Operating Procedure: 1
Reference 1/2012 (Approved September 2012)
Review Date: September 2014

Mantra Medical Ltd

Document Recording and Control System

Documents to which this Procedure Applies

All documents used within the organisation related to the quality system itself or the execution of individual contracts including:

- Product specifications
- Plans/drawings
- Customer orders
- Quality Assurance Manual
- Operating Procedures
- National/International Standards
- Codes of Practice

Approval Arrangements for Documents to which this Operating Procedure Applies

All relevant documents will be submitted to the Board for approval.

Process for Production of relevant Documents

The initiation and production of any document will be the responsibility of the relevant Director as prescribed in the "Authority and Responsibilities" section of the Quality Assurance Manual.

The initiator will agree with the Clerk to the Board a document reference number.

In submitting a document to the Board, the responsible Director will specify within the documentation, or in the case of externally produced documents such as plans , standards or codes of practice, as an Appendix the following:

- Distribution list
- Document review date or, where this is not appropriate to specify this
- Obsolete documents which are superseded by the document and confirmation that such documents will be withdrawn from use and archived for a minimum period of 2 years or in the case of relevance to a specific product, for the lifetime of the product

- Arrangements for regularly contacting external suppliers of documentation to ensure that documents held by Mantra Medical Limited remain current

Process for Review of Documents

Responsibility for review will rest with the initiator of the document or by a person designated by the Managing Director.

Distribution, Registration and Retention of Documents

Following Board approval, day to day responsibility for distributing documents is controlled and recorded by the Clerk to the Board. The Clerk is required to hold a register of documents showing date produced, revision dates, responsible officer for production/maintenance, distribution lists and dates of distribution. The Clerk will ensure that all documents remain legible and easily identifiable whether held electronically or in hard copy.

Master copies of all original and revised documents will be held by the Clerk to the Board.

Each supplier and customer contract will have an individual file.

Distribution List

- Board of Mantra Medical Limited
- Clerk to the Board

Document Review Date

September 2014

Obsolete Documents to be Withdrawn

N/A

Arrangements for Regularly Contacting External Suppliers

N/A

Initiators of this Operating Procedure

- Tony Hercock, Director (Management Systems and QA)
- Ann Hercock, Clerk to the Board