



Human Factors for Giraffe OmniBed Carestation

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Human Factors in Medical Devices

Human error is a critical factor in the safety and efficacy of medical devices. Healthcare professionals and users of medical devices are human after all, making them susceptible to mistakes. In fact, user error continues to be a serious and significant theme in the medical device industry; it's also recognized by the U.S. Food and Drug Administration (FDA). It is estimated that about 69% of patient injuries in hospital results from human error.¹ According to the FDA, 40% of product recalls and adverse events have roots in user-device interaction. Between 2010 and 2012 alone, complex or non-intuitive user interfaces were identified as one of the four factors that resulted in more than two-thirds of medical device recalls.² These statistics are clear indicators of just how important it is for medical devices to be intuitive and easy to use.

Complexity in Perinatal Care

Labor and Delivery (L&D) and the Neonatal ICU (NICU) are complex, high-stress environments that increase the potential for medical errors. Factors such as clinician workload, stress, workflow interruptions, sleep deprivation, and the need to care for multiple patients simultaneously while also lacking consistency in staff and equipment consistency between care areas are proven to increase the likelihood of medical errors^{3,4,5,6,7}. Like all hospital patients, pre-term or ill infants in the NICU are also susceptible to medical errors. But with underdeveloped organ systems, patients in the L&D or NICU are more vulnerable to the deadly consequence of such errors. Medical devices used within the L&D and NICU environments – such as incubators, warmers, hybrid devices, ventilators, CPAP, phototherapy and transport devices – must not complicate user workload; such added stress can increase the likelihood of errors.

Technology and Decision Making

At a high-level, decision making is based on the information we receive (perception), how we process this information (cognition) and how we interact with the system (action). Technology today has changed all three components. And while it may seem that technology has improved the ability to make more informed decisions, the abundance of information isn't always positive. Much of it may not be relevant or aide in patient care decision making. And that can increase mental workload, reduce situational awareness and thus deteriorate decision making. Research has shown that adopting human factors design principles to medical device design can reduce cognitive workload and errors by 50 percent, and improve efficiency by 15 percent.⁸

How the Giraffe OmniBed Carestation promotes safety, efficiency and efficacy through human factors design

The Giraffe OmniBed Carestation is a hybrid device – an incubator that converts into an open bed warmer with a single user action, thus performing all functions of a typical incubator and warmer.

Fundamentals of ergonomics, anthropometry and human factors, along with guidance from FDA (HE75), are incorporated in the physical product and graphical user-interface of the Giraffe OmniBed Carestation. Below, we focus on the critical human factors principles that impact clinical decision making, and in turn, safety (reduce use errors), efficacy and efficiency (adapted from Neilson and Molich, 1990).

I. Decision Making – Perception

Perceptual errors occur when information provided to the user is difficult to locate, illegible and cluttered.

Visibility – Perceptibility of information is essential to enabling detection and recognizing information. Information displayed on the graphical interface or physical product interface needs to be visible to the user, and clear and legible in clinical use context.

Giraffe OmniBed Carestation –

Critical parameters such as air and baby temperature (required to regulate the thermal environment) are available to the user as larger text on the display. Secondary information such as Air Boost, servo oxygen levels and incubator humidity levels are available as smaller yet still legible text. Visual information on the device is provided as white text on either a black background (best contrast) or blue background (good contrast). Moreover, system status such as active mode (baby vs air vs manual) or when the Air Boost, servo oxygen or humidity features are in use, is clearly displayed to the user. The in-bed scale provides on-screen visual animation



as well as text instructions for weighing the patient. The weight is then available to the clinicians and family in larger, brighter text displayed on a family-friendly (away) screen. Additionally, on the physical front, the user can determine water levels in the humidifier reservoir placed directly in front of the device.

Impact – Brightness contrast seen in the OmniBed is likely to reduce visual search time, thereby increasing visual efficiency.⁹ Visible system status helps clinicians maintain good situation awareness in the complex L&D or NICU environments.¹⁰

Visual Clutter – Visual clutter is important in visual search. For complex NICU environments, clutter distorts visual information and makes it challenging to process information. It can impair the ability to identify critical information, such as alerts and patient status, on visual displays.

Giraffe OmniBed Carestation – To reduce visual clutter, device and clinical parameters are functionally grouped. Frequently used parameters are shown on the main display. For example, set, actual parameter values (e.g., thermal controls, individual patient care needs, and patient care/trends, etc.) are grouped together on the main display. Alarm limits associated with the parameter are also spatially located in the parameter block. Furthermore, a dedicated space is available to display active alarms. These attributes reduce visual clutter.



Impact – Visual clutter is directly linked to reaction time.¹¹ For a clinician taking rounds in the NICU, the spatial arrangement and functional grouping enables the clinician

to quickly and easily see an overview of the patient and device with minimal visual distractions. Moreover, the dedicated area for alarms allows the user to quickly take notice of alerts.

II. Decision Making – Cognition

Cognition errors occur when information provided to the users is delayed, complex, inconsistent or requires mental computation.



Real World – A user mental model of the display use is directly linked to how users scan and view things. A Nielsen research study (2007) shows that when users view content on display, they follow a 'F' pattern.¹² To align with this mental model, primary information needs to be placed on top of the display, followed by next level of information located at the left, and center thereafter to complete the 'F' pattern.

Giraffe OmniBed Carestation – Critical information (temperature parameters and patient information) on the device is placed horizontally on the top area. Secondary information is kept vertically on the left side of the display (air boost, oxygen, humidity). This pattern arrangement allows the user to first glance through the important parameters in order to perform other operations, such as changing device settings, viewing trends or taking baby weight. In the same F pattern, patient trends are presented to allow the user to efficiently evaluate specific conditions of the patient and device environment to evaluate status.

Impact – Following the same pattern that humans view displays/websites daily results in faster information processing, thereby increasing efficiency of use.

Minimize memory load – Spare mental capacity is one of the factors for workload determination. This factor is important to consider in complex work environments such as the NICU. The theory is that as more load is imposed on the memory, less space is available to perform other tasks, deteriorating performance.¹³ For a clinician, patient care is the primary task; device operation is secondary.

Giraffe OmniBed Carestation – Upon receiving an alarm, the device provides contextual help. This help feature provides context-based information to the user on what activated the alarm (activation criteria), the cause of the alarm (possible cause) and next steps to be performed (actions). This information eliminates the need for users to remember the alarm and corresponding details from the memory. Second, the weighing sequence provides step-by-step task guidance to obtain weight. Patient weight details (last weight and other weights from history) are easily available to the user on a secondary screen; allowing users to quickly determine weight progression during the period of care on the Giraffe OmniBed Carestation.



Impact – Providing users with relevant information as and when needed reduces the load on working memory to recall, thus reducing cognitive workload (error likelihood) and improving performance (efficacy).

Feedback – One of the ways through which humans detect a change is through feedback (visual, audio or tactile). Feedback on information or change in state is vital to reducing ambiguity in determining device status.

Giraffe OmniBed Carestation – For every click/touch on the graphical interface or on the physical device, there is instantaneous feedback to the user. For graphical interface, when a button is pressed, the color of the button changes along with the value/state being changed in form of visual feedback. The Air Boost, for example, animates the icon when activated. For the physical product, tactile and visual feedback is provided to the

user when raising the patient compartment; visual and audio feedback is provided by latching the compartment doors and porthole.



Impact – Feedback to the user can reduce data misinterpretation and confusion, thereby improving efficacy of use.

III. Decision Making/Ergonomics – Action

Action-based errors occur when users have opportunities to inadvertently touch and contact the device, and when controls are difficult to reach and operate.

Fitts Law – Fitts Law shows that the time required to move to a target (on graphical user interface or physical interface) is a function of the distance and width (size) of the target. In simple terms, the larger the target, operations are faster and errors are fewer.¹⁴

Giraffe OmniBed Carestation – Careful research and conscious effort has gone into the activation areas of the Giraffe OmniBed Carestation. Soft buttons, as well as physical buttons/controls, are larger to accommodate body anthropometrics (finger: touch screen; hand: controls; foot: switches for canopy lift and elevating base, etc.).

Impact – With larger surface contact on the device, operations can be performed faster with fewer unintended clicks/key presses, thereby reducing use errors (safety).

Preventing Errors – Good design prevents errors without relying on labels and error messages to reduce them.

Giraffe OmniBed Carestation – To prevent inadvertent contact with the graphical user interface and physical product, the device allows the user to lock the screen (away mode) and disable elevating pedals respectively. In away display, the device graphical interface locks itself to prevent accidental touches on screen during device cleaning and when not in use (e.g., during kangaroo care). Likewise, during a clinical procedure such as ECMP or HFOV, when accidental foot pedal activation may occur, the users can disable the elevating column.



Impact – Purposeful design helps prevent use errors (safety).

While the device features described above ease clinical workflow and aid in decision making, other features of the device are aimed to improve parent and clinical user experience.

Parent Experience

Parents provide kangaroo care with their baby in the L&D and NICU environments. Known to improve physiological responses and decrease pain response in preterm infants, kangaroo care also reduces stress and increases bonding. To allow parents easy access to their infant, the mattress tray (patient bed) can be translated out (toward parents) by six inches and the drawer can be pushed out (away from parents). If the baby (patient) is positioned in opposite direction on the mattress where access is limited, the mattress tray can be rotated for desired orientation (reducing negative touches). These simple movements allow parents to comfortably sit right beside their baby, who continues to be continuously monitored and cared for within the Giraffe OmniBed Carestation. These attributes are likely to improve parent experience.

Clinical User Experience

Alarm fatigue is a well-documented phenomenon in the healthcare environment.¹⁶ Upon alarm onset, the clinical user is required to click on the screen/interface to silence. Therefore, the number of clicks and hand movements increase on multiple alarms. During a procedure in a sterile environment or during glove use, the action required to silence alarms interrupts clinical workflow. The Giraffe OmniBed Carestation addresses this problem in two pivotal ways. First, with Smart Alarms, the device automatically disables the alarms in pre-heat mode. Second, with a hands-free alarm silence feature, the user can simply wave a hand in front of the screen to silence



the alarm. Additionally, the 360° rotation of the Giraffe OmniBed Carestation mattress provides flexibility of movement when positioning a patient for clinical procedure; more so when performing complex procedure wherein multiple pieces of equipment are placed around the Giraffe OmniBed Carestation. Both factors are intended to improve clinical user experience.

Occupational Injuries and Ergonomics

Nurses and nursing aides, are susceptible to musculoskeletal injuries. Injuries to the shoulder and neck are prevalent among

nurses in hospitals.¹⁷ Repetitive work in awkward posture is one of the primary contributing factors for physical fatigue and injury development.¹⁸ Work-related injuries have direct consequence on quality of care and patient safety.¹⁹ With the Giraffe OmniBed Carestation, the user can convert the incubator into an open bed warmer with a single user action warmer with one-touch of a button or by depressing the foot pedal. By eliminating manual operation of repetitive lifts and reaching above the shoulder, the device supports good ergonomics and reduces the risk of shoulder and neck fatigue. This automation is likely to reduce direct and indirect costs associated with neck and shoulder injury within the NICU environment.

What does this mean for you?

With the Giraffe OmniBed Carestation, clinical users are systematically provided with relevant, timely information that enables better, faster and more informed decisions. While the device uses human factors principles to improve clinical decision making, its attributes and features such as mattress translation, rotation, hands-free silence, etc., contributed to an improved parent and clinical user experience. In summary, incorporating human factors principles, in new design or iterations after product release, can help to reduce use-errors (safety), increase information processing (efficiency), reduce mental workload (performance), and also enhance parent and user experience.

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Imagination at work

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