

# DESIGN AND DEVELOPMENT OF AN ACCESSIBLE REMOTE DOSING DEVICE FOR THE CADD PATIENT-CONTROLLED ANALGESIA PUMP

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## INTRODUCTION

- Patient Controlled Analgesia (PCA) infusion devices allow for patient-self-administered narcotic doses within prescribed limits [1].
- PCA therapy is indicated for postoperative, obstetrics, terminally ill, & trauma patients [1].
- Drug delivery is activated via direct interaction with the PCA pump or, more commonly, a button on a cord connected to the pump (Figure 1).
- The button on a cord enables remote dosing from a patient's hospital bed.



Figure 1. Smith's Medical's CADD PCA Infusion Pump [1].

## OBJECTIVE

Building on ethnographic data, we are developing an alternative remote dosing device for the CADD PCA Pump for easier patient accessibility & usability.

## DESIGN PROCESS

- Our device design's use cases, user needs, & intended uses were considered to inform our specifications (Table 2).
- Post killer experiments, additional features pursued include visual/auditory user feedback, accidental push mitigation, & cleanability.

Dimensions	100% greater surface area*
Required Force	50% decrease in force required*
Software	Compatible with CADD PCA Pump
Durability	Drop test @ 30, 33, & 36"

Table 2. Example Product Design Specifications (PDS).  
\*Concerning the original PCA button.

## UNMET CLINICAL NEED IDENTIFICATION

### Ethnography Activities

- Anesthesiologist was shadowed at Children's Hospital of Pittsburgh.
- PCA pump biotechnicians were interviewed.
- Medical personnel (clinicians, nurses, etc.) & previously hospitalized patients were surveyed (Table 1).
- CADD PCA Pump was obtained for component autopsy.

Characteristics	Clinician Input (n = 19)	Patient Input (n = 5)
Age, groups		
Under 18	12 (63)	
18-35	6 (32)	1 (20)
35-65	8 (41)	3 (60)
65+	5 (26)	1 (20)
PCA Therapy		
Yes	13 (68)	3 (60)
Sometimes	6 (32)	2 (40)
Button Difficulty		
Yes	6 (32)	2 (40)
Sometimes	6 (32)	1 (20)
No	7 (37)	2 (40)

Table 1. Ethnographic data from clinician & patient inputs.

### Data-Derived Takeaways

- The majority of patients experience difficulties pressing the dosing button during PCA therapy.
- Muscle weakness & fine-motor difficulties are the primary causes of difficulty pressing the button (Figure 2).

### Causes of Pressing Difficulty

#### Hard-to-Press Button Causations

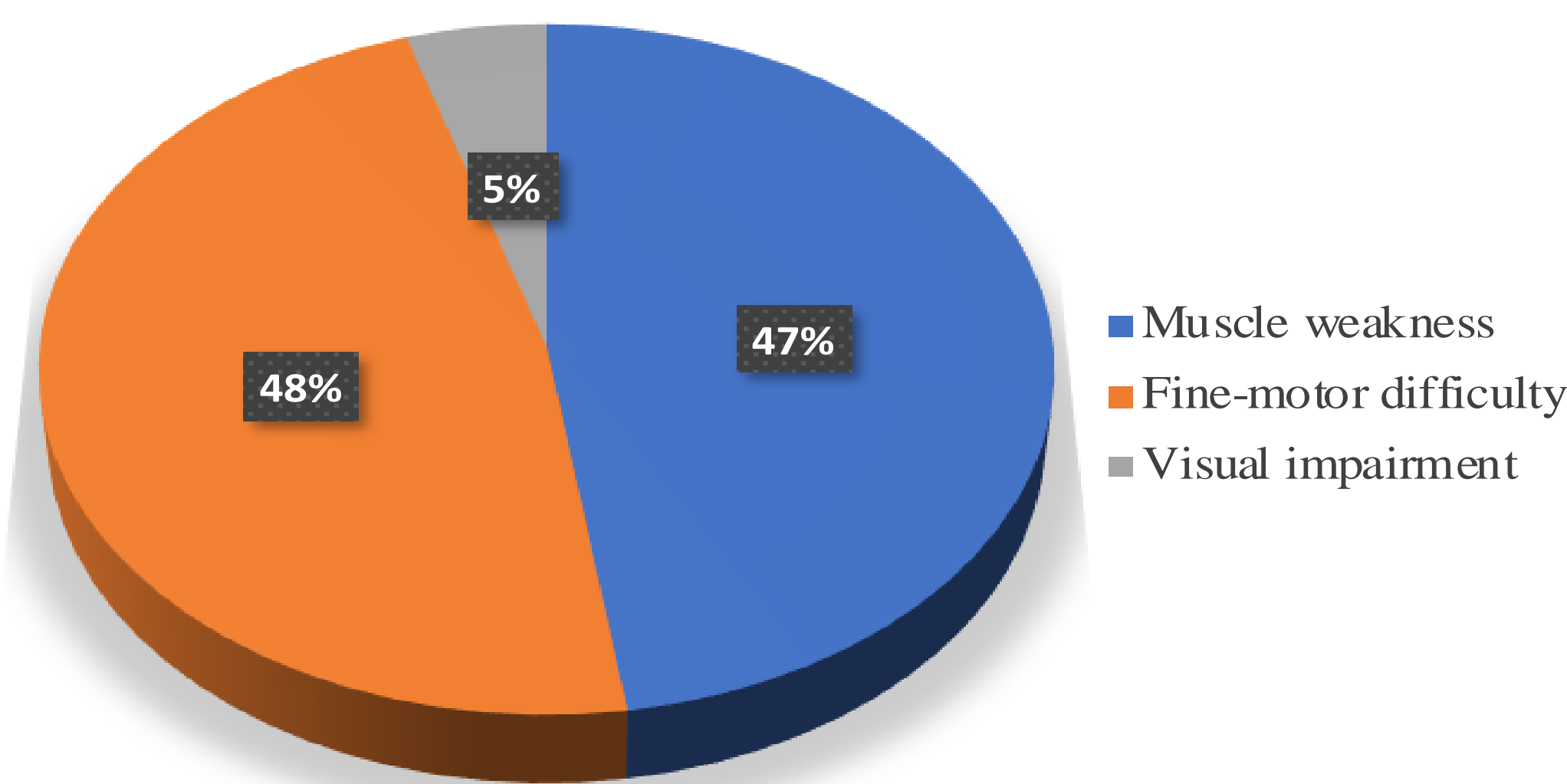


Figure 2. Clinician-observed breakdown of causes for pressing difficulty in patients.

### Concept to Prototype:

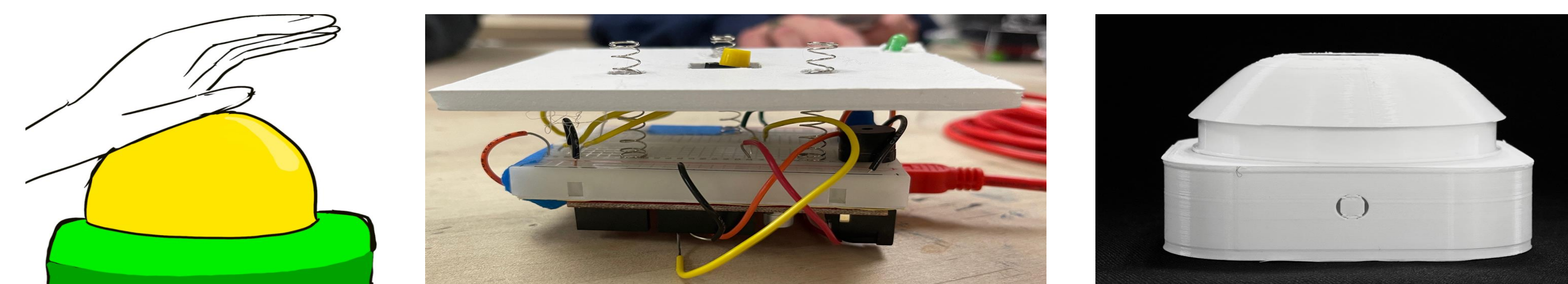


Figure 3. (from left to right) Evolution of design from initial sketch to low-resolution prototype to medium-resolution prototype.

- Prototyping efforts focused on electronics & a housing enclosure.
- Housing and electronic prototyping have reached a design freeze.

## RISK ANALYSES

- Performed several iterations of the initial hazards assessment, failure mode effects analysis, & fault-tree analysis (Figure 4) to evaluate the design risk.

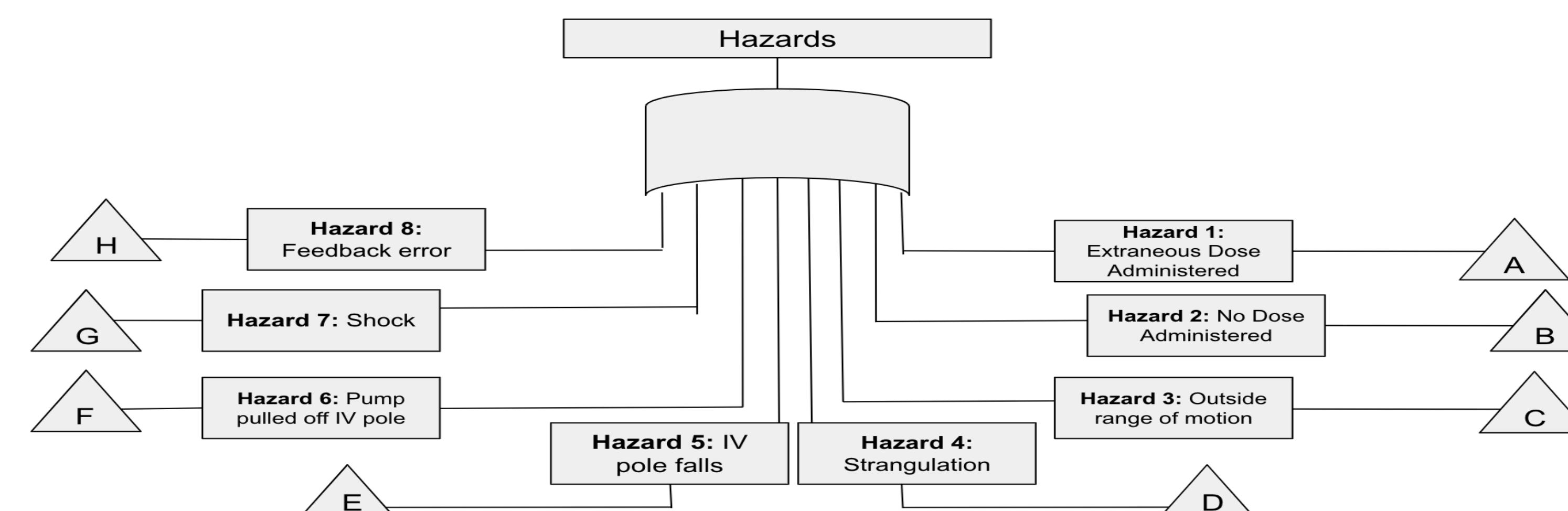


Figure 4. System-level Fault-tree analysis (FTA) for our device design.

## VERIFICATION & VALIDATION TEST PLAN

### Verification: 21 CFR 820.30(f)

- Verification testing confirmed that design outputs satisfy the design inputs (Table 2).
- Testing included verifying dimensional requirements, accidental push mitigation, user feedback, cleanability, & required executable force (Figure 5).
- The team's device successfully met all acceptance criteria.



Figure 5. Force-gauge testing.

### Validation: 21 CFR 820.30(g)

- Validation testing was performed to confirm that design outputs satisfy the user needs (Table 2).
- Testing included validating the prototype's usability and overall function with clinical professionals and healthy subject focus groups (Figure 6).
- The team's device successfully met all acceptance criteria.

### Better Overall User Experience

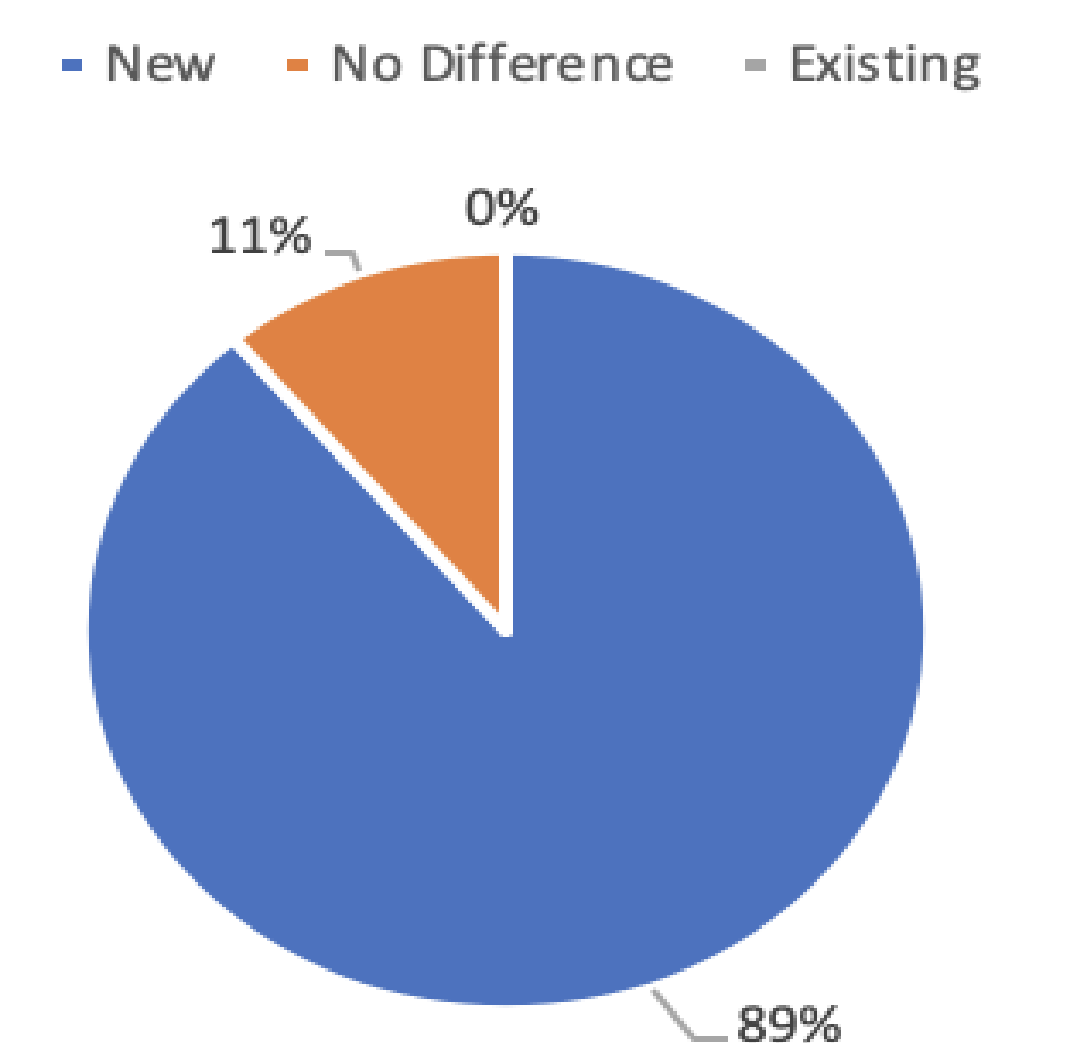


Figure 6. Validation testing result.

## DISCUSSION

- We have successfully reached a design freeze for our prototype.
- Our production equivalent was manufactured via additive manufacturing & will be a product of injection molding.
- The current prototype passed all testing, proving its potential impact.
- Future direction may involve designing for manufacturing and further testing.

## ACKNOWLEDGMENTS

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## REFERENCES

- [1] Lehmann KA. 1995

