Risk Management
Mobile Cart Computer, Model: VENUS-222

Company:	**ONYX HEALTHCARE INC.**
Creation Date:	**2015-06-04**
Abbreviation:	**VENUS-222**
Project Number:	**141201001_1135**
Project Description:	**The model VENUS-222 is a Mobile Cart Computer for medical equipment used.**
Version Number:	**1.01**
Version Description:	**1. Adding new models designation VENUS-192xxxxxxxxxx (where x can be 0~9, A~Z, "-" or blank) 2. Adding 19' panel and alternate enclosure dimension 3. Changing the connecting PCB of USB and battery connector from needs to optional 4. P/N 150401801-1465**
Life Cycle Phase:	**Design and Development**

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	Implemented	Tested	Released
Name	James Chen	Eric Shen	Dean Lin
Date, Signature			Dean Lin

Definitions and Abbreviations

Definitions

Word	Explanation
Abnormal Use	Intended act or intended omission of an act by the user or operator of equipment as a result of conduct that is beyond any reasonable means of risk mitigation by the manufacturer.
Adverse Event	Any device-related event that has or may have caused or contributed to a death, or serious injury/deterioration (of patient, user or other person), or has allegedly involved a device malfunction that would be likely to cause or contribute to a death or serious injury (deterioration) if the malfunction were to recur. Such events require notification to the appropriate regulatory agency per defined regulations.
Approval	Agreement that an item or set of actions is complete, has been reviewed, and that the approver concurs or agrees with the outcome and endorses any follow-up actions through a valid signature. To give formal or official sanction to an item.
Design History File	This contains or references the documents that constitute the compilation of records describing the design history of a finished device. The Design History File is not necessarily in a single location. The Design History File covers the technical requirements for Quality System Regulations and the Medical Device Directive.
Direct Harm	Caused by the energy or substance delivered, or not delivered, by/through the product. (i.e. Ventilator)
Harm	Physical injury or damage to the health of people or damage to property or the environment. NOTE: Include unreasonable psychological stress or unwanted pregnancy as part of “damage to the health of people.”
Hazard	Potential source of harm.
Hazardous Situation	The possibility of any degree of injury, actual or potential, associated with an event.
Indirect Harm	An injury caused when a product leads an individual to either perform an action or fail to perform an action based on its performance.
Intended Use	Use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacturer.
Labeling	Written, printed, electronic, or graphical information included on the device, packaged with the device, accompanied with the device or marketing material, including web-based promotional material. Labeling includes instructions for use, product labels, data sheets, marketing materials/information and promotional materials, installation and service manuals.
Medical Device	used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: - Diagnosis, prevention, monitoring, treatment or alleviation of disease, - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - Investigation, replacement or modification of the anatomy or of a physiological process, - Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means NOTE: The term “medical device” is defined by national law; therefore, consult the laws of the host country.
Medical Intervention	Intervention by a medical professional to help, treat or cure a condition, this includes medical or surgical.