Systematic development of medical devices following the CDIO methodology

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Driving question

What makes us engineers?

…

UN Sustainable Development Global Goals

- Collection of 17 Goals set by the United Nations Development Programme.
- Transforming our World: The 2030 Agenda.
- 17 Goals, 169 targets and 304 indicators to measure compliance.

UBORA and the Global Goals

UBORA pursues:

- **Equitable access to healthcare technologies.**
- **Involvement of end users in medical technology development.**
- **Innovation through education and shared knowledge.**
- **International collaboration in the biomedical field.**

General Index

1. The CDIO approach

1.1. The CDIO product development approach

- Systematic product development:
  - Minimizes errors and costs
  - Improves time to market
  - Promotes creative problem solving
  - Constitutes a new educational model
  - Enables engineering very complex systems…
  - … In a reliable and efficient way

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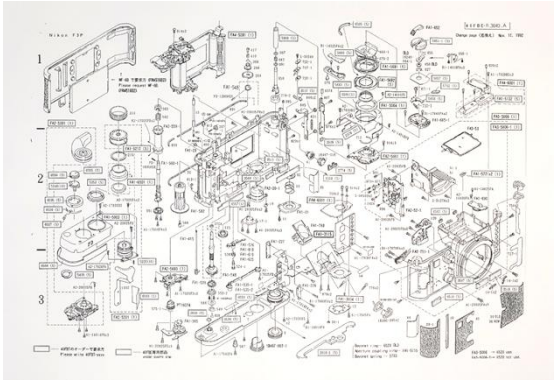
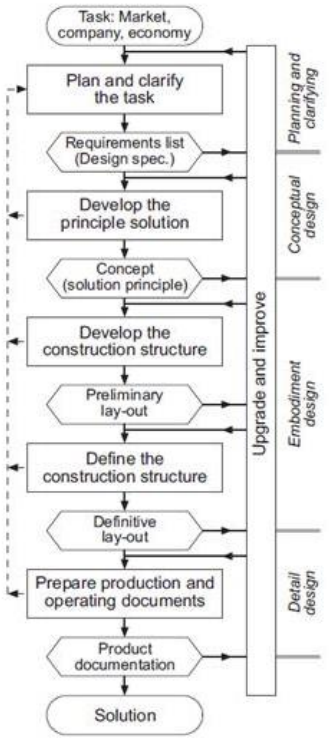
http://cdio.org/

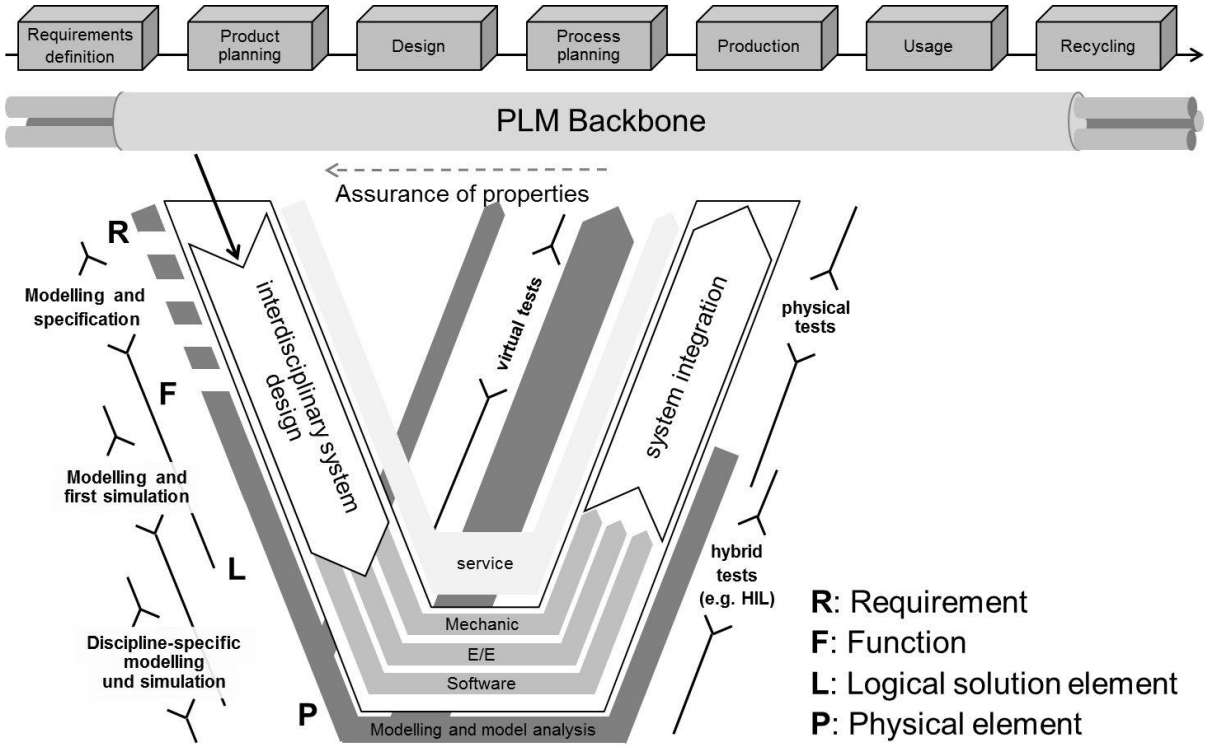
Complex engineering systems: From toys to machines



Nikon diagram source:
Japan Camera Hunter

1. The CDIO approach





Classic
"Pahl – Beitz" model

"VDI 2206 exended V-model"
Eigner-Gilz-Zafirov

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2. Conceive

2.1. Conceive: Product planning & Conceptual design

C.I.Product planning & specs.

- Find a relevant need.
- Study existing solutions.
- Select an objective market.
- Analyze economical viability.
- Analyze related regulations.
- Define objective price & cost.
- Define technical specifications.
- *Interacting with main agents!*

C.II.Conceptual design

- Define main function.
- Describe subfunctions.
- Establish functional structure.
- Analyze solving principles.
- Generate product ideas.
- Evaluate product ideas…
- … then, you have the concept.
- *Eventually protect IP!*

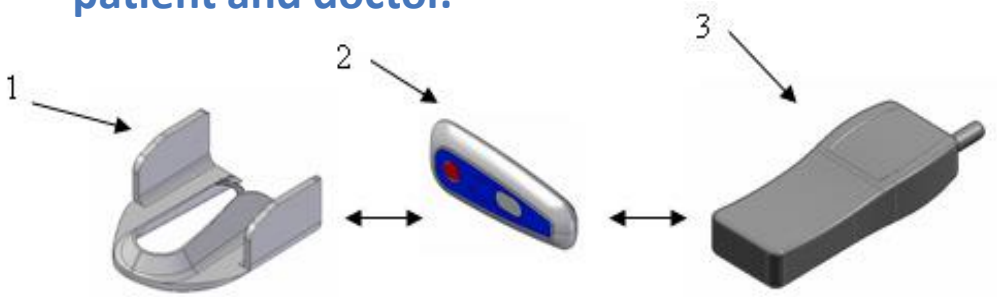
2. Conceive

2.2. Conceive: Application case ("bruxholter" device)

The need: Bruxism, an oral parafunctional activity consisting of excessive teeth grinding or jaw clenching. Limitations in current diagnostic and monitoring processes.

Bruxist jaw source: Broxogard TM

The proposed device: System for detecting teeth grinding, assessing the episode, storing the information and eventually alerting the patient and doctor.



From the need to the specifications → … → From the specifications to the concept

Application example: Systematic development of a biomedical device for measuring bite force
Source: Part of PhD Thesis by Andrés Díaz Lantada on "Development of medical devices based on smart polymers".

3. Design

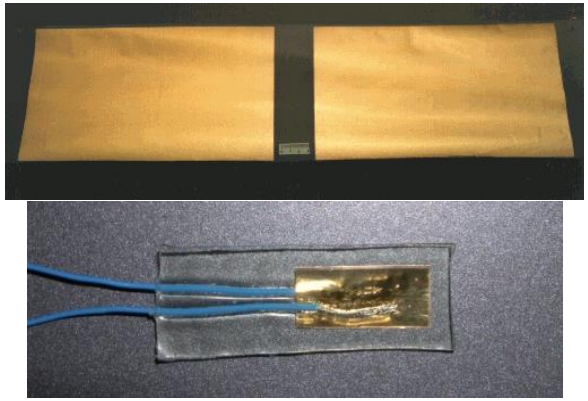
3.1. Design: Basic engineering and optimization

- Design basic geometries (CAD programmes and existing space).
- Optimize considering geometries-materials-processes (simulations).
- Design and model subsystems and subdomains.
- Select commercial elements and off-the-shelf components.
- Integration between domains: Mechanical, electrical, thermal, fluidical.
- Perform preliminary testing of subsystems.
- Revise economical & technical viability.
- Revise fulfillment of specifications.
- ***Continue involving patients and their families, as well as medical professionals during the whole development process.***

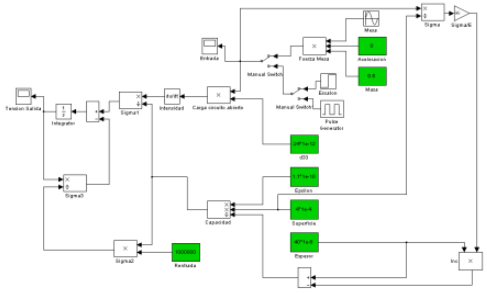
3. Design

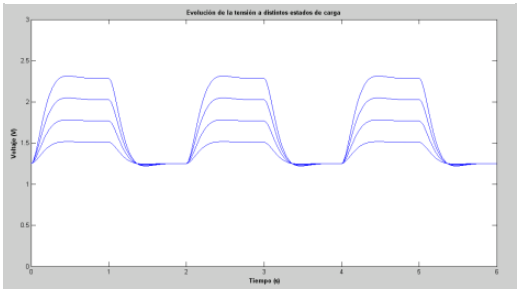
3.2. Design: Application case ("bruxholter" device)

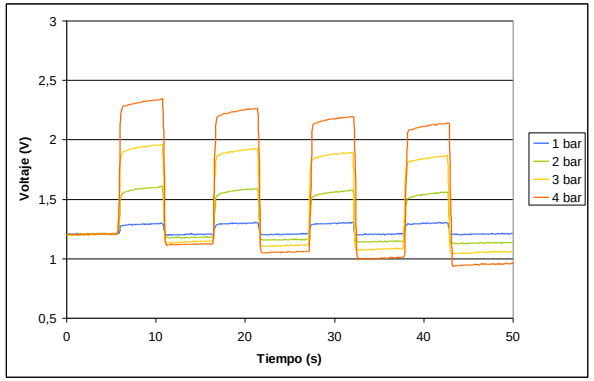
Materials selection, definition of geometries, preliminary tests



Modeling subsystems and subdomains, validating the models with support of characterization tasks







Revising technical and economical viability…

From the concept to the design

Application example: Systematic development of a biomedical device for measuring bite force
Source: Part of PhD Thesis by Andrés Díaz Lantada on "Development of medical devices based on smart polymers".

4. Implement

4.1. Implement: Prototyping and testing

- **Adapt design to prototyping processes.**
- **Analyze mounting and joining of subsystems.**
- **Perform controlled technical trials (i.e. in vitro).**
- **Perform advanced tests (i.e. in vivo / first test clients).**
- **Validate modeling approaches and their use for optimization.**
- **Revise economical & technical viability.**
- **Revise fulfillment of specifications.**
- **Redesign as needed and prototype again.**
- **Validate before approaching production.**
- ***Find the right support towards device validation (i.e. well-equipped animal testing facilities and operating rooms with adequate professionals).***

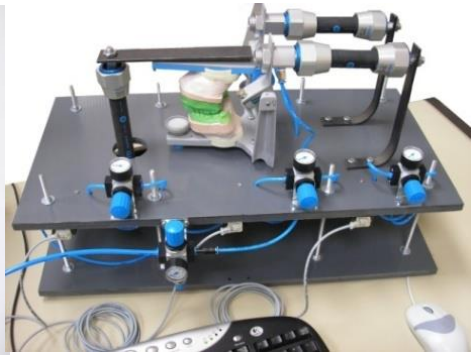
4. Implement

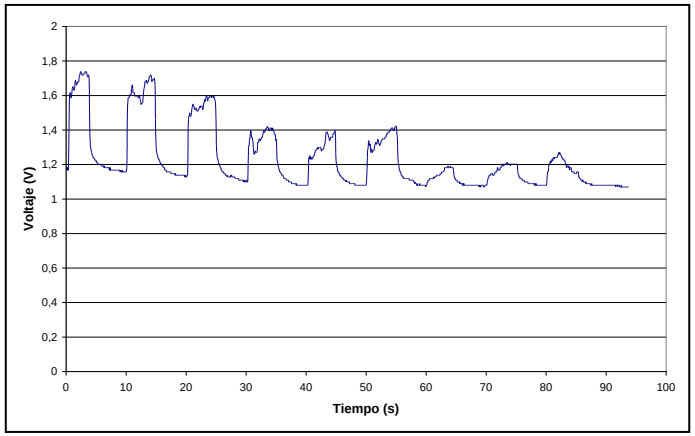
4.2. Implement: Application case ("bruxholter" device)

Prototyping and testing:
Exhaustive in vitro tests before approaching in vivo trials

Pre-production validations

Ad hoc test benches + standardized procedures





From the design to the prototype

Application example: Systematic development of a biomedical device for measuring bite force
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5. Operate

5.1. Operate: Production and products' life

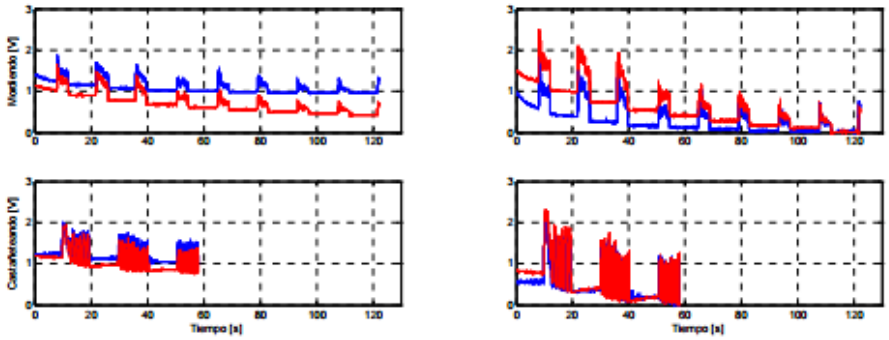
- Fine-tune design to final production processes
- Interact with suppliers and define joint strategy
- Generate technical documentation (mounting, joining, operation…)
- Generate regulatory-related documents for pre-production marking
- Define the warranty strategy
- Accomplish short runs and final production series
- Reach the final customers supported by the marketing strategy
- Manage and continuously adjust the supply chain
- Manage and continuously adjust maintenance plans and end of life
- ***Rely on the support of experienced professionals towards device commercialization.***

5. Operate

5.2. Operate: Application case (“bruxholter” device)

Extensive documentation of trials and systematic evaluation of effectivity and performance

Labelling for commercialization (depending on medical device class → self-certified (for very low risk devices) or externally assessed.



Dental clinic image source: Ezzo.ro

From the prototype to the product

Application example: Systematic development of a biomedical device for measuring bite force
Source: Part of PhD Thesis by Andrés Díaz Lantada on “Development of medical devices based on smart polymers”.

6. Conclusions and references

Main conclusions

- → **Systematic product / process development methodologies, including the CDIO process, help to promote innovation, while keeping reliable along the development process.**
- → **Innovating medical devices means continuously interacting with patients, patient associations and medical professionals along the whole product development process.**
- → **Typically, relevant and successful devices place medical needs first and then develop the adequate technology for solving the need in more efficient or effective ways.**
- → **Engineering design methodologies adapted to the medical field help to minimize errors and promote an straightforward approach to the final solution.**

6. Conclusions and references

Some references and websites

- → EU Regulation on Medical Devices (MDR 2017/745).
- → Díaz Lantada, A. (2013). Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices. Springer.
- → Pahl, G.; Beitz, W.; Feldhusen, J.; Grote, K.H. (2007, 3rd ed.). Engineering Design: A systematic approach. Springer.
- → Yock, Zenios, et al. (2015). Biodesign: The Process of Innovating Medical Technologies. Cambridge University Press.

- → http://ubora-biomedical.org
- → http://www.cdio.org (Worldwide CDIO Initiative)

Thanks for your attention

UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education

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