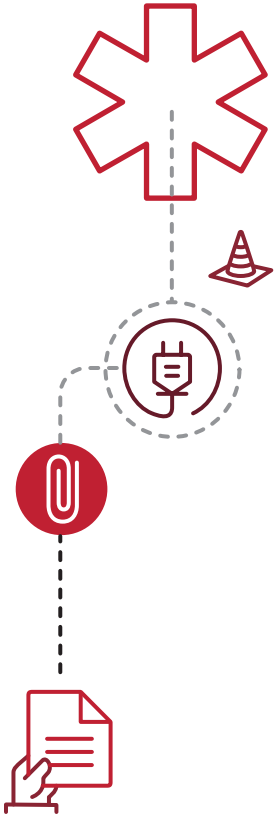
Understanding the Critical Component List



What is the Critical Component List?

Also known as the List of Critical Components (**LoCC**), it details the **safety-critical components used in the construction** of a medical device, such as:

- Constituent parts
- Sub-assemblies
- Third-party components
- Accessories

It is a **key UL deliverable** and forms an important part of the **test report** we create for your device.

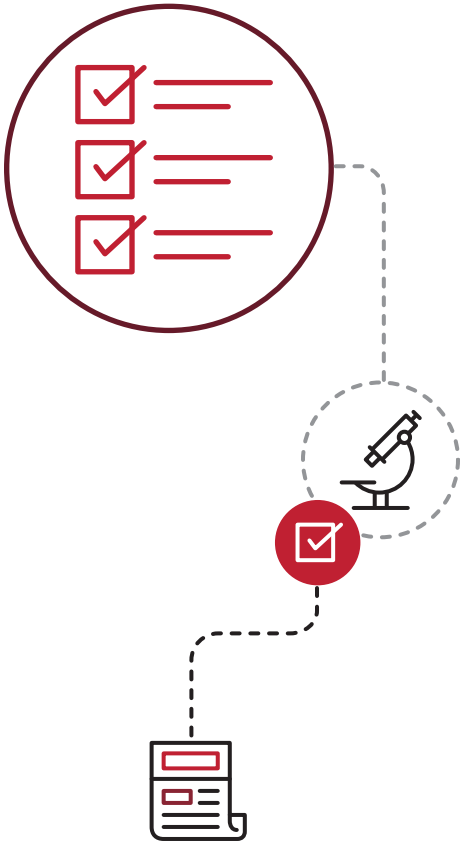
Why do we need the LoCC?

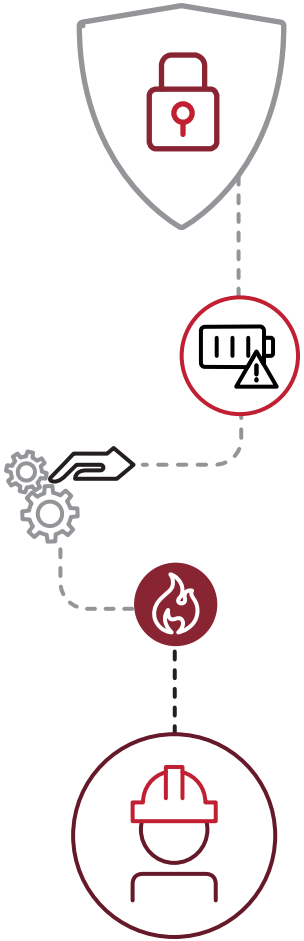
To comply with international standard IEC 60601-1.

The LoCC provides **the required definition** of the safety-critical **components used within your device**, which IEC 60601-1 states must be used “in accordance with their specified ratings.”

The LoCC also provides a stable technical description of your device and its components, which:

- Provides a **clear technical specification** against which a UL Mark/CB certificate is issued
- Makes it easier to **identify the root cause** of any device failure, both during testing and within “live” use
- Enables **accurate re-creation** of the test configuration, should tests require re-running
- Provides a **basis for future audit** and assessment of your device





What information does the LoCC contain?

Every LoCC is different, but some components are listed in virtually every LoCC:

- Components that **carry an electrical charge** in the supply circuit
- Components that are **essential** to the safe working of the device

The latter could include components whose **failure or malfunction might result in** a patient or operator being exposed to:

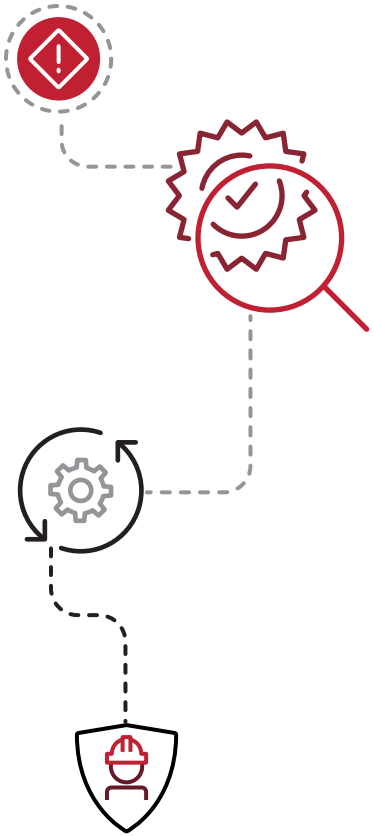
- Mechanical hazards
- Excessive temperatures
- Software hazards, e.g., software failure resulting in device malfunction
- Information hazards, e.g., incorrect warning labels
- Other hazards noted in applicable standards

How is the LoCC created?

We work with you to gather the information needed to create the LoCC for your device

Here is the typical process:

- **You generate the first-cut** version of the LoCC, which is **then reviewed by a UL engineer** and amended as necessary. This might include adding information on:
  - **Third-party accessories** and components that have already been certified by UL
  - **Additional items** that may help in ensuring your device achieves **compliance** with the standard
  - Information gathered from UL's **initial construction evaluation** of your device
- The LoCC also includes **data from UL testing**



Does the LoCC ‘lock’ a device?

The LoCC is a snapshot of your device and its components at a specific point in time:

- The design and construction of your device must be relatively **stable** before before the LoCC can be created
- A stable, complete LoCC is essential to achieving **successful certification** of your device

Note that the LoCC does **NOT** ‘lock’ your device – **you can make changes** to the device and its components in the future:

- In most instances, changes will **NOT** require full re-certification
- Often a **minor alternate project** can be opened to cover any **exchange** of components
- And if you know that you will want to use a range of **substitute** components in your device in the future, these can be listed in the LoCC at the outset – thus saving you time and money

Thank you.

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