Quality Manual

010-01-0001B

Mission Statement

We will provide the highest quality, innovative solutions in physical evaluation and rehabilitation to meet our customers' needs. We will achieve this by:

- Employing, training and developing the best people and recognizing and rewarding their contributions to the team
- Excellence in business processes
- Listening to our customers.

Through our success, we will continue to grow and broaden our opportunities in diverse markets.

Quality Policy

BTE employees are committed to providing products and services that meet or exceed the expectations of all customers. We will accomplish this goal by the implementation of an effective quality management system compliant with applicable standards and regulations.

Employee Responsibility Statement

All employees must follow the BTE Quality Policy. This means:

- Every employee must stop a process when it is out-of-control or when a defective product is detected. Management must then be notified by the employee.
- Every employee must prevent the occurrence of any product defect.
- Every employee must identify problems related to products and processes including safety problems.
- Every employee is empowered and encouraged to recommend solutions for all problems.

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1 Company and Product Information

1.1 Contact Information

Corporate Headquarters/Manufacturing Site:

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Website: www.btetechnologies.com

Email†: regulatory@btetechnologies.com

Contact person: Eric Finegan, Quality and Regulatory Manager

In company documentation, the abbreviation BTE is used to represent BTE Technologies.

† This email address has been created for correspondence with regulatory agencies.

1.2 Profile and Historical Background

BTE's expertise is the evaluation and treatment of human physical performance. BTE clinical experts, engineers, and technical staff work together to provide the latest advances in physical evaluation and rehabilitation, delivering products and services that advance the industry–improving patient outcomes and business efficiency.

BTE provides evidence-based physical therapy systems for clinics, hospitals, and private practices. BTE provides therapists with technology and processes, enabling them to optimize patient and clinic results. BTE's systems achieve this through documentation of assessment, treatment, and outcomes–supporting decision-making throughout the continuum of care.

History

Baltimore Therapeutic Equipment (BTE) began developing automated rehabilitation solutions when pioneering hand surgeon, Dr. Raymond Curtis, enlisted the help of John Engalitcheff, a mechanical engineer and inventor, to automate the process of hand rehabilitation. The original machine is proudly displayed at the world-renowned Curtis National Hand Center at Union Memorial Hospital in Baltimore, Maryland. The company was formed in 1979.

Hanoun Medical was founded in 1987 in Toronto, Ontario by Reed and Remon Hanoun to develop and manufacture exercise systems. Around 1997, the company switched its focus to the development of digitally interfaced systems to assess cervical spine movement and functional testing systems through an affiliation with Dr. Leonard Matheson. In 1998, the company added Mark Dakos to its management team, which ultimately led to the development of Workforce Solutions.

BTE merged with Hanoun Medical in December of 2003. The merger brought together BTE, historically known for manufacturing and distribution of physical therapy and rehabilitation equipment, and Hanoun Medical, a manufacturer and distributor of software and equipment for human performance assessment and rehabilitation, primarily in the workplace.

In 2019, BTE Technologies divested its Workforce Solutions division, and is dedicated to the manufacturing and distribution of physical therapy and rehabilitation equipment.

The BTE product family includes Eccentron, Primus, Simulator, MCU, EvalTech, PTK, and Evaluator.

2 BTE Product Information

2.1 Product Classification

BTE medical devices and their classifications are provided in *Regulatory Compliance*.

2.2 Product Lifespan

BTE products are designed to last many years -- modules and components can be upgraded and/or replaced. BTE product lifespan has been established as 10 years and applies to all products.

3 Terms and Definitions

Relevant terms and definitions used in the BTE QMS are included in the *BTE Glossary of Terms*. Additional regulatory terms are included in the *Regulatory Glossary of Terms*.

Additional references for terms include: FDA regulations, European regulations, ISO 13485 - *Medical devices--Quality management systems--Requirements for regulatory purposes*, ISO 9000 - *Quality Management Systems--Fundamentals and vocabulary*.

If definitions differ, the definition listed in the *Quality Manual*, in the FDA, and European regulations, and in the ISO standards apply (in this order).

4 QMS Structure

4.1 General Requirements

4.1.1 QMS Overview

BTE personnel are committed to achieve customer satisfaction by complying with the requirements of the Quality Management System. The main activities and assignments that directly affect product quality are identified in the QMS documentation.

The Quality Management System has been implemented to ensure that BTE consistently provides products that meet customer, statutory, regulatory, and company requirements.

The Quality Management System includes:

- Quality Policy
- Quality Objectives
- Quality Manual
- Documented procedures required by applicable standards and regulations
- Documents needed by BTE personnel to ensure the effective planning, operations, and control of processes
- Quality records required by BTE personnel and applicable standards and regulations

4.1.2 Applicable Standards and Regulations

BTE's Quality Management System is compliant with the following applicable standards and regulations:

- FDA regulation **21 CFR 820**, ***Quality System Regulation***.
- International Standard **ISO 13485:2016**, *Medical devices – Quality Management Systems – Requirements for regulatory purposes*.
- Selected devices are compliant with additional regulatory requirements such as the European Medical Devices Directive (**Council Directive 93/42/EEC** as amended[M5]) and the European Medical Device Regulations (**Regulation (EU) 2017/745 of the European Parliament and of the Council**, in particular Article 120 §3, the MDR Transitional Provisions).

Action taken to fulfill regulatory requirements is documented in the procedure *Regulatory Compliance*. Documents that describe other regulatory-related activities include, but are not limited to, *Organizational Regulatory Roles*, *Advisory Notice/Recall*, *Medical Device Reporting*, *Technical Documentation*, *Handling of Customer Complaints* and *Change Notification to Regulatory Agencies*.

4.1.3 QMS Scope

BTE's Quality Management System Scope

The design, development, manufacture, on-site assembly, and servicing of physical rehabilitation equipment used for evaluation, testing, and treatment.

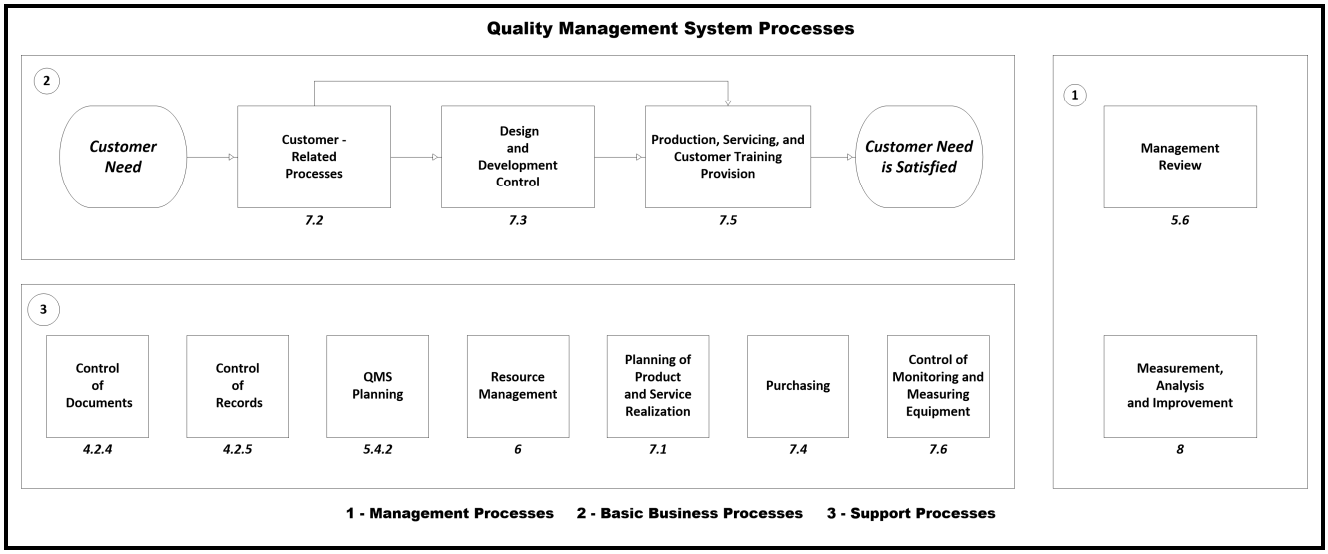
4.1.4 QMS Exclusions / Non-application

Exclusions and non-applications of regulations, standards, or requirements relevant to the BTE QMS are included in this *Quality Manual* through the document *Quality Management System Exclusions*.

4.1.5 QMS Processes

QMS processes, their application throughout the organization, and the sequence and interaction of the processes are presented in the document *Business Processes*, within the chart *BTE Main Processes* and below in Chart 1, Quality Management System Processes.

Chart 1: Overview of the Quality Management System Processes



4.2 QMS Documentation

4.2.1 QMS Documentation Structure

The Quality Manual (Level I) is the primary document supported by three tiers of documentation: Level II, Level III, and Level IV, each tier progressively becoming more detailed.

The *Quality Manual*, procedures, work instructions, forms, and other documents of the QMS are cataloged in the *QMS Documentation Matrix*. Drawings, specifications, and bills of material can be referenced through the current ERP software. Most documents are maintained in an electronic format on the BTE network. Some records are stored as paper files.

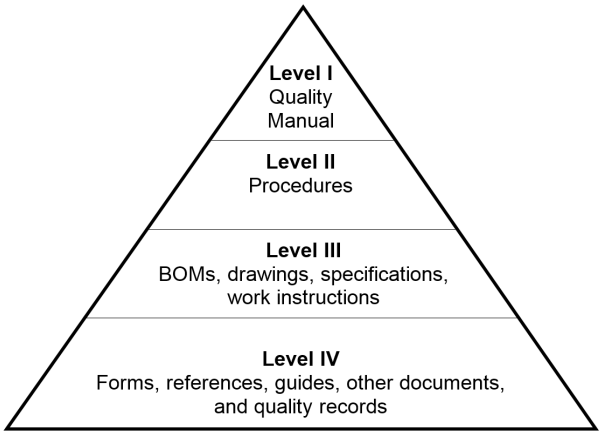


Diagram 2 – QMS Documentation Structure

4.2.2 Quality Manual

The *Quality Manual* allows BTE to communicate the Quality Management System to personnel, customers, suppliers, providers, regulators, auditors, and other external parties. It defines the structure of the QMS and describes the organizational policies, authorities, responsibilities, and procedural controls corresponding to the required elements of applicable standards and regulations.

The *Quality Manual* is the highest level document within the QMS and includes or references documentation required by the BTE quality management system. In order to provide clarity in description of processes,

specific documents are referenced in the *Quality Manual*. The complete list of procedures, work instructions, forms, and other QMS documentation is catalogued in the *QMS Documentation Matrix*.

The *Quality Manual* fulfills the Quality System Record requirements laid out in 21 CFR 820.186, Quality System Record.

The *Quality Manual* is maintained by the Quality Manager. As needed, Management Review and/or the Quality Manager reviews the manual for effectiveness.

4.2.3 Medical device file

BTE maintains medical device files for each BTE medical device as required by the FDA, EU or any other regulatory body according to the *Medical Device Files* procedure.

A Device Master Record (DMR) is created and maintained for BTE medical devices per 21 CFR 820.181, Device Master Record. Bills of material, bills of manufacturing, build plans/quality plans, drawings, and documents listed in the QMS Documentation Matrix and other documents are referenced in the DMR.

Technical documentation required by European regulations for each medical device family is created and maintained according to *Technical Documentation*.

Reviews and updates to medical device files are performed as necessary according to planned arrangements.

4.2.4 Control of Documents

Quality system documentation is controlled according to the *Control of Documents* procedure. The current revision of the documents is available through the BTE network.

The Quality Manual, procedures, work instructions, forms, and other documents are controlled in the QMS Documentation folder and are listed in the *QMS Documentation Matrix*. Personnel use the matrix to view or print documents, or to verify that the document that they plan to use is current.

The approval and distribution of controlled documents are described in the procedure *Control of Documents*. Documents and subsequent changes are reviewed for accuracy and completeness prior to issue and approved through the document control process.

4.2.5 Control of Records

Quality records are managed in accordance with the procedure *Control of Records* which has been established to define the means needed for the legibility, identification, storage, security and integrity, retrieval, retention time, and disposition of records.

Quality records have been established and are maintained to provide evidence of conformity to requirements and effective operation of the QMS. Department managers or functions defined in the QMS documentation are responsible for the control of their applicable records.

Methods for addressing confidential health information contained in records are documented in *Control of Confidential Health Information*.

5 Management Responsibility

5.1 Management Commitment

The executive management provides resources needed and maintains an organizational structure that is sufficient for the development and implementation of the QMS as well as for the continual improvement of system effectiveness.

5.2 Customer Focus

Executive management ensures that customer requirements and applicable regulatory requirements are determined, understood and consistently met.

5.3 Quality Policy

BTE's Quality Policy is declared in the BTE *Quality Manual*.

The Quality Policy establishes the basis for the BTE Quality Objectives measurements. The Quality Policy is communicated through the organization and is understood by personnel and reviewed for continuing suitability during Management Review.

5.4 Planning

Quality planning involves establishing Quality Objectives and specifying necessary processes and related resources to fulfill the objectives. The Quality Manual is the master plan for all quality processes within BTE.

5.4.1 Quality Objectives

BTE Quality Objectives have been developed to:

- Ensure that requirements for services, products, and processes are met (including regulatory)
- Provide a way of measuring whether or not the Quality Policy is adequate and effective
- Ensure continual improvement of the Quality Management System
- Provide a measure of customer satisfaction

The Quality Objectives apply to appropriate levels within the company. BTE personnel whose work affects product quality influences the results by which the Quality Objectives are measured.

During Management Review, the status of achieving the Quality Objectives is evaluated, trends are analyzed, and changes to corporate Quality Objectives may be decided upon.

BTE Quality Objectives

- **Eliminate Out-of-Box Failures (OBF)**. BTE strives to deliver all products to its customers without issues.
- **Eliminate Failed-on-Arrivals (FOA)**. BTE strives to provide trouble-free replacement parts when servicing or repair is necessary.
- **Reduce Service Events within 1 Year of Warranty**. Service event rates are used to determine general product reliability.
- **Improve Results of Customer Surveys**. Customers surveys are performed to determine how well BTE met customer expectations.
- **Provide Timely Service**. Customers expect BTE to provide timely service.
- **Provide Safe Products and Services**. BTE products are used in a medical environment and the safety of our customers is important. Safety incidents are tracked as required.

5.4.2 QMS Planning

Quality planning includes the development of quality plans for BTE medical devices. The executive management ensures that:

- Planning activities are carried out in order to meet the requirements of the QMS and company quality objectives.
- Effectiveness of the QMS is continually improved.
- Integrity of the QMS is maintained when changes are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The responsibility, authority, and interrelation of personnel who manage, perform, and verify work affecting product quality is established by the executive management.

BTE personnel have the independence and authority required to carry out their assignments documented in the organization chart, job descriptions, and other relevant QMS documentation.

BTE provides an *Employee Responsibility Statement* that outlines employee responsibility and how their activities fulfill the BTE Quality Policy.

5.5.2 Management Representative

BTE has appointed a management representative with the responsibility and authority to ensure that processes and requirements needed for the QMS are established, their effectiveness is maintained, and continual improvement is assured. See *Management Representative* [010-40-0004].

5.5.3 Internal Communication

Communication processes are established within BTE regarding the effectiveness of the quality management system.

5.6 Management Review

BTE performs regular Management Reviews of the Quality Management System for continuing suitability, adequacy, and effectiveness as defined in *Management Review*.

Quality objectives and trends are analyzed during reviews, and appropriate actions are determined. Other items reviewed include statutory and regulatory requirements, process improvements, QMS changes, improvement of products and services and any resources needed to accomplish these goals.

6 Resource Management

6.1 Provision of Resources

Executive management determines and provides resources needed to:

- Implement the QMS and continually improve its effectiveness.
- Comply with applicable standards and regulations.
- Enhance customer satisfaction by meeting and exceeding customer requirements.

6.2 Human Resources

BTE:

- Ensures that personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.
- Identifies training needs and provide training for personnel who perform activities that affect product quality.
- Ensures that there are sufficient personnel to carry out all QMS activities.

6.3 Infrastructure

BTE determines the infrastructure needed to address product requirements, product servicing, and prevent product mix-up and ensure orderly handling of product.

BTE personnel have access to the work areas, equipment, tools, and information systems needed to perform jobs according to quality plans and build plans.

Infrastructure needs, including storage and maintenance requirements are described in *Infrastructure Requirements*.

6.4 Work Environment and Contamination Control

BTE determines the work environment and contamination control requirements needed to address product requirements, product servicing, and ensure orderly handling of product.

Work environment needs are described in *Work Environment Requirements*.

7 Product and Service Realization

7.1 Planning of Product and Service Realization

Product realization incorporates the appropriate activities performed by BTE personnel, suppliers, and contractors to design, develop, manufacture, deliver, service and perform any other post-distribution activities. Planning of product realization is accomplished through the establishment of quality practices, resources, and sequences of activities necessary to achieve our quality plans.

Risk management activities are conducted to ensure product safety. Requirements for risk management throughout product realization are described in the procedure *Risk Management*.

7.2 Customer–Related Processes

Determination and review of requirements related to products and services are conducted. Requirements for the development, distribution and support of our products come from a variety of sources, including customer requirements, regulatory requirements, training and user needs.

Optional (post-installation) training is available to customers for select products and services.

Customer communication processes cover product information, customer enquiries, contracts and orders, customer feedback and complaints, and necessary advisory notices.

7.3 Design and Development

7.3.1 General

Design and development processes are employed to transform requirements into specifications and products. The design and development of products is controlled according to the *Design and Development* procedures.

7.3.2 Design and Development Planning

The Engineering department controls the design and development of all products. Designs are planned throughout product development and controlled to ensure that requirements have been satisfied.

Activities and resources are planned to ensure that the product meets customer, statutory, regulatory and BTE requirements, allowing products to be produced and maintained in an efficient manner.

Design plans are developed, reviewed, updated and approved as necessary throughout the design and development process (*Hardware Project Plan Checklist* and *Software Project Plan Checklist*).

7.3.3 Design and Development Inputs

The requirements that form the design and development input establish a basis for design and development tasks and validation. Product design input requirements are identified, documented, and their selection is reviewed for adequacy and approval.

Patient and user safety, results of risk management, regulatory and medical device licensing requirements as well as other requirements are included. Incomplete, ambiguous or conflicting requirements are addressed and resolved prior to the start of detailed design.

7.3.4 Design and Development Outputs

Design and development outputs include the deliverables that meet the appropriate input requirements in a form suitable for verification. The identified and documented acceptance criteria for the product characteristics include those essential for its safe and proper use.

The final design output consists of the product, its labeling and packaging, and the relevant medical device files. This includes all appropriate information for purchasing, producing and servicing the product and its components.

7.3.5 Design and Development Review

Design and development reviews are performed in accordance with planned arrangements. This allows BTE to evaluate the ability of the design to meet requirements, and to identify and propose necessary activities.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other personnel (specialists, customers, or independent personnel as necessary).

7.3.6 Design and Development Verification

Design and development verification is performed in accordance with planned arrangements and involves confirmation by examination and objective evidence that the design output conforms to the design input.

7.3.7 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements. Design validation is conducted on initial production units or their equivalents, and includes testing of units under actual or simulated use conditions prior to the delivery or implementation of the product.

Validation ensures that the resulting product is capable of meeting the requirements for the specified application, user needs or intended use. BTE performs clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.

7.3.8 Design and Development Transfer

BTE ensures that the device design is correctly translated into production specifications. Design and development outputs are verified as suitable for manufacturing before becoming final production specifications and production is capable of meeting product requirements.

Drawings, specifications, bills of material, procedures, work instructions, forms and other documents are released on change orders for use by Production.

7.3.9 Control of Design and Development Changes

Design changes and modifications are identified, documented, reviewed, validated, verified and approved according to the *Change Control* and *Design and Development* procedures. Design changes are evaluated within risk management, ensuring that changes do not introduce new hazards.

The Change Review Board reviews changes to products and processes and approved changes become part of the product Design History File (DHF).

7.3.10 Design and development files

A design history file for each medical device family is maintained to demonstrate that the design was developed in accordance with the approved design plan.

Design History Files (DHF) that describe the design and development history are maintained for these products and include or refer to records of the reviews, verification, validation and changes.

7.4 Purchasing

Purchasing activities are performed according to the *Purchasing Controls* procedure to ensure that the contracted services and the purchased products conform to the specified requirements.

7.4.1 Purchasing Process

BTE maintains procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

Controlled suppliers and providers of outsourced processes are used on the basis of their ability to meet BTE requirements.

Providers of outsourced processes are suppliers, contractors, and consultants selected by BTE to conduct activities such as design, development, calibration of measuring equipment, store and backup data, or service BTE equipment on the customer site.

BTE does not purchase any finished devices for distribution. Purchasing controls apply to assembly, components and sub-assemblies. These include, but are not limited to, machined parts, sheet metal assemblies, printed circuit boards, computers, cables, and motors.

Products and services that affect the quality of BTE products and services are only purchased from controlled suppliers. Suppliers are evaluated, selected, and re-evaluated according to *Supplier Management*. Identification of suppliers and their classification is maintained by the Operations Manager and is proportionate to the risk associated with the relevant medical device.

7.4.2 Purchasing Information

Purchase orders contain or refer to descriptions and specifications of the required products or services. The information is stored in the ERP software and/or on the BTE network.

7.4.3 Verification of Purchased Product and Service

The supplier's stated ability to meet product specifications is verified during the receiving process, in-process inspection, and the finished product final inspection. Selected products must pass a receiving or specification inspection before the items are placed in inventory as described in the work instruction *Product Inspection*.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

BTE's production and service activities ensure product conforms to specification through planning, execution and monitoring.

Production controls are implemented at BTE that include, but are not limited to: documented production procedures, appropriate qualified infrastructure, measuring equipment, packaging and labelling operations, and the implementation of product release, delivery and post-delivery activities.

Equipment is manufactured by BTE in the Hanover facility where the final assembly and testing are conducted. BTE applies methods of control to new products, reconditioned products, and products serviced at BTE's facility or at customer sites. The ERP and other applications are used to store and control necessary information for production, servicing, sales, purchasing, and other activities.

Product acceptance and release processes are performed according to the procedure *Product Inspection*.

7.5.2 Cleanliness

BTE does not supply products with sterilization requirements, and further cleanliness requirements are outlined in *Work Environment Requirements*.

7.5.3 Installation Activities

BTE product installation processes are documented and performed.

7.5.4 Servicing Activities

BTE product servicing (repair) processes are documented and performed.

7.5.5 Particular Requirements for Sterile Medical Devices

BTE does not supply products with sterilization requirements.

7.5.6 Validation of Processes for Production and Service Provision

Any processes for production and service where the results cannot be fully verified by subsequent inspection and test will be deemed special processes.

Process validation is required to ensure that the special processes will achieve planned results. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

The Quality Manager establishes criteria for the review and approval of special processes on an as-needed basis.

7.5.7 Validation of Processes for Sterilization and Sterile Barrier Systems

BTE does not supply products with sterilization requirements.

7.5.8 Identification

Activities documented in the procedure *Product Identification and Traceability* are conducted to ensure product identification and status throughout product realization. Only product that has passed the required inspections and tests, or has been released under concession, is dispatched, used or installed.

BTE implements the relevant regulatory unique identification requirements (UDI) for medical devices, as described in *Unique Device Identifier (UDI)*.

Identification of the product status is maintained throughout the receiving process, production, staging for shipment, storage, on-site assembly, and servicing.

7.5.9 Traceability

7.5.9.1 Traceability – General

Traceability activities are described in *Product Identification and Traceability* addressing the unique identification of the product, component identification and labeling activities.

BTE ensures the traceability of products and that labeling of products is performed in accordance with the procedure *Labeling, Packaging, Handling, and Storage Control*. Labeling instructions are included in the bills of materials and assembly drawings. Product labels affixed to complete systems include the product name, model name (identifier), serial number, BTE name and address (according to current regulatory requirements). Every device and certain components have a unique serial number assigned according to *Product Serial Number*.

7.5.9.2 Traceability – Particular requirements for implantable medical devices

BTE does not supply implantable medical devices.

7.5.10 Customer Property

Customer property in BTE's possession is controlled in accordance with *Customer Property*. Customer property controlled at BTE includes both physical property and electronic files.

BTE controls customer property from receipt to the time it is no longer in BTE's possession (or when product status is changed). Products owned by customers (turnarounds) that are received by BTE for servicing are identified and protected in accordance with the *Turnaround Policy* and *Turnaround*.

7.5.11 Preservation of Product

Preservation of product is incorporated into the QMS to ensure that conformity of products is preserved during processing, storage, handling, and distribution. The following procedures have been established to ensure compliance: *Preservation of Product*; *Labeling, Packaging, Handling, and Storage Control*; *Shelf Life and Storage Requirements*, and *Released Software Control*.

BTE ensures that component, incoming, in-process, and finished products are preserved in accordance with the established procedures, including protection from deterioration, loss or damage.

7.6 Control of Monitoring and Measuring Equipment

The procedure *Control of Monitoring and Measuring Equipment* describes any monitoring and measurement that is to be undertaken and the equipment needed to provide evidence of conformity of product to determined requirements.

BTE maintains procedures for the validation of the application of computer software used for the monitoring and measurement of requirements (*Master Validation Plan*). The activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software.

8 Measurement, Analysis and Improvement

8.1 General

BTE plans and implements necessary monitoring, measurement, analysis and improvement processes to:

- Demonstrate conformity of manufactured, reconditioned, and serviced products to established requirements.
- Ensure conformity of the Quality Management System to applicable standards and regulations.
- Maintain the effectiveness of the Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Customer Feedback / Customer Satisfaction

Satisfaction of customers is used to verify the performance of the Quality Management System. Customer satisfaction is included in Management Reviews, and the status of achieving Quality Objectives indicates customer satisfaction with the products, product delivery, on-site assembly, in-service, classes and seminars, and conduct of BTE personnel.

8.2.2 Complaint Handling

Customer complaints, including adverse events, are addressed according to the procedure *Handling of Customer Complaints*.

The Quality Manager ensures that customer complaints are reviewed, and corrective action requests issued according to the established procedures.

8.2.3 Reporting to Regulatory Authorities

The Regulatory Manager issues advisory notices and recalls and will report incidents to authorities if required as outlined in procedures *Advisory Notice/Recall* and *Medical Device Reporting*.

8.2.4 Internal Audit

Internal audits are conducted to determine the effectiveness and suitability of the activities of the QMS in achieving the stated Quality Objectives and compliance to applicable standards and regulations.

The responsibilities and requirements for planning and conducting audits as well as for reporting results and maintaining records are defined in *Internal Audit*.

Results of internal audits are reviewed at Management Reviews and department meetings.

8.2.5 Monitoring and Measurement of Processes

Processes are monitored and measured to verify that BTE's Quality Management System is being utilized as planned, and that it demonstrates the ability of the processes to achieve planned results. When the planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the process.

The measurement of processes includes tracking the status of achieving Quality Objectives. QMS processes and their effectiveness are reviewed during Management Reviews and department meetings.

8.2.6 Monitoring and Measurement of Product and Service

Monitoring and measurement of the characteristics of the product are conducted to verify that product requirements have been met.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

The monitoring and measurement of products is established and implemented by the Quality Manager.

The monitoring and measurement activities are carried out at the appropriate stages of the product realization process according to the build plan (quality plan) and the established procedures. Verification that the product requirements are met is achieved by monitoring and measurement of incoming, in-process, and finished products.

Product release and delivery do not proceed until all planned arrangements have been satisfactory completed.

8.3 Control of Nonconforming Product

Nonconforming products are controlled to prevent customers from inadvertently receiving or using products that do not meet requirements.

Nonconforming products are handled according to *Control of Nonconforming Product*.

8.4 Analysis of Data

BTE establishes processes needed to determine, collect, and analyze the appropriate data.

Data generated as a result of the monitoring and measurement processes is used to demonstrate the suitability, adequacy and effectiveness of the QMS and to evaluate where improvements of the quality system can be made.

Analysis of data is reviewed during Management Reviews.

8.5 Improvement

8.5.1 General

BTE identifies and implements changes necessary to ensure and maintain the continued suitability, adequacy, effectiveness and improvement of the QMS as well as medical device safety and performance.

The QMS is continually improved through the implementation of the quality policy, quality objectives, audit result review, post-market surveillance, customer feedback, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Corrective action is implemented to identify and eliminate causes of nonconformities in order to prevent recurrence. Department managers have the responsibility and authority to take corrective actions regarding nonconformities in the product, the process or the QMS and to verify the implementation of those actions.

Corrective action activities are described in the *Corrective Action and Preventative Action (CAPA)* procedure and are reviewed during Management Reviews.

8.5.3 Preventive Action

Preventive action is implemented to identify and eliminate causes of potential nonconformities in order to prevent their occurrence. Department managers have the responsibility and authority to take preventive actions regarding potential nonconformities in the product, the process or the QMS and to verify the implementation of those actions.

Preventive action activities are described in the *Corrective Action and Preventative Action (CAPA)* procedure and are reviewed during Management Reviews.

9 Quality Manual Revision Control

Rev	Date	CO	Author	Changes / Updates
A	2020-01-07	CO 5381	Eric Finegan	Updated from 422D9000, Revision N; Updates for ISO 1346:2016 and Workforce Solutions information; Core structure of the QMS did not change. 422D9000N was last QM to reference Canada/CMDCAS and ISO 13485:2003;
B	2021-05-14	CO 5500	Eric Finegan	Update to the reference to the EU regulations to address the upcoming EU 2017/745 Medical Device Regulation.