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Service Documentation and the Biomedical Engineer: Results of a Survey

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Abstract

It is essential that medical equipment manufacturers provide high quality service documentation for their products. Without it, the maintenance and repair of equipment becomes difficult and inefficient for biomedical engineering departments. Due to the key role documentation plays in their daily work, biomeds expect high quality manuals covering issues such as equipment installation, maintenance, troubleshooting and repair. A survey of 40 biomeds in the US and UK confirms that service manuals play a key role in troubleshooting equipment failures. It also showed that 65% of respondents rate service manuals on average as *good* rather than *very good* and indicated a number of areas which manufacturers can improve in their documentation, including diagrams and troubleshooting flowcharts. These results have strong implications for medical manufacturers—there are a number of issues that need to be improved in order to make documentation more effective.

Introduction

High quality service documentation is central to the role of biomedical engineering departments—without good documentation, effective equipment maintenance and repair becomes difficult, or even impossible. Surprisingly, considering the key role of service documentation, there has been comparatively little written about the characteristics of good medical equipment documentation. What are the attributes of good service documentation? What are biomeds' key documentation requirements? Are equipment manufacturers meeting these? What are the trends in documentation requirements? These were the sort of questions which prompted a survey of biomedical engineers' views on technical documentation.

The need for a survey was established from a review of the literature. The importance of good quality documentation is mentioned in a number of papers which are reviewed in the next section. However, it appears that no surveys have been previously

conducted on biomeds' views on documentation[*]. This was an omission which the authors felt should be rectified, especially since the findings could have implications for equipment manufacturers. Consequently, a survey was made to determine how biomeds perceive manufacturers' service documentation and identify some of the trends in biomeds' documentation requirements.

Medical Equipment Documentation Overview

All types of medical equipment documentation are important as "these are considered an essential part of the equipment"[1]. Obviously the three main types of documentation are sales literature, operating manuals and technical (service) manuals.

Sales literature usually consists of brochures, advertising, data sheets, etc. Manufacturers must ensure that the product descriptions given in sales literature are accurate and do not make unrealistic claims about possible product usage. Otherwise sales literature may encourage inappropriate product usage which can, in the event of an accident, lead to manufacturer liability [2].

Operating manuals normally cover the correct use, operation, testing and cleaning of equipment. They need to be clear, concise and make equipment easier to understand through the appropriate use of diagrams [3]. The increasing complexity of much equipment and the medical / legal environment in which it is used has several implications for manufacturers' documentation:

- The accuracy of the information in operating guides needs to be carefully checked by manufacturers as it can have legal implications in the event of an incident [2]
- "Instructional manuals have had to increase in size to describe the more numerous hardware and software options available. Manufacturers' efforts to limit the size of their manuals can expose them to claims of omission and lack of clarity" [4].
- A number of countries, including France, Germany and Sweden, have regulations requiring that the operating information for medical products is translated into the local language[1]
- Hospitals must ensure that operating manuals are easily accessible to staff [1].

The above points mean that good operating documentation is essential but, "unfortunately, the quality of a manual varies among manufacturers" [5].

Although both the above types of documentation are important, the focus of this study is technical (service) documentation—the type of documentation most extensively used by biomeds.

Technical Documentation—Literature Review

Biomedical engineers need good quality technical documentation covering five main areas:

1) How to install equipment.

[*]The key biomedical engineering literature from the last ten years was checked, including this journal, *J. Biomed. Eng., J. Clinical Monitoring, Biomedical Instrumentation and Technology* and *Med. & Biol. Eng and Comput.*

2) How equipment works (termed *Theory of Operation* by many manufacturers) with block diagrams and explanations of how both circuits and software function.
3) Maintenance of equipment; information on the checks, calibration and maintenance necessary.
4) Fault-finding (*troubleshooting*) and repair information. Troubleshooting covers the use of built-in diagnostics or gives decision-tree diagrams based on the observable symptoms. Repair documentation should contain accurate spare part identification and ordering details.
5) Upgrading information.

In addition to the above five areas, biomeds need timely and accurate information on equipment design changes (*updates*) and how these changes affect the above documentation.

Manufacturers are responsible for providing service documentation but US biomedical engineering departments also have a related legal responsibility. They must ensure that technical manuals are available for all equipment in a hospital[6]. The lack of availability of service documentation is a key reason why much equipment is poorly maintained and often inoperable in some developing countries[7].

Installation Documentation

The complexity of an installation is obviously dependent on the type of device. Installation documentation may need to cover unpacking, equipment assembly, physical and electrical integration and functional / safety testing.

Most installation work is done by the manufacturers' (or distributors') support organizations and therefore biomeds do not always have to use installation documentation. However, some biomedical engineering departments may perform installations of particular types of equipment to lower costs. The advantage of this has been noted—"Installation by technical services may result in improvement because the biomedical equipment technicians have a vested interest in a high-quality installation"—but no mention was made of the type of documentation required to optimize installation[8].

Maintenance Documentation

Maintenance of modern equipment consists mainly of cleaning, calibration, performance and safety testing, as opposed to the exchange of worn-out components. Consequently, the older term *preventive maintenance* is slowly being replaced by *periodic maintenance*[1]. Detailed records of the maintenance of individual pieces of equipment are required by the JCAHO and must be kept for the lifetime of the product in the US[4], or 10 years in the UK[9]. To make the task of planning and documenting equipment maintenance easier, computer management software has been developed—many examples are given in the literature (see, for example [10,11]).

Maintenance documentation needs to clearly state which procedures must be performed and at what intervals. Clear explanations of the testing and maintenance procedures are essential, as they are the main reference from which biomedical engineering departments define their equipment maintenance programs "Unfortunately, the majority of firms provide either insufficient guidelines or no guidelines whatsoever on maintenance" [12].

In today's cost-conscious environment, the frequency of maintenance needs careful monitoring to ensure that it is cost-effective[10]. Weighed against this, however, is the liability issue if hospitals fail to maintain equipment correctly. However, "a maintenance department with properly trained staff who attend manufacturer's [sic] training courses and work according to the relevant maintenance manuals would have little to fear from any legal action" [13].

Troubleshooting and Repair Documentation

Troubleshooting and repair are central responsibilities of biomedical engineering departments. To make it possible for biomedical engineers to repair equipment efficiently, good documentation and quick delivery of spare parts are essential[14].

Some issues on service documentation were identified in two papers. Nash[15] discusses troubleshooting methods saying that a "complex set of symptoms may necessitate use of the manufacturer's documentation to localize the problem" and where "a service manual is available, test-point and signal levels may already be documented".

Two authors discuss laptops for carrying service information. Metaban[16] discusses the use of a laptop computer containing detailed technical information to help troubleshoot infusion pumps. As the source of this information, "the troubleshooting guide in IMED's service manual was used. Each fault has an associated test or repair". In producing the troubleshooting guide on the laptop, a number of problems were encountered; "While building the knowledge base, several inconsistencies were encountered with the service manual, specifically its troubleshooting guide and parts list. These were quickly cleared up with a phone call to IMED, but showed the potential for the knowledge base process to validate a service manual". Rice[17] also describes a laptop used as a field service tool for biomeds.

Upgrade Documentation

Many types of equipment are upgraded at least once during their working lifetimes. For example, in ultrasound imaging the pace of technological advance is so fast that most hospitals buying equipment expect to be able to add additional features later—"upgradability is the key to a cost-effective ultrasound acquisition" [18]. Upgrade documentation needs to include good descriptions of the tools and skills required to perform the upgrade, an estimate of the time required, clear checklists for each stage of an upgrade and the tests necessary to test the upgraded product.

Although performing upgrades can be an important role for biomeds, no mention of upgrade documentation was found in the literature. This omission results perhaps from the fact that many upgrades are performed by manufacturers' engineers and in these cases, biomeds do not use upgrade documentation themselves.

Update Documentation

Update documentation is necessary for two reasons—it either corrects mistakes in the original service documentation, or details equipment design changes. Due to its complexity, mistakes in documentation do occur and manufacturers will normally correct these in later additions. Biomed departments which have the earlier editions should be informed of the corrections by manufacturers—some do offer *change sheets*.

Manufacturers often modify and improve the design of technical equipment. These changes normally have implications for the work of the biomed—for instance new improved components may be used (with new part numbers) or maintenance procedures might change in improved designs.

Biomeds need to be informed of updated documentation. Obviously many manufacturers offer telephone (*response center*) support covering technical aspects of equipment. Although many of these centers are able to answer biomeds questions on documentation, many biomeds questioned by the authors felt frustrated that they were not given the same level of update documentation that apparently was available to the staff at manufacturers' response centers.

Literature Summary

The review of the literature showed:

- The role of documentation as a key part of manufacturers' support; "Pertinent manufacturer provisions include the... quality of the [technical] instruction manuals" [4]
- That there are a number of papers which mention documentation, indicating points such as the need for good information on maintenance procedures. However, no previous article has focused exclusively on technical documentation issues
- That apparently there has been no previous survey of biomeds' documentation requirements

Study Aims and Design

The objective of the research was to conduct an exploratory study on technical documentation with four main aims:

1) To understand how service documentation is typically used by biomeds (the *use model*).
2) To identify ho biomedical engineers perceive the quality of service documentation.
3) To check which areas of a service manual typically do not meet biomeds' quality expectations.
4) To identify whether new formats (as opposed to paper-based manuals) would be acceptable to biomeds.

Research Methodology

A survey approach was chosen as the most suitable method to learn more about biomeds' views on technical documentation. There were two main stages to the research:

1) A series of semi-structured telephone interviews with a pilot sample of ten biomedical engineers. Even though the cost of this approach was high (it involved trans-Atlantic telephone calls) it had several advantages. Firstly it allowed a detailed picture of biomeds' views on documentation to be drawn. This enabled a questionnaire to be designed which was relevant to biomeds and minimized the risk of questions which might be misinterpreted.
2) A questionnaire was faxed to the 40 respondents in March, 1995. Those individuals who had not returned the questionnaire within 14 days were contacted by telephone and asked if they would like to complete the questionnaire over the telephone—to save time and inconvenience. This approach helped generate a 100% reply rate, as did the

extra motivation given respondents by promising them a copy of the resulting report. (Almost all respondents requested a copy of this report—these were sent in Summer 1995—indicating that biomeds have a high level of interest in technical documentation.)

Questionnaire Design / Sample

The questionnaire was deliberately kept simple, in order to reduce the risk of a low response. It had a total of 12 questions, covering how service documentation is used by biomeds, the perceived quality of documentation, areas where improvements are necessary and format issues. Many questions allowed biomeds to express multiple requirements and did not restrict them to one answer. For instance, one question on the areas of manuals which manufacturers should improve allowed respondents to tick several areas. This approach ensured that a broader picture of requirements was drawn.

The choice of the sample is important in all survey research—it governs whether the results are representative of the population. On the one hand, larger samples lead to more representative results but, on the other hand, higher costs. The total number of biomeds surveyed was 40 (n = 40); a fairly small sample. This number was for chosen for reasons of budget and also because the current survey can be seen as exploratory—gathering information but not covering a definitive sample. It is important to note that the survey was relevant to all respondents—they unanimously stated that service manuals were important for their work (answering *yes* to the first question: *are service manuals important in your day-to-day work?*).

Fourteen biomeds were surveyed in the US and 26 in the UK. The names of the biomeds in the US were provided by the manufacturer which partly sponsored the research—therefore this sample was biased to the extent that the biomeds all worked in hospitals that used some of that manufacturer's (Hewlett Packard's) equipment. The sample in the UK was, in contrast, drawn at random by telephoning 26 hospitals across the country and asking for the biomedical engineering department.

Results

The results will be discussed by the main areas investigated; how service manuals are typically used; how biomeds perceive the quality of typical manuals; what could be improved; changes to manuals and updating; finally the format most useful to biomeds.

The Use Model

The way in which biomeds use manuals is interesting because it can have implications for documentation design. Table 1 shows the main uses of service manuals. Over half of the respondents use manuals to gain familiarity with equipment and so the product descriptions and theory of operation are very important to them. As might be expected, fewer respondents (25%) use them to source information for training medical staff—reflecting that most of the information for training medical staff will come from the operating manuals. Table 1 clearly shows that the main use of service manuals is for maintenance, troubleshooting and as a reference for specifications and part numbers.

Table 1: The Answers to the Question: *How do you use service manuals?*

Number	Alternatives	Answers	Frequency
1	To familiarize yourself with the product	22	55%
2	To source information for medical staff	10	25%
3	As an aid to maintenance	37	92.5%
4	As an aid to fault finding / servicing	40	100%
5	As a source of specs and part numbers	40	100%

Since manuals are used for troubleshooting, it is useful to understand at what stage they are used. Table 2 shows that most biomeds try to resolve the problem first and, if unsuccessful, turn to the manual. As shown from the figures, some biomeds may use different approaches at different times, sometimes using the manual first and sometimes trying to resolve the problem first. No respondents call the manufacturer's response center before trying to resolve the problem. The key point from these results is that manuals are often used in a situation where a problem has arisen and where it is crucial to find a solution quickly—this has implications for the way manufacturers structure their documentation. The discussions with biomeds in the pilot stage of the investigation produced a lot of anecdotal evidence on this; biomeds clearly want well structured documentation.

Table 2: The Answers to the Question: *When the machine develops a problem, do you normally...*

Number	Alternatives	Answers	Frequency
1	Look at the manual first for a solution to the problem	9	22.5%
2	Try to resolve the problem yourself and, if unsuccessful, turn to the manual	33	82.5%
3	Try to resolve the problem yourself and, if unsuccessful, telephone the service response center	10	25%
4	Telephone the service response center first	0	0%

Further information on the methods biomeds adopt to quickly find information in manuals is shown in Table 3. This shows that the table of contents and index are very important. This also emerged from discussions with some of the respondents, who were critical of manuals from some companies who did not provide comprehensive indexes.

Table 3: The Answers to the Question: *What method do you usually use to find information within a service manual?*

Number	Method	Answers	Frequency
1	Use the table of contents to find the section required	34	85%
2	Use the index to find specific page numbers	35	87.5%
3	Flick through, until you find the section you want	10	25%

Perceived Quality

Several of the survey questions investigated the biomeds' perception of the quality of service manuals. Table 4 summarizes the answers to the question on how the quality is perceived. The majority of respondents (65%) answered that manuals were, on average, *Good*, although interestingly none rated manuals as *Very good*. Some respondents rated manuals, on average, as *Neither good nor bad* (25%) or *Poor* (10%). This means that there are significant opportunities for manufacturers to improve their documentation. Obviously some individual manuals, or manuals from a particular company, may be very good. Consequently some respondents commented that it was hard to give an "on average" opinion. For instance, one respondent said "*[this question was] very difficult to answer as some manuals are very good and others are very poor. I would like to answer the question against a number of manufacturers"*. Although it was beyond the scope of the current survey to identify the manufacturers producing the best manuals, biomeds could certainly provide this information in a future survey.

During discussions with biomeds it became apparent that many saw the quality of documentation as polarized into two groupings. On the one hand major manufacturers generally supply good documentation, whereas the quality from smaller manufacturers—and many from non-English speaking countries—was perceived to be poor and sometimes dreadful. However, it cannot be said that all manuals from smaller, or foreign manufacturers were bad; biomeds objected to poor documentation regardless of its source.

Table 4: The answers to the question: *On average, how would you rate the quality of the service manuals that you use?*

Number	Quality	Answers	Frequency
1	Very good	0	0%
2	Good	26	65%
3	Neither good nor bad	10	25%
4	Poor	4	10%
5	Very poor	0	0%

Table 5 gives results on specific areas for improvement. It is interesting to note that the area which 29 respondents (72.5%) think needs improvement is the diagrams—the number and their clarity. However, over half of the respondents also think that the text—descriptions and explanations—is an area for improvement. Other area where approximately half of the respondents think that improvements could be made are: warnings and cautions; indexes; troubleshooting flowcharts and updating.

Table 5: Areas of Service Manuals that could be Improved by Manufacturers.

Number	Areas for Improvement	Answers	Frequency
1	Tables	8	20%
2	Diagrams	29	72.5%
3	Illustrations	21	52.5%

4	Print size of the text	4	10%
5	Style of the prose	13	32.5%
6	Descriptions	17	42.5%
7	Explanations	22	55%
8	Overviews	10	25%
9	Headings	4	10%
10	Warnings, cautions and notes	21	52.5%
11	Contents pages	13	32.5%
12	Indexes	19	47.5%
13	Troubleshooting flowcharts	17	42.5%
14	Page layout and design	13	32.5%
15	Updating	21	52.5%

Table 5 shows a lot of areas for improvement. To identify the priority areas, biomeds were asked to *list the three most important factors that need to be improved in service manuals.* The factor most commonly mentioned was the call for better circuit diagrams because:

- Rarely are sufficient diagrams supplied
- Many diagrams are reduced to a size that makes them unreadable
- Diagrams are often reproduced for too small a functional area, forcing biomeds to keep turning pages backwards and forwards to obtain and overview and locate a problem (A single large, or series of larger diagrams, showing a wider section of circuitry would be ideal.).

The second most frequently mentioned factor was the need for better preventive maintenance (PM) information. Although some manufacturers do provide this information in clearly labeled and structured sections, many do not.

The third area of priority for improvement is the parts listings and. ideally, linking these to circuit and block diagrams. Identifying part numbers is all too often, respondents complain, made difficult by manufacturers' poor (inaccurate) and illogical listings.

Format

Almost all biomeds use computers in their work. All 40 survey respondents reported using a PC or laptop computer as past of their normal job function. Therefore, it is possible that biomeds may prefer alternative media to conventional manuals (printed / in three-ring binders). There could be an opportunity to supply service documentation in digital format, although apparently manufacturers are not yet doing this (only one respondent reported that he had received a copy of a manual in digital format [on floppy disk]).

The results of the survey show that paper manuals are currently still the most popular format—50% of respondents simply prefer paper manuals, as shown in Table 6. Reasons for this preference included that paper manuals are "*what I am used to!*" and "*traditional manuals are still required for bench work. Not every engineer can have access to a computer*". However, other media are becoming important, as indicated by the number of biomeds interested in CD-ROM documentation. Four respondents (12.5%) already preferred CD-ROM alone, whereas 10 (25%) preferred CD-ROM in combination

with a paper manual. Many respondents recognized advantages of having CD-ROM documentation but still saw a need for paper. As one respondent said, "*paper... permits me to take service manual to study at home, hotels and at repair site where PC is not available.*" Other media for documentation were either rejected (microfiche documentation was not preferred by any of the respondents), or are currently less important (only 3 respondents preferred Internet documentation, even in combination with paper). The newer possibilities may, however, be gaining in importance.

With the fast changes in information technology, documentation media is likely to become a key issue in the near future. In telephone conversations, a number of biomeds expressed optimism that advances in technology would make update information and corrections to mistakes in manuals more readily available.

Table 6: Biomeds' Views on the Media of Choice for Technical Documentation.

Number	Alternative Formats	Answers	Frequency
1	Paper (supplied in ring binders) only	20	50%
2	Floppy disk (for access via a PC) only	1	2.5%
3	Floppy disk and paper combination	2	5%
4	On CD-ROM only	4	10%
5	CD-ROM and paper combination	10	25%
6	On a network (e.g. Internet) only	0	0%
7	On a network and paper	3	7.5%
8	Microfiche	0	0%
9	Microfiche and paper combination	0	0%
10	Total preferences for paper and paper / other media combinations	35	87.5%
	Total	40	100%

Currently, updating information is not always available to biomeds. As one respondent commented "*some manufacturers do provide some form of written update notification. Unfortunately, most do not*". Most biomeds (75%) want update information by post, although nearly half of the respondents (47.5%) would accept it by fax. Currently only 10% of respondents would want updating information by electronic mail. Those respondents who were interested in receiving electronic updates also saw the advantages of update information being available on a network. One respondent said, "*this would mean an up-to-date source of changes available 24 hours. It would also mean faster access to a range of information*".

Discussion / Implications

The survey has some key implications for the manufacturers of medical equipment. It shows that there is a need for manufacturers to improve the quality of their service documentation. The three main priorities are:

1) Improved troubleshooting information, with better charts backed by comprehensive, well produced circuit diagrams.

2) Comprehensive preventive maintenance information in a well-structured format. (Clearly stating the recommended frequency of PMs, the time, skills and tools required.)
3) Better parts identification, through accurate listings linked to block, mechanical and circuit diagrams.

The key role of service documentation in the work of the biomed is confirmed, as the importance of biomeds being updated about changes or corrections to documentation. The fast changing role of technology in publishing and distributing information is certain to influence service documentation in the future—there is already a strong interest from biomeds to receive documentation on CD-ROM in addition to paper copies (CD-ROM would bring advantages such as the ability to word search for information, etc.)

Further research

The project identified a number of issues requiring further research. These include the need for a wider survey, investigating how documentation is audited during the new equipment purchasing process and determining the requirements for training and operating manuals.

A Wider Survey

There is a need for a larger, fully representative, study of biomeds—for instance a survey of the members of a biomedical engineering professional association. This type of survey could build on the results reported in this current study and would potentially provide a definitive reflection of biomeds' technical documentation needs. The scope could also be widened to cover, for example: the cost implications of poor documentation; and specific examples of good manuals, as these would provide evidence of the "best-in-class" documentation preferred by biomeds.

Equipment Purchasing and Documentation

Biomeds usually evaluate new equipment purchases before the final decision is made—"Once the manufacturers' proposals have been received, the equipment's features such as maintainability, operability, liability, adaptability... can be evaluated"[19]. However, to what level of detail do biomed typically evaluate manufacturers' documentation? What are the best practices in this area? For instance, the UK's Department of Health assesses medical equipment and publishes the results—including users' opinions on the quality of the supplied documentation[20]. Are these types of evaluation sufficient? These are the sort of questions that could be investigated by a further study.

Operating and Training Documentation

This is a area where there appears to be a real need for a survey on whether manufacturers are meeting the expectations of users (including clinical personnel and biomeds) in the quality and type of documentation they supply for operating and training purposes. This is particularly relevant to biomeds because, as equipment becomes more reliable, service is becoming less important. The need to support users—by regular training—is however increasing, particularly on complex equipment such as imaging devices[21].

Training staff is not easy; “One of the most important and difficult tasks of clinical engineering is making sure clinical personnel know how to operate a particular piece of medical equipment” [22] and so good documentation is essential. Biomeds rely heavily on manufacturers’ documentation when preparing training since “manufacturers describe their expectations and the minimum training of operators as these factors relate to their device. These expectations are included in their inservice presentations, operator manuals, and training materials” [5]. Although many hospitals give supervised hands-on experience to new staff the quality of this training is not always high; “the in-service education that they [new staff] get is still geared to casual word-of-mouth communication, and so their understanding of equipment technology comes only from outside experiences, which are often inadequate” [23].

The authors actively challenge readers to consider the insight that such a survey on training and operating documentation could bring and the potential improvements that could be achieved if this information was fed back to manufacturers. Previous research by one of the authors showed that good training documentation—which helps biomeds efficiently train nursing staff—is essential but is seldom being supplied by manufacturers with the required format and content[24].

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David Price studied technical communications at Coventry University, England. As part of this degree he worked twice on extended placements in industry—with Hewlett-Packard in Germany—and has detailed experience of writing operating and service manuals for cardiotocographs and other types of medical equipment. From his experience of preparing documentation, David saw the value of understanding biomeds’ documentation requirements and this led him to base his final year degree project on the survey described in this paper. He graduated with a BA in 1994 and is serving as a policeman with the West Midlands Police, England. He continues to have an active interest in the field of technical documentation and in publishing.

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