FAA Requirements Engineering Management Handbook

1. System Overview
Comments on Student Homework Solutions

SAnToS Laboratory
Kansas State University
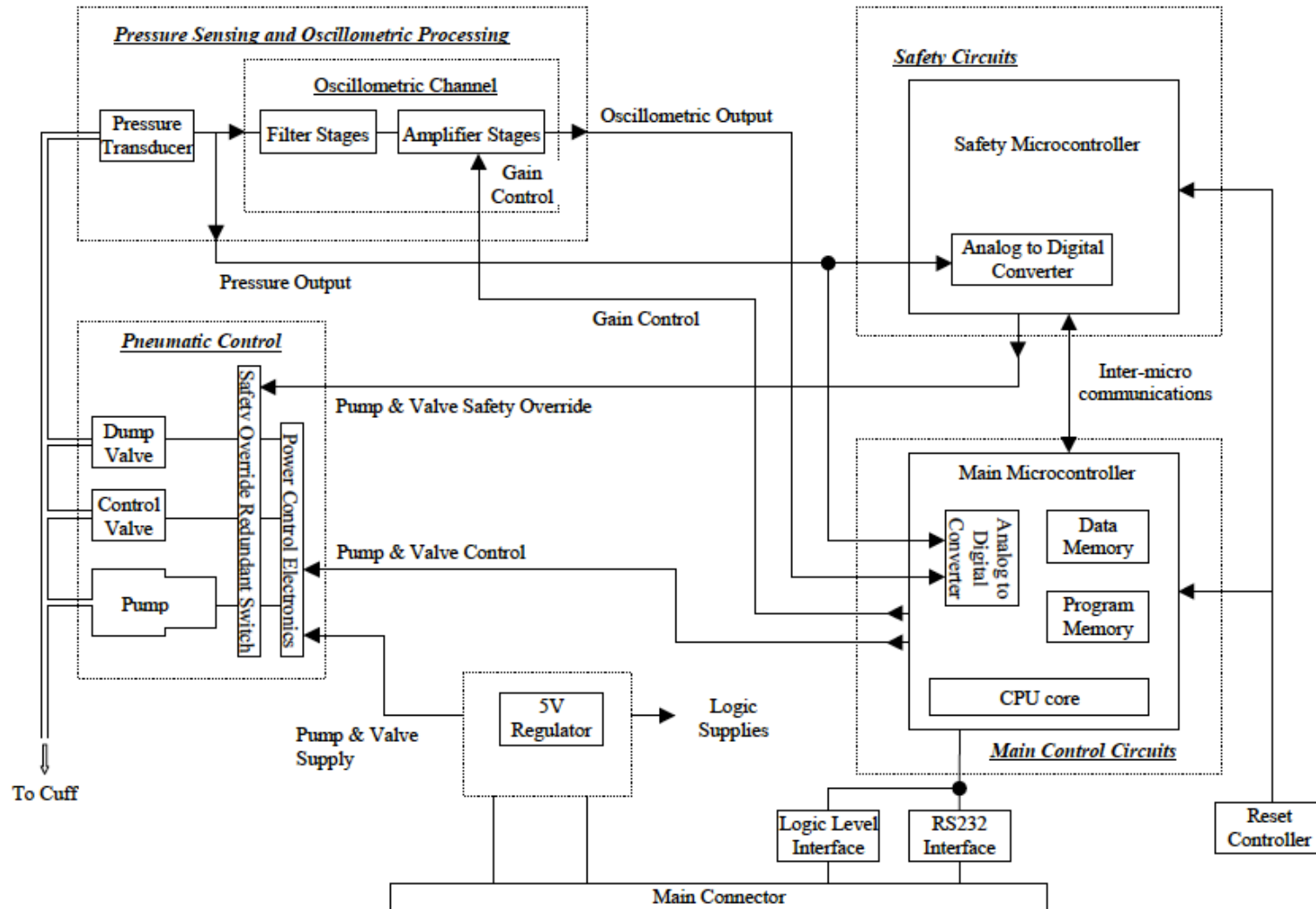
Purpose

- These slides provide advice on proper construction of the System Overview as described in the FAA REMH.

- The advice is phrased in terms of comments on student solutions to a project in a previous semester involving an Non-invasive Blood Pressure device.

Device Schematic
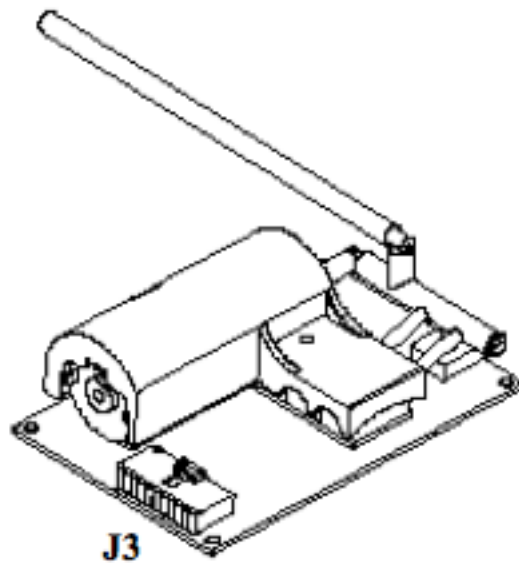
Device Schematic

Figure 5-1: Advantage Model 2 OEM NIBP Module

1.2 Provide System Synopsis

The system synopsis should…

- Give a brief narrative to start overview
  - Short, clear, avoids implying a specific design
- Name the system
- Describe its purpose
- Summarize the system's capabilities

Example System Synopsis

"The system being specified is the Thermostat of an Isolette. An Isolette is an incubator for an Infant that provides controlled temperature, humidity, and oxygen (if necessary). Isolettes are used extensively in Neonatal Intensive Care Units for the care of premature infants."

"The purpose of the Isolette Thermostat is to maintain the air temperature of an Isolette within a desired range. It senses the Current Temperature of the Isolette and turns the Heat Source on and off to warm the air as needed. If the temperature falls too far below or rises too far above the Desired Temperature Range, it activates an alarm to alert the Nurse. The system allows the Nurse to set the Desired Temperature Range and to set the Alarm Temperature Range outside the Desired Temperature Range of which the alarm should be activated."

Student Solutions -- Analysis

- The system being specified is the Wildcat OEM NIBP Module. The OEM blood pressure system is an oscillometric method of non-invasive blood pressure measurement that can be used to obtain systolic, MAP and diastolic blood pressures accurately by monitoring the cuff pressure fluctuations while controlling the cuff deflation rate.

- The purpose of the Wildcat OEM NIBP Module is to take the blood pressure measurements on demand. The system is intended to work in three modes - adult mode, pediatric mode and the neonate mode. The system receives the blood pressure measurement command from the Host system and responds to it with the blood pressure values (Systolic, MAP and Diastolic). The system ignores all other commands from the Host system while a blood pressure measurement is in progress. The system will discard all the previous blood pressure results after each blood pressure measurement.

Pretty good except need to define all acronyms, and it would be good to acknowledge specific safety goals...

Student Solutions -- Analysis

Purpose:

To take blood pressure on demand basis.

It is intended for three patient groups, that is, neonate, pediatric and adult.

Blood pressure range in cuff is maintained automatically based on the type of patient. OEM system is the guts of the system and it can have different housing.

It is not just focused on the blood pressure reading but the environment in which the blood pressure measurement is taken. This attention to detail sets it apart from all other conventional BP devices.

Please use complete sentences.

Avoid colloquialisms.

Avoid unsubstantiated padding and "filler" text.

Student Solutions -- Analysis

After the module goes through the power on, it will initialize the operating parameters for the module as needed, based on the group to which the patient belongs. Typical operation of the module consists of four commands, that is,

START_BP, GET_BP_DATA and the GET_CUFF_PRESSURE command. Once the required command is issued to the module by the host, the module will acknowledge command and responds with BP data values (systolic, diastolic, etc.)

It is made convenient to be used on group of people for multiple measurements. It maintains blood pressure range automatically. The systolic, mean arterial pressure (MAP) and diastolic blood pressures can be accurately calculated while controlling the cuff deflation rate. It can be used in many other applications through out the world like general multi parameter patient monitors, cardiac output monitors, dialysis machines etc. Acceptable units of measurement to display include mmHg and kPa.

Too low-level. Avoid overly-specific characterizations and non-essential distinctions.

Somewhat inaccurate. Be precise in descriptions.

Avoid using abbreviations with defining full term.

Student Solutions -- Analysis

The system being specified is "Wildcat OEM NIBP Module". This module is controlled via system commands issued from a host system through an asynchronous serial data port. The purpose of the system is to take blood pressure measurements on demand. It monitors the amplitude of cuff pressure changes during cuff deflation to determine arterial blood pressure. It determines the systolic, mean arterial pressure (MAP) and diastolic blood pressures accurately. It is capable of determining blood pressure for three groups of patient's neonate, pediatric, adult. After each blood pressure measurement, the module will discard the previous results. The module always defaults to Adult mode monitoring with initial inflation pressure 160mmHg. Module will acknowledge the command, take blood pressure measurement, and return data packet indicating that command has been executed. It has the capability to ignore the commands other than 'ABORT', request cuff pressure values when module is taking BP measurement and module respond with 'Busy' data packet. It has the capability to operate automatically and manually.

Student Solutions -- Analysis

...This device is intended for three types of users neonate, pediatric and adults. ...

Don't confuse roles ("user" vs "patient")

1.6 Capture Preliminary System Goals

Preliminary System Goals…

- Give informal statements of system stakeholders' needs
  - Not verifiable
  - Not detailed enough to guide system development
- Provide guidance on what is being built and why it is important
- May conflict with one another
- Should be presented early
  - Small projects can use the system overview, but
  - Large projects may need a separate section or document

Student Solutions -- Analysis

List the safety goals…

S.1) Durable enough for multiple measurements on multiple people.

S.2) Design with patient safety and comfort in mind.

S.3) Should ensure to check the limb for proper circulation when cuff is positioned on patient for a long period of time.

S.4) Maximum cuff inflation time and duration of blood press based on the mode it is used on, is monitored and should m specification.

S.5) To obtain accurate blood pressure reading the cuff must be of correct size and also must be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings.

S.6) Fabric material should be taken care of to avoid adverse reactions in the area of the cuff.

S.7) Standard Accessories like hose and cuff should meet specifications listed to ensure performance.

Not a safety goal…

Vacuous…

Imprecise… who/what "checks"?

Not a safety issue…

Student Solutions -- Analysis

List the safety goals…

SG1 – Patient should be safe from adverse reactions

SG2 – Power supply should be in regulated voltages

SG3 – The module should invoke a timer which aborts any measurement in progress after 150 sec and deflate the cuff until the pressure falls below 10mmHg.

On the right track in the sense that an important safety property is specified, but we don't not want to set specific requirements on time/pressure limits at this point. Instead, speak in terms of the accidents/harm that might result.

Student Solutions -- Analysis

List the functional goals…

F.1) Ease of use and patient comfort, paired with accurate reliable reading should mark the focal point of the pressure cuff design.

F.2) Ensure consistent and accurate measurements of blood pressure in wide varieties of environment.

F.3) The cuff design should be a complete design to meet clinical needs.

Vague…

F.4) Performance should be met, that is, blood pressure measurements made by OEM BP module should be equivalent to those obta... trained observers using the cuff/stethoscope auscultation method and intra-arterial blood pressure devices for pediatric/adult patient and neonatal patient population respectively, within the limits prescribed by ANSI/AAMI SP10:1992&2002.

F.5) Methods of measurement, Blood pressure range, Pulse rate range, Cuff deflection, Initial inflation pressure, Pressure transducer accuracy, Operating and Storage condition specifications should be meet to ensure performance.

Student Solutions -- Analysis

List the functional goals…

The High-Level Goals (F) of the system are:

F1- The default mode of operation is Adult

F2- To calculate the systolic and diastolic pressure accurately

F3- The values are reset to default once the BP is measured

F8 – The data packet returned by the module should consist of a Start byte, followed by number of bytes in the packet, the parameter data, and a checksum byte.

Too low level…

Student Solutions -- Analysis

List the functional goals...

1) To obtain accurate blood pressure readings of the patient.

2) The cost of manufacturing the module should be as low as possible.

3) To measure systolic and diastolic pressures accurately.

3) To improve reliability of the system

4) To provide integrity to the calibrated data.

5) To reduce the size and weight of the system in order to make it portable.

6) To provide an ease to the users to operate the system.

(1) and (3) are redundant.