सत्यमेव जयते
Department of
Health Research

Compendium of Medical Devices and Diagnostics

Evaluated by Health Technology Assessment India

March 2025

Department of Health Research
Ministry of Health and Family Welfare
Government of India

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Compendium of Medical Devices and Diagnostics

A Comprehensive Repository of Medical Technologies

Released at International Symposium on Health Technology Assessment on 8th March 2025

जगत प्रकाश नड्डा
JAGAT PRAKASH NADDA

सत्यमेव जयते

मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार
Minister
Health & Family Welfare
and Chemicals & Fertilizers
Government of India

MESSAGE

Health Technology Assessment in India (HTAIn) serves as a cornerstone in our nation's journey towards equitable healthcare, ensuring that every citizen has access to affordable, high-quality medical interventions. As we strive towards the vision of *Viksit Bharat @2047* and realization of the Sustainable Development Goals, HTAIn's role in evidence-based policymaking is indispensable. By systematically assessing healthcare technologies, HTAIn helps in bridging gaps in access to healthcare and enhances resource optimization.

The HTAIn-Assessed Technology Compendium is a significant initiative that consolidates innovative and cost-effective health technologies, providing a strategic roadmap for informed decision-making. This compendium serves as a vital document for policymakers and healthcare providers for facilitating the adoption of technologies that enhance efficiency, affordability and accessibility in healthcare delivery.

I hope that HTAIn-Assessed Technology Compendium will serve as a guiding document for future health policy interventions, reinforcing India's leadership in innovative, evidence-based and inclusive healthcare solutions for generations to come.

(Jagat Prakash Nadda)

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सदस्य
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MEMBER

सत्यमेव जयते

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March 5 2025

Message

The National Health Policy 2017 envisages the highest possible level of health and well-being for all. It aspires to achieve increased and more equitable access to healthcare by improving quality and investment in public health. An important step in this direction is conducting Health Technology Assessment of innovative technologies to ensure that these technologies are safe, effective, and cost-effective, ultimately providing the best value for patients. Health Technology Assessment India (HTAIn) under the Department of Health Research has taken the lead to conduct these rigorous systematic evaluations.

Since its inception in 2017, HTAIn has conducted analysis to generate evidence on the cost-effectiveness and clinical effectiveness of health technologies, including medicines, devices, diagnostics, surgical interventions, programmatic and digital health interventions. This in-turn supports resourceful utilization of the health budget and aims to improve access to quality healthcare while reducing out-of-pocket expenses for citizens.

The initiative to collate profiles of all HTA evaluated medical devices and diagnostics is a crucial step to make available at hand information on newer technologies that can be integrated into our healthcare system so as to improve quality healthcare at affordable costs.

I would take this opportunity to congratulate the team of Health Technology Assessment India led by Secretary and Joint Secretary, DHR including the resource centers and all subject experts for coming up with the compendium. I sincerely hope that HTAIn will continue to conduct rigorous HTA evaluations and deliver high-quality outputs to meet the growing demands of the health system.

(Vinod Paul)

डॉ. राजीव बहल, एमडी, पीएचडी
DR. RAJIV BAHL, MD, PhD

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

सचिव
भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक
भारतीय आयुर्विज्ञान अनुसंधान परिषद
Secretary
Government of India
Department of Health Research
Ministry of Health & Family Welfare and
Director-General
Indian Council of Medical Research

MESSAGE

Health Technology Assessment India (HTAIn) plays a transformative role in shaping India's healthcare landscape, ensuring that our nation's progress is driven by evidence-based, cost-effective, and high-quality health interventions. Through rigorous assessment and systematic evaluation, HTAIn has been instrumental in guiding policy decisions that strengthen the public health system and improve healthcare outcomes for all citizens.

The Health Technology Compendium will serve as a valuable repository of assessed health technologies for medical devices and diagnostics. By documenting and disseminating crucial insights, this compendium empowers stakeholders—policymakers, healthcare providers, researchers, and innovators—to make informed decisions that align with the principles of affordability, accessibility, and adoptability in healthcare systems.

As we work towards achieving a self-reliant and resilient healthcare system, the role of HTAIn in fostering indigenous innovation and technology adoption cannot be overstated. By bridging the gap between research and implementation, HTAIn is enabling the deployment of impactful healthcare solutions at scale. I commend the dedicated efforts of the HTAIn team in compiling this compendium, which will serve as a guiding document for strengthening our commitment for affordable and accessible health care.

Raju Bahl

(Dr. Rajiv Bahl)

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अनु नागर
संयुक्त सचिव

ANU NAGAR
Joint Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य अनुसंधान विभाग

Government of India
Ministry of Health & Family Welfare
Department of Health Research

MESSAGE

Established under the aegis of the Department of Health Research, Health Technology Assessment India (HTAIn) is a body driving evidence-based policymaking to promote the adoption of cost-effective and high-quality healthcare interventions. By systematically evaluating health technologies, HTAIn plays a crucial role in strengthening India's healthcare system. HTAIn's efforts have been instrumental in strengthening the healthcare system, making patient care more affordable, and ensuring a healthier life for all citizens across the country.

In India's pursuit of a stronger healthcare system, a collaborative approach between the central and state governments is essential. Our commitment lies in prioritising healthcare and optimising resource allocation for maximum health benefits. These efforts are crucial for enhancing healthcare delivery and reducing out-of-pocket healthcare expenses for our population.

Over the past eight years, HTAIn has conducted a wide range of health technology assessments (HTA) of medical devices, diagnostics, surgical procedures, public health interventions, clinical treatments, and digital health innovations. The HTA studies have provided invaluable evidence-based recommendations, enabling both central and state governments to make informed choices that enhance the effectiveness and efficiency of the public health system.

This Technology Compendium provides policymakers and healthcare providers with a consolidated overview of HTA-assessed medical devices and diagnostics, focusing on the product specification, HTAIn recommended price and the availability of similar devices in the Government e Marketplace (GeM) with a range of prices. This enables evidence-based decision-making in adopting cost-effective and high-quality interventions. I believe this compendium serves as a reference guide for stakeholders, ensuring awareness and accessibility of emerging technologies and bridging the gap between innovation and implementation.

(Anu Nagar)

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Preface

Health Technology Assessment (HTA) plays an indispensable role in healthcare system by providing a structured, evidence-based approach to evaluate the effectiveness, cost and broader impact of medical technologies, treatments, and interventions. Globally, HTA is recognized as a critical tool for the efficient allocation of health resources, ensuring that technologies bring value not only in terms of clinical outcomes but also in cost-efficiency, thus improving healthcare delivery at all levels.

In India, Health Technology Assessment, India, under the Department of Health Research., with a network of resource centers across the country reviews and evaluates new technologies with the focus on two crucial aspects: clinical effectiveness and cost-effectiveness. Clinical effectiveness assesses the safety and efficiency of technologies in real-world settings, while cost-effectiveness evaluates the affordability and value for money, ensuring that technologies can be scaled to benefit the broader population.

HTAIn reviews and evaluates various types of technologies including medicines, medical and diagnostic devices, surgical interventions, health programs and digital health interventions, e.g., artificial intelligence, machine learning, etc. This compendium provides a comprehensive showcases the findings from HTA evaluations of 29 different technologies, each reviewed for its clinical and cost-effectiveness. Through this compilation, we offer evidence-based insights into how these technologies contribute to healthcare improvement and their potential for widespread adoption across the country.

As we continue to face the complexities of healthcare delivery in a large and diverse country like India, the role of HTA becomes even more critical. By systematically assessing both new and existing technologies, HTA supports the adoption of interventions that are not only safe and effective but also aligned with the health needs of the population, ensuring equitable access and better outcomes for all citizens.

We hope that this work serves as a valuable resource for healthcare providers, researchers, and policymakers, fostering informed decision-making and the adoption of best practices in health technology for the betterment of healthcare in India.

Acknowledgements

We extend our sincere gratitude to all those who contributed to the development of this HTA Compendium of Medical and Diagnostic Devices. This compendium is the result of collaborative efforts aimed at strengthening evidence-based decision-making for healthcare technologies in India.

We acknowledge the invaluable support of the Secretary, Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW) for his leadership and guidance in advancing Health Technology Assessment (HTA) in India. We also extend our heartfelt thanks to the Joint Secretary, Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW) for her unwavering support and mentorship.

Our heartfelt appreciation goes to the Health Technology Assessment India (HTAIn) Secretariat, resource centers, and domain experts who meticulously assessed these technologies, ensuring a rigorous evaluation of their clinical effectiveness, cost-effectiveness and overall impact on the healthcare delivery.

We also recognize the contributions of industry stakeholders, regulatory bodies and healthcare professionals whose insights and feedback enriched the assessment process. Their engagement has been instrumental in shaping policies that drive the adoption of innovative and cost-effective medical technologies.

Finally, we extend our thanks to all those involved in the compilation, review, and publication of this compendium. We hope this repository serves as a valuable resource for policymakers, healthcare providers, and researchers in making informed decisions for improving public health outcomes.

Abbreviations

AB-PMJAY	Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana
ABR	Auditory Brainstem Response
AI	Artificial intelligence
ARD	Automated Resuscitation Device
ASHA	Accredited Social health Activist
BERA	Brainstem Evoked Response Audiometry
BTE	Behind-The-Ear
CDSCO	Central Drug Standard Control Organization
CHC	Community Health Centre
CHO	Community Health Officer
CMV	Conventional Mechanical Ventilation
Co-Cr-Mo Alloy	Cobalt- Chromium- Molybdenum alloy
CPAP	Continuous Positive Airway Pressure
CT-scan	Computed Tomography Scan
CXR	Chest X- Ray
DHR	Department of Health Research
ECG	Electrocardiogram
ENT	Ear-Nose-Throat
ETDRS	Early Treatment Diabetic Retinopathy Study
ETO	Ethylene Oxide
FBNC	Facility Based New-born Care
GeM	Government e- Marketplace
HTA	Health Technology Assessment
HTAIn	Health Technology Assessment in India
HWC	Health and Wellness Centre
IMNCI	Integrated Management of Neonatal and Childhood Illness
IoT-enabled	Internet of Things enabled
IPHS	Indian Public Health Standards
IPPV	Intermittent Positive Pressure Ventilation
LARC	Long-Acting Reversible Contraceptive
LCPV	Low-Cost Portable Ventilator
LTBI	Latent Tuberculosis Infection
MCH	Maternal and Child Health
MoHFW	Ministry of Health & Family Welfare
MPW	Multipurpose Worker

Cont….

MSICS	Manual Small Incision Cataract Surgery
NAVA	Neutrally Adjusted Ventilatory Assist
NHM	National Health Mission
NIRS	Near-Infrared Spectroscopy
NPCBVI	National Programme for Control of Blindness and Visual Impairment
NPCDCS	National Programme for Prevention and Control of Cancer, Diabetes, CVD and Stroke
NPPA	National Pharmaceutical Pricing Authority
NPPCD	National Programme for Prevention and Control of Deafness
NTEP	National Tubeculosis Elimination Program
NVHCP	National Viral Hepatitis Control Program
PEEP	Positive End-Expiratory Pressure
PHC	Primary Health Center
PLI	Production Linked Incentive
PMMA	Polymethyl Methacrylate
POC	Point Of Care
PPH	Post Partum Haemorrhage
RBCs	Red Blood Cells
RBSK	Rashtriya Bal Swasthya Karyakram
RDT	Rapid Diagnostic Test
RUP	Re-Use prevention
SCD	Sickle Cell Disease
SCT	Sickle Cell Trait
SES	Safety Engineered Syringes
SIP	Sharp Injury Prevention
SNCU	Special Newborn Care Unit
TAC	Technical Appraisal Committee
TAT	Turn-Around Time
TBHV	Tuberculosis Health Visitor
TICH	Traumatic Intra-Cranial Haemorrhage
TKR	Total Knee Replacement
UBT	Uterine Ballon Tamponade
UNFPA	United Nations Population Fund
UTI	Urinary Tract Infection
VIA	Visual Inspection with Acetic acid

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Cont..

1. Health Technology Assessment India

1.1 Background

The Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), envisions the mandate of Translating Research into Action for Improving the Health of the Population. To achieve this, DHR has initiated various programs to bolster health research which include enhancing infrastructure, building human resource capacities, and developing tools to combat outbreaks, as depicted in Figure 1.

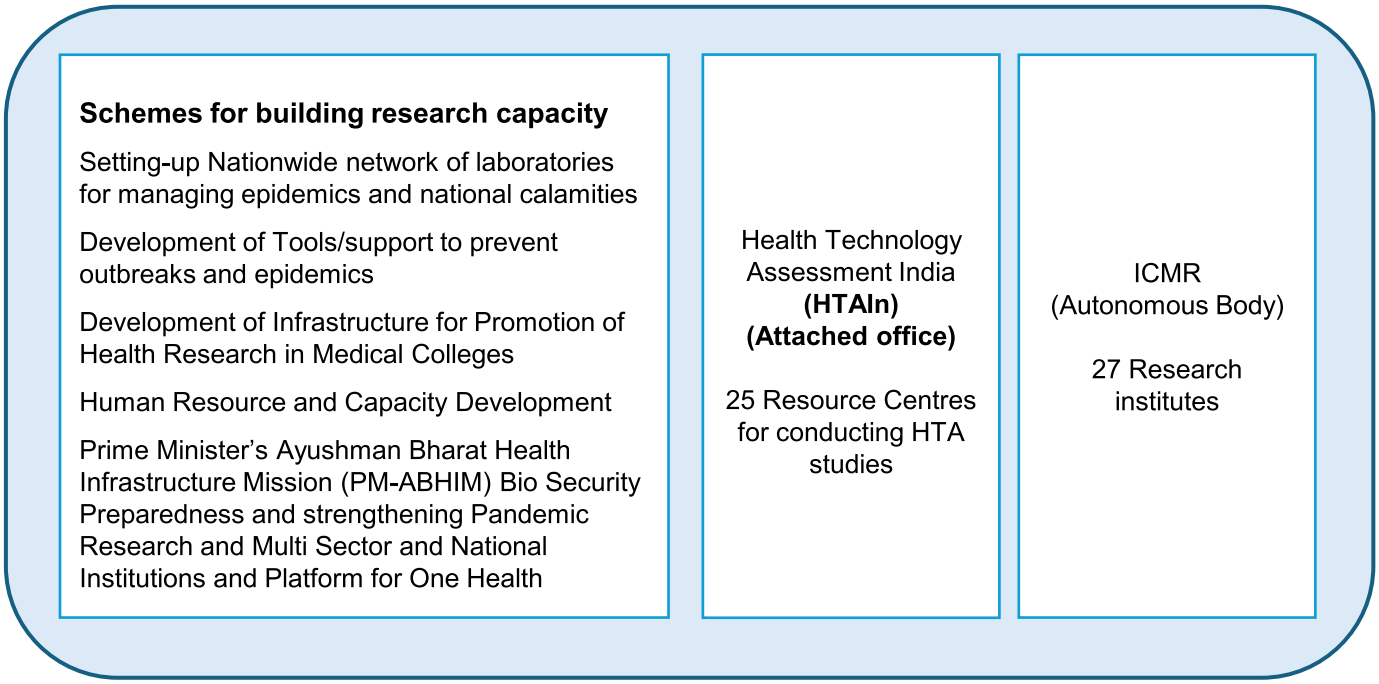

Figure 1: Programs under Department of Health Research

Health Technology Assessment India (HTAIn), is an attached office to the Department of Health Research, with the task of generating clear, evidence-based policies to advance the nation toward universal health coverage. HTAIn undertakes evaluations to scrutinize the cost-effectiveness, clinical benefits, and fairness of introducing health technologies such as pharmaceuticals, medical devices, and health initiatives. This effort is instrumental in closing the gap between evidence and policy, ensuring that academic research and policy directives converge through HTA. The ultimate aim is to enhance the decision-making process for the distribution of health resources, thereby improving the health outcomes for the people of India.

1.2 Objectives

- To undertake HTA studies aiming at maximizing health in the population, reducing out of pocket expenditure (OOP) and reducing inequity.
- To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.
- Develop systems and mechanisms to assess new and existing health technologies by a Transparent and inclusive processes.
- To appraise health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety.
- To collect and analyse evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy.
- Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health.

1.3 Structure

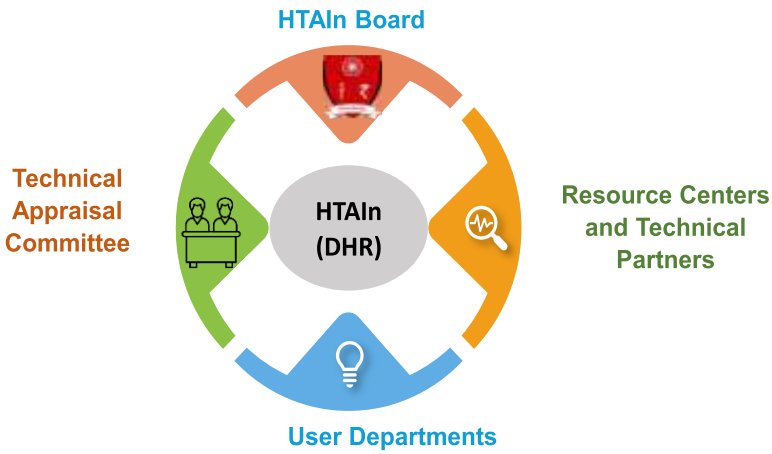

Figure 2: HTAIn Structure

HTAIn comprises the HTAIn Secretariat, Technical Appraisal Committee (TAC), HTAIn Board, and Regional Resource Hubs (RRHs) and Centres (RRCs) & Technical Partners (TPs). The Secretariat coordinates among these entities and also suggests ways to improve the methodology of assessment.

- **HTAIn Board:** The Board consists of a diverse group of stakeholders, including policymakers, clinicians, bureaucrats, and experts from central and state government bodies. It is responsible for reviewing, endorsing, and approving the outcomes and recommendations of HTA studies approved by the Technical Appraisal Committee (TAC). It meets every 6–12 months for the Final Approval of the studies and may suggest topics or research areas for evidence generation.

- **Technical Appraisal Committee (TAC):** TAC is a multidisciplinary group of experts in economics, clinical medicine, research, social sciences, and health policy, chaired by a distinguished subject expert. It provides guidance and oversight in feasibility assessments, topic allocation, proposal development, and outcome review. TAC ensures the quality and rigor of HTA studies and convenes every 1–2 months.

- **Regional Resource Hubs/ Centres (RRHs/ RRCs) and Technical Partners (TP):** These centres conduct HTA studies assigned by the HTAIn Secretariat and collaborate with state governments to identify relevant study topics and support implementation. Currently, there are six Resource Hubs and 19 Resource Centres. The network of RRH and RRCs is depicted in Figure 3.

- **HTAIn Secretariat:** The Secreterait serves as the central coordinating unit within the organization that periodically conducts TAC, board meetings and meetings with the stakeholders as and when needed. It facilitates communication and collaboration among the other stakeholders.

1.4 Methodology

The topics are submitted to the HTAIn Secretariat, which are reviewed, prioritized by the Topic Prioritization Committee, and approved by the Technical Appraisal Committee (TAC). Assigned Technical Partners (TPs) or Resource Centres develop study proposals detailing research questions, methodology, timelines, manpower, and budget. Following the approval from TAC, the HTA study is conducted **using systematic or rapid reviews, meta-analysis, data extraction, simulation models, and economic evaluations such as ICER calculations and Budget Impact Analysis.** The assessment also considers equity issues related to accessibility and affordability. Upon completion, the outcome Report is reviewed by TAC and submitted to the Board for final approval. A flowchart representing this process is shown below in Figure 3.

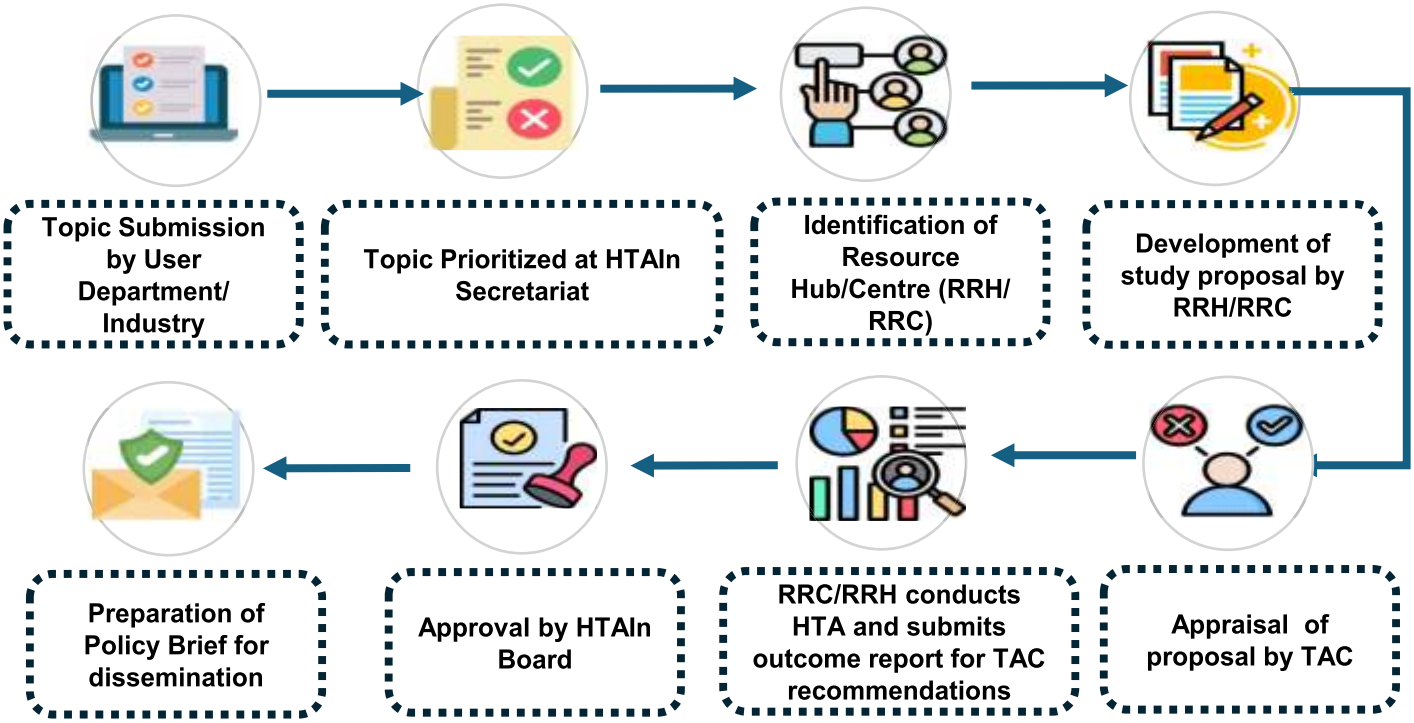

Figure 3: Process Flow of Conducting Health Technology Assessment

1.5 Purpose and Scope

Pricing and Procurement: Ensuring cost-effective acquisition and distribution of medical products and services.

Introduction of New Technologies: Introducing innovative solutions to enhance healthcare efficiency and outcomes.

Support to Health Program: Strengthening initiatives to improve public health and healthcare accessibility.

Health Benefit Package Revision: Updating health coverage policies to align with evolving healthcare needs and priorities.

1.6 Location Regional Resource Hubs and Centers of HTAIn

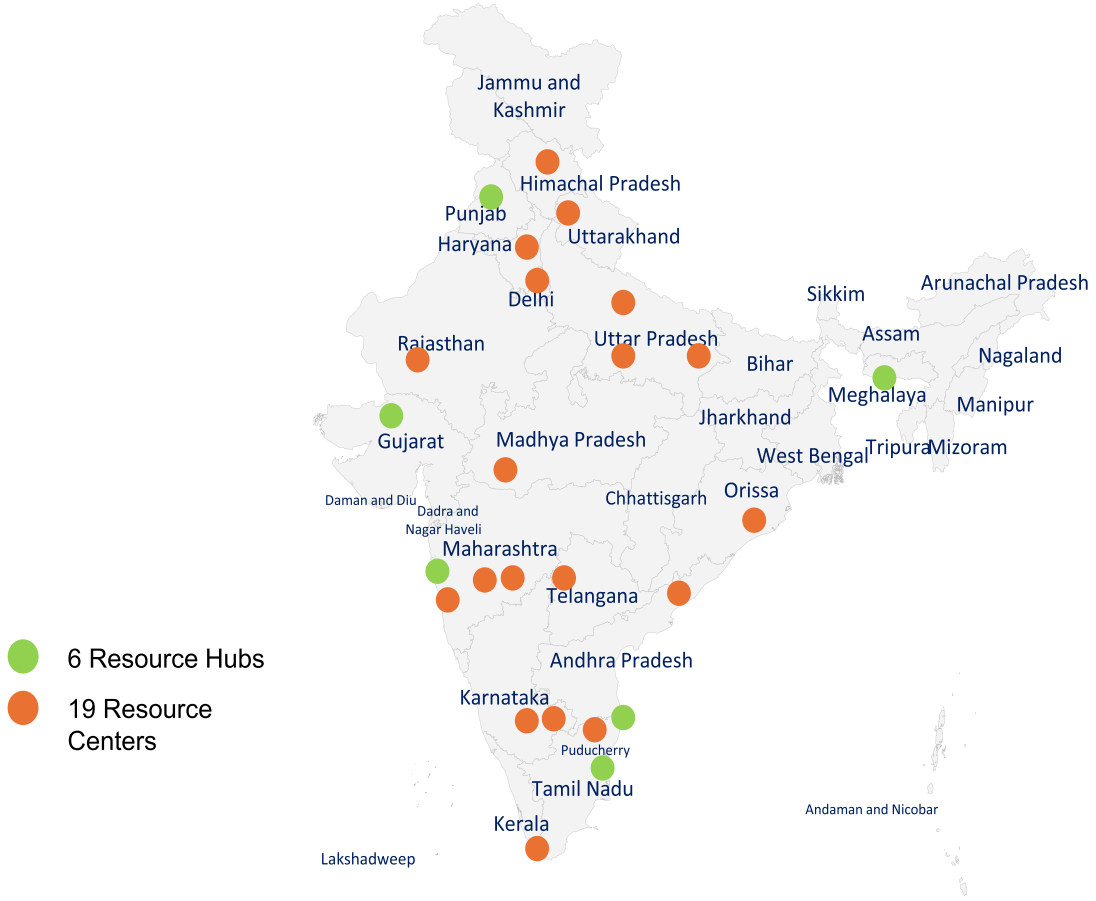

Figure 4: Regional Resource Hubs and Regional Resource Centres

Regional Resource Hubs
Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh.
Indian Institute of Public Health, Gandhinagar
National Institute for Research in Reproductive Health, Mumbai
Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry.
National Institute of Epidemiology, Chennai
Indian Institute of Public Health, Shillong

Regional Resource Centres
Indian Institute of Technology, Delhi
All India Institute of Medical Sciences, Jodhpur
National Institute of Virology, Pune
National Centre for Disease Informatics and Research, Karnataka
Indian Institute of Science, Bengaluru
Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum
National Institute for Research in Tuberculosis, Chennai
Indian Institute of Public Health, Hyderabad
Kalam Institute of Technology, Vizag

Regional Resource Centres
Regional Medical Research Center, Bhubaneswar
State Cancer Institute and King George Medical University, Lucknow
All India Institute of Medical Sciences, Rishikesh
Institute of Medical Sciences, Banaras Hindu University, Varanasi
Dr Rajendra Prasad Government Medical College, Kangra
Tata Memorial Hospital, Mumbai
Armed Forces Medical College, Pune
All India Institute of Medical Sciences, Bhopal
Indian Institute of Public Health, Delhi
Indian Institute of Technology, Kanpur

2. Compendium of Medical Devices & Diagnostics

The HTA recommendations for medical devices and .diagnostics have been collated in this compendium with the purpose to generate awareness and encourage the integration of cutting-edge innovative technologies into the healthcare delivery ecosystem. Furthermore, it is positioned as a valuable resource for engaging and guiding policymakers through informed and strategic choices.

2.1 Objectives of the Compendium

Consolidated Repository

Gather and present a collection of medical devices & diagnostics assessments conducted by HTAIn

Technology Insights

Offer detailed technical insights into innovative technologies to ensure they meet clinical needs and address healthcare challenges effectively.

Procurement Guidelines

Act as a persuasive instrument for evidence based informed choices by government bodies, and non-profit organisations.

Advocacy

Foster and enhance the recognition of clinically effective and economically viable technologies among a broad spectrum of stakeholders.

2.2 Elements of Technology Profiles

The profiling of the HTAIn assessed medical devices and diagnostic technologies is discussed in this resource booklet on the following parameters:

Product Description

Outlines the fundamental operating principles of the technology

Product Components

Catalogs the associated parts & supplementary items

Market Coverage

Mentions about the Indian* and Global markets where the technology is available

Recommendations from HTAIn

Summarizes the technology's features, technical specifications, suggested pricing in specific settings and applicability in healthcare settings

Policy Advocacy/ Adoption of Technology

Entails the implications of HTA at the policy level and adoption in states

*Technologies not on GeM portal in India are in the process of being on-boarded onto GeM

Technology Profiles

Portable ECG

Country of Origin: India
Category: Medical Devices
Primary Use: Screening, Diagnosis and Monitoring of cardiac abnormalities

Product Description

Portable ECG is a handheld machine used for screening of cardiac abnormalities in primary care settings in high-risk population. It is a compact A-4 size digital system, with m-health application which enables to establish linkage with physicians for reading ECG through cloud-based interface for identification and confirmation, timely management and referral for Cardiovascular diseases in the "GOLDEN HOUR" (first 60 minutes of a heart attack). It has a display screen and in-built PDF convertor which facilitates transfer of ECG from device to USB in pdf. More than 50 ECG can be carried out on a fully charged battery.

Product Components

Lead cable: 1 unit

USB cable: 1 unit

Suction bulb: 6 units

Clamp electrodes: 4 units

Jelly Bottle: 1 unit

Market Coverage

India:
Available on GeM portal at **minimum price of INR 15,000**

Outside India:
Ghana, Nairobi, Zambia, Uganda

Recommendations from HTAIn

Technology Features

Cloud Based telemedicine system

Patient App to register and view report

Facility of Comparison with previous ECG

Compact & Portable

Signals Aert for Critical Cases

Quick Reporting

Easy to use

Technical Specifications

Channels	12 lead
Cable Type	10 Lead
Filter	0.05 to 100hz
Speed	25 mm/s 12.5 25 50
A/D Resolution	24 bits 5 10 20
Gain	10 mm / mV
Sample Rate	500 Ssmples / Second per channel
Data Capturing Length	10 Sec. / 30 Sec. / 60 Sec.

Maximum HTA Recommended Price (2021)

INR 70,000

Applicability in Healthcare Setting

Ideal for basic health facilities, this low-infrastructure technology enables swift emergency response with a single day's training and extends healthcare reach via telemedicine in remote areas.

Policy Advocacy/ Adoption of Technology

Gujarat, Tamil Nadu, Maharashtra, Kerala, Himachal Pradesh, Andhra Pradesh and North-East region states have adopted this technology.

Portable Automated ABR (Auditory Brainstem Response)

Country of Origin: India

Category: Medical Devices

Primary Use: Screening

Product Description

The Portable ABR device, using BERA (Brainstem Evoked Response Audiometry) and AI, offers accurate and reliable newborn hearing tests without sedatives, even in noisy areas. It delivers auditory clicks at various decibels, with instant results reviewed remotely by audiologists for further action. This non-invasive, safe device to screen neonates for hearing impairment with high sensitivity and specificity and is specially designed for mass screening of neonates in resource-constrained settings.

Product Components

Electrodes: Stainless steel

Gel: for protection for electrodes

Power requirement: 220-240 Vac; 50-60 Hz along with rechargeable inbuilt battery

Market Coverage

India:
Available on GeM portal at **minimum price of INR 2,00,000**

Outside India:
Uganda, Tanzania, Bhutan, Guatemala

Recommendations from HTAIn

Technology Features

Quick and Safe

Minimal Training Required

Telemedicine Enabled

Automated Algorithm

Noise Resilience

Reusable Electrodes

Neonate Suitable

Click Stimuli Operation

Technical Specifications

Electrodes	In-built re-usable
Stimulus Type	Click and Chirp
Siimulation Level	35db, 50 db, 70db, 90db
Frequency for Screening Test (Hz)	135-1500 Hz, 1500-8000Hz

Maximum HTA Recommended Price (2021)

INR 3,30,000

Applicability in Healthcare Setting

The Portable ABR device enhances newborn hearing tests in remote areas with simple training and minimal infrastructure.

Policy Advocacy/ Adoption of Technology

1. Portable Automated ABR is included in the essential list of diagnostic tools under the operational guidelines for *Rashtriya Bal Swasthya Karyakram* (RBSK).
2. Punjab, Tripura, Himachal Pradesh, Rajasthan, Maharashtra, Karnataka, Chhattisgarh, Andhra Pradesh have adopted this technology.

Safety Engineered Syringes

Country of Origin: India
Category: Medical Devices
Primary Use: Therapeutics

Product Description

Safety-engineered syringes (SES) are utilized in therapeutic care and incorporate both reuse prevention (RUP) and sharp injury prevention (SIP) features to mitigate the risks of syringe reuse and needle-stick injuries (NSI). The RUP feature is designed to ensure that the syringe becomes inoperable after a single use, either by causing the plunger to break or by locking it with a metal clip. The SIP feature automatically encases the needle with a plastic shield after use, providing an additional layer of protection. SIP is meant for preventing NSI among healthcare professionals and waste handlers.

Product Components

Syringe type : 3 piece
- Barrel
- Plunger
- Rubber gasket on the tip of the plunger

Needle type: Automatic retractable

Market Coverage

India:
Available on GeM Portal at **minimum price of INR 3**

Recommendations from HTAIn

Technology Features

Single-use

Manual plunger

Automatic retractable needle

Variable dosage marks

Enhanced Safety

Durability

Technical Specifications

Syringe	
Material	Medical grade plastic
Type	Single use with variable dosage marks
Needle	
Material	Stainless steel
Type	Automatic retraction

Maximum HTA Recommended Price (2018)

INR 5.9

Applicability in Healthcare Setting

SES can be adopted in the Indian public health system if eligible human resource is trained on its usage, safety and waste disposal.

Policy Advocacy/ Adoption of Technology

1. The National Viral Hepatitis Control Program's Operational Guidelines mandate the exclusive utilization of Re-Use Prevention (RUP) syringes across all government healthcare establishments.
2. Punjab, Andhra Pradesh, Delhi, Uttar Pradesh, Rajasthan, Maharashtra, West Bengal have adopted this technology.

Digital Fundus Photography

Country of Origin: India

Category: Medical Devices

Primary Use: Screening of diabetic retinopathy

Product Description

The phone-based fundus camera, equipped with AI, swiftly detects diabetic retinopathy. . It captures multiple retinal images, surpassing Early Treatment Diabetic Retinopathy Study (ETDRS) standards, and integrates with chinrests or slit-lamps for seamless use. The images are acquired when diabetic patients visit the health centres are transferred by electronic means to the base hospital, where the ophthalmologist or a trained optometrist interprets the images. Mobile tele-screening (Phone-based non-Mydriatic) is an ophthalmologist-led screening program that takes eye care facilities to the rural population.

Product Components

Camera: Smartphone based non-mydriatic fundus

Software: Image management systems which store databases, process and acquire images

Market Coverage

India:
Available on GeM portal at **minimum price of INR 1,31,250**

Outside India:
United States of America, Dominican Republic, Armenia, Poland

Recommendations from HTAIn

Technology Features

Tele-screening model

Non mydriatic fundus camera

Wider view of field

AI- algorithm enabled

Automatic image capture

Technical Specifications

Imaging modalities	Non- Mydriatic
Dioptre Correction	-30 D to +30 D
Minimum pupil size	3 mm
Illumination	Annular technique
Field of view	40 degrees
Camera	.>= 80 lp/mm
Working distance	33 mm
Device weight	1.1 kg
Dimensions (l*w*h)	68*273*209 mm

Maximum HTA Recommended Price (2021)

INR 3,50,000

Applicability in Healthcare Setting

Tele-screening for diabetic retinopathy can be integrated into the healthcare system if staff trained in retinal imaging is available to manage the case load.

Policy Advocacy/ Adoption of Technology

1. The current guidelines on HWCs- Health and Wellness Centres (2022) by the GoI include Diabetic Retinopathy screening using non-mydriatic fundus cameras and referral as a key activity.
2. Orissa, Kerala, Puducherry, Tamil Nadu, Delhi have adopted this technology have adopted this technology.

Automated Neonatal Resuscitation Device

Country of Origin: India
Category: Medical Devices
Primary Use: Resuscitation

Product Description

Automated Neonatal Resuscitation Device facilitates easy automatic resuscitation featuring CPAP, bubble CPAP, and ARD modes for newborn stabilization post-resuscitation. The T-piece resuscitator ensures consistent PIP and PEEP for effective IPPV and CPAP delivery. It attaches to the patient interface, with ventilation controlled by covering an exhalation hole, supporting care until transfer to advanced facilities. T-piece resuscitators have an inline manometer for continuous monitoring of the pressure. The device is designed to support asphyxiated new-born and assist in maintaining their breathing once spontaneous respiration begins.

Product Components

T-piece resuscitator (with manometer): It consists of the following parts-
- Front panel with user controls
- Rear Panel: Electrical supply connections
- SS box: The device is housed inside this SS cabinet.

Gas supply tubes

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Dual input gas supply

Integrated Design

Automated functioning

Operational reliability

Requires minimal skills

Portable

Easy maintenance

Technical Specifications

T-piece resuscitator with manometer

Dimensions	4 cm long and 2 mm in diameter
Dimensions	170 (L) X 110 (W) X 180 (H) mm
Weight	2.5 kgs (approx.)
Inbuilt flow meter	0-15 LPM
Material	Silicon and medical grade polymers
Electricity supply	AC power source/ generator external battery
Gas flow rate	5-15 LPM

Maximum HTA Recommended Price (2020)

INR 1250

Applicability in Healthcare Setting

The Automated Neonatal Resuscitation Device is clinically effective and affordable in tertiary care settings with even minimum training of human resource.

Policy Advocacy/ Adoption of Technology

Andhra Pradesh, Uttar Pradesh, Madhya Pradesh, Rajasthan, Bihar have adopted this technology.

Pulse Oximeter

Country of Origin: India

Category: Diagnostics

Primary Use: Screening of childhood pneumonia

Product Description

Pulse oximeter is a compact, portable device designed to provide accurate and reliable measurements of blood oxygen saturation (SpO2) and pulse rate. The device features advanced photoelectric sensors and dual-wavelength LEDs, it ensures precise readings displayed on the screen. With its user-friendly one-button operation, lightweight design, and battery-powered convenience, it is perfect for home monitoring, clinical use. The newer models also offer Bluetooth connectivity for seamless data transfer to the smartphone, making it easy to track and analyse health metrics over time.

Product Components

Lithium Battery

USB line

Oximeter probe

Power adapter

Market Coverage

India:
Available on GeM portal at **minimum price of INR 449**

Outside India:
Ethiopia, Burundi, Bangladesh, Malawi

Recommendations from HTAIn

Technology Features

Portable

Battery powered

Display Screen

Photoelectric sensor

Dual Wavelength LEDs

Bluetooth connectivity

Technical Specifications

SpO2 measurement rate	40-70 and 70 to 99 %
Accuracy of SpO2	±1% for range 40-70 ±3% for range 70-99
Accuracy of Pulse rate	Better than ±5 bpm
Power Consumption	1.5 watt
Power input and frequency	220 to 240 V, 50 Hz

Maximum HTA Recommended Price (2020)

INR 2500

Applicability in Healthcare Setting

Pulse oximeters, can be integrated into the Integrated Management of Childhood Illness (IMCI) framework at Primary Health Centers (PHCs) and Community Health Centers (CHCs) as it requires minimal power and training and has shown significant benefits in pneumonia screening and diagnosis at the community level.

Policy Advocacy/ Adoption of Technology

1. Under the NHM guidelines(2022), pulse oximeters are included in the list of essential equipment for CHCs and PHCs to monitor oxygen saturation levels in patients.
2. Kerala, Madhya Pradesh, Uttar Pradesh have adopted this technology.

Long-Acting Reversible Contraceptive (LARC)

Country of Origin: United States of America

Category: Medical Devices

Primary Use: Contraception

Product Description

LARC is a single small, soft, flexible rod implant with 68 mg of etonogestrel, provides three years of contraception. It's placed under the skin in the upper arm, releasing progesterone continuously which prevents the release of an egg cell from the ovaries or causes changes in the cervix that make it difficult for sperm to enter the womb Its radiopaque nature and simple insertion and removal make it suitable for breastfeeding mothers, individuals with hypertension and women seeking non-daily birth control measures. It gives protection against pregnancy for a period of three years, but for overweight and obese women, it can be replaced early, if needed.

Product Components

Implant: It is a non- biodegradable, white to off-white soft plastic rod

Disposable Applicator: consists of needle shield to cover the needle, textured area to facilitate proper grip, slider and bi-bevelled needle S

Market Coverage

India:
Currently not available on GeM portal

Outside India:
Africa, Indonesia, Nepal, Thailand, Bangladesh, North America, Latin America, Europe, Australia

Recommendations from HTAIn

Technology Features

Easy insertion

Single Rod

Sustained Protection

Complete Reversal of Fertility

Fast-Acting

Safe & Well Tolerated

Technical Specifications

Implant		
Dimensions		4 cm long & 2 mm in diameter
Opacity		Radiopaque
Composition	Core	Etonogestrel- 68mg Ethylene vinyl acetate copolymer (EVA)- 43 mg Barium Sulphate- 15 mg Magnesium stearate- 0.1mg
	Skin	Ethylene vinyl acetate copolymer (EVA)- 15% vinyl acetate, 15 mg)
Applicator		Disposable

Maximum HTA Recommended Price (2019)

INR 800

Availability in Healthcare Setting

LARC can be integrated into the public health system with trained staff and availability of necessary logistics.

Policy Advocacy/ Adoption of Technology

1. In 2023, single-rod subdermal implant was introduced in the contraceptive basket of choices under the National Family Planning Program.
2. The implant has been rolled out in Uttar Pradesh, Bihar Rajasthan, Assam, Gujarat, Rajasthan, Tamil Nadu, Odissa, Karnataka and West Bengal through central procurement.

Uterine Ballon Tamponade

Country of Origin: United States of America

Category: Medical Devices

Primary Use: Management of post-partum haemorrhage

Product Description

UBT (Uterine Balloon Tamponade) is an innovative medical device designed to effectively manage postpartum haemorrhage (PPH). It is made from high-elasticity latex, it conforms to the shape of the uterus to ensure optimal control of bleeding. The device features a drainage lumen at the top of the catheter, allowing for continuous monitoring of haemostasis. It has undergone rigorous trials under the supervision of leading gynaecologists and obstetricians, and has been approved for its efficacy in significantly reducing bleeding in the shortest possible time.

Product Components

No. of Syringes: 2
Urinary catheter
Condom
O-rings
Luer-lock : one-way valve
Drainage Lumen

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Easy to use

High Elasticity

Single use

Requires minimal training

Fast- Acting

Non - pharmaceutical

Technical Specifications

Material	Flexible latex
Balloon capacity	500 ml
Balloon shape	Flexible round shape
Tube Length	480±20mm
Usage	Single use
Shelf life	5 years
Sterilized	Yes (with ethylene oxide)
Tip	Open tip for blood drainage and monitoring

Maximum HTA Recommended Price (2020)

INR 397

Applicability in Healthcare Setting

UBT is a non surgical method and Its intervention at PHCs is quite effective as no other surgical procedure is feasible at this level to effectively control PPH (post partum haemorrhage).

Policy Advocacy/ Adoption of Technology

1. Under the NHM guidelines (2022), the use of UBT is promoted in public health facilities to manage PPH effectively. This includes training healthcare providers in the use of UBT and ensuring its availability in delivery rooms and emergency obstetric care units.
2. Delhi, Uttar Pradesh, Karnataka have adopted this technology.

Telemedicine Enabled Otoscope

Country of Origin: United States of America

Category: Medical Devices

Primary Use: Screening/Diagnosis for ear diseases

Product Description

The telemedicine otoscope improves ear health by enabling early disease detection and specialist access, especially in remote areas. It's cost-effective, reducing travel and in-person visits, and trains health workers for better care and patient triage, leading to enhanced healthcare delivery and outcomes. It consists of a smartphone with an otoscope directly attached to the camera lens. The device projects an image of the ear canal and tympanic membrane onto the smartphone screen. The instrument is used throughout the entire process from screening to treatment and rehabilitation.

Product Components

Otoscope Head: This includes a camera and a battery-operated light source

Smartphone: The device connects with smartphones, to record and transmit images and videos for remote consultations.

Software Application: An app to manage patient data for remote consultations

Market Coverage

India:

Currently not available on GeM portal

Outside India:

United States,, Germany, Australia, United Kingdom, Canada, Japan

Recommendations from HTAIn

Technology Features

Smartphone integration

In-built Algorithm for field triaging of ear diseases

Portable Design

High Resolution Camera

In-built Software to store and share patient history

Wireless Connectivity

Technical Specifications

Sensitivity	82% (CI- 0.78- 0.95)
Specificity	95% (CI- 0.93-0.96)
Dimensions	180 mm X140mm X 80mm
Weight	< 300 gm
IP class	Ip22
Device Classification MMD	Class I
IEC Classification	Class II
Operating Voltage	3.7 V
Software class	Class A

Maximum HTA Recommended Price (2022)

INR 61750

Applicability in Healthcare Setting

Integrating otoscopes into health systems by training healthcare workers, collaborating with ENT specialists, ensuring data security, and securing funding will enhance care and prevent ear diseases.

Policy Advocacy/ Adoption of Technology

Odisha, Maharashtra, Karnataka, Tamil Nadu, Gujarat, Uttar Pradesh have adopted this technology.

Low- Cost Portable Ventilators (LCPV)

Country of Origin: India

Category: Medical Devices

Primary Use: Ventilation support in intensive care settings

Product Description

LCPV is an alternative to high end mechanical invasive ventilator. It has two components—a tablet size ventilator, a valve that attaches to patient's wind pipe and drives the air in and an android phone. This ventilator requires an external oxygen supply and it can also work with the air present around us. It takes the air steadily with the required quantity and the peak respiratory rate is 40 to 60 breath per minute. These ventilators are valuable assets in scenarios with limited resources and a scarcity of ventilators. It is ideal for patients with head injuries, cervical and spinal injuries, respiratory problems often need ventilator at home.

Product Components

Breathing circuit

High pressure tube

Valve: It attaches to patient's windpipe and drives the air in

Face mask

Android phone

FiO2 sensor

Market Coverage

India:
Available on GeM portal at **minimum price of INR 3,35,000**

Recommendations from HTAIn

Technology Features

Non-invasive

Portable

Electricity & Battery- Operated

Sensitive FiO2 sensors

Standby and all Safety Alarm

User-Friendly

Technical Specifications

Peak Flow Rate	100 Liters per minute
Peak pressure	60 cm H20
Trigger Flow Sensitivity	1 Liter per minute to 20 Liter per minute
PEEP	0 cm H2O to 20 cm H2O
Volume Accuracy	10% of the full scale between (10 L/min - 80L/min)
Min inspiratory time	0.5 to 2.5 seconds
Tidal Volume	50 ml to 1200 mL

Maximum HTA Recommended Price (2021)

INR 6000

Applicability in Healthcare Setting

States can adopt LCPVs for adequately staffed and monitored ward. It is a useful resource in settings where there is shortage of ventilators.

Policy Advocacy/ Adoption of Technology

1. The Ministry of Health and Family Welfare procured LCPV to help overcome shortage of ventilators during COVID-19 pandemic.
2. Uttar Pradesh, Delhi, Karnataka, Manipur, Bihar, Jharkhand, Madhya Pradesh, Rajasthan, Uttarakhand have adopted this technology.

Digital Adherence Technology for Tuberculosis Monitoring

Country of Origin: India
Category: Diagnostics
Primary Use: Improve adherence to Tuberculosis regimen

Product Description

Digital adherence technology comprises three key components: an IoT-enabled pill dispenser, a web dashboard, and an alert system. The pill dispenser, can store up to 15 days' worth of medication, reminds patients to take their doses and can be refilled every two weeks. If a patient misses a dose, the system alerts their primary caregiver, and if there's no response, a TB health visitor (TBHV) is notified to follow up. The web dashboard collects data on medication usage, helping pharmacists prepare refills in advance and providing officials with insights to monitor TB across larger areas.

Product Components

Reusable pill dispenser: 2 parts
- Durable Dispensing unit
- Communication Module

Mobile Application

Market Coverage

India:
Currently not available on GeM portal

Outside India:
Ethiopia, South Africa, Tanzania, Philippines , Ukraine

Recommendations from HTAIn

Technology Features

IoT device

Rechargeable battery

Cellular network technology

Durable

Light weight

Tamper-proof

Technical Specifications

Medication holding capacity	15 days
Battery Life	30 days
Dosing reminders to patients	Yes
Automatic Reporting	Yes
Dosing History	Enabled
Data Integration	Yes
Send Reminders	Yes

Maximum HTA Recommended Price (2022)

INR 6573

Applicability in Healthcare Setting

Helps in optimizing the efforts of TB Health visitors by reducing paperwork and digitizing the whole process and compliments National Tuberculosis Elimination Program by improving adherence to treatment regimen.

Policy Advocacy/ Adoption of Technology

1. Guidelines for Programmatic management of TB treatment issued by the Central TB Division, MoHFW highlight the use of digital platforms to strengthen adherence monitoring. This technology is integrated on the Nikshay platform where patients' treatment adherence is reported which in-turn supplements TB case notification and monitoring efforts.
2. Maharashtra and Gujarat have adopted this technology.

Digital Hemoglobinometer

Country of Origin: India

Category: Medical Device

Primary Use: Screening of anaemia

Product Description

Hemoglobinometer is non- invasive device that operates on the principle of reflectance photometry. When a drop of blood is applied to the strip, it spreads through the hydrophilic mesh. Haemoglobin is extracted from the red blood cells (RBCs) and, with the aid of reagents in the strip, is converted into a complex. The optical reflectance is then measured, which is inversely proportional to the haemoglobin concentration in the blood sample. This measurement corresponds to the total haemoglobin present in the blood.

Product Components

Haemoglobinometer

Test Strips

Lancets

Lancing Device

Market Coverage

India:
Available on GeM portal with **minimum price of INR 500**

Outside India:
Ethiopia, Kenya, Nigeria, Bangladesh

Recommendations from HTAIn

Technology Features

Portable

Battery operated

USB connectivity

Large Storage for Readings

Quick Results

Technical Specifications

Measurement Method	Reflectance Photometry
Measurement range	0-24 g/dl
Sample Size	≤50 micro litre
Accuracy	≥86%
Testing time	≤60 seconds
Connectivity	USB
Weight of system	< 60 gm
Battery Life	≥ 500 measurements

Maximum HTA Recommended Price (2019)

INR 2750

Applicability in Healthcare Setting

The device facilitates on-site haemoglobin testing in various health settings, including remote areas with scarce lab resources, supporting immediate anaemia assessment.

Policy Advocacy/ Adoption of Technology

Delhi, Karnataka, Tamil Nadu, West Bengal, Himachal Pradesh, Rajasthan have adopted this technology.

Intraocular Lenses

Country of Origin: India

Category: Medical Device

Primary Use: Vision correction for age –related cataract

Product Description

Rigid intraocular lenses (IOLs) are durable, biocompatible PMMA lenses used in cataract surgery with excellent optical clarity and UV protection. Their non-foldable design requires a larger incision (5-7 mm) but ensures stable fixation and long-term reliability. Thes are cost-effective and widely used in Small Incision Cataract Surgery (SICS) due to their affordability, durability, and ease of implantation.

Recommendations from HTAIn

Technology Features

- **UV Protection**
- **Optical Clarity**
- **Sterile, single-unit packaging**
- **High shelf life**
- **Sterilized using ETO**
- **Durable**

Product Components

Sterile PMMA lens

Patient Lens Implant **Identification Card**

Technical Specifications

Material	Acrylic & Silicon
Type	PMMA
Optic Design	5.50 x 8.00mm
Power	17.00D
Optic Size	5.50 x 8.00mm

Market Coverage

India:
Available on GeM portal at **minimum price of INR 4000**

Maximum HTA Recommended Price (2018)

INR 7405 per package

Applicability in Healthcare Setting

Manual Small Incision Cataract Surgery with rigid lens is ideal for cataract treatment in India, considering efficacy, cost, and access. Phacoemulsification is reserved for areas with the necessary resources.

Policy Advocacy/ Adoption of Technology

1. Subsequent to the HTA conducted, the intraocular packages under the National Program for Control of Blindness and Visual Impairment (NPCBVI) have been revised.
2. Cost of AB-PMJAY packages for Cataract surgery using IOL lenses are also below HTA recommended price.
3. Uttarakhand and Punjab have adopted this technology.

Total Knee Replacement Implant

Country of Origin: India

Category: Medical Device

Primary Use: Relieve pain and treat osteoarthritis

Product Description

Total Knee Replacement (TKR) is a surgical procedure designed to relieve pain and restore function in patients with severe knee arthritis or injury. The procedure involves replacing damaged cartilage and bone with prosthetic components, including a femoral component, tibial tray, and polyethylene insert. The femoral component, typically made of Co-Cr-Mo alloy, ensures durability and smooth articulation, while the tibial tray provides a stable base for load distribution. Modern knee implants feature bone-sparing designs, enhanced flexion, and improved patellar tracking to optimize mobility and longevity.

Product Components

Polyethylene Tibial Components

Q Insert Components

Cobalt-chromium Alloys

Market Coverage

India:
Available on GeM portal at **minimum price of INR 4000**

Recommendations from HTAIn

Technology Features

Long term Durability

Corrosion Resistant

Bio-compatible metals

High Tensile Strength

Reduced Anterior Flange

Enhanced Cam & Spine Design

Technical Specifications

Types of Total Knee Implants	Posterior stabilized
Design	PCL-substituting style
Types of Knee Implant Fixation	With bone cement
Size of Polyethylene Tibial Components	8 mm
Size of Q Insert Components	30 mm
Shelf Life	24 month

Maximum HTA Recommended Price (2024)

Cobalt Chromium : INR 54720
High flexibility Implants : INR 56490
Zirconium-Titanium : INR 76600

Applicability in Healthcare Setting

TKR being cost-effective can be integrated in the health system provided human resource specialized in this technique is available.

Policy Advocacy/ Adoption of Technology

Maharashtra, Tamil Nadu, Andhra Pradesh, Rajasthan, Gujarat have adopted this technology.

Rapid Diagnostic Test- Lateral Flow Immunoassay

Country of Origin: India

Category: Diagnostics

Primary Use: Screening and Diagnosis of sickle cell disease

Product Description

Point of care test for detection of sickle cell disease works on the principle of sandwich-type lateral flow immunoassay utilizing monoclonal or polyclonal antibodies. It identifies HbA, HbS & HbC variants of Haemoglobin. The time taken for carrying out the test is reported to be less than other POC tests Its ease of performance and interpretation makes it suitable to be used by non- skilled personnel. This test can be used for screening and diagnosis in newborns using cord blood.

Product Components

Cartridges

Capillary sampler and pre-treatment modules (buffer)

Package insert

Market Coverage

India:
Available on GeM Portal at **minimum price of INR 25**

Recommendations from HTAIn

Technology Features

Easy to use

High Precision

Easy interpretation

Stability and Reliability

Long term shelf life

Quick Reporting

Technical Specifications

Testing Principle	Lateral Flow immunoassay
Sensitivity	98.2%
Specificity	98.9%
Complete Test Duration	5- 15 minutes
Blood required	1.5- 5 micro liters
Storage temperature	2 - 30 °C
Buffer Solution	Pre-packaged stable liquid
Packaging	Individually foil-sealed tests

Maximum HTA Recommended Price (2022)

INR 100

Applicability in Healthcare Setting

States can adopt this technology for sickle cell screening for the age group of 0-2 years as the existing solubility test cannot be used for this age group.

Policy Advocacy/ Adoption of Technology

1. Based on the HTA evaluations, the National Health Mission (National Sickle cell Anaemia Elimination Mission 2023) has guided the SCD endemic states in India to consider procuring these POC tests at the recommended rates(avg. cost INR 100), for screening and diagnosis of sickle cell disease.
2. Tamil Nadu, Chhattisgarh, Maharashtra, Odisha, Jharkhand, Gujarat, Delhi and Madhya Pradesh have adopted this technology.

Rapid Diagnostic Test- Absorbance Spectroscopy

Country of Origin: India

Category: Diagnostics

Primary Use: Screening and Diagnosis of sickle cell disease

Product Description

Point of care test for detection of sickle cell disease works on the principle of absorbance spectrometry It is a single step, low cost method for rapid and accurate screening and diagnosis of Sickle Cell Trait (SCT) and Sickle Cell Disease (SCD), based on the principle of absorbance spectrometry-based assay. The performance of this simple and easy to use confirmatory test is comparable to the gold standard HPLC test. The test kit is used along with a compatible low-cost spectrometer to obtain the diagnosis. The sample is mixed with the working buffer prepared using the test kit, incubated, and placed in the spectrometer to obtain the diagnosis.

Product Components

Kit contains

- No. of Plastic Tubes: 3
- Salt- 1 sachet/packet for buffer preparation

Cuvette

Spectrometer

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Easy to use

High Accuracy

ML integrated testing method

Mobile app-Digital Access

Absorbance based readout

Faster turn-around

Technical Specifications

Testing Principle	Absorbance spectrometry-based assay
Sensitivity	100%
Specificity	100%
Time taken for results	15 minutes
No. of tests completes/kit	40

Maximum HTA Recommended Price (2023)

INR 114 per test

Applicability in Healthcare Setting

This point-of-care test is a cost-effective diagnostic tool to distinguish SCT and SCD especially for remote settings.

Policy Advocacy / Adoption of Technology

1. As per guidelines of National Sickle cell Anaemia Elimination Mission, 2023, absorbance spectrometry based point-of-care test shall be used at the PHC – HCWs and UPHC – HCWs for screening and diagnosis.
2. Tamil Nadu, Chhattisgarh, Maharashtra, Odisha, Gujarat and Madhya Pradesh have adopted this technology.

Rapid Diagnostic Test- Electrophoresis

Country of Origin: United States of America and India

Category: Diagnostics

Primary Use: Screening and Diagnosis of sickle cell disease

Product Description

This point of care(POC) test works on the principle of electrophoresis. The instrument uses a one-time-use cartridge holding a lysed blood specimen. Once in the reader, it undergoes electrophoresis via an electric charge to distinguish various haemoglobin variants. An algorithm then detects and measures these variants, essential for precise patient evaluation, as certain Hb levels correlate with specific health issues. The device accurately discerns and measures multiple Hb variants, offering diagnostic interpretations for 19 distinct phenotypes and related medical conditions.

Product Components

Hb Variant Cartridge: to detect and quantify different types of haemoglobin variants

Hb Variant Buffer bottle: specialized solution to identify and separate different type of Hb variants

Hb Variant marker fluid

Hb variant stampers:

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

POC test to quantify Hb

Miniature machine for Electrophoresis

Multiple tests on one platform

High Accuracy

Early Detection

Withstand high temperature & humidity

Technical Specifications

Hb Variant Test Multipack

Principle	Electrophoresis
Time to result	8 min
Sample Material	20 micro litres whole blood
Reader	
Operating Temp	5 – 45 degrees
Relative humidity	5 – 95 % (operating)
Connectivity	Wireless transfer of patient info and test results to cloud
Reader Size	15.24 cm x 19.56 cm x 25.40 cm

Maximum HTA Recommended Price (2023)

Kit: INR 40; Machine: INR 90,000

Applicability in Healthcare Setting

The device is particularly useful in low-resource areas where electricity, trained personnel, and high costs make traditional blood tests challenging.

Policy Advocacy/ Adoption of Technology

1. As per guidelines of National Sickle cell Anaemia Elimination Mission, 2023, electrophoresis based point-of-care test shall be used at the PHC – HCWs and UPHC – HCWs for screening and confirmation of diagnosis.
2. Tamil Nadu, Chhattisgarh, Maharashtra, Odisha, Gujarat, Madhya Pradesh have adopted the technology.

Rapid Diagnostic Tests for Hepatitis B and C

Country of Origin: India

Category: Diagnostics

Primary Use: Screening and Diagnosis of hepatitis B and C

Product Description

Hepatitis B and C Rapid Diagnostic Tests swiftly and precisely detect HBsAg and HCV antibodies in serum/plasma. These sensitive, specific kits yield reliable, rapid results, are cost-effective, user-friendly, and ideal for initial point-of-care screening in resource-constrained settings. These rapid tests serve as screening approach for further testing and diagnosis of Hepatitis B and Hepatitis C. Those who test positive with rapid test will be further referred to tertiary health care for gold standard ELISA test. Individuals test positive for ELISA will progress to HBV treatment. Individuals who test negative for rapid test and ELISA will progress to HBV vaccination.

Product Components

Test Cassette/Card: The primary device where the blood sample is applied and the result is read

Sample Collection Tools: Lancets or pipettes for collecting blood samples

Buffer Solution: A reagent used to process the sample and facilitate the reaction.

Dropper

Market Coverage

India:
Available on GeM portal at **minimum price of INR 7.5**

Recommendations from HTAIn

Technology Features

Long Shelf Life

Portable and Convenient

High Sensitivity & Specificity

Rapid Results

High Accessibility

Non-Invasive

Ease of Use

Technical Specifications

Detection Method	Immunochromatographic assay
Sensitivity	>99%
Specificity	>99%
Result Time	5-10 min
Storage	2 - 30 Degree Celsius

Maximum HTA Recommended Price (2020)

Hepatitis B – INR 85 per test;
Hepatitis C – INR 110 per test

Applicability in Healthcare Setting

States can adopt RDTs effectively by training health workers, increasing public awareness, securing supply chains, ensuring quality control, managing data efficiently, and implementing well-funded policies with proper monitoring..

Policy Advocacy/ Adoption of Technology

1. The National Viral Hepatitis Control Program (NVHCP), emphasizes the use of RDTs for early detection and diagnosis of Hepatitis B and C.
2. Maharashtra, New Delhi, Karnataka, Tamil Nadu, West Bengal, Punjab, Kerala have adopted this technology.

AI X-Ray screening and interpretation tool for Tuberculosis

Country of Origin: India
Category: Diagnostics
Primary Use: Screening and Diagnosis of tuberculosis

Product Description

AI tool enhances the precision of chest X-ray analysis. Leveraging deep learning, it categorizes X-rays into normal or abnormal and pinpoints signs of tuberculosis (TB). It recognizes TB markers like lung opacities, abnormal lymph nodes, and pleural effusion. A TB score, varying from 0 to 1, indicates the algorithm's certainty in identifying TB-related changes. The score's threshold is adjustable to suit the particular clinical environment, guaranteeing precise and relevant interpretations.

Recommendations from HTAIn

Technology Features

High Accuracy

Faster TAT

Multilingual Support

Cloud Deployment

Early Diagnosis

Product Components

Image processing Module

Cloud and on-premise deployment

AI enabled algorithm software

Reporting tools

Technical Specifications

Screening Type	AI enabled
Specificity	96%
Sensitivity	100%
Accuracy	96%
Processing Time	10 – 60 seconds
Input format	PA/ AP view chest X-rays

Market Coverage

India:
Currently not available on GeM portal

Outside India:
Vietnam, UK, UAE

Maximum HTA Recommended Price (2024)

INR 400 per screening

Applicability in Healthcare Setting

States can adopt this technology as it enhances screening procedures by addressing the issue of human resource constraints and also reduce the delays in the diagnosis and treatment of tuberculosis.

Policy Advocacy/ Adoption of Technology

1. The National Tuberculosis Elimination Program has incorporated AI-based chest X-ray (CXR) for TB screening and diagnosis.
2. Operational Guidelines for TB Services at Health & Wellness Centres recommend the use of AI-based CXR tools.
3. Maharashtra, Rajasthan, Tamil Nadu have adopted this technology.

Latent TB Infection Test (LTBI)

Country of Origin: India

Category: Diagnostics

Primary Use: Screening of latent TB infection

Product Description

Latent Tb diagnostic test is a specific skin test for detecting latent TB infection. Designed for point-of-care use, the test can be administered in the field without the need for a lab facility. The test is unaffected by prior BCG vaccination, requires no sample handling, and is easy to administer using the Mantoux technique.

Product Components

Smart Patch: for patient tracking

AI- driven app: TB Connect App for seamless registration

Multidose vial containing the antigens

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Easy to administer

Point of care test

No need of sample handling

Unaffected by BCG vaccination status

High Accuracy

Smart patch for tracking

Technical Specifications

Dosage	0.1 ml
Composition (one dose 0.1 ml contains)	
rdESAT - 6	50 ng
rCFP - 10	50 ng
Shelf life	18 months
Stable temp	2 – 8 degrees
Sample Type	Whole Blood

Maximum HTA Recommended Price (2023)

INR 204

Applicability in Healthcare Setting

States can adopt latent TB test for household contact tracing as it is unaffected by BCG vaccination, and suits special groups like HIV patients and children.

Policy Advocacy/ Adoption of Technology

1. The National Tuberculosis Elimination Programme (NTEP) has included indigenously developed latent TB test to eliminate TB by 2025.
2. Latent TB testing is integrated into the Ni-kshay platform, allowing easy reporting and quick case identification and treatment initiation by healthcare providers.
3. Uttar Pradesh, Madhya Pradesh, Jharkhand, Orissa, Karnataka have adopted this technology.

RT- PCR Kits for Influenza A

Country of Origin: Europe

Category: Diagnostics

Primary Use: Screening and diagnosis of Influenza A

Product Description

Influenza A RT PCR Kits are sophisticated tools to swiftly and precisely identify Influenza A virus RNA. Leveraging RT-PCR, they provide high accuracy, even at low viral levels, and can detect other viruses like Influenza B and SARS-CoV-2 concurrently. Results are ready in less than 2 hours, and the kits come complete with all required components, suitable for clinical, epidemiological, and research use.

Recommendations from HTAIn

Technology Features

Ready to Use Kit

Compatible with various instruments

High Sensitivity and Specificity

Rapid Results

Product Components

RT-PCR Enzyme Mix: Essential for the reverse transcription and amplification processes

Primers and Probes: Specific for detecting Influenza A virus RNA

Positive and Negative Control: Ensures the test is functioning correctly

Nucleic Acid Extraction Reagents

Market Coverage

India:
Available on GeM portal at a **minimum price of INR 20**

Outside India:
United States, Japan, Canada, China, South Korea

Technical Specifications

Detection Method	Qualitative Real Time PCR
Sensitivity	100%
Specificity	100%
Time to complete test	4 hours
Reactions per Kit	Available in 100, 500, and 1,000 reaction sizes
Storage Conditions	Store at -20 Degree Celsius
Stability	Stable for up to 12 months when stored as recommended

Maximum HTA Recommended Price (2020)

INR 2015 per sample

Applicability in Healthcare Setting

Integrating RT-PCR kits for Influenza A enhances patient care through rapid and accurate virus detection but necessitates trained personnel and specialized equipment.

Policy Advocacy/ Adoption of Technology

1. National Medical Devices Policy 2023 and Production Linked Incentive (PLI) Scheme aim to enhance the growth and self-reliance of India's medical devices sector, including diagnostic kits like RT PCR kits by providing financial incentives to manufacturers.
2. Mumbai, New Delhi, Bangalore, Chennai, Hyderabad, Kolkata, Pune, Ahmedabad have adopted this technology.

Chip based RT PCR test for Mycobacterium Tuberculosis

Country of Origin: India
Category: Diagnostics
Primary Use: Detection and Diagnosis of Tuberculosis

Product Description

Chip based RT PCR test system is a cutting-edge, battery operated, portable molecular diagnostic platform designed for rapid and accurate detection of infectious diseases, including tuberculosis (TB) and multi-drug resistant TB (MDR-TB). The sample preparation device extracts and purifies RNA or DNA from the sample, removing any contaminants. The purified genetic material is then analysed by the PCR analyser, which uses real-time Polymerase Chain Reaction (PCR) technology to amplify and detect specific genetic sequences.

Product Components

Device: Portable, battery operated

Kit : Each kit contains

- Micro PCR chip: 1 unit
- Microtube with freeze dried PCR reagents: 1 unit
- DNase & RNase free pipette tip: 1 unit
- Desiccant pouch : 1 unit

Market Coverage

India:
Available eon GeM portal at a **minimum price of INR 716**

Recommendations from HTAIn

Technology Features

Single use disposable microchip

High sensitivity and specificity

Rapid TAT

Battery operated

Portable

wi-fi enabled

Technical Specifications

Sensitivity	90%
Time to result	35 min
Storage temp	2 – 30 degree Celsius
Reagent stability duration	2 years

Maximum HTA Recommended Price (2020)

INR 800 per sample

Applicability in Healthcare Setting

The device works well in various environmental conditions, needs little user input, and suits primary care with automated reports and real-time data for disease tracking and surveillance.

Policy Advocacy/ Adoption of Technology

1. Following HTA, the National Tuberculosis Elimination Program has recommended chip based RT PCR test for the detection of MTB and rifampicin resistance in sputum samples from people with signs and symptoms of TB.
2. Andhra Pradesh has adopted this technology.

Visual Inspection Kit with Acetic Acid

Country of Origin: India

Category: Diagnostics

Primary Use: Screening of CA- cervix

Product Description

The Visual Inspection with Acetic Acid (VIA) cervix screening kit is an essential tool for early detection of cervical abnormalities. It is a simple and effective method for identifying precancerous lesions and cervical cancer. It includes a sterile vaginal speculum, acetic acid solution, cotton swabs, examination gloves, and a light source. By applying a dilute acetic acid solution to the cervix, abnormal tissues temporarily turn white, allowing for immediate visual identification.

Recommendations from HTAIn

Technology Features

Low Cost

Simple & Effective

Minimal Infrastructure Requirement

Product Components

5% acetic acid solution

Speculum

Consumables: Disposable gloves, cotton swabs, distilled water, light source

Technical Specifications

Ingredients(per 100 ml)	
Glacial acetic acid	5 ml
Distilled water	95 ml

Market Coverage

India:
Available on GeM portal at a **minimum price of INR 130** (500 mL acetic acid)

Maximum HTA Recommended Price (2019)

INR 344 (screening cost)

Applicability in Healthcare Setting

The kit is designed for use in low-resource settings, requiring minimal infrastructure and providing reliable results. It empowers healthcare providers to conduct timely and accurate cervical cancer screenings, improving women's health outcomes.

Policy Advocacy/ Adoption of Technology

Karnataka, Uttar Pradesh, Odisha, Delhi, Madhya Pradesh have adopted this technology.

m-Health Technology for Improving Maternal and Child Health

Country of Origin: India

Category: Health Program

Primary Use: Improve coverage and data quality of health services

Product Description

It is a comprehensive mobile and web-based application developed by the Government of Gujarat to enhance healthcare service delivery and monitoring. It serves as a job-aid for healthcare workers, enabling real-time data entry and tracking of health services. Initially focused on reproductive, maternal, newborn, and child health (RMNCH), the application has expanded to cover nutrition, non-communicable diseases, cerebral palsy, and ophthalmology.

Product Components

Mobile Health Technology Application

Data Quality and Validation

Interdisciplinary Approach

Policy Support

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Real time data entry

Dashboard and automatic report generation

Alert for high-risk cases

Tracks Beneficiaries

Supportive Supervision & Monitoring

Technical Specifications

Data Entry	Real –time, both online and offline
User Interface	Tailored for different types of healthcare workers, including ASHAs, MPWs, and CHOs
Integration	With other healthcare platforms

Maximum HTA Recommended Price (2021)

INR 2424 (per beneficiary)

Applicability in Healthcare Setting

States can adopt this technology as it is capable of enhancing data accuracy, identifying MCH high-risk cases, and improving healthcare quality by integrating current data with healthcare services for coordinated care thereby improving MCH health outcomes.

Policy Advocacy/ Adoption of Technology

Gujarat, Maharashtra, Uttar Pradesh, Bihar have adopted this technology.

Rapid Diagnostic Kit for Uncomplicated Urinary Tract infection

Country of Origin: India
Category: Diagnostics
Primary Use: Diagnosis for bacterial infection (UTI)

Product Description

The rapid, portable, and affordable diagnostic kit provides bacterial identification and AST results within 4 hours. Using an optical sensor and indigenous software, it determines bacterial load and antibiotic sensitivity without requiring specialized lab infrastructure. Detection is based on chromogenic endpoints which are measured using a set of optical sensors. the output is analysed using lab-developed algorithm based software which reports the sensitivity of the pathogen to the panel of antibiotics tested. It is suitable for clinics, small labs, and primary healthcare centers.

Product Components

Machine consists of an optical reader

Kit includes:
- Pre-loaded antibiotic strips for UTI
- Pi and P1 – P6 strips
- Dehydrated BITGEN vial: 1pc
- Sterile water ampule: 1pc

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Easy to use

High Accuracy

Portable

Screening for multiple antibiotics

Optical Sensors

Quick results

Technical Specifications

Sensitivity	95.4% (CI: 92.44- 97.48)
Specificity	85.6% (CI: 82.10- 86.11)
Detection Type	Quantitative
Sample prep time	20 minutes
Incubation time	2-3 hours
Optical read out	10 minutes
Analysis of results	10 minutes

Provides bacterial identification and AST results within 4 hours

Maximum HTA Recommended Price (2022)

INR 550 per kit

Applicability in Healthcare Setting

Implementing Rapid Diagnostic Test Device for screening and diagnosis at community level will be a cost-effective strategy to provide quality and quicker treatment for UTI infections.

Hearing Aid Device for Older Adults

Country of Origin: India

Category: Medical Device

Primary Use: Hearing impairment

Product Description

Digital Hearing aid is an advanced auditory device engineered to enhance auditory perception through sophisticated sound processing algorithms. It effectively attenuates ambient noise while amplifying speech frequencies, thereby improving speech intelligibility in various acoustic environments. It features rechargeable lithium-ion batteries, providing sustainable power and reducing the need for frequent replacements. Constructed with durable materials, it is resilient to moisture and earwax, making it suitable for individuals with diverse degrees of hearing impairment.

Product Components

Microphone

Earmold

Battery

Tubing

Market Coverage

India:
Available on GeM portal at **minimum price of INR 5000**

Recommendations from HTAIn

Technology Features

Durable

Rechargeable Battery

Customizable fit

Versatile

Bluetooth Connectivity

Technical Specifications

Maximum OSPL 90	135 dB(max)
HF Avg. OSPL 90	125.1 dB - 135 dB
HF Avg. Full on Gain	60 dB (min) (at 50 dB input)
Frequency Range	200 Hz to 4000 Hz
Total Harmonic Distortion	≤ 7% at frequency 500, 800 & 1600 Hz at RTG position
Battery Current	≤ 2 mA
Equivalent Input Noise Level	≤ 30 dB

Maximum HTA Recommended Price (2025)

INR 8000

Applicability in Healthcare Setting

Central and state governments can prioritize the inclusion of hearing aids in geriatric health policies and programs so as to ensure improved communication and mental wellbeing of senior citizens.

Portable Intracranial Bleed Detector

Country of Origin: India

Category: Medical Device

Primary Use: Screening and Diagnosis for intracranial bleed

Product Description

Portable Intracranial Bleed Detector is an instant, non-invasive, and portable intracranial bleed detector using Near-Infrared Spectroscopy (NIRS) to diagnose traumatic intracranial haemorrhages (TICH). It emits NIR light to assess blood absorption through the skull, detecting hematomas by measuring haemoglobin concentration changes. Designed for ambulances and healthcare settings, it is user-friendly and safe for repeated use, enhancing prompt and accurate assessments to improve outcomes for traumatic brain injury patients.

Product Components

NIRS Probes: Receive the scattered light to measure absorption

Machine Learning Algorithm: A software to interpret data collected from the NIRS probes

Display Interface: Enables medical personnel to initiate scans, view results, and interpret data easily

Market Coverage

India:

Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Non-Invasive

Real time Data Processing

Portable

User Friendly Interface

Multi-Depth Examination

Clinical Reliability

Machine Learning Algorithm to interpret data collected

Technical Specifications

Wavelength Range	Between 700 nm to 1000 nm
Light Source	Near-Infrared (NIR) light-emitting diodes, Laser Diode
Software	ML Algorithms Trained
Detection Method	CCD (Charge-Coupled Device)
Battery Life	4-8 Hours
Connectivity	Wireless Capabilities
Data Processing Unit	Integrates display, processing, and control functions and possesses a sensor with an eye-safe NIR diode laser and an optical detector

Maximum HTA Recommended Price (2025)

INR 13,66,000

Applicability in Healthcare Setting

This technology can complement CT scan and serve as a tool to enhance screening, early detection, streamline triage, and prioritize cases for CT imaging This approach will improve early detection and treatment of traumatic brain injuries, ultimately enhancing patient outcomes and reducing healthcare costs.

ICU Ventilators with Neutrally Adjusted Ventilatory Assist

Country of Origin: India

Category: Medical Device

Primary Use: Mechanical ventilation in ICU

Product Description

Neutrally Adjusted Ventilatory Assist (NAVA) is an innovative mechanical ventilation mode that synchronizes with the patient's natural breathing efforts by monitoring the electrical activity of the diaphragm (Edi). NAVA is versatile, suitable for both invasive and non-invasive ventilation, and can be used post-extubation to monitor respiratory effort. By improving patient-ventilator synchronization and facilitating a smoother weaning process, NAVA represents a significant advancement in respiratory care, providing a more personalized and effective approach to mechanical ventilation.

Product Components

Ventilator

Edi Catheter

Edi Module

Market Coverage

India:
Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Patient synchronized support

Comprehensive monitoring

Minimize sedation need

Improved weaning process

Versatile application

Technical Specifications

X-ray identification	Barium Sulfate strips
Sterilization	Gamma Sterilized
Gastric tube Material	Polyurethane
Electrode material	Stainless steel
Operation temp	10° to 45°C
Humidity	15 to 100 % RH
Pressure	500 to 1500 mbar
Voltage	5 kv

Maximum HTA Recommended Price (2025)

INR 60,518

Applicability in Healthcare Setting

States can adopt NAVA as it reduces cost per patient as compared to CMV (Conventional Mechanical Ventilation), and also lowers ICU resource utilization through reduction in mechanical ventilation duration.

Point of Care Test Kit for Haemophilia A and Von Willebrand Disease

Country of Origin: India
Category: Diagnostics
Primary Use: Diagnosis

Product Description

The Haemophilia A test kit is designed to measure the activity of Factor VIII in the blood, essential for diagnosing and managing Haemophilia A. The Von Willebrand disease test kit, on the other hand, is used to diagnose and evaluate the functional activity of von Willebrand factor (VWF) in the blood. It comprises VWF antigen and activity assay reagents, control plasmas, calibrators, and microplate wells with antibodies specific to VWF34. Both kits are crucial for accurate diagnosis and effective management of these bleeding disorders.

Product Components

Test device

Dropper – 30 microlitre

Silica gel

No. of tests conducted per kit: 10

Consumables: Reagents, control plasmas, calibrators, buffers, diluents and microplate wells

Market Coverage

Currently not available on GeM portal

Recommendations from HTAIn

Technology Features

Ease of use

High Sensitivity & Specificity

Long Shelf life

Portable

Rapid Results

Technical Specifications

Specifications	Von Willebrand kit	Hemophilia A kit
Detection Method	Immunochromatography	
Accuracy	-	98%
Specificity	-	99%
Sample Volume	70 microlitre	-
Sample material	Human Plasma	-
Result Time	10 min	15 min
Storage	2 – 30 degree Celsius	2 - 25 Degree Celsius

Maximum HTA Recommended Price (2025)

Von Willebrand Disease kit: INR 200 , Haemophilia A kit: INR 250

Applicability in Healthcare Setting

States can adopt Point-of-care (POC) test kits at all levels of public healthcare system - primary, secondary, and tertiary as it ensures detection of additional cases, thereby enhancing overall health outcomes.

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A. Related to Technology

- The presence of a particular technology in the Compendium is subject to modification in light of any fresh evidence that may come to the attention of HTAIn at a later date.
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- The recommendations provided are indicative of the technology's capabilities and specifications for a specific use and do not endorse or show preference for any specific brand.
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