

1. Introduction

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3.3 System Features

Functional Requirements

Functional requirements are essential to your product because, as the name implies, they provide some sort of functionality.

Asking yourself questions such as “does this add to my tool’s functionality?” or “what function does this provide?” can help with this process. Within medical devices especially, these functional requirements may have a subset of domain-specific requirements.

You may also have requirements that outline how your software will interact with other tools, which brings us to external interface requirements.

External Interface Requirements

External interface requirements are specific types of functional requirements. These are especially important when working with embedded systems. They outline how your product will interface with other components.

There are several types of interfaces you may have requirements for, including:

- User
 - Hardware
 - Software
 - Communications
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