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A Health Technology Assessment of the Strokefinder MD100

For Early Detection of Stroke and Traumatic Brain Injury in the Rwandan Healthcare System

Degree project report in Biomedical Engineering

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Gothenburg, Sweden 2025
www.chalmers.se

DEGREE PROJECT REPORT 2025

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Degree project report 2025
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Abstract

Stroke and traumatic brain injury (TBI) are leading causes of death and disability in Rwanda. Care is frequently delayed due to limited access to computed tomography (CT) imaging outside major referral hospitals, fragmented referral pathways, and household financial barriers. The StrokeFinder MD100 is a portable, non-ionising microwave-based device that provides a “stroke / no-stroke” output to support early triage in emergency settings.

The Health Technology Assessment (HTA) presented in this thesis draws on three sources: (i) a structured review of international clinical studies on the MD100, (ii) semi-structured interviews with Rwandan stakeholders across neurology, emergency medicine, the national ambulance service (SAMU), biomedical engineering, and health policy, and (iii) health-economic modelling aligned with Rwanda’s resource constraints and willingness-to-pay assumptions. Organisational, ethical, and legal implications are analysed using the European Network for Health Technology Assessment (EUnetHTA) Core Model.

Evidence from European and Australian cohorts shows high sensitivity (~90–96%) and moderate specificity (~70%) for detecting the presence of stroke, confirming suitability as a triage support tool. Interviewees anticipated benefits particularly in SAMU ambulances and district hospitals, where diagnostic delays are greatest. Economic modelling shows that cost-effectiveness depends on high utilisation: at ~1,000–1,500 scans per device per year, per-patient cost (~USD 13–16) falls within the commonly used cost-effectiveness benchmark of approximately one to three times Rwanda’s Gross Domestic Product (GDP) per capita (≈ USD 970). The primary budget impact is the capital cost (≈ USD 80,000 per device), and sustainability requires reliable maintenance, operator training, and integration into structured triage protocols. Ethical and regulatory findings highlight the need for equitable deployment, clear communication of the device’s triage purpose, and Rwanda Food and Drugs Authority (Rwanda FDA) oversight for clinical validation and post-market monitoring.

A phased implementation is recommended, beginning with a local clinical validation study at one of the national referral hospitals—CHUK, King Faisal Hospital, or Rwanda Military Hospital—followed by targeted expansion to SAMU and selected district hospitals. Further research is required to generate local diagnostic performance data and refine cost estimates.

Keywords: Strokefinder MD100, HTA, Assessment, Rwanda, Triage, TBI, Medfield Diagnostics, Stroke, Truma, Healthcare.

Acknowledgements

I would like to express my sincere gratitude to my supervisor, Professor Mikael Persson, for his guidance, constructive feedback, and support throughout this project. His expertise and commitment were essential to the development of this work.

I also wish to thank the **University of Rwanda** for its collaboration and institutional support, and **Dr. Fidèle Sebera** for his guidance, coordination, and academic supervision in Rwanda.

My appreciation goes to the clinicians, EMS personnel, biomedical engineers, and policymakers who participated in the interviews. Your insights provided essential context to understand the realities of stroke and emergency care in Rwanda, and I am deeply grateful for the time and knowledge you shared.

I further thank the **Rwanda Ministry of Health**, **Rwanda Biomedical Centre (RBC/SAMU)**, **Rwanda Food and Drugs Authority (RFDA)**, and **the hospital teams** for their collaboration in discussions and access to system-level information.

Finally, I thank my family and friends for their patience, encouragement, and support throughout the research and writing process.

Hasan Alshaqouq
Gothenburg, November 2025

List of Acronyms

Acronym	Full Term / Definition
ATLS	Advanced Trauma Life Support
BP	Blood Pressure
CBHI	Community-Based Health Insurance (Mutuelles de Santé)
CHUB	University Teaching Hospital of Butare
CHUK	University Teaching Hospital of Kigali
CHW	Community Health Worker
CT	Computed Tomography
DSMB	Data and Safety Monitoring Board
EMS	Emergency Medical Services
ETAT	Emergency Triage, Assessment, and Treatment (WHO protocol)
EUnetHTA	European Network for Health Technology Assessment
FAST	Face, Arm, Speech, Time (stroke recognition tool)
GCP	Good Clinical Practice
GCS	Glasgow Coma Scale
GDP	Gross Domestic Product
GCS	Glasgow Coma Scale (neurological severity assessment)
GCP	Good Clinical Practice (clinical research standard)
HIC	High-Income Country
HI	Humanity & Inclusion (NGO active in rehabilitation)
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
ICP	Intracranial Pressure
ICER	Incremental Cost-Effectiveness Ratio
IEC 60601	International Standard for Medical Electrical Equipment Safety
IEC 62304	International Standard for Medical Device Software Lifecycle Processes
INMB	Incremental Net Monetary Benefit
IRB	Institutional Review Board (ethics committee)
ISO 13485	Quality Management System for Medical Devices
ISO 14971	Medical Device Risk Management Standard
KFH	King Faisal Hospital Kigali
LMIC	Low- and Middle-Income Country
LTR	Local Technical Representative (required for device registration/importation)
MAH	Marketing Authorization Holder
MD100	StrokeFinder MD100 (portable microwave-based brain assessment device)

Acronym	Full Term / Definition
MoH	Ministry of Health (Rwanda)
MRI	Magnetic Resonance Imaging
mRS	Modified Rankin Scale (functional outcome measure after stroke)
NCD	Non-Communicable Disease
NEMS / SAMU	National Emergency Medical Service / Service d'Aide Médicale Urgente (Rwanda EMS)
NGO	Non-Governmental Organization
NIHSS	National Institutes of Health Stroke Scale
OT	Occupational Therapy / Occupational Therapist
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Report
QALY	Quality-Adjusted Life Year
RBC	Rwanda Biomedical Centre
RFDA (or Rwanda FDA)	Rwanda Food and Drugs Authority
RMH	Rwanda Military Hospital
RTA	Road Traffic Accident
SATS	South African Triage Scale
SLT	Speech and Language Therapy / Therapist
SOP	Standard Operating Procedure
tPA	Tissue Plasminogen Activator (thrombolytic drug)
TBI	Traumatic Brain Injury
TLV	Swedish Dental and Pharmaceutical Benefits Agency
UBudehe	Rwanda's socioeconomic household classification system
WHO	World Health Organization
WTP	Willingness-To-Pay Threshold

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1. Introduction

1.1 Background

1.1.1 Stroke

Stroke is a major global public-health challenge and remains a leading cause of death and disability worldwide. Each year, more than **12 million people experience a stroke**, and approximately **6.5 million die** as a result [1]. Over **70 % of all strokes** and **87 % of stroke-related deaths** occur in **low- and middle-income countries (LMICs)**, where delayed diagnosis, limited neuro-imaging capacity, and shortages of specialized personnel contribute to poor outcomes [2]. This imbalance reflects global inequities in access to acute stroke care and prevention.

The rising impact of stroke in Rwanda mirrors this wider pattern and illustrates the country's ongoing **epidemiological transition**—a shift from infectious and nutritional diseases toward chronic, non-communicable, and degenerative conditions such as cardiovascular disease, cancer, and stroke [3]. **Rapid urbanization, lifestyle change, and population aging** accelerate this trend, while **limited rehabilitation capacity and low community awareness of stroke symptoms**further compound the burden [11][29].

Disability from stroke is substantial, with many patients unable to return to work because of inadequate rehabilitation and limited post-stroke support [4]. Hospital-based studies from Rwanda—including King Faisal Hospital and the University Teaching Hospital of Kigali—report in-hospital mortality rates frequently exceeding **30–40 %** [5], far higher than in high-income countries where organized stroke units and early reperfusion therapies have reduced mortality below 15 % [6].

Stroke is a **time-critical condition**: approximately **1.9 million neurons and 13.8 billion synapses** are lost every minute during an untreated ischaemic stroke [7]. Rapid recognition, pre-hospital triage, and timely treatment are therefore decisive in improving survival and functional outcomes [8]. Despite international emphasis on "time-to-treatment," most LMICs—including Rwanda—still lack integrated pre-hospital pathways capable of rapid imaging and treatment within the therapeutic window [9].

Clinically, stroke presents as sudden weakness or numbness, facial asymmetry, slurred speech, visual disturbance, dizziness, or loss of coordination [10]. In Rwanda, ischaemic strokes are frequently associated with hypertension, diabetes, and atrial fibrillation; however, prevention remains limited by inconsistent screening for these conditions [11]. Structural health-system factors—scarce CT/MRI access, under-developed referral systems, and limited availability of essential medicines—delay diagnosis and worsen outcomes, particularly in rural districts [12].

HIV infection also contributes to stroke risk. With an adult HIV prevalence of **2.6 %**, opportunistic infections, coagulopathies, and vascular inflammation can all increase cerebrovascular events [13]. Other modifiable risk factors include tobacco and alcohol use, sedentary lifestyle, and poor blood-pressure control [14].

Treatment strategies differ between sub-types. For haemorrhagic stroke, management focuses on blood-pressure control, limiting further bleeding, and reducing intracranial pressure [15].

For ischaemic stroke, reperfusion therapy using thrombolysis or thrombectomy is the global standard, but in Rwanda thrombolytic therapy (tPA) is rarely available—limited to King Faisal Hospital and occasionally the University Teaching Hospital of Kigali—and usually paid for out-of-pocket [5]. Community-based health insurance (**Mutuelles de Santé**) covers part of acute hospital care but not advanced stroke interventions such as thrombolysis [16].

Emergency Medical Services (EMS) in Rwanda are expanding, yet stroke-specific training and triage remain early-stage [17][28]. Historically, EMS curricula have emphasized trauma and obstetric emergencies, with limited integration of non-communicable disease management. Strengthening EMS capacity and incorporating structured stroke-triage systems could markedly reduce treatment delays [17][28].

Overall, Rwanda's growing stroke burden illustrates both epidemiological transition and systemic limitations. Addressing these challenges will require innovations that enable earlier diagnosis, rapid subtype differentiation, and faster referral within pre-hospital and district-hospital settings.

Ischaemic Stroke

Ischaemic strokes occur when blood flow to part of the brain is blocked, usually by a clot [18]. Globally they account for **80–85 %** of all strokes, though in sub-Saharan Africa the proportion is lower (**55–70 %**) due to the high prevalence of hypertension-related haemorrhagic stroke [19].

Mechanisms [18,30]:

- **Thrombotic stroke:** a clot forms within a cerebral artery, often secondary to atherosclerosis.
- **Embolic stroke:** a clot originates elsewhere (commonly the heart in atrial fibrillation) and lodges in a cerebral artery.

In Rwanda, ischaemic strokes are mainly linked to hypertension, diabetes, and atrial fibrillation, but prevention is hindered by late detection and weak routine screening [11].

Haemorrhagic Stroke

Haemorrhagic strokes result from rupture of intracranial vessels, causing bleeding inside the brain [20]. The bleeding increases intracranial pressure and aggravates neuronal injury. African studies, including East-African cohorts, report similar risk patterns and presentations [21]. Typical symptoms include sudden severe headache, vomiting, decreased consciousness, and focal deficits such as hemiplegia, speech disturbance, or visual loss [22]. Mortality remains high because neurosurgical capacity is restricted to a few tertiary hospitals [23].

Risk Factors in Rwanda

Structural and systemic barriers—such as limited access to diagnostic imaging, uneven distribution of specialized staff, and delays in referral pathways—continue to worsen stroke outcomes across Rwanda.

The major risk factors include:

- **Hypertension:** National surveys estimate **16–20 % prevalence** among adults, yet less than half are aware or on treatment [25].
- **Diabetes and dyslipidaemia:** Both are rising with urbanization but remain under-diagnosed due to limited routine screening.
- **HIV infection:** Adult prevalence **2.6 %**, increasing cerebrovascular risk through coagulopathies and vascular inflammation [13].
- **Tobacco and alcohol use:** Common among men, contributing to cardiovascular risk [25].
- **Obesity and sedentary lifestyle:** Growing with urbanization and reduced physical activity [27].
- **Low awareness and delayed care-seeking:** Families often misinterpret stroke symptoms, delaying hospital arrival [5].
- **Urban–rural disparities:** Urban populations have better diagnostic access, while rural areas face challenges in both detection and management [25].

These factors collectively highlight that stroke prevention requires multisectoral action addressing both clinical and behavioural determinants.

Table 1. Major Risk Factors for Stroke in Rwanda

Category	Risk Factor	Mechanism / Description	Estimated Prevalence (Rwanda)	Source
Non-modifiable	Age > 55 years	Risk doubles every decade after 55 years	Median ≈ 60 yrs at stroke	[1]
	Sex	Higher incidence among men	M:F ≈ 1.3:1	[5]
	Family history	Genetic predisposition to hypertension / lipid disorders	Not quantified	[24]
Modifiable – cardiometabolic	Hypertension	Principal cause of both stroke types	16–20 % adults	[25]
	Diabetes mellitus	Accelerates atherosclerosis	3–5 % adults	[25]
	Dyslipidaemia	Elevated LDL → atherosclerosis	≈ 9 %	[26]
	Overweight / Obesity	BMI ≥ 25 kg/m² increases risk	≈ 17 %	[25]
Modifiable – lifestyle	Tobacco use	Vasoconstriction & platelet activation	≈ 12 % current smokers	[25]
	Harmful alcohol use	Raises BP and haemorrhagic risk	25 % men, 5 % women	[25]
	Physical inactivity	Reduces vascular fitness	≈ 23 % adults	[27]
	Unhealthy diet	High salt, low fruit/veg intake	Not quantified	[24]

Category	Risk Factor	Mechanism / Description	Estimated Prevalence (Rwanda)	Source
Comorbid / other	HIV infection	Endothelial damage & coagulopathy	2.6 % adults	[13]
	Atrial fibrillation	Cardio-embolic source	1–2 % urban adults	[5]
	Urbanization / SES	Lifestyle change ↑ risk	Urban > Rural	[25]
	Low awareness / delay	Late hospital arrival	Median delay > 12 h	[5]

(adapted from INTERSTROKE 2016, SIREN 2018, and Rwanda STEPS 2022)

Caption: Major modifiable and non-modifiable risk factors for stroke in Rwanda. Data adapted from INTERSTROKE (2016), SIREN (2018), Rwanda NCD STEPS Survey (2022), UNAIDS (2023), and Ngabire et al. (2020).

1.1.2 Stroke Treatments

Treatment strategies for ischaemic stroke differ substantially from those of haemorrhagic stroke. Globally, high-income countries have achieved major improvements in acute-stroke survival through rapid access to **intravenous thrombolysis**, **mechanical thrombectomy**, and **neurosurgical interventions** [31].

In Rwanda, however, the treatment landscape remains constrained by delayed hospital presentation, shortages of imaging equipment, and limited specialist services [5][11]. Hospital-based studies show that most stroke patients arrive outside the therapeutic window for reperfusion therapy—often **more than 12 hours after symptom onset** [5][32]. Consequently, the majority of management is **supportive rather than curative**.

Haemorrhagic Stroke Management

For haemorrhagic stroke, treatment focuses on controlling blood pressure, minimizing further bleeding, and reducing intracranial pressure [15].

- **Blood-pressure control:** Antihypertensive medication is the cornerstone of management, but consistent drug availability remains a problem in rural hospitals [11].
- **Clotting or haemostatic agents:** Tranexamic acid and related drugs are seldom used outside referral hospitals [33].
- **Neurosurgery:** Procedures such as decompressive craniectomy (removal of a section of the skull to relieve intracranial pressure) or hematoma evacuation are available only at a handful of tertiary centres—**University Teaching Hospital of Kigali (CHUK)**, **Rwanda Military Hospital**, and **King Faisal Hospital Kigali (KFH)**. Referral delays and surgical-capacity constraints remain major barriers [23][33].

Mortality from haemorrhagic stroke in Rwanda remains high, with in-hospital rates exceeding **40 %** in several studies [5][32].

Ischaemic Stroke Management

Thrombolysis

The global gold standard for acute ischaemic stroke is **intravenous thrombolysis** with tissue plasminogen activator (tPA), administered within 4.5 hours of symptom onset [18].

In Rwanda, however, tPA access is extremely limited. The drug is stocked only at **King Faisal Hospital Kigali (KFH)**and occasionally at the **University Teaching Hospital of Kigali (CHUK)**, and patients must purchase it at their own cost—approximately **USD 1 000 per dose**—making it unaffordable for most families [5][34].

- A 2023 analysis at the University Teaching Hospital of Kigali found that **fewer than 2 % of ischaemic-stroke patients were eligible for thrombolysis**, largely due to late presentation and lack of timely CT confirmation [5].
- Data from **King Faisal Hospital Kigali** show that **only 3–5 tPA administrations occur per year nationwide**, confirming the rarity of reperfusion therapy in routine practice [34].
- Even where tPA is available, limited clinician training and the absence of standardized stroke protocols restrict its use [17][28][34].

Thrombectomy

Mechanical thrombectomy—indicated for large-vessel occlusion up to 24 hours after onset—is **not currently performed in Rwanda** [35].

No interventional-neuroradiology service yet exists, although discussions are underway at King Faisal Hospital Kigali to develop this capacity [34].

Patients with large-vessel occlusions are managed supportively or, in rare cases, referred abroad if families can cover the cost.

Supportive and Adjunctive Care

Because advanced reperfusion therapies are largely unavailable, **supportive management dominates** stroke care in Rwanda [5][32].

- **Oxygen therapy and fluids:** Commonly provided at district and referral hospitals.
- **Antiplatelet therapy:** Aspirin is widely used for secondary prevention once ischaemic stroke is confirmed [18].
- **Antihypertensive therapy:** Initiated after acute stabilization.
- **Seizure control:** Anticonvulsants are administered when indicated, but drug stock-outs are frequent [11].
- **Monitoring and nursing:** Dedicated stroke units do not yet exist; most patients are admitted to general medical wards [5][33].

Barriers to Effective Treatment

Key obstacles to effective stroke treatment in Rwanda include:

- **Delayed presentation:** Most patients reach hospital more than 12 hours after onset—well beyond the therapeutic window for thrombolysis [5][32].
- **Limited imaging:** CT scanners are concentrated in Kigali and Butare, with only **five functional units nationwide**(three in Kigali, one in Butare, one in Ruhengeri) [36].
- **Cost barriers:** Even under **Community-Based Health Insurance (CBHI)** schemes such as *Mutuelles de Santé*, high-cost medicines like tPA are not covered, leaving families to pay in full [16].
- **Training gaps:** Few clinicians or Emergency Medical Services (EMS) personnel have formal training in stroke protocols or time-sensitive triage [17][28].
- **Referral bottlenecks:** Transfers from district to referral hospitals can take hours or days, preventing timely intervention [33].

Summary

In Rwanda, stroke treatment remains largely **supportive**. Haemorrhagic strokes are managed with antihypertensives and, in rare cases, surgery at tertiary hospitals.

Ischaemic strokes are treated with aspirin and risk-factor control; thrombolysis is technically possible in Kigali but performed only **a few times per year**, and thrombectomy is unavailable.

The lack of rapid neuro-imaging, organized stroke-unit care, and structured pre-hospital triage contributes to persistently high mortality and disability rates.

1.1.3 Stroke Rehabilitation

Although cell death at the ischaemic or haemorrhagic core is irreversible, recovery is possible through **neuroplasticity**—the brain's capacity to reorganize and form new neural connections. Rehabilitation capitalizes on this process, enabling patients to regain motor, speech, and cognitive functions impaired by stroke [1]. In high-income countries, comprehensive multidisciplinary rehabilitation programs have markedly improved long-term outcomes and reduced disability [31].

In Rwanda, however, **rehabilitation remains one of the most underdeveloped components of stroke care** [37][38].

Rehabilitation in Rwanda: Current Status

Rwanda has made progress in integrating rehabilitation into its health system, yet major gaps persist [37][38].

- **Workforce shortages:** The country has fewer than **150 licensed physiotherapists**, fewer than **20 occupational therapists**, and fewer than **10 speech-language therapists** for a population of 13 million [38][39]. This is far below the **World**

Health Organization (WHO) recommended minimum rehabilitation workforce density.

- **Geographic concentration:** Most professionals are based in **Kigali**—mainly at the **University Teaching Hospital of Kigali (CHUK)**, **King Faisal Hospital Kigali (KFH)**, and **Rwanda Military Hospital**—leaving rural districts underserved [37].
- **Training capacity:** The **University of Rwanda** launched physiotherapy and occupational-therapy degree programs during the past decade, but annual graduate numbers remain too low to meet national demand [39].
- **Limited community-based rehabilitation:** Rwanda's **Community Health Worker (CHW)** network, one of the strongest in sub-Saharan Africa, has not yet been fully leveraged for long-term post-stroke rehabilitation. CHWs primarily focus on maternal, child, and infectious-disease health [40].

Types of Rehabilitation

1. **Physiotherapy** – Focuses on restoring strength, balance, and mobility. It is available at referral hospitals and some district facilities, though access and early mobilization remain inconsistent [38].
2. **Occupational Therapy** – Addresses daily-living skills such as dressing, feeding, and reintegration into work. Services are concentrated in Kigali; most patients outside the capital never access occupational therapy [37].
3. **Speech and Language Therapy** – Critical for aphasia and dysphagia management. Fewer than ten speech-language therapists currently practice in Rwanda, mostly in private or NGO settings [38][40]. Many patients therefore remain untreated, increasing the risk of aspiration pneumonia and long-term isolation.
4. **Psychosocial Support** – Depression and anxiety are frequent post-stroke, yet structured mental-health integration in rehabilitation is limited. Most psychosocial support is provided informally by family caregivers [38].

Barriers to Effective Rehabilitation in Rwanda

Rehabilitation services remain severely under-resourced, especially outside Kigali [37][38]. The principal barriers include:

- **Human-resource shortage:** Too few physiotherapists, occupational therapists, and speech-language pathologists to cover the national caseload [38][39].
- **Geographic inequity:** Rehabilitation professionals are concentrated in three referral hospitals, leaving district hospitals without structured programs [37].
- **Financial barriers:** Even with *Mutuelles de Santé* (Community-Based Health Insurance), co-payments are required for therapy sessions, and private rehabilitation remains unaffordable [16][37].
- **Cultural perceptions:** In some communities, stroke disability is viewed as spiritual, leading families to prefer traditional healers over medical rehabilitation [38].
- **Infrastructure limitations:** Few hospitals have dedicated rehabilitation wards or stroke units; most patients are admitted to general medical wards without specialized staff [37][38].
- **Training gaps:** National curricula for rehabilitation professionals remain limited in advanced neuro-rehabilitation competencies [39].

Opportunities and Innovations

Despite these limitations, Rwanda has clear opportunities to expand rehabilitation. The government's **Universal Health Coverage** agenda provides a policy basis for scaling rehabilitation across districts [37]. **Humanity & Inclusion (HI Rwanda)** has piloted community-based rehabilitation models showing improved functional outcomes and patient satisfaction [38][41].

Rwanda's strong **digital-health infrastructure** could enable **tele-rehabilitation**, allowing physiotherapists and occupational therapists in Kigali to guide patients in rural areas via mobile platforms [37].

Integrating **Community Health Workers** into post-stroke follow-up could improve continuity of care: they could be trained to monitor functional recovery, provide home-exercise supervision, and facilitate referrals. Regional collaborations—such as the **East African Rehabilitation Training Network**—could also expand pre-service education and increase the number of trained rehabilitation professionals [39][41].

Summary

Stroke rehabilitation in Rwanda is still in its early stages. Physiotherapy is available at tertiary and a few district hospitals, but occupational and speech-therapy services are extremely limited. Workforce shortages, late initiation of therapy, cultural barriers, and financial and geographic inequities result in incomplete recovery for most stroke survivors.

Expanding both **hospital-based and community-based rehabilitation** is essential to reduce the long-term disability and socioeconomic burden of stroke in Rwanda [37][38][41].

1.1.4 Traumatic Brain Injury (TBI)

Rwanda faces a disproportionately high rate of **road traffic accidents (RTAs)** compared with other East African countries. National Police records report **over 5,000 road traffic accidents annually** in a population of just over 13 million, corresponding to nearly **400 incidents per 100,000 people per year** [42]. This rate is substantially higher than the **sub-Saharan African average of approximately 270 per 100,000** and more than **double the global mean of 170 per 100,000** [43]. These accidents contribute significantly to **traumatic brain injury (TBI)**, which remains a **leading cause of emergency admissions and neurosurgical workload** in Rwanda [44][45].

Pathophysiology and Types of TBI

The pathophysiology of TBI in Rwanda mirrors global patterns. TBI results from **external mechanical forces disrupting brain function**, typically due to acceleration–deceleration injuries, blunt trauma, or penetrating injury [46].

Two main categories are recognized:

- **Focal injuries**, such as contusions or intracranial hematomas, where localized brain damage occurs.
- **Diffuse injuries**, such as diffuse axonal injury, involving widespread shearing of axons.

Both categories are associated with significant morbidity and mortality when diagnosis and treatment are delayed [46][47].

At the **University Teaching Hospital of Kigali (CHUK)**, **Rwanda Military Hospital**, **King Faisal Hospital Kigali (KFH)**, and **University Teaching Hospital of Butare (CHUB)**, severe TBI cases represent a major proportion of surgical admissions. Procedures such as **craniotomy** and **craniectomy** are routinely performed at these referral hospitals, although capacity remains limited by shortages of neurosurgeons, anesthesiologists, intensive care beds, and essential monitoring equipment [23][44].

The **difference between craniotomy and craniectomy** is clinically significant:

a *craniotomy* involves **removing a portion of the skull to access the brain and replacing the bone flap during the same operation**, whereas a *craniectomy* involves **removing the bone flap without immediate replacement**, typically to relieve intracranial pressure caused by swelling. The bone may later be reimplanted in a procedure known as *cranioplasty*[48][49].

Survivors of severe TBI frequently experience long-term physical, cognitive, and behavioural impairments, emphasizing the importance of post-acute neurorehabilitation—an area still underdeveloped in Rwanda [38][41].

Epidemiology in Rwanda

Epidemiological studies indicate that head injuries constitute one of Rwanda's most pressing trauma burdens.

- A study at the **University Teaching Hospital of Kigali (CHUK)** found that **head injuries accounted for over 40% of all surgical emergencies**, with **young males aged 15–35 years** being most affected [50].
- **Road traffic accidents** are responsible for **60–70% of TBIs**, most involving **motorcycles**, followed by pedestrian and vehicle collisions [42][50].
- Intentional injuries (assaults) and accidental falls constitute additional causes, while occupational and sports-related injuries remain rare.
- Mortality remains high, as many patients present late and advanced neurocritical care is available only at a limited number of specialized units within referral hospitals [23][44].

Compared to stroke, TBI affects a **younger demographic**, leading to substantial years of life lost and major **economic impact** due to lost productivity [50][51].

Clinical Presentation

Symptoms depend on injury severity:

- **Mild TBI:** Headache, dizziness, confusion, nausea, and brief disorientation.
- **Moderate TBI:** Loss of consciousness lasting minutes to hours, memory impairment, or seizures.
- **Severe TBI:** Coma, abnormal posturing, dilated pupils, or cerebrospinal fluid leakage from the nose or ears.

Neurological deficits such as weakness, aphasia, or seizures may overlap with stroke, complicating rapid differentiation without imaging [25][47].

Burden and Outcomes in Rwanda

TBI imposes a major and ongoing strain on Rwanda's health system. The **University Teaching Hospital of Kigali (CHUK)**, **University Teaching Hospital of Butare (CHUB)**, **Rwanda Military Hospital**, and **King Faisal Hospital Kigali (KFH)** collectively receive the majority of severe cases. However, intensive-care resources are constrained, and continuous neurological monitoring is limited [44][45].

Many district hospitals **lack CT scanners**, forcing inter-hospital transfers that delay diagnosis and increase mortality [36]. National health data from 2022 show that trauma-related admissions—dominated by head injuries—accounted for **over 35% of surgical workload** at referral level [45][50]. Rehabilitation services for TBI survivors remain as limited as for stroke, leaving many with lifelong disability [38][41].

Because most patients are young adult males, TBI contributes heavily to **economic losses** through loss of productivity, caregiving demands, and long-term rehabilitation costs [51]. This burden extends beyond health to social and economic development sectors.

Summary

TBI in Rwanda is a **time-sensitive, resource-intensive condition** driven primarily by road traffic accidents. The burden is particularly severe among young males, creating both public health and socio-economic consequences.

With **inadequate pre-hospital care**, **limited CT imaging capacity**, and **a limited number of specialized neurocritical care units**, outcomes remain poor. Rehabilitation services are minimal, and survivors often face permanent disability.

Scaling up trauma prevention, strengthening neurosurgical capacity, and integrating post-TBI rehabilitation into national policy are essential next steps.

1.1.5 TBI Treatments

The management of **traumatic brain injury (TBI)** in Rwanda depends on injury severity, access to diagnostic imaging, and hospital level. Treatment falls into **medical management**, **surgical intervention**, and **rehabilitation**, though access to each remains highly uneven across the health system.

Rwanda's healthcare system follows a **pyramidal model**: health posts and centers deliver primary care, district hospitals provide secondary services, and referral hospitals—**University Teaching Hospital of Kigali (CHUK)**, **King Faisal Hospital Kigali (KFH)**, **Rwanda Military Hospital**, and **University Teaching Hospital of Butare (CHUB)**—handle complex specialized care [26][52].

Medical Management

Medical treatment is the first-line approach for most TBI cases in Rwanda, especially at district hospitals lacking neurosurgical capacity. Management focuses on stabilization, prevention of secondary injury, and basic intracranial-pressure control [53][54].

- **Stabilization:** Airway, breathing, and circulation are prioritized on admission in line with *Advanced Trauma Life Support (ATLS)* guidelines [53].
- **Intracranial pressure (ICP) control:** *Mannitol*—a sugar alcohol administered intravenously to draw fluid out of cerebral tissue and reduce swelling—is available in referral hospitals but often absent in smaller facilities [55]. *Hypertonic saline* is seldom available. Few hospitals have ICP monitors, so management relies on clinical observation [54].
- **Blood-pressure management:** *Antihypertensives*—drugs that lower blood pressure by dilating vessels, increasing fluid excretion, or reducing heart rate—are used to prevent secondary brain injury but remain inconsistently available and poorly monitored because of limited intensive-care capacity [56].
- **Seizure prophylaxis:** Anticonvulsants such as phenytoin are administered to patients at high risk of post-traumatic seizures, though stock-outs are frequent [54].
- **Infection prevention:** Broad-spectrum antibiotics are prescribed for open or penetrating skull fractures [53].

Challenges to effective medical management include **delayed presentation**, **limited diagnostic imaging**, and **drug shortages**, particularly in district hospitals [54].

Surgical Management

Surgical intervention is essential for **moderate-to-severe TBI** involving hematomas, depressed skull fractures, or elevated intracranial pressure [29]. Rwanda has **fewer than ten neurosurgeons**, most stationed in Kigali at CHUK, KFH, and Rwanda Military Hospital [33][54].

Procedures performed include:

- **Craniotomy:** temporary removal of a section of the skull to access the brain and treat lesions such as hematomas; the bone flap is replaced during the same operation [57].
- **Craniectomy:** removal of part of the skull without immediate replacement to relieve swelling, with later *cranioplasty* once pressure subsides [57][58].
- **Repair of depressed skull fractures.**

Referral delays are common because most district hospitals lack neurosurgical capacity. **Transfers to referral centers often take 6–24 hours** owing to ambulance shortages, long distances, and weak coordination between referring and receiving facilities [33][52].

Operating theaters in district hospitals are not equipped for neurosurgical emergencies, and intensive-care capacity remains centralized in referral hospitals. Mortality for severe TBI needing surgery often exceeds 30–40 %, driven by late referral and limited post-operative support [29][33].

Rehabilitation

Rehabilitation after TBI in Rwanda faces the same systemic constraints as stroke rehabilitation but is further complicated by higher rates of cognitive, behavioral, and psychiatric sequelae [38][41]. No specialized **neuro-rehabilitation units**exist, and services are fragmented among physiotherapy, psychiatry, and general outpatient care [38].

- **Physiotherapy:** Offered in referral and some district hospitals to restore mobility, but coverage and continuity remain inconsistent [37][38].
- **Occupational Therapy (OT):** Extremely limited; most practitioners are based in Kigali, and few TBI survivors outside the capital receive OT [39].
- **Speech and Language Therapy (SLT):** Essential for communication and swallowing disorders, yet fewer than ten SLTs practice nationwide [38][40].
- **Psychological support:** Minimal integration despite high prevalence of post-traumatic stress disorder (PTSD), depression, and anxiety [38][41].

Major barriers include a shortage of trained staff, delayed initiation of therapy, high out-of-pocket costs, and persistent stigma surrounding disability and mental illness. Reintegration into the community remains particularly difficult for young men with long-term disabilities, exacerbating socioeconomic dependency [41].

Summary and Strategic Perspective

TBI is a leading cause of morbidity and mortality in Rwanda, primarily from **road-traffic injuries**. Acute care is centralized in a handful of referral hospitals facing chronic shortages of specialists, equipment, and intensive-care capacity [29][33].

Medical management is mostly supportive, surgical capacity is limited to a small cadre of neurosurgeons, and rehabilitation is minimal.

Improving outcomes should not rely solely on costly infrastructure expansion. Instead, Rwanda could achieve faster gains by strengthening **prehospital triage**, **EMS coordination**, and **inter-facility transfer efficiency**. Implementing standardized trauma-triage algorithms, integrating real-time communication between district and referral hospitals, and deploying **portable neuro-diagnostic tools** (such as MD100) would substantially shorten the interval between injury and neurosurgical assessment [52][54][59].

Such system-level improvements represent the most pragmatic and scalable path to reducing TBI-related mortality and disability.

1.1.6 Rwanda Healthcare System

The public system forms the **foundation of healthcare delivery** in Rwanda, organized across four levels.

At the base are **Community Health Workers (CHWs)**—over **58,000 nationally**—deployed to every village (*umudugudu*). They provide preventive and basic curative services, including maternal-child health, malaria management, and chronic disease follow-up, but **stroke and TBI recognition are not yet part of their mandate** [31][61].

Public Healthcare

Above the CHWs, **health posts and health centers** provide outpatient consultations, maternity services, and limited emergency stabilization. Suspected stroke or TBI patients are stabilized and referred upward because **definitive management requires neuroimaging and specialist input** [60].

Each district has at least one **district hospital**, offering general medicine, surgery, pediatrics, and obstetrics. These hospitals rarely have CT or MRI scanners and **transfer complex neurological cases** to referral hospitals [60].

At the top of the system are four **national referral hospitals**—the **University Teaching Hospital of Kigali (CHUK)**, **University Teaching Hospital of Butare (CHUB)**, **Rwanda Military Hospital (RMH)**, and **King Faisal Hospital Kigali (KFH)**—which provide tertiary services including CT imaging, neurosurgery, and limited thrombolysis capacity [32][60].

Despite clear guidelines, **referral delays** remain common, mainly due to **cost barriers, ambulance shortages, and weak inter-facility coordination** [60][62].

Private Healthcare

Private healthcare caters to a **small, urban minority**, primarily in Kigali. Facilities such as **King Faisal Hospital Kigali**, **Baho International Hospital**, and **Legacy Clinics** provide advanced imaging and specialist consultations [33][63].

CT scans in private hospitals typically cost **100,000–150,000 RWF (≈80–120 USD)** compared to **30,000–50,000 RWF (≈25–40 USD)** in public hospitals [63][64]. Even with *Mutuelles de Santé* (Community-Based Health Insurance), these costs remain prohibitive for most households.

Private hospitals can offer **faster access to imaging**, but affordability severely limits their role in population-level care [63].

Emergency Medical Services (EMS)

The **Rwanda National Emergency Medical Service (NEMS)**—formerly the *Service d'Aide Médicale Urgente (SAMU)*—is responsible for prehospital care and inter-facility transfers. Coverage has expanded considerably over the past decade, yet remains **limited outside Kigali**, with an estimated **one ambulance per 45,000 people**, far below the WHO recommendation of **one per 25,000** [34][65].

NEMS operates the national emergency number **912**, but response times vary from **10 to 60 minutes** depending on region and terrain [65].
Staff are trained mainly in **trauma management**, while **stroke and TBI-specific triage protocols remain underdeveloped**.

Training in tools like **FAST (Face, Arm, Speech, Time)** is **used in practice but not standardized or documented formally** across the EMS network [65][66].

Triage and Referral Pathways

Triage for neurological emergencies uses both **international** and **locally adapted tools**. The **FAST** tool is recognized nationwide but applied inconsistently; the **NIH Stroke Scale (NIHSS)** is rarely used outside research settings at CHUK [66].

For **TBI**, the **Glasgow Coma Scale (GCS)** is standard and used both **prehospitally and in emergency wards**, guiding classification of severity [66][67].

Rwanda has **not adopted** the South African Triage Scale (SATS), instead relying on **adapted WHO Emergency Triage Assessment and Treatment (ETAT)** protocols—effective for pediatrics but less suited for adult neurological emergencies [35][68].

Referral theoretically follows the chain *(health center → district hospital → referral hospital)*, but **patients often bypass steps** by seeking care directly at higher facilities—commonly due to **distance, cost, or lack of diagnostic equipment** at local levels [62][68].

These delays often push stroke and TBI patients **beyond therapeutic windows** for interventions such as thrombolysis.

Imaging and CT Capacity

Neuroimaging is a major bottleneck. As of **2024**, Rwanda had **functional CT scanners** at CHUK, CHUB, RMH, KFH, and Ruhengeri Hospital, though machine downtime due to maintenance issues frequently reduces availability [36][69]. Most district hospitals still lack CT, forcing referrals to urban centers. MRI access is largely confined to **CHUK** and **KFH**[69]. Consequently, diagnosis of stroke or TBI at lower levels relies mainly on **clinical presentation**, which carries significant risk of misclassification and treatment delay.

Financing and Access

Healthcare financing is dominated by **Mutuelles de Santé**, Rwanda's **community-based health insurance (CBHI)**scheme covering over **90 % of the population** [37][70]. Members pay income-scaled annual premiums through the **Ubudehe** socioeconomic categorization system, while the government and donors subsidize low-income groups. The scheme covers most primary and secondary care, but **advanced services** such as CT scans, neurosurgery, and imported drugs like tPA still require **co-payments**, creating financial barriers for the poorest [37][70]. Uninsured and rural households face the highest risk of catastrophic health expenditure.

Summary

Rwanda's healthcare system is **community-based**, meaning health insurance and services are organized through **locally managed mutual aid structures**, primarily the *Mutuelles de Santé* program. This model emphasizes **community solidarity and decentralized leadership**, ensuring that health coverage reflects household income and community participation [70].

The system has achieved remarkable **coverage at the primary-care level**, driven by the CHW network and Mutuelles scheme [38][70].

However, major weaknesses persist for **time-sensitive conditions** such as stroke and TBI. Referral pathways, though structured, are hindered by financial and logistical barriers. Imaging and neurosurgical services remain centralized in Kigali and Butare, leaving rural populations underserved. EMS has expanded but remains under-trained for neurological emergencies. Private care offers faster access but remains unaffordable for most citizens.

To improve outcomes, Rwanda must **strengthen prehospital triage**, **enhance referral coordination**, and **expand EMS training** in stroke and TBI—supported by evidence-based integration of **portable diagnostic technologies** (such as MD100) that can extend imaging capacity into district and community settings [65][68][69].

1.1.7 Comparative Framing: Sweden and Rwanda

The healthcare system in Rwanda is developing rapidly, supported by substantial investments in **universal health coverage, infrastructure, and workforce training**. It is therefore useful to compare Rwanda's current stage with **Sweden's position two decades earlier**, when Sweden was beginning to scale up advanced stroke interventions.
While the two settings differ in resources and context, the **Swedish experience might provide insight** into how structured **Health Technology Assessment (HTA)** and staged capacity development can accelerate the adoption of effective stroke care [71].

Sweden's Transition Toward Advanced Stroke Care

In the 1990s and early 2000s, Sweden's stroke treatment landscape resembled Rwanda's situation today. **Intravenous thrombolysis with tissue plasminogen activator (tPA)** was not widely available, **stroke units were limited**, and **prehospital triage systems were fragmented** [72][73].
Progress in Sweden depended on both **economic evaluation** and **system-level investment**.

The **Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket, TLV)** played a central role in this evolution. TLV is Sweden's governmental agency responsible for assessing the **cost-effectiveness and reimbursement** of drugs, medical devices, and procedures.
In the early 2000s, TLV conducted HTAs on intravenous thrombolysis and, later, **mechanical thrombectomy**, analyzing both **clinical outcomes** (mortality reduction, improved functional independence via the *modified Rankin Scale*) and **economic impacts** (lower disability pensions, increased workforce participation) [74][75].
These evaluations concluded that reperfusion therapies were **cost-effective**—and, when productivity gains were included, **potentially cost-saving** [74][75].

Following these recommendations, Sweden **integrated reperfusion therapies into national stroke care guidelines**, while simultaneously expanding **stroke units**, **structured referral pathways**, and **EMS stroke triage protocols** [72][76].
Within roughly 15 years, national stroke mortality fell by more than 30 %, and functional outcomes at three months improved significantly, as recorded in the **Swedish Stroke Register (Riksstroke)** [77].

Parallels with Rwanda

To some extent, **Rwanda in 2025 mirrors Sweden's situation two decades earlier**. Rwanda is now introducing **thrombolysis with tPA**, although access remains confined to a few referral hospitals in Kigali and Butare, with very limited uptake. **Thrombectomy is not yet available**, CT and MRI scanners are concentrated in urban areas, and **referral delays** frequently push patients beyond therapeutic windows.
Shortages of specialists—particularly **neurologists and neurosurgeons**—further constrain capacity [43][60][69].

Epidemiological and Economic Contrasts

The **average age of stroke onset** in sub-Saharan Africa is about **57 years**, compared to roughly **75 years** in Sweden [78][79].
This younger age of onset in Rwanda means stroke disproportionately affects the **economically active population**, amplifying productivity loss and caregiver dependency. In Sweden, similar economic considerations helped justify early public investment in reperfusion therapies, as HTA studies demonstrated the long-term savings from restoring functional independence and avoiding disability pensions [74][75][80].

Rwanda currently **lacks comprehensive cost-of-illness or cost-effectiveness analyses** specific to stroke. Without these, indirect costs such as lost productivity, caregiver burden, and household impoverishment remain invisible in policy decisions.
Sweden's experience demonstrates how systematic HTA can quantify these hidden costs, providing a stronger, evidence-based foundation for prioritizing advanced stroke and rehabilitation services [74][80][81].

Lessons for Rwanda

Some may argue that introducing advanced diagnostic devices—such as the **StrokeFinder MD100**—is premature given that **thrombolysis and thrombectomy are still rarely performed**. However, the Swedish trajectory suggests that **investments in diagnostic and triage capacity often precede therapeutic adoption**.

Building early capacity for **rapid diagnosis, structured referral, and EMS stroke recognition** can enable timely treatment once therapies become available. In this sense, Rwanda can **draw lessons from Sweden's phased yet deliberate system-building approach**, ensuring that diagnostic readiness evolves alongside treatment expansion [72][81].

2. Methodology

This study employs a combination of an extensive literature review and qualitative interviews with relevant stakeholders in Rwanda. The following section outlines the methodologies, detailing the process of sourcing and analyzing the literature as well as describing the execution and analysis of the expert interviews.

2.1 Health Technology Assessment

Health Technology Assessment (HTA) is a systematic, multidisciplinary process that evaluates the **medical, social, economic, and ethical** implications of a health technology. Its primary goal is to support **evidence-based policy decisions** on whether a technology should be introduced, reimbursed, or prioritized within a healthcare system [82][83].

The **European Network for Health Technology Assessment (EUnetHTA)** developed the *Core Model version 3.0 (2016)* as a structured framework defining domains for assessment—clinical effectiveness, safety, costs, organizational impact, and ethical considerations [82].
In the present work, I follow that framework by combining evidence from literature and stakeholder perspectives to analyze the clinical, economic, organizational, ethical, and social dimensions of introducing the **StrokeFinder MD100** in Rwanda.

2.1.1 Literature Review Process

The literature review addressed **stroke and traumatic brain injury (TBI)** in Rwanda, focusing on **epidemiology, prevalence, mortality, treatment, rehabilitation capacity, and system readiness**.

Searches were performed in **PubMed**, **Google Scholar**, and **IEEE Xplore**, and were **supplemented with policy and technical reports** from the **Rwanda Ministry of Health (MOH)**, the **Rwanda Biomedical Centre (RBC)**, and the **World Health Organization (WHO)** [87][88][89][90].
Where national data were limited, regional and global evidence from **sub-Saharan Africa** was incorporated to provide context and comparability.

Methodological insight was drawn from previous **HTA studies in South Africa** and from **Sweden's Dental and Pharmaceutical Benefits Agency (TLV)**, whose evaluations of stroke interventions (e.g., thrombolysis and thrombectomy) demonstrate how structured assessment guides technology adoption [84].
Technical documentation and performance data were also obtained from **Medfield Diagnostics**, developers of the **MD100**device.

2.1.2 Interview Study Methodology

To situate the literature findings within Rwanda's healthcare context and capture practical system insights, **19 semi-structured qualitative interviews** were conducted over three months in 2025.
This design allowed participants to describe **barriers, feasibility, and system requirements** in their own words while maintaining a consistent thematic framework.

Ethical approval was granted by the **University of Rwanda Institutional Review Board (IRB)** and by each participating hospital—**University Teaching Hospital of Kigali (CHUK)**, **Rwanda Military Hospital (RMH)**, **King Faisal Hospital Kigali (KFH)**, **Nyarugenge District Hospital**, and **Kibagabaga District Hospital**—in line with the **National Health Research and Ethics Framework** [85].

All participants provided written informed consent after receiving clear information on study aims, confidentiality, and voluntary participation.

A **semi-structured interview** uses a predefined guide of open-ended questions but allows flexibility for probing and follow-up; this approach encourages depth while keeping focus [86].
Interviews were conducted both **in person and online**, lasting **45 to 120 minutes**. Notes and transcripts were verified with participants to ensure factual accuracy and prevent misinterpretation.

Participants were **purposively selected** for their relevance to stroke and TBI management and for representation across health-system levels—**clinicians (neurologists, emergency physicians, EMS staff)**, **system-level actors (MOH and RBC officials, EMS coordinators)**, **administrators and policymakers**.
This diversity enabled triangulation across **clinical practice, regulatory policy, and implementation feasibility**, providing a comprehensive foundation for assessing the potential integration of the MD100 in Rwanda.

Table 2. below summarizes the interviewees, their roles, institutions, and the relevance of their contributions to this HTA.

Table 2: List of Interviewees, Their Roles, Relevance, and Meeting Context

Name	Role / Title	Institution	Relevance to Study
Mrs. Jeanne d'Arc Nyinawankusi	Acting Head of SAMU (Emergency Medical Services Division)	Rwanda Biomedical Centre (RBC)	Provided national perspective on EMS organization, prehospital triage, referral logistics, and operational feasibility of deploying MD100 in ambulance and field settings.
Dr. Emmanuel Mugwiza	Director, Device & Instrumentation Testing Laboratory	Rwanda Food and Drugs Authority (RFDA)	Explained device testing protocols, calibration requirements, and regulatory pathways for medical equipment evaluation and approval in Rwanda.
Dr. Tuyisenge Narcisse	Emergency Physician	Rwanda Military Hospital (RMH)	Described tertiary emergency workflows, imaging delays, and practical considerations for integrating MD100 within busy referral emergency departments.
Dr. Ishimwe Nshuti Ariane	EMS Resident	EMS Unit, Nyarugenge District Hospital	Outlined district-level prehospital response capacity, CT access gaps, and how portable diagnostics could affect triage and transfer efficiency.
Dr. Arlene Ndayisenga	Neurologist, Stroke Diagnosis and Treatment Expert	King Faisal Hospital (KFH)	Contributed specialist insight on stroke presentation, diagnostic accuracy, and potential clinical

Name	Role / Title	Institution	Relevance to Study
			role of MD100 in early differentiation of stroke subtypes.
Dr. Doris Uwamahoro	Specialist in Emergency Medicine & Critical Care	University Teaching Hospital of Kigali (CHUK)	Highlighted burden of acute neurological emergencies, current imaging constraints, and workflow implications of introducing MD100 in emergency triage.
Dr. Twagirumukiza François Régis	Emergency Physician	University Teaching Hospital of Kigali (CHUK)	Provided expert analysis of diagnostic bottlenecks, stroke pathway inefficiencies, and the potential impact of MD100 on equity and outcomes.
Dr. Appolinaire Manirafasha	Head, EMS Department	King Faisal Hospital (KFH)	Clarified internal EMS coordination, inter-departmental communication, and operational scenarios where MD100 could reduce imaging delays.
Dr. Clarisse Mutimukeye	Emergency Physician	EMS, Kibagabaga District Hospital	Offered district-hospital perspective on referral barriers, patient decision-making, and acceptance of portable diagnostic tools.
Dr. Ernest Nahayo	Head of Emergency Department	Rwanda Military Hospital (RMH)	Described emergency-department burden, triage priorities, and health-system implications of integrating MD100 into national emergency workflows.
Dr. Niyonshuti Patrick	Prehospital & EMS Specialist; Coordinator of SAMU	Ministry of Health (MoH)	Provided strategic overview of national EMS policy, resource allocation, and feasibility of scaling MD100 within Rwanda's prehospital system.
Dr. Niyirora Patrick	Neurology Resident	King Faisal Hospital (KFH)	Shared clinician-in-training perspective on diagnostic accuracy, workflow timing, and educational integration of new technologies like MD100.
Dr. François Xavier Uwimana	EMS Physician; Supervisor of EMS Team	Nyarugenge District Hospital	Discussed ambulance operations, training protocols, and MD100 usability in real-time emergency scenarios.
Dr. Agabe Nkusi	Neurosurgeon	King Faisal Hospital (KFH)	Addressed neurosurgical decision-making, need for rapid

Name	Role / Title	Institution	Relevance to Study
			intracranial diagnosis, and potential of MD100 to improve pre-operative triage.
Dr. Evariste Ntaganda	Head of Cardiovascular Diseases	Rwanda Biomedical Centre (RBC)	Linked stroke prevention and NCD program priorities with policy adoption potential for point-of-care diagnostic technologies.
Dr. Joseph Habiyaremye	Analyst, Medical Devices and IVD Import/Export	Rwanda Food and Drugs Authority (RFDA)	Explained import licensing, classification procedures, and compliance considerations for introducing the MD100 into Rwanda’s medical-device market.
Dr. Lazare Ntirenganya	Head, Clinical Trials and Post-Market Surveillance	Rwanda Food and Drugs Authority (RFDA)	Outlined clinical-evaluation requirements, post-market surveillance obligations, and risk-management expectations for diagnostic devices.
Dr. Pascal Mugemangango	Emergency Physician	University Teaching Hospital of Kigali (CHUK)	Discussed acute neurological case management, diagnostic prioritization, and workflow fit for MD100 during emergency admission.
Dr. Steven Nkusi	Regulatory Expert, Medical Devices Classification and Registration	Rwanda Food and Drugs Authority (RFDA)	Provided detailed input on device registration, conformity assessment, and national approval processes relevant to MD100 introduction.

2.2 Health Economy

The **health-economic dimension** is a core pillar of Health Technology Assessment (HTA) and determines whether a new medical technology can be **financially and operationally integrated** into an existing healthcare system [91][94].
This evaluation examines the potential **cost-effectiveness and budget impact** of introducing the **StrokeFinder MD100**within Rwanda’s referral and prehospital settings, using established **health-economic concepts and principles** adapted to the national context [91][94][95].

Because manufacturer-specific economic data for the MD100 were unavailable, the analysis adopted a **conservative base-case assumption** of a **five-year functional lifespan** for each device. This estimate aligns with international HTA guidance for portable diagnostic technologies, which typically operate for **five to seven years** under standard maintenance conditions [91][92].
This assumption was applied consistently across **cost-effectiveness**, **sensitivity**, and **budget-impact** analyses to ensure comparability and transparency [91].

Other parameters—including **estimated device unit cost**, **expected utilization rates** (number of scans per year across district and referral levels), and **GDP-based willingness-to-pay thresholds** derived from Rwanda's **per-capita income**—are specified in the following subsections.
These variables collectively inform whether the MD100 could represent a **cost-effective complement** to CT-based stroke diagnostics in settings with limited imaging access [93][94][95].

2.2.1 Quality-Adjusted Life Years (QALYs)

One such concept is the **Quality-Adjusted Life Year (QALY)**, a standard metric in health economics used to quantify health benefits in terms of both **length and quality of life** [96][97].
One QALY represents one year of life lived in perfect health. If health status is less than perfect, the value of a year is weighted by a "utility score" ranging from 0 (death) to 1 (perfect health).

For example:

- One year lived in perfect health (utility = 1.0) = 1 QALY.
- Two years lived at half of perfect health (utility = 0.5) = 1 QALY (2 × 0.5).

Thus, QALYs capture both survival and health-related quality of life, allowing comparison across diseases and interventions. This makes them the preferred outcome measure in cost-utility analyses used by HTA agencies such as EUnetHTA, NICE, and TLV [96].

2.2.2 Incremental Cost-Effectiveness Ratio (ICER)

Another valuable concept is the **Incremental Cost-Effectiveness Ratio (ICER)**, which compares the additional cost of a new technology with the additional health benefit it provides [96][98].

$$ICER = \frac{\Delta C}{\Delta B}$$

Where:

- **ΔC** = difference in cost between the new intervention and standard care,
- **ΔB** = difference in benefit (measured in QALYs).

The ICER is evaluated against a **willingness-to-pay (WTP) threshold**, representing the maximum amount a healthcare system is prepared to pay per QALY gained.
If the ICER is **below the threshold**, the intervention is considered **cost-effective**.

Rwanda does not have an official threshold; however, **WHO-CHOICE** recommends using **1–3 × GDP per capita** as a proxy [94]. With Rwanda's 2025 GDP per capita estimated at approximately **USD 900** [93], the implied WTP threshold is **USD 900–2,700 per QALY**.

2.2.3 Incremental Net Monetary Benefit (INMB)

The **Incremental Net Monetary Benefit (INMB)** approach simplifies interpretation by converting both health gains and costs into monetary terms [96]:

$$INMB = (\lambda \times \Delta B) - \Delta C$$

Where:

- **λ** = WTP threshold,
- **ΔB** = QALYs gained,
- **ΔC** = incremental cost.

If **INMB > 0**, the intervention yields a **positive net monetary value** and is considered economically attractive compared with current practice.
This metric is often preferred in policy settings because it directly expresses value in monetary units, facilitating comparison between alternative investments.

2.2.4 Cost Distribution per Patient (with Maintenance)

For capital equipment such as the **StrokeFinder MD100**, economic viability depends on how the total purchase and maintenance costs are spread across expected usage during the device's lifetime [92][95].
Assuming:

- **Purchase price:** USD 80 000
- **Annual maintenance:** USD 1 500
- **Lifespan:** 5 years

Total 5-year cost = 80 000 + (1 500 × 5) = USD 87 500.

Scenario A – District Hospital (~3 patients/day ≈ 1 000 per year)

- 5-year volume = 1 000 × 5 = 5 000 scans
- **Cost per scan = 87 500 ÷ 5 000 = USD 17.50**

Scenario B – Ambulance (~1 patient/day ≈ 300 per year)

- 5-year volume = 300 × 5 = 1 500 scans
- **Cost per scan = 87 500 ÷ 1 500 ≈ USD 58.30**

These figures exclude staff time, training, consumables, and downtime.
They demonstrate that **utilisation drives cost-efficiency**: at least **1 000–1 500 patients annually** are required to keep the per-scan cost in a sustainable range for Rwanda's public-sector reimbursement models [93][95].
Pooling device use across several hospitals or regional EMS units would significantly improve affordability and value for money.

2.2.5 Discounting

In health-economic evaluations, **discounting** adjusts for the reduced present value of future costs and health benefits.
A **3 % annual discount rate** is recommended by both the **World Health Organization (WHO)** and the **European Network for Health Technology Assessment (EUnetHTA)** [91][96][99].

In this study, discounting has **limited relevance**, since the economic and health effects of the **StrokeFinder MD100** occur within a short time frame—typically within days or weeks of a suspected stroke event.
The 3 % rate is acknowledged for methodological consistency with international HTA standards but was not materially applied, as short-term outcomes dominate the analysis.

2.2.6 Break-Even and Time-to-Benefit Interpretation

The **break-even point** estimates the minimum health gain (in QALYs) required for the **StrokeFinder MD100** to be **cost-effective** within Rwanda's health-system context.
Following the **WHO-CHOICE** framework, a **willingness-to-pay (WTP)** threshold of **1–3 × GDP per capita** was applied [94][99].
With Rwanda's 2025 GDP per capita estimated at roughly **USD 900** [93], the **upper benchmark** for cost-effectiveness is **≈ USD 2 700 per QALY**.

At this threshold, **0.003 QALY**—approximately **one day of healthy life**—is valued at about **USD 8**.
Therefore, if the MD100 enables **earlier identification of potential stroke cases in the field** and shortens **recognition-to-treatment time**, even modest gains—such as **3–5 additional disability-free days per patient**—would make the device cost-effective under Rwandan conditions.

Empirical evidence indicates that each minute saved between **stroke onset and hospital arrival** contributes to measurable improvements in functional recovery and long-term independence [100][101].
In Rwanda, where **imaging capacity is limited and prehospital triage delays are common**, such time savings could significantly improve patient outcomes while optimizing use of scarce CT and specialist resources [102][103].

Hence, the **economic value** of the MD100 arises not from differentiating stroke subtypes, but from its ability to **flag probable stroke cases early**, strengthen **EMS triage decisions**, and **reduce time to definitive imaging and treatment**—translating into tangible health gains and cost savings across the system.

2.2.7 Model Parameters and Assumptions

Table 3 summarizes the key parameters used in the health-economic modelling of the **StrokeFinder MD100**, including base-case values, sensitivity ranges, and data sources.
These parameters were derived from published literature, expert interviews, manufacturer specifications, and context-specific estimates for Rwanda.

Worked examples applying these assumptions—along with detailed cost-effectiveness, net monetary benefit results, and a detailed utilisation threshold calculation—are presented later in **Section 4.3 (Economic Modelling Results)**.

Table 3 Model parameters, base-case values, and sensitivity ranges

Parameter	Base-case value	Range (sensitivity)	Units	Source
Device purchase price (Capex)	80 000	70 000 – 90 000	USD	Medfield Diagnostics (estimate; no Rwanda quote yet)
Device lifetime (L)	6	5 – 7	years	Medfield Diagnostics technical data
Discount rate (r)	0.03	0 – 0.05	annual	WHO guidelines [99]
Annual maintenance	1 500	1 000 – 3 000	USD/yr	Medfield Diagnostics estimate
Annual training	1 000	500 – 2 000	USD/yr	Assumption based on Rwanda EMS/MoH input
Consumables per scan	2	1 – 5	USD/scan	Comparable portable diagnostic device inputs
Annual scans per device (N)	1 000 (district) / 300 (ambulance)	300 – 1 500	patients	Rwanda MoH stroke incidence and EMS expert interviews
Incremental treatment cost (ΔTreatment)	+5	–10 – +20	USD/patient	Interview insights; stroke cost literature
Incremental transport/imaging cost (ΔTransport)	–10	–20 – 0	USD/patient	EMS coordinator interviews (transfers avoided)
Avoided adverse events (ΔAE)	–5	–15 – 0	USD/patient	Neurologist interviews; clinical judgement
Incremental QALY gain (ΔQALY)	0.020	0.005 – 0.050	QALY/patient	Stroke timeliness studies [100][101]; expert assumption
Utility weight (mRS 0–2 vs ≥3)	0.85 / 0.40	0.80–0.90 / 0.30–0.50	QALY weight	EuroQol data
GDP per capita (2025)	900	900 – 1 100	USD	World Bank [93]

Parameter	Base-case value	Range (sensitivity)	Units	Source
WTP thresholds (λ)	500 / 1 000 / 3 000	—	USD/QALY	WHO-CHOICE [94][99]

This chapter outlined the methodological and analytical framework applied in the assessment, including literature review procedures, stakeholder interview design, and the health-economic modelling structure.
Parameters were defined in accordance with international HTA guidance, with adaptations for the Rwandan health system context.
The modelling incorporated conservative assumptions for device cost, lifespan, utilisation, and QALY gains to ensure robustness under data uncertainty.

The following chapter presents the **results** derived from both the **qualitative interview study** and the **quantitative economic evaluation**, providing empirical and modelled evidence on the potential feasibility, clinical utility, and cost-effectiveness of the StrokeFinder MD100 in Rwanda.

3. Results

3.1 Health problem and current use of technology

3.1.1 Stroke (literature findings)

Published studies from Kigali's major referral hospitals show that stroke patients in Rwanda tend to be considerably younger than in high-income countries, with many cases occurring in their 40s and 50s compared to a median age of about 70 years in Europe [104][105].
Stroke is predominantly linked to hypertension, diabetes, and atrial fibrillation — conditions that often remain undiagnosed until after the first cerebrovascular event [106].
Functional outcomes are poor, largely because of limited access to physiotherapy, occupational therapy, and speech-language services [107].

Neuro-imaging capacity remains concentrated in tertiary facilities — the University Teaching Hospital of Kigali (CHUK), Rwanda Military Hospital (RMH), King Faisal Hospital (KFH), and the University Teaching Hospital of Butare (CHUB) — leaving most district hospitals reliant on clinical judgment alone for diagnosis [108][109].

3.1.2 Stroke (interview evidence)

Neurologists and emergency physicians at the University Teaching Hospital of Kigali (CHUK) and King Faisal Hospital (KFH) reported a high and rising burden of stroke among relatively young patients.
Dr. François Régis Twagirumukiza (CHUK) noted that "most of our stroke patients are in their 40s or 50s, not the elderly like in Europe — hypertension is almost always there, but often untreated."
Dr. Arlene Ndayisenga (KFH) described stroke as "a daily emergency now — we see several cases every shift, yet most arrive long after the treatment window."

Physicians at district hospitals echoed similar challenges.
Dr. Clarisse Mutimukeye (Kibagabaga Hospital) explained that "we recognise stroke clinically, but families often refuse referral when they hear about CT scan costs or transport fees."
Several district-level respondents confirmed that ambulance shortages and financial barriers routinely delay transfer to referral centres.
EMS officials, including Mrs. Jeanne d'Arc Nyinawankusi (RBC/SAMU), acknowledged that "stroke cases are transported, but there's no stroke protocol — priority is usually trauma."

These findings highlight a consistent system gap between initial recognition and definitive imaging, with cost, logistics, and limited EMS stroke triage being the key bottlenecks.

3.1.3 Traumatic Brain Injury (literature findings)

Traumatic brain injury (TBI) is also a major health burden in Rwanda, with road-traffic collisions—particularly involving motorcycles—accounting for most severe cases [110][111].
National Police records estimate more than 5 000 RTAs annually among a population of 13 million, equating to approximately 400 incidents per 100 000 people per year [110].
Severe TBI cases are managed primarily at CHUK, RMH, and KFH, all of which face neurosurgical workforce shortages.
Most district hospitals lack CT imaging, causing heavy reliance on clinical presentation and delayed definitive management [112][113].

3.1.4 Traumatic Brain Injury (interview evidence)

Emergency physicians and neurosurgeons described traumatic brain injury (TBI) as one of the most common and resource-intensive emergencies in Rwanda.
Dr. Ernest Nahayo (Head of Emergency, RMH) stated that "TBI dominates our emergency caseload — almost all from motorcycle crashes."
Similarly, Dr. Agabe Nkusi (Neurosurgeon, KFH) confirmed that "we operate daily for severe head injuries, but delays from the districts are killing patients before they reach us."

At district level, Dr. Ariane Ishimwe Nshuti (EMS Resident, Nyarugenge Hospital) and Dr. Clarisse Mutimukeye described frequent diagnostic uncertainty and long transfer times.
They emphasised that many patients arrive without prior stabilisation or imaging, forcing reliance on clinical judgement alone.
Multiple respondents also pointed out the absence of post-acute rehabilitation capacity.
As Dr. Appolinaire Manirafasha (Head of EMS, KFH) observed: "We save the patient in the acute phase, but most never recover functionally — there's nowhere for proper rehab."

3.1.5 Current Diagnostic Practices

Stroke and TBI diagnosis in Rwanda remains heavily dependent on clinical presentation because of the limited availability of diagnostic imaging.
According to the Rwanda Biomedical Centre (RBC), only four tertiary hospitals—University Teaching Hospital of Kigali (CHUK), University Teaching Hospital of Butare (CHUB), Rwanda Military Hospital (RMH), and King Faisal Hospital (KFH)—have functional CT

scanners, while most district hospitals lack imaging capacity entirely [108][109][112]. Machine downtime is frequent due to maintenance issues and shortages of trained radiographers [107][120].

Interviewees at district hospitals confirmed that suspected stroke patients are often managed based solely on symptoms and clinical judgement.
Dr. Doris Uwamahoro (CHUK) explained, “Without CT, it’s all clinical guesswork—you treat what you think it is.”
Dr. Clarisse Mutimukeye (Kibagabaga Hospital) reported that families sometimes refuse referral to Kigali because of the cost of CT scans or transport.
Even when patients reach referral hospitals, out-of-pocket costs and machine downtime create further delays.

For TBI, assessment relies primarily on the **Glasgow Coma Scale (GCS)** and basic neurological examination [115].
District hospitals rarely have imaging capacity, forcing reliance on clinical observation to distinguish mild from severe injuries [111][113].
Dr. Patrick Niyirora (Neurology Resident, KFH) noted, “We depend on GCS, pupils, and clinical evolution—but it’s risky when there’s no imaging.”
EMS staff also indicated that prehospital triage is limited to airway and trauma scoring, with no portable neuro-diagnostic tools available.

3.1.6 Current Treatment Pathways

Treatment pathways for stroke and TBI in Rwanda are fragmented and limited by late presentation, financial barriers, and constrained specialist capacity.

For **stroke**, literature shows that thrombolytic therapy with tissue plasminogen activator (tPA) is available only at King Faisal Hospital and CHUK, with use restricted to a very small number of patients annually [114][116].
The limited uptake reflects both delayed hospital arrival—often more than 12 hours after onset—and high costs (approximately USD 1,000 per dose) [116].
No thrombectomy services currently exist in Rwanda [114].
Haemorrhagic strokes are managed with blood-pressure control, supportive care, and, in some cases, neurosurgical procedures such as craniotomy or decompressive craniectomy at tertiary hospitals [112][117].
Dr. Arlene Ndayisenga (KFH) confirmed that “we probably use tPA fewer than five times a year—most patients arrive too late or can’t afford it.”

For **TBI**, management typically involves initial stabilisation at district hospitals, followed by transfer to referral centres for surgical care.
Severe cases are concentrated at CHUK, RMH, and KFH, which together have fewer than ten neurosurgeons nationwide [113][118][119].
Procedures include craniotomy, craniectomy, and repair of depressed skull fractures [117].
However, referrals are slow, often taking several hours due to ambulance shortages and administrative steps.
Dr. Ernest Nahayo (RMH) stated, “Time lost on the road is brain lost.”
Post-operative outcomes are further constrained by limited intensive-care capacity and scarce rehabilitation follow-up [107][120].

3.1.7 Systemic Barriers

The combined literature and interview data reveal multiple structural and systemic obstacles that limit effective stroke and TBI management in Rwanda.

Financial constraints are the most immediate barrier.
Although Rwanda's community-based health insurance (*Mutuelles de Santé*) covers most primary and secondary care, advanced imaging, thrombolysis, and neurosurgery remain partially or fully out-of-pocket [114][120].
Dr. Clarisse Mutimukeye (Kibagabaga Hospital) noted that "families delay transfer because even with Mutuelle, they can't cover CT or ambulance fees."
This frequently leads to delayed or incomplete care.

Organisational gaps also persist.
The referral system is theoretically linear—from community level to district hospitals and onward to referral centres—but in practice, it is fragmented and poorly coordinated [108][120].
EMS leaders, including Dr. Niyonshuti Patrick (MoH/SAMU) and Mrs. Jeanne d'Arc Nyinawankusi (RBC/SAMU), confirmed that while the National Emergency Medical Service (NEMS) has expanded coverage, "stroke and TBI protocols are not yet standardised—training still focuses on trauma."
Ambulance availability remains below WHO recommendations, and response times vary widely outside Kigali [122].

Human-resource shortages were consistently cited by respondents and supported by workforce statistics.
Rwanda has fewer than ten neurologists and an equivalent number of neurosurgeons serving the entire population [119][121].
Dr. Evariste Ntaganda (Head of NCDs, RBC) stressed that "most strokes are managed by general physicians because specialists are so few."

Cultural and social factors also contribute.
Several district physicians described cases where families refused referral or rehabilitation, either due to cost or fatalistic beliefs about stroke outcomes.
This leads to missed treatment windows and incomplete recovery.

In summary, the literature and field interviews converge on a common conclusion: despite strong national commitment to universal health coverage, stroke and TBI care in Rwanda remain hindered by late diagnosis, high out-of-pocket costs, and limited system capacity for emergency triage and rehabilitation.

3.2 Description and technical characteristics

The **StrokeFinder MD100** is a portable diagnostic system developed by *Medfield Diagnostics AB* (Gothenburg, Sweden) in collaboration with the *Chalmers University of Technology*.
It applies **low-energy microwave technology (MWT)** to detect dielectric contrasts between normal and pathological brain tissue, allowing rapid distinction between **stroke** and **no stroke** conditions at the point of care [124][125].

The system combines a lightweight helmet containing multiple antennas with a processing unit that analyses the reflected microwave signals using machine-learning algorithms.
It is designed for use by trained healthcare personnel in **ambulances**, **emergency departments**, or **district hospitals** lacking immediate CT access.

Each examination takes approximately two minutes. The patient's head is enclosed by the antenna array, which emits microwaves at safe, non-ionising frequencies well below international exposure limits [126]. The returning signals are processed to produce a **binary output ("stroke / no stroke")** together with a probability score.
This output is **decision-support information**, not a replacement for CT or MRI, but an early screening step to identify patients who require urgent imaging or transfer.

An overview of the StrokeFinder MD100 system and its functional components is illustrated in **Figure 3.1** below.

Figure 1 Functional Overview of the StrokeFinder MD100 System

Schematic representation of the StrokeFinder MD100 diagnostic workflow. The system consists of a lightweight helmet with integrated microwave antennas connected to a processing unit. When the helmet is positioned on the patient's head, the antennas sequentially transmit and receive low-energy microwave signals through the brain. The reflected signals are processed in real time using proprietary machine-learning algorithms to detect dielectric contrasts indicative of stroke.

Description:

Signal Acquisition: The antenna array emits microwaves (1–3 GHz) into cranial tissue and records reflections at multiple angles. Each measurement point corresponds to the dielectric properties of brain regions, allowing detection of asymmetries caused by bleeding or ischemia.
Data Processing: The collected signals are transferred to the processing unit. The embedded

algorithm, trained on reference datasets, evaluates the signal patterns and computes a probability score (0–1) for stroke presence.
Output and Decision Support: Results are displayed on-screen as a binary output — "Stroke" or "No Stroke" — accompanied by the probability score. The operator (EMS, nurse, or emergency physician) uses this information to determine whether the patient requires urgent transfer to a referral centre for CT confirmation and treatment.
Integration in Rwanda: In ambulances, the system could allow prehospital teams to prioritise true stroke cases and notify referral hospitals early. In district hospitals, it could support clinicians in deciding whether a costly and time-consuming transfer to Kigali is justified when CT is unavailable.

(Image source: Medfield Diagnostics AB, 2024)

3.2.1 Device Overview

The MD100 consists of:

- **A helmet module** containing 8–12 transmitting and receiving antennas that surround the patient's head.
- **A processing and display unit** performing real-time signal acquisition, feature extraction, and classification through proprietary neural-network algorithms.
- **A power source** (battery or AC), enabling mobility for prehospital use.

Clinical validation studies in Europe have demonstrated that microwave signatures can differentiate stroke from non-stroke with sensitivities around 75–85% and specificities of 70–80% when compared with CT as the reference standard [124][127].
The device is CE-marked as a Class IIa medical device under EU MDR.

Table 4 Technical Specifications of the StrokeFinder MD100

Parameter	Specification	Source / Note
Manufacturer	Medfield Diagnostics AB, Gothenburg, Sweden	[125]
Device type	Portable diagnostic system for microwave-based stroke triage	[124][125]
Technology principle	Low-energy microwave tomography detecting dielectric contrast in brain tissue	[124][125]
Primary function	Binary classification output: **"Stroke / No Stroke"**, with probability score	[125]
Antenna array	8–12 dual-polarised transmitting and receiving antennas embedded in helmet shell	[124]
Operating frequency	1.0–3.0 GHz (non-ionising microwave range)	[124][126]
Acquisition time	~2 minutes per scan	[125]
Power supply	100–240 V AC or rechargeable battery pack (≥ 3 hours continuous use)	[125]

Parameter	Specification	Source / Note
Dimensions	Helmet diameter ≈ 30 cm; Processing unit ≈ 35 × 25 × 15 cm	[125]
Weight	Helmet ≈ 1.8 kg; Processing unit ≈ 5 kg	[125]
Data interface	USB / Ethernet connection to display and cloud-based update system	[125]
Output display	Visual score (0–1) indicating probability of stroke; text summary on screen	[125]
Intended operator	EMS personnel, emergency clinicians, or trained nurses	[125][128]
Safety compliance	CE-marked, Class IIa under EU MDR 2017/745	[125]
Microwave exposure	< 1 % of ICNIRP limit; no ionising radiation	[126]
Maintenance	Preventive service every 12 months; functional calibration 6-month intervals	[125]
Software	Proprietary AI algorithm (Medfield v3.1); periodic remote update	[125]
Expected lifetime	5–7 years under standard hospital operating conditions	[125]
Estimated unit cost	≈ USD 80,000 (excluding maintenance and training)	[125]
Potential use in Rwanda	Ambulances and district hospitals for rapid triage when CT unavailable	Interviews: Nyinawankusi (SAMU), Mutimukeye (Kibagabaga)

3.2.2 Intended Use in Rwanda

In the Rwandan setting, **one possible use** is as a **triage tool** to accelerate early stroke recognition where neuro-imaging is unavailable.
Two deployment levels were repeatedly mentioned by national stakeholders:

1. **Ambulances and prehospital services (SAMU/NEMS)** – to help EMS personnel decide which suspected stroke cases should be prioritised for rapid transfer to referral centres.
2. **District hospitals** – to guide physicians in deciding whether urgent referral to Kigali or Butare is necessary when CT is not accessible.

Mrs Jeanne d'Arc Nyinawankusi (Acting Head of SAMU, RBC) noted that "ambulances currently transport all suspected strokes blindly; a simple yes/no tool could prevent unnecessary transfers and save critical time."
Dr Clarisse Mutimukeye (Kibagabaga Hospital) added that "families hesitate when referral is expensive—an on-site test confirming stroke could help us convince them to move fast."
Neurologists such as Dr Arlene Ndayisenga (KFH) and Dr François Régis Twagirumukiza

(CHUK) stressed that the device would **not replace imaging**, as it cannot identify stroke subtype or lesion location, but they agreed it could strengthen prehospital and district-level triage.
Dr Ernest Nahayo (RMH) cautioned that "since thrombolysis is rarely used, its immediate therapeutic impact may be limited, but it prepares the system for when we scale up."

3.2.3 Expected Benefits and Limitations

Evidence from literature and expert interviews indicates several **anticipated benefits**:

- **Reduced diagnostic delay.** Earlier recognition could shorten transfer times and enable more efficient use of the few CT scanners available in Rwanda [108][109][112].
- **Improved triage efficiency.** EMS coordinators highlighted that a binary "stroke / no stroke" signal would help prioritise limited ambulance and imaging capacity.
- **System readiness.** RBC officials and neurologists noted that adopting triage technology now would build operational experience ahead of wider thrombolysis and thrombectomy availability.
- **Decentralisation.** District clinicians viewed the MD100 as a means to empower non-specialist staff to make informed referral decisions.

The **main limitations** concern:

- Lack of capability to determine stroke subtype (ischaemic vs haemorrhagic) or lesion location;
- Algorithms trained predominantly on European datasets whose generalisability to Rwanda's younger, hypertension-driven population is unverified [124][128];
- Dependence on stable power supply, calibration, and preventive maintenance infrastructure.

3.2.4 Maintenance and Regulatory Considerations

Routine **preventive maintenance** (inspection, calibration, cleaning) and **corrective servicing** follow standard medical-device protocols.
Predictive maintenance, supported by device-embedded logs, can forecast component wear to prevent downtime.
Mrs Jeanne d'Arc Nyinawankusi (RBC) and Dr Joseph Habiyaremye (Rwanda FDA) both noted that integration into Rwanda's biomedical maintenance system would require inclusion in the national equipment registry and local engineer training.
Rwanda FDA officials also emphasised that post-market surveillance and local performance verification would be prerequisites for clinical adoption.

The MD100 operates at power levels **orders of magnitude below safety thresholds** defined by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) [126].
No adverse biological effects have been reported in clinical trials [124][125][126].

3.2.5 Local Considerations

Introducing the StrokeFinder MD100 in Rwanda requires consideration of the country's specific operational, environmental, and regulatory realities. The device's success depends not only on technical performance but also on usability, maintainability, safety, and integration within the existing emergency care structure.

Training and Usability.
Ease of use was repeatedly highlighted as essential. Dr. Ariane Ishimwe Nshuti (Nyarugenge Hospital, EMS) and several emergency nurses emphasized that most ambulance and district-level personnel have limited neurology training; therefore, the device interface and workflow must be intuitive. They suggested short simulation-based modules and visual prompts to support correct operation during high-pressure prehospital scenarios. Similar emphasis on simple, self-guided operation has been recommended in WHO guidelines for technology adoption in low-resource settings [129].

Maintenance and Reliability.
Dr. Emmanuel Mugwiza (Rwanda FDA) and Dr. Joseph Habiyaremye (RFDA) both underlined the importance of establishing local maintenance capacity. They explained that medical equipment in Rwanda often fails prematurely due to environmental factors, supply-chain delays, and dependency on imported spare parts. For the MD100, they recommended local technician training, clear maintenance schedules, and accessible spare-part procurement through regional suppliers. These recommendations align with WHO guidance on sustainable medical device management in LMICs [130].

Connectivity and Data Sharing.
Stakeholders such as Dr. François Xavier Uwimana (Nyarugenge Hospital, EMS) proposed that MD100 results be integrated into Rwanda's national telemedicine network, allowing neurologists at referral hospitals to remotely confirm findings and guide transfer decisions. This would be consistent with the Ministry of Health's *National Telemedicine and eHealth Strategy 2022–2027*, which prioritizes digital interoperability across facilities [131]. Improved connectivity could strengthen early notification systems and optimize referral timing.

Regulatory and Validation Requirements.
Dr. Emmanuel Mugwiza (Rwanda Food and Drugs Authority) noted that before market authorization, the device would need local or regionally comparable validation data. Algorithms trained primarily on European cohorts may behave differently in populations with younger stroke onset and distinct comorbidity profiles. Rwanda FDA would therefore require evidence from domestic or LMIC field evaluations to confirm performance, usability, and reliability under local conditions [132].

Safety Considerations.
Unlike CT scanners, the StrokeFinder MD100 operates using non-ionizing microwaves, meaning there is no radiation risk to patients. The main safety concern identified by interviewees related to potential misclassification — for instance, if the device failed to detect a stroke that was present. Neurologists such as Dr. François Régis Twagirumukiza (University Teaching Hospital of Kigali) and Dr. Arlene Ndayisenga (King Faisal Hospital) emphasized that such errors could delay treatment or referral. They therefore stressed that MD100 should strictly be used as a **triage aid**, indicating the likelihood of stroke presence

(*stroke* or *no stroke*), and that confirmatory imaging must follow whenever possible. Dr. Joseph Habiyaremye (RFDA) also noted that safe operation depends on consistent calibration and preventive maintenance. He highlighted that Rwanda's limited biomedical engineering workforce presents a challenge and advised that local technician training and manufacturer-supported service partnerships be included in any deployment plan. These measures would ensure reliability and safe use of the technology [130][133].

Environmental and Infrastructure Constraints.
Rwanda's high ambient temperatures, humidity, and intermittent power supply pose additional challenges for sensitive electronics. Hospitals and ambulances may require surge protection and climate-tolerant casing for consistent performance. These conditions underline the need for ruggedization—an adaptation already emphasized by several interviewees across hospital and EMS settings [130][131].

The practical deployment of the StrokeFinder MD100 must therefore be considered alongside Rwanda's organizational and system-level structures, discussed in the following section.

3.2.6 Perceived Limitations of the Technology

While stakeholders recognized the potential value of the StrokeFinder MD100 in accelerating prehospital triage, several concerns were raised during interviews regarding its practical limitations and readiness for integration in Rwanda.

Neurologists including **Dr. François Régis Twagirumukiza** (University Teaching Hospital of Kigali) and **Dr. Arlene Ndayisenga** (King Faisal Hospital) emphasized that the device does not replace computed tomography (CT) or magnetic resonance imaging (MRI). They noted that MD100 provides only a binary output ("stroke" or "no stroke") and cannot determine stroke subtype, lesion size, infarct location, or rule out stroke mimics. As a result, they considered it a useful triage adjunct but insufficient for definitive diagnosis or treatment planning.

Another concern related to **algorithmic generalizability**. Multiple clinicians and regulatory officials pointed out that the MD100's classification algorithms were primarily trained and validated on European patient datasets. **Dr. Emmanuel Mugwiza** (Rwanda FDA) and **Dr. Arlene Ndayisenga** highlighted that Rwanda's stroke population is notably younger and may exhibit different comorbidity patterns, potentially affecting device accuracy. They stressed the need for local or regionally comparable validation before regulatory approval and widespread adoption in Rwanda.

A further issue raised by **Dr. Ernest Nahayo** (Rwanda Military Hospital) and **Dr. Joseph Habiyaremye** (RFDA) concerned the current **treatment gap** in Rwanda. Since thrombolysis and thrombectomy are rarely available, the immediate clinical impact of rapid stroke triage remains limited. However, they also agreed that prehospital differentiation could still offer indirect benefits by reducing unnecessary transfers, improving resource allocation, and strengthening system readiness for future reperfusion therapies once capacity expands.

Finally, several experts—including **EMS coordinators at Rwanda Biomedical Centre (RBC)**—remarked that any introduction of MD100 should be framed within a structured care pathway that includes confirmatory imaging, feedback loops, and clinical oversight. They stressed that early triage technologies must complement, not replace, existing diagnostic and treatment processes to maintain patient safety and clinical accountability.

3.2.7 Summary

The StrokeFinder MD100 is a lightweight, portable triage tool developed by Medfield Diagnostics (Sweden). It operates using low-energy, non-ionising microwave signals to detect dielectric differences in brain tissue associated with stroke. The device consists of a helmet with multiple antennas connected to a processing unit that analyses reflected signals using trained algorithms and displays a binary output—*stroke* or *no stroke*—to assist in prehospital and early hospital triage.

In the Rwandan context, the MD100 could be applied within ambulances and district hospitals to support rapid clinical decision-making where CT imaging is unavailable. The system's main technical features include its short measurement time, rechargeable power supply, embedded processing algorithms, and radiation-free operation. Stakeholders acknowledged its potential to accelerate referral decisions and improve use of scarce imaging resources.

At the same time, several practical considerations were identified. These included the need for clear maintenance pathways, operator training, local performance validation, and integration into existing EMS and hospital workflows. Concerns were also expressed regarding algorithmic generalisability, device reliability in Rwanda's environmental conditions, and the risk of misclassification if used outside appropriate clinical oversight.

Overall, the technical characteristics and stakeholder feedback suggest that MD100 is a promising adjunct for early stroke triage, provided its deployment is supported by structured training, local validation, and sustainable service capacity.

3.3 Safety

3.3.1 Device Safety

The StrokeFinder MD100 is **CE-marked** under the EU Medical Device Regulation (MDR 2017/745) for use as a **stroke triage support system**, providing a binary output — *stroke* or *no stroke* — rather than a diagnostic classification. It emits **low-energy, non-ionising microwaves** that operate well below the exposure thresholds set by the **International Commission on Non-Ionizing Radiation Protection (ICNIRP)** [125][126][136].
Published European and Australian studies have reported **no exposure-related adverse biological effects** [124][127]. Biomedical engineers and Rwanda FDA officials interviewed confirmed that with proper **preventive maintenance and calibration**, the likelihood of physical harm or malfunction is minimal.

From a **clinical-safety perspective**, the key concern is **mis-triage** rather than physical risk. The device demonstrates **high sensitivity**, meaning false-negative results are **unlikely**, but **moderate specificity**, so **false positives** (identifying a non-stroke as stroke) can occur [125][127]. **Dr. François Régis Twagirumukiza (CHUK)** and **Dr. Arlene Ndayisenga (KFH)** noted that false positives could increase referrals and imaging demand at tertiary hospitals. They emphasised that the device should always be applied **as a triage aid** within established referral pathways, with **confirmatory CT or MRI**whenever available — consistent with the manufacturer's intended use [125].

3.3.2 Operator Safety

Operators are **not exposed to harmful radiation** while using the MD100. Paramedics and emergency-department staff interviewed in Kigali described the primary safety challenges as **ergonomic** (helmet fit and weight during fast-paced use) and **infection-control** (cleaning between patients). These risks were considered **manageable through training and strict reprocessing protocols**, consistent with WHO guidance on safe reuse of non-critical medical devices [125][137].

3.3.3 Patient Safety and Reliability

No interviewee or publication identified any direct physical hazard to patients.
Instead, **patient safety depends on reliability, calibration, and correct operation**. **Dr. Joseph Habiyaremye** and **Dr. Emmanuel Mugwiza** of the Rwanda FDA stressed that new devices must have clear **maintenance schedules, local service arrangements, and operator training** to ensure consistent performance. This aligns with WHO recommendations for **sustainable maintenance systems** in low-resource settings [130][132].
In addition, several clinicians observed that maintenance delays are a known weakness across Rwandan hospitals, and that MD100's success will depend on an accessible **local service and calibration pathway** supported by both the manufacturer and national biomedical units.

3.3.4 Need for Local Validation

Both neurologists and regulators emphasised that **local validation trials** are essential before widespread deployment. The MD100's algorithms were trained primarily on **European datasets**, whereas Rwanda's stroke population is typically **younger** and has a **higher proportion of haemorrhagic stroke**. **Dr. Régis**, **Dr. Arlene**, and **Dr. Mugwiza** each underscored that performance data specific to Rwandan or regional populations are needed to confirm sensitivity, specificity, and predictive accuracy under local conditions [125][132].
Our literature review identified **no peer-reviewed clinical evaluations** of MD100 in sub-Saharan Africa, supporting the need for such studies before national rollout (see Chapter 2 search methodology).

3.3.5 Summary

The MD100 meets international biophysical-safety standards for electromagnetic exposure and is CE-marked for use as a **stroke-triage support tool** [125][126][136]. No adverse exposure events have been reported [124][127]. The **main safety considerations** are operational: maintaining calibration, ensuring infection-control, and preventing mis-triage through adequate user training.
Stakeholders—including neurologists, EMS physicians, and Rwanda FDA engineers—agreed that **high sensitivity** makes false-negative results rare, but **moderate specificity** can generate false positives that increase imaging load. All participants stressed that the device's role must remain **supportive**, complementing, not replacing, CT-based diagnosis.
Finally, the absence of **local validation data** was identified as the single most important safety prerequisite for adoption. Verification in Rwandan conditions—through structured

clinical trials, maintenance planning, and formal operator certification—will be necessary to confirm both safety and reliability before national scale-up.

3.4 Clinical Effectiveness

3.4.1 Evidence from International Studies (literature findings)

StrokeFinder MD100 is a **stroke triage support tool** designed to distinguish suspected stroke patients from non-stroke cases in the prehospital and early hospital setting. It has been clinically evaluated in **Europe and Australia**, with key studies published by **Persson et al. (2014)**, **Fhager et al. (2018)**, **Candefjord et al. (2020)**, and **Hood et al. (2022)** [124][127][138][173].

Across these studies, the MD100 demonstrated **high sensitivity (≈92–97%)** and **moderate specificity (≈70%)** for detecting stroke presence compared to healthy controls, confirming its potential to enhance prehospital stroke triage. Reported specificity varied between studies—from approximately **48% in the pilot by Hood et al. (2022)** to around **70% in larger European cohorts**—reflecting differences in study design, case mix, and comparator populations.

The system has not yet been evaluated in **African populations**. The need for local validation prior to implementation was emphasised by Rwandan neurologists and policymakers interviewed during this study, including **Dr. François Régis Twagirumukiza (CHUK)** and **Dr. Ernest Nahayo (RMH)**, who noted that differences in patient profiles—particularly younger age and higher haemorrhagic prevalence—could influence algorithm performance.

3.4.2 Potential Clinical Impact (literature and interview findings)

International studies indicate that prehospital and early-hospital triage using the MD100 can reduce time-to-decision in stroke pathways, particularly in systems where reperfusion therapies are available [124][127][138]. In Rwanda, where thrombolysis and thrombectomy are not routinely accessible, interviewees noted that earlier triage may still offer clinical value by accelerating referral and improving supportive management.

Stakeholders highlighted several context-relevant advantages:

- **Earlier triage:** By identifying probable stroke at first contact, the device could shorten transfer delays between district and referral hospitals, which currently often exceed 12 hours.
- **Resource optimisation:** With CT scanners concentrated in Kigali and frequently overloaded, MD100 could help prioritise which patients require urgent imaging.
- **System readiness:** Clinicians, including **Dr. Arlene Ndayisenga (KFH)**, noted that early adoption of triage technologies can build operational experience and prepare the healthcare system for broader use of reperfusion therapies once capacity expands.

These observations describe potential operational benefits rather than demonstrated clinical outcome improvements. Their realisation would depend on how the device is integrated into referral protocols, staff training, and availability of imaging and specialist care.

3.4.3 Stakeholder Perspectives on Clinical Utility (interview findings)

During the interviews, stakeholders expressed strong interest in evaluating the **StrokeFinder MD100** for integration into Rwanda's stroke care pathway.

Neurologists, including **Dr. François Régis Twagirumukiza (CHUK)** and **Dr. Arlene Uwineza (KFH)**, highlighted the potential of the device to accelerate early recognition and referral of suspected stroke cases from prehospital and district levels.

Emergency physicians, such as **Dr. Ernest Nahayo (RMH)**, noted that short-term clinical impact may remain limited while thrombolysis is still rare in Rwanda. However, they agreed that MD100 could strengthen prehospital triage, streamline referrals, and help build readiness for future adoption of advanced stroke treatments.

EMS leadership, represented by **Dr. Patrick Niyonshuti (Ministry of Health / SAMU)**, described the device as a valuable addition for **prehospital decision support**, potentially enabling ambulance teams to prioritise stroke patients more effectively and reduce unnecessary transfers or delays.

3.4.4 Limitations to Effectiveness

The **clinical value** of the **StrokeFinder MD100** in Rwanda will depend on both its **technical limitations** and the **organisational constraints** of the health system.
Evidence from international studies shows that while the device's **sensitivity for stroke detection is high**, its **specificity remains moderate**, which may lead to **over-triage and false positives** [124][127][138].
Algorithm performance remains untested for **African populations**, whose demographics and stroke profiles differ from those in training datasets.
Moreover, even with faster triage, the absence of **routine reperfusion therapies (tPA or thrombectomy)** limits immediate clinical benefit.
Interviewees noted that **stroke mimics**—such as seizures, migraines, or hypoglycaemia—may complicate interpretation in real-world use, and that **infrastructure readiness** (ambulance coverage, imaging, and referral coordination) ultimately determines impact.

3.4.5 Summary

Evidence from **Sweden, Norway, and Australia** indicates that the **StrokeFinder MD100** can detect the presence of stroke with **high sensitivity** and **moderate specificity**, supporting its use as a reliable **stroke triage support instrument**[124][127][138]. These results confirm its potential to accelerate early identification and referral, particularly in resource-limited settings where imaging access is constrained.

However, the absence of peer-reviewed data from **sub-Saharan Africa** represents a significant evidence gap. The device's algorithms have not yet been validated in populations with **younger age profiles** and **higher haemorrhagic stroke prevalence**, such as Rwanda, which may limit immediate clinical benefit until local trials are performed.

Rwandan experts viewed MD100 as **potentially beneficial** for early recognition and prioritisation of suspected stroke cases—especially within **ambulances** and **district hospitals**—provided that its introduction is accompanied by **robust training**, **maintenance systems**, and **local validation studies**. Its ultimate clinical value will depend on parallel progress in developing **Rwanda's stroke-treatment and referral infrastructure**.

3.5 Cost and Economic Evaluation

3.5.1 Approach

The economic evaluation assessed whether the StrokeFinder MD100 could be cost-effective within Rwanda's current healthcare system. Analyses applied standard health-economic concepts using the QALY, ICER, and INMB framework described in Section 2.2, with willingness-to-pay (WTP) thresholds based on WHO-CHOICE and World Bank guidance for low-income economies [139–141].

All calculations assumed a base-case device cost of USD 80 000, a 3 % annual discount rate, and an expected lifespan of 5–7 years. Costs were annualised using the Equivalent Annual Cost (EAC) method. Scenarios covered both high-volume use (≥ 1 000 patients/year – typical of referral hospitals or EMS hubs) and low-volume use (< 500 patients/year – typical of smaller district hospitals).

3.5.2 Economic Modelling Results

To estimate the conditions under which the MD100 could be cost-effective in Rwanda, model inputs and parameters defined in Section 2.2 were applied to calculate cost per patient and incremental cost-effectiveness under varying utilisation levels. Because the MD100 is a capital device with a defined lifespan, costs were distributed across an assumed 5–7 year period of use. For a unit purchase cost of **USD 80,000**, this corresponds to an approximate annual cost of **USD 16,000 per year** if used for five years, or **USD 11,400 per year** if used for seven years.

The cost-per-scan therefore depends primarily on device utilisation. For a given number of scans per year (N), cost-per-scan can be expressed as:

$$\text{Cost-per-scan} = \frac{\text{Annual device cost}}{N} + \text{Consumables and operating cost}$$

A base-case health gain of **ΔB = 0.02 QALY per patient** (equivalent to approximately seven additional disability-free days) was applied. Rwanda's willingness-to-pay (WTP) threshold is interpreted as **one to three times GDP per capita**, corresponding to approximately **USD 970–2,910 per QALY**.

Utilisation Threshold

Applying these values, the model indicates that **the MD100 would need to be used for approximately 1,000–1,500 scans per year** to maintain cost-per-patient within the Rwandan WTP threshold. Lower utilisation, or smaller clinical benefit, increases the cost-per-scan and makes cost-effectiveness less likely. In practice, this means that **deployment in high-volume sites is necessary** for economic viability.

Scenario Analysis

To illustrate how utilisation affects cost-effectiveness, three scenarios were evaluated:

Table 5 Utilisation-Dependent Cost-Effectiveness Scenarios for the MD100 in Rwanda

Scenario	Annual Scans (N)	Effect on Cost-per-Scan	Cost-Effectiveness Outcome
A. High Utilisation (≈1,500 scans/year)	High patient volume reduces cost-per-scan	Cost-per-patient decreases substantially	**Cost-effective**; may be **cost-saving (dominant)** under base assumptions
B. Reduced System Savings (same utilisation, fewer avoided transfer/adverse-event savings)	Moderately higher cost-per-scan	Cost per patient rises slightly	**Still cost-effective** at standard Rwanda WTP thresholds (≥ USD 500/QALY)
C. Low Utilisation (≈800 scans/year)	Low patient volume raises cost-per-scan	Cost-per-patient increases significantly	**Not cost-effective** under Rwanda WTP thresholds; requires higher utilisation to justify cost

This table reinforces that **utilisation rate is the primary determinant of cost-effectiveness.** The model does *not*conclude that MD100 is universally cost-saving; it is likely to be cost-effective **only when deployed in high-volume EMS hubs or referral hospitals**, where annual use can exceed ~1,000 scans.

These results indicate that **economic performance is driven more by utilisation volume than by variation in transport savings or operating costs**. This means that **where the device is deployed—and how frequently it is used—is the primary determinant of cost-effectiveness**.

Across all modelled scenarios, **cost-effectiveness is achievable only when the device is placed in settings with sufficiently high patient throughput**. This corresponds to **referral hospitals and central EMS hubs**, where suspected stroke and TBI cases are concentrated. **Deployment at low-volume district hospitals would not reach required utilisation levels under current system conditions**, and therefore would not be cost-effective.

3.5.3 Health-System Cost Considerations

This subsection addresses the operational and financial dynamics surrounding stroke care in Rwanda, beyond the modelled cost-effectiveness outputs. Unlike the economic modelling, which estimates cost per QALY gained, **health-system cost considerations** relate to how stroke cases move through referral pathways and how associated expenditures arise for facilities, EMS, and households.

National cost-of-illness data for stroke and TBI are limited. Officials from the Ministry of Health and the Rwanda Biomedical Centre confirmed that indirect costs—such as productivity loss and informal caregiving—are not routinely recorded (interviews: **Dr. Evariste, RBC**; **Dr. Patrick N., MoH**, 2024). Consequently, system-level financial patterns are inferred primarily through workflow descriptions and expenditure reports from hospitals and EMS services.

Interview findings indicated several areas where changes in triage timing could influence cost flows within the system:

- **Unnecessary transfers:** EMS providers, including **Dr. Uwimana (Nyarugenge Hospital EMS)**, noted that many suspected stroke cases transported to referral hospitals are later found to be stroke mimics. These transfers consume ambulance resources and contribute to emergency department congestion.
- **Multiple-step referral pathways:** Current pathways often involve sequential transfers (health centre → district hospital → referral hospital). District clinicians (e.g., **Dr. Clarisse, Kibagabaga District Hospital**) reported that these multi-stage referrals generate repeated transport costs and administrative delays.
- **Treatment misclassification costs:** Emergency physicians, including **Dr. Ernest (RMH)**, highlighted that misclassification of stroke type at early stages sometimes leads to administration of treatments later deemed inappropriate once imaging is performed, creating avoidable downstream treatment and monitoring expenditure.
- **Household spending:** Clinicians at district hospitals described frequent out-of-pocket transport payments by families when referral decisions are uncertain. These expenditures represent a significant share of household financial burden, particularly in rural cases.

These findings are consistent with international evidence that earlier identification of stroke status can influence **patient routing and transport-related expenditure** within a health system [146–148].
No claim of cost savings magnitude is made at this stage, as these effects depend on utilisation levels, referral patterns, and system capacity, all of which require further empirical evaluation.

3.5.4 Incremental Cost-Effectiveness (ICER)

The incremental cost-effectiveness ratio (ICER) was calculated using the model outputs described in Section 3.5.2. The base-case analysis applied a willingness-to-pay (WTP) threshold derived from Rwanda's GDP per capita (USD 970 in 2024), with a commonly used range of 1–3× GDP per capita corresponding to USD 970–2 910 per QALY gained [149].

Across utilisation levels, ICER values were primarily driven by the number of scans performed per year. At annual usage of approximately **1 000–1 500 scans per device**, the incremental cost per patient remained within the WTP threshold range, indicating that the MD100 would be considered cost-effective under these conditions. When utilisation decreased below roughly **500 scans per year**, ICER values rose above the threshold, indicating that cost-effectiveness would not be achieved at lower use levels.

Interviewed policymakers (**Dr. Patrick N., MoH**, and **MoH Health Financing Unit staff, 2024**) similarly noted that **high utilisation rates are necessary** for capital equipment to achieve value within Rwanda's public-sector budget structure. This aligns with the modelling findings, which indicate that deployment in **shared, high-volume clinical settings**—such as major referral hospitals or EMS hubs—would be required to maintain cost-effectiveness [150].

3.5.5 Sensitivity Analysis

A one-way sensitivity analysis was performed to examine how changes in key parameters affected cost-effectiveness outcomes. The analysis showed that **utilisation rate (number of scans per year)** had the largest influence on the ICER. When annual utilisation fell below approximately **500 scans per device**, the ICER values exceeded the WTP threshold (USD 970–2 910 per QALY), indicating loss of cost-effectiveness. At utilisation levels above **1 000 scans per year**, the ICER remained within the threshold range.

Adjusting the assumed device lifetime from **5 to 7 years** reduced the annualised device cost and improved the ICER by approximately **20–25%**, while varying the discount rate between **3–5%** produced minimal change in model outcomes. These results indicate that **device utilisation volume** and **service lifespan** exert notably greater influence on cost-effectiveness than discount assumptions [145][146].

3.5.6 Budget Impact

Interviews with policy and procurement officials in the Ministry of Health indicated that the MD100 would be treated as a **capital medical device acquisition**, with funding likely channelled through national emergency-care programmes or external financing mechanisms (interviews: Dr. Patrick N., MoH; Dr. Evariste, RBC).

Using a unit procurement cost of **USD 80 000**, the device cost per patient depends on annual utilisation.
At **~1 200 scans per year** over a five-year service period, the implied cost is approximately **USD 13 per scan**.
At **~500 scans per year**, the cost increases to approximately **USD 32 per scan**, reflecting reduced amortisation efficiency [147][148].

If one device were procured for each of the three referral hospitals (CHUK, KFH, RMH) and one for the National Ambulance Service, the total **initial capital expenditure** would be approximately **USD 320 000**. Under utilisation levels of **~1 200 scans per device per year**, the average per-patient cost would remain in the **USD 15–20** range; at utilisation levels **≤600 scans**, the per-patient cost would approximately double [149–151].

These estimates reflect **budgetary scale** rather than net cost-effectiveness and are contingent on device lifespan, maintenance continuity, and realised utilisation volumes.

3.5.7 Summary

The economic modelling indicates that the MD100 is **potentially cost-effective in Rwanda under the assumed willingness-to-pay (WTP) threshold of approximately USD 500 per QALY**. Under this assumption, cost-effectiveness is primarily determined by utilisation: at ≥ **1 000 scans per device per year**, the estimated cost per patient falls within the WTP range, and cost offsets from reduced transfers may result in neutral or slightly favorable net system costs. At **lower utilisation levels**, cost per patient increases, and ICER values exceed the modeled WTP threshold.

Uncertainty remains due to the absence of local stroke cost data, limited availability of reperfusion therapies, and unknown maintenance performance in district and prehospital settings. As a result, the economic viability observed in the model is contingent on realised utilisation, device service continuity, and alignment with broader stroke-system development.

3.6 Ethical Analysis

3.6.1 Ethical Framework

Ethical evaluation in health technology assessments commonly draws on the principles of beneficence, non-maleficence, autonomy, justice, and legitimacy [152]. These principles frame how new technologies may affect patients and health systems.

In Rwanda, these considerations occur within a context of **finite diagnostic capacity**, geographic differences in access to referral centres, and a national commitment to equity under the *Mutuelles de Santé* community-based health insurance scheme. International studies report that the StrokeFinder MD100 is physically safe and well tolerated during use [146][147]. Therefore, ethical questions raised in this assessment did not concern the device's physical safety, but rather **the conditions under which it would be introduced, governed, and communicated** within the health system.

Interview findings suggest that ethical considerations for MD100 in Rwanda relate primarily to **fair distribution of benefits**, clarity about the device's **triage function**, and the **need for locally generated performance evidence** before large-scale clinical implementation (interviews: Dr François Régis Twagirumukiza, CHUK; Dr Ernest Nahayo, RMH).

3.6.2 Findings from Interviews: Ethical Concerns and Tensions

Interviews with neurologists, emergency physicians, EMS leadership, biomedical engineers, and regulatory officials identified several ethical considerations regarding the introduction of the MD100 in Rwanda.

Beneficence and Non-maleficence
Neurologists **Dr François Régis Twagirumukiza (CHUK)** and **Dr Arlene Ndayisenga (KFH)** expressed that earlier identification of suspected stroke at the point of first contact could reduce delays to specialist evaluation. At the same time, they noted that **over-reliance on the device in cases of diagnostic uncertainty could delay referral** if clinical judgment is not prioritised. Both emphasised that **local performance validation is required before clinical implementation**, given Rwanda's younger stroke population and higher proportion of haemorrhagic cases.

Autonomy and Communication
Emergency clinicians at **Nyarugenge District Hospital** and **Kibagabaga District Hospital** reported that families sometimes interpret medical devices as providing definitive diagnoses. They highlighted the need for **clear communication** explaining that MD100

output represents a **probability estimate**, not a final diagnosis, to support informed decision-making during referral discussions.

Justice and Equity
Policy stakeholders including **Dr Patrick Niyonshuti (MoH / EMS coordination)** and **Mrs Jeanne d'Arc Nyinawankusi (RBC EMS services)** expressed concern that concentrating devices only in Kigali referral hospitals could reinforce existing rural–urban disparities in timely stroke assessment. They identified **equitable site selection**, particularly where referral delays are longest, as an important consideration for social fairness.

Data Governance and Accountability
Regulatory officials **Dr Emmanuel Mugwiza (Rwanda FDA medical devices division)** and **Dr Joseph Habiyaremye (Rwanda FDA post-market surveillance)** emphasized the importance of **traceability of device performance and reporting mechanisms** for misclassification events. They noted that the MD100 does not currently store personal identifiers, but any future use involving data transmission would need to comply with national data protection regulations.

3.6.3 Ethical Trade-offs

Interview findings indicated recognition of several practical trade-offs associated with introducing the MD100 into Rwanda's stroke care pathway.

Benefit versus risk of misclassification
Clinicians at **CHUK** and **KFH**, including **Dr François Régis Twagirumukiza** and **Dr Arlene Ndayisenga**, noted that earlier identification of suspected stroke holds potential to reduce referral delays. However, they also acknowledged the possibility that **false-positive results could temporarily redirect clinical resources** or prioritise patients who ultimately do not have stroke.

Equity versus operational efficiency
Policy stakeholders such as **Dr Patrick Niyonshuti (MoH / EMS)** observed that deploying the MD100 in **high-volume urban sites** would optimise utilisation and operational feasibility. At the same time, **Mrs Jeanne d'Arc Nyinawankusi (RBC)** noted that this approach may limit access for rural populations, where diagnostic delays are greatest, raising concerns regarding equitable distribution.

Innovation versus competing health priorities
Biomedical personnel, including **Dr Emmanuel Mugwiza (Rwanda FDA)**, highlighted that introducing new diagnostic technologies requires resources for training, servicing, and oversight. They emphasised that this must occur **alongside ongoing investment in CT maintenance, hypertension management, and rehabilitation**, which remain foundational elements of stroke care.

3.6.4 Policy-Relevant Ethical Safeguards

Interviewees identified several measures they considered necessary for ethical acceptability of introducing the MD100 in Rwanda. These were not framed as policy recommendations, but as **conditions raised repeatedly across stakeholder groups**.

Transparent site-selection processes
Policy stakeholders, including **Dr Patrick Niyonshuti (MoH / EMS)** and **Mrs Jeanne d'Arc Nyinawankusi (RBC)**, emphasised the importance of **clear justification for where the MD100 is deployed**, to avoid perceptions of preferential allocation to better-resourced urban hospitals.

Training and operator competency
Neurologists at **CHUK** and **KFH** (e.g., **Dr François Régis Twagirumukiza** and **Dr Arlene Ndayisenga**) highlighted the need for **structured training** so that clinicians and EMS personnel understand the device's intended function and interpret results consistently.

Communication with patients and families
Emergency physicians, including **Dr Ernest Nahayo (RMH)**, noted that **simple, standardised patient explanations**would be necessary to prevent assumptions that the device provides a complete diagnosis, particularly in settings where familiarity with medical technology varies.

Performance monitoring and traceability
Biomedical and regulatory experts (**Dr Emmanuel Mugwiza** and **Dr Joseph Habiyaremye**, Rwanda FDA) emphasised the need for **routine monitoring of device performance**, including documentation of inconclusive results, device downtime, and instances of suspected misclassification.

Equity tracking over time
Several policy interviewees (MoH and RBC) expressed that **deployment outcomes should be periodically reviewed** to assess whether the MD100 benefits districts currently experiencing the longest referral delays, rather than concentrating benefit in Kigali alone.

3.6.5 Summary

The interview findings indicate that ethical considerations surrounding MD100 in Rwanda do not concern the device's inherent safety, which has been demonstrated in prior international use, but rather the conditions under which it would be introduced. Stakeholders emphasised that the device should be used strictly as a triage support tool and not assumed to replace imaging. Clear communication with patients and families was identified as necessary to avoid misinterpretation of the device's output. Ensuring equitable distribution across regions, rather than concentrating the device only in Kigali, was regarded as important for maintaining fairness in access. Regulatory and biomedical experts highlighted that implementation should include defined oversight mechanisms for performance monitoring and data handling. Ethical acceptability therefore depends on transparent deployment decisions, structured training, and consistent operational safeguards.

3.7 Organisational Impact

3.7.1 Overview

The introduction of the StrokeFinder MD100 would affect several operational levels of Rwanda's health system — from prehospital emergency care to district and referral hospitals. Across all interviews, the technology was perceived as a **triage support tool** that can accelerate recognition of suspected stroke and prioritise referrals, but **not** as a substitute for CT or MRI imaging.

International literature supports this interpretation, noting that the device's primary organisational value lies in streamlining patient flow and reducing diagnostic uncertainty [146][147][156].

3.7.2 Implementation in EMS

Within Rwanda's EMS service, Service d'Aide Médicale Urgente (SAMU), the MD100 could enable earlier recognition of suspected stroke in the field. EMS coordinators at the Ministry of Health and RBC (Mrs Jeanne d'Arc Nyinawankusi; Dr Patrick Niyonshuti) explained that paramedics currently transfer all suspected strokes "blindly," often over-triaging patients who later prove not to have stroke.

The MD100 could provide an additional confirmation layer alongside existing tools such as the FAST scale, supporting more efficient ambulance prioritisation. Similar results were reported in European studies, where prehospital stroke screening using microwave-based devices shortened time to imaging and treatment [146][156].
In Rwanda, where thrombolysis remains rare, stakeholders viewed the benefit primarily as **earlier and more accurate referral**, not direct treatment acceleration.

3.7.3 Use in District Hospitals

District hospitals without CT scanners represent the most immediate beneficiaries of the MD100.
Clinicians such as **Dr Claris M.** (Kibagabaga District Hospital) stated that the device could "support clinical judgment and justify urgent referral" when families hesitate due to transport costs.
By confirming a high likelihood of stroke, the MD100 could help overcome referral delays and reduce diagnostic uncertainty.
Administrators cautioned, however, that effective adoption requires **local maintenance arrangements** and **budget allocations for training and servicing**, since previous imaging technologies suffered downtime due to lack of spare parts or contracts.

3.7.4 Use in Referral Hospitals

At tertiary hospitals (CHUK, RMH, KFH), neurologists emphasised that the MD100 would not replace CT, but could indirectly reduce caseload pressure.
Dr Régis Rugwizangoga (CHUK) explained that filtering out stroke-negative cases at district level could "reduce unnecessary referrals and help referral hospitals focus on patients who need urgent imaging."
Biomedical engineers agreed that referral hospitals are best equipped to host initial pilots, as they have higher patient volumes and access to maintenance expertise.
This aligns with international recommendations to deploy advanced diagnostic tools first in high-throughput environments [157].

3.7.5 Training and Capacity Building

Training emerged as a recurring theme across interviews.
Paramedics, nurses, and district physicians expressed unfamiliarity with microwave-based technologies.

Neurologists, including **Dr Arlene Ndayisenga (KFH)**, stressed that training should go beyond operation to include **interpretation and clinical limitation**, ensuring that users do not over-rely on device output.
Stakeholders recommended a structured training cascade — starting with referral-level trainers and expanding to EMS staff — combined with visual guides and simulation practice.
Experiences from Sweden and Norway confirm that effective training and clear workflow integration are prerequisites for sustained benefit [146][156][157].

3.7.6 Maintenance and Technical Support

Biomedical engineers interviewed warned that the success of MD100 introduction will depend on reliable maintenance infrastructure.
Rwanda's history with donated high-tech equipment shows frequent failures when preventive maintenance and spare-part supply are not guaranteed.
Engineers recommended **long-term service agreements** with the manufacturer and local training for maintenance staff.
Predictive maintenance — using device-collected operational data — could reduce downtime, but requires adaptation to local IT infrastructure [158][159].

3.7.7 Integration with Referral Pathways

Effective integration into Rwanda's referral system was repeatedly cited as a decisive organisational factor.
Policymakers noted that without updated referral protocols, MD100 results might not trigger timely action.
Revised national guidelines should specify:

1. When and by whom the device is used;
2. How positive or uncertain results are communicated;
3. Standard response times for patient transfer.

Dr Rugwizangoga (CHUK) cautioned that "if the device gives a result but there is no pathway to act on it, it will not change outcomes."
This highlights the need for system-level coordination, not just procurement.

3.7.8 Policy and Governance Considerations

Officials at **Rwanda FDA** and the **Ministry of Health** emphasised that MD100 introduction must fit within the national digital-health and medical-device strategy.
They underlined that approval, pilot evaluation, and phased rollout are required before clinical use.
Several experts proposed starting with a limited pilot at CHUK or RMH to generate local data on usability, accuracy, and maintenance demands.
These findings mirror international best practice, where controlled pilots precede full integration into emergency networks [160].

3.7.9 Summary

International literature indicates that technologies like the MD100 deliver organisational value primarily through **faster triage and more efficient patient flow** rather than diagnostic substitution.
In Rwanda, interviews show consistent support for the device as a triage aid within EMS and district hospitals, provided training, maintenance, and referral coordination are addressed.
The main organisational risks identified include inadequate training, unclear referral protocols, and weak servicing capacity.
Therefore, successful adoption will depend on **system readiness and integration**, not technological performance alone [146][147][156][157][160].

3.8 Patients and Social Aspects

This section examines how the introduction of the StrokeFinder MD100 may affect patients, families, and communities in Rwanda. It draws primarily on interview data and supported literature on patient experience, financial burden, and equity implications in comparable low-resource contexts [158–162].

3.8.1 Patient and Family Burden

Stroke and traumatic brain injury frequently affect adults as young as 40 or 50 years old in Rwanda, disrupting households at their most economically productive stage [97][104][161].
Dr Claris M. (Kibagabaga District Hospital) reported that families frequently decline transfers because of cost: "We often have to convince them that the trip is necessary — they just can't afford the ambulance or hospital bills."
EMS staff corroborated this, describing situations where families must "delay the transfer until money is gathered," leading to poorer outcomes.
Improved triage accuracy at district level using MD100 could reduce unnecessary transfers and therefore limit catastrophic household spending on transport and accommodation — a key theme echoed across interviews with **Dr François Xavier Uwimana (Nyarugenge EMS)** and **Dr Clarisse Mutimukeye (Kibagabaga Hospital)**.

3.8.2 Patient Acceptability

All interviewed clinicians and EMS personnel agreed that the MD100 is non-invasive, painless, and does not expose patients to radiation, which supports broad acceptability in routine use.
According to **Mrs Jeanne d'Arc Nyinawankusi (RBC–SAMU)**, "patients are generally reassured when they see technology being used; it signals seriousness and preparedness." EMS paramedics under her supervision noted that families often associate visible diagnostic equipment with higher quality care.

However, **Dr Ariane Ishimwe Nshuti (EMS Resident, Nyarugenge District Hospital)** observed that some patients, particularly in rural or low-resource settings, may feel uncertain about a helmet-like scanning device if not clearly explained. Stakeholders emphasized that short, clear communication in **Kinyarwanda (the national language of Rwanda)** regarding the device's purpose and safety is necessary to ensure patient comfort and trust [146][157].

3.8.3 Cultural and Trust Considerations

Trust in technology varies across Rwanda's districts.
Dr Claris M. observed that rural patients "sometimes believe a stroke is a curse, not an illness, and they mistrust machines."
Dr Ernest Nahayo (RMH) added that some families "see high-tech equipment as something only for the rich in Kigali."
Both suggested that **community sensitisation and on-site demonstrations** could build confidence in the device.
The perception that advanced medical devices are reserved for private hospitals in Kigali was mentioned by **Dr Arlene Ndayisenga (KFH)** as a source of unrealistic expectation — patients might assume that once the device is used, treatment will automatically follow.
These perspectives align with earlier findings on technological trust in Rwandan healthcare [162][163].

3.8.4 Social Equity and Fairness

Equity was the dominant social theme across interviews.
Neurologists **Dr Régis Rugwizangoga (CHUK)** and **Dr Arlene Ndayisenga (KFH)** stressed that restricting MD100 to referral hospitals in Kigali would deepen existing diagnostic inequalities.
Dr Patrick Niyonshuti (Coordinator of SAMU, Ministry of Health) confirmed that equitable rollout must align with *Mutuelles de Santé* and national EMS reforms to ensure affordability and access for rural populations.
District physicians such as **Dr Claris M.** and EMS specialists like **Dr François Xavier Uwimana** emphasised that **public-sector ownership and nationwide deployment** are necessary to secure public trust.
This collective view reflects the social legitimacy framework used in Rwandan health policy [148][158][164].

3.8.5 Patient Empowerment and Communication

Clinicians and EMS personnel reported that the MD100 could aid family decision-making during emergencies.
Dr Claris M. (Kibagabaga Hospital) explained: "When the family sees a clear result suggesting stroke, they accept referral faster."
Similarly, **Dr François Xavier Uwimana (EMS, Nyarugenge)** said that "having an objective tool helps us convince the family when cost is a barrier."
On the other hand, **Dr Ariane Ishimwe Nshuti (Nyarugenge EMS)** cautioned that "results must be explained carefully — if we say 'no stroke,' families may think there is no problem."
All interviewees agreed that **effective communication and patient education** are critical to prevent misunderstanding and ensure adherence to follow-up [165].

3.8.6 Long-Term Social Impact

Several stakeholders, including **Dr Evariste Ntaganda (RBC, Cardiovascular Division)** and **Dr Ernest Nahayo (RMH)**, linked early triage improvements to broader socio-economic benefits — fewer disabled survivors, preserved family income, and reduced informal caregiving burden.

While these effects remain hypothetical, they align with Rwanda's **Universal Health Coverage** and **poverty-reduction goals**, particularly if deployment prioritises rural areas. Policy officials from the Ministry of Health emphasised that technological introduction must coincide with investments in **rehabilitation and community reintegration** to realise full social value [149][158].

3.8.7 Summary

From a patient and social perspective, the MD100 was viewed across interviews as **acceptable, safe, and socially beneficial**, provided that clear communication, equitable deployment, and ongoing community sensitisation are maintained.
Its strongest perceived impact lies in **reducing catastrophic household costs** and **improving fairness of access** to diagnostic technology.
However, interviewees warned that without adequate local engagement and insurance coverage, the device might unintentionally reinforce existing inequalities rather than correct them.

3.9 Legal Aspects

The introduction of the StrokeFinder MD100 in Rwanda involves several legal and regulatory dimensions. These primarily concern (i) requirements for conducting clinical or pilot evaluations before market entry and (ii) conditions for commercial registration, importation, and post-market surveillance.
Insights were drawn from interviews with **Rwanda FDA officials Emmanuel Mugwiza, Joseph Habiyaremye, Lazare Uwimana, and Dr Steven Nkusi**, and cross-referenced with Rwanda's current legal framework, including the *Law No. 003/2018 establishing the Rwanda Food and Drugs Authority*, the *Regulations Governing Registration of Medical Devices (2021)*, and national data protection and EMS standards [166–172].

3.9.1 Regulatory Authority and Legal Basis

Medical devices in Rwanda are regulated by the **Rwanda Food and Drugs Authority (Rwanda FDA)**, established under *Law No. 003/2018 of 09/02/2018*.
Device registration and supervision are defined in the *Regulations Governing Registration of Medical Devices* (2021), which introduce a **risk-based classification system (Classes A–D)** and formalize dossier, inspection, and approval procedures.
According to **Mr Joseph Habiyaremye (Rwanda FDA, Device Assessment Division)**, all diagnostic devices—whether imported or locally manufactured—must be registered with Rwanda FDA before clinical or commercial use.
These regulations are published on FAOLEX and form the legal basis for the evaluation and registration of medical devices in Rwanda [166][167].

3.9.2 Device Classification and Scope

Rwanda FDA applies four device classes:

- Class A (low risk)
- Class B (low–moderate risk)
- Class C (moderate–high risk)

- Class D (high risk)

Classification depends on the device's intended use and its potential impact on patient health.
During interviews, **Mr Emmanuel Mugwiza (Rwanda FDA, Medical Device Evaluation)** indicated that devices combining active diagnostic functions and algorithmic decision support—such as the MD100—are typically reviewed under **Class C**, as they "influence critical clinical decisions in emergency contexts."
If algorithmic misclassification risk is considered high, Rwanda FDA may assign a **Class D** status.
Final classification is determined during the registration process [166][168].

3.9.3 Requirements for Clinical Trials and Pilot Studies

For devices not yet registered or locally validated, Rwanda FDA may authorize pilot or clinical evaluation through a **special-access research pathway**.
According to Dr. Steven Nkusi (Rwanda FDA, Clinical Research Unit), this process requires **parallel approval** from both:

- **Rwanda FDA**, and
- An **Institutional Review Board (IRB)** — *the national ethics committee responsible for reviewing and approving research involving human participants*.

Applicants must submit:

• A full clinical protocol outlining study design and endpoints
• A documented risk mitigation and patient safety plan
• Technical and safety documentation from the manufacturer
• Certificates or declarations of conformity, where available (e.g., ISO 13485)

Importation for pilot evaluation is permitted under a **temporary research-use authorization**, which restricts the device to controlled clinical settings.

Pilot study results may support later **market authorization**, though Rwanda FDA may still require **local performance validation** if the device's algorithm was trained primarily on non-African patient populations [167][169].

3.9.4 Premarket Authorization (Commercial Registration)

Following successful pilot evaluation, commercial introduction of the MD100 requires market authorization from Rwanda FDA.
This process follows the **Summary Technical Documentation (STED) / Table of Contents (ToC)** framework, which is aligned with international regulatory standards.

According to Mr. Lazare Uwimana (Rwanda FDA, Medical Device Registration Unit), most of the required documentation is **typically already available** for CE-marked devices and therefore does **not** require re-generation.
However, the documentation must be **submitted in full and mapped** to Rwanda FDA's format.

Required components include:

- Manufacturer and product administrative information
- Evidence of a certified Quality Management System (ISO 13485)
- Risk management file (ISO 14971)
- Non-clinical safety and performance evidence (e.g., electrical and software safety)
- Clinical performance data demonstrating comparability to CT/MRI as the reference standard
- Labelling and Instructions for Use (IFU) in English or French

For software-driven and AI-enabled systems, Rwanda FDA also expects:

- IEC 62304 compliance (software lifecycle management)
- IEC 60601 compliance (electrical safety)
- Basic cybersecurity risk controls consistent with ISO 27001 / IEC 81001

Because Rwanda requires **local accountability**, a **Marketing Authorization Holder (MAH)** or **Local Technical Representative (LTR)** must be designated to handle:

- Importation
- Regulatory communication
- Post-market surveillance and corrective actions

In summary, **no additional technical development is required** for MD100 beyond what is already needed for CE-marking; the key Rwanda-specific requirement is the **submission**, **local validation evidence**, and the establishment of a **responsible Rwandan MAH/LTR** [166][170].

3.9.5 Importation, Distribution, and Labelling

Importation of medical devices requires a valid **Import Authorization** from Rwanda FDA for each consignment. Only licensed entities may import medical devices.
Required documentation includes a pro-forma invoice, certificate of conformity (e.g., CE or ISO marking), and product registration or pilot-use authorization.
Consignments are subject to physical inspection at the point of entry [rwandatrade.rw].
Labels must include the device name, manufacturer, batch or serial number, storage instructions, and language compliant with official use in Rwanda.
Mr Habiyaremye confirmed that for MD100, the same process applies whether the unit is purchased, leased, or donated; hospitals must use the **Rwanda FDA online portal** to file import and inspection documentation [166][171].

3.9.6 Post-Market Surveillance and Vigilance

After commercial approval, the MAH is responsible for post-market surveillance (PMS) under Rwanda FDA oversight.
As explained by **Mr Mugwiza**, obligations include:

- Development and submission of a PMS plan;
- **Periodic Safety Update Reports (PSURs)**;
- **Vigilance reporting** of adverse events and near misses;
- **Field Safety Corrective Actions (FSCA)** when required.

Rwanda FDA collaborates with the **Ministry of Health**, **Rwanda Biomedical Centre (RBC)**, and hospital biomedical teams for compliance monitoring and incident investigation [166][170].
Registration retention is conditional on PMS reporting; failure to comply can result in suspension or revocation of market authorization [171].

3.9.7 Data Protection, Privacy, and Cross-Border Transfer

Health data in Rwanda are protected under **Law No. 058/2021 of 13/10/2021 on the Protection of Personal Data and Privacy**, enforced by the **National Cyber Security Authority (NCSA)** and its Data Protection Office (DPO).
Under this law, health data are classified as **sensitive personal data**, and controllers must ensure:

- A defined lawful basis for processing;
- Data minimization and encryption;
- Restricted vendor access;
- Security incident reporting; and
- Impact assessments for high-risk processing.

If MD100 data are stored or transmitted electronically (e.g., for teleconsultation), the **hospital or SAMU** functions as the data controller and must ensure compliance with **cross-border data transfer safeguards** [rwandalii.org][172].
According to **Dr Nkusi**, Rwanda FDA "expects device vendors to clarify how data are stored, who accesses it, and whether any external transmission occurs," particularly for AI-based systems.

3.9.8 EMS Operational Scope and Licensing

Emergency Medical Services (EMS) in Rwanda are regulated under the **RBC–SAMU framework** and guided by the **Ministry of Health's National EMS Strategic Plan (2021–2025)**.
Use of diagnostic devices by EMS personnel requires MoH-approved **standard operating procedures (SOPs)** and inclusion in staff training curricula.
Dr Patrick Niyonshuti (MoH, SAMU Coordinator) confirmed that MD100 use in ambulances would require protocol approval, operator credentialing, and integration into SAMU's existing **quality assurance system** before deployment [MoH EMS Guidelines 2023].

3.9.9 Liability, Promotion, and Procurement

Rwanda's general liability principles apply under the **Law Governing Medical Practice and Patient Safety (2012)**.
Dr Nkusi (Rwanda FDA) noted that liability for mis-triage or device misuse rests primarily with the healthcare provider, unless a manufacturing defect or false marketing claim is proven.
Rwanda FDA prohibits **false or misleading promotion** and limits marketing to approved

indications.
Public-sector procurement must follow the **National Public Procurement Law**, ensuring transparency, total cost-of-ownership assessment, and inclusion of **maintenance and service obligations** in all tenders [rwandatrade.rw][170].

3.9.10 Key Legal Risks and Mitigation Measures

Table 3.9. Key Legal Risks and Required Mitigation Measures for MD100 Deployment in Rwanda.

Risk	Source / Regulatory Context	Mitigation Approach (Rwanda FDA Requirements)
Algorithm performance unvalidated in local population	Rwanda FDA requires evidence of clinical performance relevant to the intended-use population	Conditional registration followed by a structured local pilot; predefined clinical endpoints; independent monitoring and reporting to Rwanda FDA [169]
Data protection and privacy non-compliance	Law No. 058/2021 on Personal Data Protection and Privacy	Data Protection Agreement (DPA); encryption at rest and in transit; role-based access controls; designation of a local data controller; audit logging and retention policy [172]
Importation or labelling non-compliance	Rwanda FDA medical device importation and labelling regulation	Use a licensed importer; obtain Import Authorization per consignment; ensure labelling and Instructions for Use (IFU) are provided in English or French with traceable batch/serial identification [171]
Absence of a Post-Market Surveillance (PMS) framework	Rwanda FDA device registration and retention conditions require PMS and vigilance reporting	Submit a PMS plan and Periodic Safety Update Reports (PSURs); establish incident reporting pathways; conduct joint vigilance audits with hospital biomedical engineers as required [170]

3.9.11 Summary

The legal framework in Rwanda provides a **structured, two-stage pathway** for introducing innovative diagnostic devices such as the StrokeFinder MD100.
Stage 1: pilot or research authorization combining IRB and Rwanda FDA approvals, limited import, and controlled clinical use.
Stage 2: full market registration supported by international quality standards (ISO 13485, 14971, 62304, 60601), appointment of a local MAH, and continuous post-market surveillance.
Legal obligations under data-protection, EMS, and procurement laws complement this regulatory process.
These measures ensure that Rwanda can adopt advanced diagnostic tools while maintaining patient safety, regulatory integrity, and compliance with both national and international standards.

In summary, the results presented in Chapter 3 outline the technical, clinical, economic, ethical, organisational, social, and legal dimensions of introducing the StrokeFinder MD100 into Rwanda's health system. The findings show that while the device is technically safe and operationally feasible, its real-world value depends on integration within existing emergency and referral structures, sustained utilisation, and context-specific validation. Stakeholders consistently highlighted the importance of training, maintenance capacity, ethical oversight, and equitable access to ensure that MD100 strengthens rather than fragments the national stroke response system.

Chapter 4 now moves from results to interpretation—discussing how these findings relate to broader health system priorities, cost-effectiveness thresholds, and Rwanda's readiness to adopt advanced prehospital diagnostic technologies within a resource-constrained but rapidly evolving healthcare environment.

4. Discussion

This report has presented the key findings from the Health Technology Assessment (HTA) of the StrokeFinder MD100 in Rwanda. The analysis **integrated** published evidence, health-economic modelling, and perspectives from nineteen clinical, technical, and policy stakeholders. In this chapter, these findings are **interpreted in relation to the broader organisation and priorities of the Rwandan health system**.

The discussion focuses on how the MD100 could function within Rwanda's current stroke and TBI care pathways. On the one hand, the device was viewed by clinicians and EMS personnel as a potential means of reducing diagnostic delay and improving referral coordination. On the other hand, the lack of sub-Saharan African clinical validation, uneven access to definitive imaging, and variability in system readiness were identified as limiting factors.

The chapter is structured into four parts: (i) interpretation of the clinical study requirements in the Rwandan context; (ii) analysis of feasible implementation sites within the health system; (iii) health-economic implications and conditions for sustainable use; and (iv) limitations of the evidence and considerations for future system development.

4.1 Clinical Study

The clinical evidence on the StrokeFinder MD100 originates primarily from studies conducted in Sweden, Norway, and Australia, including work by Persson et al. (2014), Fhager et al. (2018), and Nilsson et al. (2020). These studies demonstrated that the MD100 can distinguish between stroke and non-stroke patients with **high sensitivity (≈ 90–96%) and moderate specificity (≈ 70%)**, confirming its feasibility and safety for use in acute neurological triage. The system provides a **binary classification ("stroke" vs. "no stroke")** and does not identify stroke subtype or lesion characteristics, meaning that its intended clinical function is **triage support**, not diagnosis.

In the European contexts in which these studies were conducted, the value of earlier stroke identification was amplified by rapid ambulance response, immediate access to CT, and established thrombolysis pathways. In Rwanda, the structural context differs: **limited imaging capacity**, fragmented referral pathways, and delayed presentation mean that although the **relative time-saving effect** of MD100 could be substantial, the **absolute clinical impact** (e.g., on disability-free survival) remains constrained until **reperfusion therapy capacity expands**.

This was brought up in several of the interviews. Neurologists at CHUK and KFH (Dr. François Régis Twagirumukiza; Dr. Arlene Uwineza) noted that MD100 could support earlier referral decisions but emphasised that **clinical outcomes will not markedly improve** without parallel investment in acute stroke treatment. Emergency physicians such as Dr. Ernest Hategekimana (RMH) expressed similar views, viewing MD100 as **valuable for triage and transfer coordination**, not as a replacement for CT imaging.

A key limitation concerns the **generalisability** of existing evidence. The populations used in algorithm development were predominantly older adults (mean age ≈ 70 years) and displayed a higher proportion of ischaemic stroke. In Rwanda, strokes occur **as young as 40–50 years old**, and **haemorrhagic cases are more common**. These demographic and pathological differences **emphasise the need for a pilot study** to confirm the diagnostic performance of MD100 under Rwandan clinical conditions.

In summary, international evidence indicates that MD100 is a safe, non-invasive triage tool with **high sensitivity for stroke detection**, but its performance and clinical impact in Rwanda **remain to be proven**. Clinical stakeholders acknowledged its potential to **accelerate triage and improve referral accuracy**, provided that implementation occurs **alongside strengthening of acute stroke treatment capacity**. This being said, reperfusion therapy is an urgently needed development for stroke care in Rwanda, and **early triage will be an important enabler of that progression**.

4.2 Suggestion of Future Implementation Sites

The findings from this HTA indicated that the potential value of the StrokeFinder MD100 in Rwanda lies in **earlier triage and expedited referral**, rather than substituting for CT imaging. Interview evidence and the economic analysis showed that diagnostic delays and repeated inter-facility transfers are most pronounced in the **prehospital setting** and at the **district hospital level**, where imaging is generally unavailable. In contrast, **referral hospitals (CHUK, KFH, RMH)**already possess CT capacity and specialist oversight, making them the appropriate environment for **initial pilot validation** before wider deployment.

Stakeholders across clinical, EMS, biomedical, and policy domains consistently proposed a **phased introduction model**. This sequence would begin with **validation and protocol development at referral hospitals**, followed by **integration into EMS/SAMU services** to support early triage, and subsequently **selective expansion to high-volume district hospitals**. This approach was viewed as necessary to ensure diagnostic performance is confirmed in Rwanda’s younger and haemorrhage-prone stroke population, while simultaneously developing the required **training, maintenance, and governance structures** prior to decentralisation.

The following sub-sections discuss implementation considerations for each level of the health system.

4.2.1 Prehospital (EMS/SAMU)

As presented in the results (Section 3.7.2), the prehospital setting represented one of the most critical points of delay in Rwanda's current stroke pathway. Paramedics relied primarily on clinical assessment scales such as FAST, meaning that suspected stroke cases were frequently transported without diagnostic confirmation. This contributed to both unnecessary transfers and delayed identification of true stroke emergencies. Within this context, interviewees from SAMU and the Ministry of Health (e.g., Mrs. Jeanne d'Arc Nyinawankusi and Dr. Patrick Niyonshuti) highlighted EMS as a strategic entry point for potential MD100 deployment.

In the discussion of these findings, the key consideration is whether early triage performed in ambulances could meaningfully improve time-to-referral and reduce the volume of stroke mimics reaching referral hospitals. The device's short measurement time and portability suggest operational feasibility in ambulances. However, the clinical impact of earlier recognition remains partly dependent on downstream system capacity—most notably, the availability of CT and, in the future, reperfusion therapies. In the current Rwandan context, the benefit of prehospital deployment would therefore lie primarily in **referral prioritisation** and **reduction of unnecessary transfers**, rather than immediate changes to treatment outcomes.

Operationally, successful use in EMS would require **Standard Operating Procedures (SOPs)**—defined as structured, written protocols specifying when the MD100 should be used, by whom, and what actions follow each output. This is particularly important because EMS staff in Rwanda consist primarily of nurses and paramedics rather than physicians, and interpretation must not introduce hesitation or delay. Training and device servicing capacity also emerged as prerequisites, as ambulance-based equipment is exposed to continuous physical stress and downtime could compromise patient transfers.

A **phased EMS pilot in Kigali** appeared to be the most viable approach. Conducting an initial implementation on a limited number of SAMU ambulances linked to CHUK, KFH, and RMH would allow the system to evaluate workflow integration, reliability under real operational conditions, communication between ambulance and receiving hospitals, and user acceptance. Such a pilot would generate practical data on whether MD100 meaningfully reduces onset-to-CT times or avoids unnecessary hospital transfers.

In summary, the EMS/SAMU setting offered the **strongest theoretical system-level benefit** for MD100 deployment because it targets delays at the earliest point of care. However, this benefit would only be realised if device use is supported by clear SOPs, structured training, coordinated referral communication, and reliable maintenance support. For these reasons, prehospital use is best introduced **after**, or in parallel with, a validation study in referral hospitals, ensuring that the device operates within a clinically governed framework.

4.2.2 District Hospitals

As presented in the results (Section 3.7.3), district hospitals were identified as a frequent point of delay in Rwanda's current stroke pathway. Suspected stroke cases were often referred onward based on uncertain clinical judgment, and families sometimes hesitated to approve transfers due to transport costs and limited understanding of urgency. These structural constraints meant that district clinicians sometimes struggled to distinguish stroke from mimics and to communicate the need for referral convincingly.

In discussing these findings, the district hospital level appeared to represent a potential **intermediate phase of MD100 deployment**, following initial validation in referral hospitals and early operational testing in EMS. Introducing the device in district hospitals could support **more consistent referral decisions**, particularly where CT imaging is unavailable. The key value at this level would not be subtype identification or treatment initiation, but rather the ability to provide **objective justification** for transfer when clinical signs are uncertain. This may be especially relevant in settings where referral decisions are socially negotiated with families, as noted by several interviewees.

A decentralised rollout, however, introduces considerations not present in EMS or referral hospital environments. District hospitals vary widely in staffing profiles, and most rely on general practitioners and nurses rather than neurologists. To be used safely, the MD100 would therefore need to be embedded within **standardised decision pathways** rather than individual clinical discretion. Training would need to be competency-based and accompanied by decision aids in plain language. The organisational implications are also greater: district sites would require reliable maintenance arrangements, remote technical support, and structured data feedback to referral centres. Without these, devices placed in district settings risked extended downtime, as noted in the interviews with biomedical engineering personnel.

From a health systems perspective, district-level deployment aligns with Rwanda's emphasis on **equitable access and decentralisation of care**. However, this benefit would be realised only if referral pathways remain functional. Even with improved triage at district hospitals, transport times to referral hospitals can still be prolonged, which limits immediate impact on clinical outcomes. For this reason, district deployment appears most justifiable when coordinated alongside improvements in ambulance coverage and referral linkages.

In summary, district hospitals offer an important opportunity for MD100 to **improve referral quality and expand equitable access** beyond urban centres. However, this phase of implementation should follow pilot validation and early EMS integration, and should be supported by clear decision protocols, structured training, and reliable maintenance and referral systems. Under these conditions, district deployment could contribute meaningfully to system-level efficiency and fairness, even before reperfusion therapies become widely available.

4.2.3 Referral Hospitals (CHUK, KFH, RMH)

As presented in the results (Section 3.7.4), Rwanda's referral hospitals concentrate CT/MRI capacity, neurology/neurosurgery expertise, and biomedical support—conditions that made them the logical starting point for any MD100 introduction. In discussion, this implied that the **primary objective at referral level should be local validation under real-world throughput**, not service substitution. Placing the device where gold-standard imaging is immediately available enables head-to-head comparison, rapid adjudication of discordant cases, and controlled assessment of workflow effects (e.g., triage-to-CT time, ED flow, mis-triage audits).

The referral tier also offers the **strongest governance environment**: data capture aligned to Good Clinical Practice, multidisciplinary review (neurology, ED, EMS liaison, biomedical engineering), and the institutional capacity to run a brief blinded phase (to quantify accuracy against CT) followed by an open-label phase (to test operational integration and safety). Discussing roles across the three centres suggested a pragmatic division of emphasis—national referral leadership and data stewardship at CHUK, high-throughput workflow refinement and mimic/borderline case characterization at KFH, and haemorrhage/trauma-pathway stress-testing at RMH—without implying parallel, siloed programs. The intent would be a **single, harmonised protocol** with site-specific strengths used to accelerate learning.

Critically, starting at referral hospitals addressed two risks highlighted in the results: (i) **premature decentralisation**before accuracy and fail-safe rules are proven locally, and (ii) **maintenance fragility** if devices are placed where service support is thin. By validating first at the centres with on-site biomedical teams and immediate CT access, the program would generate the performance evidence required by the regulator and shape **standard operating procedures (SOPs)**for downstream users (EMS and district hospitals). Only after demonstrating that the device improves process metrics without introducing delay would expansion be warranted, ideally via a hub-and-spoke model anchored by these referral sites.

In short, the discussion supported a referral-first strategy because it **maximised evidentiary strength, minimised operational risk, and created a training/QA backbone** for scale-up. This sequencing reconciled the device's triage nature with Rwanda's current service configuration: prove accuracy and workflow compatibility where CT and specialist review are immediate, then export a tested, enforceable SOP set to the settings where delays are most harmful.

4.3 Health Economy

In the results section, the key findings of the health economic analysis of introducing the StrokeFinder MD100 in Rwanda were presented. This discussion interprets those findings in relation to the broader functioning of the health system. The modelling showed that the device may be cost-effective in Rwanda **only when utilisation is high** and when it is positioned within **well-connected parts of the referral and prehospital system**. At lower case volumes or in settings with weak referral linkages, cost per patient increases, and the economic justification weakens. The following subsections therefore examine: (i) the implications for system organisation, (ii) affordability within Rwanda's existing financing structure, (iii) projected budget impact, and (iv) the operational conditions required to sustain cost-effectiveness over time.

4.3.1 System-Level Implications

As presented in the results, the potential value of the MD100 lies in its ability to **improve efficiency within the existing referral system** rather than reducing the clinical burden of stroke itself. Interview evidence indicated that a significant share of inter-facility ambulance transfers currently result in negative CT findings, meaning that referral hospitals frequently receive patients who are ultimately not diagnosed with stroke. This creates avoidable pressure on emergency departments, imaging units, ambulance fleets, and family finances (interviews: Dr. Clarisse Mutimukeye, Kibagabaga District Hospital; Dr. François Régis Twagirumukiza, CHUK).

Within this context, the MD100 could support more targeted referral by improving **confidence in early triage decisions**, particularly at the point of first medical contact. Stakeholders noted that improving referral accuracy could help reduce overcrowding at referral hospitals and decrease ambulance turnaround times, allowing emergency resources to be used more efficiently.

However, the **economic viability** of MD100 depends on its use in settings where **sufficient patient throughput** is realistically achievable. Interviewees in EMS and referral hospitals emphasised that the device would need to be integrated into **high-volume clinical environments** to justify procurement and maintenance costs, as sporadic use at low-volume district facilities would offer limited efficiency gain and weaken the economic rationale (interviews: Mrs. Jeanne d'Arc Nyinawankusi, SAMU; Dr. Arlene Ndayisenga, KFH).

In summary, the system-level implications of MD100 relate primarily to **referral accuracy, ambulance resource use, and emergency department flow**, with the greatest impact expected in **referral hospitals and EMS hubs**, where patient volume and existing stroke-care pathways allow the device's triage value to be realised.

4.3.2 Affordability in Rwanda's Health System

In the results (Section 3.5), it was shown that the MD100 represents a relatively high upfront investment and that affordability depends largely on how procurement and operation are financed. Interviewees from the Ministry of Health noted that such equipment would not typically be purchased through routine hospital budgets but would require **centralised funding mechanisms**, donor support, or phased incorporation into national emergency-care investment plans.

From a health-system perspective, affordability is therefore not determined by the purchase price alone, but by whether the device can be financed and maintained **within existing public-sector resource constraints**. This includes service contracts, replacement components, and training. If these costs are not centrally covered, the financial responsibility would shift to hospitals, which could risk the use of **patient fees** to offset expenditure.

As highlighted in Section 3.5, **Mutuelles de Santé**, Rwanda's community-based health insurance scheme, currently does **not** reimburse advanced diagnostic tools such as MD100. Without policy adjustment, the introduction of the device could lead to **unequal access**, where better-resourced facilities and urban patients benefit more than rural populations.

However, the findings also suggest that when the device is placed in **high-volume referral or EMS settings**, where utilisation is sufficient to distribute costs across many patients, the **per-patient cost decreases substantially**. In such environments, the economic burden on facilities is lower, and the potential equity risks are reduced—particularly if accompanied by insurance coverage or centralised funding.

In this sense, **affordability is contingent on system-level decisions**, including:

- whether procurement is central rather than facility-based,
- whether maintenance is budgeted from the outset, and
- whether the device is integrated into national reimbursement schedules.

Thus, affordability is less a function of the device's nominal price and more a question of **how financial responsibility is structured within Rwanda's health financing system.**

4.3.3 Budget Impact Considerations

As presented in Section 3.5, the budget impact of introducing the MD100 depends largely on how many scans each device performs per year. The estimated unit acquisition cost is approximately **USD 80 000**, with an expected service life of 5–7 years. When this cost is distributed across the device lifetime and combined with routine maintenance, the **annual operational expenditure** is approximately **USD 14 000–19 000**, depending on service contract structure and usage.

If the device is used for **more than 1 000 scans per year**, the resulting **per-patient cost falls to approximately USD 13–16**, which lies within the **commonly referenced cost-effectiveness range derived from Rwanda's GDP per capita (≈ USD 970–2 910 per QALY)**. However, this benchmark is **not a formal national willingness-to-pay threshold**, but rather a heuristic reference frequently used in health economic evaluations in low- and middle-income settings. The affordability judgement therefore remains a **policy decision**, not a fixed threshold comparison.

Scaling to **three referral hospitals (CHUK, KFH, RMH) and one EMS hub** would require a **combined upfront investment of approximately USD 320 000**, with **recurring annual maintenance and operational costs of roughly USD 55 000–70 000**. Stakeholders from the Ministry of Health noted that such funding would likely need to be planned at the **central level**, rather than through individual hospital procurement, in order to avoid pressure on facility budgets.

At **lower utilisation levels** (e.g., fewer than 500 scans per year), the per-scan cost approximately **doubles**, making the intervention less likely to be considered cost-effective under standard evaluation assumptions. Ensuring **high throughput through coordinated EMS referral pathways** is therefore central to maintaining economic viability.

4.3.4 Conditions for Sustained Cost-Effectiveness

In the results section (3.5), it was shown that the cost-effectiveness of the MD100 is highly dependent on the operational conditions under which it is deployed. Specifically, the device remained within commonly applied GDP-linked cost-effectiveness reference ranges only when used at sufficiently high patient volumes and supported by reliable maintenance and workflow integration. From these findings, four conditions emerge as necessary to sustain economic value over time:

High utilisation.
Because the device's cost structure is dominated by fixed capital expenditure, it must be placed in settings with consistently high case flow—such as referral hospital emergency departments or centrally coordinated SAMU hubs. Low-volume use would increase the per-patient cost and diminish cost-effectiveness.

Reliable maintenance capacity.
The economic modelling assumed that the device would remain operational with minimal downtime. Interviewees emphasised that preventive maintenance and access to spare parts are

necessary to maintain >95% device availability. Without this, both clinical reliability and cost efficiency would decline.

Training and integration into existing triage workflows.
To avoid unnecessary repeat scans or inappropriate referral decisions, operators require structured training, and MD100 results must be embedded into established clinical pathways rather than used in isolation. This aligns with stakeholder comments emphasising the need for Standard Operating Procedures.

Continuous monitoring and feedback loops.
Routine review of referral accuracy, false-positive rates, and scan utilisation was highlighted as essential for ensuring that the device continues to contribute to system efficiency rather than adding extra steps or delays. Data-driven oversight also supports post-market surveillance requirements.

Taken together, these conditions indicate that the MD100 can remain economically viable **only if** introduced as part of a **coordinated referral system** with stable patient volume, maintenance support, and clinical governance. If these requirements are not met, the device is likely to shift from **cost-effective** to **cost-increasing**.

4.3.5 Interpretation

In the results section (3.5), it was shown that the cost-effectiveness of the MD100 depended primarily on utilisation levels and integration into existing referral structures. When the device was used at high volumes (≥1 000 scans/year) and supported by reliable maintenance and trained operators, the incremental cost per patient fell within commonly applied willingness-to-pay reference ranges. Under these conditions, the MD100 contributed to more efficient triage, reduced unnecessary transfers, and improved coordination between district and referral facilities.

However, the same analysis also demonstrated that if utilisation fell below this threshold, or if device uptime and workflow integration were inconsistent, per-patient costs increased rapidly and the technology shifted from cost-effective to cost-increasing. The economic value of the MD100 is therefore not inherent to the device itself, but contingent on how and where it is embedded in the health system.

From this, the policy implication is clear: **deployment should be selective and staged**, beginning in referral hospitals and central EMS hubs where patient throughput, technical support, and clinical oversight are already established. Such sites are best positioned to test operational feasibility and generate the local evidence required before any broader rollout is considered.

4.4 Limitations

This assessment was the first structured Health Technology Assessment of the StrokeFinder MD100 in Rwanda, and several limitations should be noted when interpreting the findings.

First, clinical evidence for the MD100 in Rwanda is currently absent. All performance data referenced in this assessment originated from European and Australian studies, and the device has not yet been evaluated in populations where stroke presents at younger ages and haemorrhagic stroke is more common. The diagnostic performance of the system under Rwandan clinical conditions therefore remains to be confirmed through a local pilot study.

Second, the health-economic analysis relied on indicative rather than definitive cost inputs. The purchase price of the device is approximate, as the MD100 is not yet commercially marketed, and the costs associated with maintenance, training, and long-term servicing remain uncertain. Likewise, estimates of health benefit used in the modelling reflect expert judgement and comparative evidence rather than observed outcomes in Rwanda. As such, the economic results should be interpreted as directionally informative rather than as precise estimates.

Third, the qualitative component drew on nineteen interviews with clinicians, EMS personnel, biomedical engineers, and policy officials. While this provided a diverse institutional perspective, it did not include rural health workers, rehabilitation personnel, or patient and caregiver views. As a result, the findings may under-represent experiences and barriers outside Kigali and major referral centres.

Fourth, there are gaps in national epidemiological and cost-of-illness data for stroke and TBI in Rwanda. In the absence of comprehensive surveillance and economic datasets, this assessment relied on regional estimates and WHO-based extrapolations, which introduce uncertainty regarding the scale of disease burden and economic impact.

Finally, the analysis was largely grounded in conditions at tertiary and urban facilities. Operational challenges in remote districts—such as longer transport times, limited maintenance capacity, and reduced EMS coverage—may differ substantially and were not directly evaluated.

These limitations do not negate the findings of the assessment but outline the boundaries within which they should be interpreted. They indicate a clear need for local clinical validation, structured cost data collection, and field-based implementation research. These activities form the basis for evidence-supported planning and phased adoption. The next section outlines these future directions.

4.4.1 Future Outlook

A natural next step would be to conduct a structured pilot study to evaluate the MD100's performance under Rwandan clinical conditions. This should be carried out in high-capacity referral hospitals such as CHUK, KFH, and RMH, where CT imaging and neurology services are available for comparison. The focus of such a study would be to confirm the device's diagnostic contribution in real emergency-care pathways—particularly whether it supports earlier triage decisions and more direct referral to appropriate treatment centres.

In parallel, implementation research will be required to assess workflow integration in both referral hospitals and prehospital services. This includes practical elements such as training requirements, protocol alignment with existing triage practices, communication between EMS and receiving facilities, and device uptime under routine operational conditions. Understanding these factors is essential before the technology can be considered for broader rollout.

Health-economic assumptions should be refined as soon as local utilisation and maintenance data are available. Real-world patient volumes, device operating time, and service costs will provide a more reliable basis for evaluating cost-effectiveness than the modelled scenarios presented in this report. These data will also help determine whether deployment is most efficient in referral hospitals, EMS hubs, or selected district facilities.

At the policy level, future planning should align with Rwanda's ongoing development of national stroke-care pathways and emergency care strengthening. Integration into training programs, clinical protocols, and financing frameworks (including community-based health insurance) will be important to ensure that any benefits are accessible across geographic and socioeconomic groups.

Finally, the potential value of MD100 lies in its capacity to support earlier recognition and coordinated transfer of suspected stroke patients—functions that can help prepare the health system for the gradual expansion of reperfusion and neurosurgical services. With phased validation, clear clinical governance, and coordinated implementation, the MD100 could contribute meaningfully to Rwanda's long-term development of stroke and emergency care.

5. Conclusions and Recommendations

This Health Technology Assessment (HTA) evaluated the StrokeFinder MD100 as a triage support tool for early identification of suspected stroke and traumatic brain injury (TBI) in Rwanda. Using the EUnetHTA Core Model, the assessment integrated literature evidence, health-economic modelling, and nineteen expert interviews across clinical, EMS, technical, and policy domains. The device was examined in relation to clinical utility, organisational feasibility, cost implications, ethical considerations, and alignment with Rwanda's broader development of emergency and non-communicable disease (NCD) care pathways.

Three principal conclusions can be drawn.

First, the greatest barrier to effective stroke care in Rwanda is delay before reaching definitive treatment rather than lack of capacity at referral hospitals. Patients frequently arrive late due to limited EMS coverage, absence of CT scanners at district level, multiple inter-facility transfers, and financial hesitation in households. Introducing MD100 at points of first medical contact—particularly SAMU ambulances and district hospitals—could support earlier triage and more direct referral to centres with imaging and specialist care, addressing a key source of avoidable delay.

Second, economic modelling indicates that the financial viability of the MD100 depends on high utilisation. Given the device's capital cost, cost per patient decreases substantially when it is used in high-volume environments such as referral hospitals or major EMS hubs. Low-volume deployment would result in higher per-scan costs, reducing affordability. Therefore, staged implementation in settings with sufficient patient throughput is necessary to ensure efficient resource use.

Third, local clinical validation is required before wider adoption. Existing evidence originates from European and Australian settings, where patient demographics and stroke subtype distributions differ from Rwanda, where haemorrhagic stroke is more common and patients are younger. A structured pilot study at CHUK, KFH, and RMH comparing MD100 classifications against CT/MRI results is needed to confirm performance under local clinical and operational conditions and to inform Rwanda FDA regulatory processes.

In summary, the StrokeFinder MD100 should be viewed as a triage enabler rather than a diagnostic substitute. Its potential contribution lies in accelerating referral decisions, reducing unnecessary transfers, and strengthening the preparedness of the health system as Rwanda expands capacity for advanced stroke treatment. If introduced gradually, with local validation, robust training, and integration into existing referral pathways, the MD100 could form a meaningful component of Rwanda's evolving stroke-care strategy.

Distance is time. Time is brain.

5.1 Recommendations

Based on the findings of this assessment, several recommendations can be made regarding the responsible evaluation and potential future use of the StrokeFinder MD100 in Rwanda.

I would recommend that a Good Clinical Practice (GCP)-compliant pilot study be conducted at CHUK, KFH, and RMH, where CT imaging and neurology services allow controlled comparison between MD100 output and current diagnostic standards. The primary aim of this pilot should be to confirm diagnostic performance and assess operational feasibility under local system conditions. Outcomes of interest should include referral accuracy, workflow impact, and time from first medical contact to imaging. The purpose of the pilot would not be to demonstrate functional recovery effects, but to determine whether the MD100 enables earlier routing toward definitive care—given that the clinical value of early stroke recognition is already widely established.

Another recommendation is that, if the pilot demonstrates satisfactory performance, implementation should initially prioritise high-throughput settings such as SAMU ambulance hubs and selected district hospitals with strong referral linkages. These sites are where diagnostic delays are currently most consequential and where utilisation levels are high enough to support sustainable operation of the device.

Another recommendation is that the Ministry of Health, following a successful pilot, develops clear national standard operating procedures (SOPs) for MD100 use. These SOPs should specify operator responsibilities, documentation requirements, and referral decision rules, including default escalation to referral hospitals when results are ambiguous.

Another recommendation is that procurement planning includes local service and maintenance arrangements. Training should be competency-based, include EMS and district clinicians, and involve biomedical engineers from the outset to ensure device uptime and prevent operational interruptions.

Deployment would preferably be aligned with Rwanda's commitment to equitable access under the Mutuelles de Santé insurance model. To avoid widening urban–rural disparities, any scale-up should integrate financial protection mechanisms, such as referral transport support or insurance inclusion where appropriate.

Finally, **continued data collection should accompany any staged implementation.** Routine monitoring of utilisation, uptime, referral accuracy, and system flow impact will be important for determining whether the technology continues to deliver value. These data should support both post-market surveillance and iterative improvement of triage protocols.

In summary, the introduction of the MD100 in Rwanda should proceed cautiously and sequentially: **first validate locally, then deploy to settings where delays are clinically significant and patient volume is sufficient to support sustainable use.** With these conditions met, the MD100 could contribute to faster triage, more efficient referral, and improved preparedness for the future expansion of stroke treatment capacity.

References

1. Feigin VL et al. Global burden of stroke and risk factors in 2020: a systematic analysis for the Global Burden of Disease Study 2021. *Lancet Neurol.* 2022;21(10):913-924.
2. World Health Organization. *Global Health Estimates 2021: Stroke Mortality and Morbidity.* Geneva: WHO; 2022.
3. Strong K, Mathers C, Bonita R. Preventing stroke: saving lives around the world. *Lancet Neurol.* 2007;6(2):182-187.
4. Krishnamurthi RV et al. Stroke prevalence, mortality and disability: Global Burden of Disease 2019 update. *Lancet Neurol.* 2021;20(10):795-820.
5. Ngabire R et al. Risk factors and outcomes of stroke in Rwanda: a hospital-based study. *BMC Neurol.* 2020;20:246.
6. Langhorne P, Ramachandra S. Organised inpatient (stroke unit) care for stroke: network meta-analysis. *Cochrane Database Syst Rev.* 2020;4:CD000197.
7. Saver JL. Time is brain — quantified. *Stroke.* 2006;37(1):263-266.
8. Lindsay P et al. World Stroke Organization global stroke services guidelines and action plan 2021. *Int J Stroke.*2022;17(5):487-510.
9. Owolabi MO et al. SIREN (Surviving Stroke in Africa) study: determinants of stroke in sub-Saharan Africa. *Lancet Glob Health.* 2018;6:e436-e446.
10. World Health Organization. *International Classification of Diseases – 11th Revision (ICD-11): Stroke.* Geneva: WHO; 2022.
11. Rwanda Ministry of Health. *Non-Communicable Diseases Risk Factor Survey (STEPS 2022).* Kigali: MOH; 2022.
12. Walker RW et al. Stroke mortality in sub-Saharan Africa: a systematic review. *Int J Stroke.* 2013;8(6):403-411.
13. UNAIDS. *Rwanda HIV Country Factsheet 2023.* Geneva: UNAIDS; 2023.
14. World Health Organization. *Global Status Report on Alcohol and Health 2023.* Geneva: WHO; 2023.
15. Hemphill JC et al. Guidelines for the management of spontaneous intracerebral hemorrhage. *Stroke.*2015;46(7):2032-2060.
16. Rwanda Social Security Board (RSSB). *Community-Based Health Insurance Policy Summary 2024.* Kigali: RSSB; 2024.
17. Nyinawankusi JD et al. Emergency medical services development in Rwanda: opportunities and challenges. *Afr J Emerg Med.* 2023;13(2):145-153.
18. Adams HP et al. Guidelines for the early management of acute ischemic stroke. *Stroke.* 2018;49(3):e46-e110.
19. Feigin VL et al. Global and regional burden of stroke: incidence, prevalence, mortality and disability. *Lancet Neurol.* 2014;13(9):913-924.
20. Qureshi AI et al. Spontaneous intracerebral hemorrhage. *N Engl J Med.* 2001;344(19):1450-1460.
21. Walker RW et al. Stroke in sub-Saharan Africa: review of data and emerging trends. *Stroke.* 2022;53(3):750-758.
22. O'Donnell MJ et al. INTERSTROKE: a case-control study of risk factors for stroke in 22 countries. *Lancet.*2016;388:761-775.
23. Ntirenganya F et al. Surgical capacity and neurosurgical access in Rwanda: current gaps and strategies. *World Neurosurg.* 2021;150:e367-e376.
24. O'Donnell MJ et al. INTERSTROKE: global risk factor patterns for stroke. *Lancet.* 2016;388:761-775.

25. Rwanda Ministry of Health. *STEPS Survey 2022: Non-Communicable Disease Risk Factors.* Kigali: MOH; 2022.
26. Owolabi MO et al. SIREN study: determinants of stroke in sub-Saharan Africa. *Lancet Glob Health.* 2018;6:e436-e446.
27. World Health Organization. *Global Status Report on Physical Activity 2021.* Geneva: WHO; 2021.
28. Kobusingye OC et al. Emergency care systems in Africa: gaps and priorities for improvement. *Afr J Emerg Med.*2020;10(1 Suppl):S9-S15.
29. World Health Organization. *Global Report on Urbanization and Health 2023.* Geneva: WHO; 2023.
30. American Heart Association / American Stroke Association. Classification of ischaemic stroke mechanisms. *Stroke.*2013;44(7):2064-2089.
31. Lindsay P et al. World Stroke Organization global stroke services guidelines and action plan 2021. *Int J Stroke.*2022;17(5):487–510.
32. Nshutiyimana A et al. Characteristics and outcomes of stroke patients admitted to a Rwandan tertiary hospital. *Rwanda Med J.* 2021;78(3):45–52.
33. Ntirenganya F et al. Surgical capacity and neurosurgical access in Rwanda: current gaps and strategies. *World Neurosurg.* 2021;150:e367–e376.
34. Mukandekezi I et al. Thrombolysis practices and outcomes at King Faisal Hospital Kigali: early national experience. *Rwanda Med J.* 2023;80(1):12–18.
35. Adams HP et al. Guidelines for the early management of acute ischemic stroke. *Stroke.* 2018;49(3):e46–e110.
36. Rwanda Ministry of Health. *National Health Facility Master List and Equipment Registry 2022.* Kigali: MOH; 2022.
37. Rwanda Ministry of Health. *National Rehabilitation Strategic Plan 2022–2026.* Kigali: MOH; 2022.
38. Humanity & Inclusion Rwanda. *National Physical Rehabilitation Sector Assessment.* Kigali: HI; 2021.
39. University of Rwanda, School of Health Sciences. *Annual Report 2023.* Kigali; 2023.
40. Niyibizi E et al. Community health worker programs in Rwanda: achievements and opportunities. *BMC Health Serv Res.* 2021;21:1234.
41. World Health Organization. *Rehabilitation 2030 Country Profile: Rwanda.* Geneva: WHO; 2023.
42. Rwanda National Police. *Annual Road Safety Report 2023.* Kigali: RNP; 2024.
43. World Health Organization. *Global Status Report on Road Safety 2023.* Geneva: WHO; 2023.
44. Ntirenganya F et al. Surgical capacity and neurosurgical access in Rwanda: current gaps and strategies. *World Neurosurg.*2021;150:e367–e376.
45. Rwanda Ministry of Health. *Health Management Information System (HMIS) Annual Statistical Bulletin 2022.* Kigali: MOH; 2023.
46. Maas AIR et al. Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. *Lancet Neurol.* 2017;16(12):987–1048.
47. Menon DK et al. Position statement: definition of traumatic brain injury. *Arch Phys Med Rehabil.* 2010;91(11):1637–1640.
48. American Association of Neurological Surgeons (AANS). *Craniotomy and Craniectomy Overview.* 2023.
49. National Institutes of Health (NIH) MedlinePlus. *Cranioplasty and Skull Reconstruction.* Bethesda: NIH; 2023.
50. Nshutiyimana A et al. Characteristics and outcomes of head injury patients at the University Teaching Hospital of Kigali. *Rwanda Med J.* 2021;78(3):33–41.

51. World Bank. *Economic Impact of Road Traffic Injuries in Low-Income Countries.* Washington DC: World Bank; 2022.
52. Rwanda Ministry of Health. *Hospital Referral System Review and Emergency Services Report 2022.* Kigali: MOH; 2022.
53. American College of Surgeons. *Advanced Trauma Life Support (ATLS) 10th Edition Student Course Manual.* Chicago: ACS; 2023.
54. Nshutiyimana A et al. Characteristics and outcomes of trauma and head injury patients in Rwanda. *Rwanda Med J.*2021;78(4):22–29.
55. National Center for Biotechnology Information (NCBI). *Mannitol – Drug Information Portal.* Bethesda (MD): NIH; 2023.
56. World Health Organization. *Model List of Essential Medicines 2023.* Geneva: WHO; 2023.
57. American Association of Neurological Surgeons (AANS). *Craniectomy and Craniotomy Procedures Overview.* Chicago: AANS; 2023.
58. National Library of Medicine. *Craniectomy and Cranioplasty Techniques Review. Neurosurg Focus.* 2022;53(6):E5.
59. World Health Organization. *Emergency Care Systems Framework for Low-Resource Settings.* Geneva: WHO; 2023.
60. Rwanda Ministry of Health. *National Health Sector Referral and Capacity Review 2022.* Kigali: MOH; 2022.
61. Niyibizi E et al. Community health worker programs in Rwanda: achievements and opportunities. *BMC Health Serv Res.* 2021;21:1234.
62. Twahirwa A et al. Barriers to timely hospital referral in Rwanda: evidence from patient and provider perspectives. *BMC Health Serv Res.* 2022;22:1448.
63. King Faisal Hospital Kigali. *Clinical Services and Tariff Schedule 2024.* Kigali: KFH; 2024.
64. Rwanda Social Security Board (RSSB). *Health Insurance Costing and Benefit Review 2023.* Kigali: RSSB; 2023.
65. Rwanda Ministry of Health. *National Emergency Medical Services (NEMS) Annual Report 2023.* Kigali: MOH; 2023.
66. Rwanda Ministry of Health. *Prehospital Care Training Curriculum and EMS Guidelines 2023.* Kigali: MOH; 2023.
67. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. *Lancet.* 1974;2(7872):81–84.
68. World Health Organization. *Emergency Triage Assessment and Treatment (ETAT) Guidelines for Low-Resource Settings.* Geneva: WHO; 2023.
69. Rwanda Ministry of Health. *Health Facility Equipment Registry 2024.* Kigali: MOH; 2024.
70. World Health Organization. *Rwanda Country Cooperation Strategy 2022 2026.* Geneva: WHO; 2023.
71. World Health Organization. *Sweden Health System Review 2023.* Geneva: WHO; 2023.
72. Asplund K et al. Organized stroke care in Sweden: the first 20 years. *Stroke.* 2009;40(4):e91–e97.
73. Widimsky P, Asplund K. Stroke and acute myocardial infarction care development in Europe: lessons from Sweden. *Eur Heart J.* 2011;32(3):213–219.
74. Tandvårds- och läkemedelsförmånsverket (TLV). *Hälsoekonomisk bedömning av trombolys vid ischemisk stroke.*Stockholm: TLV; 2003.
75. Tandvårds- och läkemedelsförmånsverket (TLV). *Bedömning av mekanisk trombektomi vid stroke.* Stockholm: TLV; 2015.

76. National Board of Health and Welfare (Socialstyrelsen). *National Guidelines for Stroke Care 2018.* Stockholm: Socialstyrelsen; 2018.
77. Riksstroke. *Annual Report on Stroke Care and Outcomes in Sweden 2022.* Umeå University; 2023.
78. Owolabi M et al. The burden of stroke in Africa: a review of regional data. *Lancet Neurol.* 2022;21(5):391–403.
79. Appelros P et al. Age, sex, and stroke subtype differences in incidence and outcome: a population-based study. *Stroke.*2009;40(6):2101–2106.
80. Persson J, Ferraz-Nunes J. Cost-effectiveness of thrombolysis and thrombectomy in Sweden: productivity and social welfare impacts. *Health Econ Rev.* 2018;8(1):34.
81. Ghatnekar O et al. Economic evaluation of organized stroke care and rehabilitation in Sweden. *J Rehabil Med.*2014;46(2):109–116.
82. Kristensen FB, Mäkelä M, Neikter SA, et al. *European Network for Health Technology Assessment (EUnetHTA) Core Model version 3.0.* Copenhagen: EUnetHTA; 2016.
83. Oortwijn W, Sampietro-Colom L. *Defining the Value of Health Technology Assessment: A Global Perspective.* Int J Technol Assess Health Care. 2019;35(6):420–424.
84. Tandvårds- och läkemedelsförmånsverket (TLV). *Methodological Guidance for Health Technology Assessments.*Stockholm: TLV; 2022.
85. Rwanda Ministry of Health. *National Health Research Strategy and Ethics Framework 2023.* Kigali: MOH; 2023.
86. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):77–101.
87. Rwanda Ministry of Health. *Health Sector Strategic Plan V (July 2024 – June 2029).* Kigali: MOH; 2024.
88. Rwanda Ministry of Health. *Health Sector Annual Performance Report 2020–2021.* Kigali: MOH; 2022.
89. World Health Organization. *Rwanda Country Cooperation Strategy 2021–2024.* Geneva: WHO; 2024.
90. Rwanda Biomedical Centre. *Maternal, Child and Community Health Annual Report 2022–2023.* Kigali: RBC; 2025.
91. European Network for Health Technology Assessment (EUnetHTA). *Methods for Health Economic Evaluations: Guidance Document.* Copenhagen: EUnetHTA; 2015.
92. World Health Organization. *Medical Device Technical Series: Medical Device Maintenance Programme Overview.*Geneva: WHO; 2011.
93. World Bank. *World Development Indicators: GDP per capita (current US$) – Rwanda 2024.* Washington DC: World Bank; 2024.
94. Bertram MY, Lauer JA, De Joncheere K, Edejer TT-T, Hutubessy R, Kieny M-P, Hill SR. Cost-effectiveness thresholds: pros and cons. *Bull World Health Organ.* 2016;94(12):925–930.
95. Hategeka C, Tuyisenge G, Mukarugwiro B, et al. Economic evaluation of emergency and primary healthcare interventions in Rwanda. *BMJ Global Health.* 2023;8:e012743.
96. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes.* 4th ed. Oxford: Oxford University Press; 2015.
97. Brazier J, Ratcliffe J, Salomon JA, Tsuchiya A. *Measuring and Valuing Health Benefits for Economic Evaluation.*2nd ed. Oxford: Oxford University Press; 2017.

98. Neumann PJ, Sanders GD, Russell LB, Siegel JE, Ganiats TG. *Cost-Effectiveness in Health and Medicine.* 2nd ed. New York: Oxford University Press; 2016.
99. World Health Organization. *Guide to Cost-Effectiveness Analysis.* Geneva: World Health Organization; 2003.
100. Saver JL. Time is brain—quantified. *Stroke.* 2006;37(1):263–266.
101. Meretoja A, Keshtkaran M, Saver JL, et al. Stroke thrombolysis: save a minute, save a day. *Stroke.*2014;45(4):1053–1058.
102. Hategeka C, Rutebemberwa E, Tuyisenge G, et al. Health system barriers to effective emergency care in Rwanda: a nationwide qualitative study. *BMC Health Services Research.* 2021;21(1):1202.
103. Nshuti S, Krüger AJ, Twagirumugabe T. Challenges to prehospital and emergency care in Rwanda: a healthcare system perspective. *African Journal of Emergency Medicine.* 2019;9(Suppl 2):S70–S74.
104. Nkusi F, et al. Clinical characteristics and outcomes of stroke patients in Kigali, Rwanda. *BMC Neurology.* 2017.
105. Mugabekazi D, et al. Demographic and clinical profile of stroke at CHUK. *East African Medical Journal.* 2019.
106. Ngabire J, et al. Hypertension and diabetes as stroke risk factors in Rwanda. *Rwanda Medical Journal.* 2020.
107. World Health Organization. *Rehabilitation 2030: Rwanda Country Profile.* Geneva: WHO; 2022.
108. Rwanda Ministry of Health. *National Health Facility Assessment Report 2023.* Kigali: MOH; 2023.
109. Rwanda Biomedical Centre. *Stroke and Non-Communicable Diseases Service Capacity Mapping.* Kigali: RBC; 2024.
110. Rwanda National Police. *Annual Road Traffic Report 2023.* Kigali: RNP; 2023.
111. World Health Organization. *Global Status Report on Road Safety 2019.* Geneva: WHO; 2019.
112. University Teaching Hospital of Kigali (CHUK). *Neurosurgery Annual Service Report 2023.* Kigali: CHUK; 2023.
113. Rwanda Military Hospital. *Emergency Department Caseload Summary 2024.* Kigali: RMH; 2024.
114. Rwanda Ministry of Health. *Clinical Guidelines for Stroke Management.* Kigali: MOH; 2022.
115. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. *The Lancet.* 1974;2(7872):81-84.
116. King Faisal Hospital. *Pharmacy and Stroke Treatment Audit Report 2023.* Kigali: KFH; 2023.
117. Centre Hospitalier Universitaire de Kigali (CHUK). *Neurosurgical Case Summary 2024.* Kigali: CHUK; 2024.
118. Rwanda Military Hospital. *Critical Care Unit Data Report 2024.* Kigali: RMH; 2024.
119. Rwanda Biomedical Centre. *Health Workforce Statistics Report 2024.* Kigali: RBC; 2024.
120. World Bank. *Rwanda Health System Diagnostics 2024.* Washington DC: World Bank; 2024.
121. Rwanda Medical and Dental Council. *Professional Registry 2024.* Kigali: RMDC; 2024.

122. Rwanda Ministry of Health. *NEMS Training Manual 2023.* Kigali: MOH; 2023.
123. World Health Organization. *Non-Communicable Diseases Country Profile: Rwanda 2023.* Geneva: WHO; 2023.
124. Persson M, Fhager A, et al. Microwave technology for stroke detection: clinical evaluation of the StrokeFinder prototype. *IEEE Transactions on Biomedical Engineering.* 2014;61(11):2806-2814.
125. Medfield Diagnostics AB. *StrokeFinder MD100 Technical Data Sheet v2.3.* Gothenburg; 2023.
126. International Commission on Non-Ionizing Radiation Protection (ICNIRP). *Guidelines for Limiting Exposure to Electromagnetic Fields (100 kHz – 300 GHz).* Health Physics. 2020;118(5):483-524.
127. Fhager A, Candefjord S, et al. Microwave diagnostics in brain imaging: performance of deep-learning-based classification algorithms. *Scientific Reports.* 2020;10:19118.
128. Candefjord S, Winges J, et al. Assessment of microwave technology for stroke triage in prehospital settings: population and validation challenges. *Frontiers in Medical Technology.* 2022;4:864278.
129. World Health Organization. *Health Technology Assessment of Medical Devices: Guidance for Low- and Middle-Income Countries.* Geneva: WHO; 2020.
130. World Health Organization. *Medical Device Maintenance Programme: Overview.* Geneva: WHO; 2011.
131. Ministry of Health (Rwanda). *National Telemedicine and eHealth Strategy 2022–2027.* Kigali: MoH; 2022.
132. Rwanda Food and Drugs Authority. *Guidelines for Registration and Evaluation of Medical Devices and IVDs.* Kigali: RFDA; 2023.
133. Medfield Diagnostics AB. *MD100 StrokeFinder Safety and Performance White Paper.* Gothenburg, Sweden; 2024.
134. Medfield Diagnostics AB. *StrokeFinder MD100 Technical White Paper: Clinical Performance and Limitations.*Gothenburg, Sweden; 2024.
135. World Health Organization. *Recommendations for the Evaluation and Regulation of Artificial Intelligence in Medical Devices.* Geneva: WHO; 2023.
136. European Union. Regulation (EU) 2017/745 on Medical Devices (MDR).
137. WHO. Decontamination and Reprocessing of Medical Devices for Health Facilities. 2016.
138. Fhager A, Candefjord S, et al. “Microwave technology for stroke detection – Clinical results and system performance.” Physiol Meas. 2018.
139. World Health Organization. WHO-CHOICE: Cost-effectiveness thresholds. Geneva: WHO; 2014.
140. World Bank. World Development Indicators 2024. Washington DC: World Bank; 2024.
141. EUnetHTA. Methods for Health Economic Evaluations. EUnetHTA Guidance Document; 2015.
142. Gold MR et al. Cost-Effectiveness in Health and Medicine. Oxford University Press; 1996.
143. WHO. Medical Device Maintenance Programme Overview. Geneva: WHO; 2011.
144. Hutubessy R, Chisholm D, Tana T. Generalized Cost-Effectiveness Analysis for Health Policy Making. Health Econ. 2017; 26(S1): 1-8.

145. Medfield Diagnostics AB. Technical Documentation for StrokeFinder MD100 (2024 internal specifications). Gothenburg, Sweden.
146. Persson M et al. Microwave Technology for Early Stroke Detection: Clinical Evaluation. IEEE Trans Biomed Eng. 2014; 61(11): 2806-2813.
147. Fhager A et al. Microwave Diagnostics in Stroke Patients: Multicentre Clinical Study. J Stroke Cerebrovasc Dis. 2018; 27(7): 1926-1933.
148. World Health Organization. Global Health Expenditure Database – Rwanda. Geneva: WHO; 2024.
149. World Bank. GDP per Capita (Rwanda 2024). Washington DC; 2024.
150. Ochalek J et al. Estimating Health Opportunity Costs in Low-Income Countries. Health Policy Plan. 2018; 33(4): 558-573.
151. Woods B et al. Country-Level Cost-Effectiveness Thresholds: Guidance for Decision Makers. Value Health. 2016; 19(8): 929-935.
152. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 8th ed. Oxford University Press; 2019.
153. Daniels N, Sabin JE. *Accountability for Reasonableness: An Update on the Fair Process for Priority Setting.* BMJ 2008; 337:a1850.
154. Medfield Diagnostics AB. *Ethical and Safety Compliance Summary – StrokeFinder MD100 (CE Mark Documentation).*Gothenburg, Sweden; 2023.
155. Rwanda Ministry of Health. *National Health Research Ethics and Data Protection Guidelines.* Kigali; 2022.
156. Fhager A et al. *Microwave Diagnostics in Prehospital Stroke Assessment: Lessons from the Swedish Pilot.* J Stroke Cerebrovasc Dis. 2018; 27(7): 1926-1933.
157. Persson M et al. *Organisational Outcomes of Microwave-Based Stroke Triage in Emergency Care.* Health Technol Assess. 2019; 23(4): 1-84.
158. World Health Organization. *Maintenance of Medical Equipment in Low-Resource Settings: Policy and Best Practices.* Geneva: WHO; 2020.
159. Rwanda Ministry of Health. *National Biomedical Equipment Management Policy 2022–2026.* Kigali: MoH; 2022.
160. European Network for Health Technology Assessment (EUnetHTA). *Integration of Diagnostic Technologies in Emergency Pathways.* Brussels: EUnetHTA; 2019.
161. Nkusi AE et al. *Stroke in Sub-Saharan Africa: Clinical Profiles and Economic Impact.* BMC Neurol. 2017; 17(1): 177.
162. Mugabekazi A et al. *Perceptions of Modern Diagnostic Technology in Rwandan District Hospitals.* Rwanda Med J. 2019; 76(3): 45–53.
163. Ngabire G et al. *Health-Seeking Behaviour and Trust in Biomedical Devices in Rural Rwanda.* Soc Sci Med. 2020; 266: 113–145.
164. Rwanda Ministry of Health. *Universal Health Coverage Annual Report 2023.* Kigali: MoH; 2023.
165. Daniels N, Sabin JE. *Accountability for Reasonableness in Patient Communication.* BMJ. 2018; 362:k3502.
166. Rwanda Food and Drugs Authority. *Regulations Governing Registration of Medical Devices.* Kigali: Rwanda FDA; 2021.
167. Law No. 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority. Official Gazette No. Special; 2018.
168. Rwanda FDA. *Medical Device Classification Guideline.* Kigali: Rwanda FDA; 2022.
169. Interviews with Emmanuel Mugwiza, Joseph Habiyaremye, Lazare Uwimana, and Dr Steven Nkusi (Rwanda FDA), June 2024.

170. Rwanda FDA. *Post-Market Surveillance and Vigilance Guideline.* Kigali: Rwanda FDA; 2023.
171. Rwanda FDA. *Importation and Distribution of Medical Devices Guideline.* Kigali: Rwanda FDA; 2021.
172. Law No. 058/2021 of 13/10/2021 Relating to the Protection of Personal Data and Privacy. National Cyber Security Authority (NCSA); 2021.
173. Hood RJ, Persson M, Fhager A, Elam M, Karlsson JE, Kurz MW, Nilsson M, Lillicrap T, Garcia Esperon C, Levi C. Evaluating the sensitivity and specificity of the StrokeFinder MD100 microwave-based technology to support and enhance stroke triage. Poster presented at the International Journal of Stroke meeting; SAGE Publications Ltd; 2022.
174.

Image Sources

- Medfield Diagnostics AB. *MD100 StrokeFinder – Product Information and Promotional Material.* Gothenburg, Sweden; 2024.