use of

Cardiac catheterization laboratory, mobile

Country of origin | United States of America

Primary function | Diagnosis

Health problem addressed

Cardiovascular diseases (CVDs) are the number 1 cause of death globally: an estimated 17.5 million people died from CVDs in 2012, representing 31% of all global deaths. Of these deaths, an estimated 7.4 million were due to coronary heart disease and 6.7 million were due to stroke. Over three quarters of CVD deaths take place in low- and middle-income countries. Out of the 16 million deaths under the age of 70 due to noncommunicable diseases, 82% are in LMICs and 37% are caused by CVDs.



Disease addressed

Diseases of the circulatory system.

Technical descriptions

The device is a mobile catherization laboratory (cath lab). It can be powered from 15 A single phase wall socket, is easy to install, provides high quality image and has low dose features. The precision imaging algorithm can provide consistent imaging. Advanced active tube cooling enables longer and more complex procedures. The arm structure provides flexible patient access and overscan for steep angulations, such as spider view.

Developer's claims of products benefits

Existing state-of-the-art technology is a fixed cath lab, typically with 80 kW or more capacity. The main shortcoming of the existing technology when addressing rural and peri urban markets is the fact that it needs 3-phase power and draws significantly more power than the present solution. This device is a 15 kW system needing just single phase power and with an overall power consumption of 6 kVA. This significantly reduces running cost and complexity during installation.

Operating steps .

This product is meant to be used by a trained physician (interventional cardiologist) with support from a technologist. Operating manual and contact information are provided along with the system.

Regulatory status and standards compliance

United States of America (FDA), Canada (Health Canada), Australia (TGA), Japan (JMHLW) and others. DICOM conformance statement for OEC 9900 system available in PDF which can not be attached. Please refer to http:// www3.gehealthcare.com/en/products/interoperability/dicom/surgery_dicom_conformance_statements for OEC 9900 Elite conformance statements.

Use and maintenance

User: Technician, specialised physician (interventional cardiologist).

Training: One day application and product training is required to familiarise the product to the user.

Maintenance/Calibration required: No

Environment of use

Setting: Secondary level (general hospital), tertiary level (specialists hospital), cath labs and emergency departments. Energy requirements: Continuous power supply.

Weight (kg): 540

Accessories: Cardio vascular table, hemo dynamic monitor,

radiation protection devices.

Product specifications .

Consumables: Catheters, guide wires, stents, etc. General product: Physiological monitors, radiation

protection devices. Lifetime: 10-15 years In UN catalog: No

Commercial information

Year of commercialization: 2012 Number of units distributed: 101-1 000 Software requirements: Proprietary

Model: OEC 9900 Elite

Other features: Portable, reusable (assuming appropriate decontamination and/or other reprocessing between uses)

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