



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

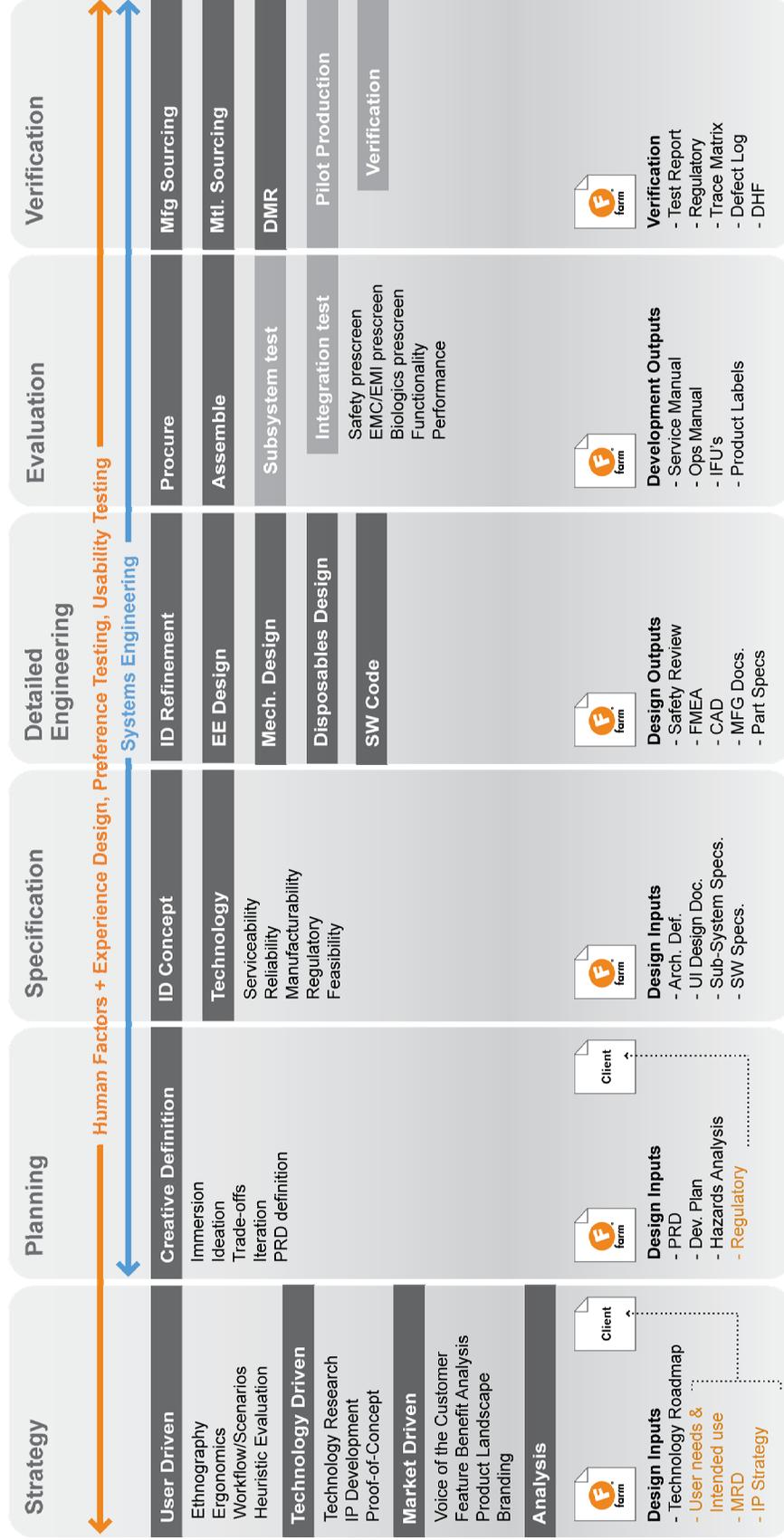
Medical + manufacturing expertise

Two facilities including labs

FDA and ISO compliant



TOTAL PRODUCT DEVELOPMENT



820.30(b) • Planning

ISO 13485 (7.3.1) • Planning

820.30(d) • Design Output

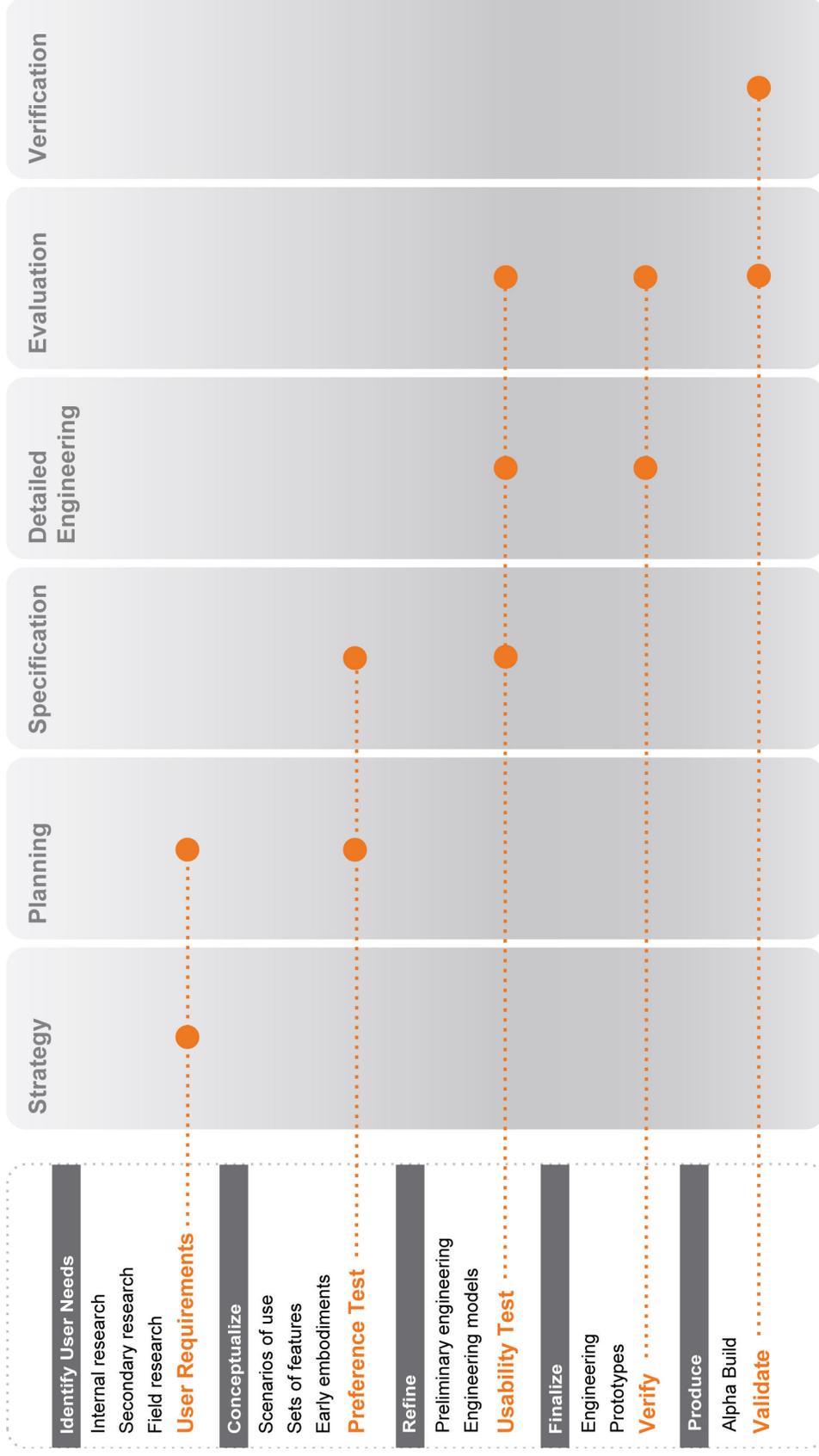
ISO 13485 (7.3.3) • Design + Development Outputs

820.30(e) • Verification

ISO 13485 (7.3.5) • Design + Dev. Verification



User-centered design



Multi-disciplinary approach

Industrial Design

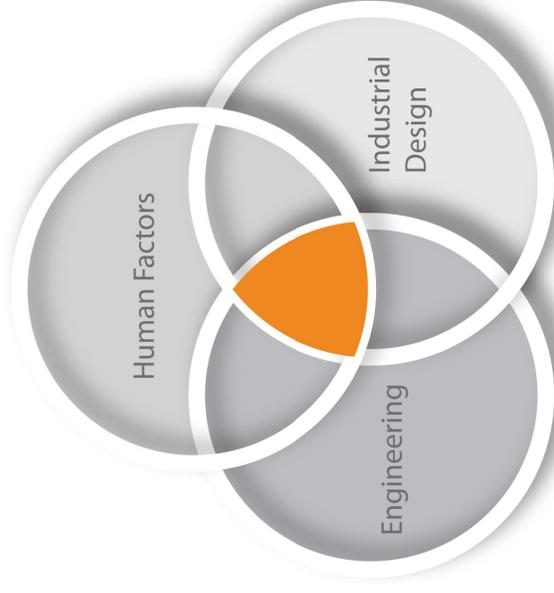
Aesthetic and ergonomic problem solving
Visual communication – sketches, graphics, 3D models

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



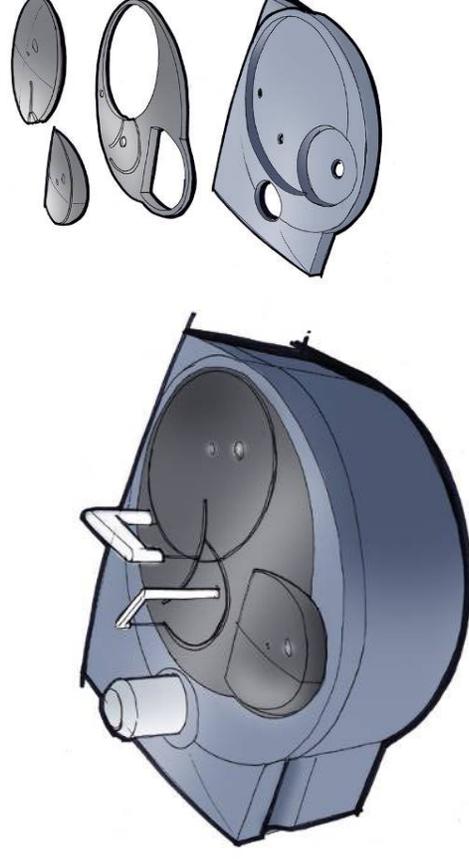
Design development

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

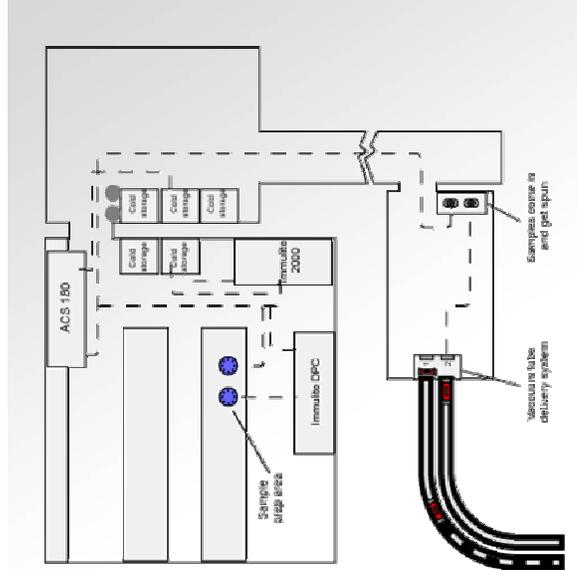
Clinical Analyzer



BIOKIT

Field context

Environment observations



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



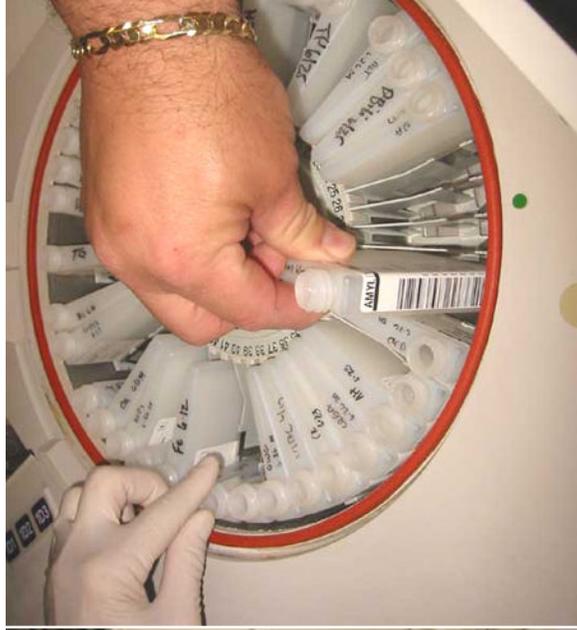
BIOKIT

Field context

User interactions



Loading options



Evaluate spacing

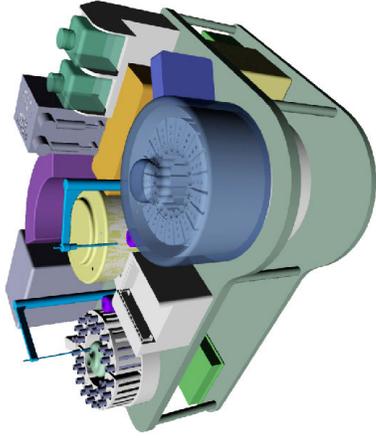


Evaluate cuvette packaging

BIOKIT

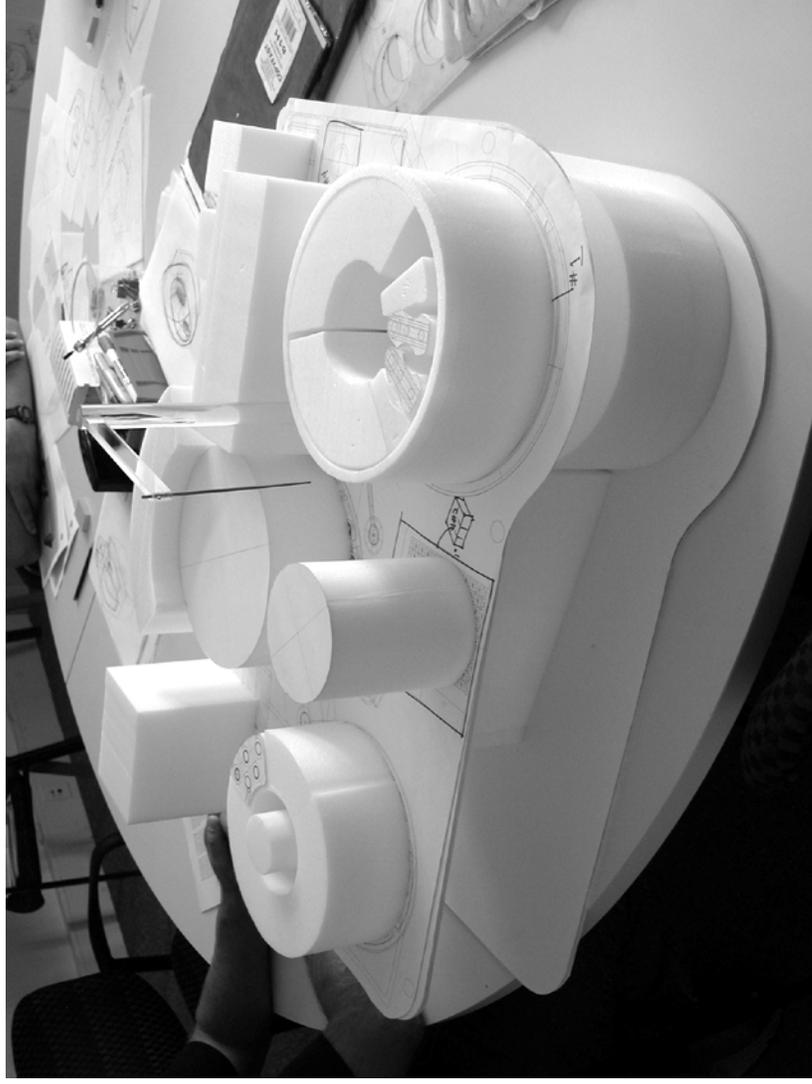
Component architecture

Evaluation of scale



Component assembly - understanding components and their relationships to one another

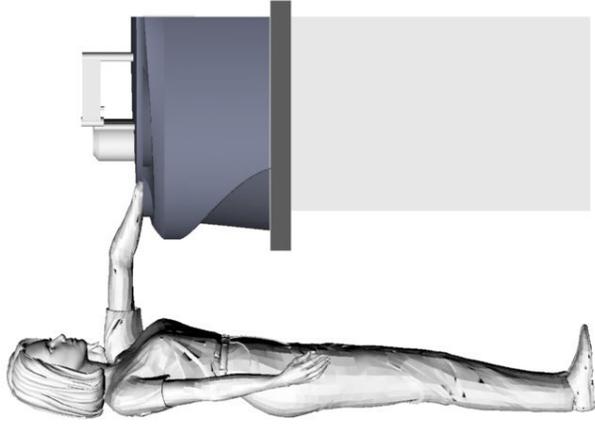
Foam mock-up - for evaluating and modifying scale, components, and working heights



BIOKIT

Human factors

User access

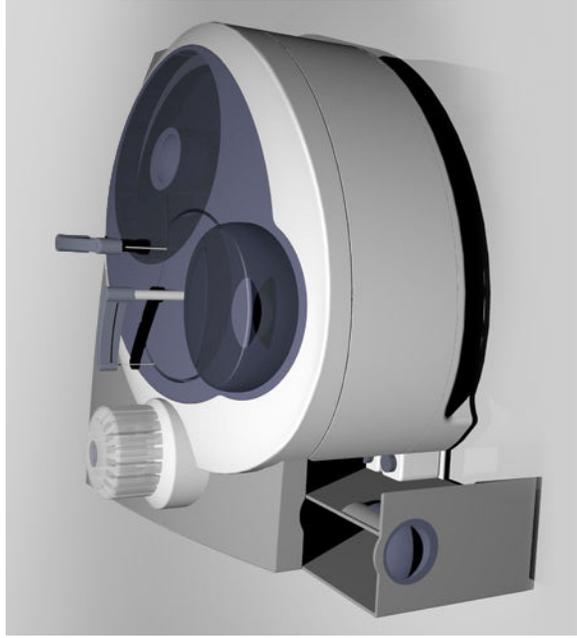


Evaluate working height + spacing
for overall height and user access to
samples and reagent wheel

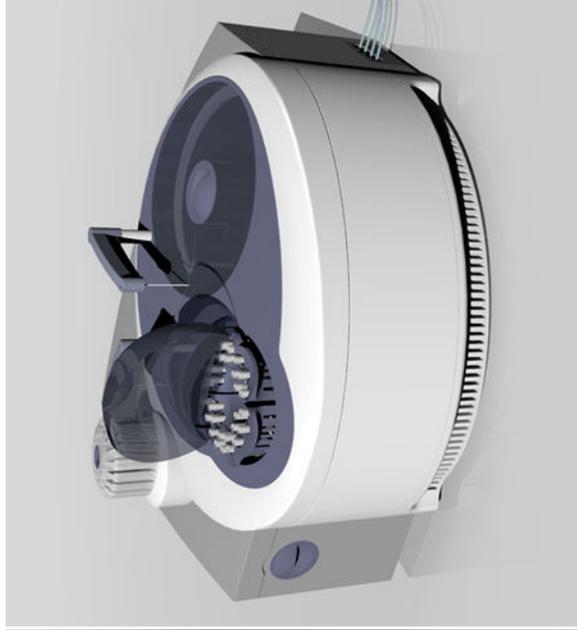


BIOKIT

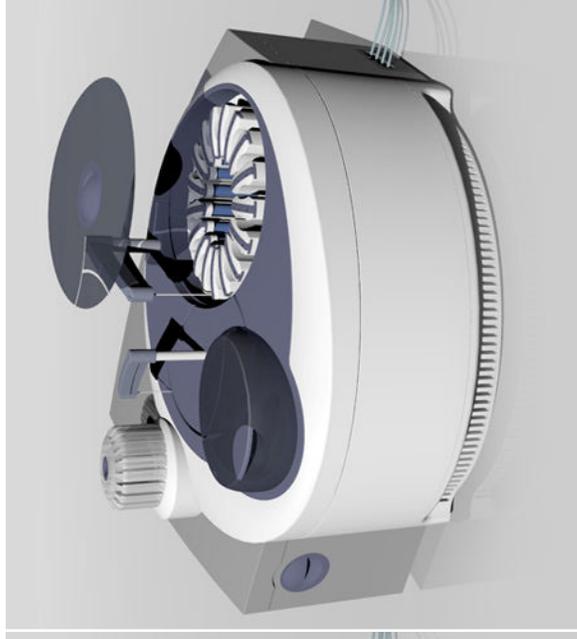
Selected design direction



Waste bin slides forward for access to bulk reagents



Cover hinges to access sample carousel

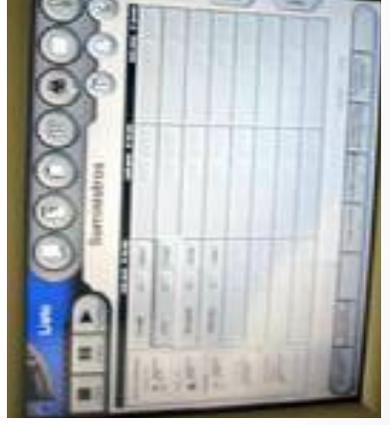
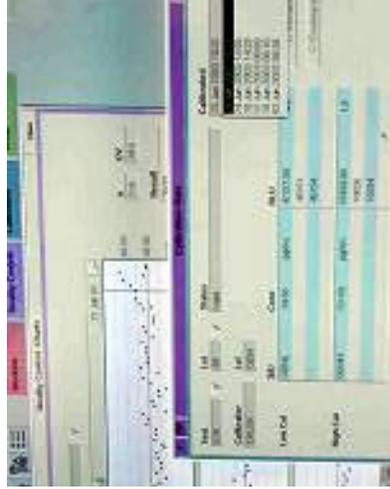
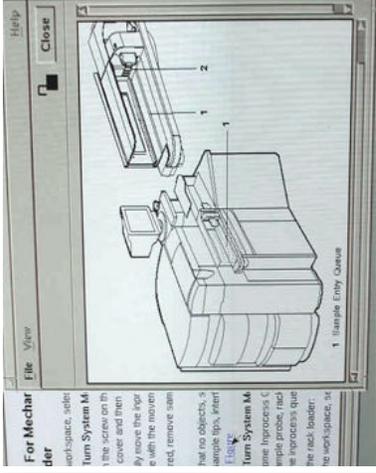


Top access to reagent carousel

BIOKIT

Graphical user interface

Competitive audit



BIOKIT

Graphical user interface

Concept directions

06/30/2003 In process

UTILITY

RESULTS

WORKLIST

Inventory

SEARCH FOR: SLD

ID	TEST	CONC	NAME
242934479784	1540	1.298	
242934479784	1540	296.8	
242934479784	1160	122.8	Diuron
242934479784	895	1.65	
242934479784	AL5	34.7	
242934479784	AL5	1.548	
242934479784	80023	24.9	
242934479784	LE5	5.098	
242934479784	AL0	145.8	
242934479784	EL0	96.78	
242934479784	LE0	3.298	
242934479784	DIL5	1.45	
242934479784	AL0	4.298	
242934479784	AL0	1.298	
242934479784	LD5	1.298	
242934479784	TD0C	79.9	
242934479784	J015	134.8	
242934479784	PS1L	456.8	

UTILITY

SCHEDULE

ZAPLES

RELEASE

SELECT

REPEAT

EXIT QUEUE

Text-based

INVENTORY

Reagent Carousetl selected

Reagent Carousetl Details:

- Reagent Pack ID: 4725910
- Reagent pack name: DDTAP
- Reagent lot #: 4487154
- Position on board: 23
- Time remaining on board: 15
- Position on board: 23
- Time remaining on board: 15

Inventory

Worklist

Results

Utility

Simple / sophisticated

biokit

INVENTORY

WORKLIST

RESULTS

QC

UTILITY

View Details

Reagent Carousetl Details:

- Reagent Pack ID: 4725910
- Reagent pack name: DDTAP
- Reagent lot #: 4487154
- Position on board: 23
- Time remaining on board: 24 min
- Status: Processing

Bulk Reagent:

- Reagent Pack ID: 4724880
- Reagent pack name: DDTAP
- Reagent lot #: 4487154
- Position on board: 23
- Time remaining on board: 5
- Status: Complete

Sample Carousetl:

- Reagent Pack ID: 4725910
- Reagent pack name: DDTAP
- Reagent lot #: 4487154
- Position on board: 23
- Time remaining on board: 14
- Status: Error

Attention! Two errors occurred.

Approachable / robust



BIOKIT GUI refinements

Instrument Summary

Item	Status
Samples	OK
Reagents	OK
Sys. Rinse	Present
Fluid Waste	Present
Triggers	Both present
Waste Drawer	Capacity: 179 of 300
Bottle A	Not present
Bottle B	Not present
Bottle C	Not present
Incubator temp.	37.0C
Reagent temp.	2.0C
Trigger temp.	39.9C
LIS Status	Not enabled

Task List

Sample cover unlocked
Reagent cover unlocked

No work in progress
System Status: Ready

Time remaining: ---
User: operator

Logout

QC - 5 of 6

QC Maintenance
Calibration
Configure
Help
About
Exit

Assay	Last QC	QC Due	Status
DBimer	6/25/08		In control
AB2GPI_Ljg	6/25/08		In control
AB2GPI_LjM	6/25/08		In control
aCL_Ljg	6/25/08		In control
aCL_LjM	6/25/08		In control
AB2GPI_Ljg_ald			In control

Initialize and Prime
Initialize Without Priming
Prime All
Prime Probes and Magstations
Prime Triggers
Prime Probes
Prime Magstations
Flush Lines
Empty Lines

Levey-Jennings
Show all assays
Log

Sample cover unlocked
Reagent cover unlocked

No work in progress
System Status: Ready

Time remaining: ---
User: operator



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

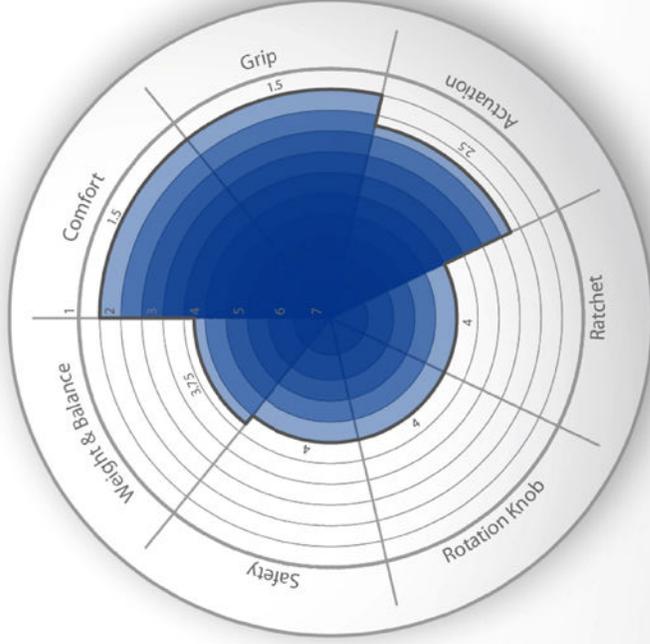
Snowden Pencer rating exercise based on sorted attributes

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 Spencer 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

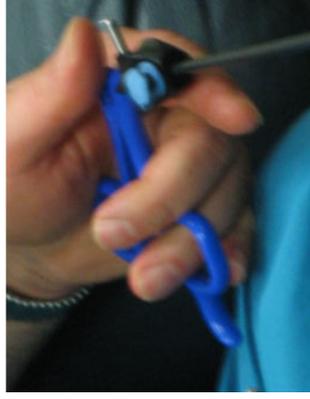


Variant observation

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

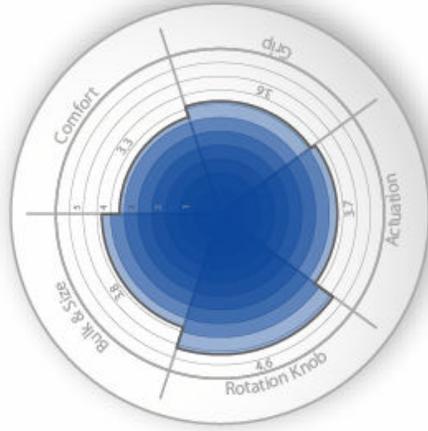


Preference testing

Iterative models



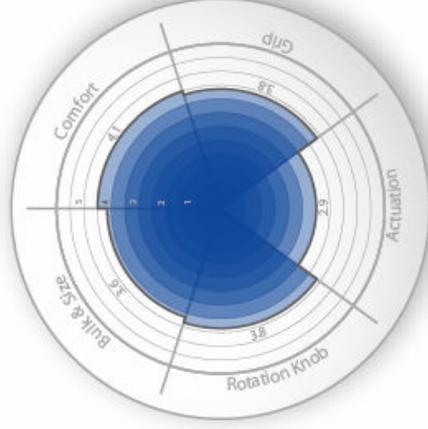
Concept A



Concept A



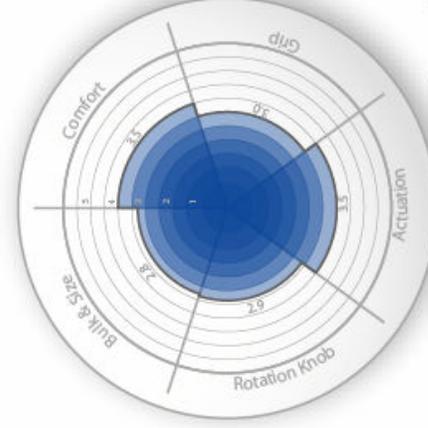
Concept B



Concept B



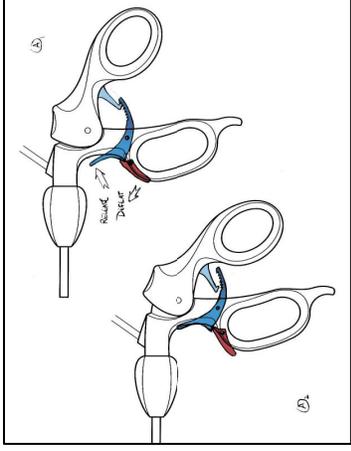
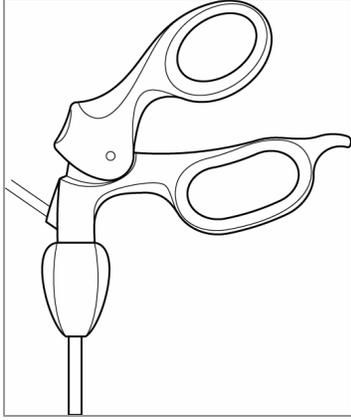
Concept C



Concept C

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



THANK YOU.



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