How Research Informs Medical Device Design

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Topics

Farm UCD process

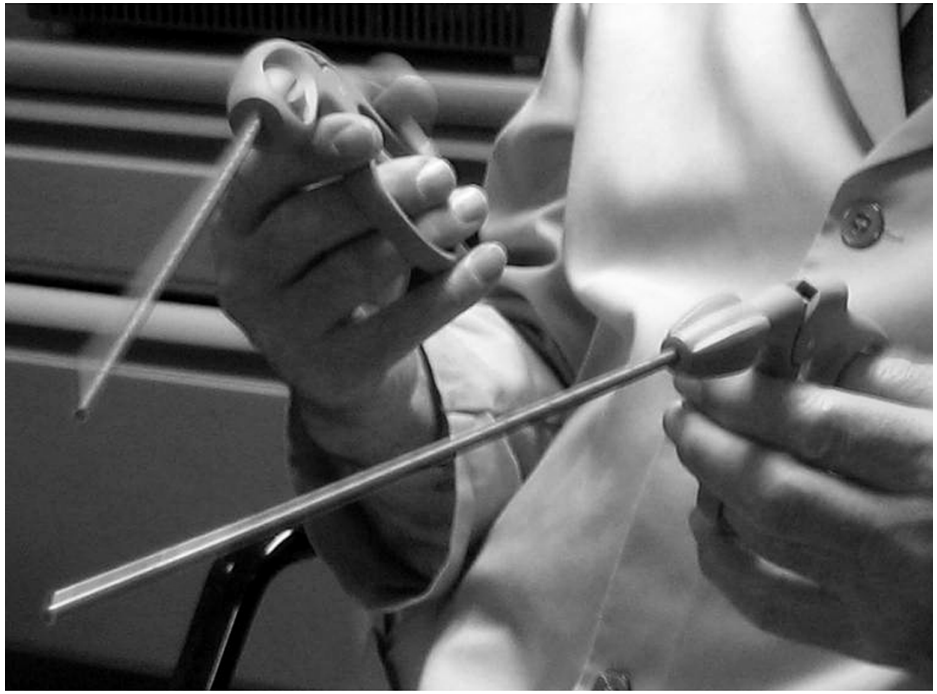
User requirements gathering

Analysis & design

User testing

Case study : Biokit

Case study : Cardinal



About Farm

Over 30 years of experience

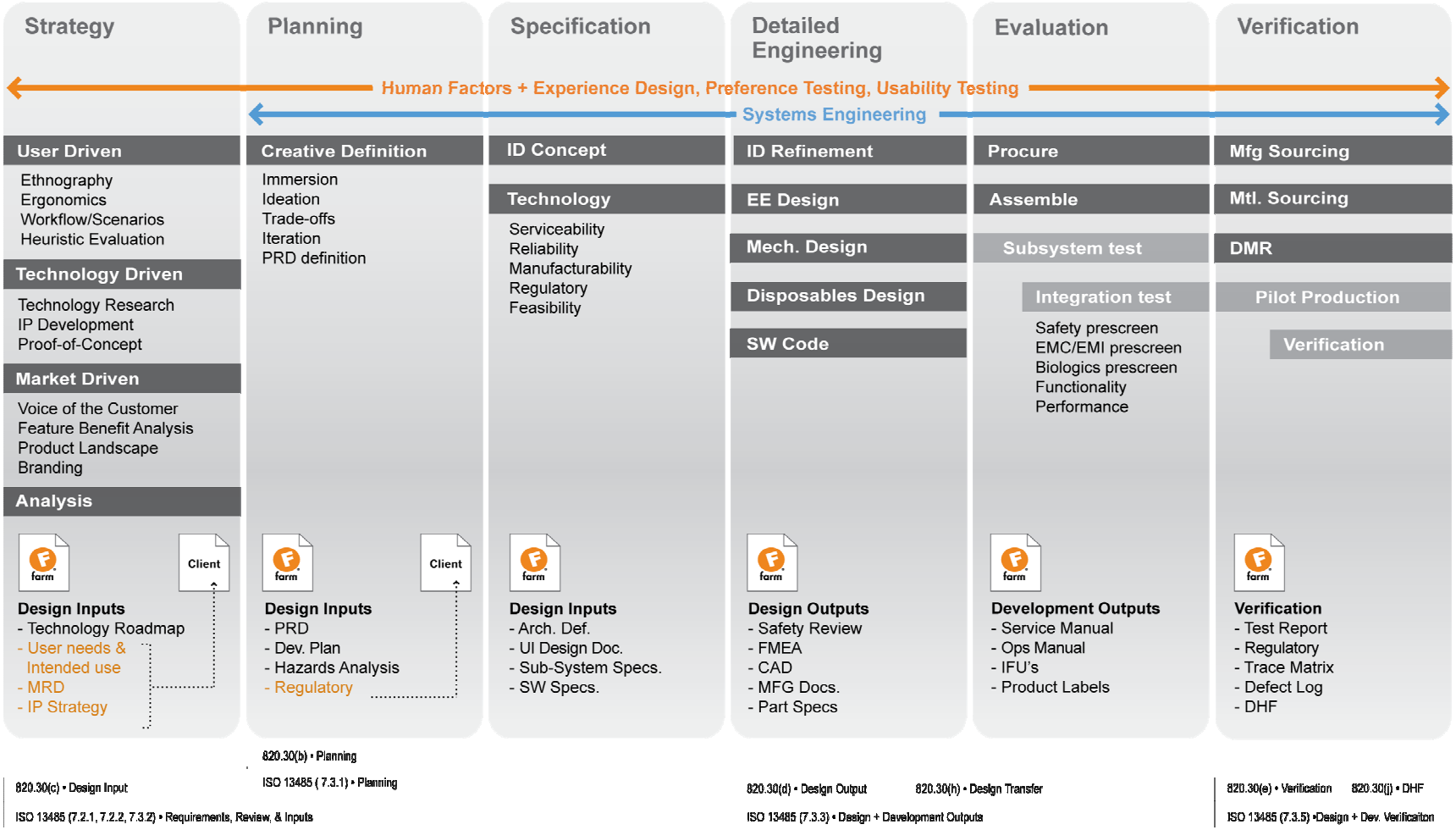
50+ employees

Medical + manufacturing expertise

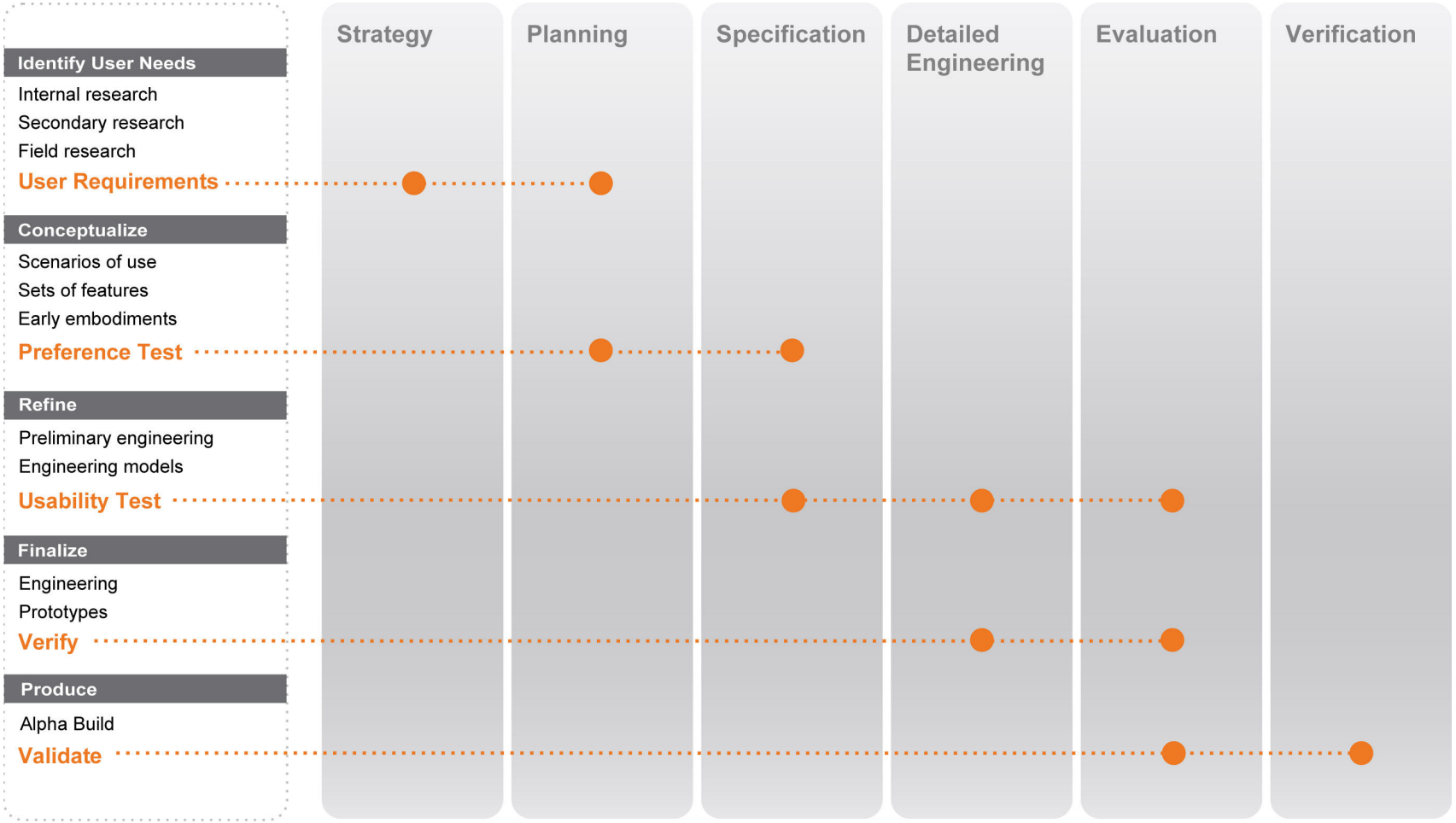
Two facilities including labs

FDA and ISO compliant

TOTAL PRODUCT DEVELOPMENT



User-centered design



Multi-disciplinary approach

Industrial Design

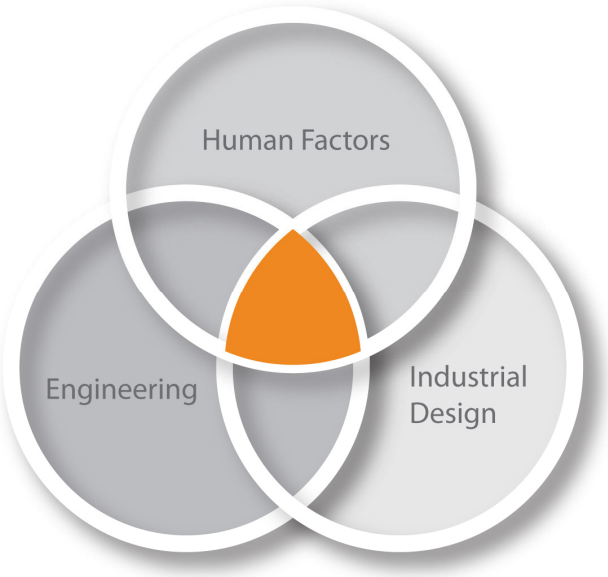
- Aesthetic and ergonomic problem solving
- Visual communication – sketches, graphics, 3D models

Human Factors

- Ergonomic and interaction problem solving
- Written communication – reports, charts, graphs

Engineering

- Performance and manufacturing problem solving
- Database communication – CAD models, charts, graphs



Research

Domestic and international

Patient and clinician interviews

Surgical and lab observation

Product line strategy and planning

Product requirements and features

Multidisciplinary participation

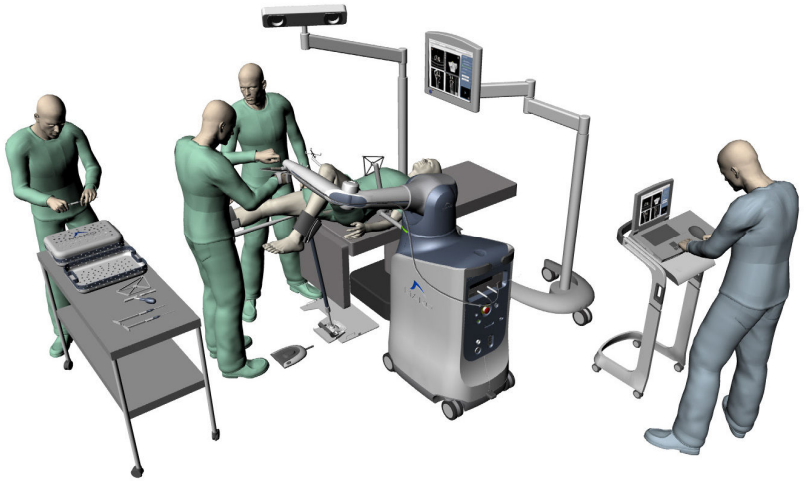
User requirements gathering

Mostly field research:

- Workflow analysis
- Ergonomics
- Environment

Poorly met and unmet needs

Articulated and unarticulated



Analysis: Discovering and prioritizing insights

Prioritize based on business goals and opportunity

Look for:

- Patterns of behavior
- Repeated complaints
- Inefficiencies in work process
- Incompatibilities
- Homemade solutions
- Work-arounds

farm

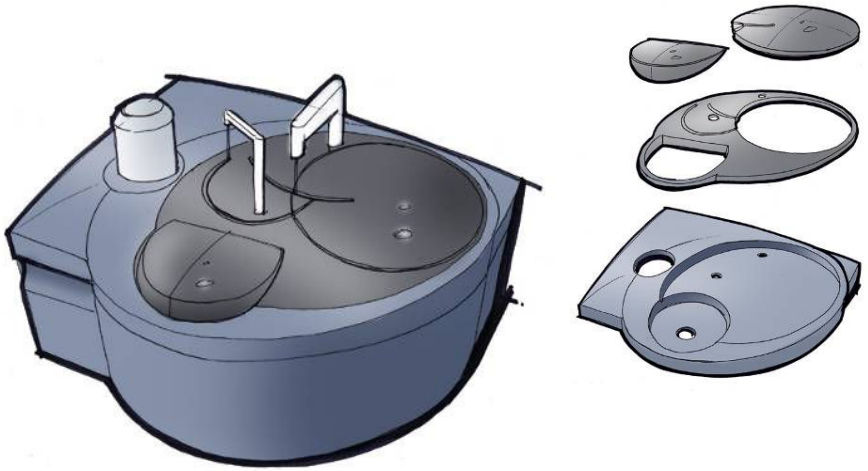
Design development

Solving for design inputs

Brainstorming

Developing concepts using 2D and 3D – sketches, foam models, and CAD

Aesthetic and ergonomic problem solving



Preference testing

Uses early embodiments

Presents multiple options

Addresses some or all usability aspects

One-on-one or groups

Usability testing and evaluation

- Usability testing
  - Actual end users
  - Actual or simulated environment
  - Actual scenarios
- User FMEAs, including misuse scenarios
- Part of design verification as required by FDA

Biokit

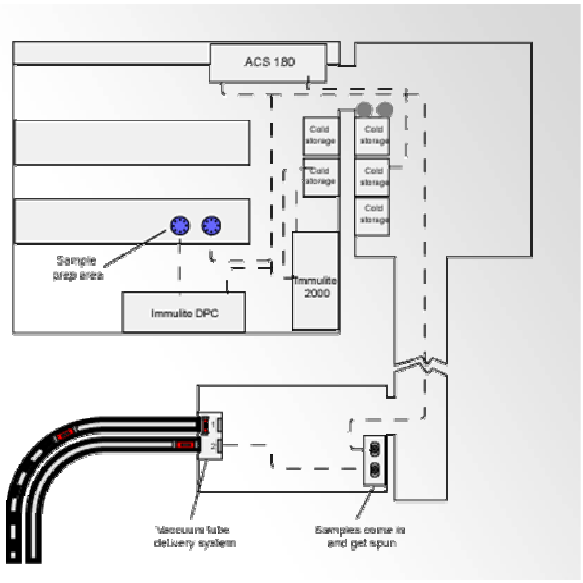
Clinical Analyzer

Farm Design, Inc. 2009

BIOKIT

Field context

Environment observations



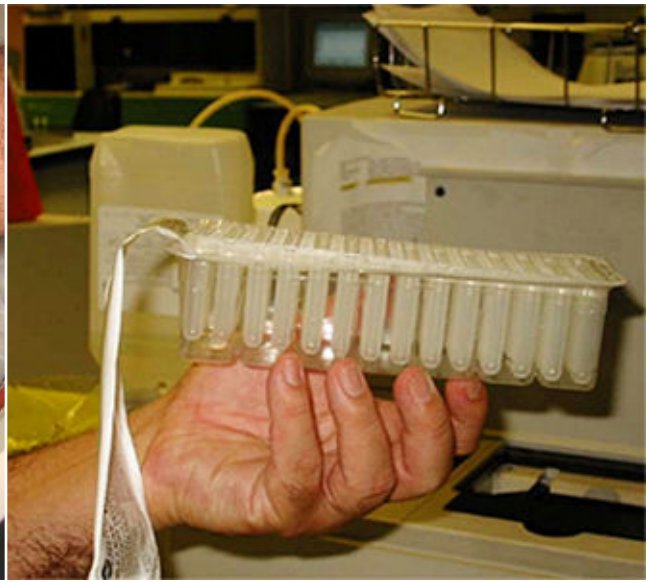
- Narrow, crowded labs
- Minimal bench space
- A range of working heights
- Different workflows for each lab

Field context

User interactions

Loading options

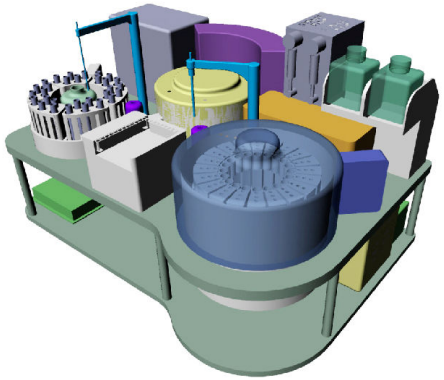
Evaluate spacing



Evaluate cuvette packaging

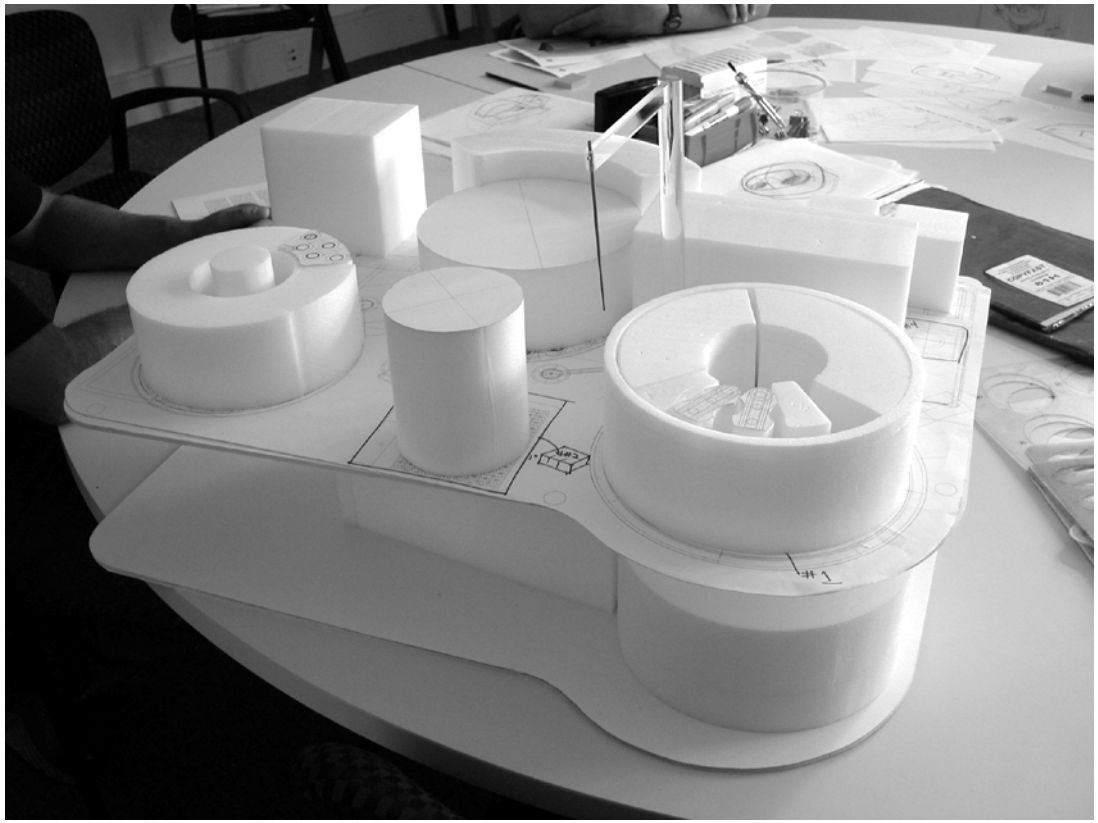
Component architecture

Evaluation of scale



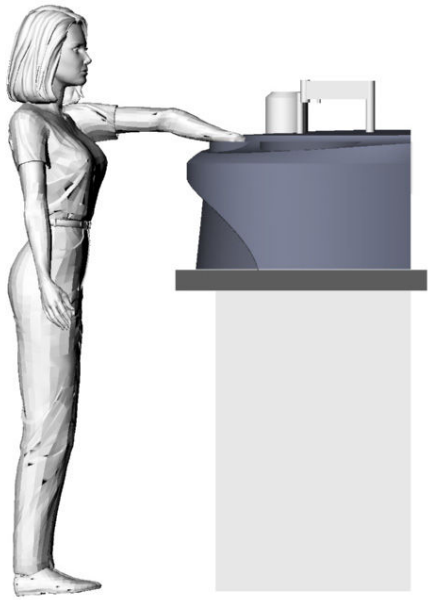
Component assembly - understanding components and their relationships to one another

Foam mock-up - for evaluating and modifying scale, components, and working heights

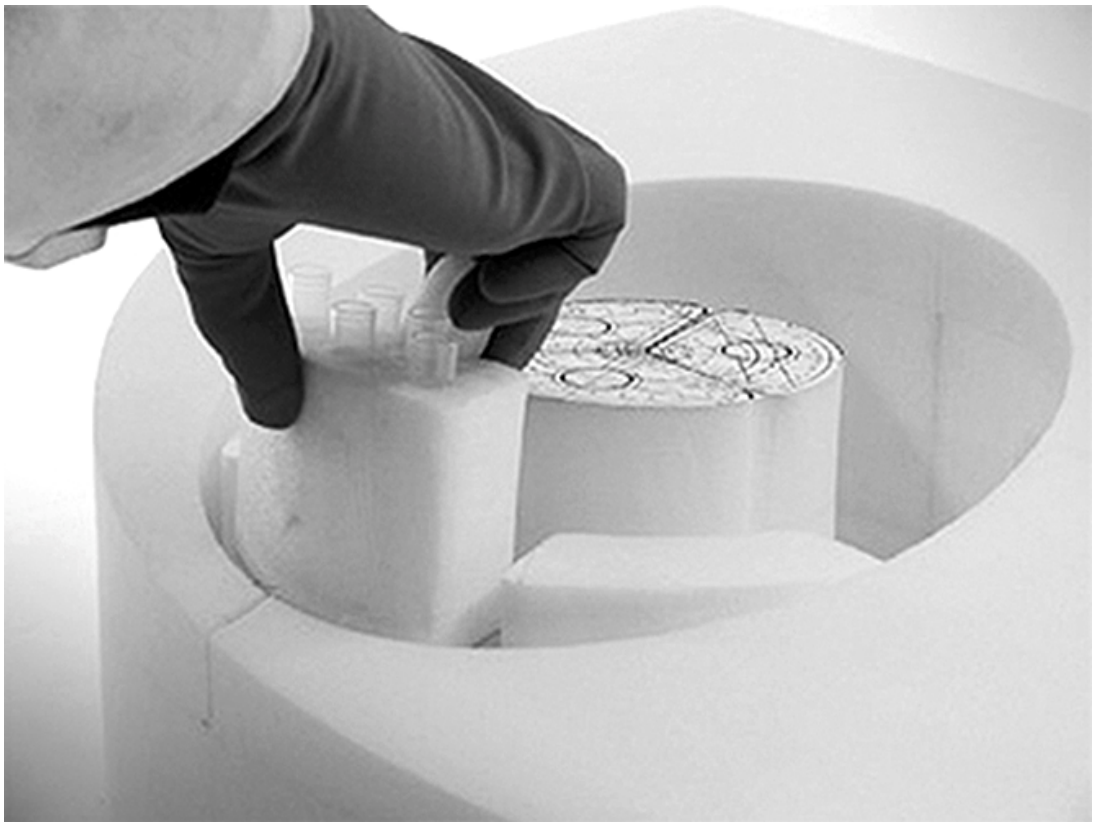


Human factors

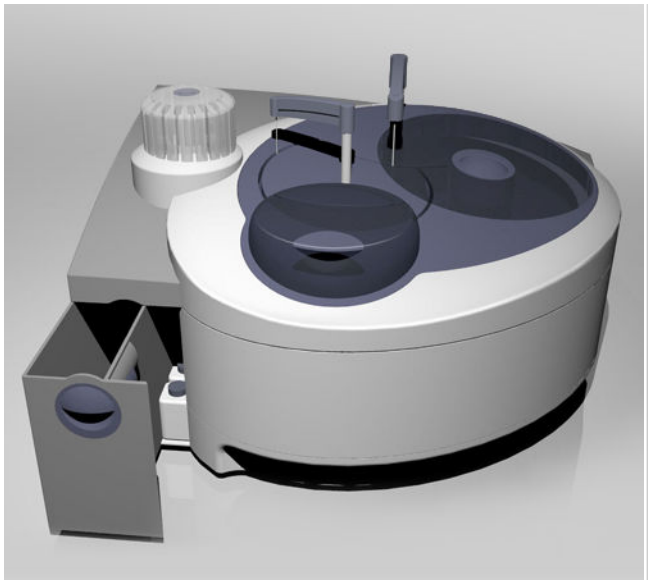
User access



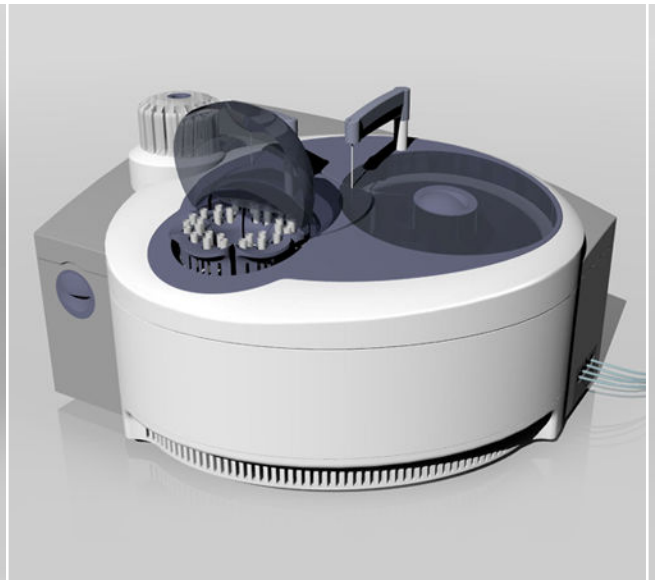
Evaluate working height + spacing
for overall height and user access to samples and reagent wheel



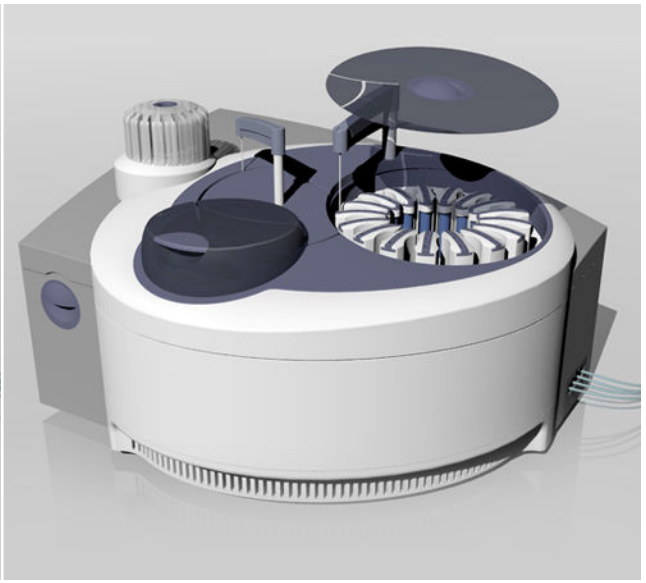
Selected design direction



Waste bin slides forward for access to bulk reagents



Cover hinges to access sample carousel



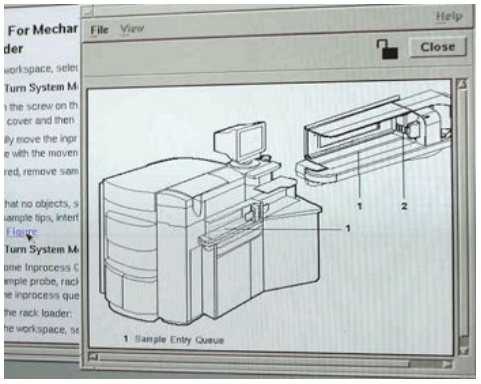
Top access to reagent carousel

BIOKIT

Graphical user interface

Competitive audit



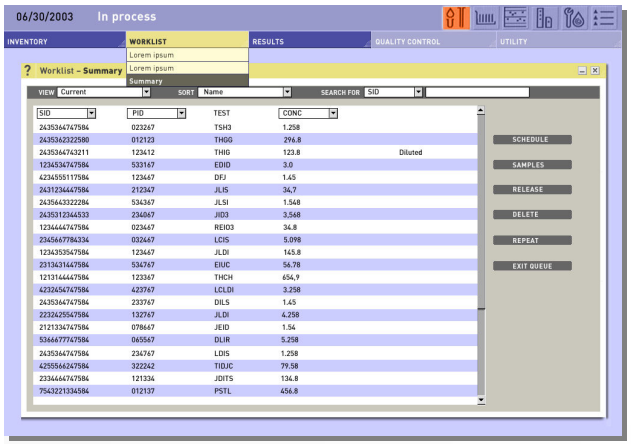




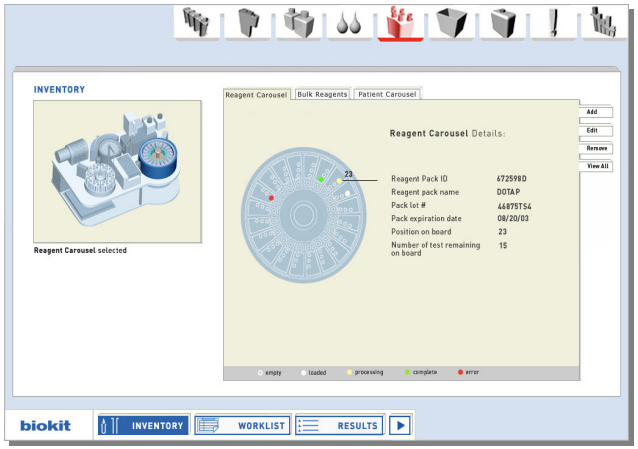
BIOKIT

Graphical user interface

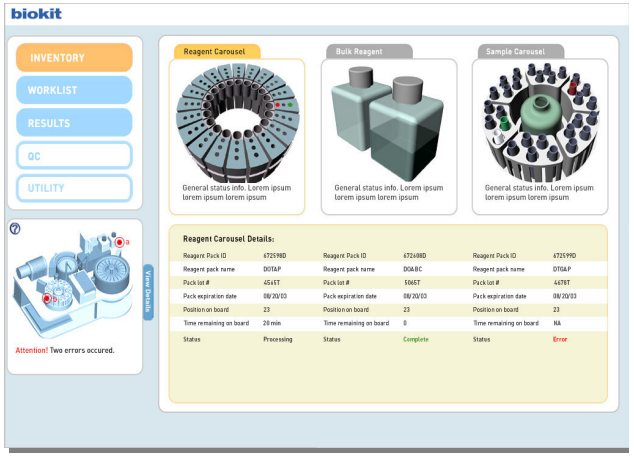
Concept directions



Text-based



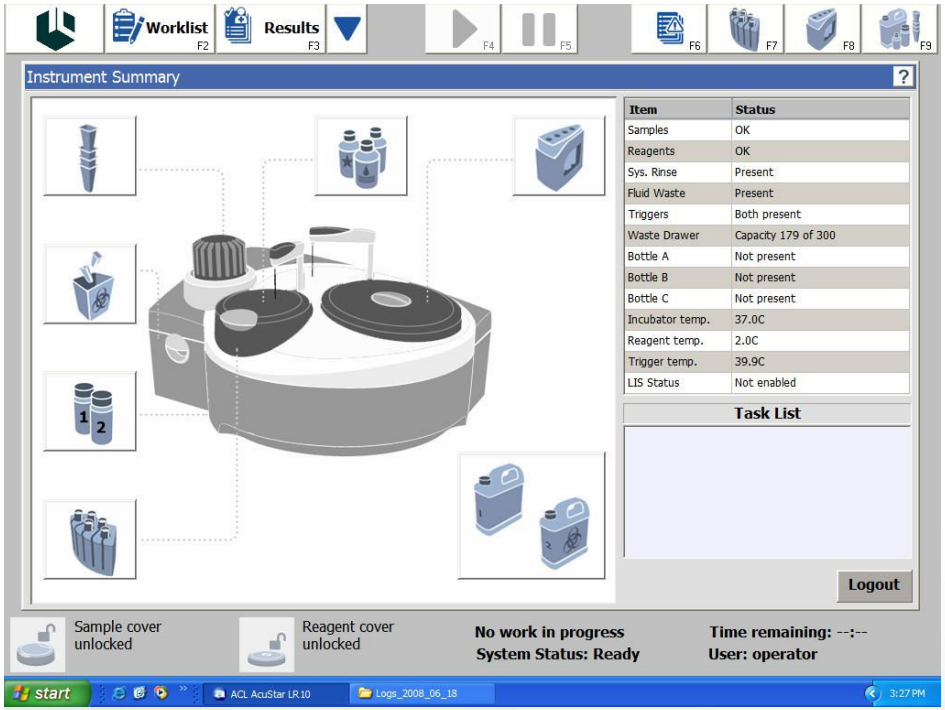
Simple / sophisticated

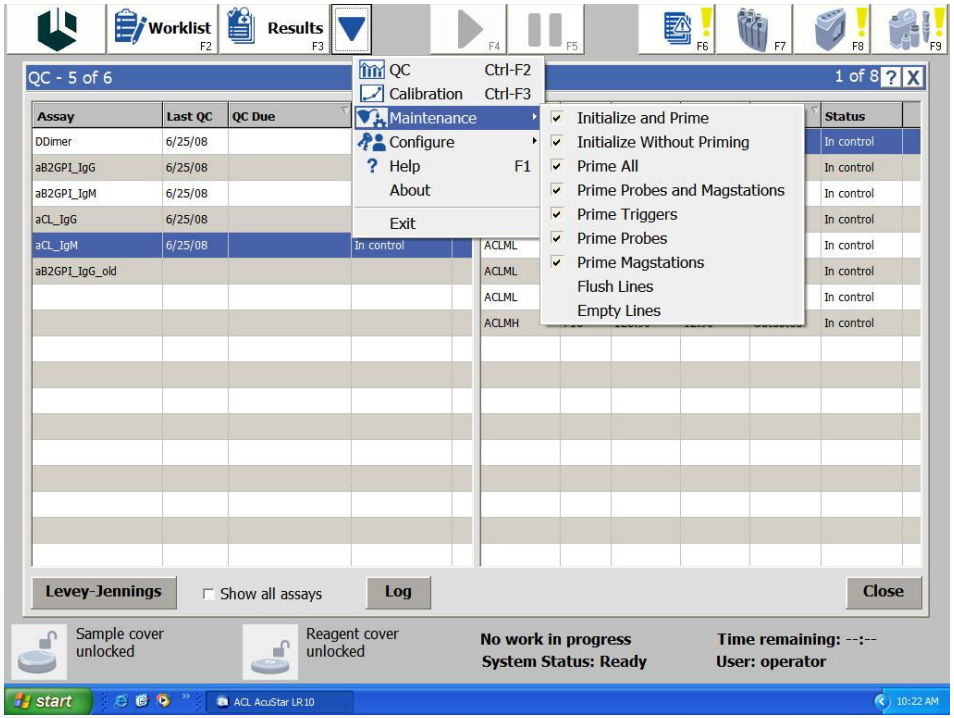


Approachable / robust

BIOKIT

GUI refinements





BIOKIT

Final design

Cardinal Healthcare

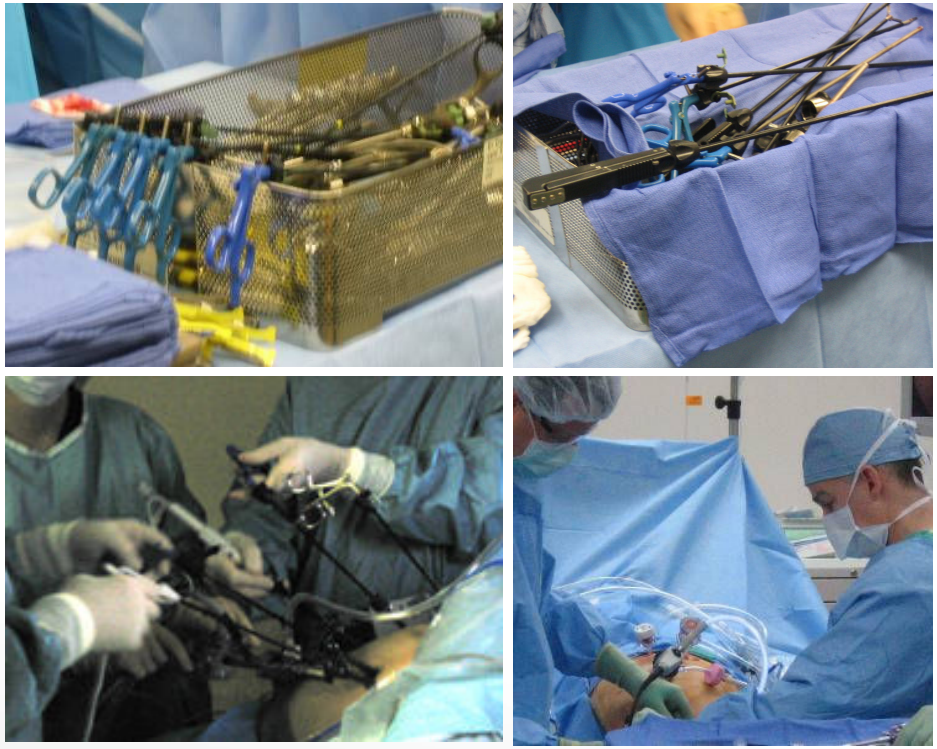
Case study

CARDINAL HEALTHCARE

Competitive audit

Surgical observations

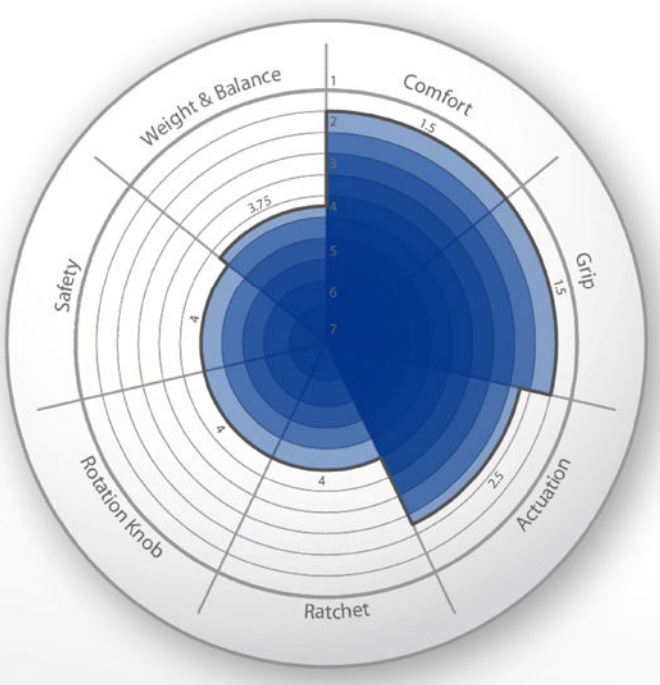
- Procedure-specific hand positions
- Grip styles
- Actuation – rotation knob, ratchet, etc.
- Function-specific activities – lead vs. assist
- Workflow within the sterile field
- Arm positions and stance
- Patient position
- Peripheral instrument relationships



Interviews

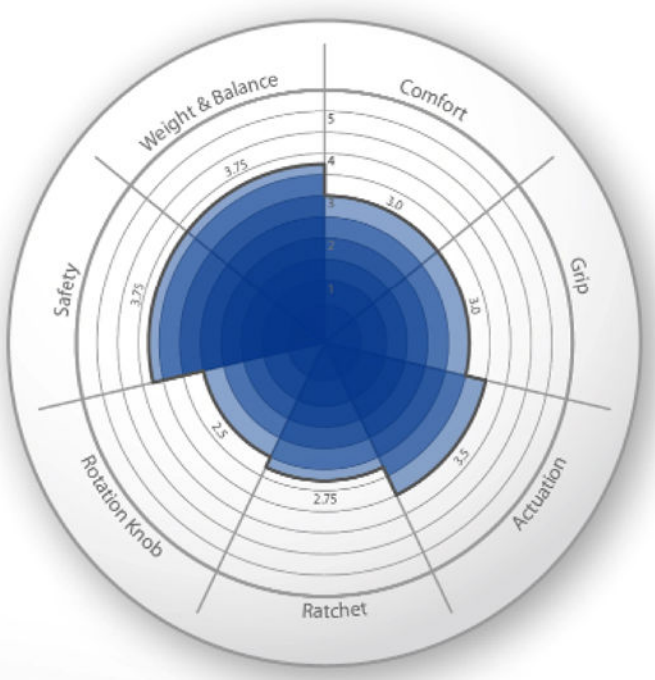
- Preparatory phone interviews
- Surgeon demonstration
- Attribute ranking via card sorting
- Snowden Pencer rating exercise based on sorted attributes
- Pugh Analysis comparing competitive products to Snowden Pencer
- Questions covering ergonomics and brand

Attribute rankings + Snowden Spencer ratings



Rankings: 1 = most important 7 = least important

Attribute Ranking (n = 23)



Ratings: 1 = poor 5 = excellent

Snowden Pencer Rating (n = 21)

Pugh Analysis

Results

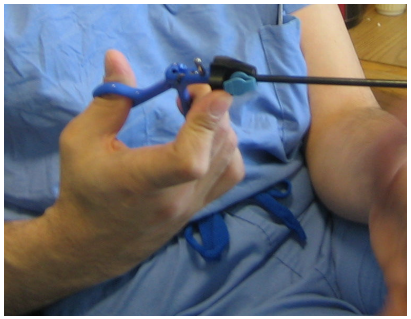
	A	B	C	D	E	F	G	H
								
Comfort	2	1	5	-3	7	6	-12	-6
Grip	-4	-8	4	-8	0	0	-8	-5
Actuation	-1	0	0	-4	1	-5	-8	4
Ratchet	-1	-2	-3	n/a	n/a	-5	-10	1
Rotation Knob	-11	3	1	9	10	2	-2	7
Safety	-2	-5	0	-4	0	2	-6	-2
Weight & Balance	-3	-3	0	0	2	2	-10	-1

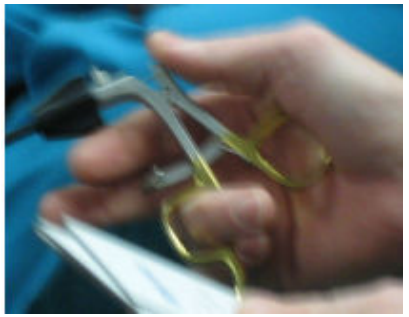
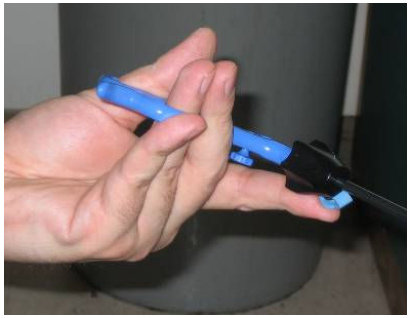
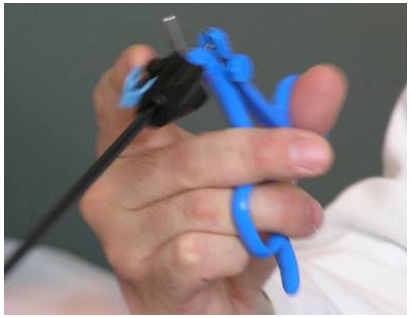
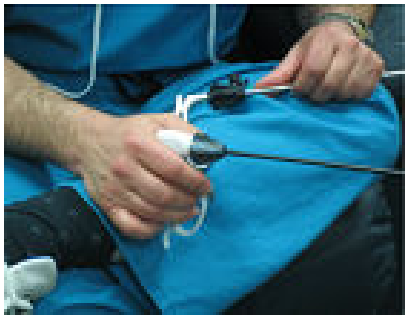
Variant observation

Grip styles

Ring variants: One finger above front ring, two fingers above front ring, two fingers in front ring
Implications: Rotation knob location, space allocation above front ring, ergonomic angle

Palming variants: Ring finger in front ring, middle finger in front ring, no finger in front ring
Implications: Need to facilitate opening of handle with no fingers in the rear ring


Research recommendations

Attributes

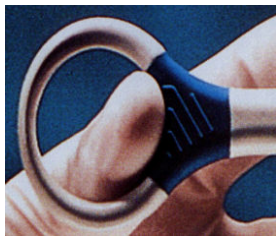
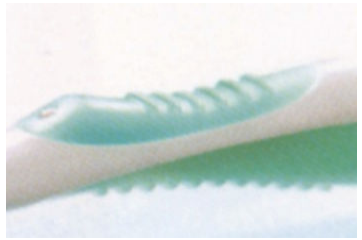
Comfort

Enlarged rings, contoured fit
Distributed pressure
Soft materials



Grip

Texture for thumb actuation while palming
Finger rest above front ring
Minimize bulk
Accommodate different grip styles


Rotation knob

Longer finger channels
Softer / easier detents when turning



Ratchet

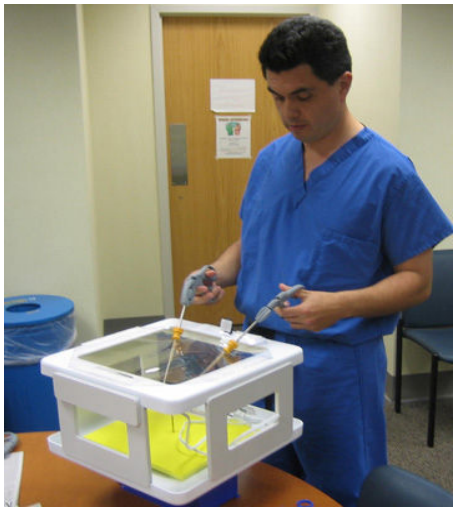
Relocate release button
Add defeat mechanism



CARDINAL HEALTHCARE

Preference testing

Iterative models



CARDINAL HEALTHCARE

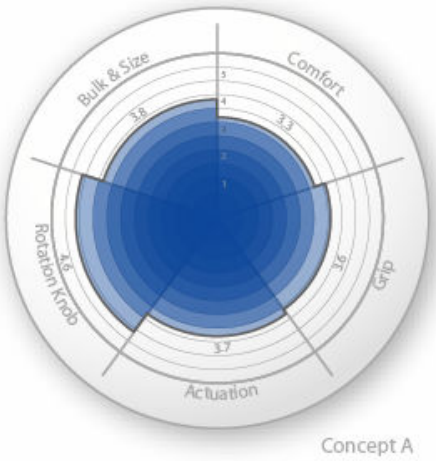
Preference testing

Iterative models

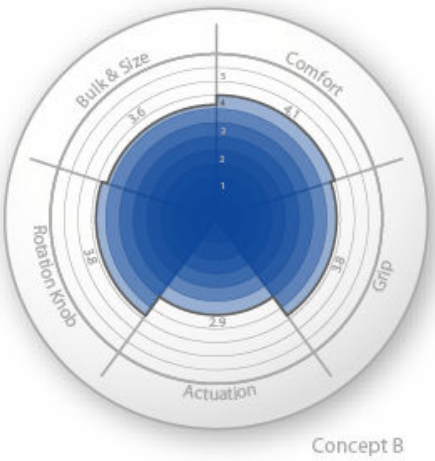
Concept A

Concept B

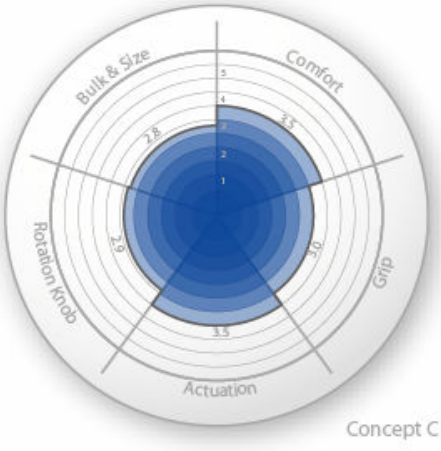
Concept C



Concept A



Concept B

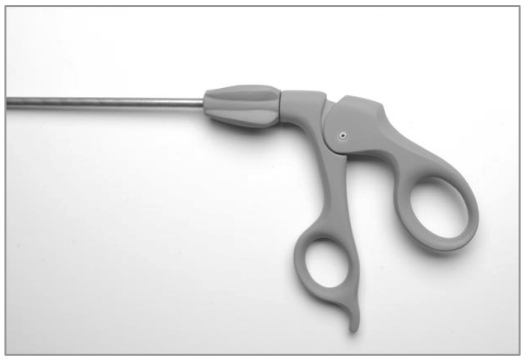


Concept C

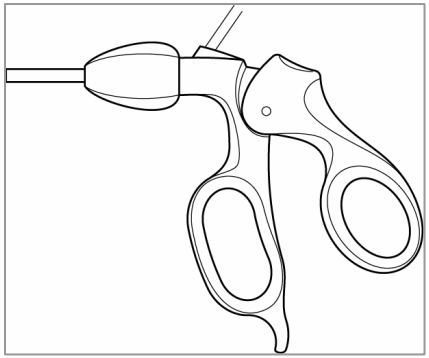
CARDINAL HEALTHCARE

Preference testing

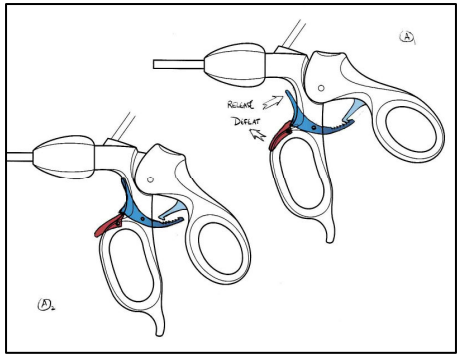
Working model development process



Chosen concept



Refinement



Ratchet design

CAD development

Working model

Cardinal Healthcare

Final design

Research informs medical device design

Following good UCD process is critical (and *required*) for medical devices

Field research is crucial due to physical interactions

Research involved during all phases of development

Multidisciplinary teams achieve the best results

farm

THANK YOU.

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