X-ray Computed Tomography

KIHT Technical Compendium

KIHT
विज्ञानेन जातानि जीवन्ति

X-RAY COMPUTED TOMOGRAPHY

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Version 1.0

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LIST OF ABBREVIATIONS

AC	Alternative Current
AMPR	Adaptive Multiple Plane Reconstruction
CAGR	Compound Annual Growth Rate
CAT	Computerized Axial Tomography
CDRH	Centre for Devices and Radiological Health
CE	European Conformity
CFDA	China Food and Drug Administration
CT	Computed Tomography
DC	Direct Current
EBCT	Electron Beam Tomography
ECG	Electro Cardio Gram
FBP	Filtered back projection
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HITU	High-intensity therapeutic ultrasound
HS	Harmonized System
HVL	Half-value layer
IEC	International Electrotechnical Commission
IR	Iterative reconstruction
ISO	International Organization for Standardization
MAH	Marketing Authorization Holder
MBIR	Model Based Iterative Reconstruction
MDCT	Multidetector row Computed Tomography
MDD	Medical Device Directive

MDT	Metal Deletion Technique
MHLW	Ministry of Health, Labor and Welfare
MHU	Mega Heat Unit
MSCT	Multi-Slice Computed Tomography
PBL	Positive beam limitation
PDA	Photovoltaic Detector Array
PET	Positron Emission Tomography
PMA	Pre-Market Approval
PMS	Post Market Surveillance
SPECT	Single Photon Emission Computed Tomography
SID	Source-to-image Distance
TGA	Therapeutic Goods Administration

EXECUTIVE SUMMARY

Cross-sectional imaging did indeed dramatically change our knowledge of the incidence and the evolution of many diseases. It rapidly became the basic clinical tool for diagnosis and follow-up and had a fundamental impact on medicine. X-ray computed tomography (CT) has been one of the most popular cross-sectional imaging modalities in radiology for saving patients' lives or improving their quality-of-life. It is quite fair to say that CT is the best and most robust imaging modality to fulfil the requirements imposed by the vast majority of clinical applications, although it has its own shortcomings in term of soft tissue contrast delineation and temporal resolution. This underlies the fact that CT has been playing an indispensable role in management of the diseases or traumatic conditions.

Two major developments that have greatly expanded the applications of CT are spiral and multi-slice CT. With spiral CT, a much faster scanning and larger coverage of the whole trunk of the patient in single breath hold became possible. The introduction of array of detectors of different sizes has permitted multi-slice CT in which slice thickness can be varied. The advent of MDCT has opened in new avenues in clinical imaging especially, non-invasive direct visualization of the coronary arteries with enhanced spatial resolution, with improved lesion detection of benign as well as malignant abdominal tumours. MDCT also offers previously unparalleled options in neurovascular domain with comprehensive stroke imaging which includes perfusion CT and CT angiography.

The Global CT Scanner Market is 4.76 billion in 2017 and projected to reach USD 6.20 Billion by 2022, at a CAGR of 5.4% during the forecast period. On the basis of technology, the CT scanners market is segmented into high-slice CT, mid-slice CT, low-slice CT, and cone beam CT technology. The cone beam CT technology segment is expected to grow faster than the other segments during the forecast period, majorly due to factors like procedural advantages; rising market demand for cosmetic dentistry; and ongoing product development & commercialization across major healthcare markets.

The main objective of this technical compendium is to cover the entire spectrum pertaining to a medical equipment called x-ray computed tomography. This report explains the clinical aspects, requirements, and principles to understand the need for and working of the equipment. The detailed technical aspects shed light on the criticality of the product at component level and provide a glimpse on the relevant standards and regulations. In addition, the report is also briefly touching upon the export & import analysis.

ABOUT:

Andhra Pradesh MedTech Zone (AMTZ) is an enterprise under the Government of Andhra Pradesh, a 270 Acre zone dedicated for medical device manufacturing with 200-250 manufacturing units. AMTZ provides the one-stop solution for all the manufacturers by providing, common scientific testing facilitates (EMI/EMC, Electrical Safety, Radiation, Biomaterials Testing, 3D printing facilities), commercial facilities such as expo halls and warehouse.

Kalam Institute of Health Technology (KIHT) in the premises of AMTZ facilitates focused research on critical components pertaining to medical devices, technology transfer of innovative technologies through e-auction, market innovation, and access. These end to end solutions help to reduce the cost of manufacturing up to 40% and make health care products more affordable and accessible.

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