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Interventional cardiovascular lab

Country of origin India

Health problem addressed _

Cardiovascular diseases (CVDs) are the number one cause of death globally. An estimated 17.3 million people died from CVDs in 2008. Out of that, more than 80% of CVD deaths take place in low and middle-income countries due to lack of access to affordable equipment for diagnosis and treatment.

Product description _

The catheterization lab has a high power 80 KW generator digital X-ray system, a patient table, and a gantry stand with varying degrees of movements, and different X-ray modes.

Product functionality _

The X-ray system provides real time images which help to visualize and identify blocks in blood vessels and makes it possible to treat them by means

of stenting, coiling, etc. The patient table and gantry stand allows imaging that makes it possible to view blood vessels in different parts of body in real time. Different X-ray modes facilitate the imaging.

Developer's claims of product benefits _

The economy catheterization lab is tailored for the economy section as it has the flexibility to perform a wide variety of procedures. Infrastructure requirements are also lesser as the system has a small footprint which makes it possible to fit it in even small hospitals emerging economies. Low cost of ownership/maintenance makes the product ideal for low and middle-income sections. The lab requires less training to operate as it has an intuitive user interface and simple workflow. User manual and localized software interface helps ensure the product is well-suited for different countries. Overall, it is a robust product and withstands high workload demand, which is typical for resource-constrained countries. Configurable options and mobile table allow a variety of procedures in cardiac and vascular areas.

Operating steps _

The principle of operation is that of a general x-ray system. For specifics, the user manual reference needed.

Development stage _

Internal verification and validation testing completed. External evaluations done at hospitals globally. CE marked product. Compliance to European Medical Devices Directive MDD/93/42EEC. Manufacturing facility is ISO13485 certified. The catheterization lab has been commercially released and is in use in various markets like India, Nepal, Egypt, Turkey, Latin America and Eastern Europe.

Future work and challenges

Availability of trained interventional cardiologist and radiologist is one of the major challenges and targeting this would be the next step.

User and environment _

User: Interventional cardiologist and interventional radiologist

Training: Required

Maintenance: Annually

Environment of use ____

Settings: Rural settings, urban settings, secondary (general hospital), tertiary (specialists hospital)

Requirements: Stable 120 kVA power supply and good earthing. Procedure room should be semi-sterile. Lead shielding on doors and windows should be present to protect from scattered radiation. Technician operating the system needs to be trained. Temperature range is 15-35°C and humidity range is 30-75%.

Product specifications _

Dimensions (mm): 2000 x 1000 x 2000 Weight (kg): 300

Retail Price (USD): 180000 - 250000

List price (USD): 180000 - 250000

Other features: Software use, installed stationary, reusable

Year of commercialization: 2010 Currently sold in: India, Nepal, Egypt, Turkey, Chile, Columbia, Peru, Poland

