- Regression analysis is a documented evaluation of the impact of a software change based on review of the relevant documentation (e.g., software requirements specification, software design specification, source code, test plans, test cases, test scripts, etc.) to determine whether regression testing is needed. If regression testing is needed as determined by the regression analysis, the sponsor should identify the necessary regression tests to be run. Regression testing is the rerunning of test cases that a program has previously executed correctly and comparing the current result to the previous result in order to detect unintended effects of a software change.

- System level test protocol including expected results derived from software requirements, actual results that are observed and recorded, objective pass/fail determination (i.e., actual results are acceptably equivalent to expected results) and a system level test report. The system level test report should demonstrate that the protocol has been acceptably executed with passing test results and any unresolved anomalies have been acceptably deferred based on a risk assessment for the candidate release version.

### (2) Enhanced Documentation Level

In addition to the documentation requested for the Basic Documentation Level, all unit and integration level test protocols and reports should be provided, including expected results derived from software requirements and design, actual results that are observed and recorded, and objective pass/fail determination (i.e., actual results are acceptably equivalent to expected results). The unit and integration level test reports should demonstrate that the protocols have been acceptably executed with passing testing results and any unresolved anomalies have been acceptably deferred based on a risk assessment for the candidate release version.

## I. Software Version History

The documentation should include the history of software versions that were tested and documented at the unit, integration, and system levels as part of verification and validation activities, beginning with the version that became subject to the design controls, as described in 21 CFR 820.30. This typically takes the form of a line-item tabulation including the date, version number that was tested (including, if applicable, bench, animal, and clinical testing) and a brief description of all changes in the version relative to the previously tested version.

The last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

If the software version history includes a version(s) that corresponds to a previously released cleared or approved version of the software, the sponsor should highlight in the version history document each prior released cleared or approved version and the premarket submission number(s) associated with that release.

If the device is a multiple function device product and includes software function(s) that are considered "other functions," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations," the recommendations described in the aforementioned guidance should be considered when preparing the software version history.

## J. Unresolved Software Anomalies

An anomaly is any condition that deviates from the expected behavior based on user needs, requirements, specifications, design documents, or standards. Anomalies may be found during the review, test, analysis, compilation, or use of the software (whether before or after release, or whether inside a sponsor's organization or outside it) or at other times. An unresolved software anomaly is a defect that still resides in the software because a sponsor deemed it appropriate not to correct or fix the anomaly, according to a risk-based rationale about its impact to the device's safety and effectiveness.

A list of unresolved anomalies should document the following items (e.g., in tabular format) for each unresolved anomaly present in the software:

- A description of the anomaly;
- Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly;
- Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations;
- Outcome of the evaluation; and
- Risk-based rationale for not correcting or fixing the anomaly in alignment with the sponsor's risk management plan or procedure(s).

Additionally, the Agency recommends considering the utilization of a defect classification system, or taxonomy, for each anomaly, such as ANSI/AAMI SW91's *Classification of defects in health software*.[58] Regardless of the defect classification system used, the sponsor should evaluate the impact of an unresolved anomaly on the device's safety and effectiveness based on the software's intended use.

Where appropriate, a sponsor should communicate to end users any mitigations or possible work-arounds for unresolved anomalies to assist in the proper operation of the device to fulfill its intended use. FDA recommends that any planned or already distributed communication

[58] As stated in ANSI/AAMI SW91, a defect classification system, or taxonomy, is used to classify or categorize the types of defects that might exist in software. A defect classification system is neutral with respect to programming language, methodology, product, intended use, risk (severity of anomalies), and regulatory status.

(customer notification, labeling, etc.) to end users regarding unresolved anomalies is referenced in the premarket submission.

# VII. Additional Information - Regulatory Considerations for Software Functions

Section 3060(a) of the Cures Act amended section 520 of the FD&C Act on December 13, 2016, removing certain software functions from the definition of device in section 201(h) of the FD&C Act. Sponsors should consider the following reference materials to learn more about FDA's regulatory considerations for software functions:

- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act[59]
- General Wellness: Policy for Low Risk Devices[60]
- Policy for Device Software Functions and Mobile Medical Applications[61]
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices[62]
- How to Determine if Your Product is a Medical Device[63]
- Clinical Decision Support Software[64]

# Appendix A: Documentation Level Examples

The following list of example devices is intended to demonstrate the implementation of the Documentation Level risk-based approach. Please note that these generalized examples do not necessarily account for every possible detail, risk, or consideration a sponsor should evaluate, and should not be taken to mean that the devices described do or do not require a certain Documentation Level. These examples do not define the appropriate Documentation Level for a particular device type. As such, the Documentation Level should be uniquely considered for each particular device or device modification and in consideration of the device's intended use. The rationales in the examples below are abbreviated and FDA encourages sponsors to provide a detailed assessment that accounts for the specifics of their device (such as the device's risk assessment,[65] software description, etc.) when addressing the recommendations in Sections V and VI.A of this guidance.

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[59] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act.
[60] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.
[61] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.
[62] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.
[63] Available at https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device.
[64] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software.
[65] For more information on risk assessment refer to Section VI.C of this guidance.

1. A hardware-only non-patient-matched hip prosthesis.

   **Description:** The device is a non-patient-matched hip prosthesis that contains no firmware or other means for software-based control.

   **Rationale:** The device does not contain software.

   **Outcome:** No Documentation Level

2. A non-contact infrared thermometer intended for intermittent measurement of body temperature from the forehead.

   **Description:** The device is intended to measure body temperature from the forehead using an infrared sensor. The device is a hand-held, battery powered, reusable device for home and professional healthcare facility use.

   **Rationale:** In general, a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

   **Outcome:** Basic Documentation Level

3. A non-invasive blood pressure monitor with inflatable cuff.

   **Description:** The device is intended to measure a person's systolic and diastolic blood pressure in units of mmHg through software-controlled inflation and deflation of the cuff. The device is a battery powered, reusable device for home and professional healthcare facility use.

   **Rationale:** In general, a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

   **Outcome**: Basic Documentation Level

4. A device software function for optical camera-based measurement of pulse rate and breathing rate.

   **Description:** The device is intended for non-contact, periodic, spot measurement of pulse rate and breathing rate when the subject is at rest. The software analyzes compatible video signals of subjects in single occupancy rooms of subjects that do not require continuous vital signs monitoring or critical care. The device is

intended for use by trained staff and is not intended to be the sole method of checking the physical health of a subject.

**Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

**Outcome:** Basic Documentation Level

5. A computerized behavioral therapy device to treat psychiatric disorders.

   **Description:** The device is a prescription software device intended to provide a computerized version of condition-specific cognitive behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients who have been previously diagnosed with a psychiatric condition. It is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes. It is not intended to substitute for routine in-person therapy sessions.

   **Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

   **Outcome:** Basic Documentation Level

6. A traumatic brain injury (TBI) eye movement assessment aid.

   **Description:** The device is a prescription device that is intended to track a patient's eye movements using a commercial OTS mobile phone and camera and analyze the tracked eye movements to aid in the assessment of mild TBI, commonly known as "concussion." The device provides a positive or negative indicator about the presence of eye movements that are consistent with mild TBI.

   **Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures. The device is intended for use as an aid in the assessment of mild (non-severe) injury and is not intended as a standalone diagnostic.

   **Outcome:** Basic Documentation Level

7. An implantable sensor for measuring pulmonary artery (PA) pressure.

**Description:** The device is a system comprising a permanent implant that is placed in the PA and an external software-controlled reader that retrieves and transmits PA pressure measurements. The PA hemodynamic data are used by the physician for heart failure management and with the goal of reducing heart failure hospitalizations. There are no device software functions located on the implant.

**Rationale:** While the device is a class III device, a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures. Risks of death or serious injury to the patient in this scenario are due to the implantable nature of the device and failure of the hardware or implant procedure itself, not the device software function(s).

**Outcome:** Basic Documentation Level

8. Over-the-counter (OTC) application for identification of irregular heart rhythms.

   **Description:** The software application is intended for analysis of photoplethysmograh data, identification of episodes of irregular heart rhythms suggestive of Atrial Fibrillation (AF), and providing notification to the user of the irregular rhythm episodes. It is intended to opportunistically provide a notification of possible AF and the absence of a notification is not intended to indicate that no disease is present. It is intended for OTC use and it is not intended to replace traditional methods of diagnosis or treatment.

   **Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

   **Outcome:** Basic Documentation Level

9. An *in vitro* nucleic acid test for the qualitative detection of Human Papillomavirus (HPV) DNA in human cervical specimens.

   **Description:** The test is intended for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US (atypical squamous cells of undetermined significance) cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors.

**Rationale:** While the test is classified as a class III device, a failure or latent flaw of the device software function(s) would not present a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures. There are several alternatives for the detection of cervical cancer precursors including testing by cytology alone, co-testing with HPV alongside or as a follow-up to cytology or HPV testing as a first line screening test for cervical cancer. The patient's age, medical history, and thorough physical examination will provide further information on the risk of cervical disease, as well as the need for referral to colposcopy. The test should only be used in conjunction with this clinical information in accordance with professional clinical patient management guidelines.

**Outcome:** Basic Documentation Level

10. An *in vitro* nucleic acid test for the qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors.

    **Description:** The test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.

    **Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures.

    **Outcome:** Basic Documentation Level

11. A device software function on a commercial OTS head-mounted display (e.g., augmented reality/virtual reality/mixed reality (AR/VR/MR)) that superimposes pre-surgical images on a patient's body.

    **Description:** The device is intended to provide real-time superimposition of medical images on the patient during a surgical procedure, but is neither intended to directly guide surgical planning or procedures nor be worn by the lead surgeon.

    **Rationale:** A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures, since the device is neither intended to directly guide surgical planning or procedures nor be worn by the lead surgeon.

**Outcome:** Basic Documentation Level

12. A laser system for the treatment of acne vulgaris.

    **Description:** The device is a laser system used in dermatology offices used to treat acne vulgaris through heating of dermal tissue. The device software only operates the laser engine. Delivery of therapy requires the operator to depress a physical switch on the handpiece.

    **Rationale:** A failure or latent flaw of the device software functions(s), such as not delivering the laser energy when directed, would not present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    **Outcome:** Basic Documentation Level

13. A radiological display device.

    **Description:** The device is intended for displaying clinical radiology images for review, analysis, and diagnosis by trained medical practitioners. The software contained in the device is limited to the following functionalities: display controls, ambient light sensing, luminance calibration tools, and quality-control software.

    **Rationale:** A failure or latent flaw of the device software function(s), such as inadequate quality of displayed images, would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

    **Outcome:** Basic Documentation Level

14. An electric breast pump.

    **Description:** The device is intended to be used by lactating women to express and collect milk from their breasts. The device uses a DC-powered motor driving the vacuum pump which is controlled electronically to provide a range of user-selected suction levels at specified cycle frequencies. The device display provides the user with information on the pumping mode, timer, battery level, and suction.

    **Rationale:** A failure or latent flaw of the device software function(s) (e.g., software fails to properly control the suction level) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures.

    **Outcome:** Basic Documentation Level

15. An implantable cardiac pacemaker used to treat bradycardia.

    **Description:** The device is an implanted, programmable dual-chamber pulse generator intended to provide rate-adaptive bradycardia therapy as well as other therapeutic and diagnostic functionality. It senses the heart's electrical activity and generates electrical impulses to cause the heart to contract or beat according to the programmed patient's needs. It communicates with a programmer and the patient's home monitoring device.

    **Rationale:** A failure or latent flaw of the device software function(s), such as failure to pace or a latent flaw leading to incorrect sensing of an ectopic beat, would lead to a hazardous situation that would present a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

16. A facility use continuous ventilator.

    **Description:** The device is intended to provide continuous ventilation for adult, pediatric, and neonatal patients who require invasive or noninvasive respiratory support. It allows clinicians to set ventilator control parameters, set alarm limits, and view monitored values and waveforms for patient management. It includes respiratory monitoring as well as both mandatory and spontaneous ventilation modes. It is intended for use in professional healthcare facilities.

    **Rationale:** A failure or latent flaw of the device software function(s), such as failure to provide appropriately timed ventilation, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

17. A multi-parameter patient monitor for use in a professional healthcare facility.

    **Description:** The device is a multi-parameter monitor intended for use on adult, pediatric, and neonatal patients in a professional healthcare facility. It is used for monitoring of various hemodynamic and respiratory vital signs and parameters, including central venous oxygen saturation, electrocardiogram (ECG), arrhythmia detection, invasive and non-invasive blood pressure, temperature, cardiac output, hemoglobin concentration, pulse oximetry, spirometry, airway gases, and gas exchange. It is designed to detect alarm conditions and generate alarm signals. It can be connected to the hospital network and other monitors to allow for remote viewing and management of patients.

**Rationale:** A failure or latent flaw of the device software function(s), such as incorrect calculation of parameters or an exploited cybersecurity vulnerability that compromises its ability to provide life-threatening arrhythmia detection and alarms, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

**Outcome:** Enhanced Documentation Level

18. A Blood Establishment Computer Software (BECS) or BECS accessory.

    **Description:** The device is used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. A BECS accessory is a device intended for use with BECS to augment the performance of the BECS or to expand or modify its indications for use.

    **Rationale:** A failure or latent flaw of the device software function(s), such as a failure to prevent the release of unsuitable blood and blood components, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

19. A qualitative *in vitro* nucleic acid screening test for the direct detection of Babesia DNA and RNA in whole blood samples from individual human donors.

    **Description:** The device is a screening test that includes device software for detection of Babesia DNA and RNA in whole blood samples to prevent the release of unsuitable blood and blood components.

    **Rationale:** A failure or latent flaw of the device software function(s), such as an inaccurate result in the identification of a transfusion-transmitted infection, would present a hazardous situation with a probable risk of death or serious injury to a patient, or serious injury, prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

20. An infusion pump intended for use in a health care facility to pump fluids and medications into a patient.

    **Description:** The device is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of fluids, medications, blood, and blood

products through clinically accepted routes of administration (intravenous, intra-arterial, subcutaneous, epidural, and enteral). It is intended for use by trained health care professionals in healthcare facilities.

**Rationale:** A failure or latent flaw of the device software function(s), such as providing the incorrect flow rate or failing to deliver fluids/medications, would present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

**Outcome:** Enhanced Documentation Level

21. An *in vitro* nucleic acid test for the quantitative measurement of Cytomegalovirus (CMV) DNA in human plasma or whole blood.

    **Description:** The test is intended for use as an aid in the management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, DNA measurements can be used to assess viral response to treatment. The results from the test must be interpreted within the context of all relevant clinical and laboratory findings and is not intended for use as a screening test for blood or blood products

    **Rationale:** The test is classified as a class III device. Furthermore, a failure or latent flaw of the device software function(s), such as failure to provide correct test results, would present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

22. A device software function that provides a sepsis alarm to a healthcare provider in a critical care environment.

    **Description:** Software intended to analyze patient demographics, vital signs, and lab results from an electronic medical record to provide asepsis alarm identifying patients with sepsis or at risk of developing sepsis earlier than a healthcare provider would otherwise. The patient clinical data used as an input for the software is part of ongoing or active monitoring of the patient's current health state in a critical care environment.

    **Rationale:** A failure or latent flaw of the device software function(s), such as failure to provide a sepsis alarm) would present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

23. A continuous glucose monitoring system.

    **Description:** The device is intended to provide real time, continuous glucose monitoring for the management of diabetes in persons 2 years of age and older. It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. It aids in the detection of episodes of hyperglycemia and hypoglycemia and facilitates both acute and chronic therapy adjustments.

    **Rationale:** A failure or latent flaw of the device software function(s), such as failure to provide correct blood glucose measurement or detection of hypoglycemia, would present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

24. Powered Lower Extremity Exoskeleton.

    **Description:** A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.

    **Rationale:** A failure or latent flaw of the device software function(s), such as loss of remote control or movement signal processing, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

25. A retinal diagnostic software device.

    **Description:** The device is limited to prescription use and incorporates an AI/ML-enabled algorithm that is intended to evaluate images for diagnostic screening to identify retinal diseases or conditions.

    **Rationale:** A failure or latent flaw of the device software function(s), such as a diagnostic algorithm failure that provides a false result, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

26. A radiation therapy treatment system (e.g., Linear accelerator).

**Description:** The device is intended to noninvasively deliver a focal dose of radiation to a specified volume of a patient's anatomy while sparing the surrounding normal tissues and structures.

**Rationale:** A failure or latent flaw of the device software function(s), such as under- or overdose to a target volume or delivery to the wrong volume, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

**Outcome:** Enhanced Documentation Level

27. A drug-device combination, with the device constituent part detecting ingestion of the drug component to prevent treatment failure.

    **Description:** The product is a combination product comprised of two regulated components (drug and device). The "primary mode of action"[66] is the drug component, provided as a tablet. The device constituent part detects ingestion of the tablet component to monitor adherence to the drug regimen. A missed dose greatly increases the likelihood of treatment failure for a life-threatening condition. The device constituent part includes hardware (sensors) and software (signal processing).

    **Rationale:** A failure or latent flaw of the device software function(s), such as a false detection of tablet ingestion, would present a hazardous situation with a probable risk of death or serious injury to either a patient (through worsening of the life-threatening disease), user of the device, or others in the environment of use, prior to the implementation of risk control measures.

    **Outcome:** Enhanced Documentation Level

[66] Section 503(g)(1)(C) of the FD&C Act states that the term "primary mode of action" means "the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product."

# Appendix B: System and Software Architecture Diagram Examples

The three example diagrams below are simplified for the purpose of demonstrating how the considerations described in Section VI.E (System and Software Architecture Diagram) could be implemented into diagrams that facilitate a clear understanding of the system and software. Each diagram is supported by descriptive text and a brief discussion on notable features. The examples are intended for illustration purposes only and do not describe a complete and comprehensive system and software architecture diagram.

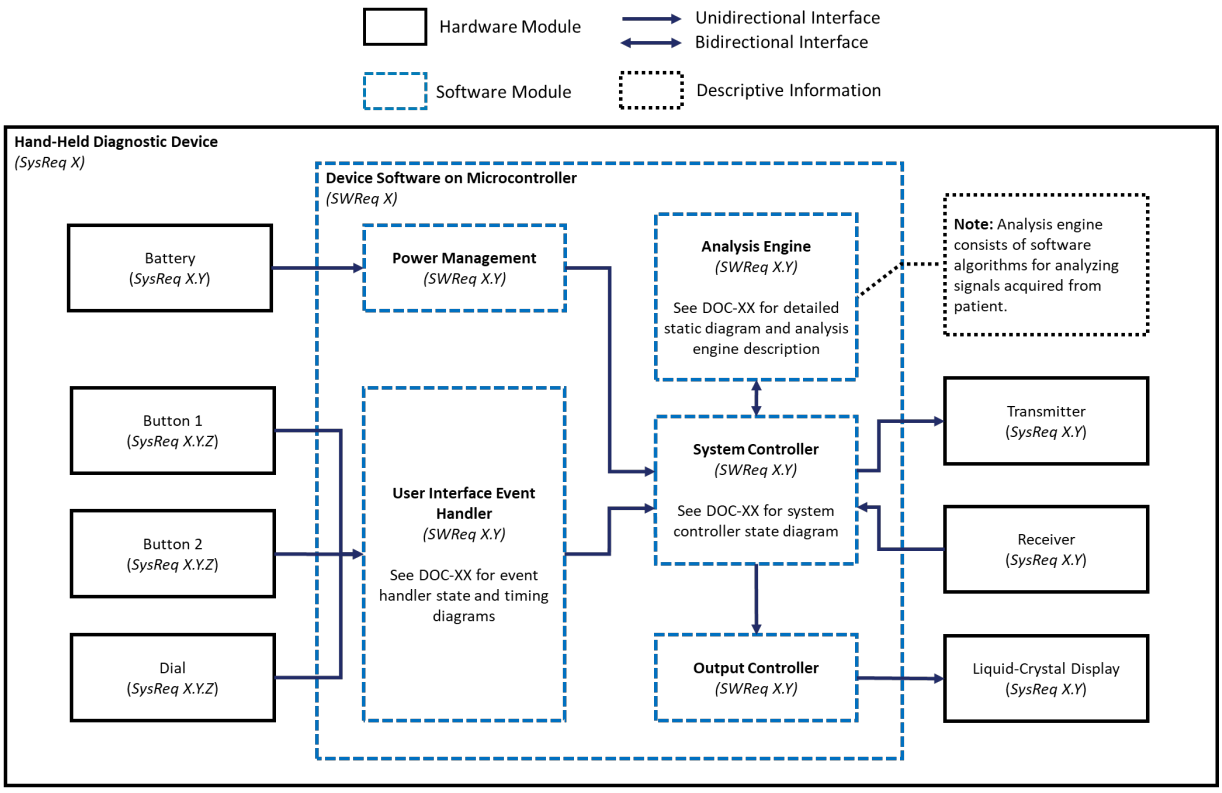
The illustrative diagrams are based on the following distinct example devices:

1. A hand-held diagnostic device

2. An implantable therapeutic device with patient- and provider-facing applications

3. A cloud-based device algorithm for analyzing previously captured medical images

The diagrams are largely static diagrams with high-level identification of interfaces between system and software components. The use of any specific design or formatting features is only provided as a suggestion and does not preclude the use of alternative approaches and/or OTS modeling languages or platforms.




***SysReq*** refers to the system requirement(s). Refer to the *System Requirements Document* (SysRS-XX Rev. X) for detailed information.
***SWReq*** refers to the software requirement(s). Refer to the *Software Requirements Document* (SRS-XX Rev. X) for detailed information.

**Figure 1: Example System and Software Architecture Diagram – Hand-Held Diagnostic Device**

Figure 1 depicts a static, high-level system and software architecture diagram of the modules in a fictional hand-held diagnostic device. A legend is provided to describe visual features used to identify different components. References are provided to documents containing more information, including other static diagrams, dynamic diagrams, and detailed descriptions. An annotation is provided to improve clarity on the purpose of one module. Text is provided with adequate clarity and font size for readability.