Procedure: Installation and Servicing

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For simplicity, this procedure combines installation and servicing. In practice and if applicable, it may be preferable to split these into two separate procedures.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for:

* developing and documenting installation instructions
* performing device servicing

# Scope

The scope of this procedure includes all devices requiring installation and devices received for servicing at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Production Manager |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Installation

Installation may be:

a) not applicable

b) performed by the company or agent prior to delivery

c) performed by the customer or end user after delivery.

Delete any sections of this procedure that do not apply (or delete this whole procedure if neither installation nor servicing is performed).

If installation is performed by the company prior to delivery, it should be covered by fully documented procedures and include:

a) process specifications

b) work instructions

c) inspection and test acceptance criteria

d) a training program

e) installation verification/acceptance records.

Installation by the company should be controlled at least to the same extent as other production processes and may require a stand-alone procedure.

This procedure describes installation performed by the customer or end user, following written instructions enclosed with the product.

Modify this procedure to reflect the company’s practices and procedures.

Device installation instructions and specifications should be developed as part of the device design. As such they should be subject to the controls described in Procedure QP703*: Design Control*.

Installation instructions should include written directions on how to install the device and an inspection check list or test procedure. These should verify that the installed device is safe, performing satisfactorily and ready for use.

Installation instructions must be validated.

A group of individuals, with qualifications and experience that can reasonably be expected of customers, are asked to install the device and verify the installation using the installation instructions.

The validation and its results are documented and the instructions are approved for release in accordance with Procedure QP703: Design Control.

Installation instructions are enclosed with the device and the master copies are maintained in the Device Master Record (DMR). Changes to installation specifications and instructions are controlled in accordance with the following documents:

* Procedure QP704: Control of Design and Process Changes
* Procedure QP401: Control of Documents
* Procedure QP402: Device Master Record

## Servicing

Delete this section of the procedure if servicing is not required (or delete this whole procedure if neither installation nor servicing is performed).

If servicing is subcontracted, this procedure is not required. However, as part of supplier evaluation, ensure that the subcontractor has an equivalent system.

This procedure provides the basic framework only and will need to be expanded to cover the company’s actual servicing procedures. The following section only highlights the issues that should be addressed, i.e.

a) servicing procedures must be documented

b) servicing must be verified in accordance with documented procedures

c) there must be a servicing report (or other record) to include details of service performed

d) any test and inspection data should be statistically analysed.

CFR 820 requires that, if a service report presents an event which requires reporting to the regulators, the event must be considered as a complaint and processed accordingly.

## General

Device servicing requirements and instructions are developed during product design and are subject to the associated controls.

Servicing processes are planned, documented and controlled according to the procedures that apply to the related manufacturing processes.

Qualification and training of service technicians are the same as for process operators and QC inspectors involved in manufacturing and verification.

## Receiving devices and initiating service request

Devices received for servicing are delivered to the service desk. Service desk personnel initiate a service report by recording the device and customer ID in the first block of *Form FM711-1: Medical Device Service Record*.

The device is tagged with a service job number and forwarded to the servicing department with the Form FM711-1: *Medical Device Service Record*, together with any additional documents the customer has provided.

The service department retrieves the corresponding Return Authorisation Number (RAN) and associated record of the customer’s description of the problem.

The Return Authorisation Number is issued to a customer when first contact is made with regard to a problem or a servicing requirement. Expand this section to describe how such issues are handled.

The warranty status of the device is determined and whether or not a quotation for the cost of the repair is required.

The result of this investigation and any decisions are documented in the INITIATION block of the Service Report form. The form and the RAN printout are returned to the service department.

## Allegation of serious injury or death

If it is reported that a problem with a device caused a serious injury or death, the report is automatically considered to be a complaint. It is then processed in accordance with Procedure QP809: Customer Complaints.

The first step in processing such a complaint is to investigate whether it represents an event which must be reported to the regulators.

If the event does require reporting to the local regulatory authority, proceed as per Procedure QP809: Customer Complaints.

## Diagnosis, repair and verification

The service technician reviews the customer’s description of the event, inspects the device and carries out the necessary testing. When the cause of the problem has been determined, appropriate repairs can be carried out.

Results of this investigation are recorded in the DIAGNOSIS block of the Service Report form.

If the device is not covered by warranty (refer to Section 4.4), the technician prepares a quotation for the repair which is then forwarded to the customer.

If the device is under warranty or when the customer has accepted the cost of the repair, the technician proceeds with repairing or servicing the device.

Repair processes are normally limited to identifying defective (sub)assemblies or modules and replacing them with new ones. These types of repairs follow the same instructions and use the same drawings as are used in production.

When servicing processes differ significantly from production (i.e. they involve rework or repair of basic components) these procedures are documented in special servicing specifications and work instructions.

For unique repairs, one-off hand-written instructions may be used and retained as a record of the work carried out. Expand this section to reflect the company’s actual practices.

When servicing is complete, the technician verifies whether or not the service meets requirements or corrects the problem. The verification is normally carried out by visual inspection and functional testing of the device. Where appropriate, the same acceptance criteria and inspection and test procedures and checklists are used. For unique repairs, special procedures and checklists are developed to verify the particular servicing processes.

Measuring and testing equipment used for verification of servicing are calibrated and controlled as defined in Procedure QP715: *Measuring and Monitoring Equipment*.

Repairs performed, components, parts or subassemblies replaced and the results of inspections and tests, are recorded in the SERVICE block of the Form FM711*-1: Medical Device Service Record*.

CFR 820.200 requires that the actual test and inspection data be documented in a service report.

Verification of all servicing performed is recorded in the VERIFICATION AND RELEASE block in Form FM711-1: *Medical Device Service Record*. Release of the repaired device is authorised by the signature of the technician performing the verification.

## Service report analysis

CFR 820.200 specifies "Each manufacturer shall analyse service reports with appropriate statistical methodology in accordance with 820.100.". Paragraphs below address this requirement at a basic level only. Develop this procedure to include, where appropriate:

a) checkboxes on the Service Report forms with pre-defined categories of service

b) component and part checklists for replaced parts

c) a system for tracking part shipping trends.

Describe in more detail how and how often the data is tabulated and analysed and how it is reported and used. This system also provides a level of compliance to ISO 13485 Section 8.4, Analysis of Data.

Service reports are analysed each month by the Servicing Manager to identify systemic failures and quality problems that should be addressed by corrective or preventive actions. Results are tabulated and, where appropriate, charted. This includes events such as the occurrence of each type of failure or problem and the frequency and types of parts replaced.

Using this analysis, the QA Manager selects particular failures or problems to be addressed with formal corrective or preventive actions, in accordance with Procedure *QP810: Corrective and Preventive Action*.

Implementation of these actions requires further investigation to determine the actual failure mechanism and cause. Though coordinated by QA, the actual investigation and analysis may be carried out by Engineering or Production, depending on the area of expertise required.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP401 | Control of Documents |
| QP402 | Device Master Record |
| QP703 | Design Control |
| QP704 | Control of Design and Process Changes |
| QP715 | Measuring and Monitoring Equipment. |
| QP809 | Customer Complaints |
| QP810 | Corrective and Preventive Action |
| FM711-1: | Medical Device Service Record |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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