The Approach to the Development of an Assessment Method for IEC 80001-1

Silvana Togneri MacMahon, Fergal McCaffery, Frank Keenan

Regulated Software Research Group, Department of Computing & Mathematics, Dundalk Institute of Technology & Lero, Dundalk, Co. Louth, Ireland
{silvana.macmahon,fergal.mccaffery,frank.keenan}@dkit.ie

Abstract. IEC 80001-1 is a risk management standard that addresses the risks associated with the incorporation of a medical device into an IT network. Our research in the area of IEC 80001-1 has to date been focused on the development of a Process Reference Model (PRM) and Process Assessment Model (PAM) for assessment against IEC 80001-1. In this paper we present the approach to the next phase of our research which focuses on the development of an assessment method which will be used to perform an assessment using the IEC 80001-1 PAM. The assessment method will ensure a standardized approach to performing an assessment while identifying key success and will contain a list of questions which will allow assessors to determine the capability level of processes within the PAM. The results of the assessment can be used as a basis for process improvement.

Keywords: IEC 80001-1, ISO/IEC 15504 – Process Assessment, Risk Management, Medical IT Networks, Assessment Method.

1 Introduction

When using a medical device, the safety of the patient must be the primary concern. In order to ensure that the use of medical devices do not compromise the safety of the patient, medical devices are stringently regulated by the authorities within the region in which they are to be marketed. However, other factors may influence the safety of a device which has achieved regulatory compliance, such as the incorporation of that device into an IT network. Traditionally, if a medical device was to be added to a network, the medical device manufacturer who provided the device would also provide the network. This method of networking devices led to a situation where a hospital may have a plethora of private networks. This can become unmanageable and has led to medical devices being designed to be incorporated into the hospitals general IT network which allows for true interoperability. Hospital networks can carry traffic which can range from life critical patient data to emails. The incorporation of a device into a network can introduce risks that may not have been considered during the design and manufacture of the medical device. These risks were identified when, in 2003 and 2004, the FDA received a cluster of attacks on hospitals which led to the FDA producing guidance on cyber security for networked medical devices

incorporating off the shelf software [1]. During the preparation of this guidance it was recognized that the whole area of networking of medical devices would need to be reviewed. To be effective, a standard would need to be addressed not only to medical device manufacturers but also to the HealthCare Delivery Organizations (HDO) who were responsible for the establishment and maintenance of these networks and to providers of other IT technology who may be the providers of the hospitals general IT network. This was to be the origin of IEC 80001-1: Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities [2]. IEC 80001-1 is a risk management standard which addresses the risks specifically associated with the incorporation of a medical device into an IT network. IEC 80001-1 advocates a life cycle approach to risk management and emphasizes the need for a new level of cooperation and communication among all parties involved in the performance of risk management activities [3]. Risk management activities are performed in order to preserve the 3 key properties of the network – Safety, Effectiveness and Data and System Security. Safety ensures that harm is not caused to the patient or to the user of the medical device. Effectiveness is the ability of the device to produce the intended result from the usage of the medical device for the patient and the HDO. Data and System Security is concerned with ensuring that information assets are protected from degradation in terms of availability, confidentiality and integrity. The standard is addressed to Responsible Organisations (ROs), Medical Device Manufacturers (MDMs) and Providers of Other IT Technology (POs). An RO is defined as an entity, usually a HDO, responsible for the establishment and maintenance of a medical IT network. Currently, there is no method by which HDOs can assess the capability of their risk management processes against the requirements of IEC 80001-1. Section 2, of this paper presents the PRM and PAM which has been developed to facilitate assessment against the requirements of IEC 80001-1. An assessment cannot be completed using the using a PRM and PAM alone but requires in addition the use of an assessment method. Section 3, details the approach to the development of an assessment method which (in conjunction with the PAM) may be used to assess against IEC 80001-1. Section 4, presents the conclusions of this paper and also presents future work in this area.

2 IEC 80001-1 PRM and PAM

2.1 Approach to the Development of the PRM and PAM for IEC 80001-1

Research to date has focused on the development of a PRM and PAM for IEC 80001-1. In order to develop the PRM and PAM, a review of the requirements of IEC 80001-1 was undertaken. Once these requirements were understood, it was necessary to determine the approach of how these requirements were to be organised to form the PRM and PAM. ISO/IEC 15504 -2 [4], sets out the requirements for the development of PRMs and PAMs. ISO/IEC 15504-5 [5] provides an exemplar PAM for the processes which are contained in ISO/IEC 12207 [6]. These standards were reviewed to ensure that the PRM and PAM which were developed for IEC 80001-1 would be compliant with the requirements of SPICE.

IEC 80001-1 takes a life cycle approach to risk management. IEC 80001-1 is similar to ISO/IEC 20000-1 Information technology - Service management - Part 1: Service management system requirements [7] and ISO/IEC 20000-2 Information technology - Service management - Part 2: Guidance on the application of service management systems [8] which also take a life cycle approach but do so in the context of Service Management. In order to develop the PRM and PAM, a review of the development of assessment models and methods for these Service Management standards was undertaken. The research focused on models which are compliant with the requirements of ISO/IEC 15504-2 and particularly focused on the method of development of the Tudor IT Service Management Process Assessment (TIPA) [9]. TIPA can be used for assessment against ISO/IEC 20000 or another Service Management standard – the Information Technology Infrastructure Library (ITIL) [10, 11]. The TIPA model no longer updates the PAM for assessment against ISO/IEC 20000 but was used as an input for the development of ISO/IEC TS 15504-8 [12] which is the international standard for assessment against ISO/IEC 20000. This model was reviewed for its applicability to the requirements of IEC 80001-1 and was also reviewed from the perspective of the approach that was taken to the development of the model.

While ISO/IEC 15504-2 is detailed in terms of the requirements for PRMs and PAMs it does not provide guidance on how to organise domain requirements in a way that can produce an ISO/IEC 15504-2 compliant PRM or PAM. This was recognised during the development of TIPA and the TIPA transformation process was developed to address this need [13, 14]. The TIPA transformation process is a goal oriented requirements engineering technique which can be used to produce PRMs and PAMs. The transformation process also takes into account the requirements of ISO/IEC TR 24774 Systems and software engineering - Life cycle management - Guidelines for process description [15] which provides guidance on how the most common elements of processes should be described. Based on the successful use of the TIPA transformation process in the development of an assessment model for ISO/IEC 20000, the TIPA transformation process was used in the development of the PRM and PAM for IEC 80001-1 which are described in the following sections of this paper.

2.2 IEC 80001-1 PRM

This section of the paper describes the IEC 80001-1 PRM. Using the approach detailed in the section above, the IEC 80001-1 was developed to describe the risk management processes which are contained within IEC 80001-1. The IEC 80001-1 PRM contains 14 processes. These processes are divided into 2 process categories. The Primary Process Category contains processes which are implemented in the performance of risk management activities while the Organisational Process category is concerned with the planning of the performance of the risk management activities contained within the Primary Process Category. The representation of standards in the PRM for IEC 80001-1, follows the same “Plan, Do, Check, Act” approach that is used in the PRM for ISO/IEC TR 20000-4 Information technology - Service management - Part 4: Process reference model [16]. This approach is maintained due to the lifecycle approach which is used in both standards. The processes within the PRM are shown in the figure 1.

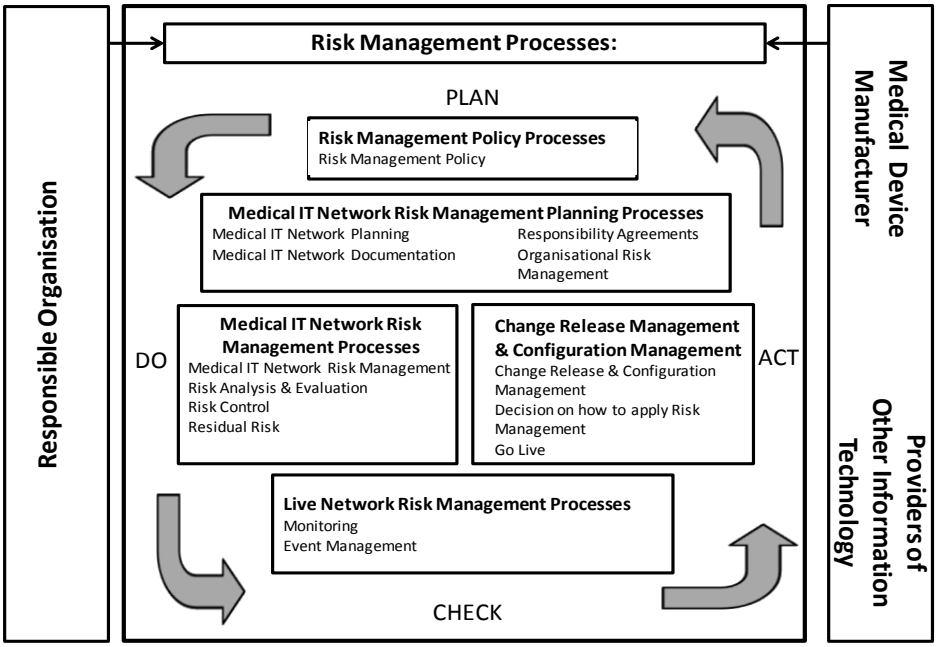

Fig. 1. Processes within the IEC 80001-1 PRM showing process categories, process groups and "Plan, Do, Check, Act" Approach.

Organisational processes are contained within 2 process groups within the "Plan" section of the lifecycle while the remaining 3 process groups contain the Primary processes. As illustrated within figure 1, the RO, MDM and OP are involved in risk management activities throughout the lifecycle. Each of the 14 processes is described in terms of the process purpose and the process outcomes. The descriptions of the processes are compliant with the requirements of ISO/IEC 15504-2 and ISO/IEC TR 24774. The PRM provides a description of the processes that will be assessed by the PAM.

2.3 IEC 80001-1 PAM

The PAM extends the PRM with the addition of a measurement framework. The addition of the measurement framework, as described in ISO/IEC 15504-2, can be used as the basis for an assessment through which the capability level of the process can determined. The results of the assessment can identify strengths and weaknesses within the performance of the process which can then be used as the basis for process improvement. To allow the capability level of the process to be determined, the descriptions of processes within the PRM are extended to include base practices and work products. A base practice is an activity that is performed in order to achieve the process purpose. A work product is used or produced during the performance of the process.

The IEC 80001-1 PAM can be used for assessment of all 14 processes within the IEC 80001-1 PRM. In accordance with the requirements of ISO/IEC 15504-2, Table A.1 in Annex A shows the mapping of the processes within the PRM to the PAM. The IEC 80001-1 PAM maintains traceability from the requirements of IEC 80001-1 to the outcomes of the process, the base practices to achieve the outcomes and the work products used or produced during the implementation of the process. This traceability is shown in Annex C of the IEC 80001-1 PAM.

The IEC 80001-1 PAM described in this paper was presented at the September 2012 meeting of IEC SC 62A JWG7 standards meeting in Vienna and as a result the PAM has been raised as a New Work Item Proposal in January of 2013 and will be circulated to member states for comment. The final PAM is scheduled for inclusion as part of the IEC 80001-1 family of standards.

3 Approach to the development of the Assessment Method for IEC 80001-1

In order to perform an assessment against the requirements of IEC 80001-1, a PRM and PAM are not sufficient. An assessment method is also required. An assessment method provides details on the organizations performance through using a set of questions (related to each process) to enable the assessor to determine the capability level at which the process is being performed. In order to develop the assessment method to accompany the IEC 80001-1 PRM and PAM, a number of factors will need to be considered which are discussed in section 3.1.

3.1 IEC 80001-1 Assessment Method – Goals and Concerns

The goal of the PAM is to allow ROs to assess the capability of risk assessment processes which have been used to manage the risks associated with the incorporation of a medical device into an IT network. However risk management activities are not performed by the medical IT network risk manager in isolation. In order to perform risk management activities effectively, requires input from all risk management stakeholders. This not only requires communication between the RO and MDMs and POs but also requires a high level of communication within the RO among risk management stakeholders. These stakeholders can include clinicians, IT department staff and bio medical departments. The development of an assessment method for the IEC 80001-1 PAM will need to address all risk management activities from the perspective of these groups.

An RO is defined within IEC 80001-1 as an entity responsible for the establishment and maintenance of a medical IT network but this can vary from a GP who has established a small network incorporating a medical device to a large hospital that has a large number of medical devices which have been incorporated into the IT network. The development of an assessment method will need to take into account this variation in scale among ROs and ensure that the capability level of processes can be successfully assessed regardless of the size of the RO in which the process is taking place.

During the development of the assessment method, consideration must also be given to the fact that the standard requires that an appropriately qualified medical IT network risk manager is appointed. In practice due to resource constraints and due to the variations in scale in the RO, the medical IT network risk manager may not be fully versed in the performance of risk management activities. The assessment method will need to ensure that capability levels can be accurately measured through self-assessment and that where opportunities for improvement are identified, that recommendations can provided for process improvement and commonly understood capability levels can be communicated to risk management stakeholders regardless of the experience level of medical IT network risk manager. In addition given these resource constraints, the assessment method will need to be a light weight method, not in terms of reduced number of processes from the PRM but in terms of resource usage, in order not to place additional burden on staff during the performance of the assessment.

In order to inform the development of the assessment method and to address these concerns, sections 3.2, 3.3 and 3.4 present the development of the assessment method which centers on a review of both standards for assessment methods of related assessment methods in the area of medical device development, Service Management and Risk Management.

3.2 Process Assessment Standards

In order to inform the development of the assessment method, a review of the standards related to the performance of an assessment has been conducted. These standards provide a standardized approach to the performance of an assessment and will ensure that capability levels can be understood and communicated. This standardized approach will also help to inform how the assessment method can be scaled to accommodate assessment of HDOs of varying sizes. The standards which have been reviewed are ISO/IEC 15504-2 [4] and ISO/IEC 15504-3 [17]. A review of the requirements of the Appraisal Requirements for CMMI® Version 1.3 (ARC) [18] and the Standard CMMI Appraisal Method for Process Improvement (SCAMPI), Version 1.3 [19] was also undertaken and is discussed in this section.

Clause 4 of ISO/IEC 15504-2 sets out the requirements for performing an assessment and ensures that the output of the assessment is self-consistent and also ensures that evidence is given to substantiate any ratings that are given during the assessment. This standard requires that assessments are documented and that the documentation process is sufficient to meet the scope of the assessment. This standard requires that the documented process contains as a minimum the following activities – the assessment should be planned, the required data should be collected and validated and on the basis of the validated data, a process attribute rating should be assigned for each process which should then be reported to the assessment sponsor. ISO/IEC 15504-2 also defines the roles and responsibilities of the assessment sponsor, the competent assessor and the assessor. The requirements for defining the initial assessment input and the requirements for recording the assessment output are also discussed within this standard.

ISO/IEC 15504-3 provides guidance on performing an assessment. This standard builds on the requirements expressed in ISO/IEC 15504-2 in terms of assessments and

provides additional guidance on the use of tools in performing an assessment, competency of the assessment team and assessment approaches. This standard also outlines success factors for process assessment. In developing the assessment method for IEC 80001-1 these success factors will need to be taken into account and be incorporated into the assessment method. The planning, data collection and validation, the process attribute rating and reporting are discussed in detail as are the roles and responsibilities of those involved in the assessment.

Appraisal Requirements for CMMI (ARC) defines the requirements for appraisal or assessment methods and is intended for use not only with CMMI but also can be used for assessment of other reference models. ARC defines 3 separate classes of appraisal which are based on the degree of rigor of the assessment with the appraisal classes being Class A, B and C with Class A being the most rigorous. ARC provides high level guidance for developers of appraisal methods and discusses the benefits and features of CMMI Appraisal Methods. Requirements for CMMI Appraisal Method Class Structure are also discussed with classes being differentiated on the basis of the types of objective evidence gathered, the ratings generated, the organisational unit coverage required and the requirements of the appraisal team leader. The requirements for CMMI appraisal methods are also discussed and it is these requirements which will be reviewed for applicability to IEC 80001-1.These requirements include documentation requirements, planning and preparation requirements prior to the appraisal, the rating generated during the appraisal and requirements for the communication of this rating. Our research focuses on requirements for a Class C appraisal as this is the most lightweight appraisal approach..

As with ARC, our review of SCAMPI will focus on Class C [20]. Requirements for SCAMPI appraisal, as with ARC, focus on the planning and preparation of an appraisal, the conducting of the appraisal and the reporting of the results. These requirements will also be considered for their applicability in the development of the assessment method for IEC 80001-1.

The review of process assessment standards in combination with a review of available assessment methods as detailed in section 3.3 forms the basis of the development of the assessment method. Using these standards as a foundation for the development of the assessment method will address a number of the concerns which were highlighted in section 3.1. Basing the assessment method on these standards will facilitate a common understanding of capability levels as expressed in these standards. This common understanding can be used as the basis for fostering communication among various risk management stakeholders. The issue of scaling the method for assessment of HDOs of various sizes is not addressed in these standards but will be addressed during the validation of the assessment method and will form part of the future work of this research. The following section of this paper will discuss other assessment methods that will be reviewed to inform the development of the IEC 80001-1 assessment method and review both general assessment methods and those which are used in the medical device domain.

3.3 Review of Assessment Methods

To further inform the development of the assessment method, a review of other available assessment methods will be undertaken. This review will focus on assessment methods which have been developed for the assessment of the capability of processes for developing medical device software. A review of assessment methods for standards similar to IEC 80001-1 will focus on the TIPA assessment method. As a lightweight assessment method is required for IEC 80001-1, our research will focus on lightweight assessment methods. The review will focus on a lightweight assessment method based on ISO/IEC 15504, Rapid Assessment for Process Improvement in software Development (RAPID) [21], and a similar lightweight method based on CMMI, Express Process Appraisal method (EPA) [22]. Two additional assessment methods will also be reviewed in depth – TIPA: an ISO/IEC 15504 compliant assessment method to assess against ITIL and ISO/IEC 20000. These are standards which have been identified as being similar to IEC 80001-1. The review will also study the Med-Adept [23] method for assessment of medical device software development processes. As development of the assessment method progresses, other assessment methods may also be reviewed in addition to those mentioned in this paper. Figure 2 shows the standards discussed in section 3.2 and the assessment methods which will inform the development of the IEC 80001-1 assessment method.

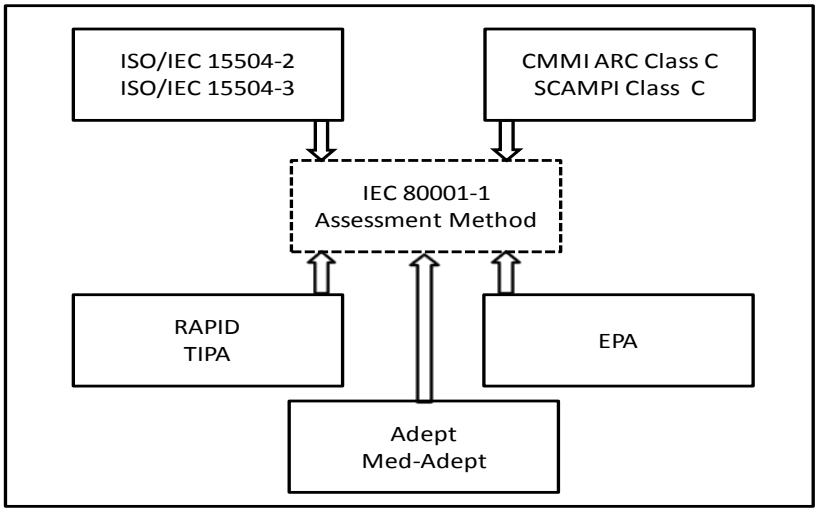

Fig. 2. Approach to the Development of IEC 80001-1 Assessment Method

This section provides a brief description of each assessment method and the reason for the review of each method in terms of its applicability to IEC 80001-1 and its ability to inform the development of the assessment method for IEC 80001-1.

Rapid Assessment for Process Improvement in Software Development (RAPID)

RAPID is a lightweight ISO/IEC 15504 compliant assessment method with a limited scope of 8 processes. This assessment method has been chosen for review due to its

compliance with ISO/IEC 15504 (the PRM and PAM which have been developed for assessment of IEC 80001-1 are also compliant with ISO/IEC 15504) and due to the inclusion of the risk management process within the 8 processes which have been selected for assessment.

The RAPID assessment instrument contains a comprehensive set of 210 questions which will be reviewed focusing on the questions related to the risk management process. As a lightweight assessment method, the RAPID method requires two assessors in order to perform the assessment. The key focus of the RAPID assessment is to identify the strengths of the organisation and also to identify risks and improvement opportunities.

Express Process Appraisal (EPA)

The EPA method was developed in 2003. EPA is aimed at small to medium enterprises and focuses on foundational processes that will bring the most benefit to these organisations and reduce the scope of CMMI. EPA is based on 6 processes of the continuous representation of CMMI.

EPA does not provide a rating. EPA is aimed at organisations that have little or no experience of software process improvement programs. EPA has been chosen for review due to the fact that it is aimed at organisations lacking in experience of process improvement programs. This is a concern in the development of the assessment method. As IEC 80001-1 is aimed at ROs, these organisations will generally not have had experience of process improvement programs so the assessment method will need to address this issue. EPA has also been chosen for review as it forms the basis of the Adept [24] and Med Adept assessment methods which are discussed in the following section.

Adept and Med Adept

Adept which was developed on 2007, is based on EPA, however, Adept extends the processes contained in EPA to include 11 processes, with 4 processes being mandatory and the remaining 8 being optional. Adept is based on ISO/IEC 15504 and CMMI processes.

Med-Adept is based on the Adept assessment method. The Med-Adept method provides a method for assessment of processes which are deemed applicable for medical device software development both for those currently producing medical device software and those who wish to become medical device software developers. Med-Adept method provides coverage of 11 CMMI process areas, 12 ISO/IEC 15504-5 and 11 AAMI/IEC 62304 processes. The Med-Adept process also includes the Risk Management process. Med-Adept will be reviewed due to its inclusion of the risk management process which is based on the risk management processes contained in IEC 62304:2006 Medical device software - Software life cycle processes [25] combined with the risk management process areas from CMMI and ISO/IEC 15504. Risk management processes within IEC 62304 are based on ISO 14971 [26] which is closely aligned with IEC 80001-1.

Tudor IT Service Management Process Assessment (TIPA)

The TIPA assessment method allows for assessment against two standards which are similar to IEC 80001-1 – ISO/IEC 20000 and ITIL. These standards take a life cycle approach to Service Management. Due to the lifecycle nature of ISO/IEC 20000, it is reviewed in Annex D of IEC 80001-1 for its ability to meet the requirements of IEC 80001-1. While TIPA is not a lightweight assessment method, its assessment of standards which are similar to IEC 80001-1 and the involvement of multiple stakeholders in the Service Management process makes it relevant for inclusion as part of this review of assessment methods.

The TIPA assessment method approaches the assessment through 6 main phases – Definition, Preparation, Assessment, Analysis, Results Presentation and Closure. Each of these phases will be reviewed in detail to assess if the outlined approach is suitable for assessment of IEC 80001-1.

The results from the review of each of the models will inform the development of the assessment method for IEC 80001-1.

3.5 Validation of the IEC 80001-1 Assessment Method

The assessment method is being developed based on the approach outlined in the previous sections of this paper. The assessment method will be validated in a hospital context. The assessment method will be used to assess the capabilities of risk management processes. For validation, we will use a previously implemented medical device network project which took place in the Intensive Care Unit of the hospital as a case study against which the assessment method will be applied. This was a large scale project incorporating a large number of medical devices and will simulate a large scale project in a HDO. The assessment method will also be validated using data from a smaller scale implementation project which took place in a clinic within the hospital. This will simulate a small scale implementation and will allow validation to take place to ensure that the assessment method can be scaled for use in smaller scale HDOs.

4 Conclusion and Future Work

In order to allow HDOs to be assessed against IEC 80001-1, a PRM, PAM and assessment method is required. Research to date has focused on the development of the PRM and PAM for IEC 80001-1. The PAM for IEC 80001-1 has been raised as a New Work Item Proposal in January 2013 and will be subject to comments from member states. The PAM will be updated and validated on the basis of these comments. A trial of the final PAM will take place in a large hospital environments in both the US and Ireland.

Future work will focus on the development and validation of the IEC 80001-1 assessment method. The assessment method will be developed in accordance with the approach described in this paper and will allow for an assessment against IEC 80001-

1 to take place. This assessment method will accompany the IEC 80001-1 PAM which is scheduled for inclusion in the IEC 80001-1 family of standards.

Having an assessment method for IEC 80001-1 will allow HDOs regardless of size to assess the capability of risk management process for the incorporation of medical devices onto an IT network. These capability levels can then be used as a basis for process improvement which will allow risk management activities to be performed more efficiently and will allow the benefits of networked medical devices to be realized while ensuring that the intended outcome for the patient is achieved while ensuring the safety or the patient.

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