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Can You Stall a Baclofen Pump During a Magnetic Rod Lengthening?

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Disclosures

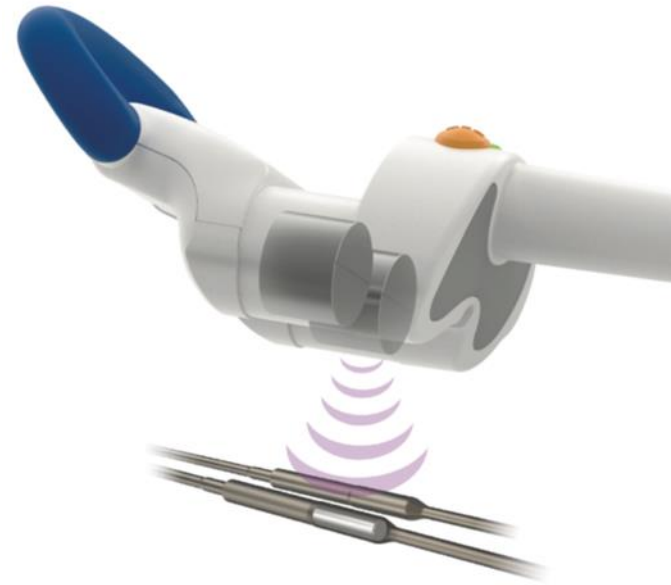
- I am a consultant for:
 - Medtronic Neuromodulation
 - Orthopediatrics
- I am only speaking about the Medtronic Pump, not the Flowonix Pump.




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Background

- A growing number of kids are being implanted with magnetically controlled growing rods.
- Some also have baclofen pumps, a device that delivers a neuromodulating drug using a magnet.



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A healthcare professional in a white lab coat is using a handheld medical device on a patient's arm. The device is white and blue, with a screen and several buttons. The patient is wearing blue shorts and is lying down. The background is a clinical setting with a white counter and some equipment.

There has been no previous testing to determine if the External Remote Controller (ERC) would stall a baclofen pump during magnetic rod lengthening, a potentially **life-threatening** event.



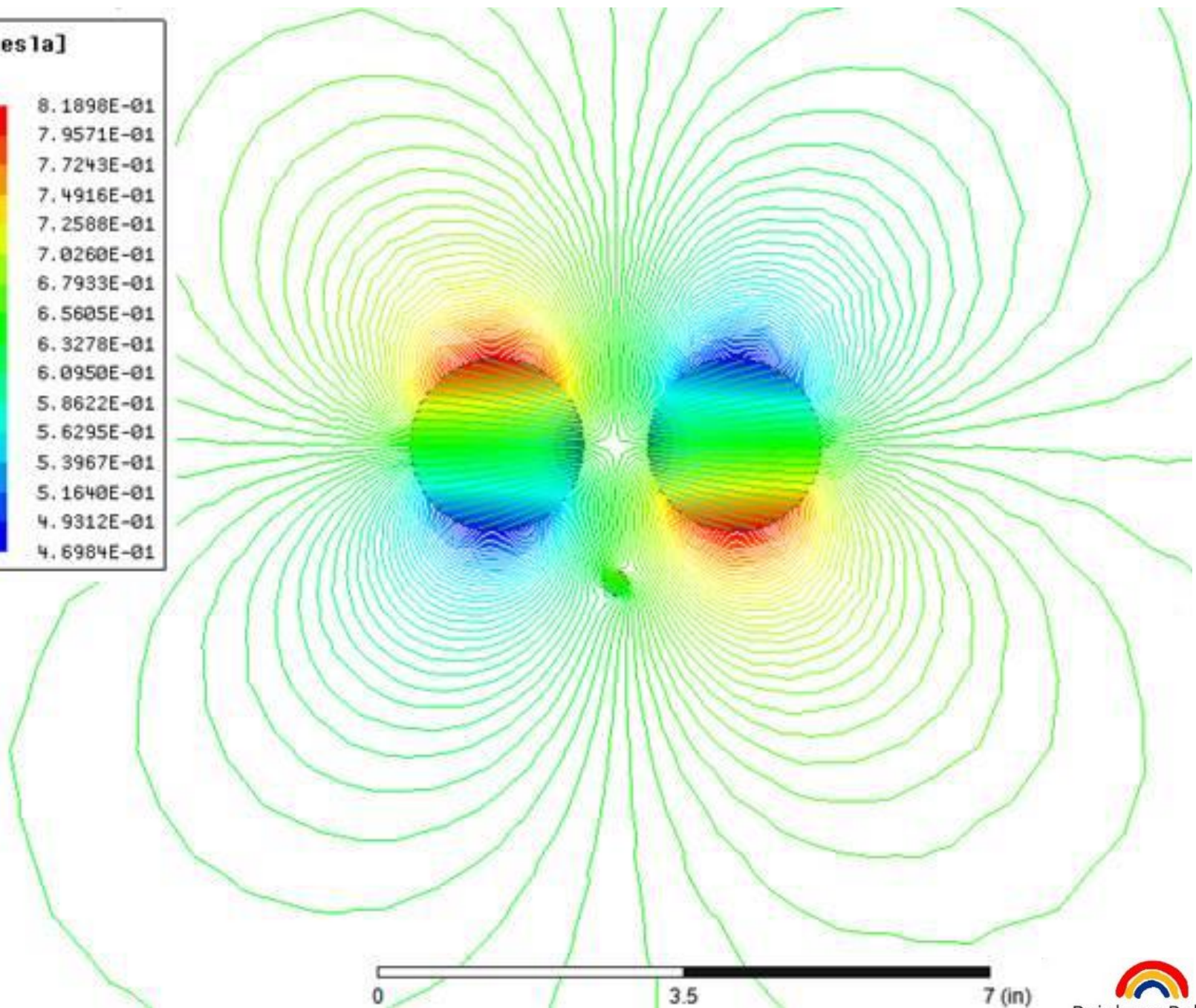
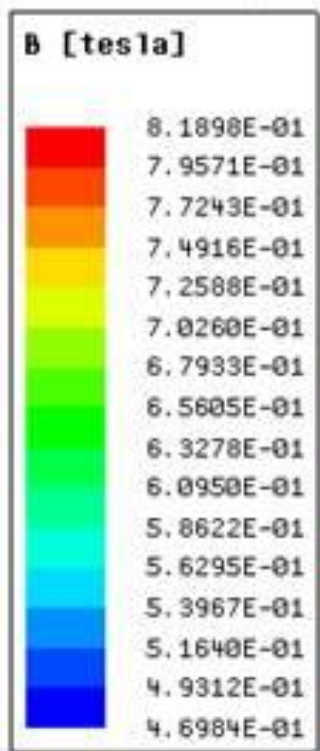
Two baclofen pumps (20mL and 40mL) were used for testing.

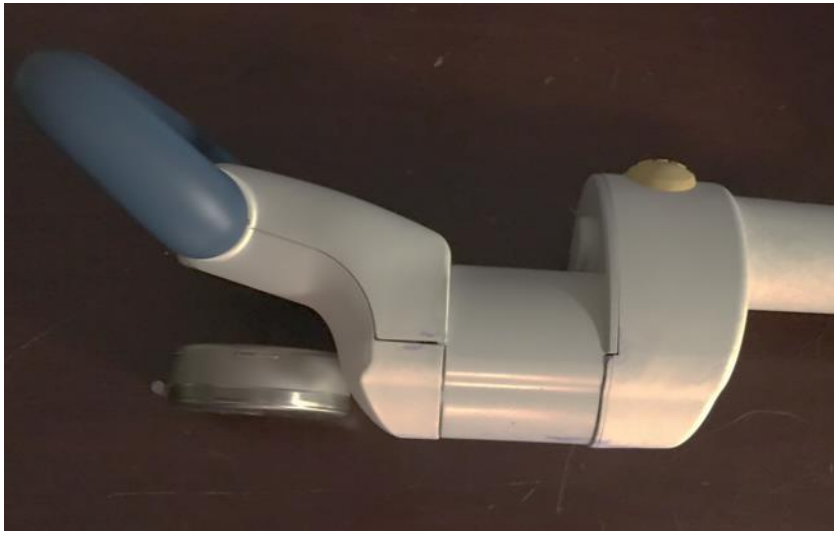


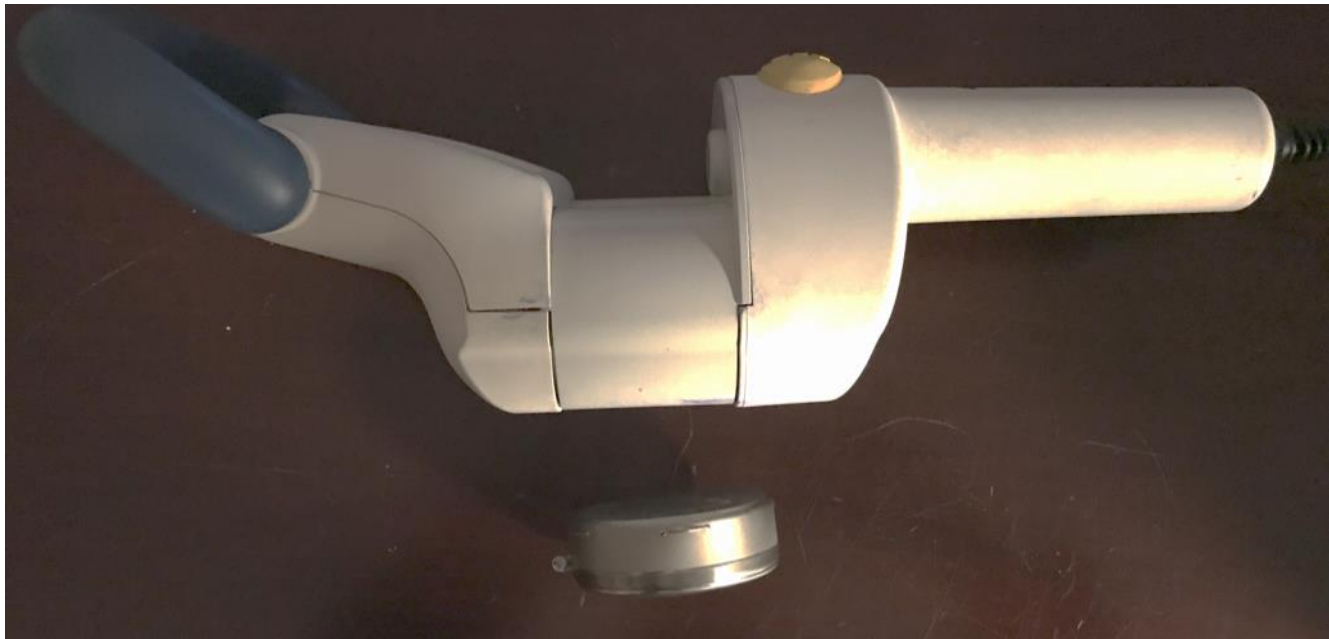
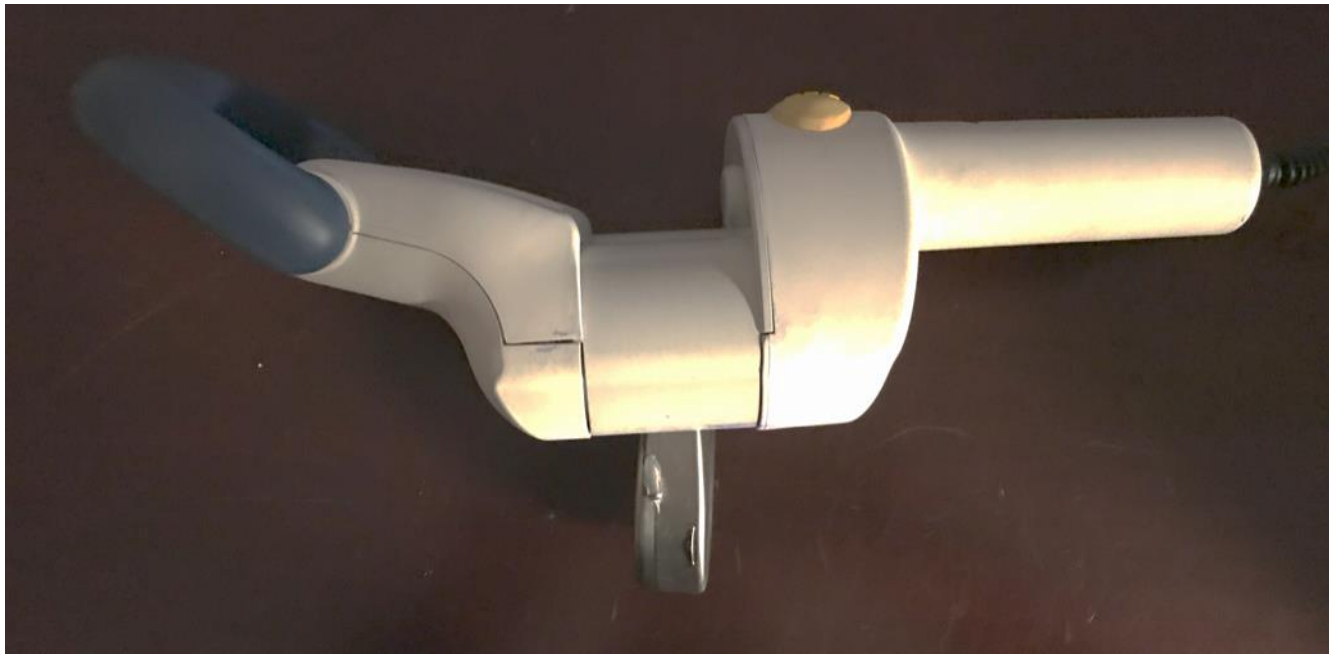
Methods

- During testing we varied:
 - The distance of the pump from the ERC
 - The orientation of the pump relative to the ERC
 - The speed (dose) which the pump was running
 - The time the ERC was run (in mm and in seconds)
- Endpoint was presence or absence of a stall









Results

Pump	Setting	Lengthening	Position	Distance	Outcome	Time to Stall
20 mL	100/day	3 mm	Over center	0 mm	No Stall	
20 mL	100/day	5 mm	Over center	0 mm	No Stall	
20 mL	900/day	3 mm	Over center	0 mm	No Stall	
20 mL	900/day	5 mm	Over center	0 mm	No Stall	
20 mL	900/day	10 mm	Over center	0 mm	No Stall	
20 mL	900/day	30 mm	Over center	0 mm	Stall	1 min
20 mL	900/day	30 mm	In front	0 mm	Stall	1 min
20 mL	900/day	30 mm	Behind	0 mm	Stall	5 min



Results

Pump	Setting	Lengthening	Position	Distance	Outcome	Time to Stall
40 mL	100/day	3 mm	Over center	0 mm	No Stall	
40 mL	100/day	5 mm	Over center	0 mm	No Stall	
40 mL	100/day	3 mm	Over center	0 mm	No Stall	
40 mL	100/day	5 mm	Over center	0 mm	No Stall	
40 mL	100/day	10 mm	Over center	0 mm	No Stall	
40 mL	100/day	20 mm	Over center	0 mm	No stall	
40 mL	100/day	30 mm	In front	0 mm	Stall	1 min
40 mL	100/day	30 mm	Behind	1 cm	Stall	2 min



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Magnetic Fields

- The tesla decreases exponentially with distance.

ERC						
Distance	Mm	4.1	25.4	152.4	304.8	609.6
Magnetic Flux	Tesla	0.434	0.226	0.0107	0.00177	0.00024
	Gauss	4340	2260	107	17.7	2.4



Distances tested

Distance in the body



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Relevant Findings

- The pump would NOT stall if:
 - Lengthening was under 30 mm
 - Distance from the ERC was more than 1 cm
 - The lengthening was not done continuously
- If the distance was more than 1 cm, no amount of lengthening would not stall the pump.



Relevant Findings

- The dose (speed) of the pump did not matter
 - Previous reports have suggested that pumps at a higher rate of speed are more susceptible to stall, but this has never been proven.
- The pump was more likely to stall “in front” or “behind” the ERC. It only stalled once in the “over center” position.
- If a stall did occur
 - Up to 12 minutes after the lengthening
 - Critical alarm always occurred



Clinical Anecdotes

After each patient who has a baclofen pump undergoes a rod lengthening, I interrogate the pump.

- No critical alarms have occurred.
- No stalls have occurred.
- No parent has reported a stall later.



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Conclusions

- Baclofen pumps are always more than 1 cm away from the magnetic rods when both are implanted in a child.
- The typical lengthening interval is under 10 mm, much less than the 30 mm required to stall a baclofen pump.
- The ERC is **highly unlikely to stall** a baclofen pump during a magnetic rod lengthening, making a **life-threatening event almost impossible**.



Thank You!



Questions?