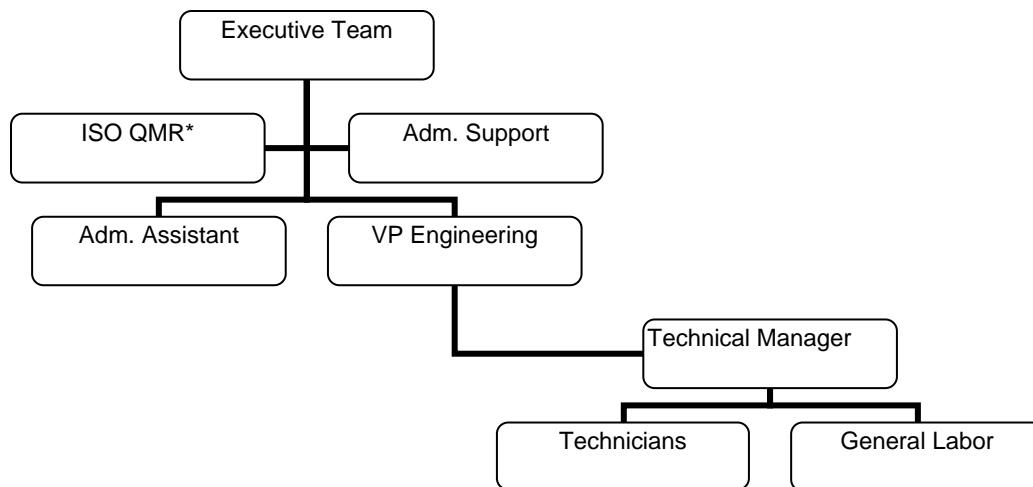
documentation is evidence of quality planning. The President of Endure Medical is ultimately responsible for the Quality Planning Process. The responsibility for administering the quality system lies in the position of the VP of Engineering, who is also the ISO Quality Management representative.

- a) The Quality Planning process at Endure is evidenced by the various SOP's which specify planning for meeting the customer's requirements.
- b) Changes to the system are implemented according to our document control procedures and require the appropriate levels of approvals to insure the integrity of our quality system and continued conformance to those requirements. Changes may be identified by an employee, manager, customer or other interested party or during management reviews and meetings or in some other manner brought to the attention of management. Changes are implemented according to stated procedures.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The management and employee responsibilities and authority are outlined in the organizational chart and detailed in **SOP-551P001** *which also outlines the responsibilities and authority, interrelationships of personnel and the independence of authority as appropriate*. The organization chart is as follows:



**Note: The ISO Quality Management Representative is a function fulfilled by the VP of Engineering and is not a separate position.*

5.5.2 Management Representative

- a) The ISO quality management representative is a member of management, is appointed by the President and is responsible for reviewing processes

of this QMS. The management representative will determine if any new processes exist that have not been documented or if new processes need to be added to the quality management system by reviewing corrective and preventive actions; internal audits; key indicators and management reviews. If deemed necessary new processes will be established and included in the documentation of the quality system according to the established document control procedures. These reviews are noted in the Management Review Minutes.

- b) The quality management representative (QMR) reports on the effectiveness of the quality system during the Management Review meetings and uses the quality goals, business goals, internal audits and other quality records as necessary to evaluate and report on the quality system.
- c) Promoting Customer awareness of **customer and regulatory requirements** within the organization is a responsibility of the President and the Quality Management Representative in Endure. Supervisors and employees are made aware of **customer and regulatory requirements**, generally verbally or through sales orders, checklists and/or SOP's; and, appropriate information is communicated to the employees.

5.5.3 Internal Communication

Effective and simple internal communications systems are vital in our organization. The management review process and other meetings or conversations are the primary means of communication among the Endure management team for the effectiveness of the QMS. Monthly reviews are held with information from sales, service, accounting, engineering or technical, shipping and general performance as inputs for the executive team. One-on-one conversations with employees are the primary means of communicating with employees for the effectiveness of the quality system. In daily operations, routine employee discussions, as well as daily reporting requirements and customer files or device files are key components of our internal communications.

5.6 Management Review

5.6.1 General

The Executive Team of Endure reviews the entire Quality System at least annually for effectiveness and to identify opportunities for Continual Improvement.

Management review includes a review of the quality policy, objectives, customer satisfaction, corrective and preventive action and internal audits. ***New or revised regulatory requirements, if any, are covered in the review.***

5.6.2.1 Management Review Inputs are defined in SOP-560P001.

5.6.2.2 Management Review Outputs are defined in SOP-560P001.

6. Resource Management

6.1 Provision of Resources

Endure is committed to providing the resources necessary to ***maintain*** and improve the effectiveness of the quality management system and to insure continued and enhanced customer satisfaction while meeting ***customer and regulatory requirements***. This is accomplished through resource reviews as stated in 5.1.e of this manual and in the appropriate SOP's.

6.2 Human Resources

6.2.1 Endure realizes the strength of the organization lies in its commitment to developing our people. The process for training and developing personnel is in SOP-622P001.

6.2.2 Competency, Awareness and Training

- a) The matrix of required competencies referenced in SOP-622P001 is the vehicle for identifying and listing the competencies required and/or ***training needs*** for each position in our organization. These are reviewed by management; and, the responsibility for providing the necessary training lies with management. These include quality system and quality responsibilities as well as specific job task requirements.
- b) Endure is committed to providing the necessary training to insure that we have competent employees performing the tasks within our organization. The training SOP is SOP-622P001.
- c) Training effectiveness is generally monitored by the Executive Team or specific supervisor to insure that employees are adequately trained in the specific tasks related to product quality and operations as defined in the training SOP. This may include the observation of tasks, OJT results and/or testing. Records of this determination are addressed in the SOP.
- d) It is the responsibility of the managers and the QMR to insure that all personnel are aware of how their job activities relate to the overall quality system and accomplishing our objectives. This is also verified during internal audits by interviewing employees.
- e) Training records are maintained according to SOP-424P001.

6.3 Infrastructure

Endure determines infrastructure requirements necessary to meet customer requirements through the resource review process as described in this manual and in the management review SOP. These include, at a minimum:

- a) Buildings, workspaces, utilities, security systems, parking areas
- b) Process equipment or other related equipment needed for operation
- c) Support Services; i.e. communications equipment such as computers, cell phones.

The required provision and maintenance of these resources is the responsibility of Endure management.

Documented requirements for maintenance activities are provided when the lack of such documentation could affect product quality. These may be in the form of procedures or checklists.

6.4 Work Environment

The work environment at Endure includes both the physical facilities and the organizational environment. Endure is committed to providing the necessary facilities and work spaces to accomplish our objectives, using the resource review process previously outlined.

There are specific industry regulations (FDA and OSHA) that must be met by our work environment.

The organizational environment is equally important to Endure. We encourage teamwork and expect each employee to be responsible for the quality of work each day.

a-b) There are no requirements for specific health, cleanliness or clothing because such contact between our employees and our products does not adversely affect product quality. Thus, there is no requirement for a procedure addressing these issues.

c) Any temporary personnel that may be required to work directly on our products are appropriately trained.

d) There are no special requirements pertaining to contaminated products due to the nature of the product produced at Endure.

7. Product Realization

7.1 Planning of Product Realization

Quality planning and the process flow chart in SOP 750P001 titled Manufacturing Operations and Quality Plan, are the vehicles by which we insure appropriate product realization functions for our customers. These include:

- a) Any objectives and requirements for the product,
- b) Establishing the appropriate process documents and resources which are generally in the form of SOP's or Work Instructions.
- c) Product testing and/or inspection is done by Endure according to our quality plan. Requirements for inspection, verification and/or testing are shown on the appropriate procedures or flow charts.
- d) Records are maintained according to the Quality Records Procedure, SOP-424P001.

Output of planning is in a form suitable to the Endure organization, which may be SOP's and/or other specific quality related documents such as checklists or work instructions as required by our processes. SOP 750P001 is our manufacturing and quality plan.

Risk management is addressed in the appropriate procedures (SOP 710P001). The principals used in our Risk Management process are based upon ISO 17941:2007. A Process and Product Integrity Matrix along with Failure Mode Effects Analysis (FMEA) are the tools we use to determine risks and manage risks. Records are maintained.

7.2 Customer Related Process

7.2.1 Determination of requirements related to the product are by the contract review process as described in SOP 721P001. This procedure addresses the specific requirements of the ISO standard and includes requirements, documentation, feasibility, capabilities, resolving differences, and amendments or changes to orders. These aforementioned reviews also include:

- a) Requirements that are stated by the customer, including any special shipping or delivery requirements.
- b) There are no requirements that are not stated but known.

c) There are product related statutory or regulatory requirements that must be met relative to FDA Class I medical devices and are included in our management systems.

d) Any additional requirements that may be identified are addressed contractually.

7.2.2 Review of requirements related to the product are defined in SOP 721P001 of this manual and include responsibilities related to the following:

a) Defined product requirements

b) Resolution of differences if order requirements differ from those previously expressed.

c) Ability to meet requirements

Amendments to contracts/orders and evidence of reviews are addressed in the procedure.

7.2.3 Customer Communications

The Sales Team and the Technical Team members are the primary channels of communications with our customers. Their responsibilities include:

a) Appropriate product information such as model numbers, catalogues and components.

b) Enquiries, contracts, order handling, amendments as addressed in section 5.2 and 7.2.1 of this manual.

c) Customer feedback, including complaints which are included in section 8.3 of this manual and in the appropriate procedures. Also customer satisfaction is addressed in our quality objectives and corrective and preventive action systems.

d) Advisory notices are addressed in SOP 851P004.

7.3 (EXCLUSION) Design Control does not apply in all cases of re-furnished or even the assembly of the new products. It is generally an activity that lies with the original manufacturer of the optics and/or stands. However, there are cases where certain components may be designed by Endure Medical and thus we are including design control in the scope of our QMS.

7.3.1. Design and development planning

Endure Medical has a documented procedure for design and development, SOP 730P001. This procedure covers the planning and control for product design and development.

The technical personnel involved in design and development have the appropriate background, experience or training to effectively accomplish the associated tasks.

The procedure for design and development addresses the stages of design and development, ***the review, verification, validation and design transfer activities that are appropriate to our products and the responsibilities and authority of those employees involved in the process.***

Managing the interfaces between the various interested parties is accomplished via internal meetings, communications and records so that effective communications occur and responsibilities are understood. Being a small organization this does not require a significant division of departments, but is rather a teamwork approach to the design and development process involving those who may be affected within Endure Medical.

Planning output is documented in an appropriate manner for Endure Medical and may simply be in the form of meeting minutes, emails, logbooks, drawings or other information that is routinely reviewed and updated as the project progresses.

7.3.2 Design and development inputs

Design Input generally originates within Endure Medical as we evaluate products that are currently on the market and seek to improve the design or create new products. Design input includes:

- a) Functional, performance and relevant safety requirements for intended product use.***
- b) Applicable statutory and regulatory requirements are also input to the process.
- c) Information from previous designs will be considered where applicable. A database of designs is maintained by the Vice President Endure Medical Engineering to facilitate transfer of information among designs.
- d) Other requirements essential for design and development are included by the Vice President Endure Medical Engineering and/or the design team.

- e) The outputs of the risk management assessments are also utilized as design input as appropriate.***

The various design inputs are reviewed by the design team for adequacy and approved as the process moves forward.

Incomplete, ambiguous or conflicting requirements are resolved. Design input takes into consideration the results of contract review activities.

7.3.2 Design and Development Outputs

Through the design procedures, the design output is verified and validated against design input requirements. Design output must meet the design input requirements, contain or make reference to acceptance criteria and identify Special Characteristics, where required. The design and development outputs include:

- a) How well we are meeting the design input requirements
- b) Providing the appropriate information for purchasing, production and servicing
- c) Product acceptance criteria or references
- d) Specifying and characterizing any safety and proper use requirements

Records of the design output are maintained according to our records procedure, 424P001.

7.3.3 Design and Development Review

Design Reviews are held and documented at appropriate phases or stages of the design process. These reviews are to:

- a) Evaluate the ability of the design and development process to meet the requirements that have been established.
- b) Identify potential problems with the design and propose necessary actions.

Participants in these reviews are from the appropriate functions and represent a multi-disciplinary approach to design reviews to insure the necessary functions and expertise are represented.

Records of these reviews are maintained according to our records procedure, 424P001.

7.3.4 Design and Development Verification

Design verification is defined as design input requirements meeting design output requirements. Design verification measures are recorded in design reviews. Design verification is to insure that we meet the planned outcomes of the design planning process. Records of these verification reviews are maintained.

7.3.5 Design and Development Validation

Design validation is defined as a design that functions, operates and works the way in which it was intended. Design validation is recorded in Design Reviews. Design and development validation is performed as planned in the design process to ensure that the product is capable of meeting the requirements for the specified application or intended use. This validation is completed prior to the delivery of the product.

Records of design validation are maintained according to our records procedure 424P001.

There are no national or regional requirements for clinical evaluation of these devices.

7.3.7 Control of design and development changes

Design changes are to be identified in the appropriate documents and or device files. These records are maintained by the Vice President Endure Medical Engineering. Changes are reviewed, verified and validated, as appropriate, prior to implementation of the changes. The review includes evaluation of the results of the changes on devices that may have already been delivered.

Records of change reviews are maintained according to our records procedure, 424P001.

7.4 Purchasing

7.4.1 Purchasing Process

The Executive Team is responsible for the procurement system and purchasing functions of Endure. The purchasing system is defined ***in SOP 740P001*** and includes requirements for purchase orders and approvals on purchased items. ***It also includes procedures to ensure that purchased product conforms to specified requirements.***

Major equipment purchases are approved by the Endure President and the Board of Directors.

A master list of approved vendors is maintained by the ISO QMR. Suppliers are approved on the basis of their historical and continued acceptable performance with Endure. The basis for selection, evaluation and re-evaluation includes availability, service, on-time delivery, specifications, pricing and general satisfaction with the supplier. These records are reviewed during management review and are maintained by the QMR.

The VP Engineering selects suppliers for daily operational items that may fall outside the normal scope of the Approved Suppliers in an emergency.

Used microscopes or assemblies that are purchased for re-furbishing fall outside the normal purchasing process are generally reviewed by the Executive Team prior to purchase orders being issued. However, this may be delegated to the Administrative Assistant in certain cases; and is addressed in SOP 740P001.

Certain components used in new assemblies may require certificates of conformance or other records from the supplier. In these cases the necessary information is to be included on the purchasing documents.

7.4.2 Purchasing Information

Purchasing information is specified and recorded on product related items purchased. Included, as appropriate are:

- a) Requirements for approval of product, procedures, processes or equipment where an on-site inspection may be necessary. This is not a typical situation for Endure and is detailed here simply to cover such situations should it become necessary.
- b) Qualifications of personnel, and
- c) Quality Management System Requirements such as NIST requirements for calibration services.

Determining the adequacy of vendors and/or information prior to placing orders is accomplished through the approved vendor list, the vendor selection criteria; and, the placed order is evidence of this determination.

Traceability is maintained on certain specified components by requiring serial numbers from our vendors and this is specified in our purchasing process.

7.4.3 Verification of Purchased Product

Verification of purchased product is addressed in the purchasing procedure, SOP-740P001 and in our inspection processes and procedures. The purpose is to verify that we got what we ordered and that it meets intended requirements.

Vendor audits may be required or performed due to the nature of our business and the audit form is a part of our QMS. We also reserve the right to inspect any capital equipment or raw materials prior to acceptance.

Records of purchased product verification are maintained according to 424P001.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 General Requirements

Processes at Endure are carried out under controlled conditions as specified in the various SOP's related to our processes. These include, as applicable:

- a) Information that describes product characteristics is provided in the various quality system documents used within Endure.
- b) ***Documented procedures (SOP's), documented requirements*** and/or Work Instructions, checklists, ***reference materials and reference measurement procedures***, as necessary, are available to employees.
- c) It is the responsibility of the Executive Team to insure that necessary and suitable equipment is available to insure effective process operations and customer satisfaction.
- d) Monitoring and measurement equipment is available and is controlled according to SOP 760P001.
- e) Implementation of monitoring and measurement is accomplished through our system of controlled documentation and management involvement. Quality records provide evidence of necessary process monitoring.
- f) Implementation of release, delivery and post-delivery activities are critical at Endure due to the nature of our product .These are covered in the appropriate documents and include installation and servicing.
- g) ***There is a defined operation for labeling and packaging which is covered in SOP 751P002.***

Each device that is shipped is uniquely identified to insure traceability and certain components within the device are serialized as well. A batch is considered one medical microscope.

The batch record is the sales order/checklist which is reviewed and approved by a member of the Technical Team prior to shipment.

7.5.1.2. Specific Requirements

7.5.1.2.1 Cleanliness of Product and Contamination Control

We have no sterile products at Endure Medical and our products are not subjected to a sterilization process after shipment. There are no process agents to be removed from the product during manufacture. There are no requirements for contamination control due to the nature of our product.

7.5.1.2.2 Installation Activities

The documented requirements relative to installation of medical microscopes are found in the appropriate product literature and the checklists for installation that specify acceptance criteria. These apply equally to products installed by Endure personnel, dealers and/or end users. The installation process is described in the flow chart.

Records of installation are maintained for products installed by Endure personnel. There are authorized agents doing installation for Endure and these agents are qualified by Endure Medical on the basis of training, experience or observation. When dealers do installation, they are the product owner at that point and not Endure Medical.

7.5.1.2.2 Servicing Activities

Endure Medical provides warranty claims servicing as well as repairs and other servicing for the flow chart which covers the specific instructions as well as reference measurements as appropriate.

Records of servicing are maintained in the customer file.

7.5.1.3 Particular Requirements for Sterile Medical Devices

There are no requirements for sterilization, thus this clause is excluded.

7.5.2 Validation of Processes for Production and Service Provision

7.5.2.1 General Requirements

Validation of Processes is not required and is excluded from the quality management system. There is no requirement to validate special processes since the processes at Endure can be properly verified through our control and measurement processes.

Product related software written by Endure is bench tested before being released for production use. Software that is a part of the design process is covered under SOP 730P001. Records are maintained by the VP Engineering.

7.5.2.2 Particular Requirements for Sterile Medical Devices

There are no requirements for sterilization, thus this clause is excluded.

7.5.3 Identification and Traceability

7.5.3.1 General

Product Identification and status is via tags and serial numbers that tie a microscope to a sales order and the customer required documents for shipping or delivery. ***The procedure for identification and traceability is 753P001.*** There is traceability for each microscope that is delivered by Endure. The system is intended to comply with customer and regulatory requirements.

Each microscope is tied to a unique sales order which provides the necessary information for traceability. Serial numbers of certain components are recorded and maintained in the customer or device file. These records are maintained according to the Quality Records procedure.

Products returned by the customer are identified and distinguished from internally identified nonconforming products. This procedure is documented in 830P001.

7.5.3.2 Particular Requirements for Active Implantable and Implantable Medical Devices.

The microscopes assembled by Endure Medical are not active implantable or implantable devices, thus we are excluding this clause.

7.5.3.3 Status Identification

Since assembly and testing are carried out in the same area of the facility each product is identified with a tag that ties it to a particular

sales order. Only product that has passed final inspection and is verified using the appropriate checklist can be moved to shipping. Additionally, shipping verifies the checklist prior to packaging for proper approvals for the product.

When a product is being installed or serviced the responsibility for tagging or identifying lies with the product owner. They are responsible for removing the microscope from service or otherwise identifying it for service by Endure Medical.

7.5.4 Customer Owned Product

If customer owned property is on-site and loss or damage occurs or other non-conformities are identified with customer owned property it is handled according to our non-conforming products SOP and the owner of the product is notified. The VP of Engineering or a member of the Technical Team is responsible for this notification.

7.5.5 Preservation of Product

The nature of the products produced at Endure and the controlled storage of finished product is such that deterioration of product is not an issue.

Products are handled, stored, and packaged for shipment by properly trained employees who follow proper methods of handling these products.

Storage is in a protected, secure and temperature controlled environment for the products within our facility.

Product handling and delivery is based upon requirements defined by the customer. All products are shipped to the customer using packaging to keep the product from being damaged. ***The procedure for packaging and shipping is SOP 751P002.***

No routine inspections are required during storage due to the nature of the products and storage system. Products are produced to order, so generally there is no inventory of finished goods stored for shipments.

Product integrity is preserved by proper identification of products during processing and/or storage and delivery.

There are no shelf-life issues with our medical microscopes, thus there is no procedure for special storage conditions.

7.6 Control of Monitoring and Measuring Devices

Inspection, measuring and test equipment control is specified in SOP 760P001 which also specifies how we carry out monitoring and measurement in a manner consistent with established requirements.

This procedure provides for the unique identification, calibration, adjustments, handling, traceability to NIST or other approved standards, dealing with out of calibration conditions, calibration frequencies and recall system.

There are no requirements for computer software satisfying intended applications in our products.

Records are maintained according to our records procedure, 424P001.

8. Measurement, Analysis and Improvement

8.1 General

Endure's plan for and implementation of monitoring, measurement and analysis, and improvement of processes is a part of the quality management system and is outlined in the various sections of this manual and the appropriate Standard Operating Procedures. This plan includes:

- a) Product inspection and testing as specified by internally stated requirements, customer requirements or industry standards.
- b) The quality system includes provisions for insuring continuing conformity to ISO 9001:2000/ISO 13485:2003 through systematic and planned internal audits, registrar audits, management reviews and corrective and preventive actions. The internal audit system is in 8.2.2 of this manual and in SOP-822P001.
- c) The quality system plans include the ***maintaining the effectiveness*** of the quality management system through internal audits, management reviews and the corrective and preventive action systems as outlined above.

Management reviews have determined that the application of statistical techniques includes the monitoring and measuring of quality objectives. Statistics such as averages are used in reporting these, as well as graphs and trend lines along with certain statistical comparison techniques that are used from time to time. It is the responsibility of the Quality Management Representative to identify and properly document and implement additional statistical methods. This review should be documented in the Management Review minutes when it occurs.

8.2 Monitoring and Measurement

8.2.1 Feedback and Customer Satisfaction

The process for determining customer satisfaction **and meeting customer requirements** is defined in SOP-821P001. Customer satisfaction and **how well we are meeting requirements** is monitored and results tabulated for management review, by the President. **Meeting customer requirements is also monitored via warranty claims and service information.**

Customer Complaints are recorded and addressed as a part of our corrective and preventive action systems. Each formal customer complaint is a part of management review, however we also review general customer feedback and perceptions that are provided to us by our customers.

Procedure 821P001 also documents a feedback system to evaluate complaints, feedback and warranty issues to provide an early warning system for quality problems that may arise in the field. This information is also input to our corrective and preventive action process.

8.2.2 Internal Audit

Internal audits are conducted at planned intervals according to an internal audit schedule. The internal audit system is defined in SOP-822P001 and is designed to insure continual conformance to the ISO-9001:2000, the ISO-13485:2003 standard and stated internal requirements. This procedure addresses audit planning, status and importance of processes or areas being audited, previous audit results, audit scope, schedules, conducting audits and follow-up for any findings.

Endure conducts internal audits of the quality system as directed or scheduled by the Management Representative. Each process and each clause of the ISO-9001:2000 and ISO 13485:2003 standards are audited at least annually.

Reports are made to Management, corrective actions taken and documented.

Management is involved in follow-up for corrective action.

8.2.3 Monitoring and Measurement of Processes

Monitoring and measurement of processes is planned and carried out according to the various sections of this quality manual and Standard Operating Procedures. These include plans for measuring and for monitoring process performance to insure ability to meet planned results. The corrective action system is utilized when necessary based upon results. This is specified in SOP-853P001.

8.2.4 Monitoring and Measurement of Product

8.2.4.1 General Requirements

Product quality monitoring and measurement requirements are noted on the appropriate quality system documents which include procedures, checklists, forms, instructions, etc. and may include sampling and acceptance criteria as appropriate. ***Product characteristics to be monitored are identified on the checklists so that we may determine how well the product meets requirements.*** Additionally, quality objectives are monitored and aid in determining the overall effectiveness of our QMS.

Evidence of conformity to acceptance criteria is maintained in the customer or device file as appropriate. These records contain the name of the person releasing the product.

Due to the nature of our operations there is no provision for urgent release of product. All inspections and testing must be completed.

8.2.4.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices.

The microscopes assembled by Endure Medical are not active implantable or implantable devices, thus we are excluding this clause.

8.3 Control of Non-Conforming Product

Endure has defined procedures to identify, control and prevent delivery of non-conforming products. The non-conforming materials procedure is SOP-830P001

The Quality Manager is responsible for the disposition of nonconforming products.

Records of non-conforming product are maintained according to our quality records procedure and the non-conforming products procedure.

Re-verification for re-worked new products (not re-furnished) is the same as for initial inspection criteria and the necessary procedures, documented requirements or work instructions apply. Prior to re-work the product is reviewed to determine if there are any adverse effects and this review is documented.

Any product accepted by concession must meet all applicable customer and regulatory requirements.

8.4 Analysis of Data

Procedure 840P001 describes our process for determining, collecting and analyzing data to demonstrate the suitability and effectiveness of the QMS and to evaluate if improvement of effectiveness can be made.

Quality objectives and process results are used to measure many facets of our operations at Endure. These include:

- a) ***Customer feedback*** and satisfaction
- b) Conformity to product requirements
- c) Characteristics and trends of processes and products including opportunities for preventive actions
- d) Vendor Performance where applicable

These data are monitored, tabulated or graphed as appropriate and reviewed by management. It is the responsibility of the QMR to review data for trends and identify appropriate corrective and/or preventive actions and continual improvement of the quality system.

Records of these results are maintained according to 424P001.

8.5 Improvement

8.5.1.1 General (and Continual Improvement)

Endure continually ***maintains and improves the effectiveness*** of the QMS through use of quality policy reviews, quality objectives, audit results, analysis of data, Corrective & Preventive Action, and Management Review.

851P004 is the procedure that provides for the issue and implementation of advisory notices.

Records of all customer complaints and customer investigations are maintained in the appropriate file and format. Relevant information is exchanged between the customer and Endure and dealers should that be necessary.

If a customer complaint does not generate a corrective or preventive action the reason will be recorded and authorized by the appropriate senior manager.

There are no regional or national regulations requiring notification of adverse conditions or events.

The data are reviewed by management and continuous improvement actions documented in the manner specified in our SOP's and actions implemented and verified. *We take the approach of the simplest and quickest way of improving our system with minimal bureaucratic steps as obstacles to improvement.*

8.5.2 Corrective Action

Corrective actions are identified in a variety of ways including internal audits, external audits, customer complaints, employee initiated, regulatory, etc. The corrective action system at Endure is defined in SOP-852P001.

Responsibility for initiating corrective action lies with the employee who discovers a problem with nonconforming product, customer complaints, process problems or system improvements.

Customer Complaints can come from formal complaints by customers as well as informational type conversations with customers. We treat customer complaints seriously at Endure. ***Customer complaints are documented and corrective action taken as necessary. The procedure for dealing with customer complaints is defined in SOP 821P001. This procedure includes provisions for determining causes, evaluating the need for action to prevent re-occurrence, determining and implementing the actions needed, records of results and reviewing corrective actions for implementation and effectiveness.***

Continual Improvement - Customer complaints and corrective actions are documented and reviewed by Management for appropriate corrective actions effectiveness and continual improvement.

8.5.3 Preventive Action

The Preventive Action procedure, SOP-853P001 defines the steps taken to insure that Endure is taking the appropriate preventive actions. Preventive actions are based upon trends, daily operations and other criteria specified in the SOP. ***This procedure includes implementation, recording actions taken and reviewing for effectiveness.*** These results are reviewed by Management. Preventive Maintenance is a part of the Preventive Action processes of this QMS.

9. Revision Record

9.1

Revision	Effective Date	Reason for Revision
Initial Issue	Sept. 25, 2007	Initial Issue for ISO 9001:2000 and ISO 13485:2003 QMS
REV 1	Nov. 28, 2007	Cleaned up various typographical errors; changed SOP references on p. 20 from 750P001 to 750P002; added reference to 710P001 in section 7.1; changed 753P001 to 751P002 in section 7.5.5; added "New Product" to definitions.
REV 2	Feb. 7, 2008	Page 1 and 3, corrected two grammatical errors; 4.1.b. clarified that flow charts are in the relevant SOP's; 4.2.2.c deleted the reference to SOP 410P001; 5.1.c. added Executive Team reviews of goals; 7.1 changed 410P001 to 750P001 and clarified wording; 7.1 added reference to ISO 14971 risk management principals; 7.4 clarified wording about "off the shelf items" being excluded; 7.5.1 corrected the numbering to 7.5.2.1 and changed validated to bench tested and added reference to 730P001; 8.2.2 added reference to ISO 13485.
REV 3	Feb. 13, 2008	1.2 Exclusions, Design clause, 7.3 is excluded but references are left in the manual for future use if needed. Wording in 7.4.1/7.4.2 was revised to delete the reference to "off the shelf or catalogue" items.
REV 4	Feb. 14, 2008	Changed scope to reflect all of the system is ISO 13485 and ISO 9001.
REV 5	March 27, 2008	4.2.1 clarified ISO 3485 requirement; 4.2.1.2.f. clarified that device files required by ISO 13485 are for all microscope systems to reflect the scope change of the QMS.