



Batteries in Medical Devices: a Systems Engineering Perspective

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Battery-Powered Medical Devices
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No one should hesitate to use any medical devices that his or her physician has prescribed. Adverse events involving batteries are rare, and in all of the examples that I'm going to present here, the underlying design issues have been corrected, or the product is no longer in use. My message is that there is room for improvement in the design of medical devices that incorporate batteries. In many cases, the application of established systems engineering principles can prevent even infrequent adverse events.

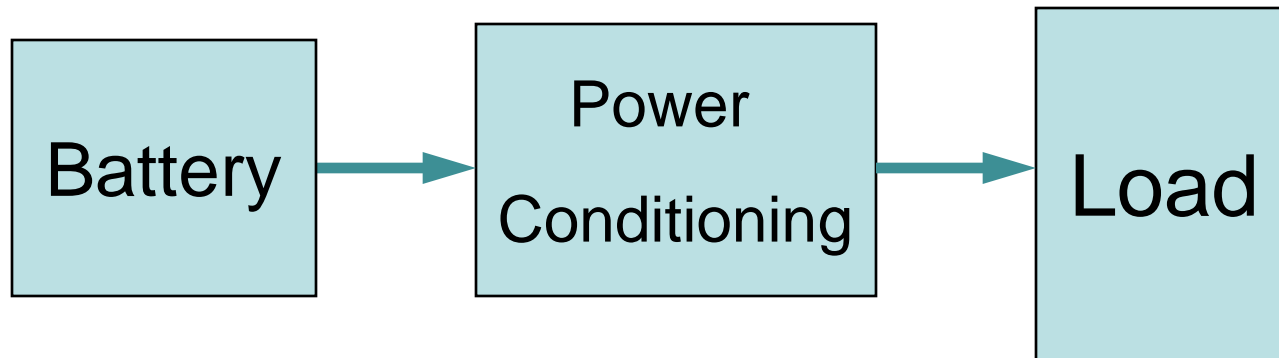


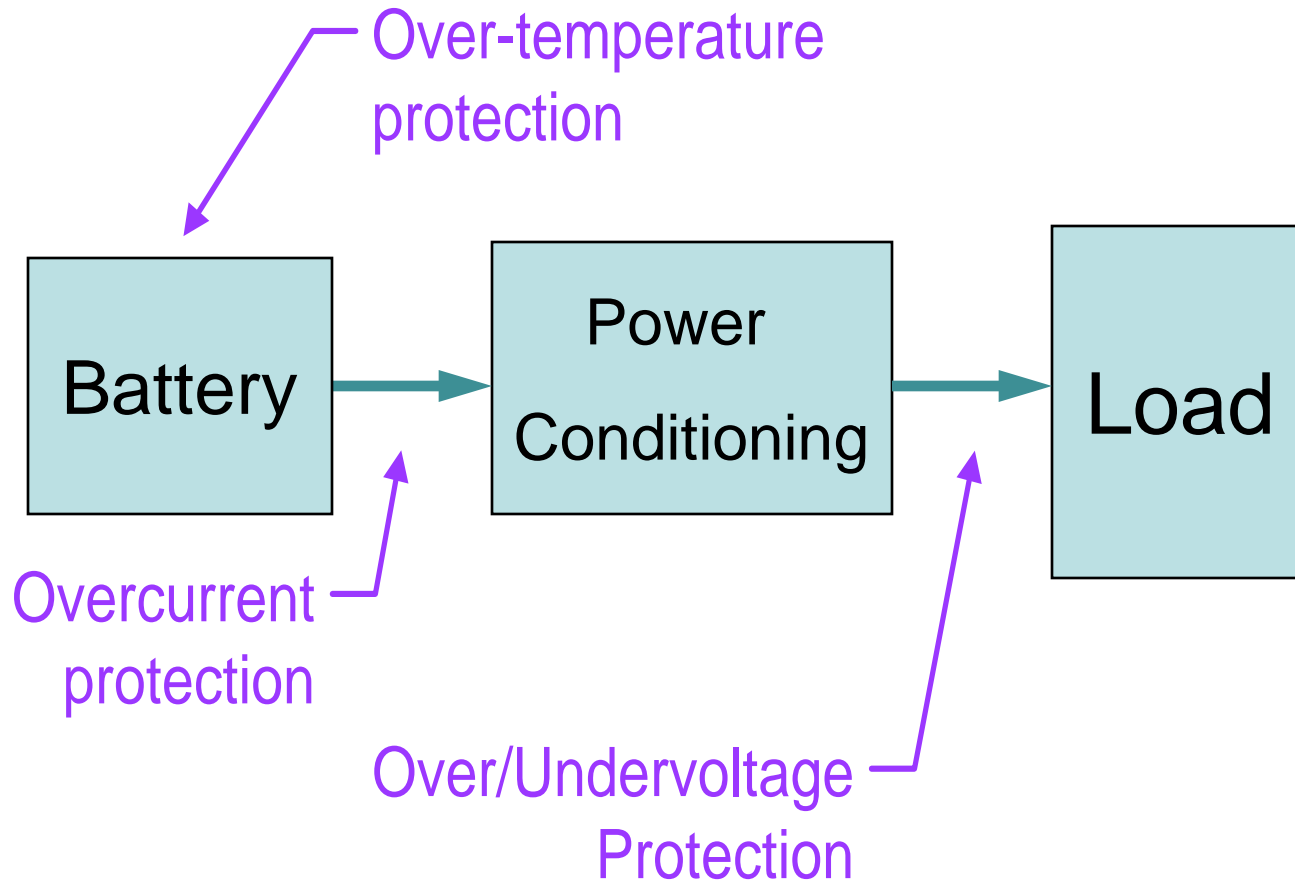
System Engineering Perspective

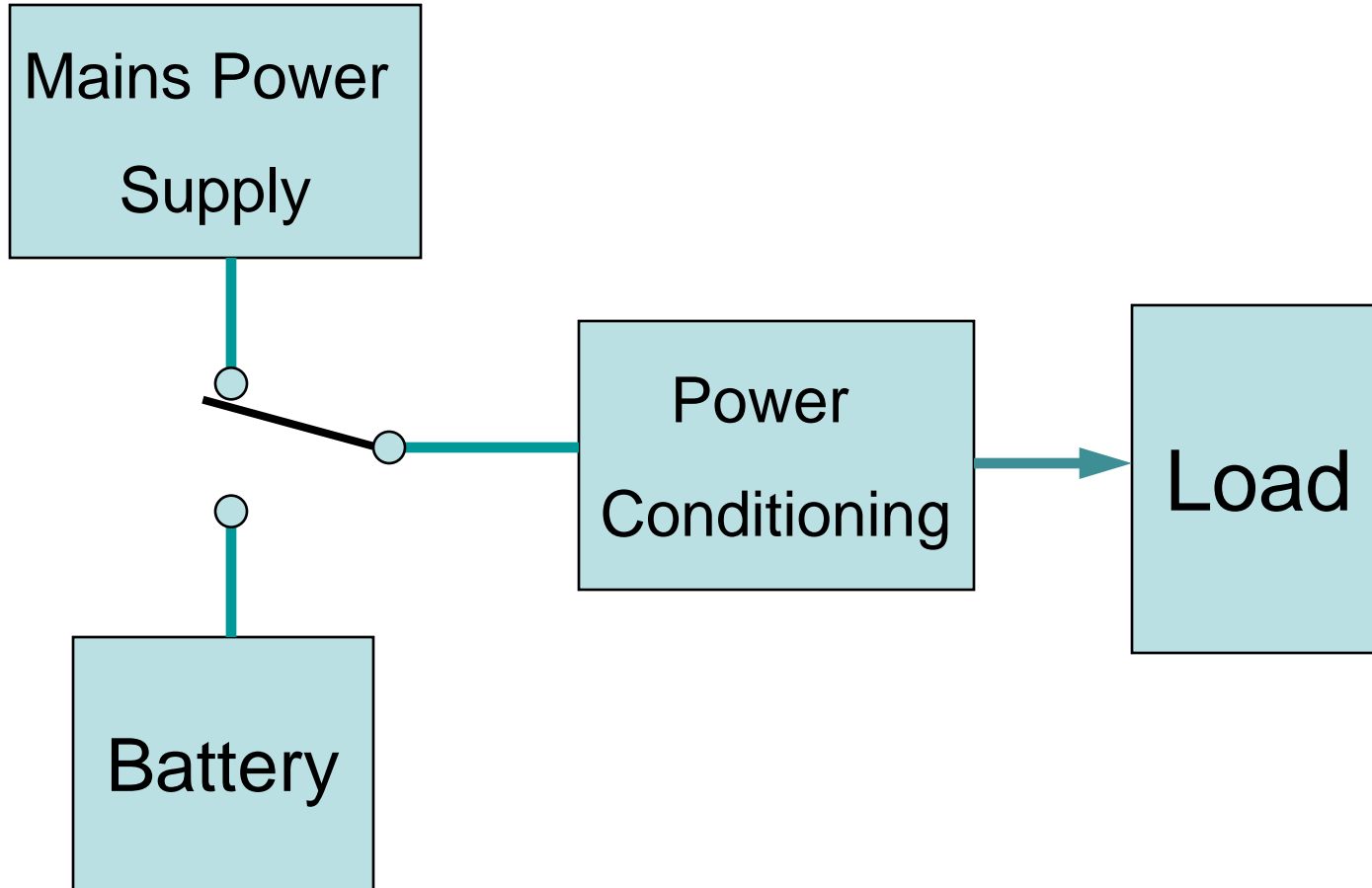
- Assuring the safety of the devices requires us to understand how the battery interacts with rest of the system.
- Even in those situations where the battery failure cannot be prevented, the system can often be designed so the failure cannot harm the patient.

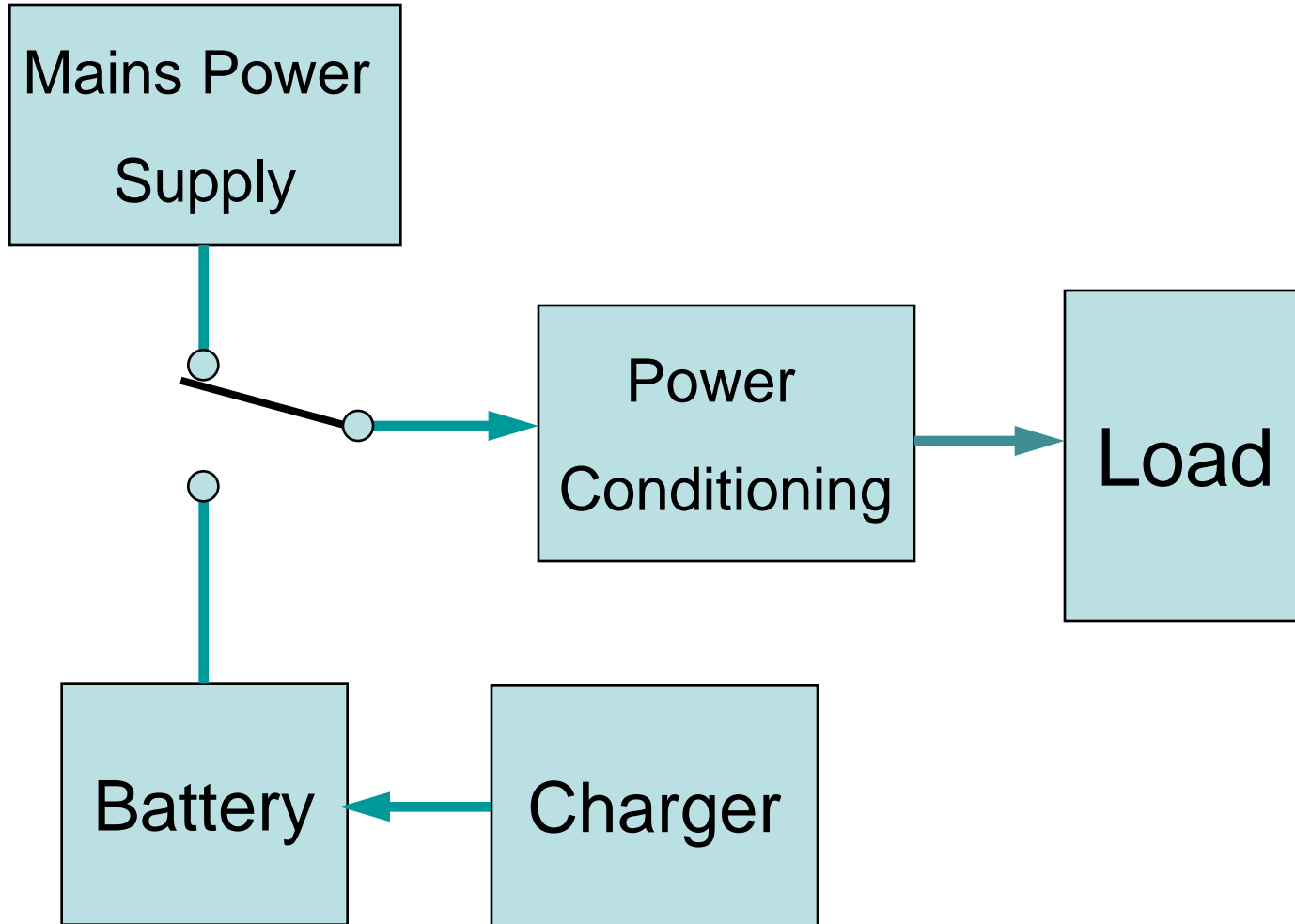
What is a System?

A system is a set of interrelated or
Interacting elements. (*ISO 9000:2005*)

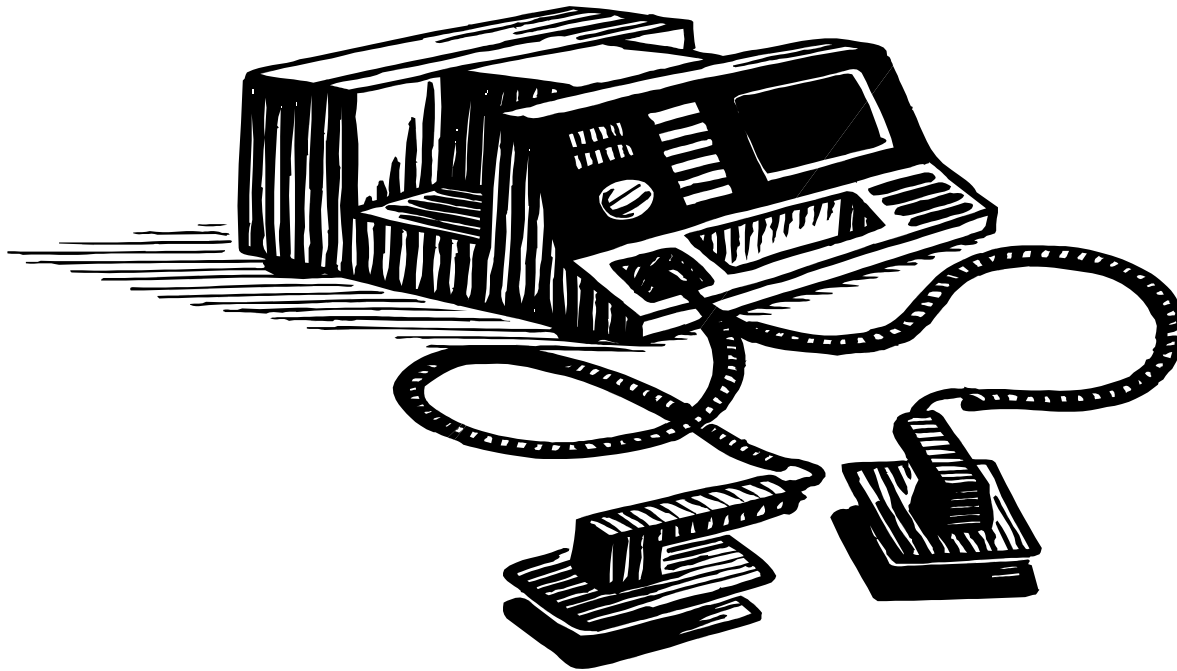








Case of a Defibrillator



Case of a Defibrillator

- Firm received complaints indicating that the device sometimes shuts itself off during analysis and/or treatment due to an apparent low-battery condition.
- Firm testing demonstrated that the battery was substantially charged
- A design flaw in the battery monitoring circuit caused inappropriate shut down



device at these or any other conditions above those indicated in the operational sections of this specification is not implied.

NOTES:

1. Connecting any terminal to voltages greater than V+ or less than GND may cause destructive latchup. It is recommended that no inputs from sources operating from external supplies be applied prior to “power up” of ICL7660S.
2. θ_{JA} is measured with the component mounted on an evaluation PC board in free air.

Electrical Specifications $V_+ = 15V, T_A = 25^\circ C, C_{OSC} = 0$, Unless Otherwise Specified. Refer to Figure 14.

PARAMETER	SYMBOL	TEST CONDITIONS		MIN	TYP	MAX	UNITS
Supply Voltage Range - Lo	V+L	$R_L = 10k\Omega, LV = GND$	$Min < T_A < Max$	4.5	-	11	V
Supply Voltage Range - Hi	V+H	$R_L = 10k\Omega, LV = Open$	$Min < T_A < Max$	9	-	20	V
Supply Current	I+	$R_L = \infty, LV = Open$	$T_A = 25^\circ C$	-	0.25	0.60	mA

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'Exploding' electric toothbrushes recalled

CBC News Posted: Nov 3, 2011 9:05 AM AT | Last Updated: Nov 3, 2011 8:56 AM AT

External Links

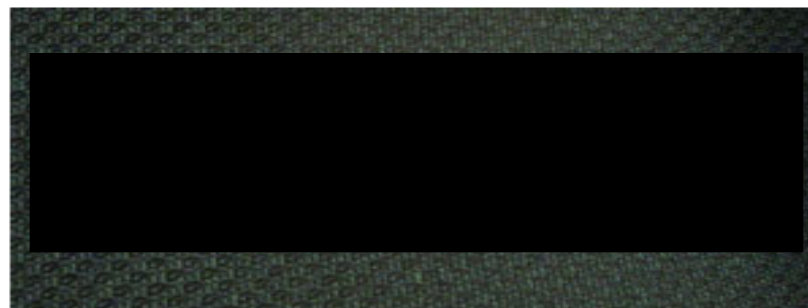
- Health Canada recall notice

(Note: CBC does not endorse and is not responsible for the content of external links.)

Health Canada is warning people to stop using [REDACTED]

after reports they "exploded," but the devices might still be available in stores.

The manufacturer, [REDACTED] is recalling the battery-operated devices after nine reports from Canadians that the toothbrushes "exploded."



The [REDACTED] Electric Toothbrush might still be available in stores until the recall is complete. (CBC)

CBC News was able to purchase the toothbrush Thursday morning in a P.E.I. store's "blowout sale."

Health Canada announced the recall on Wednesday, but noted the toothbrushes may still be found on shelves until the recall is completed.

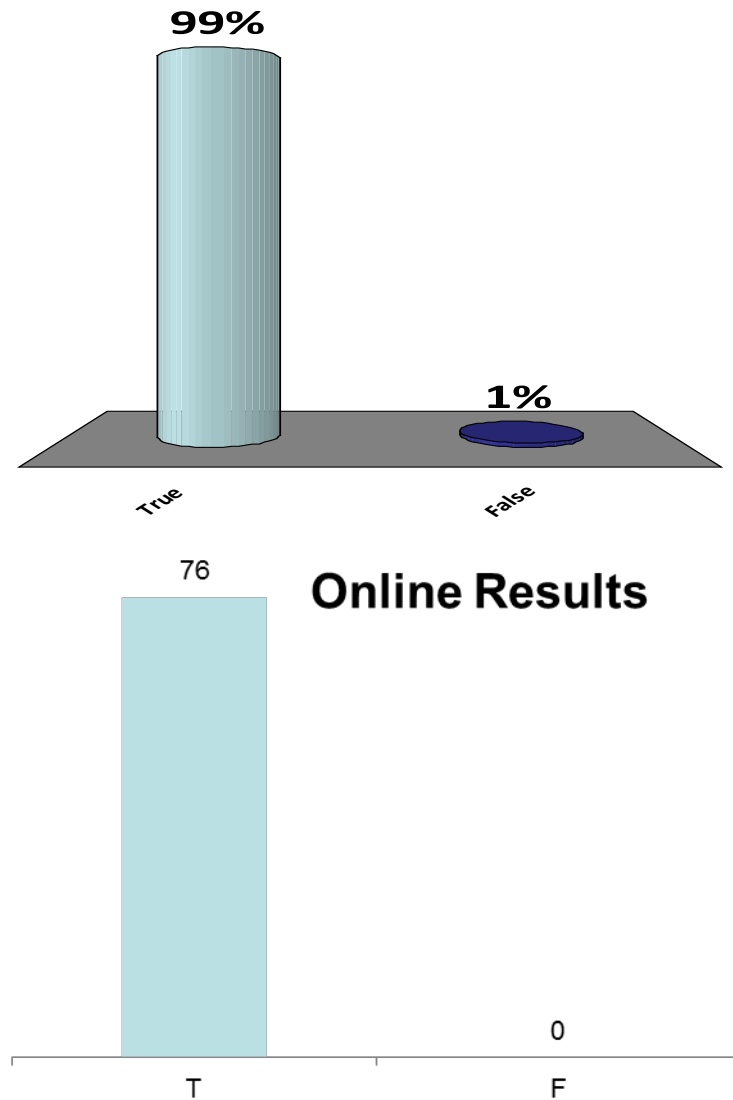
Conclusion

- The battery is one component of a complex system.
- It needs to be chosen correctly to assure that the host device meets its specifications.
- The device design needs to satisfy the operating requirements of the battery.
- The design engineer's task is to know the failure modes of these components and design the system to fail safe if any of the components fail.

The performance of medical devices can be improved through the use of systems engineering practices.

A. True

B. False





Thank you