The Supportability of Medical Devices

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Abstract

Clinical Engineering (CE) and Health Technology Management (HTM) appears to be spending more time trying to get medical device manufacturers to provide support for inhouse servicing than ever before. Surveys conducted by AAMI in 2015 and CMBES in 2016 revealed that model-specific technical training and documentation were the top two priorities for this group of respondents. Many manufacturers and even healthcare institutions seem to minimize the value or even the existence of CE/HTM programs. It is important to note that these programs operate to save hospitals and healthcare money and also serve to provide quick and necessary support for healthcare technology in the clinical setting. They are now being challenged by many of their commercial partners. Almost every other acquisition of medical equipment now requires the need to negotiate support for inhouse services and is met with a balance of success and failure. It appears manufacturers are designing equipment without considering the customer's option to service it. These customers include medium to large hospitals that have the capacity, economies of scale, and know-how to create and sustain CE/HTM departments. At the same time, there are many companies that provide good support for inhouse servicing. Their examples of appropriate support strategies may serve as a baseline for most other companies to make their products serviceable and to ensure CE/HTM is qualified and properly equipped to perform the required service. This paper highlights most of the issues surrounding the notion of Supportability in the CE/HTM world. These issues affect independent service organizations (ISOs) in a similar way. There are efforts to manage the supportability issue and ideas on how certain barriers might be dealt with. The paper attempts to recognize these and the rationale behind certain behaviors. There are standards and regulations, or an absence of them, which either help or hinder the issue.

Keywords

Supportability • Serviceability • Service manual
Training • Clinical engineering • OEM • HTM
ISO

1 Early Efforts

In 2012, Mike Capuano CBET/CCE, Manager of Hamilton Health Sciences Biomedical Technology department, began to look at the situation as an issue worth investigating. He knew the challenges clinical engineers faced on a day to day basis. One of those challenges—the support of medical devices inhouse—seemed to take on a definitive persona. As a long-time member of AAMI (the Association for Advancement of Medical Instrumentation) and active contributor on its various boards and committees, he began to think that these activities may provide an opportunity to bring the issue to the forefront. There were no existing efforts on supportability at the time. Capuano decided that he would submit a work proposal to the standards board of AAMI just to see what would happen. It was not approved for development but it did result in the publication of an AAMI Leading Practice document on the Supportability of Medical Devices [1]. This was the first action taken on the topic ever. It coined the first definition of supportability as follows: The degree to which a medical device or system can be effectively and economically supported, in terms of its design features and product support (information, training, technical support, tools, and spare parts), throughout its lifecycle. Capuano extends this definition as being executed by 'entities other than representatives or direct agents of the original equipment manufacturer (OEM)' (e.g. CE/HTM, ISOs, etc.).

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If there is something the company can do in the field but prevents the customer's technical personnel or ISOs from being able to do it; this is a supportability barrier. Factors that may contribute to supportability include: equipment design, vendor policies; availability of education, phone assistance, and service aids; bundling practices/contract options, etc. (see Table 1). Since this early effort, AAMI continued to address the issue by various means and from a wider scope of contributors. Articles on supportability started to pop up in the form of contributed articles, blogs, conference sessions, and even a cover story in AAMI's journal, '*Biomedical Instrumentation and Technology (BIT)*' [2].

Other organizations and their publishers also began broaching the topic. On top of this, another phase of action began to take shape. This came in the form of organized groups working to address the issue in teams and sub-committees. The AAMI Technology Management Council (TMC) assigned a sub-committee in 2015 known to be the Supportability Task Force. The task force began acting on the need to address some of the polarized viewpoints coming from both CE/HTM and industry sectors. It is important to note that AAMI's breadth and influence comes from its diverse membership including biomedical technicians, clinical engineers, and single/corporate memberships coming from the OEMs. The AAMI Forum on the Supportability of Medical Devices was held in November of 2015 at AAMI Headquarters in Arlington, VA. It was one of the first events of its type where, by invitation, CE/HTM and OEM representatives came together to identify what was driving the perceptions on supportability and try to break them down into actionable pieces. This strategy had some success and sparked the creation of sub-groups under the TMC's Supportability Task Force. These included the creation of a comprehensive service level agreement template, an AAMI reference on competencies required for the support of medical devices, and recommendations on the sourcing of replacement parts. These actions stem directly from the prioritized breakouts facilitated at the forum in Arlington.

Table 1 Factors affecting supportability

Access to:
Service manuals
Technical training
Diagnostic codes
Error codes
Event logs
Test equipment
Service updates
Phone support
Other:
Bundling practices
Service options
Equipment design
Availability of replacement parts

2 Remaining Issues

Despite the progress made to address the issue, the concern remains and appears to be of particular concern in Canada. Based on transcribed comments from the 2015 World Congress held in Toronto, several countries came forward at the CMBES-hosted World Summit on the Supportability of Medical Devices and stated that they too face the challenge of obtaining supports especially from OEMs originating abroad. In Canada, most of the technologies supported inhouse originate in the United States and are distributed through either a separate vendor, subsidiary, or a Canadian arm of the OEM situated in our country. The concerns, as indicated above, come in the form of various limitations or barriers that may be as a result of marketing strategy, technological force, procurement strategy, competency, weak standards, and the interpretation of regulatory requirements. These barriers can get in the way of providing safe, cost-effective, and expedient service to medical equipment in the field. They drive increases in the cost of service and also limit the ability of competent inhouse or independent servicers to conduct prompt, and sometimes crucial, on-site services.

Viewpoints from both CE/HTM and OEMs cover common themes. Some of the CE/HTM community feels that OEMs limit support for inhouse programs in order to affect revenue. Several OEMs state that increasing supports for inhouse may affect reliability of their product and that designing supportability may limit its level of sophistication. Hospitals may take serious heed in OEM claims of heightened complexity and risk. Lofty warranty options and service agreements that capture software upgrades tend to sell the client and take CE/HTM out of the equation. Group purchasing strategies tend to sideswipe CE/HTM because they satisfy the many smaller centers that lack CE/HTM support and pass over the opportunities that are available to the larger centers that use CE/HTM. This is a common occurrence in Canada.

In light of the increased awareness of companies that do not provide adequate supportability, there is still a base of companies that still provide excellent support for inhouse programs. They appear to support the notion that good supportability means increased uptime for their product, adds value, and is representative of good business practice.

Today's devices and systems are becoming increasingly similar from hardware and software perspectives. The level of distinction among competing products and vendors is

shrinking. As a result, values and options provided to the customer is becoming more so a critical component of any transaction.

The customer pays for and owns the equipment. They have a right to obtain support mechanisms that are compatible with their abilities and infrastructure (e.g. CE/HTM). However, for reasons not completely understood or thought out, the issue remains contentious.

3 Survey Data

Surveys from both AAMI (2015) and CMBES (2016) have helped to shed light on the topic. The surveys included a request for respondents to prioritize the survey statements (questions). The AAMI 2015 survey showed that for CE/HTM, the top three priorities out of 12 statements were:

1. **Training is inaccessible (not affordable, not available, etc.)**
2. **Service documentation is not readily available**
3. **Products are not designed with supportability in mind**

And for OEMs, they were:

1. **Aptitude of non-OEM individuals working on equipment is unclear/unverifiable/insufficient**
2. **Non-OEM individuals working on equipment make changes (improper replacement parts, etc.) to equipment, thus making it unsafe to use**
3. **Non-OEM technicians in the field don't keep up with technology changes**

This was the first marker to show the polarizing perspectives from each of these stakeholders on the question of supportability. Other issues from the CE/HTM response were: unrealistic manufacturer recommendations for maintenance, the usefulness of service documentation, and the ability to reach phone/human support. Other issues from the OEM response were: concern for repairs being done right and clarity around what customers want in terms of supportability. This has led to some of the AAMI efforts underway which focuses on competency and the type of service level agreement between the OEM the customer.

From the CMBES survey conducted in 2016, the top three statements affecting respondents were:

1. **Access to comprehensive device-specific technical training**
2. **Access to comprehensive service documentation**
3. **Access to diagnostics**

Out of 232 respondents (mostly CE/HTM), responses to statements gauging adequacy of these resources are as follows:

1. **Access to comprehensive device-specific technical training is adequate**.
   Agree 47%
   Neutral 25%
   Disagree 29%
2. **Access to comprehensive service documentation is adequate**.
   Agree 42%
   Neutral 21%
   Disagree 37%
3. **Access to equipment diagnostics (without having to purchase passwords, dongles, service agreements or training) is adequate**.
   Agree 24%
   Neutral 23%
   Disagree 53%

There were other very important responses from the CMBES survey worth mentioning (see Table 2). There is some agreement that Remote Phone Support is adequate (54%) but disagreement that Test Equipment (47%) and disagreement that Regulatory Oversight of Supportability (50%) appears to be significant.

53% agree that obtaining inhouse support for equipment purchased through Group Purchasing Organizations (GPOs) requires more effort than with regular capital purchases. This places a light on how hospital-vendor acquisition processes can affect supportability. CE/HTM's involvement can be impeded based on a central entity that makes decisions in isolation of the larger members of the GPOs most likely to have CE/HTM services.

74% agree that, in the last 5–10 years, changes in technology and design has contributed to a change in the supportability of medical devices. This implies that there may be a certain element in the factor of supportability that will remain constant regardless of any effort undertaken to improve it.

78% of agree that, in the last 5–10 years, business practices of the OEMs (vendors) has contributed to a change in the supportability of medical devices. What may drive this could possibly be linked with the technology question. However, many dispute this as indicated in several of the comments submitted with the survey.

70% agree that, in the last 5–10 years, hospital and procurement practices has contributed to a change in the supportability of medical devices. Decision-makers and trends taking place in purchasing departments may be leaving out CE/HTM in their evolving processes. Some onus is placed on CE/HTM to provide advice and influence on these

Table 2 Responses from the CMBES survey (2016)

Survey statement	Agree (%)	Disagree (%)
Vendors currently provide adequate access to comprehensive technical training	47	**29**
Vendors currently provide adequate access to comprehensive service documentation	42	**37**
Vendors currently provide adequate access to remote phone support	54	20
Vendors currently provide adequate access to equipment diagnostics	24	**53**
Vendors currently provide adequate access to specialized test equipment	27	**47**
Regulatory bodies or standards play a sufficient role to ensure vendors support inhouse service of medical devices	26	**50**
Obtaining inhouse support for equipment purchased through Group Purchasing Organizations (GPOs) requires more effort than with regular capital purchases	**53**	10
Changes in technology/design has contributed to a change in the supportability of medical devices over the last 5–10 years	74	12
Changes in business practices by vendors has contributed to a change in the supportability of medical devices over the last 5–10 years	**78**	6
Changes in business/purchasing practices by hospitals has contributed to a change in the supportability of medical devices over the last 5–10 years	**70**	13
BMETs working inhouse have the abilities and knowledge to support most equipment (assuming support from vendors is adequate)	86	6
BMETs working inhouse continually keep up with technology changes (assuming support from vendors is adequate)	80	9
A list of vendors good at supporting inhouse service should be posted online to improve the supportability of medical devices	**87**	5
A list of vendors bad at supporting inhouse service should be posted online to improve the supportability of medical devices	**78**	8
It is currently difficult to comprehensively support medical devices inhouse	**41**	28
The supportability of medical devices inhouse is becoming more difficult	**69**	16
Prior to the survey, I was not aware there were efforts under way to address the issue (CMBES, AAMI, ACCE, etc.)	54	29

decision-makers. However, when the effort is made on a continuous basis and with no policy change, getting heard becomes a frustrating and futile process.

83% agree that clinical engineers, biomedical technicians, and technologists continue to keep up with changes in technology and are able to maintain ability and knowledge to support medical devices inhouse. There is a bias element to this question. However, the response is likely not an inaccurate representation of the confidence and competency of the respondents.

An especially interesting response was to the question of having an on-line rating system to help improve supportability (from OEMs). A notable 83% of respondents agreed. As to the form in which such a system would take is yet to be discussed. This bold mechanism would directly impact the perception of OEMs and in real time.

A dynamic indicator was built into the CMBES survey in the form of two survey questions. These relate to CE/HTM's ability to comprehensively support medical devices inhouse. 41% agree that it *is* currently difficult. 69% agree that it is becoming more difficult. This indicates where we are and where we may be in the near future. The ability to comprehensively support medical devices inhouse depends heavily on the OEM. It is important to realize that unless mechanisms are instituted now, the benefits of CE/HTM services are at risk.

50% of respondents were not aware of the efforts currently underway in dealing with the supportability question. Publicity on the topic has been relatively minimal considering its importance. Several responses were Neutral because many vendors do a good job on supportability. This quandary left respondents not knowing how to respond. Nevertheless, an average of 38% agreed that these three elements of supportability are adequate.

Despite efforts from the many OEMs that make supportability a priority, results of the AAMI Survey and the significant top three responses that Disagree from the CMBES Survey (Avg 40%), points to a weighty situation. Current efforts, although noble, are having to work fast to catch up with what appears to be a developing tide.

On the international front, the survey did end up in the hands of respondents in thirteen countries outside of Canada. None came from the United States. Although it is a small segment (in the order of single digits) of the overall response (9%), about half of these felt supportability is an issue (see Table 3). This, in combination with a large turnout at the 2015 World Congress—Summit on the Supportability of Medical Devices and comments from that event, indicates that this is likely a global issue.

The World Summit was followed by two additional follow up events in 2017. One at CMBEC40 in Winnipeg, Canada and an open CMBES Webinar held in October. These efforts were organized by Mike Capuano of Hamilton Health Sciences and co-presented by Jean Ngoie, now at the Ninewells Hospital in New Dundee, Scotland. All of these events involved a panel of clinical engineers representing the

Table 3 International response

Survey statement	Agree (%)	Comment
Brazil	1	Issue
Bhutan	1	Issue
Canada	177	Issue
Ghana	1	Issue
Hungary	1	Issue
India	1	No issue
Iran	2	Somewhat
Pakistan	1	Somewhat
Peru	1	No issue
Saudi Arabia	1	Somewhat
South Africa	1	Somewhat
Spain	1	Somewhat
UK	4	Issue
Yemen	1	Issue
Total	194 (out of 232)	

CMBES and in Winnipeg, a panel of OEM representatives (GE, Spacelabs, Drager, and BD) were present to provide their perspectives. The CMBES panel consists of CMBES President, Martin Poulin (Victoria), Kelly Kobe (Calgary), Mario Ramirez (Toronto), Andrew Ibey (Vancouver), Murray Rice (Toronto), and Marco Carlone (Toronto).

Although metrics do well in providing a figurative picture of the issue, the survey comments are much more descriptive and direct. Probably the most profound set of comments in that survey are those directed at hospitals and purchasing departments. Several institutions have seen a change from when everything automatically went to 'Biomed' to now seeing every device or system requiring a project assignment and intense negotiation to obtain the required supports.

The message appears to be that hospital administration needs to better-recognize that CE/HTM is good for the institution and that vendors must be holistically accountable to the healthcare organization.

4 The OEM Lobby

In 2016, the FDA opened a docket for comments (Docket N-0436) on the 'Refurbishing, Reconditioning, Rebuilding, Remarketing, or Remanufacturing of Medical Devices.' The purpose of the docket was to obtain comments and feedback pertaining to the risk of third party service on medical devices. It is believed that it was initiated by representatives of certain OEMs regarding the quality of work performed by these third parties. Nevertheless, the docket, which closed in June of 2016, contained important information on the supportability of medical devices. In a presentation at the 2017 AAMI conference in Austin, Texas; Capuano and Binseng Wang shared the results of an analysis of the docket responses [3]. Out of 171 responses to the docket, 83 recommended improved supportability from OEMs (49%) (see Fig. 1a). This comment category had the highest number of responses compared with all other comment categories (see Fig. 1b).

Conversely, responses in the docket addresses the question of regulation but from a different perspective. Where comments from the CMBES survey centered on OEMs being regulated to provide better supportability, the docket responses focused more on regulating third party servicers. These came mostly from the OEM community looking to achieve an improved method of capturing failure data on their products. It was also seen as a means to give the FDA the ability to register all third party entities that provide services on medical devices. This desire on the part of the OEMs and the FDA has advanced to the political level. With Bill 2118, Congress has asked the FDA to produce a report on how the FDA might implement a process requiring all independent service organizations to register with the FDA, file adverse event reports, and maintain a complaint-handling system. The FDA must submit this report by May 15, 2018. The intent of the bill is to give the FDA 'more oversight and patient protections to the third-party servicing process.' [4]. They want to know how many businesses are 'engaged in servicing medical equipment' and a 'better handle on adverse events to ensure that they never happen again.'

Certain groups are opposed to this indicating that it is costly to the business side and may jeopardize many independent service organizations. Robert J. Kerwin, general counsel for IAMERS (International Association of Medical Equipment Resellers and Servicers), told a Congressional subcommittee that 'this is a solution for which there has been no evidence of a problem.' [4]. Members of the American College of Clinical Engineering (ACCE) and the ECRI Institute have cited their opposition to it as well. Although AAMI remains neutral because of their diverse representation, they did provide an informative response to Docket N-0436 citing the benefits of a well-supported CE/HTM programs (and ISOs). They continue to promote the idea that CE/HTM/ISO and OEMs need to work on resolving issues together. This is evident based on their collaborative efforts thus far.

5 Service Information, Training, and Access to Diagnostics

It is common now to see equipment, traditionally made serviceable in the field, now severely limited in supportability. This is found to be true based on product design, sales

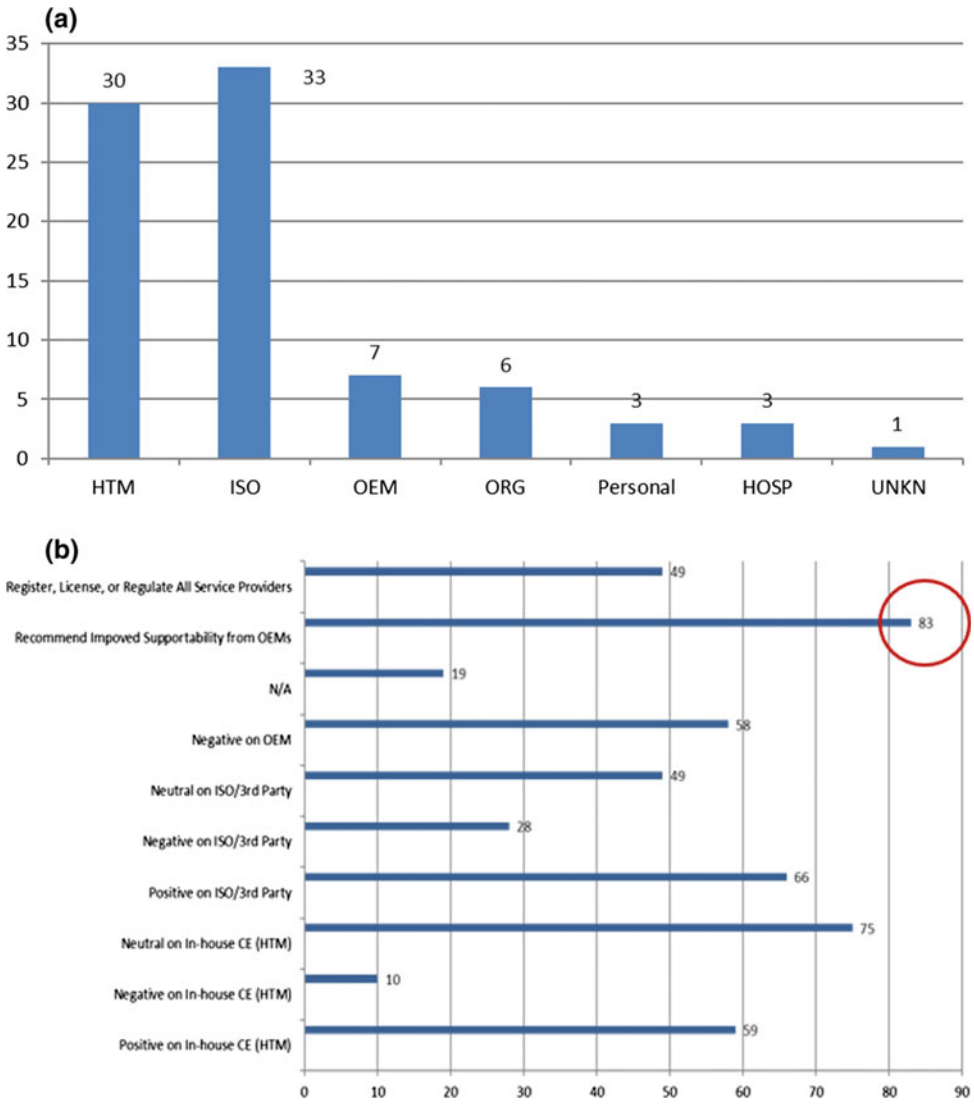

Fig. 1 **a** FDA Docket N-0436 responses recommending improved supportability from OEMs. **b** FDA Docket N-0436 responses recommending per comment category

policy, and limits on exactly what information can be obtained. Notations such as, '…not field serviceable,' '…limited number of serviceable parts,' and '…training [is] required to be eligible to receive the service tool' are becoming much more common within the limited service information we are beginning to see (see Figs. 2, 3 and 4). Regarding the training required to get the service tool, the cost of the training mentioned above is very high. In this example, the training was 'on-line' at a cost of $900 CDN per person. For this device, a medium sized inhouse program would likely train 10–12 people, thus accumulating a cost of about $10,000 CDN. To bring someone on-site to do the training it would have costed $12,000 CDN plus $2,000 per person. For 10 people it would have costed $32,000 CDN.

An issue more relevant in Canada is that of obtaining good quality service training at a reasonable cost. Since most of the devices acquired in Canada are manufactured or distributed in the United States or abroad, access to appropriate technical training is more of a challenge to obtain or it comes at relatively higher cost. This is due primarily to the need for Engineers and Biomedical Engineering/Equipment Technicians and Technologists (BMETs) to travel to the United States for factory training or to attend a custom service school in one of Canada's bigger cities. Some companies add a premium (per attendee) taking advantage of customers wishing to train several of their staff. For example, one manufacturer of a common medical device charged about $737 CDN per attendee (no cap). For 19 attendees, it came to $14,000 CDN.

Access to service diagnostics for troubleshooting and quality assurance testing is also a control factor some OEMs employ in order to keep the reigns on their product. Schemes such as requiring a separate license for each device, requiring a purchase order for a one-time use of a passcode, and keeping access away from competent BMETs unless they take an expensive training course.

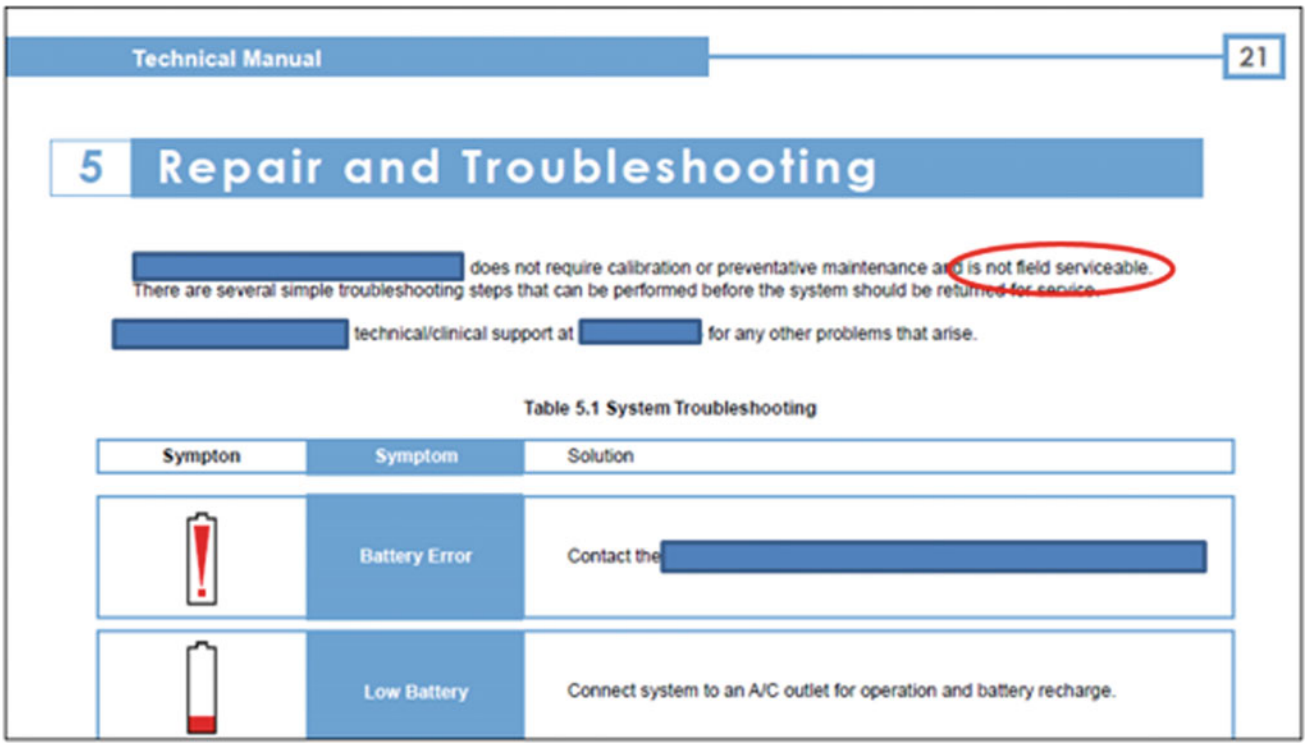

Fig. 2 Limits on field serviceability

There are several reasons that many company representatives will typically cite when attempting to resolve the supportability issue. A popular one is the risk of revealing trade secrets or intellectual property; for example if too much information were to be released. This rationale is seldom an issue especially if the technology is appropriately patent-protected.

Liability concerns are also cited. OEMs continue to cite the potential for litigation should its product be maligned in the hands of an unqualified individual. At the end of the day, every wrongful injury or death suit is based on the unique and individual merits of the case and rarely on any biased presumptions of guilt. In almost all circumstances of equipment related litigations, the forensic evidence usually points to the root cause whether it be a faulty component of design or to the work of an unqualified person.

Another attempt at justification is the reference to FDA requirements (21CFR 820). One should not accept this as a reason an OEM cannot provide service information. Simply put, there is no such requirement.

6 Standards/Regulations

The **NFPA 99 Healthcare Facilities Code (2012)**, used primarily in the United States, provides recommendations concerning service and maintenance of equipment in healthcare institutions. The code indicates what manufacturers 'shall furnish' with the sale of their products [appliances]. In Sect. 10.5.3 it states that documents shall contain at least a technical description, instructions for use, and a means to contact the manufacturer. It also states that illustrations showing locations of controls and step by step procedures for testing and proper use be provided; as well as schematics, wiring diagrams, and repair procedures. This standard, although held in high regard and used religiously throughout the United States, appears to be loosely-followed by a growing number of manufactures. The elements mentioned above are congruent with what we know as a 'service manual;' a term not used in this standard or other similar standards. For example, **CAN/CSA-C22.2 No. 60601-1:08 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, Section 7.9.2.16** refers to a technical description indicating that 'instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found (e.g. 7.9.3.3 Circuit diagrams, component part lists, etc.). It also states that 'The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of

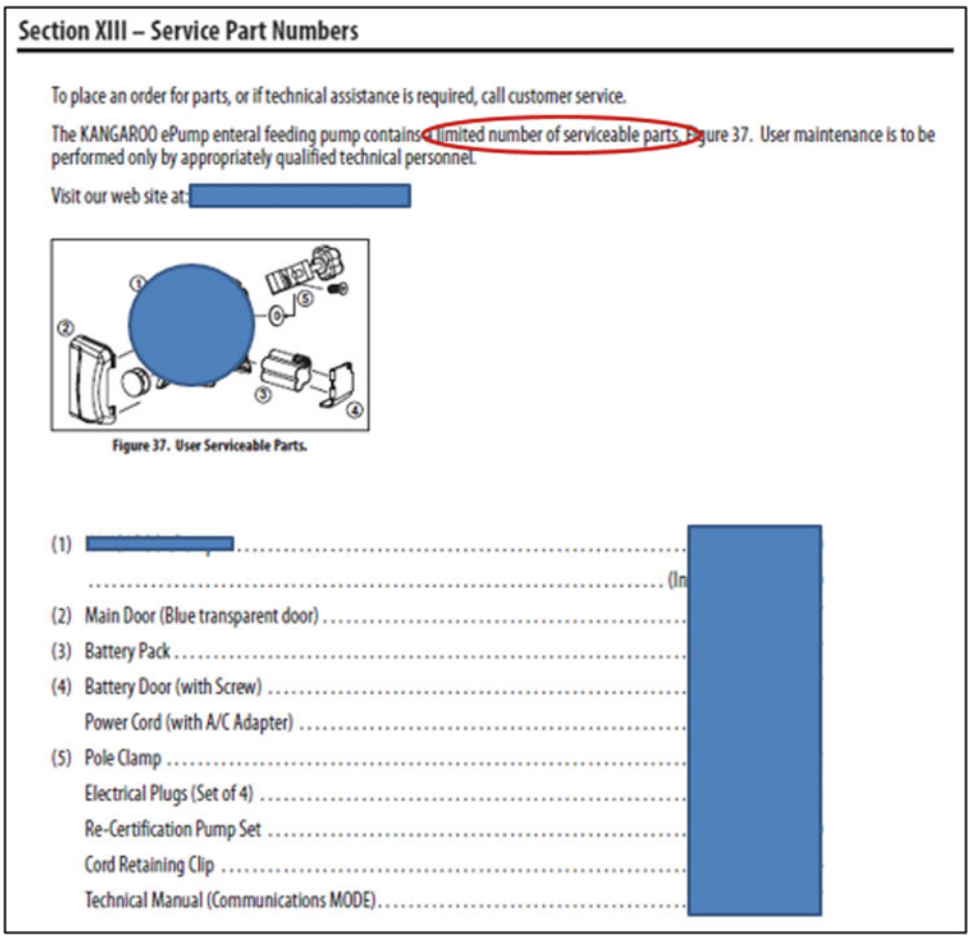

Fig. 3 A limited number of serviceable parts

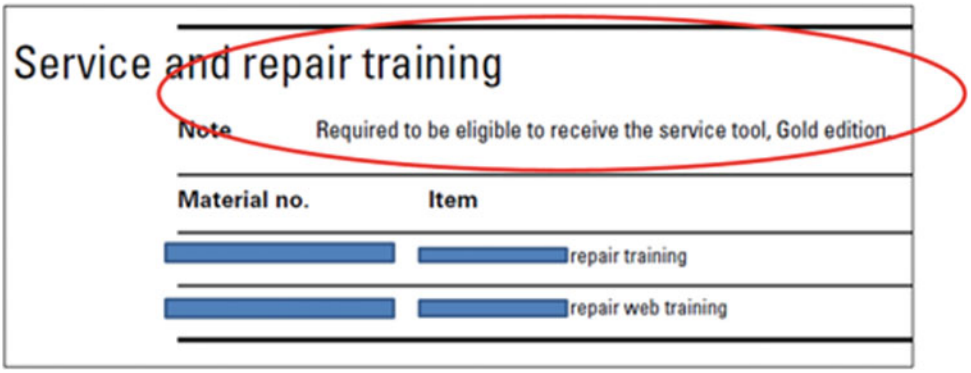

Fig. 4 Training [is] required to be eligible to receive the service tool

ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.'

Not mentioning the term 'Service Manual' is a missed opportunity. Clearly indicating the need for this type of information would certainly help non-OEM service communities. The standards do little to make manufacturers comply with the need to provide information comprehensive enough to adequately service their product.

As mentioned previously, the United States Food and Drug Administration (FDA) does not prevent manufacturers from providing service information to their customers. However, it does not require them to provide it either. This does little to help non-OEM entities obtain what they need. They do require OEMs to provide service information for medical lasers as indicated in **Section 21 CFR 1040.10.** It states as follows, 'To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model.'

Table 4 Effectiveness of standards and regulations

Reference	Effective?
NFPA 99	No
CSA 22.2	No
FDA CFR 21 040.10	No
ISO 13485	No
JC—EC.01.01.01, EP 3	Somewhat

Health Canada has no requirement to make service information available. Its requirement to satisfy **ISO 13485 Quality Standard for Medical Devices** does not address servicing in the field. As indicated in comments from the CMBES survey, some stakeholders wish they did.

At both the 2015 World Congress Summit and the AAMI Forum on Supportability, one of the gaps identified was the absence of supportability covered in the evaluations that ECRI Institute were conducting. ECRI Institute is a well-known and well-utilized nonprofit organization dedicated to the non-biased evaluation of medical devices. In around December of 2015, ECRI Institute began publishing 'Service and Maintenance' as a criteria in their evaluations. This, along with the Joint Commission's latest requirement for HTM programs to house a 'library of information,' [5] may indicate that some of the recent efforts on supportability are paying off (see Table 4). Organizations such as AAMI, CMBES, ACCE, the Joint Commission, and ECRI Institute continue to address the issue of supportability in CE/HTM.

7 Summary

Information from a combination of survey results; industry, organizational and government forums; device documentation, standards, regulations, and home-grown examples of barriers to supportability; all point to an authentic issue. CE/HTM and ISOs are facing challenges more prominent now than once perceived. At this point in time, the issue appears to be at a cusp where Supportability will continue to be increasingly evasive or, due to efforts currently under way, it will subside or improve from its current state. The CMBES is an advocate for the efficient utilization of Clinical Engineers and BMETs to effectively manage and support medical devices in Canada's healthcare institutions. One of its aims is to advance and promote the theory and practice of engineering sciences and technology to medicine. Their members do this by providing safe, cost-effective, and expedient technical and technological services to medical devices in the field. They believe that a healthy presence of relevant CE/HTM and ISO entities greatly benefits healthcare. A stable backing from manufacturers and healthcare institutions is crucial to maintaining the unique and necessary services of the Clinical Engineering/Healthcare Technology department.

Conflict of Interest The author declares that he has no conflict of interest.

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