Decision Matrix for Maintenance Contracts for Medical Technology Planning

Christian Kesselring, and Daniel Sieber

***Abstract*—Medical devices provide today's society with a wide range of remarkable treatment and diagnostic possibilities. The inherently high cost of these technologies is also due to special safety measures to protect patient welfare. Medical devices are critical to the efficacy and quality of healthcare services. Maintenance of Medical devices is a sensitive topic. The subject of maintenance expenses emerges in times of smaller healthcare finances, increased legal and normative requirements, and the desire for high availability of medical and nursing infrastructure. We present in this paper a reliability-centered decision aid for maintenance contracts based on a literature research. Different approaches are discussed. Legislative provisions, equipment criticality, labor and spare parts costs and maintenance knowledge levels form the foundation of the decision aid. The knowledge and concepts gathered from the literature for industrial plants and healthcare maintenance are discussed and merged into an algorithm.**

The presented algorithm has been tested with real examples and delivers the desired results. A uniform decision support was developed.

***Index Terms*—Medical technology planning, maintenance, service contracting, healthcare industry, healthcare mangement.**

I. Introduction

A Medical device (MD) is an item used in the preservation or rehabilitation of human health. A MD therefore fullfills one ore more purposes in human medicine. [1], [2] The major share of hospitals expenditures are personnel costs. A big share of non-personal costs are periodic payments for maintenance [3], [4]. Medical devices play a vital role in the effectiveness and quality of healthcare services [5]. Tighter hospital budgets [6], increasing legal and normative requirements [1] and the demand for high availability of the medical and nursing infrastructure [4], [7] arises the need of critical questioning of maintenance costs. Healthcare providers need to reduce costs while improving patient outcomes [7] and the quality of patient care [4], [5], [7]. Efficient use and utilisation of medical technology systems is becoming increasingly important for healthcare providers. The financial expenditure of a device procurement includes all services of the bidder up to the technical acceptance of the device and handover to the user. [8] Medical equipment takes up a large share of the hospital budget and contributes to the effectiveness of healthcare services quality. It is therefore essential to have a good maintenance program. [3], [5], [9], [10] An effective medical equipment maintenance program starts with identifying the medical devices that need to be maintained. The next step is the financial, personal and operational management as well as the implementation of the performance monitoring and improvement. Last step would be the implementation of the maintenance program. [9], [11] The most critical and expensive component in managing maintenance is human resources [9], [12], [13].

The economic consequences of the malfunction of a device or item range from repair of the damage to partial loss of services to costs arising from the complete loss of services and acquisition of a new item and even the worst: damage to patients. The follow-up costs depend on the degree of integration of the system into the company processes. In the case of interlinked processes, this can cause several systems to fail, the so called secondary failure. [12], [14]–[16]

In medical technology planning and quality management maintenance contracts increasingly are discussed [3]–[6], [17]. Technical, administrative and managerial actions during the life cycle of any item are referred to as maintenance. Maintenance aims to preserve or restore a state in which the item can fulfil the required function [14], [18]–[20] and is the collective term for servicing, testing, inspection and repair [14], [19], [20]. A breakdown of systemically important device in a critical environment would lead to a potential patient harm [21]–[23].

Already in facility planning or in the procurement process, the maintenance costs over the life of the equipment in operation are of great importance as part of the basis for decision-making [12], [18], [24], [25].

The task of maintenance for medical devices may only be entrusted to persons or bodies who are capable of doing so on the basis of their professional training, experience and knowledge [20]. The maintenance is therefore often outsourced due to its high complexity [4]. In that case a so called contractor assumes responsibility for a service [26], [27]. Often the original equipment manufacturer (OEM) is entrusted with the maintenance [27]. An OEM is interested to minimize the expected warranty costs as well as to offer a high up-time over the life cycle of the item [28]. Preventive maintenance activities consist of time-based maintenance, TBM, and condition based maintenance, CBM. TBM is a perodically checkup and maintenance of the items, while CBM the preventive maintenance actions are based on the system condition. [29]

Warranty is attached to provide compensation for the customer according to the warranty terms when the item fails to perform their intended function [30], [31]. Additional to the standard

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warranty period, the health care provider usually chooses a service plan (MSP) [4]. The health care providers pays an annual fee for full-protection plan and partial-protection plan. First includes charges for labor as well as material costs, while the latter only includes labor costs. The third MSP is the time and material contract, where the health care provider has to pay for labour and material expenses, but does not have to pay an annual fee. [4] Full cover is suitable if the area of use represents a risk or the expected repair costs are higher than the price of the maintenance contract [27]. The framework conditions are contractually laid down in the MSP [4].
VDI 5707 [26] reports that evidence-based maintenance can bring advantages in efficiency and economy compared to the manufacturer's recommendation.
The biggest challenge for medical technology maintenance is to maximise availability and efficiency while minimising costs. Prioritisation of medical equipment allows for a weighted distribution of financial expenditure. This means that prioritised devices have a larger budget while the overall costs for maintenance are decreasing. [29]
To the author's knowledge, there is no reliability-centred decision aid for maintenance contracts that also takes into account applicable national and European law.

II. Methods

A. Literature Research

Literature for maintenance in industry is selected using a Google Scholar search with the keywords „technical Maintenance ", based on relevance and a publication date from 2023. These restrictions were chosen to cope with the large amount of data. For the medical technology literature, a Pubmed search with the search string „((Medical[Title/Abstract]) AND (Equipment[Title/Abstract]) AND (Maintenance[Title/Abstract])) OR ((Medical[Title/Abstract]) AND (Device[Title/Abstract]) AND (Maintenance[Title/Abstract])) " is used. Non-technical papers as well as low quality journals are manually excluded. In addition, technical standards and applicable law are used as a source.
The search query via Pubmed returned 1,092 results and from Google Scholar about 18,200. The restriction to the first 15 pages in the Google Scholar search query limits it to 150 publications. The results of both queries were then manually reduced to 91. Of these 91, 43 were considered for the creation of the algorithm. Subsequently, 8 publications were excluded due to low impact and repetitive content. In the end, 35 publications were the basis for the algorithm, 16 of them from the Google Scholar query and 19 from Pubmed.

III. Decision Aiding Algorithm

A reliability centered maintenance approach is a systematic approach to determine the most effective maintenance strategy for an item [32]. VDI 5707 [26] reports that evidence-based maintenance can bring advantages in efficiency and economy compared to the manufacturer's recommendation. The decision aiding algorithm presented afterwards is a risk-based approach, which includes the following points:

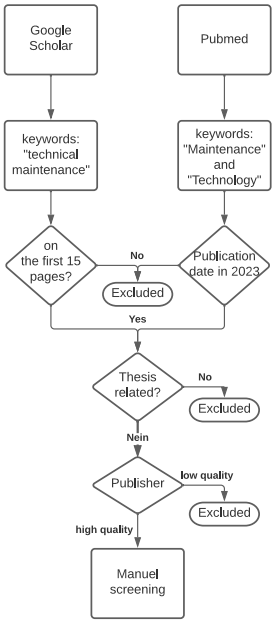


Fig. 1: Literature Research

- Legislative Provisions, discussed in section III-A
- Risk Based Classification, covered in section III-C with the Equipment Criticality
- Cost assessment for the decision whether in-house or outsourced maintenance, elucidated in section III-D

A. Legislative Provisions

Medical devices must be maintained in a traceable and professional manner according to the specifications of the OEM by means of maintenance measures. Functionality must be guaranteed for patients, users and third parties throughout the life cycle. [33] Anyone who uses a medical device professionally or commercially in Austria shall take all necessary precautions to ensure that the maintenance of a medical device is carried out properly [20], [33].
The starting point of the algorithm is therefore to check the manufacturer's instructions for maintenance and servicing and, if applicable, other legal requirements.

B. Spare Parts Costs

A full protection maintenance contract can cope the costs of expensive spare parts [4], [29]. Section **??** shows an example for expensive spare parts with a lower expected lifetime than the device has. For the case of a possible large investment for spare parts the decision aiding alogrithm suggests a full protection plan. It is to mention that this type of maintenance contract does mandatory not include the aforementioned spare parts.

C. Equipment Criticality

The criticality metrics G is determined according to formula 1 with A being the degree of complexity of the maintenance, B the function, C the risk, D the degree of the mission importance and E the device age. [29], [34]

$$G = A + B + C + D + E \tag{1}$$

1) Degree of Complexity of the Maintenance: The degree of complexity of the maintenance is described by the coefficient A which consists on one hand of the complexity of maintenance A_1, which is denoted by table I. This metrics A_1 describes the effort around the maintenance actions. Devices with a lower complexity do get a lower rating. Required STK and MTK testings form the average complexity and therefore the mean value. [29], [35], [36].
On the other hand is A defined by the influence of maintenance measures A_2, which is to be determined with help of table II. It describes the impact of maintenance actions on the reliability of a medical device. The metrics is set to the minimum value if the measures do not have an effect on the reliability. The maximum value is set if device failures can be predicted and avoided by preventive maintenance actions. [29], [35], [36].
A is denoted by the equation 2

$$A = A_1 + A_2 \tag{2}$$

Score	Description
$A_1 = 1$	low complexity; equipment that receives only visual inspections
$A_1 = 2$	below average;
$A_1 = 3$	Average; STK and MTK
$A_1 = 4$	Above average;
$A_1 = 5$	Extensive; periodic callibrations and replacement of wear parts with maintenance kits

TABLE I: Determination of the degree of complexity of the maintenance A for the calculation of the equipment criticality. [21], [29]

Score	Description
$A_2 = 1$	maintenance does not impact reliability
$A_2 = 2$	common device failures are unpredictable
$A_2 = 3$	common device failure are predictable and can be avoided by preventive maintenance

TABLE II: Determination of the influence of maintenance measures A_2 for the degree of complexity of the maintenance. [36]

2) Function and Environment: The function and environment of a medical device is described by the value B in equation 1 [29], [37]–[39]. For determination of this value equation 3 is used.

$$B = B_1 + B_2 \tag{3}$$

The coefficient B_1 in equation 3 describes the function of a medical device in its intended purpose. B_1 is determined with the help of table III. Function relates to the intended use or intended purpose of the medical device. As seen in the table III a miscellaneous devices, which is in contact with uncritical patients is rated less critical than a therapeutic device for intensive care.

Score	class	description
$B_1 = 1$	miscellaneous	in contact with uncritical patients
$B_1 = 2$		computers and related
$B_1 = 3$	analytical	laboratory accessories
$B_1 = 4$		analytical laboratory
$B_1 = 5$	diagnostic	physiological monitoring and diagnostic
$B_1 = 6$		surgical and intensive caremonitoring
$B_1 = 7$		physical therapy and treatment
$B_1 = 8$	therapeutic	surgical and intensive care
$B_1 = 9$		life support

TABLE III: Division of medical devices according to their function to determine the B value for equation 1 [21], [29], [36], [37]

The coefficient B_2 describes the environment the medical device is operating in [34]. Modern healthcare system Medical examinations and treatments shall only be carried out in appropriate rooms [38], [40]. DIN VDE 0100-710:2012-10 Part 7 [39] provides a division of environments into three categories.
For room groups 0 and 1, the examination or treatment can be stopped and repeated without harm to the patient. The difference between these two groups is that for group 1 rooms, medical electrical equipment is for external or invasive use. Applications on the heart are an exception. In a group 2 medically used area, a patient is endangered by disconnection or failure of the electrical system. Furthermore, the treatments are dangerous for the patient and not repeatable. In addition, intracardiac procedures and vital treatments are used. The higher the room group, the higher the electrical safety requirements to ensure patient safety. [38], [39] Table IV gives an overview of the room groups with examples.

3) Risk: The risk is expressed as C value in equation 1 and is the most important criterion for determining the criticality G [22], [29], [35], [41]. It is described by the frequency, severity, detectability [22] and downtime [34], [35]. The coefficient C can be determined as sum of the risk factors according to equation 4.

$$C = C_1 + C_2 + C_3 + C_4 \tag{4}$$

The risk, which can occur in case of a device damage, is described with the variable severity of risk C_1, which can be determined according to table VIII. This value describes the direct consequences of a device error. An inconvenience forms the minimum value as potential death or irreparable damage form the maximum value. [21] The indirect consequences are discussed later with the metrics D_3.

Group 0 B_2 = 1	**Group 1** B_2 = 2	**Group 2** B_2 = 3
Consulting room	Practice rooms for human and dental medicine	Operating theatres
Ordination rooms	Surgical outpatient departments	Intensive Care Rooms
Gym rooms	CT and MRI rooms	Anesthetic recovery room
Operating theatre side rooms	Cardiac catheterisation rooms (examination)	Cardiac catheterisation rooms (examination and treatment)
Massage rooms	Angiography rooms	Angiography rooms
Bandage rooms	Minimally invasive surgery rooms	Minimally invasive surgery rooms

TABLE IV: Room group classification of areas used for medical purposes with examples according to DIN VDE 0100-710:2012-10 Part 7 [39] [38]

Score	**Description**
$C_1 = 1$	no significant risk Malfunction would only lead to inconvenience
$C_1 = 1$	little effect on performance Equipment damage
$C_1 = 2$	moderate effect on performance leads to an injury without the need of medical intervention or reparable property damage without cessation of work
$C_1 = 3$	big performance degradation leads to: inappropriate therapy, misdiagnosis an injury with the need of medical intervention or reparable property damage with interruption of work
$C_1 = 4$	device stops working leads to permanent human impairment or property damage requiring a longer interrution of work
$C_1 = 5$	device stops working Potential death or irreparable property damage

TABLE V: Determination of risk coefficient C_1 risk severity [21]–[23], [26]

The coefficient C_2 from equation 4 represents the failure frequency grade. It expresses the amount of failures of an item. [21], [35] It has to be noted, that real and not reproducible failures should be expressed by this value, since both of them lead to a downtime. Devices with a not reproducible failure or a condition of no fault found get send to the maintenance staff while operating as intended. [42]

Score	**Description**
$C_2 = 2$	several occurrences in 6 months
$C_2 = 1$	several occurrences in 6-9 months
$C_2 = 0$	one occurrence in 9 - 18 months
$C_2 = -1$	one occurrence in 18 - 30 months
$C_2 = -2$	one occurrence in 30 months

TABLE VI: Determination of risk coefficient C_2, failure frequency grade [21], [35], [36], [43]

The coeffietent C_3 from equation 4 represents the expected downtime in case of a failure. It expresses the total time the item is not working as intended. The downtime starts with the occurrence of the error and ends with the return to service. [35], [44] Less than 24 hours represent the minimum value. More than 72 hours the maximum value.

Score	**Description**
$C_3 = 2$	more than 72 hours
$C_3 = 1$	24 hours to 72 hours inspection
$C_3 = 0$	less than 24 hours

TABLE VII: Determination of risk coefficient C_3 , downtime [34], [35]

The coeffietent C_4 from equation 4 describes the detectability of a failure [22], [35]. It is the abillity to detect a malfunction in the case of a failure [22]. Detectability without the need of an expert or special devices constitute the minimum ratings. The more advanced the fault detection becomes, the higher this value will be.

Score	**Description**
$C_4 = 0$	self announcing
$C_4 = 1$	reliable detection methods available
$C_4 = 2$	detectable by naked eye
$C_4 = 3$	detectable while inspection
$C_4 = 4$	detectable with tests for system components
$C_4 = 5$	no detection method available or not detectable while inspection

TABLE VIII: Determination of risk coefficient C_4 risk detectability [22], [35]

4) Mission Importance: The importance of a medical device for the medical care of a healthcare provider is expressed by the value D , the degree of the mission importance [29], [35], [45]. D is determined by equation 5 as sum of D_1, D_2 and D_3. [29], [35], [46]

$$D = D_1 + D_2 + D_3 \tag{5}$$

The first value, D_1, describes the availability of an alternative device, the redundancy. If an alternative is available, the value is to be determined by table IX.

Score	Description
$D_1 = 1$	more than four alternatives
$D_1 = 2$	up to four alternatives
$D_1 = 3$	no alternative

TABLE IX: Determination of coefficient for the degree of mission importance D_1, the variable for alternative devices [29], [35], [46]

The second value, D_2, expresses the utilization rate and is determined with help of D_3. D_3 is calculated according to equation 6 as percentage. In this case the maximum is considered to per 48 hours per week. [29], [35], [46]

$$D_4 = \frac{x}{48} \tag{6}$$

The value D_2 is derived from table X with the D_3 value.

Threshold	D_2 value
$D_4 < 30$	1
$30 \leq D_4 < 65$	2
$65 \leq D_4 < 80$	3
$D_4 \geq 80$	4

TABLE X: Determination of the subcriteria D_2 with the utilization rate D_4. [29], [35]

The value D_3 in equation 5, describes the consequences if the medical device is not available. This parameter is listed in the table XI [23]

Score	Description
$D_3 = 0$	no influence
$D_3 = 1$	other methods or devices are applicable with a short term loss of productivity
$D_3 = 2$	unacceptable loss of productivity
$D_3 = 3$	important tasks cannot be carried out
$D_3 = 4$	important cooperative tasks cannot be carried out
$D_3 = 5$	essential work tasks cannot be performed

TABLE XI: Determination of coefficient D_3 consequences if the medical device is not available [22]

5) Age: The value E of equation 1 describes the age of the device. This score is based on the perdictable lifetime. [29], [35] In literature [35] it is considered equal to 10 years. For determination of E the table XII is used. Therefore the age grade E_1 has to be calculated according to equation 7 [35] with E_x defining the device age and E_L the life span of the device.

$$E_1 = \frac{E_x}{E_L} \tag{7}$$

E_1	E - value
$0 < E_1 \leq 0.25$	1
$0.25 < E_1 \leq 0.5$	2
$0.5 < E_1 \leq 0.75$	3
$0.75 < E_1 \leq 1$	4
$E_1 > 1$	5

TABLE XII: Determination of the age related factor E with consideration of the subcriteria E_1 as value to express age of the device compared to the life span. [29], [35]

D. in-house or to outsource maintenance

The decision whether to perform maintenance actions in-house or to be outsourced is made on the basis of staff competence and labor costs. [29] First is determined by table XIII.

Level	Describition
L1	simple interventions with no particular safety risk
L2	less complex interventions performed by a technician of average qualification
L3	complex interventions performed by specialized technicians
L4	complex tasks of great importance performed by a technician with specific qualification supervised by a specialized manager
L5	complex tasks performed by OEM itself or OEM approved third party

TABLE XIII: Maintenance levels according to Norme X60-010 [47] for evaluation of in- or outsourcing the medical technology maintenance [29]

The labor costs L are calculated according to equation 8 with I being the estimated annual workload per level per device, J the wage of the necessary labors and K the type and number of labors needed for the level of maintenance. [29] The annual workload is directly proportional to the probability of equipment failure. [29], [34]

$$L = I \cdot J \cdot K \tag{8}$$

Maintenance tasks according to table XIII on L1 are taken over by the internal staff of the healthcare provider. To estimate the available workload for tasks according to table XIII on L2, L3 and L4 the workload of L1 has to be excluded. If the task can be completed at higher levels in terms of time resources, attention is then paid to the costs. If the internal personnel costs with the costs for spare parts exceed the costs of the external contractor, the maintenance is outsourced. [29]

IV. Results

Figure 2 shows an illustration of the decision aiding algorithm. First, a unit is selected. Then it must be assessed whether there are any legal requirements for maintenance. If so, the maintenance contract must also be designed according to the regulations.
If there are no regulations, it is checked whether the OEM prescribes a maintenance contract.

If there is a recommendation from the OEM, the maintenance contract must be designed according to this recommendation. If there is no recommendation, the algorithm moves on to the next step.
Here it is decided whether a replacement part causes a total economic loss of the unit. If this is the case, the decision support suggests a condition-based maintenance contract. If this is not the case, the criticality parameter is determined with the help of the metrics G. This Metrics consists of multiple sub-criteria. The maintenance contract is then determined by means of a threshold.
The allocation of maintenance is determined at the end. Here the focus is first on whether the necessary competences are available within the company. If this is the case, it is checked whether the maintenance costs for personnel and spare parts are more profitable in-house than outsourcing.

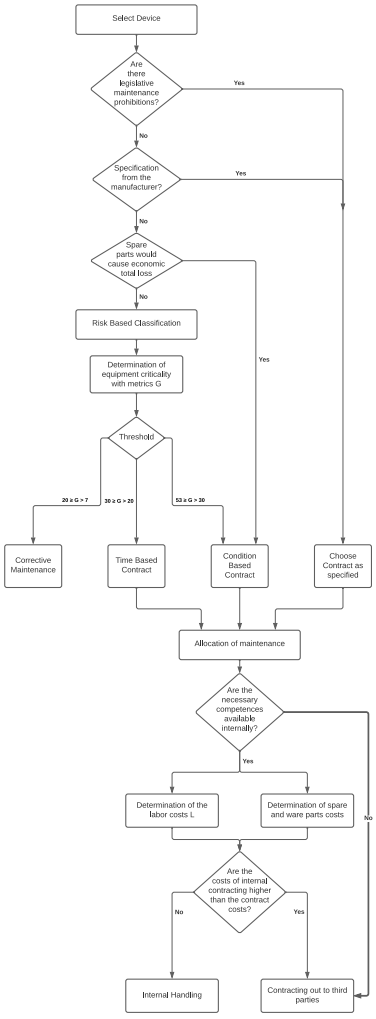
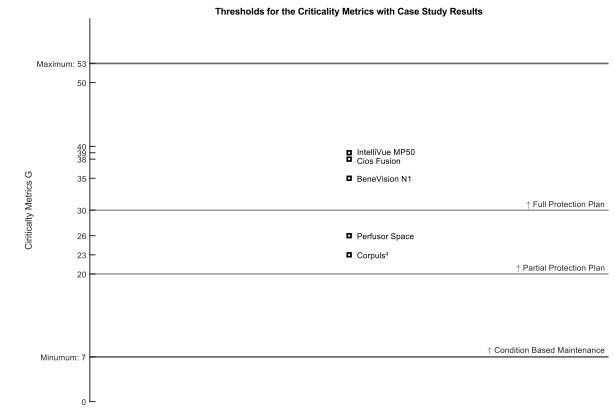


Fig. 2: illustration of the decision aid with the help of a block diagram.

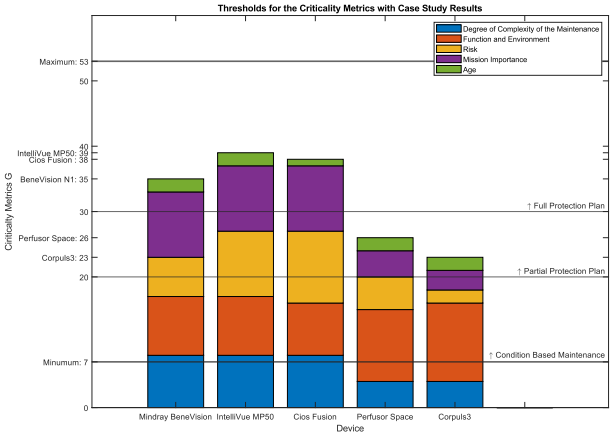
V. Discussion

This decision aiding matrix is a reliability centred approach. The goal is to identify the most suitable maintenance contract for an individual device. The six sigma approach is not part of the algorithm since it focuses on reducing process variability of production sites. [48] The classification of the equipment criticality is based and inspired of the hazard potential analysis and risk based classification. The factors of the criticality metrics G from healthcare and industrial literature allowed the presented extensive sub-criteria.
A case study was conducted to verify the algorithm. Devices with a signed maintenance contract were chosen. This information [49] was used were used as a reference for the output of the decision aid.
Figure 3 shows the result of the case study in respect to the threshold values. Figure 3 a) representing the result as data points. Figure 3 b) visualized the equiptment criticallity metrics G of the different case studies as stacked bar chart. The CT from the case study is not included in the figure 3, as a multiple change of spare parts would result in a total economic loss. This is to be expected with this type of device.
The criticality metrics provides a larger bandwidth for the full protection plan than for the other two. It should be noted that the threshold levels are the determining factor for tuning the algorithm. In addition, the full protection maintenance contract should cover a wider range of the criticality metrics G. This results from the sub-factors. The case study proved the range from 30 to 53 to be a good initial threshold. Not only very critical devices should fall into this range. The full protection maintenance contract offers prevention of high downtimes. This is also a goal for less critical devices with high usage.
The partial protection plan has the lowest bandwidth between 20 and 30. Nevertheless, this area turns out to be appropriate for the required classification of devices. In the case study, a syringe pump [50] and a defibrillator [51] were classified for this area. Although these devices are critical, the decision support and the information from within the hospital showed that the partial protection plan is best suited for these devices. The lowest value to be achieved is the minimum of 7. The range of the condition based maintenance contract is from 7 to 20. However, the case study does not include a device in this range.
Maintenance allocation is more complicated to verify, as each healthcare provider has different competencies in maintenance stuff. In order to optimise this part, information from various healthcare providers are required, which are not available to the author.

At the start of the practical application of the algorithm, the threshold values of criticality are still to be seen as variable. Furthermore, it must be examined whether this decision-making aid offers internal advantages. The decision-making tool will initially be used in parallel to the previous process for projects in question during ongoing operations. The results will be critically scrutinised and the algorithm adapted if necessary. It is expected that the awarding of maintenance contracts will become more uniform.It is important to check whether this assumption is correct. One factor influencing this point is the definition of the criteria for evaluating the different factors.
It is important to check whether the decision support offers an economic advantage. This is to be expected due to the standardised awarding process of maintenance contracts. When analysing this issue, however, the focus should not only



(a)



(b)

Fig. 3: Visualization of the different threshold levels for the Equiptment Criticallity metrics G with the results of the case study with different medical devices. a) shows the values as data point while b) is a stacked bar chart. [49]

be on the expenses for maintenance contracts, but also on the expenses for maintenance in general.

The practical application of this standardised decision support will show whether it is appropriate to developed such algorithms for other areas of medical technology planning. If the approach of a standardised decision support offers added value, it is advisable to further develop the algorithm in the form of an app. Here, an artificial intelligence could also extract the necessary information from a service specification and suggest a maintenance contract.

In future, risk profiles on the use of the devices can be collected in the course of the procurement process. This can be used as a basis for the overall consideration of the total costs of ownership, availability and quality of medical and laboratory devices. The algorithms developed can be used to simulate the operation the devices. In the context of BIM (Building Information Modelling) planning, the algorithms can be used to support operational analysis and simulation.

VI. Conclusion

The literature research provided a broad view on this topic. The various approaches and information gathered from the literature were combined into an algorithm. The different approaches allowed the creation of the presented multistage decision guidance tool. The figure 2 provides a visualization of the algorithm, which starts with the legislative prohibitions. If there are any known the maintenance shall be done as prescribed. If not the decision aid leads to a similar next step, which covers maintenance schedules recommended by the OEM. Next, the algorithm recommends a full protection maintenance contract if the expected expense of replacement parts would lead to an economic total loss. If this scenario is not to be expected, the criticality is determined with the metrics G. Sub-criteria are used for this purpose. The value of the criticality then determines the recommended maintenance contract using thresholds. For the allocation of maintenance, first thing to decide whether the necessary competences are available in the healthcare providers stuff. This is determined by means of the level of maintenance. Then it has to be checked whether it is more economical to outsource maintenance and spare parts supply or not.

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