Prognostics-Based Reliability Optimization for Consumer Healthcare Devices

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ABSTRACT This paper discusses the technical details of adopting prognostics and health management (PHM) implementation in consumer healthcare wearable devices. Consumer healthcare appliances differ from medical devices in that they do not undergo the Food and Drug Administration (FDA) approval process. The main objective of deriving a reliability assessment and optimization scheme using prognostics and health management methodology is to utilize condition-based monitoring for preventive maintenance and minimize warranty repairs. The design and implementation of reliability optimization methodologies include physics-of-failure based self-cognizant prognostics for operational reliability assessment and resource management approach that takes into consideration the usage profile of individual devices through utilizing fused data from various operational parameters such as device temperature, shock and vibration.

INDEX TERMS Condition-based monitoring, consumer healthcare, prognostics, reliability, wearable device.

I. INTRODUCTION

Numerous high-profile product recalls have been issued by manufacturers in recent years following numerous reported cases of catastrophic failures \cite{1}. The magnitude of the range of recalls by several manufacturers opens thorough discussion on the cost of failing to ensure product reliability and how consumer electronics systems degrade over time. A basic understanding of prognostics and health management (PHM) that goes beyond the practices of traditional product reliability analysis methodologies can provide important insights into optimizing the reliability of devices on an individual basis. This paper discusses a number of issues related to the design and implementation of reliability optimization strategies for low cost consumer healthcare devices; the presentation here makes use of PHM in electronics for reliability prediction under different use conditions \cite{2}.

The specific areas addressed in the implementation of reliability assessment strategies are basic reliability theory, prognostics and self-assessment of system health data manipulation, and development trends. The main objective is to provide an overview of the elementary and critical aspects of assessing and optimizing reliability for consumer healthcare devices. A case study of implementing prognostics-based reliability optimization for wearable heart monitors is also presented. Consumer electronics device manufacturers constantly have to update their products to comply with all applicable regulations. This is particularly problematic in the case of consumer healthcare wearable devices where a new model is often introduced in an annual basis to remain competitive. Any long-term reliability field tests could be completed by the time the device model becomes obsolete such that a faster method for assessing operational reliability for such consumer electronics products become vitally important for product design as well as warranty support \cite{3}.

To address this demand, the paper is organized as follows: Section II outlines the problems associated with traditional reliability assessments in many consumer electronics products along with the inherent flaws in adopting reliability handbooks that have been used for decades. Section III
describes how prognostics methodologies can provide an optimal solution for reliability assessment in consumer healthcare devices, followed by a discussion on data analytics for condition-based monitoring in Section IV. Finally, the paper concludes with a case study of a wearable heart monitored followed by a summary on future directions and standards for reliability assurance and PHM implementation in the conclusion section. The prognostics algorithm is optimized for to analyzing operational data with unknown or non-linear distributions of usage that exhibits poorly known or competing failure modes and mechanisms.

II. RELIABILITY IN CONSUMER ELECTRONICS
Reliability assessment covers a vast range of topics related to consumer electronics. Virtually all types of consumer electronics products can be affected by reliability issues. Earlier studies have been carried out on reliability issues related to consumer electronics appliances from TVs [4] to computers [5]. The concept of the reliability of any given product entails more than being powered up and running. It is also related to how well a system performs when compared to its specifications.

Rapid technological advances have significantly shortened the lifecycle of consumer electronics products. This is evident in areas such as the digital imaging and display sectors. For example, two decades ago a film single lens reflex (SLR) camera could remain in production without revision for several years, whereas models of digital cameras become obsolete after only one or two years.

A. RELIABILITY AND QUALITY ASSURANCE
The operational reliability of a given consumer electronics product is affected by many uncontrollable factors, this include operating environment like ambient temperature and humidity that can severely impact the normal operation of a device. For instance, excessive heat accumulated within the device can cause anomalies that triggers unexpected machine shutdown. While some of these operational problems can often be addressed through applying over-the-air (OTA) firmware updates, one of the important objectives for the consumer electronics industry is to minimize the cost of warranty support through getting insights into the cost of supporting a product as well as inventory planning for spare parts [6]. The remaining useful life (RUL) of a given product would have a substantial impact on issues such as warranty repair and consumption of spare parts.

B. PROBLEMS WITH TRADITIONAL ASSESSMENT METHODS
The U.S. military developed the Mil-Hdbk-217 handbook for electronics reliability prediction has been utilized as a reference across the consumer electronics industry since the beginning of the 1970s [7]. However, one of the major issues associated with this type of handbook. This concerns the inherent flaws that made field reliability prediction inaccurate since such handbook fails to take into consideration any variation in the actual use profile of each device on an individual basis [8]. Assessing the operational reliability of a given consumer electronics device entails thorough analysis of its actual usage profile given the fact that different units within the same batch from the same production line that are manufactured under identical environments will be used very differently by different consumers. For example, a product with an internal battery that is very heavily used by a user that fully charges the battery immediately after the battery is fully discharged is expected to require a battery replacement much sooner than another identical device used by another consumer that changes the battery before and after charging as well as to keep the battery changed within the 50-90% range all the time.

Each consumer electronics product sold to a different end user will be used in a different manner with very different usage profile. Within the same batch of products from the same production line that is shipped to a humid tropical country can well be expected to have a somewhat shorter life expectancy than the other one that is sold to a cool and dry region due to the very different operating environments. The assessment of system health degradation from a physics-of-failure (PoF) perspective is therefore needed to enhance the way reliability assessment is carried out that takes into consideration operating conditions such as ambient environment, usage profile, shock and vibration.

C. RELIABILITY AND QUALITY ASSURANCE
The system health of a given product can have a substantial impact on warranty support, the health of certain critical components within a consumer electronics device can often be assessed in a cloud environment with connected devices [9]. These include the state-of-charge (SoC) and state-of-health (SoH) of a battery pack found in the vast majority of portable and wearable consumer electronics devices. The needs for replacements can be estimated as the health degradation is continually assessed.

III. A PROGNOSTIC HEALTH MANAGEMENT APPROACH
Prognostics assists with the prediction of what will likely happen, estimated from certain symptoms or abnormal signs that may develop over time. Prognostics can predict how a system may behave over time to understand the behavior of system health degradation. For example, it is possible to plan a maintenance schedule for activities such as calibration or component replacement that can potentially be performed prior to an actual failure. The “health” here refers to the system’s health but not the health of a user, or the operational state of the system. PHM has been used in various industries from avionics to communications for system health management as well as risk assessment [10]. In the context of consumer healthcare devices that tend to have a very short model lifecycle of typically no more than one year, the design and implementation of a self-cognizant prognostics method for device health management is needed.
The device should incorporate a built-in prognostics mechanism for its own usage profile. Such self-monitoring can be implemented using the framework shown in Fig. 1 that commences by collecting various operational data from in-situ sensors such as accelerometers and thermistors. The device performance is assessed from a range of prognostics sensors that monitors any signs of performance degradation over time. This can be used to trigger certain protective measures such as temporarly disabling the device from overheating when the device temperature exceeds a certain predetermined threshold.

The precursors appropriate for health degradation assessment of consumer healthcare devices are shown in Table 1. Collected data is then analyzed using methods such as PoF and accelerated testing for estimating the device’s remaining useful life (RUL). These are used for prognostics analysis of fault progression and accumulated damage so that necessary actions such as preventive maintenance scheduling, advanced failure warning, and fault detection and identification can be preemptively taken [11].

Various sensors that fuse prognostics data such as temperature, pressure, accelerometers, voltage and current as well as other parameters necessary for building a usage profile are needed for the assessment of system health condition. These parameters can provide useful information about what a given device is subjected to during operation and storage [12].

The function of a device will determine what parameters to monitor. Commonly used consumer healthcare devices, for example, a non-invasive glucose meter and a wearable cardiac monitor may have very different parameters the need to be monitored. As prognostics is used in monitoring for diabetes and heart failure [13], PHM can also be applied to these consumer monitors under the same principle. These devices may have very different properties in terms of use and failure risks. We shall look at how the versatility of PHM can optimize operational reliability by addressing a number of common parameters. For example, to estimate the variation of life expectancy of components, circuits, or devices due to different usage profiles as shown in Fig. 2. This can identify any potential risks that calls for remedial actions prior to an impeding failure.

The implementation of PHM in consumer healthcare device entails both sensing and the subsequent analysis of environmental, operational as well as parameters that are relevant to system operational performance in order to estimate the system degradation over time. This is necessary to minimize the probability of a sudden system failure and to mitigate any intermittent failure through assessing and managing any sings of component degradation or change in operational environment that can have a severe impact on the RUL of certain critical components within the system.

### IV. FIELD DATA

Traditional reliability models provided by reliability handbooks are not suitable for product reliability prediction due to the fragmented characteristics of fused field data. Further, analysis of such field data usually entails either interpolation or extrapolation from the fused dataset in the design of prognostics models [14]. Extrapolation of accelerated test results from a laboratory environment can yield a computation model of a controlled usage profile under known life-cycle conditions [15]. It is then possible to derive a usage profile that is specific to an individual device such that the prognostics data can be classified logically using semantic personalization [16]. The specific usage profile can then be computed through implementing the device usage personalization scheme shown in Fig. 3.

The device health profile associated with usage profile can broadly be built from two components, the generation of device-specific usage ontology and device usage personalization profile as the device is operated. The generation of sage ontology entails operational data acquisition when the device is being used as summarized in Fig. 4. To accomplish this task requires data from appropriate built-in sensors such as temperature, pressure sensors as well as accelerometers [17]. Very often these sensors can also support various features offered by the device so that device health monitoring does not require additional hardware that would increase the cost.
of production. The actual data processing and computation is carried out externally through a cloud platform.

Device usage profile is built to serve several purposes. First and foremost, an alert message can be issued to warn of any abnormal operations such as overheating that could cause issues such as screen flickering and abrupt system shutdown. Another important purpose is to optimize operational performance through adjusting various parameters by continual self-monitoring of any changes in usage behaviour. Thirdly, the device manufacturer can gain important insights into the system health of the individual device as well as certain critical components within, this can provide important information for future device design and to detect any misuse events like excessive shock or vibration that can be used for denying warranty claims from usage anomaly [18]. Any issues related to system design such as failure related to prolonged usage and overheating due to inadequate ventilation detected using appropriate data mining from usage profile [19]. Among the dataset related to device operation, data mining is implemented in facilitating model computation of failure prognostics for extracting operation data and to identify any failure patterns that might exhibit during normal operation under different environments [20].

PHM facilitates fault avoidance and any necessary follow-up actions; it also assists with future product development for enhanced reliability. The maintenance data can be efficiently archived using the Self-Organizing Map (SOM) technique for document clustering [21]. One other important feature is computation of accumulative damage sustained under various use conditions throughout the device’s lifetime by using the data mining scheme shown in Fig. 5.

Device usage personalization profile also provides information about any sign of impeding failure, such as abnormally high rate of battery drain that can indicate either a software problem or the battery is due for replacement as indicated by the battery’s state of health (SOH). This type of advanced failure warning can be detected by searching through hypothesis spaces that match the failure data. This entails different types of field data, as illustrated in Table 2, where data mining techniques are applied for the analysis of real-time monitoring and acquisition of prognostics as well as diagnosis data for measuring operational performance linked to usage profile. Data are continuously collected for performance monitoring according to a set of precursors for an individual type of device [22].

In contrast, intermittent fault detection that addresses issues related to faults that often occur randomly is assessed with Mahalanobis distance (MD) technique for univariate data reduction [23]. MD is selected for its computational complexity over other alternative localization and mapping methodologies by measuring the distance between a given point $P$ and a distribution $D$. Thus, anomalies can be detected through the comparison of MD values that are deduced from healthy baseline as per design specifications verses the MDs collected from field faulty devices that have been operating under different usage conditions until failure [11]. Fault avoidance can then be deduced from time-series data such that historical data on device performance vary with time. Each intermittent fault can be processed as one transaction so that the historical usage data of a device can be processed such that each transaction registers the description of a fault event. As summarized in Fig. 6, realization is therefore much more straightforward for intermittent fault detection based on association rules [24].

Prognostics for advanced fault detection and subsequent avoidance requires time-series discovery and pattern-based similarity methodologies [25] such that PHM can be implemented through derivation of a Mahalanobis-Taguchi-System (MTS) [26]. This system provides insights into system fault diagnosis and forecasting from multivariate data [27].

In this multi-dimensional MTS, operational data is collected through prognostics sensors that fuse various operational parameters such as voltage, current, and temperature. The prognostics data can be correlated to a list of possible faults. Performance degradation can be assessed from certain precursors to an impending failure. These precursors, when appropriately selected, provide indications on preventive maintenance that needs to be carried out prior to an actual failure.

In the process of deriving MD values, the Mahalanobis space (MS) is computed from a set of predefined reference data from healthy baseline that in turn can be used to detect any anomaly. MS corresponds to a unit space with its mean being unity. Computations that result in values outside

| Attribute         | Prognostics for fault avoidance | Intermittent failure detection |
|-------------------|--------------------------------|--------------------------------|
| Property          | Continuous                     | Univariate                     |
| Data form         | Temporal                       | Transactional                  |
| Clustering        | K-means clustering             | Not suitable                   |
| Realization       | Difficult                      | Easy                           |

FIGURE 3. Architecture for device usage personalization.

FIGURE 4. Table of device operation database.

TABLE 2. Data type comparison for failure detection.
the MS signify an anomaly in the MTS that is verified through measurements from ambient sensors when assessing whether the device has been operating in an environment outside its design specification such as temperature and humidity. Field data analysis also provides insights into production scheduling [28] as well as warranty planning [29] with the main objective of reducing maintenance cost when optimizing device reliability through predicting the remaining useful life (RUL) of various critical components based on actual usage condition.

V. PROGNOSTICS FOR WEARABLE HEART MONITOR

We demonstrate the application of PHM through investigating the reliability tracking of a wearable Bluetooth monitor that regularly tracks a user’s electrocardiogram (ECG) and sends the reading to the user’s smartphone for storage, analysis, and subsequent forwarding to a service center if an impending cardiac failure is detected.

Each device is subjected to varying operating environments within design specifications, profiling device health degradation entails recognition of any anomalies such as performance degradation. From different precursors that may indicate a degradation in system health, that can either vary for different devices operating in an identical environment as well as the same device operating in a different environment. When the device is worn by a user, the system analysis results can refer to different people in the same area of operation under the same environment, or as the same user in different areas subject to variation in usage environment. This in turn entail the derivation of training set and testing set that are mutually exclusive at both the source that corresponds to any given degradation factor, and also the sample level that corresponds to the environment that causes degradation. Analysis of system performance on unknown or uncontrollable sources should correlate to the actual usage profile. To address the performance degradation issue, we commence by analyzing the set of operation experimental data under normal usage within a controlled environment, i.e., operation as per design specification, as shown in Fig. 7 with a comparison of feature distributions in two sets of experiments.

The classifier exhibits adequate feature representation in feature recognition such that the cross-person recognition utilizes a testing set that is similar to the training set distribution so long as the classifier is unaffected by any unknown sources. The experimental results shown for cross-person refers to different devices used by different test users, whereas cross-area measurement refers to data acquired from two different areas where one is close to the low end of the designed operating temperature of 10°C and the other set refers to the area close to the high end of 35°C.

Any anomaly detected such as operating outside the designed range can trigger an alarm either for user intervention or to initiate an automatic temporary device shutdown to avoid physical damaged to any internal component. It is also possible to program a device to perform self-protection actions before failure. The consumer healthcare device can be made self-cognizant in that it can implement necessary protection or remedial strategies according to actual operating environment.

When the classifier learns the source characteristics such that the features extracted from the samples converge, which indicates that the classifier does have the capability of learning the user device’s performance characteristics during the process.

Fig. 8 shows that the features extracted from the samples tend towards convergence, which indicates that the classifier does have the capability of learning the user device’s performance characteristics during the process. To best represent data after dimension reduction, Principal Component Analysis (PCA) has been used [30], it is linear and loses certain useful information dealing with highly nonlinear data. Other techniques include nonlinear techniques such as the mutual information (MI) based feature selection method and self-organizing map (SOM) [31]. In classifying system faults, the support vector machines (SVM) is well-known for its classification ability that relies on preprocessing the data in
a high dimension. As a result, SVM tends to be less prone to problems of overfitting than some other classifiers. The results show that SVMs are especially suited to analyze data with unknown or non-linear distributions in systems with poorly known or competing failure modes and mechanisms.

VI. CONCLUSION

In response to the known deficiencies of traditional reliability assessment methods, it is vital to establish a mechanism for assessing quantitative system health data based on actual field usage. It is intended to address the shortfall associated the widely used Mil-Hdbk-217 that does not take into consideration actual usage for assessing field reliability due to the fact that the use condition of an individual device can vary substantially. It is therefore necessary to implement system health management for individual devices that operate under different environments. Prognostics and Health Management (PHM) assesses device health and operational reliability through fusing data from its actual use condition and thereby minimizing the risk of system failure as well as to mitigate health and safety risk exposed to a user. Also, given the ability to represent graded health information, PHM methodology quantifies the expected cost related to providing warranty support of a product through utilization of failure progression information. Any new standard for mass-produced consumer healthcare devices for reliability...
assurance should have the capability of carrying out periodic measurements and self-calibration and collect information about the device such as usage profile and operating environment to analyze system health assessment. In addition, it is also necessary to establish a model to provide insight into failure progression as well as deducing a system health degradation model for a specific device. Low-cost consumer healthcare devices can thus be offered with better reliability throughout their useful live s by using the prognostics and data mining methodologies described.

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