HELP DESIGN CO.

PRODUCT DEVELOPMENT FROM STRESS ENGINEERING SERVICES

HUMAN FACTORS IS MORE THAN JUST READING STANDARDS.

Human Factors & Ergonomics

WITH PREDICTIVE ANALYSIS AND HUMAN FACTORS TESTING UNDER THE SAME ROOF, OUR ISO 13485 CERTIFIED MEDICAL DEVICE DEVELOPMENT FIRM IS RETHINKING USER-CENTERED DESIGN.

The product development team at Help Design Co. goes beyond the conventional approach to human factors by harnessing the analytical and testing horsepower of Stress Engineering Services (SES) to generate product-specific anthropometric data to both guide formative usability studies and develop the specifications against which summative studies are measured. While these methods are most often applied to medical device design, our rigorous approach to human factors has been used for consumer products as well.

By utilizing SES's testing and analytical capabilities, our team can simulate the effect of conceptual devices on human tissue before even a prototype is made. And with a prototype or competitive device in hand and access to SES's 30,000 sq. ft. testing facility, our development team can instrument devices and users to identify the real-time forces they experience while using a device. Our team has also developed several encoder-equipped prototypes for use with surgical simulators or to test the performance of prototype devices against existing competitors,on simulated tissue.

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No. 497

TRADITIONAL USABILITY STUDIES TELL YOU WHICH WAY TO GO. OUR PROCESS TELLS YOU HOW FAR.

Human Factors & Usability have been identified as important contributors to the safety and efficacy of regulated medical devices.

The US Food & Drug Administration's (FDA) regulations and guidance regarding medical device development are in place to assure the safety and efficacy of new devices. Standards such as ISO 13485, 60601, and 62366 govern the technical aspects of three classes of devices (I, II and III), according to the level of risk associated with their use. However, because "use-related hazards can exist even if [a device] operates according to specifications," these and other standards also address less technical aspects of device development, including human factors and usability (standards that are addressed, in detail, in ANSI/AAMI HE75).

Our team uses observational research methods, including contextual inquiry and storyboarding to illustrate surgical procedures, such as this gastric bypass, to look for opportunities to enhance device safety.

With this enhanced focus on human factors and usability, many design firms have found new outlets for their voice of customer research practices. These qualitative practices contribute effectively to forming high level design requirements, but they often fall short of providing the actionable metrics from which detailed product specifications can be created.

This model, created from a CT scan, was used to guide sizing calculations for a device designed to operate on the vocal folds of pediatric patients.

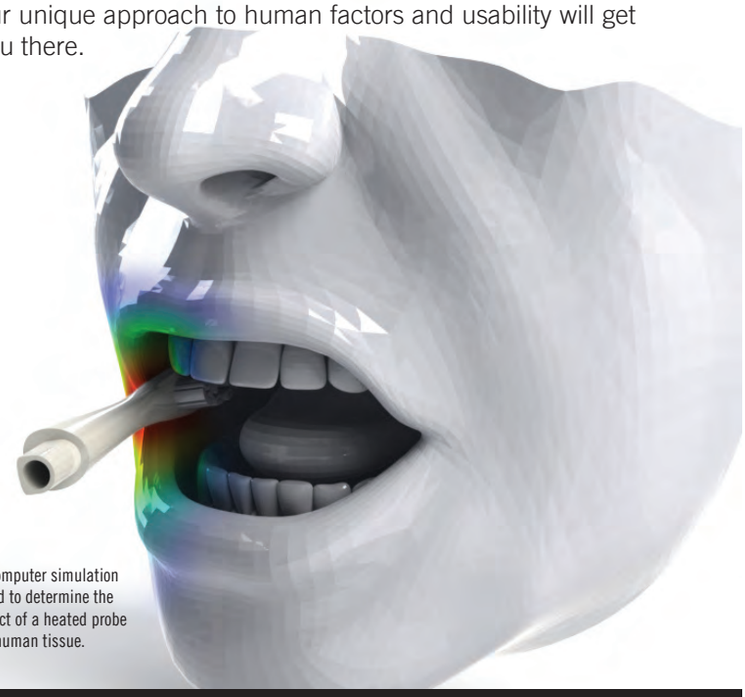
HELP Design Co. couples voice-of-customer and observational research methodologies with computer simulation and testing to develop actionable human factors metrics for both formative and summative usabilities studies. These metrics also provide the foundation of product-specific anthropometric data that drives the sizing calculations that yield a safe and usable device.

Our team has a long history of instrumenting devices and users to deliver real-time performance data. Used in a simulated clinical environment, this data can provide valuable performance information on existing or prototype devices and key technical and human factors input to inform formative or summative usability studies.

This trocar has been instrumented with strain gauges to determine the loads it experiences during a simulated surgery. Once determined, this data becomes a driver for the design requirements of future devices.

With these unique testing and analysis capabilities and our design-by-analysis approach to product development, our design team develops product-specific anthropometric data to drive the size, shape and force limitations of a new device and balances those human factors constraints against the technical, cost and clinical requirements necessary to create a successful device.

If your team is focused on the delivery of a safe, reliable and efficacious new medical device on an aggressive schedule, our unique approach to human factors and usability will get you there.



A computer simulation used to determine the effect of a heated probe on human tissue.

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