



# Your Medical Device SOW — A Simple Guide

*Correctly define what your device must do, so we can help you build it right.*

---

## Why it matters

A clear Statement of Work (SOW) helps you:



**Align with your  
development team**



**Avoid delays and  
unnecessary costs**



**Meet regulatory  
requirements**



# How to build your SOW

## 👉 Step 1: List what the device must do — and why

Focus on the outcome. What should your device achieve? Why is it important?

Example:

- Instead of: “The device must have a 5-inch touchscreen.”
- Say: “The device must display vital signs clearly from 1 meter in hospital lighting.”

## 👉 Step 2: Prioritize your requirements

Score each one:

! Use our separate SOW template (provided file) to enter your requirements and scores.

Requirement Description (What & Why)	Importance (1-5)
<i>The device must display vital signs clearly from 1 meter in hospital lighting right.</i>	<i>5 (Critical)</i>
<i>The device should provide results within 10 seconds</i>	<i>4 (High)</i>
<i>The device should have Bluetooth connectivity to transfer data to an external device</i>	<i>1 (Low)</i>
<i>The device casing should be easily disinfectable</i>	<i>5 (Critical)</i>
...	...
...	...



### 👉 What happens next?

You send us the filled table (link) to [info@kii.am](mailto:info@kii.am) (include company name, phone, etc.) and We'll review your SOW and help plan the next steps. We will add and fill two more columns:

Requirement Description (What & Why)	Importance (1-5)	Effect on Development Costs <small>(To be filled by Kii.am)</small>	Effect on Mass Production Product Price <small>(To be filled by Kii.am)</small>
		...	...

### Column Explanations

- **Requirement Description (What & Why):**  
What the device must do and why it matters.
  - **Importance (1-5):**  
Priority level (5 = critical, 1 = nice to have).
  - **Effect on Development Costs (To be filled by Kii.am):**  
We'll estimate how this impacts development cost.
  - **Effect on Mass Production Product Price (To be filled by Kii.am):**  
We'll estimate how this affects unit price in production.
- ! **You don't need to fill these — our team will analyze them to help you understand trade-offs.**

*We will review your list, assess the cost implications, and schedule a consultation meeting to discuss your project in more detail.*

**Disclaimer:** This guide provides general information and a template for creating a requirements list. Specific medical device projects may have additional or unique requirements based on their classification, intended use, and applicable regulatory standards. We recommend consulting with experienced medical device development professionals.