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Cardinal Maturity Determination of Technology Development: Medical Device Development Case Study

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Abstract

A novel application of Best Worst Method (BWM) enables one to incorporate the complexity of specific sub-criteria of technological development to assess its maturity with the pre-established Technology Readiness Level (TRL) framework. It utilizes the concept of Multi-Criteria Decision Making (MCDM) methods to determine the cardinality of endpoint quantitative processes. The model is used to determine the maturity of Class II Ventilators and to detect the consistency aspects for their selection.

Keywords: medical device development, systems engineering (SE), technology development, integrated product development

1. Introduction

With the revolutionary evolution of various technologies across the globe, the effective creation of an innovative solution is more challenging than ever. The probability and expense of improving technology to a certain standard, appropriate for making a product market-ready, is an essential aspect of the development process and must be precisely measured and examined. Several methods of design and technology management strategies have been adapted in numerous renowned firms worldwide to bring advanced products into the market. The concept of agile development dictates the perusal of accountable administrative techniques for rapid product development. Technology Readiness Level (TRL), introduced by NASA, is a measurement used to ascertain a technology's maturity index. Each technology venture is assessed against predetermined criteria and imparted a TRL classification dependent on the project's success (Mankins 1995).

The versatility of TRL has inspired the formulation of various other assessment frameworks such as Integration Readiness Level (IRL) and System Readiness Level (SRL) by Sauser (2008), Software Readiness level by Blanchette (2010), Manufacturing Readiness Level (MRL) by Department of Defense (2011) and Design Readiness Level (DRL) by Revfi et al. (2020). In a study conducted by Conrow (2011), it is observed that the stages of TRL were ordinal and thus used the Analytical Hierarchy Process (AHP) for the determination of cardinal values of the multi-staged model (Appendix 1). This model enabled one to apply mathematical functions and distinguish the degree of complexity of each level of maturity from the other. The method integrated flexible assignation of correlation parameters based on expert opinion as directed by the AHP proposed by Saaty et al. (1994). The cardinality of 7 NASA projects was also determined based on the development time consumed by each technology by Fahimian and Behdinan (2017). The study resulted in the formulation of a consistent method of maturity evaluation across different technologies. According to a study conducted by Kujawski (2013), some significant discrepancies in the application of TRL, IRL, and SRL were highlighted. He concluded that the ordinal systems of the evaluation levels arranged the data in rank order and mathematical applications over such stages are inconsistent. The primary aim of utilizing TRLs is to assist

management in making decisions regarding technological growth and change. It can be used as one of the resources used to monitor the success of an organization's R&D operation. Olechowski et al. (2020) demarcated the several shortcomings and limitations of the framework. The model has been widely used to determine the overall risk of the system. This is essential considering the readiness level of each component and attempts to enhance it as a whole. It was observed that due to the uncertainty and complexity of a large system, some assessments could be skewed and may require further investigation. Mankins (2009) also proposed an integrated framework that augmented risk management with TRL to help discern if the technology is matured or risk mitigation strategies must be employed to facilitate R&D pathways further.

Customized standard guidelines have now been established by U.S. Department of Defense (DOD) to use TRLs in complex system growth, including protection, oil and gas, and infrastructure (DOD 2011; Homeland Security Institute 2009; Hook-Barnard 2013). The mandate played a vital role in acquisition projects over various industry sectors and expanded the scope of its usage exponentially. The DoD elaborates in its Technology Readiness Assessment (TRA) Deskbook (2009) that "TRLs are not a measure of design validity. . . They do not indicate the difficulty in achieving the next TRL level". The utilization of these frameworks is directed towards assessing the maturity of various sectors of technology with multiple uses.

The multiple TRL altercations described above showed a lack of definition towards the assessment of sub-system maturity and related processes, which directly affect the overall technology development. The TRA, though it defines the TRL for biomedical technologies, only provides a suggestive pathway for the MDD processes and may not be suitable for the assessment of specific medical technologies and circumstantial developments. The methods employed in the frameworks mentioned above provide a static model definition method and fail to incorporate the process-related influences for maturity assessment fully. Due to the complexities of the proposed frameworks, the risk assessment of sub-system/sub-criteria technologies is complex. Due to mathematical conventions, the methods use time-dependent algorithms that utilize a set minimum scale of reference for the process to yield results. Therefore, these results are limited to elapsed time analysis and may be inaccurate for real-time development tracking. Thus, the objective of this study is to demarcate and eliminate these limitations while proposing a novel method of maturity estimation using the pre-established TRL framework.

2. Research Objective

This study's maturity assessment of developed devices is centered on TRL cardinal coefficients. It is expanded by a time-dependent variable, transferred to quality standards to adapt multi-leveled complexity considerations of the proposed technologies coupled with a generic methodology. Using the AHP and Best Worst Method (BWM) model to estimate cardinal coefficients of TRL and end-point functions, respectively, eases distinguishing the levels of maturity of varying concepts with similar objectives. Consequently, the purpose of this technique is an analytical technology readiness evaluation for Medical Devices (MD) attributed to the expected future growth of standard-oriented technologies.

For the clear discernment and validation of the method, this study makes relevant alterations to the generalized biomedical TRL suggested by the DOD for the maturity assessment of emergency ventilators. These changes are made based on the review of several emergency guidelines and pathways as suggested by public health organizations to alleviate the shortage of these medical devices during the COVID-19 pandemic.

3. Methodology

3.1. Emergency Use Ventilator

As COVID19 started, a global scarcity of ventilators was experienced. The research was undertaken by Wells et al. (2020) in the US identified a severe shortage of both essential care and non-invasive ventilators. An estimate of the demand was recorded to be 80,000 non-invasive and 50,000 critical care ventilators will be required in addition to the pre-existing equipment to support those in need. On 24 March 2020, an Emergency Usage Authorization (EUA) (2020) was issued to modify and develop Emergency

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Usage Ventilators (EUV). Several other related emergency notifications were released worldwide to allow the production of inexpensive but practical devices (Health Canada 2020; MHRA 2020; TGA 2020). Several more organizations have offered vast services in accordance with these criteria to promote involvement from diverse backgrounds (ISO 2020; BSI 2020; ANSI 2020; ASTM 2020; IEEE 2020; CSA 2020; AAMI 2020).

After evaluating the criteria as proposed by the various health associations, it was observed that while limited to their basic forms, the recommendations nevertheless embodied much influence over the production phase and product for risk assessment and danger reduction. An active database generated by Read et al. (2020) showed that many open-source ventilator projects were not shown to be wholly usable or valuable. Survey analysis showed that 62% of MDD is primarily influenced by regulatory and clinical influences. The EUA mentions many ISO / IEC specifications to be referenced when designing emergency ventilators.

The MDD mechanism was mapped in various ways and approaches when accounting for numerous FDA guidelines and NPD techniques. Ocampo et al. (2019) published a systematic analysis of Product Development Processes (PDPs), demonstrating the extensive regulatory mechanism impact during the production phase. Recommended standards as directed by the EUA can be divided into three categories, "General Standard" (GS), "Particular Standards" (PS), and "Collateral Standards" (CS), respectively. Similar to the structures presented in the above report, the DOD has also released a Technology Readiness Assessment (TRA) Deskbook allowing one to determine the sophistication of an MD, drug, or information technology (DOD 2009). These studies are limited to a generalized approach and are relevant to traditional production teams for typical usage case MDD.

3.2. Multi-Criteria Decision-Making Method

According to the AHP a Multi-Criteria Decision Making (MCDM) method, Saaty (1994) suggested, the cardinal values would be highly dependent on the correlation set by consensus agreement of experts towards a specific problem set ratio systems. For applying analytical models over the ordinal TRL, this study utilizes a generic cardinal framework of TRL as proposed by Conrow (2011) (Appendix 1). It suggests a basic comparison of AHP Adjusted TRL (TRLc) stages which would aggregate the complexity of each stage into cardinal stages. The formulation of cardinal coefficients is derived based on the pairwise comparison of 9 TRLs concerning each other while considering a relative complexity ratio scale to describe each level. The method for comparing nine criteria would use 36 pairwise comparisons (No of comparisons: n(n-1)/2) to estimate the weights of TRLs, which would influence the attributes studied under the said framework. In order to ensure the consistency of comparisons made for considerable decision-making progress, the consistency ratio (CR) plays a significant role in determining the accuracy of the comparison. The weights, otherwise known as cardinal coefficients, are then related to quantitative attributes for further investigating the dependence of the complexity of each maturity stage towards the latter. Thus, it is highly advised that a defined roadmap is utilized for the formulation of the cardinal TRL while accounting for the well-defined complexity parameters by expert opinion. This proposed framework supplements the cardinal TRL while accounting for multi-leveled milestone complexities, which can be quantized and therefore be applied to a cardinal framework for maturity assessment.

Furthermore, to account for the influence of milestone/endpoint processes through each technology, each stage shall also be accounted for based on the successful completion of the former. Their ordinality is the greatest challenge to acclimatizing the effects of linear subjective or immensely vast factors such as design complexity, technology standardization, functionality integration, etc. However, the computation of comparison over these broad scope methods using the AHP is challenging. Hence, the Best Worst Method (BWM) formulated by Rezaei (2015) is employed to achieve a consistent and accurate relative comparison similar to AHP. The process uses fewer pairwise comparisons (No. of comparisons: 2n-3) and uses predetermined precedence relations towards its operation.

3.3. Modified TRL Assessment

Scientific literature reviews helped map the mitigations to specific issues regarding the manufacturing process or the technology of the device using the DOD's Biomedical TRL (DOD 2009). The changes made to the technology readiness level are found in (Table 1). Comparing the attributes presented by the

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regulatory development guidelines, the TRL framework is used to analyze the maturity of an emergency use Class II Ventilator (FDA 2020; European Commission 2020; Health Canada 2020; Pietzsch 2007). The issuance of a EUA for an emerging product may vary based on the extent to which the requirements such as functional parameters, risk assessment, hazard mitigation, safety, and labeling requirements are fulfilled by the developers. There must be documented evidence for the claim of satisfying the various attributes. Hence, the mapping of the EUA in the proposed TRL is based on the evaluation of publicly disclosed information by manufacturers who have already attained a EUA for their product.

For this study, three open-source development projects and 3 EUA certified products are investigated for evaluation. The assessment utilizes the specification information presented by each project/product. However, it is critical to understand that the information available is not comprehensive, and the applications submitted for the EUA are enclosed under the privacy act. The following data and descriptions are presented as available by their respective developers and the FDA (FDA 2020).

- The MIT E-Vent (2020) developed by the Massachusetts Institute of Technology, USA. It has not been approved by the EUA and, therefore, can still be considered unfit for public usage.
- Apollo BVM (2020) by the Rice University, Texas, USA. The design received an EUA approval on 26th August 2020.
- The Partially Reprapable automated open-source BVM-based project is shared as a published article by Aliaksei et al. (2020). The project discloses significant aspects of considerations for the development of medical devices.
- MICo Medical CoroVent (2020) developed by the MICo Medical s r o. The ventilator attained the EUA approval on 21st August.
- The World Ventilator Foundation (WVF) WorldVent (2020) is proposed to supplement continuous operation ventilation to grown-up patients who need intrusive respiratory aid. The device is planned for use in clinical settings as deemed fit under the EUA.
- The adult life Pro Ventilator (2020) received EUA approval on 17th June 2020.

Upon comparing the various features and functionalities as disclosed by the developers, it was observed that the Apollo BVM and the Reprapable BVM failed to achieve all recommended functional parameters as presented by the EUV and would still need further development. Due to the designs being in their initial prototype forms and presenting a proof of concept for the attainability of the said requirements, they could be attributed to the TRL 3. The MIT E-Vent was found to satisfy the operation outputs as necessitated by the regulators fully, but there lacks the testing modules of the validation of the said systems thus was categorized as TRL 4 maturity. The EUA certified devices are considered to attain TRL 5; however, due to them being intended for use under an emergency, they do not satisfy all the regulatory standards required to their fullest. The declaration of conformity released by each developer was also recorded. (See Table 1)

The maturity of a system in the same level may vary due to the flexible evaluation and sanction of EUA approvals based on the circumstances. The demarcation of maturity in the same level is thus carried out by the extent of standard validations fulfilled by a device. The declaration of conformity by the manufacturers enables one to freely assess the maturity of such a device based on one's requirement.

With the need for rapidly developed emergency use devices, it was found that the EUA has approved 120 Devices for usage in the US (FDA 2020). Many of these devices were developed in a brief span or imported and sanctioned through other channels. The average time of development of such devices is considered six weeks from the announcement date of the EUA (24th March 2020) to the last sanctioned provision (23rd September 2020). By plotting the month of issuance versus the number of devices sanctioned with the EUA, a steep decline of these approvals is witnessed.

The results as illustrated in (Table 1) evidently show that multiple devices in the same stage of development (TRL 5) show different rates of maturity. To assess the progress of development and maturity, it is important to map the underlying development processes on to the TRL scale to track the progress of an ongoing development project.

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Table 1. TRL Assessment of Ventilators

Ventilator	Manufacturer / Developer	Development Time	Declaration of Conformity	EUA Status	TRL
MIT E-Vent, (2020)	Massachusetts Institute of Technology	Ongoing	NA	No	4
Apollo BVM V1, (2020)	Rice University	Ongoing	NA	No	3
RepRapable, (2020)	Aliaksei et al.	NA	NA	No	3
MICo Medical CoroVent, (2020)	MICo Medical s.r.o.	21 weeks	IEC 60601-1 (2012)	Yes	5
WorldVent Ventilator, (2020)	World Ventilator Foundation (WVF)	12 weeks	IEC 60601-1 (2012) ISO 80601-2-80 (2019)	Yes	5
AdultLife Pro Ventilator, (2020)	NeoNatal Rescue, LLC	12 weeks	18652-1 (2017) 18652-2 (2017) 18652-3 (2017) 18652-4 (2017) ISO 80601-2-80 (2019) ISO 80601-2-12 (2020) 13485 (2016)	Yes	5

4. Multi-Level TRL Maturity Assessment

4.1. Mapping Sub-Criteria

Many factors affect the progress of technology at each level of maturity. These factors are termed as sub-criteria of development which complements to the initial TRL's principle criteria. To analyse the effects of various sub-criteria over each stage of technology readiness, their mapping is an essential process to determine maturity or development accomplished of each stage and the overall process. The sub-criteria are milestone processes and can only be considered applicable towards the assessment upon completion.

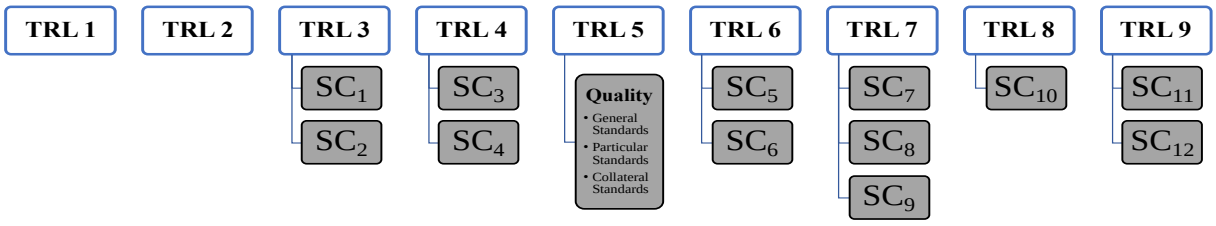

Figure 1. Mapping sub-criteria influence on TRL

For the selection of a ventilator, it has been established that regulatory standards play a major role in quality, safety, and performance maturity of the technology. The study thus maps these standards on to TRL 5 as shown in (Figure 1). To determine the cardinality of the sub-criteria the BWM is employed.

4.2. Cardinality of Sub-Criteria

Any applicable method can be employed towards the determination of cardinal coefficients of the sub-criteria. Here we apply the BWM for the ease of complexity and its homogeneity when compared to the AHP attributes. First, we determine the overall standards applicable to the evaluation of maturity for our intents and purposes. The quality of the medical device is highly controlled through various regulatory processes. The major sub-criteria at TRL 5 is thus considered Quality. To associate the concept of quality milestones easily, the entailed standards are primarily classified as GS which provides general requirements, in a series of standards, that address the basic safety and essential performance requirements of medical electrical equipment. Followed by PS which encapsulates the directives to implement and safely adapt the said technology, in this case, a mechanical ventilator. And lastly CS the enactment of which ensures the various safety features of the medical device. The application of these standards may differ based on the type of medical device but can be further broken down if necessary. For the uses of this study we shall address the

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various standards which may be required for the development of a fully safe ventilator, however, it is realised that the listed standards may not be exhaustive and may not be fully required for the approval of the ventilator and can therefore be modified.
According to the best worst method, we arrange the said standards in the order of their precedence, being: GS > PS > CS.
The arrangement of the CS can be further carried out based on their relevance, an exploratory model is shown as listed in (Table 2).

Table 2. Precedence setting of quality Sub-criteria

Categorization	Variable	Recommended Standards
General Standard	x_{gs}	IEC 60601-1 (2012)
Particular Standard	x_{ps}	ISO 80601-2-80 (2019)
Collateral Standards	x_{cs}	ISO 14971 (2019) ISO 10993 (2018) IEC 60601-1-2 (2014) ISO 18652-1 (2017) ISO 18652-2 (2017) ISO 18652-3 (2017) ISO 18652-4 (2017)

The local weights are then calculated for determining the cardinality of the said sub-criteria. The open-access BWM solver developed by Rezaei (2015) is used for expedited computation. We classify these weights as the cardinal coefficients of the quality factor. An example based on (Table 2) hierarchy is illustrated in (Table 3). We obtain the consistency ratio for the model to be 0.04 which concludes the comparison to be consistent. The local weights obtained are normalized and are applicable to the stage of maturity (TRL 5). The influence of each stage is to be obtained with the pairwise comparison performed and therefore must be strictly based on expert consensus for accuracy and well-defined process for analysis.

Table 3. Local weights of sub-criteria using BWM method

Sub-Criteria	x_{gs}	x_{ps}	x_{cs3}	x_{cs4}	x_{cs5}	x_{cs6}	x_{cs7}	x_{cs8}	x_{cs9}
Local Weights	0.22	0.22	0.11	0.11	0.088	0.063	0.063	0.063	0.063

4.3. Time Dependence

The expended time of development is a crucial factor for assessing the progress of development according to the stipulated or planned development strategy. Also, time is a consistent variable affecting each stage of readiness and can be used to navigate the current progress of a project.
Time being a cardinal quantity does not need to undergo any transformation for usability. However, for increased usability and efficient tracking of development with respect to a stipulated time frame, a normalized Time Ratio (TR) is used to assimilate the time parameter. TR is the ratio of Elapsed Time of Development in a specified TRL (Te) to the Planned Time of Development (Td) as shown in equation (1).

$$T_R = \frac{T_e}{T_d} \tag{1}$$

4.4. Maturity Assessment

The cardinal coefficients of the TRLc can be classified as global weights which affect the entirety of the development framework. Therefore, to study the effects of the sub-criteria over the entire process, the local weights then converted to global weights. The maturity at a certain TRL "M_a" $\forall\, a \in [1,2,3,\dots,9]$ can be determined as follows (Equation 2):

$$M_a = \frac{TRL_c \times (TR + \sum_{i=1}^{n} SC_i)}{n+1} \tag{2}$$

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Where,
"TRL_c" is the cardinal coefficient of the said TRL, "TR" is the Time Ratio, "SC_i" is the maturity constant of the sub-criteria and n is the number of sub-criteria used ($\forall\, n \in N$).
The Maturity Constant (SC_n) is defined as the sum of completed local sub-criteria cardinal coefficients (x_j) as illustrated in Equation 3. The maximum value of SC_i is 1 which would imply that the said sub-criteria is fulfilled and may not influence the maturity at the said stage any further.

$$SC_i = \sum_{j=1}^{n} x_j \tag{3}$$

The maximum value of the maturity at each level is the corresponding TRL_c coefficient which justifies the overall maturity of the system shall be attained upon its completion. Since the TRL_c coefficients are normalized, the full maturity of technology is attained when the sum of all preceding levels is 1.

5. Results

Comparing the data in (Table 2) and (Table 4), it is evident that the Adult Life Pro fulfilled most of the sub-criteria based on the evaluation boundary conditions, but the standards were not found identical to those proposed for assessment. Hence the equivalence of the standard is considered towards the weight assignation. The ISO 80601-2-12 and ISO 13485 were considered as CS as they did not fulfil the technical amendments proposed by the GS and PS. The sub-criteria maturity constants (SC1) were thus found as Adult Pro Life being scored at 0.68, WorldVent Ventilator at 0.44 and MICo Medical Corovent at 0.22 as illustrated in (Table 5).

Table 4. Sub criteria maturity constant calculation

Model	Declaration of conformity	Completed process sub-criteria coefficients	SC1
MICo Medical CoroVent	IEC 60601-1	x_{gs}	0.22
WorldVent Ventilator	IEC 60601-1 ISO 80601-2-80	x_{gs} , x_{ps}	0.22 + 0.22 = 0.44
AdultLife Pro Ventilator	ISO 18652-1 ISO 18652-2 ISO 18652-3 ISO 18652-4 ISO 80601-2-80 ISO 80601-2-12 ISO 13485	x_{ps}, x_{cs3} , $x_{cs4,}$ $x_{cs6,}$ x_{cs7} , $x_{cs8,}x_{cs9}$,	0.22 + 0.11 + 0.11 + 0.6 + 0.6 +0.6 + 0.6 = 0.68

Table 5. TRL 5 Technology maturity calculation

Model	TRL	TRLc	Te (in weeks)	TR	SC1	M5
MICo Medical CoroVent	5	0.07	21	0.4	0.22	0.0215
WorldVent Ventilator	5	0.07	12	0.22	0.44	0.0231
AdultLife Pro Ventilator	5	0.07	12	0.22	0.68	0.0315

Furthermore, the TR was calculated while comparing the elapsed development time in weeks (Te) to 52.15 weeks (Td) as composed in a year. The TRL5 Maturity constant was thus calculated based on Equation (2) as illustrated in (Table 5).
The maturity of each ventilator at TRL 5 is thus found to be varying unlike results obtained through originally assessed ordinal TRL. Unlike most maturity time-based assessments, the inclusion of sub-criteria influences the maturity score obtained in this model. The varying maturity level's progress localized to TRL 5 are shown in (Table 6). This can be observed with MICo Medical CoroVent being the most time mature due to its rapid development but lacks in the quality assessment criteria as shown. The Adult Life pro has the same time of development as the WorldVent Ventilator but has a higher maturity percentage due to the same reason.

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Table 6. Multi-Level maturity comparison

	MICo Medical CoroVent	AdultLife Pro Ventilator	WorldVent Ventilator
Time Maturity (%)	40	22	22
Quality Maturity (%)	22	68	44
Total Maturity at TRL 5 (%)	30.7	45	33

This method effectively allows the inclusion of various sub-criteria towards the assessment of maturity as shown above. The framework can be used to effectively track the maturity progress (as shown in Figure 2) of a development project using milestone objectives to further improve its complexity at each stage of development. The total maturity of the project can also be calculated by considering the cumulative of maturity constants of various levels as shown in Equation 4. The ideal value of Total Maturity is considered 1 due to the normalized TRLc used.

$$Total\ Maturity = \sum_{a=1}^{9} M_a \tag{4}$$

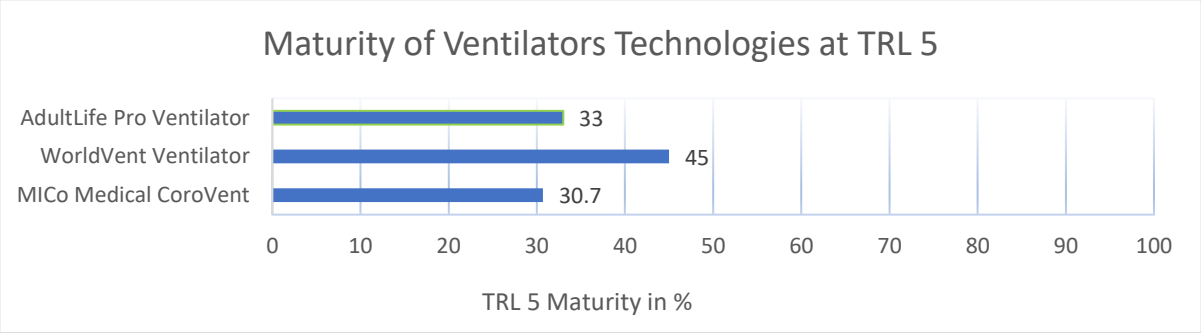

Figure 2. Maturity progress of technology at TRL 5

6. Conclusion

The application of a TRL framework in its many forms has been witnessed as a powerful tool with substantial room for improvement. The framework's versatility is appealing in comparison to the majority of complex management techniques used in the industry. The definitions of the model can be altered based on a sector's specific requirements with minimal deviation from its intended purpose. The ordinality of the model however makes it difficult to adapt and apply in a real-time dynamic environment. Many attempts have been made towards determining the cardinality of the system and facilitating the development of different concepts for active participation. One fairly advanced usage of the cardinal measure of this framework is utilized for determining the Design Readiness Level of concepts by Revfi et al. (2020). This study formulates a similar framework set by Fahimian and Behdinan (2017) for the cardinal assessment of maturity. However, many limitations are addressed over the former such as:

- The development time can now be considered 0 for fuzzy initial TRLs while not skewing its results.
- The method is more generic and flexible for the inclusion of added complexities and can investigate multiple design dimensions with similar applications.
- The maturity tracking capabilities are both local and global with simplified variables for ease in computation.
- The method realizes the varying complexities in different industries may affect the complexity consideration of the MCDM attributed TRL and thus uses an open structure to accommodate the same.

The proposed method is a novel powerful tool for development using dynamic real-time data in contrast to static elapsed time data used by the previous method. Being a flexible method to incorporate local maturity at a said TRL, the method can be used to track the maturity of individual component and the completion progress of its related end point processes to determine its overall maturity.

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Reference

A. L. Olechowski, S. D. Eppinger, N. Joglekar, and K. Tomaschek, "Technology readiness levels: Shortcomings and improvement opportunities," Syst. Eng., vol. 23, no. 4, pp. 395–408, 2020, doi: 10.1002/sys.21533.

A. Petsiuk, N. G. Tanikella, S. Dertinger, A. Pringle, S. Oberloier, and J. M. Pearce, "Partially RepRapable automated open source bag valve mask-based ventilator," HardwareX, vol. 8, 2020, doi: 10.1016/j.ohx.2020.e00131.

AAMI, "AAMI COVID-19," 2020. https://www.aami.org/news-resources/covid-19-updates/coronavirus-resources-for-the-field. (Accessed: 23rd Oct, 2020).

ANSI, "ANSI - COVID19," 2020. https://www.ansi.org/news_publications/news_story?menuid=7&articleid=27ba33a0-7482-47c5-b3a7-faa8a55518eb. (Accessed: 23rd Oct, 2020).

ASTM International, "ASTM Standards & COVID-19," ASTM International, 2020. https://www.astm.org/COVID-19/. (Accessed: 23rd Oct, 2020).

B. Sauser, J. E. Ramirez-marquez, and W. Tan, "A Systems Approach to Expanding the Technology Readiness Level within Defense Acquisition," International Journal of Defense Acquisition Management, 2008.

BSI, "COVID-19 Response – Ventilator," 2020. https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/ventilators/. (Accessed: 23rd Oct, 2020).

C. R. Wells et al., "Projecting the demand for ventilators at the peak of the COVID-19 outbreak in the USA," Lancet Infect. Dis., vol. 20, no. 10, pp. 1123–1125, 2020, doi: 10.1016/S1473-3099(20)30315-7.

CSA, "COVID-19 Response Standards & Handbooks," 2020, [Online]. Available: https://www.csagroup.org/news/covid-19-response-standards-handbooks/. (Accessed: 23rd Oct, 2020).

Department of Defense, Readiness Assessment (TRA) Guidance. Washington, D.C.: Assistant Secretary of Defense for Research and Engineering (ASD(R&E)), 2011. (Accessed: 23rd Oct, 2020).

E. Commission, "Ventilators Regulatory Requirements," 2020. https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-9_regulatory_requirements_ventilators_en.pdf. (Accessed: 23rd Oct, 2020).

E. H. Conrow, "Estimating technology readiness level coefficients," J. Spacecr. Rockets, vol. 48, no. 1, pp. 146–152, 2011, doi: 10.2514/1.46753.

E. Kujawski, "Analysis and critique of the system readiness level," IEEE Trans. Syst. Man, Cybern. Part ASystems Humans, vol. 43, no. 4, pp. 979–987, 2013, doi: 10.1109/TSMCA.2012.2209868.

FDA, "Emergency Use Authorization | FDA," Food Drug Adm., 2020, [Online]. Available: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev. (Accessed: 23rd Oct, 2020).

FDA, "Enforcement Policy," Food & Drug Administration, 2020. https://www.fda.gov/media/136318/download. (Accessed: 23rd Oct, 2020).

FDA, "Ventilators and Ventilator Accessories for COVID-19 | FDA https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical...," 2020. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/ventilators-and-ventilator-accessories-covid-19. (Accessed: 23rd Oct, 2020).

Food and Drug Administration, "Classify Your Medical Device," 2016. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/.

G. A. Van Norman, "Drugs, Devices, and the FDA: Part 2," JACC Basic to Transl. Sci., vol. 1, no. 4, pp. 277–287, 2016, doi: 10.1016/j.jacbts.2016.03.009.

H. Canada, "GUIDANCE DOCUMENT Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) Health Products and Food Branch," 2015.

Health Canada, "Interim Order respecting clinical trials for medical devices and drugs relating to COVID-19: Notice - Canada.ca," Health Canada, 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/notice-interim-order.html#a2. (Accessed: 23rd Oct, 2020).

Homeland Security Institute, "Department of Homeland Security Science and Technology Readiness Level Calculator (ver 1.1) Final Report and User's Manual," 2009. [Online]. Available: https://web.archive.org/web/20100826124930/http://www.homelandsecurity.org/hsireports/DHS_ST_RL_Calculator_report20091020.pdf. (Accessed: 23rd Oct, 2020).

I. Hook-Barnard, et al., "Technology Readiness Levels in the Department of Defense," 2013.

IEEE, "IEEE - COVID19," 2020. https://standards.ieee.org/covid-19/index.html. (Accessed: 23rd Oct, 2020).

ISO, “COVID-19 Response: Freely Available ISO Standards,” 2020. (Accessed: 23rd Oct, 2020) https://www.iso.org/covid19. (Accessed: 23rd Oct, 2020).
J. B. Pietzsch, L. M. Aquino, P. G. Yock, M. E. Paté-Cornell, and J. H. Linehan, “Review of U.S. medical device regulation,” J. Med. Devices, Trans. ASME, vol. 1, no. 4, pp. 283–292, 2007, doi: 10.1115/1.2812429.
J. C. Mankins, “Technology readiness and risk assessments: A new approach,” Acta Astronaut., vol. 65, no. 9–10, pp. 1208–1215, 2009, doi: 10.1016/j.actaastro.2009.03.059.
J. Rezaei, “Best-worst multi-criteria decision-making method,” Omega (United Kingdom), vol. 53, pp. 49–57, 2015, doi: 10.1016/j.omega.2014.11.009.
J. Rezaei, “BWM Solver Excel Sheet,” 2015. (Accessed: 23rd Oct, 2020).
J. Speer, “State of Medical Device - Product Development & Quality Management,” 2020. https://www.greenlight.guru/state-of-medical-device.
J. U. Ocampo and P. C. Kaminski, “Medical device development, from technical design to integrated product development,” J. Med. Eng. Technol., vol. 43, no. 5, pp. 287–304, 2019, doi: 10.1080/03091902.2019.1653393.
J.C. Mankins, “Technology Readiness Levels,” A White Paper. Office of Space Access and Technology, 1995.
M. Fahimian and K. Behdinan, “On characterization of technology readiness level coefficients for design,” in Proceedings of the International Conference on Engineering Design, ICED, 2017, vol. 2, no. DS87-2, pp. 309–316.
MHRA, “Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak,” Gov.Uk, 2020, [Online]. Available: https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak. (Accessed: 23rd Oct, 2020).
Mico Medicals, “Product Info: CoroVent,” 2020. https://www.micomedical.cz/product-info-corovent#detail-info. (Accessed: 23rd Oct, 2020).
MIT, “MIT Emergency Ventilator Project,” AcademiaThemes, 2020. https://emergency-vent.mit.edu/?fbclid=IwAR3JvScS-93DOpQoc827UFI2F0ygICChQA_FXwZ6THtexZM71xrtDcMFCc4. (Accessed: 23rd Oct, 2020).
R. D. (DRD) Director, Office, and D. R. and E. (DDR&E) T. Office of the Director, “Technology Readiness Assessment (TRA) Deskbook,” Technology, no. July, pp. 1-H1, 2009, [Online]. Available: http://www.dod.mil/ddre/doc/DoD_TRA_July_2009_Read_Version.pdf. (Accessed: 23rd Oct, 2020).
R. Read, “COVID-19 Ventilator Projects and Resources and FAQ,” 2020. https://github.com/PubInv/covid19-vent-list. (Accessed: 23rd Oct, 2020).
Rice University and Metric Technologies, “OEDK - Rice University - ApolloBVM,” 2020, [Online]. Available: http://oedk.rice.edu/apollobvm/. (Accessed: 23rd Oct, 2020).
S. Blanchette and S. Garcia-Miller, “Beyond Technology Readiness Levels for Software: U.S. Army Workshop Report,” 2010. Available: http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA535517&Location=U2&doc=GetTRDoc.pdf. (Accessed: 23rd Oct, 2020).
S. Revfi, J. Wilwer, K. Behdinan, and A. Albers, “Design Readiness of Multi-Material Concepts: Manufacturing and Joining Technology Integrated Evaluation of Concept Maturity Levels Using Cardinal Coefficients,” in Proceedings of the Design Society: DESIGN Conference, 2020, vol. 1, pp. 1067–1076, doi: 10.1017/dsd.2020.274.
T. L. Saaty, “How to Make a Decision: The Analytic Hierarchy Process,” Interfaces (Providence)., vol. 24, no. 6, pp. 19–43, 1994, doi: 10.1287/inte.24.6.19.
Therapeutic Goods Administration, “Ventilators and other devices intended for respiratory support for COVID-19,” TGA, 2020. https://www.tga.gov.au/behind-news/ventilators-and-other-devices-intended-respiratory-support-covid-19#alternatives. (Accessed: 23rd Oct, 2020).
Via Global Health, “Adult Life Pro – Product Specification,” 2020. https://viaglobalhealth.com/wp-content/uploads/2020/09/Neonatal-Rescue-AdultLife-Pro-Product-Guide.pdf. Accessed 23rd October 2020. (Accessed: 23rd Oct, 2020).
World Vent Foundation, “WorldVentTM Ventilator Overview,” 2020. https://www.worldvent.org/worldvent-overview. (Accessed: 23rd Oct, 2020).

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