EVOLUTION CAPITAL

EMV | INITIATION REPORT | HEALTHCARE

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No Brainer: EMVision's Brain Scanners

Evolution Capital initiates coverage of EMVision Medical Devices Ltd (ASX: EMV) with a Speculative Buy and a risk-adjusted fair valuation of $2.92/share. Stroke care today hinges on access to imaging. Without it, treatment can't begin, and time without treatment equals irreversible brain damage. EMVision is developing portable electromagnetic scanners for bedside stroke diagnosis. Its in-hospital device (Emu™) and ambulance-based device (First Responder) aim to reduce time to diagnosis by enabling stroke classification at the point of care.

The company's strategy is focused on changing the core limitation of the existing stroke workflow: patients must reach a scanner before diagnosis can occur. In practice, this delays treatment, particularly in rural hospitals, EDs under pressure, and ICUs where transporting critically ill patients is complex. EMVision is building tools to bring stroke classification to the patient – whether they're in ED, ICU, or an ambulance.

Why Now?

Fewer than 25% of eligible patients in the US receive reperfusion treatment (thrombolysis or thrombectomy) because diagnosis occurs outside of the allowed treatment window. Time is brain - 1.9 million neurons die each minute stroke is left untreated, aging the brain 3.6 years in an hour. The consequences are immense: long-term disability, including motor impairment, speech problems, cognitive decline, and depression. The economic burden is equally stark. Rural hospitals often lack 24/7 imaging access. In larger centres, EDs rely on resource-intensive CT procedures to rule out stroke. In the ICU, diagnosis of perioperative or secondary strokes is frequently delayed due to sedation, ventilation, and the clinical risks of intrahospital transport. These shortcomings are systemic, and persistent. There's a clear case for technologies that allow stroke diagnosis without relying on centralised infrastructure.

Why EMVision?

EMVision's platform leverages the dielectric differences between brain tissue, blood, and fluid. Radio waves are transmitted through the skull, and proprietary algorithms interpret the resulting signals to determine whether the pattern matches "signatures" of haemorrhage, ischaemia, or neither. This technology has been trained and clinically validated to deliver actionable diagnostic classifications in minutes, repeatedly demonstrating sensitivity >90% and specificity >80%. Unlike CT or MRI, it is portable, non-ionising, and built for frontline care.

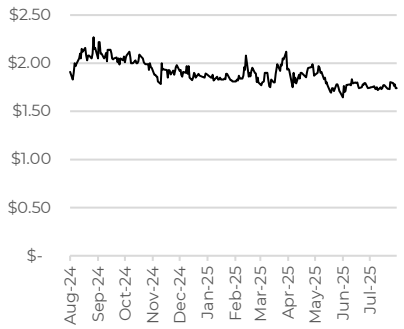
What's the Upside?

Our valuation reflects only US and Australian commercialisation of emu™ – with a primary market of ~3,500 hospitals (translating to over 10,000 units) – and First Responder. Yet the true potential is far larger. Major medtech players have a long precedent of paying premiums for early commercial, category-defining technologies – and we expect M&A interest to grow following initial market validation. In parallel, EMVision is exploring follow-on opportunities in traumatic brain injury (TBI) and other neurocritical indications. Structurally, macro forces are tailwinds: aging populations, decentralised care models, rural care investment, and a reimbursement landscape that increasingly rewards early diagnosis and cost-saving innovation all stack the odds in EMVision's favour.

Recommendation	**Spec Buy**
Share Price	**$1.725**
Fair Valuation	**$2.92**
TSR	**69%**

Company Profile	
Market Cap	~A$148M
Enterprise Value	~A$138M
SOI (diluted)	~89M
Free Float	82%
ADV (3-month)	~A$62k
52-Week Range	$1.63 - $2.35

Price Performance



Company Overview

EMVision Medical Devices is an Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, noninvasive, affordable and safe neurodiagnostic devices. Their vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

Key Expected Catalysts	
Pivotal validation study results	Q4 CY25 – Q1 CY26
First Responder Program Updates	Q4 CY25
Initial FDA de Novo Submission (emu™)	Late FY26
Commercialisation of emu™	Q1 FY27

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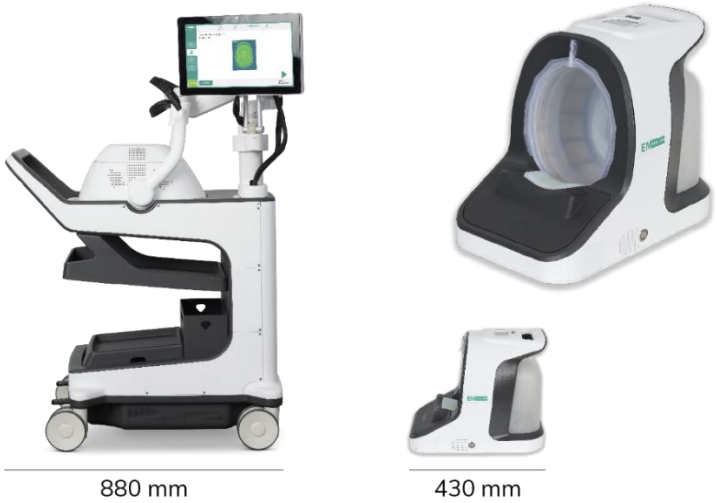
Investment Thesis

EMVision is a high-conviction opportunity in medtech, positioned to address a fundamental limitation in modern stroke care: diagnostic delay. The company's novel brain imaging technology is purpose-built to operate at the point of care – disrupting the current model of "patient-to-scanner" and enabling faster, timelier stroke triage across emergency, critical care, and pre-hospital settings.

Stroke is a time-critical emergency where every minute without treatment leads to irreversible brain tissue damage. Yet today's diagnostic workflows routinely see delays that push patients outside the therapeutic window, leading to irreversible disability or death. This is not a fringe issue. In the US, fewer than 23% of eligible patients receive thrombolysis, and only ~26% undergo thrombectomy – two potentially life-saving interventions. In many rural or community hospitals, the delay begins even earlier, with basic neuroimaging capabilities often absent or inaccessible. The result is catastrophic human and economic cost: over US$890 billion annually and growing. EMVision's portable, point-of-care electromagnetic brain scanners are engineered and strategically positioned to shatter this outdated paradigm, creating a new reality where diagnosis happens at the patient's side, when and where it matters most.

Figure 1: Images of EMVision's product pipeline with emu™ (left) and First Responder (right). Source: EMVision Company presentation.



Our investment thesis is built on the following pillars:

1. Solving Multiple Critical, Unmet Needs with Paradigm-Shifting Solutions

The current stroke pathway is a race the brain usually loses. Geographic barriers, in-hospital queues, and the logistical challenges of imaging critically ill patients mean that only a fraction of stroke sufferers receive timely, effective treatment. Neurological monitoring in the ICU is a similar "black box," where secondary brain injuries often develop undetected until it is too late. EMVision's two-product platform directly addresses these failures:

- **Emu™ (In-Hospital):** This cart-based scanner transforms the Emergency Department workflow from reactive to proactive, providing a rapid "bleed or no bleed" assessment at the bedside that allows clinicians to prepare for time-sensitive interventions long before a confirmatory CT is complete. In the ICU, it enables, for the first time, routine, radiation-free neurological monitoring of high-risk patients, offering a tool to identify the catastrophic and costly secondary strokes earlier.

- **First Responder (Pre-Hospital):** This miniaturized, backpack-portable device is designed to democratize the clinically proven but economically unscalable Mobile Stroke Unit (MSU) model. By equipping standard ambulances with a diagnostic scanner, it empowers paramedics to better perform triage in the field.

Active decisions are then made by a clinician via telehealth, ensuring patients are transported directly to the most appropriate hospital (e.g., a thrombectomy-capable or neurosurgical center), saving brain-saving time and optimizing regional stroke networks. First Responder could open the door to in-field treatment opportunities, including blood pressure management and anti-coagulation reversal for intracerebral haemorrhage.

2. Significantly De-Risked Technology and a Validated Market Strategy

EMVision is not a speculative science project; it is an execution story. The company's core technology is rooted in established science from Prof. Stuart Crozier and the University of Queensland and has been substantially de-risked through the successful 307-participant EMView clinical study. The trial demonstrated high sensitivity (92%) and specificity (85%) for haemorrhage classification, providing the confidence and foundational data to proceed with a pivotal validation trial to support an FDA De Novo submission. Furthermore, the competitive landscape provides validation, not a threat. The existence of multi-million-dollar MSUs and emerging portable MRI/CT technologies proves the immense clinical demand for point-of-care neuroimaging. EMVision is positioned not to compete on their terms, but to win by offering the first solution that is truly scalable, economically viable, and purpose-built for the core use cases of rapid triage, patient management and frequent monitoring.

3. Powerful Macro and Economic Tailwinds

The company's strategy is perfectly aligned with the most powerful forces reshaping modern healthcare:

- **Favourable Reimbursement Dynamics:** The global shift to value-based care creates a powerful incentive for technologies that prevent long-term disability. Payers like CMS in the US are actively creating pathways (e.g., NTAP, TPT, and the ET3 precedent) that reward technologies that improve outcomes and reduce downstream costs. EMVision's devices, by enabling earlier intervention, are a direct solution to the multi-hundred-thousand-dollar lifetime cost of a disabled stroke survivor, presenting a compelling health-economic argument for adoption and reimbursement.

- **Structural and Societal Tailwinds:** Aging populations across the developed world are increasing the incidence of stroke, creating greater urgency for effective diagnostic solutions. Simultaneously, a strong policy focus on closing the urban-rural healthcare gap and the broader shift towards decentralized care models (e.g., "hospital-at-home") create a fertile ground for portable, point-of-care technologies that can deliver diagnostics outside of traditional hospital walls.

4. A conservative Valuation with Significant, Uncaptured Upside

Our risked DCF-derived fair valuation of $2.92/share incorporates only the commercialisation of Emu™ and First Responder in the United States and Australia, representing a fraction of the global addressable market. The valuation does not assign any value to three major, high-probability growth vectors: geographic expansion, indication expansion, nor M&A potential. We expect EMVision to pursue a secondary, multi-billion-dollar indication in Traumatic Brain Injury (TBI). Moreover, we ultimately see EMVision in the hands of a major medtech player seeking to own a category-defining technology once commercial traction is established.

In a healthcare landscape under pressure to do more with less, EMVision's technology and strategy offers a rare combination of a disruptive, de-risked technology platform, a massive addressable market with a clear and urgent unmet need, and powerful tailwinds. The company is on a clear path to commercialisation, and we believe that as it executes on its clinical and regulatory milestones, the market will begin to recognise the significant, un-captured value in this future leader of point-of-care neurodiagnostics.

Delayed Diagnosis, Irreversible Damage

Stroke is a race the brain usually loses. In the United States, more than 795 000 strokes strike each year, and every minute of untreated ischaemia destroys about 1.9 million neurons, aging the brain 3.6 years in an hour. Yet the two proven reperfusion options are locked behind unforgiving clocks: intravenous thrombolysis must be conducted within 4.5 hours and mechanical thrombectomy within 24 hours. The earlier these treatments are applied, the more effective they are Despite this, only 23% of eligible patients ever receive thrombolysis and 26% reach the angio-suite for thrombectomy. Critically, these therapies are effective only for specific stroke sub-types – thrombolysis is contraindicated in haemorrhage, thrombectomy is reserved for large-vessel occlusion, and anticoagulation reversal is reserved only for haemorrhage – so rapid and accurate classification is the gatekeeper to treatment as well as the stopwatch: every minute spent deciding "ischaemic or haemorrhagic", "LVO or non-LVO" drains the clock and can be the difference between timely effective treatment and a lifetime of disability.

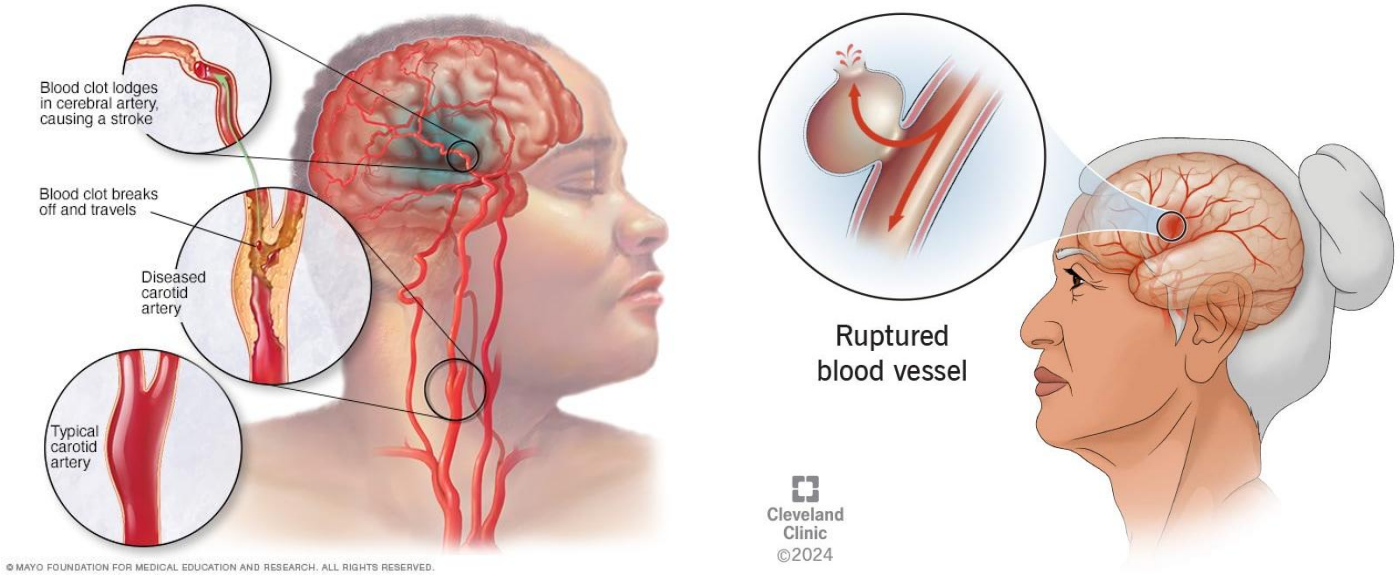
The key culprit is access – the intertwined barriers of geography, logistics, and economics that define the current standard of care. Just 26% of rural Americans live within 30 minutes of a certified stroke centre versus 70% in cities. A 2021 study of real-world data in *Stroke* – "Access to Mechanical Thrombectomy for Ischemic Stroke in the United States" – found 27.7% of rural patients were taken to a thrombectomy-capable hub vs. 69.5% of urban patients, highlighting the rural-urban access disparity.

These intertwined barriers – diagnostic delay leading to missed treatment window leading to unchecked neuronal death – translate into long-term cognitive decline, motor disability, speech impairment and mental health impacts for survivors, while payors shoulder decades of downstream cost. EMVision's Emu™ portable electromagnetic scanner is built to sever this chain, delivering point-of-care brain imaging when and where it matters.

The Cascade of Irreversible Damage

The interruption of blood flow during stroke initiates a cascade of detrimental neurological events, ultimately leading to severe, long-term complications that significantly impact patient quality of life. When ischaemic stroke blocks an artery, two zones immediately form. The inner "core" runs out of oxygen and glucose and its brain cells die within minutes. Encircling it is the ischaemic penumbra – tissue that is stunned but still recoverable if blood flow is restored quickly. Here, a short-lived energy crisis triggers a chain reaction: ion pumps fail, toxic chemicals such as glutamate accumulate, free-radical damage mounts and inflammation breaches the blood–brain barrier. Left unchecked, penumbral cells join the core. The statistic previously mentioned – 1.9 million neurons die per minute ischaemic stroke is untreated – refers to this process.

Figure 2: Image A (left) depicting an ischemic stroke, where a blood clot breaks away from a diseased carotid artery, travels to the brain, and blocks a cerebral artery. Source: Mayo Foundation for Medical Education and Research. Image B (right) depicts a hemorrhagic stroke, which occurs when a weakened blood vessel in the brain ruptures and bleeds into the surrounding brain tissue. Source: Cleveland Clinic.



Clinically, the consequences of neuronal damage are profound and multifaceted. Functional deficits, including motor impairments (paralysis or weakness), speech and language disturbances (aphasia, dysarthria), sensory impairments, cognitive dysfunction affecting memory, reasoning, and attention, and emotional and behavioural changes such as depression and impulsivity, commonly arise. These neurological disabilities substantially diminish the patient's quality of life and independence. Furthermore, dead neurons do not regenerate; therefore, recovery depends primarily on neuroplasticity, involving surviving neurons forming new connections and extensive rehabilitation efforts. Additionally, neuronal loss increases the risk of complications such as seizures and progressive neurodegeneration, contributing to a heightened susceptibility to dementia.

- **Neuronal Loss in Stroke:** during an untreated ischemic stroke, approximately 1.9 million neurons, 14 billion synapses, and 12 kilometres of myelinated fibres are destroyed each minute. This equates to the brain aging 3.6 years every hour without treatment.

- **Prevalence of Cognitive Impairment:** Within the first year after a stroke, approximately 40% of survivors experience post-stroke cognitive impairment (PSCI). This prevalence can vary between 17% to 55%, depending on factors such as assessment methods and population characteristics.

- **Long-Term Cognitive Decline**: A study analysing data from 10,814 participants found that stroke survivors experienced an acute decline in global cognition, with a standardized decrease of 0.251 standard deviations immediately following the stroke. Furthermore, the rate of cognitive decline accelerated post-stroke compared to pre-stroke trajectories.

- **Risk of Dementia**: Up to 40% of stroke survivors develop post-stroke dementia within a year, and this risk increases over time. The development of dementia post-stroke significantly impacts daily functioning and increases the burden on caregivers and healthcare systems.

- **Speech & Language**: Approximately 30% to 38% of stroke survivors develop aphasia, a language disorder that impairs speaking, understanding, reading, and writing. Dysarthria, a motor speech disorder characterized by slurred or slow

speech due to muscle weakness affects about 24% of stroke patients. In a large-scale study involving over 88,000 inpatient stroke survivors, 28% exhibited both aphasia and dysarthria, indicating a substantial overlap and compounding effect on communication abilities.

- **Prevalence of Motor Impairments**: Approximately 80% of stroke survivors experience upper limb motor impairments acutely, with over 40% continuing to have chronic deficits.

- **Upper Extremity Paresis**: More than two-thirds of stroke survivors experience upper extremity paresis, affecting arms and hands, which significantly hampers daily activities and quality of life.

- **Depression & Anxiety**: Approximately 30% of stroke survivors experience post-stroke depression (PSD) at any point following a stroke. A UK study indicates that nearly 60% of stroke survivors may experience depression within 18 years post-stroke, a rate significantly higher than the 22% observed in the general population over the same period. Post-stroke anxiety (PSA) affects approximately 20% to 25% of stroke survivors.

The Patchwork of US Stroke Care

The US has an extensive network of certified stroke centres which provide timely stroke care, however, significant gaps persist. Stroke centers are classified into four tears: Comprehensive Stroke Centers (CSCs) handle complex cases and advanced procedures like mechanical thrombectomy; Thrombectomy-Capable Stroke Centers (TSCs) offer 24/7 mechanical clot removal; Primary Stroke Centers (PSCs) provide initial acute stroke treatment including thrombolysis (tPA); and Acute Stroke-Ready Hospitals (ASRHs) deliver essential care to stabilize patients before transfer. Despite approximately 2,446 stroke-certified hospitals in the US as of 2018, these facilities represent just 44% of the 5,533 emergency departments, highlighting substantial room for improvement in stroke care access nationally.

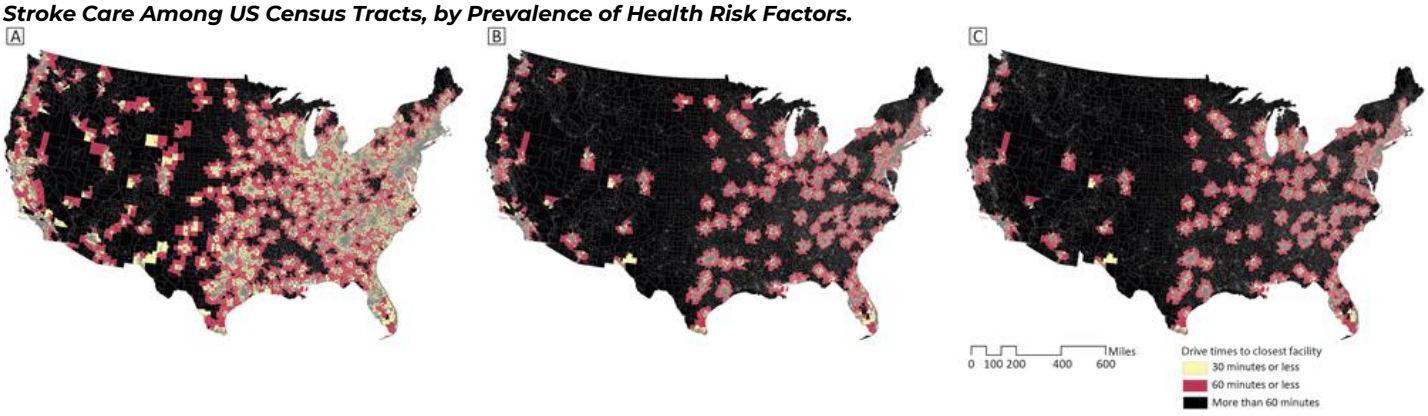
Moreover, geographic disparities remain significant, with rural and remote communities particularly underserved. While approximately 91% of Americans live within one hour of some level of stroke center and 87% within an hour of at least a primary (or higher) stroke center, only about 64% have 60-minute access to the highest-level centers (TSCs or CSCs).

Figure 3: US Certified Stroke Center Classification and Criteria. Source: AHA/ASA Journals - Heart Disease and Stroke Statistics—2021 Update.

Stroke Center Type	Criteria	Hospitals
Acute Stroke-Ready hospitals (ASRHs)	• 100% stroke admission data collection • Data collectors on staff • Vascular neurologist in person or via telemedicine • Established transfer plan • Emergency diagnosis and treatment of ischaemic and haemorrhagic stroke (stopping at IV thrombolysis and haemorrhage stabilisation) • Use of advanced neuroimaging (CT and CTA) • Clinical practice guidelines and order sets available	678
Primary Stroke Centers (PSCs)	• Meets all previous criteria • Dedicated stroke coordinator • Nurses with advanced neurovascular training • Stroke medical director with control of bed allocation • Dedicated stroke unit • Specific nurse to patient staffing ratios	1,459
Thrombectomy-Capable Centers (TSCs)	• Meets all previous criteria • Available for stroke patient transfers • Designated critical care beds for complex stroke patients • Mechanical thrombectomy services • Stroke medical director conducting and producing scholarly contributions • Nurses certified in acute neurovascular clinical practice	14
Comprehensive Stroke Centers (CSCs)	• Meets all previous criteria • Advanced practice providers with specialized training • Statistician on staff • Clinician pharmacists available for ED, inpatient, and transitions • High-functioning neurological ICU • High-volume thrombectomy and aneurysmal SAH program • Microsurgical clipping of aneurysms • Receives transfers of neurosurgical emergencies and complex strokes • Participates in patient-centred research with 3 scholarly publications p.a.	297

Putting the above into perspective, fewer than 300 CSC hubs serve ~340 million people in the US. Furthermore, only 311 stroke centers can perform mechanical thrombectomy – the preferred treatment of Large-vessel occlusion (LVO) strokes. Of the approximately 795,000 strokes in the US per annum, 87% are ischaemic, and estimates put the percentage of these being LVOs at between 24% and 46%. Using the lower bound, this translates to ~166,000 strokes per annum serviced by 311 suitable stroke centers, or roughly 1 centre for every ~534 LVO strokes.

Figure 4: Maps of the contiguous US showing census tracts within 30, 60, or more than 60 minutes' drive to (A) any stroke care (ASRH, PSC, TSC, CSC), (B) advanced stroke care (TSC/CSC), and (C) comprehensive stroke care (CSC); highlighting large geographic disparities in rapid access to certified stroke centers. Source: CDC study - *Disparities in Timely Access to Certified Stroke Care Among US Census Tracts, by Prevalence of Health Risk Factors.*



The Price Tag on Stroke-Ready Imaging

Rapid neuroimaging using CT or MRI is the cornerstone of ED stroke diagnosis. A vast majority of US hospitals do have CT scanners, however the 24/7 availability of CT services is not uniform, and the availability of MRI is more limited – at least one-third of US EDs do not have on-site MRI capabilities. Many rural hospitals forgo owning MRI due to cost and low utilisation, relying instead on weekly mobile MRI services or referring patients to distant centres.

A workhorse 64-slice CT scanner now lists at ~US$500-700k for a cardiology-grade unit. A new 1.5T to 3T MRI will cost between US$1M and US$3M, representing a significant capital outlay for hospital administrators. But these up-front cheques only tell half the story. Looking through a 10-year lens, a mid-range CT typically tops US$1.3M all-in once full-service contracts (parts and labour, 24/7; US$50-80k p.a.) and power draw (24/7 operation; US$10-20k p.a.) are factored in. The cost of a 1.5T MRI breaches US$2.5M once full-service contracts, helium, and power are accounted for. Critically, due to their energy requirements, both CT and MRI require dedicated specialist technicians to operate.

These high prices disincentivise acquisition and therefore, many community and rural hospitals run a single CT scanner for the entire campus. This results in stretched 'door-to-CT' well beyond the desired 20-minute benchmark. Real-world audits show only 20% of patients make it to CT within 20 minutes, and 70% within 45 minutes in busy EDs. As we know, a 45-minute delay in door-to-CT would result in the death 85.5 million neurons (1.9 million neurons die each minute), and therefore greater likelihood of follow-on complications.

But it isn't just the door-to-CT time that is an issue. A retrospective study of over 600 thousand strokes in the US between 2008 and 2021 found the median time from symptoms onset to ED arrival was 176 minutes, with only 38% of patients arriving within 90 minutes.

While a non-contrast CT (NCCT) can quickly answer the critical "haemorrhage or not" question, the diagnostic process often does not end there. If no bleed is detected and a severe stroke is suspected, further imaging is often required to assess the patient for a large vessel occlusion (LVO) that may be treatable with endovascular thrombectomy (EVT).

This next step requires more advanced and time-consuming scans, such as CT Angiography (CTA) or CT Perfusion (CTP). While essential for treatment planning, these advanced scans add significant delays to the diagnostic timeline. A CTA adds a median of 7.4 minutes, and a CTP adds a median of 21.9 minutes. This multi-scan process, involving contrast handling, larger datasets, and post-processing, extends the overall "scan-to-interpretation" clock well beyond the initial two-minute benchmark of a simple NCCT, further eroding the precious treatment window.

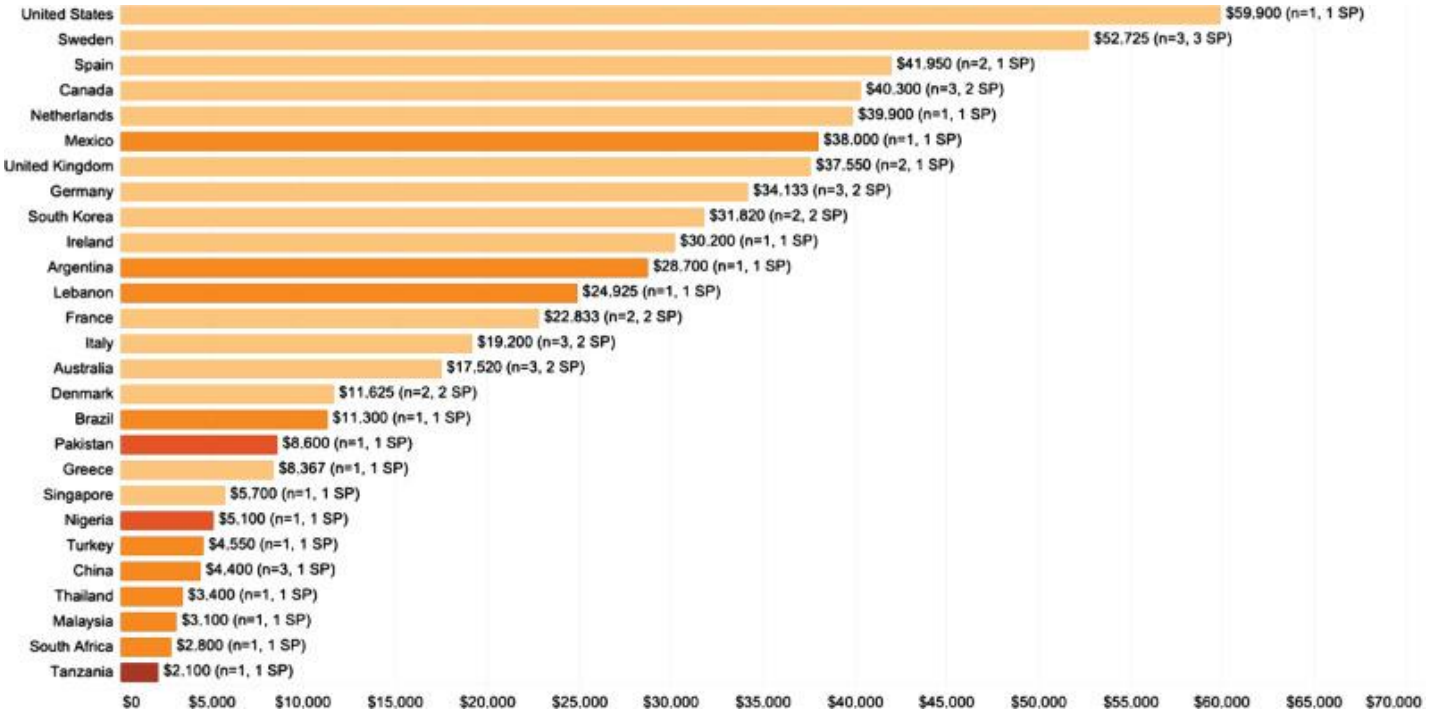
Looking again at CT prevalence, an estimated 10-15% of rural EDs do not have an on-site CT (around 180-270 hospitals). Nearly all of these hospitals also lack MRI, representing a critical access gap in stroke diagnosis. A large 2008 to 2017 Medicare analysis found the per capita incidence of acute ischaemic stroke was 12-15% higher in rural beneficiaries. This presents an added layer to the neuroimaging access problem: greater stroke incidence but lesser neuroimaging access in rural areas.

The Result: A Colossal Burden and the Imperative for Innovation

The clinical consequences of delayed stroke diagnosis translate directly into a staggering economic burden for patients, healthcare systems, and society at large. The global economic cost of stroke is estimated to be in excess of US$890 billion annually and is projected to surpass US$1 trillion by 2030. In the US alone, stroke-related costs amounted to nearly US$56.2 billion between 2019 and 2020.

These astronomical figures are driven by immense per-patient costs. The highest average annual per-patient cost is reported in the US at US$59,900 (see figure 5), while the highest lifetime cost is in Australia, at an estimated US$232,100. Crucially, these direct medical costs represent only the tip of the iceberg; indirect costs, such as long-term rehabilitation, the economic value of informal care provided by family members, and lost wages, can account for up to two-thirds of the total economic fallout. This colossal financial strain is the direct result of the diagnostic bottleneck. The logistical and financial barriers of the current "patient-to-scanner" model lead to treatment delays, which in turn lead to poorer patient outcomes and greater long-term disability, creating a vicious cycle of escalating downstream costs.

Figure 5: Comparative bar chart of average per-patient annual direct stroke costs by country. Source: *The economic burden of stroke: a systematic review of cost of illness studies* – Journal of Medicine and Life (2021).



This environment creates a powerful health-economic imperative for a paradigm shift in diagnostic technology. Emu™ is purpose-built to sever this destructive chain of events by delivering rapid, point-of-care neuroimaging precisely when and where it is needed most. By collapsing the time from patient presentation to diagnostic insight, the technology is designed to directly address the crisis, the dilemma, and the bottleneck that define modern stroke care. The solution is therefore not just clinical, but economical.

The Front Door: ED Use Case

The ED serves as the as the critical entry point for the vast majority of stroke patients and represents the first, and arguably most crucial, battleground in the race against irreversible brain damage. The current standard of care in the ED, while highly protocolized, is fundamentally constrained by a centralized, "patient-to-scanner" diagnostic model. This model forces a linear, time-consuming, and resource-intensive workflow where critically ill patients must be transported to a fixed imaging suite, creating a bottleneck that dictates the pace of all subsequent treatment decisions.

By inverting the model and bringing the scanner directly to the patient's bedside, the Emu™ introduces the potential for a new, parallel diagnostic stream at the point of care.

The Standard of Care: A Linear Pathway

The Diagnostic Funnel to CT

The acute stroke pathway in a modern ED is a meticulously choreographed sequence of events designed for speed, yet it remains tethered to the logistical limitations of conventional imaging technology.

The process initiates the moment a patient with suspected stroke symptoms arrives at the ED. Triage nurses, using validated screening tools, immediately assess the patient. International guidelines recommend assigning these patients to a high-acuity triage category, such as Canadian Triage Acuity Scale (CTAS) Level 1 or 2, or Australasian Triage Scale (ATS) 1 or 2, mandating physician assessment within minutes of arrival.

This high-priority classification triggers a "Code Stroke" or "Stroke Alert," an all-hands-on-deck call that simultaneously mobilizes a multidisciplinary team. This team typically includes the ED physician and nurses, a neurologist or stroke specialist (often via telemedicine), and notifies the radiology department to prepare for an emergent scan.

The initial bedside evaluation is swift and systematic, focusing on several key objectives:

- **Stabilization:** Assessment of Airway, Breathing, and Circulation (ABCs).
- **Confirmation of Suspicion:** A rapid neurological exam using a validated scale like FAST (Face, Arm, Speech, Time) or the more comprehensive BE-FAST (which adds Balance and Eyes) is performed to confirm the likelihood of stroke.
- **Severity Assessments:** A more detailed quantification of neurological deficit is conducted using the National Institutes of Health Stroke Scale (NIHSS). This score is a critical determinant of stroke severity and influences treatment decisions.
- **History Gathering:** Ascertaining the "time last known well" (LKW) is paramount, as it defines the eligibility window for time-sensitive therapies. Information on current medications, particularly anticoagulants, is also critical.
- **Baseline Labs:** Point-of-care (POC) glucose testing is performed, as hypoglycemia can mimic stroke symptoms. Blood is drawn for a complete blood count (CBC), coagulation studies (INR, aPTT), and basic metabolic panels.

Crucially, every one of these initial activities funnels toward a single, overriding diagnostic objective: obtaining a non-contrast computed tomography (NCCT) scan of the head. The urgency of this step cannot be overstated, as it is required to answer the most immediate and critical question in stroke care: is there blood in the brain? The presence of an intracranial haemorrhage is an absolute contraindication for intravenous thrombolysis (alteplase or tPA), the primary medical therapy for acute ischemic stroke. Administering tPA to a patient with a bleed would be catastrophic. Therefore, the NCCT scan functions as the gatekeeper to all reperfusion therapies.

Stroke care guidelines reflect this urgency, setting aggressive targets for "door-to-CT" time, typically aiming for completion within 20 to 25 minutes of the patient's arrival in the ED. However, the logistical reality of a busy hospital environment often prevents these targets from being met. Real-world audits have shown that in many EDs, only 20% of patients receive a CT scan within the 20-minute benchmark, with up to 70% waiting as long as 45 minutes. This 25-minute delay from the ideal target can result in the irreversible loss of nearly 50 million neurons, potentially converting a recoverable deficit into a lifelong disability.

The Post-CT Decision Cascade

The results of the NCCT scan trigger a sharp divergence in the patient's care pathway. If haemorrhage is confirmed, the "Code Stroke" for reperfusion is terminated. The patient

is immediately managed for a haemorrhagic stroke, which involves urgent neurosurgical consultation, aggressive blood pressure control, and potential reversal of any anticoagulant medications.

If no haemorrhage is detected, the diagnosis is presumed to be an acute ischemic stroke, and the clock for treatment accelerates dramatically. The team assesses the patient's eligibility for intravenous tPA, which must be administered within a strict 4.5-hour window from LKW. Simultaneously, if the clinical presentation suggests a severe stroke (e.g., a high NIHSS score), the team evaluates the patient for a large vessel occlusion (LVO) that may be amenable to endovascular thrombectomy (EVT). This often requires further, more time-consuming imaging, such as CT Angiography (CTA) to visualize the blood vessels or CT Perfusion (CTP) to map the extent of salvageable brain tissue (the penumbra). While essential, these advanced scans add significant delays; a CTA adds a median of 7.4 minutes and a CTP adds a median of 21.9 minutes to the diagnostic timeline, further eroding the precious treatment window.

This entire standard-of-care workflow is built around a single, immovable piece of capital equipment – the CT scanner. It is a shared hospital resource, subject to queues, and requires the transport of a potentially unstable patient, creating a mandatory, time-consuming, and high-risk bottleneck. The "door-to-CT" interval is therefore the primary rate-limiting step in the acute stroke care cascade, and any technology that can deliver critical diagnostic information before or during this bottleneck has the potential to fundamentally alter the paradigm of care.

Figure 6: The Conventional ED Acute Stroke Workflow & Key Timelines.

Workflow Step	Guideline Target	Real-World Performance	Key Activities
Patient arrival to ED physician assessment	≤10 minutes	Variable	Triage, patient registration, rooming
Door-to-stroke team notification	≤15 minutes	Variable	Activation of "Code Stroke" system
Door-to-CT scan completion	≤20 minutes	20% within 20 mins; 70% within 45 mins	Patient transport, scanner availability, technician availability
Door-to-CT interpretation	≤45 minutes	Variable	Radiologist availability, image transfer (PACS)
Door-to-needle (tPA)	<60 minutes	Variable	All preceding steps contribute to delay, pushing patients out of 4.5-hour window

Introducing a Parallel Diagnostic Stream

Emu™ is not designed to replace the high-resolution anatomical detail of CT but to function as a rapid, point-of-care triage tool that fundamentally reshapes the initial diagnostic workflow. By providing critical information at the bedside, it transforms the process from a strictly linear sequence into a parallel one, allowing for proactive decision-making long before a CT result is available.

Accelerating the Critical “Haemorrhage or Not” Determination

The primary and most impactful function of the Emu™ in the ED is to deliver a rapid, preliminary answer to the pivotal haemorrhage question. The clinical data from the EMView pilot study provides compelling evidence for this capability. The device's AI-powered "blood or not" algorithm demonstrated 92% sensitivity and 85% specificity when compared against the gold standard of CT/MRI.

The clinical implications of these figures are profound:

- Sensitivity is the true positive rate: the ability to correctly identify individuals with haemorrhage. This is paramount. Emu™’s 92% sensitivity provides clinicians with a strong, early warning signal to withhold tPA, prepare for aggressive blood pressure management, and initiate a neurosurgical consultation, potentially saving critical time and preventing a catastrophic treatment error.

- Specificity is the true negative rate: the ability to correctly identify individuals without haemorrhage. A negative result from emu™ (i.e. no haemorrhage present) can significantly increase the clinical team's confidence that the patient has an ischaemic stroke and is a potential candidate for tPA. This allows the team to proactively prepare the tPA infusion, and streamline all necessary checks, with the goal of dramatically reducing the door-to-needle time once the CT scan provides final confirmation.

Enhancing Diagnostic Confidence for Ischaemia

While the haemorrhage-detection capability is the primary value driver in the ED, emu™'s "clot or not" algorithm provides a valuable secondary data point. The EMView study showed this algorithm achieved 95% sensitivity and 80% specificity for identifying ischemic stroke. Although not intended to be as definitive as the haemorrhage detection, a positive "clot" signal from the emu™, when combined with a "no blood" signal and a corroborating clinical picture (e.g., a high NIHSS score), further strengthens the diagnosis of ischaemic stroke. This can help the team anticipate the need for advanced imaging like CTA and CTP to assess for LVO and expedite the decision-making process for potential mechanical thrombectomy.

The standard workflow is inherently reactive; the stroke team must wait for a definitive result from the CT scanner before formulating and executing a treatment plan. The introduction of the emu™ scan, performed in minutes at the bedside, provides a probabilistic but clinically actionable diagnosis much earlier in the process. This early data transforms the team's posture from reactive to proactive. They can begin to formulate parallel treatment plans – "Plan A: Ischemic/tPA pathway" versus "Plan B: Haemorrhagic/Neurosurgery pathway" – based on the emu™ result while the patient is being transported for the confirmatory CT. This fundamental shift from a single, delayed decision point to an earlier, proactive planning phase is the primary mechanism through which the emu™ compresses the overall decision-making timeline and generates significant efficiency gains.

Figure 7: EMVision emu™ Diagnostic Performance (EMView Pilot Study). Source: Company data.

Diagnostic Algorithm	Metric	Performance	Interpretation
Haemorrhage vs non-haemorrhage	Sensitivity	92%	High ability to correctly identify patients with a bleed. Crucial for safely excluding tPA.
	Specificity	85%	Strong ability to correctly identify patients without a bleed. Crucial for accelerating the tPA pathway.
Ischaemia vs non-ischaemia	Sensitivity	95%	Strong ability to correctly identify patients with an ischemic stroke.
	Specificity	80%	Good ability to correctly identify patients without an ischemic stroke.

Figure 8: emu™-Integrated ED Workflow: A Proposed Model for Time-to-Decision Compression. Source: Evolution Capital research.

Timeline	Conventional Linear Workflow	Emu™-Enabled Parallel Workflow	Time Saved Efficiency
0-10 min	Triage, vitals, IV access, labs drawn	Triage, vitals, IV access, labs drawn + Emu™ scan initiated at bedside	Diagnostic process begins 20-30 mins earlier
10-15 min	Patient transport to CT suite	Emu™ Scan complete; probable diagnosis available	Team can proactively prepare tPA and/or alert neuro
15-30 min	Patient on CT table, imaging performed	Patient transport to CT for confirmatory scan	Transport is no longer for initial diagnosis, but for confirmation and anatomical detail
30-45 min	CT interpretation, team decision	Confirmatory CT viewed, decision executed	Door-to-needle time compressed by eliminating the "wait and see" period

This ability to generate a rapid, probable diagnosis at the point of care manifests in two primary, critical use cases depending on the hospital environment. In a large, urban CSC, the primary value is workflow acceleration – compressing door-to-needle times and

preparing for advanced interventions like thrombectomy. In a rural or community hospital, the primary value is effective triage – enabling clinicians to make faster, more accurate decisions about which patients need to be transferred, where they need to go, and how urgently, thereby optimizing the entire regional stroke network.

Clinical and System-Level Impact

The value proposition of the Emu™ device extends beyond simple time savings within a single ED visit. It has the potential to drive profound clinical and system-level benefits, impacting patient outcomes and the efficiency of regional stroke networks.

Accelerating Time-Sensitive Interventions
The most direct clinical benefit of the Emu™ is its potential to reduce door-to-needle times for tPA and door-to-puncture times for EVT. The health-economic impact of such time savings is well-documented and substantial. Research has estimated that every 15-minute reduction in the delay to treatment provides a patient with an additional month of disability-free life. In the context of mechanical thrombectomy, the benefit is even more pronounced, where saving a single minute can grant a patient an additional week of disability-free life. By providing an early, high-confidence signal on stroke subtype, the Emu™™ allows the clinical team to "get ahead of the clock," preparing these powerful interventions while the final confirmatory diagnostic steps are still underway. This directly addresses the core crisis of delayed diagnosis and subsequent irreversible brain damage.

Optimizing Patient Transfer and System-Wide Triage
The impact of emu™ is magnified when viewed through the lens of regional stroke care systems, particularly in geographies like the United States with a tiered network of hospitals. ASRHs and PSCs, which constitute the majority of stroke-certified hospitals, can administer tPA ("drip") but lack the capability to perform EVT. They must therefore transfer ("ship") patients with LVO to a higher-level center, a process known as "drip-and-ship". The central challenge of this model is making the transfer decision quickly and accurately to avoid futile transfers or life-altering delays.

The placement of an emu™ in a rural ASRH or a community PSC – facilities that often lack 24/7 specialist neuro-radiology and may operate with a single, heavily utilized CT scanner – could be transformative.

- An early emu™ scan indicating a high probability of haemorrhage would allow the local team to immediately arrange transfer to a CSC with neurosurgical capabilities, bypassing wasted time and ensuring the patient gets to the right specialist faster.

- An early emu™ scan showing no blood but with a clinical picture highly suggestive of an LVO (e.g., high NIHSS score) could provide the justification needed for EMS to bypass the local PSC and transport the patient directly to a thrombectomy-capable centre. This strategy directly addresses the critical system-level risks of under-triage (delaying thrombectomy by first going to a non-capable hospital) and over-triage (delaying potentially beneficial tPA by bypassing a closer PSC for a more distant CSC).

The Critical Care Setting: Monitoring in ICU

While the Emergency Department represents a critical entry point for EMVision's technology, the company's disruptive potential extends to introducing rapid, point-of-care neurodiagnostics into one of the most challenging and high-stakes environments in modern medicine: the Intensive Care Unit (ICU). The current standard of care in this area is fraught with diagnostic delays, clinical risks, and logistical inefficiencies that lead to devastating patient outcomes and significant economic burdens.

The Unseen Neurological Decline in ICU Patients

The ICU is an environment of paradox. It is designed for maximum patient oversight, yet for neurological status, it often becomes a "black box" where insidious and catastrophic brain injury can develop undetected. Critically ill patients are uniquely susceptible to secondary brain injuries, including new strokes or the expansion of an existing haemorrhage. The ICU, which houses the most vulnerable patient populations, is paradoxically the most common location for in-hospital strokes to occur. This vulnerability is nowhere more apparent than in the population of patients recovering from major cardiac surgery, a cohort that represents a clear and high-value target market for a bedside neuroimaging solution.

Post-Operative Stroke

Stroke is a frequent and devastating complication following procedures like Coronary Artery Bypass Grafting (CABG) or valve replacements. Large-scale audits and registries place the incidence of clinically apparent stroke after cardiac surgery between 1.6% and 2.6%. While this percentage may seem modest, the sheer volume of procedures renders it a significant clinical problem. In the US, approximately 3.61 million cardiothoracic and interventional cardiology procedures were performed in 2024, including over 340,000 high-risk CABG surgeries. This volume translates into thousands of strokes annually occurring within a concentrated, identifiable patient group already under intensive observation.

The consequences of such an event are catastrophic. The perioperative mortality rate for patients who suffer a stroke after cardiac surgery is approximately 20% to 28.8%, a staggering tenfold increase compared to the ~2.4% mortality rate for cardiac surgery patients who do not have a stroke. A crucial detail is that a majority of these strokes – up to 65% in some studies – are "delayed," occurring not in the operating room but in the days following, after an initial uneventful recovery period while the patient is in the ICU. This fact dismantles the notion that a single post-operative check is sufficient and underscores the urgent need for a system of ongoing, routine neurological monitoring.

The clinical challenge culminates in a shocking treatment disparity. A landmark Yale study revealed that patients who suffer an ischemic stroke following heart surgery are less than half as likely to receive standard, life-saving treatments like endovascular thrombectomy compared to patients who suffer a stroke in the community. This is not because the treatments are contraindicated or would be ineffective; it is because the diagnosis is dangerously delayed. The very nature of post-operative ICU care, particularly the use of sedation and mechanical ventilation, effectively masks the classic symptoms of stroke such as weakness or speech difficulty. This diagnostic failure means the narrow therapeutic window for intervention closes long before the stroke is ever identified.

This creates a clear and addressable "treatment gap". The problem is not a lack of effective therapy but a fundamental failure of timely diagnosis. Emu™ could enable rapid, routine neurological assessment in this specific patient cohort and would directly address the root cause of this treatment gap. It would empower clinicians to detect post-operative strokes early enough to intervene, offering the potential to dramatically reduce the ~20-30% mortality rate and fundamentally change the standard of care for one of the most serious complications in modern surgery.

Figure 9: Stroke After Cardiac Surgery – A High-Incidence, High-Mortality Complication. Various Sources.

Metric	Key Finding	Implication for EMVision
Incidence Rate	~2.6% of cardiac surgery patients suffer a post-operative stroke.	A predictable, high-volume event in a concentrated patient population.
Timing of Stroke	Up to 65% of post-op strokes are “delayed”, occurring after initial recovery, often in the ICU.	Highlights the critical need for continuous monitoring.
Associated Mortality	Mortality rate is ~20-30% for patients with post-op stroke (vs. ~2.4% for those without).	A catastrophic outcome, creating immense clinical and economic pressure for a solution.
Treatment Disparity	Post-cardiac surgery stroke patients are <50% as likely to receive standard interventions such as thrombectomy.	A clear, addressable “treatment gap” caused by diagnostic delays.
Cause of Delay	Intubation is the key factor, adding a median of ~20 hours to symptom identification.	EMVision’s technology is uniquely suited to overcome this specific, quantifiable barrier.

Flying Blind Between Bedside Exams

The reason clinicians are unable to detect these evolving neurological injuries is rooted in a fundamental dilemma of critical care: the very interventions required to keep a patient alive mask the signs of neurological decline. The cornerstone of neurological monitoring – the serial exam assessing consciousness, speech, and motor function – is rendered completely ineffective in the ICU, where a significant portion of high-risk patients are intubated and heavily sedated to ensure physiological stability and tolerance of life support.

This creates a dangerous "Sedation Paradox," where the standard of care for stabilizing a patient is a primary contributor to diagnostic failure. The impact of this paradox is not theoretical; it is quantifiable and severe. A retrospective analysis of in-hospital stroke patients found that intubation was independently associated with a median delay of approximately 20 hours in the time from when the patient was "last known normal" to the first identification of stroke symptoms. This delay is an insurmountable barrier to time-sensitive reperfusion therapies like thrombolysis, which has a strict treatment window of just 4.5 hours from symptom onset.

Clinicians attempt to work around this diagnostic blindness with a variety of surrogate monitoring tools, but each is critically insufficient for the task of detecting a new focal stroke:

- **Neurologic Wake-Up Tests:** The practice of temporarily pausing or lightening sedation to perform a brief neurological exam is fraught with risk. For a patient with unstable intracranial dynamics or severe cardiopulmonary issues, the resulting surges in blood pressure, heart rate, and intracranial pressure (ICP) can be dangerous or even fatal. Consequently, these tests are often contraindicated precisely in the patients who need them most.

- **Automated Pupillometry:** Devices that provide a quantitative measure of the pupillary light reflex are a valuable addition to the ICU toolkit, as they can standardize one part of the neurological exam and provide an early warning of rising ICP. However, their utility is limited to this specific function. They are not designed to detect a new focal ischemic stroke in a brain region that does not immediately impact the pupillary reflex pathway. A patient could suffer a significant, disabling stroke that would go completely unnoticed by a pupillometer until it becomes so large that it causes secondary brain swelling.

- **Invasive ICP Monitors:** While essential for managing patients with traumatic brain injury or significant brain swelling, these invasive devices are not used routinely for all ICU patients, such as the post-cardiac surgery cohort. Furthermore, they are designed to measure global pressure changes within the skull and are not informative for an isolated ischemic event that does not cause an immediate, widespread pressure increase.

The combination of ineffective non-invasive tools and the high risks associated with both wake-up tests and patient transport for conventional imaging (as detailed in the next section) forces clinicians into a default posture of "wait and see." Lacking a safe, easy, and reliable method for assessing neurological status, the clinical team is compelled to accept a high degree of uncertainty, often only confirming a neurological catastrophe after it has become irreversible. This institutional inertia, born of a lack of viable options, is the primary barrier EMVision's emu™ device is designed to overcome. Its value proposition is precisely that it offers a safe, low-risk, and effective alternative to break this dangerous cycle of "flying blind."

The Dangers of Intrahospital Transport

When a neurological change is suspected in a critically ill ICU patient, the definitive diagnostic step is to obtain a CT or MRI scan. However, the process of transporting an unstable patient from the protective cocoon of the ICU to a distant radiology suite is a major clinical, logistical, and physiological challenge. This journey represents a critical bottleneck in care, one so fraught with peril that the decision to order a scan is often delayed, if not avoided entirely. The risks are threefold:

1. **Clinical Risks:** Transporting a critically ill patient is an inherently high-risk procedure. Published studies have found that up to one-third of all ICU patient transports result in an adverse event. These events range from hemodynamic instability, such as a dangerous drop in blood pressure, and cardiac arrhythmias to equipment-related mishaps like the dislodgement of intravenous lines or disconnection from a mechanical ventilator. A significant portion of these incidents – approximately 6-7% - classified as life-threatening requiring immediate emergency intervention outside the controlled ICU environment. During transport and within the scanner itself, the patient is physically isolated from the full resources and expert personnel of the ICU. Alarms on portable pumps or ventilators may not be audible, and responding to a medical emergency is exponentially more difficult than at the bedside.

2. **Logistical Burden:** The process is extraordinarily resource-intensive and inefficient. A single trip to the CT scanner requires the mobilization of a dedicated transport team, often including a critical care nurse, a respiratory therapist, and sometimes a physician. This pulls highly skilled staff away from their duties in the ICU, disrupting care routines for other patients. The entire workflow is plagued by delays. The total time from the moment a scan is ordered to when the final results are interpreted and available to the clinical team can take as long as eight hours. This multi-hour delay renders the diagnostic information completely useless for guiding acute, time-sensitive interventions. This inefficiency also carries a direct financial cost, with one analysis estimating the staff time alone costs approximately $200 per transport, a non-trivial operational expense.

3. **Physiological Stress:** Beyond the logistical challenges, the transport itself – and the additional sedation often required for the patient to tolerate it – can directly worsen the underlying brain injury. Additional sedation can trigger hypotension, which is particularly dangerous in neuro-ICU patients as it reduces cerebral perfusion pressure (CPP). This drop in blood flow can starve the salvageable tissue surrounding a stroke (the ischemic penumbra), causing it to die and expanding the size of the permanent brain damage. Sedation can also lead to respiratory depression, which causes a build-up of carbon dioxide in the blood. This, in turn, causes the blood vessels in the brain to dilate, a process that dramatically increases intracranial pressure (ICP) – a potentially fatal complication in patients with already compromised intracranial dynamics.

Figure 10: Risks associated with in-hospital patient transport for neuroimaging. Source: Evolution Capital analysis; derived from peer-reviewed studies on ICU patient transport risks.

Risk Category	Specific Hazard	Data Point
Clinical Risks	Incidence of adverse events	Up to 1/3 of transports result in an adverse event.
	Incidence of life-threatening events	6-7% of transports involve a life-threatening event requiring immediate intervention.
	Patient isolation	Patient is physically separated from ICU resources; alarms may not be audible.
Logistical Burgen	Time from order to result	Can take up to 8 hours, rendering information useless for acute intervention.
	Personnel requirement	Requires a dedicated team (nurse, RT, physician), disrupting ICU workflow.
Physiological Stress	Hypotension risk	Sedation for transport can cause hypotension, reducing cerebral perfusion and worsening brain injury.
	Increased ICP risk	Respiratory depression from sedation can increase carbon dioxide causing vasodilation and raising intracranial pressure.

Emu™ Enables Proactive, Continuous Vigilance at the Bedside

Emu™ is engineered to be the definitive solution to the crisis (unseen neurological decline), the dilemma (“flying blind” between bedside exams), and the bottleneck (the dangers of intrahospital transport) that define neurological monitoring in the ICU. The device has the potentially to fundamentally invert the current diagnostic paradigm, shifting from a high-risk, inefficient “patient-to-scanner” model to a safe, rapid, and efficient “scanner-to-patient” model at the point of care. By operating directly at the bedside, emu™ immediately and completely eliminate the clinical, logistical and physiological risks of intrahospital transport. This single feature removes the primary barrier that prevents clinicians from obtaining the routine neurological imaging necessary to monitor high-risk patients. The dangers of haemodynamic instability, the resource drain of a dedicated transport tea, and the hours-long delays in obtaining results all become non-factors.

Furthermore, emu™ directly solves the "Sedation Paradox." The device's non-ionizing electromagnetic imaging technology is not dependent on patient cooperation, consciousness, or the ability to perform a physical exam. It can acquire critical diagnostic information from a heavily sedated, intubated patient, thereby breaking the "flying blind" cycle. This capability transforms neurological assessment from a high-risk, intermittent event into a safe, routine screening procedure. For example, a clinician could order a quick emu™ scan every six hours for a post-cardiac surgery patient, creating a monitoring cadence that is simply impossible with the current standard of care.

This ability to conduct routine surveillance empowers clinicians to mitigate the crisis of unseen neurological decline. An early scan that suggests a new ischemic event or an expanding haemorrhage can trigger an immediate, targeted response. This could involve ordering a confirmatory high-resolution scan and initiating life-saving interventions well within the therapeutic window, directly addressing the treatment gap that leads to such poor outcomes in the post-operative stroke population.

Finally, the emu™ presents a compelling health-economic value proposition for hospital administrators. Beyond the direct savings from reducing costly and labour-intensive patient transports, the device has the potential to generate significant downstream economic benefits. By preventing or enabling the early treatment of secondary brain injuries, the emu™ can help reduce ICU and overall hospital length of stay, decrease the need for long-term rehabilitation, and lower the immense societal costs associated with lifelong disability.

Total Addressable Market for Emu™

Having established the clear need for Emu™ in both ED and ICU settings, we now translate these use cases into a tangible Total Addressable Market (TAM). Our analysis focuses on the US as the initial and most significant commercial opportunity, building a bottom-up model based on target facility types, likely device deployment density, and a multi-layered revenue model. This approach reveals a multi-billion-dollar opportunity in the US alone.

Addressable Facilities

EMVision's management has outlined a targeted go-to-market strategy focusing on the two ends of the stroke care capability spectrum: the nation's most advanced stroke centers and its most resource-constrained rural hospitals. The high-capability stroke center group includes CSCs, TSCs, and PSCs. While these high-volume centers have robust neuroimaging capabilities in their EDs, they face a significant diagnostic gap in their ICUs, where the emu™'s continuous monitoring capabilities provide immense value for managing post-operative and critically ill patients at high risk of secondary neurological injury. As of early 2025, there are approximately 1,770 of these advanced stroke centers in the US.

At the other end of the spectrum, Critical Access Hospitals (CAHs) were established to provide essential services in rural and sparsely populated areas. Many CAHs lack 24/7 access to CT scanners and virtually all lack on-site MRI capabilities, creating a critical diagnostic bottleneck. For these hospitals, emu™ could be a transformative tool in the ED, enabling rapid initial stroke evaluation and classification to guide urgent patient transfer decisions. As of December 2023, there were 1,366 CAHs in the US. This dual-pronged strategy is astute. It targets both the centers with the highest need for advanced ICU monitoring and those with the most acute need for any point-of-care neuroimaging. Based on our research, the primary target pool consists of approximately 3,100 hospitals.

For meaningful coverage, a hospital requires a scanner in every key stroke workflow node: the ED, the Neuro-ICU/ICU, the Stroke/Neurology Ward, and, in larger hubs, Interventional/step-down units (where rapid reassessment is required before or after endovascular procedures). We estimate that the ~1,770 advanced stroke centers would require an average of 4 emu™ units each to cover these critical touchpoints. The CAHs, with a simpler workflow focused on ED triage and general ward monitoring, would require 2 units each.

While these ~3,100 hospitals represent the primary target market, in reality, every US hospital with an emergency department is part of the broader TAM. There are approximately 5,533 hospitals with EDs in the US. Subtracting the primary targets leaves a secondary market of over 2,400 "Other Hospitals" that could benefit from emu™ deployment, particularly in their EDs.

Device and Service Pricing

EMVision's guidance indicates Emu™ will be priced around US$175,000 per unit. In addition to the upfront capital sale, the company can generate significant recurring revenue through two streams: (i) annual maintenance and support contracts targeted at 10% of capital expense per annum (US$17,500 per unit p.a.); and (ii) consumables including single use, disposable head caps required for each scan, targeted at US$25 per scan.

Based on this model, we project a total upfront market opportunity of approximately US$2.37 billion in the US, supported by a recurring annual revenue stream potential of over US$335 million per annum through servicing and consumables.

Figure 11: Breakdown of EMVision's Total Addressable Market (TAM) across US hospital segments. Source: AHA, various sources.

	Hospitals	Units	Device TAM (US$M)	Scans p.a.	Recurring Revenue Potential p.a. (US$M)
PSCs, TSCs & CSCs	1,770	7,080	1,239.0	3,332,500	207.2
CAHs (net of overlap)	1,330	2,660	465.5	302,100	54.1
Total Primary Market	**~3,100**	**9,740**	**1,704.5**	**3,634,600**	**261.3**
Other Hospitals	2,520	3,780	661.5	317,800	74.1
Total	**5,620**	**13,520**	**2,366.0**	**3,952,400**	**335.4**

Annual Scan Volume Drivers

The recurring revenue from consumables is driven by the total number of scans performed annually. We have identified four primary clinical scenarios that will drive emu™ utilization:S

1. **Confirmed Stroke in the ED:** For patients presenting with a confirmed stroke, emu™ would be used for initial classification and subsequent follow-up monitoring. We assume one baseline scan and two follow-ups at stroke centres, and one baseline scan at CAHs and other hospitals.

2. **Stroke Mimics:** A significant portion of "Code Stroke" activations are for patients experiencing stroke mimics – non-vascular conditions that present with stroke-like symptoms and are often indistinguishable from an actual stroke. The prevalence of mimics is highly variable depending on the clinical setting, but they represent a major diagnostic challenge. A large-scale review suggests they account for about 1 in 4 stroke admissions. These conditions are diverse and include seizures, complex migraines, infections, brain tumours, and metabolic issues like hypoglycaemia (low blood sugar). Misdiagnosing a mimic as a stroke can lead to the unnecessary and potentially harmful administration of thrombolytic therapy, which carries a small but real risk of haemorrhage, while also delaying the correct treatment for the patient's actual underlying condition. We assume one emu™ scan for each of these patients to rapidly rule out stroke.

3. **Post-Cardiac Surgery Monitoring:** Given the high risk of post-operative stroke, routine neurological checks in the ICU are a prime use case. With over 1 million cardiac surgeries performed annually in the US, we assume one baseline scan for this high-risk population.

4. **General ICU/Neuro-ICU Monitoring:** For critically ill patients requiring neurological surveillance due to conditions other than cardiac surgery, we assume a significant portion will receive routine monitoring scans to detect secondary brain injury.

Figure 12: Estimated annual scan volumes across key hospital-based stroke imaging use cases in the US, totalling ~4 million scans per annum. Source: Evolution Capital's analysis of the TAM, various sources.

Driver	Annual US Volume	Proportion at PSC/TSC/CSC	Proportion at CAH	Proportion at Other	Scan-per-event Assumption	Resulting Scans p.a.
Confirmed strokes presenting to ED	686,000 ED visits with stroke as primary Dx	70%	20%	10%	1 baseline + 2 follow-ups at stroke centers; 1 baseline at CAH	1,646,400
Mimic / Suspected stroke	1 mimic per true stroke = 686,000	65%	15%	20%	1 each	686,000
Cardiac surgery neurological checks	1 million	95%	n/a	5%	1 scan post-op	1,000,000
ICU / Neuro-ICU monitoring	3.1 million ED visits admitted to critical care; assume 10% require neuro surveillance	80%	10%	10%	2 scans	620,000
Total						**3,952,400**

Note: The seemingly high allocation of confirmed strokes to CAHs (20%) compared to "Other" hospitals (10%) is driven by established rural-urban disparities in stroke incidence. Research consistently shows that stroke incidence is significantly higher in rural populations compared to urban ones. Some studies indicate this increased risk can be as high as 23-30%. This is often linked to a higher prevalence of key risk factors like hypertension, diabetes, and smoking in rural communities. Moreover, CAHs are, by definition, facilities that provide essential services in rural and sparsely populated areas. They are the primary, and often only, initial point of care for these high-risk populations. Therefore, while there are more "Other" hospitals in the US, the model allocates a larger proportion of the nation's total confirmed strokes to CAHs because they serve a population that experiences strokes more frequently.

Conversely, the model allocates a higher proportion of stroke mimics to "Other" hospitals (20%) than to CAHs (15%). This is based on patient volume and the nature of stroke mimics. "Other" hospitals, which are typically non-specialized community hospitals in suburban or smaller urban areas, serve more densely populated regions than rural CAHs. This higher population density naturally leads to a greater absolute number of total ED visits for a wide variety of conditions. Stroke mimics are a diverse group of conditions, including seizures, complex migraines, metabolic disturbances, and psychiatric conditions, that present with stroke-like symptoms. It is plausible that the higher overall patient volume and more diverse population presenting to "Other" hospitals would result in a larger share of the nation's total stroke mimic cases. In rural areas with a higher stroke incidence, a patient presenting to a CAH with stroke-like symptoms has a higher pre-test probability of having a true stroke. In more urbanized settings, where the population may present to the ED for a wider range of ailments, the ratio of mimics to true strokes may be higher. Studies show the rate of stroke mimics among suspected stroke presentations can be substantial.

The Pre-Hospital Frontier

The development of EMVision's second product, a miniaturized scanner for ambulance-based use, represents a logical and powerful extension of the company's point-of-care strategy. This device is not an unproven concept but rather the scalable and cost-effective evolution of the clinically validated Mobile Stroke Unit (MSU) model. By systematically addressing the economic and logistical barriers that have hindered widespread MSU adoption, EMVision's First Responder device could democratize pre-hospital stroke diagnosis, optimize regional care networks, and capture a vast, untapped market.

Validating the Pre-Hospital Diagnostic Model

The "time is brain" axiom is the undisputed principle of stroke care, yet conventional emergency pathways are plagued by delays that systematically rob patients of the chance for a good outcome. In the US, it is estimated that only about 10% of ischemic stroke patients receive any form of reperfusion therapy (thrombolysis or thrombectomy). An even smaller fraction (a mere 1%) are treated within the "golden hour," the first 60 minutes after symptom onset, where these therapies are most effective.

To combat these devastating delays, the concept of the Mobile Stroke Unit (MSU) – a specialized ambulance equipped with a CT scanner, point-of-care lab, and a specialist team – was developed. For years, the clinical benefit of this model was debated. However, landmark clinical trials have now definitively proven its value, providing a powerful proof-of-concept for the entire pre-hospital diagnostic market segment.

- The BEST-MSU trial, a major multi-site study conducted across seven US cities, provided compelling evidence of improved functional outcomes. The results showed that for every 100 ischemic stroke patients treated on an MSU rather than through standard emergency care, 27 would have less final disability at 90 days, and 11 of those would be rendered completely disability-free.

- The B_PROUD trial in Berlin demonstrated a dramatic acceleration of care, finding a 10-fold greater proportion of "golden hour" thrombolysis with MSU deployment and an average reduction in treatment times of 25 minutes compared to conventional care.

- This trial data has been further validated by recent real-world evidence. A large observational study published in 2023 involving over 19,000 patients confirmed that pre-hospital management in an MSU was associated with a significantly lower level of global disability at hospital discharge.

The success of these MSU trials is the single most important de-risking event for EMVision's First Responder device. The key takeaway for investors is not that healthcare systems need to build more MSUs, but that the clinical model of performing a diagnostic scan and initiating treatment decisions in the pre-hospital environment is now validated by Level 1 evidence. The primary barrier to widespread adoption of this model is no longer clinical uncertainty but logistics and economics. A conventional mobile CT scanner weighs over 1,100 lbs (500 kg) and transforms the vehicle into a multi-million-dollar asset that is complex to staff and maintain.

Therefore, EMVision does not need to spend hundreds of millions of dollars and a decade proving the concept of pre-hospital stroke care; that foundational work has already been done by the academic and clinical community. The remaining challenge is one of implementation: how to scale this proven clinical model in an affordable and efficient manner. EMVision's First Responder device, being lightweight, portable, and dramatically less expensive than a full MSU, is a direct technological solution to this implementation problem. This positioning dramatically shortens its potential path to market acceptance and reduces the associated investment risk.

EMVision’s Miniaturized, Ambulance-Ready Technology

The First Responder device is a lightweight scanner, weighing less than 10kg, designed to be transported in a backpack and deployed in both standard road and air ambulances. This physical profile compares incredibly favourably to the more than 500kg weight of a mobile CT scanner, eliminating the need for a specialized, reinforced vehicle.

The proposed operational model is designed for seamless integration into existing Emergency Medical Services (EMS) workflows. The device can be operated by trained paramedics with minimal additional training. Once a scan is complete, the data and images can be transmitted via telehealth platforms to a remote stroke expert, who can then confirm the diagnosis and guide on-scene decisions. This workflow is powered by sophisticated technology, including an array of 28 antennas for full brain coverage, powerful edge AI processing using the NVIDIA Jetson platform, and AI algorithms trained on NVIDIA DGX systems to deliver rapid, actionable insights.

Figure 13: Comparison of stroke triage options. EMVision-equipped ambulances offer imaging-based triage with lower cost and weight than MSUs, enabling scalable prehospital stroke care. Source: various sources.

Feature	Standard Ambulance	MSU	First Responder-Equipped Ambulance
Diagnostic Capability	Clinical assessment only (e.g., FAST/BE-FAST). Cannot differentiate stroke type.	Gold-standard CT imaging. Differentiates ischaemic vs. haemorrhagic.	Electromagnetic imaging. Designed to differentiate stroke type.
On-Scene Treatment	None. Transport only.	Can initiate IV tPA on-scene.	Potential for telehealth-guided treatment decisions.
Triage Accuracy	Low. Relies on imprecise clinical signs. High risk of mis-triage.	High. Based on definitive imaging. ~100% accuracy in some studies.	High. Designed to provide imaging-based triage.
Vehicle & Equipment Cost	~$250,000	>$1,000,000	~$250,000 (standard ambulance) + Device Cost (est. US$60-70k).
Equipment Weight	N/A	>1,100 lbs / 500 kg for CT scanner	<25 lbs / 10 kg for EMV scanner
Required Personnel	Paramedics	Paramedics + CT Tech + Neurologist (often via telehealth)	Paramedics (trained to operate device) + Neurologist (via telehealth)
Scalability	Fully scaled.	Extremely low. Limited by cost and complexity.	High. Designed for mass deployment in existing fleets.

System-Level Impact: Optimizing Triage, Health Economics & Market Opportunity

Triage Optimization and Regional Network Efficiency

One of the most powerful benefits of pre-hospital diagnosis is the ability to enable diagnosis-based triage. In the current system, paramedics rely on imprecise clinical scales to guess the stroke type and severity, often resulting in the patient being taken to the nearest hospital, which may not be the most appropriate one. An EMVision-equipped ambulance can change this. Data from MSU trials clearly demonstrates the power of this approach. One study showed that MSUs correctly triaged 100% of patients to the appropriate level of stroke center (e.g., a comprehensive center for a complex case), compared to only ~70% for standard ambulances. Another analysis found that MSUs dramatically reduced the number of haemorrhagic stroke patients being incorrectly taken to hospitals without neurosurgical capabilities (11.3% vs. 43.0%). By replicating this capability at a fraction of the cost, the First Responder device can ensure that patients with a large vessel occlusion (LVO) are transported directly to a thrombectomy-capable center and patients with a brain bleed are taken directly to a neurosurgical center, bypassing intermediate hospitals and saving critical, brain-saving time.

Health Economics

The profound clinical benefits of earlier treatment – less disability, better functional outcomes – translate directly into compelling economic benefits. Faster and more appropriate treatment reduces the need for costly long-term care, rehabilitation, and societal support. Health economic models of pre-hospital stroke intervention programs have quantified this value, showing a significant net avoidance of Disability-Adjusted Life Years (DALYs). One such analysis estimated an average cost per DALY averted of $10,921. By enabling a massive expansion of the pre-hospital diagnostic model, EMVision's technology has the potential to unlock these substantial health-economic gains on a national and global scale, presenting a powerful argument to payors and healthcare systems.

Total Addressable Market

The market opportunity for the First Responder device is substantial. It is estimated that there are in excess of 60,000 road and air ambulances in the United States alone, with many more globally (5,200 in Australia). The MSU model, due to its immense cost and

complexity, is a niche solution, with only a few dozen units in operation worldwide. In contrast, the EMVision First Responder device is designed to be economically viable for widespread deployment across entire ambulance fleets. Its low weight, small footprint, and integration with existing personnel and vehicles make it a scalable solution. Capturing even a modest percentage of this vast addressable market represents a multi-billion-dollar revenue opportunity for EMVision, underpinning the significant long-term growth potential of the company.

Company, Product & Development

Company Overview

EMVision was founded in July 2017 by Scott Kirkland and Ryan Laws. The company's core technology – a portable electromagnetic brain scanner – is the product of over a decade of research at the University of Queensland by Prof. Stuart Crozier (current Chief Scientific Officer), Prof. Amin Abbosh and a team of over 20 researchers. EMVision licensed this novel imaging technology from UniQuest, the University of Queensland's commercialization arm, and later acquired full ownership of the related intellectual property. The company was admitted to the Australian Securities Exchange (ASX) in December 2018 after raising approximately A$6 million in its IPO.

Product Deep Dive: A New Modality in Stroke Detection

How do you shrink a CT suite into a 100kg cart? Emu™ uses ultra-high-frequency radio signals, converting them into rapid stroke-classification decisions through a proprietary and sophisticated data processing pipeline. The technology is not intended to replace the high-resolution anatomical detail of CT or MRI, but to create an entirely new capability: rapid, safe, and routine neurological assessment at the point-of-care.

Differentiating Tissue with Electromagnetic Waves

Emu™ and First Responder operate on the principle that different biological tissues interact with electromagnetic waves in distinct and measurable ways. This interaction is governed by a tissue's unique dielectric properties – primarily its relative permittivity, which is its ability to store energy in an electric field, and its conductivity, its ability to conduct an electric current.

Crucially for stroke diagnosis, the pathological changes that occur in the brain during a stroke create a significant shift in these dielectric properties. In haemorrhagic stroke, the bleed introduces blood into the brain parenchyma. Blood has high water and ion content, giving it a distinctly higher permittivity and conductivity compared to normal grey matter. This creates a strong positive dielectric contrast than emu™ and First Responder are designed to detect. In ischaemic stroke, the resulting lack of blood flow and subsequent infarction lead to a decrease in the local dielectric properties of the affected brain tissue. This creates a negative dielectric contrast.

Emu™ and First Responder work by creating a map of these electrical property variations across the brain. It is not generating a traditional anatomical picture like a CT scan; rather, it is sensing the unique dielectric signature that differentiates a bleed from no bleed and a clot from healthy tissue.

Data Acquisition & Processing

The data acquisition process is remarkably simple and fast, designed for the high-pressure emergency environment. The patient's head is placed inside a helmet-like apparatus containing an array of antennas. These antennas sequentially transmit low-power, non-ionising electromagnetic waves through the brain. As these waves encounter different tissues and the dielectric contrasts between them, they scatter in a

unique pattern. The surrounding antennas then capture these scattered signals. This entire measurement sequence is completed in minutes.

This raw signal data is then fed into the system's core—a sophisticated processing and AI-driven classification engine. The algorithms do not simply reconstruct a picture from the signals. Instead, they analyse the complex, multi-dimensional dataset to identify patterns. Through extensive training on data from hundreds of patients with known ground-truth CT/MRI scans, the AI models have learned to recognise the distinct electromagnetic "signature" of a haemorrhage versus the signature of healthy or ischaemic tissue. The system effectively asks: "Does the signal pattern from this patient's brain more closely resemble the signature of a bleed, or the signature of a non-bleed?"

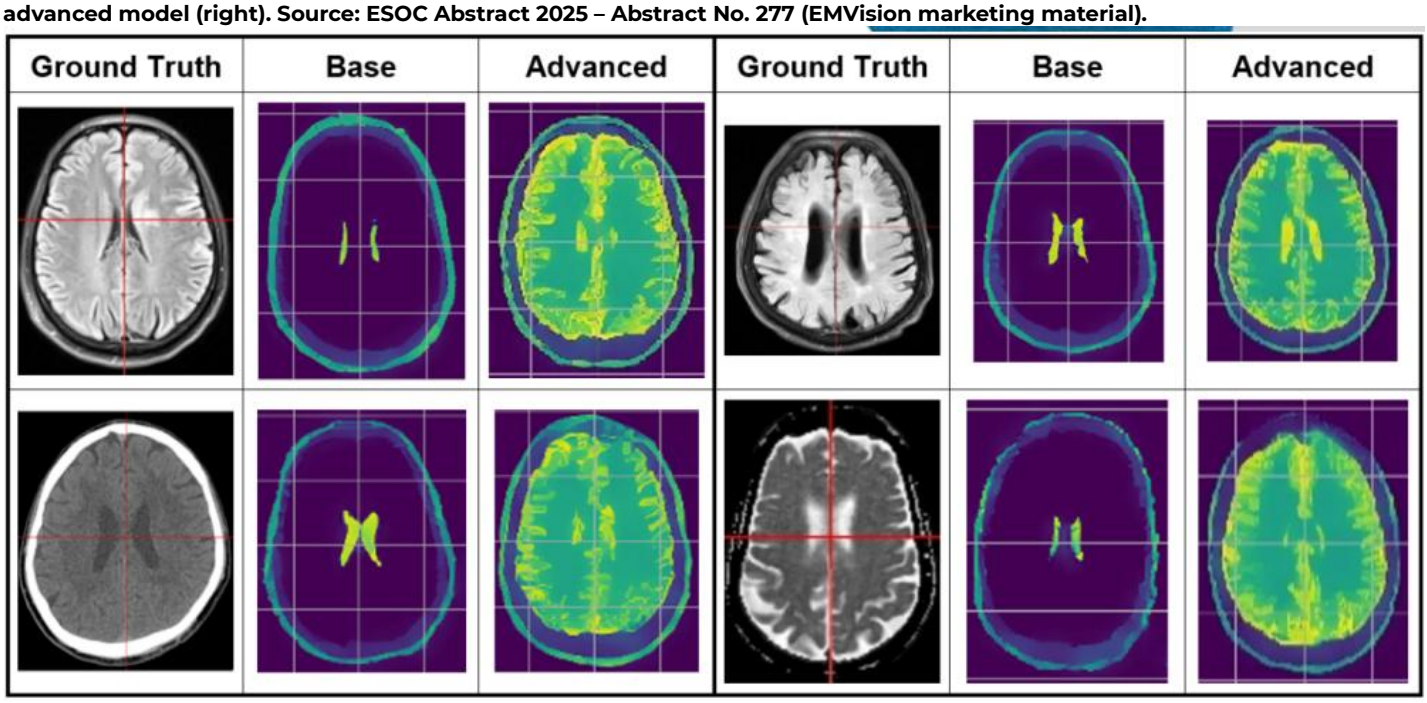
The Clinical Output

The result of this process is a clear, actionable clinical output delivered to the clinician on the device's monitor in two forms:

i. **A Definitive Diagnostic Classification:** The primary output is a binary classification that directly addresses the most critical question in acute stroke triage: is there blood present? The system provides a clear "Haemorrhage" or "Not Haemorrhage" result, and similarly, an "Ischaemia" or "Not Ischaemia" classification. This is the core decision-support function, enabling rapid triage and treatment pathway selection.

ii. **Probabilistic 3D Image Reconstruction for Localisation:** Simultaneously, the system generates a reconstructed image of the major anatomical landmarks seen by the antennas, such as the boundaries of the brain and ventricles. This is not an anatomical image in the way a CT is. Rather, it is a probability map that visually indicates the location, size, and intensity of the detected dielectric anomaly. Using a colour scale, the display shows areas with a high "similarity to haemorrhage" or "similarity to ischaemia," acting as a fiducial orientation tool

Figure 14: omparative visualisation of conventional MRI/CT (left), EMVision's base probabilistic imaging output (center), and the advanced model (right). Source: ESOC Abstract 2025 – Abstract No. 277 (EMVision marketing material).



This image illustrates the progression of emu™ imaging outputs from basic anatomical modelling to advanced tissue differentiation. The base model captures structural landmarks such as the skull and ventricles, providing a reference for device orientation. The advanced model builds on this by incorporating grey and white matter differentiation. This probabilistic imaging capability is central to emu™'s clinical value proposition as a portable, radiation-free brain scanner suitable for in-hospital stroke classification.

Clinical Validation

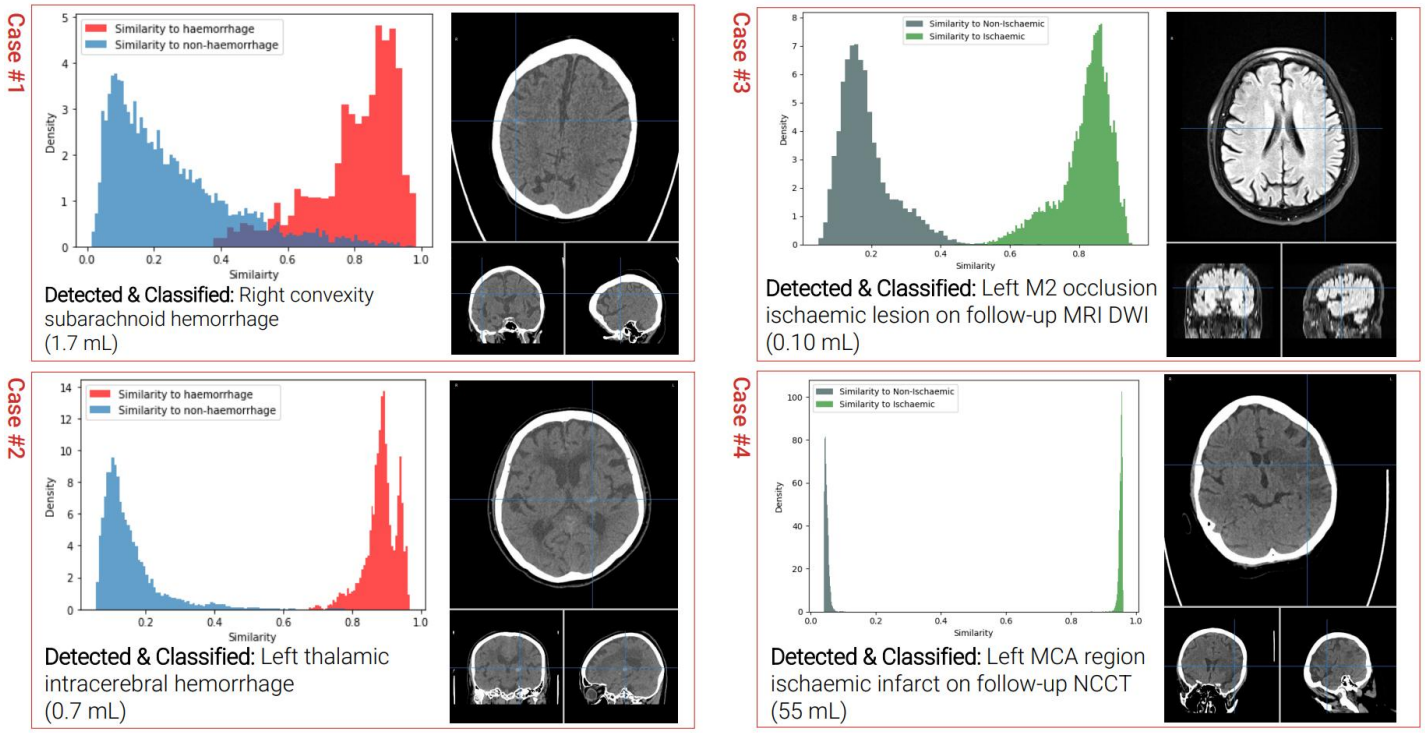
As already outlined, The clinical development of EMVision's technology is underpinned by the 'EMView' study, a multi-site trial that enrolled 307 participants, including 277 patients with suspected acute stroke. The results, announced in late 2024, demonstrated high performance when the algorithms were tested on "unseen" patient data – a critical measure of real-world effectiveness.

- Haemorrhage Detection ("Blood or Not"): The algorithm achieved 92% sensitivity and 85% specificity. This indicates a strong ability to correctly identify patients with a bleed, while also correctly ruling out those without one.

- Ischaemia Detection ("Clot or Not"): The algorithm achieved 95% sensitivity and 80% specificity.

Case studies from the trial highlighted the device's remarkable sensing capabilities, including the successful detection and classification of very small but clinically significant bleeds, such as a 0.7mL thalamic haemorrhage and a 1.7mL subarachnoid haemorrhage. The promising results from the EMView study have provided the company with the confidence to proceed with its pivotal validation trial, which will be used to support a De Novo clearance application and subsequent commercialisation.

Figure 15: Case study examples from EMVision's EMView preliminary evaluation, showing detection and classification of haemorrhagic and ischaemic stroke lesions. Source: EMVision EMView Results Poster, ESOC 2025.



Each case combines a similarity density histogram (contrasting haemorrhagic vs non-haemorrhagic or ischaemic vs non-ischaemic probability), corresponding follow-up imaging (MRI or NCCT), and classification output. Cases 1 and 2 demonstrate accurate detection of small-volume haemorrhages (1.7 mL and 0.7 mL), while Cases 3 and 4 show classification of ischaemic stroke lesions, including a large MCA infarct (55 mL). These results highlight EMView's capability to identify both subtle and large-volume stroke presentations.

Path to market

Bolstered by the promising results from the EMView study, EMVision is now proceeding with a pivotal validation trial. This trial represents the final and most critical step in the company's clinical development program before seeking market authorisation. As of today, five of the six sites have been activated and are actively recruiting patients: Royal Melbourne Hospital, UTHealth Memorial Hermann Hospital in Houston, Mayo Clinic in Florida, Mount Sinai Hospital in New York, and Liverpool Hospital in Sydney. The final US site on the West Coast has received institutional review board approval and is expected to begin recruitment shortly, bringing all six sites online.

This pivotal trial is designed to provide the clinical evidence required for an FDA De Novo clearance of the emu™ device. The enrollment period is anticipated to last approximately 6–12 months from initiation, followed by data analysis and reporting of results. A successful outcome (meeting or exceeding the >80% accuracy targets) will form the foundation of EMVision's De Novo submission to the FDA, a necessary step given the device's novel technology with no existing predicate. Management is currently targeting a late-2026 market launch for the emu™ in the US, assuming timely trial completion and regulatory approval. Importantly, obtaining De Novo clearance for the emu™ will not only enable initial commercialization but also establish the emu™ as a predicate device for the company's next product – the ultra-portable "First Responder" brain scanner – allowing that ambulance/air-ambulance unit to pursue a faster 510(k) clearance pathway. In parallel, EMVision has initiated a Continuous Innovation Study at two Australian hospitals – Princess Alexandra in Brisbane and John Hunter in Newcastle – to collect additional patient data and drive iterative algorithm and product improvements, including exploring traumatic brain injury applications, without impacting the progress of the pivotal validation trial.

Figure 16: Summary of the clinical investigation plan for EMVision's pivotal validation trial, known as "The EMU™ Study". Source: EMVision announcement.

The Emu™ Study	
Investigational Site	Leading Research Institutions and Comprehensive Stroke Centres in the United States and Australia.
Design of the Clinical Investigation	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study of the EMVision emu™™ Brain Scanner.
Primary Objective	Demonstrate haemorrhage detection sensitivity and specificity >80%.
Inclusion Criteria	1. Adults ≥22 years of age 2. Presenting to hospital with acute neurological deficit suspected to be stroke and within 12 hours of symptom onset 3. The use of the EMVision emu™™ Brain Scanner will not delay the treatment of the patient 4. CT or MRI brain imaging following clinical evaluation in Emergency Department per standard of care 5. Head size deemed suitable for scanning with the EMVision emu™™ Brain Scanner
Exclusion Criteria	• Has received treatment for current (suspected) stroke event prior to initial CT/MRI scan OR EMVision emu™™ Brain Scanner scan (such as thrombolysis) • Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography • Contraindications to emu™ Brain Scanner scan, such as conditions precluding placement of the scanner, metallic implants in the head, or an inability to lie still during the scan • Pregnant or breastfeeding • Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
Sample Size	300 suspected stroke participants across 2 study arms: A. Intracranial haemorrhage (n=150) B. Other (n=150) Note: Training verification on a small number of initial participants is performed at each site prior to enrolment of the above sample.
Duration of Clinical Investigation	Estimated 6-12 months enrolment period followed by analysis and reporting.

First Responder Programs

An advanced prototype has been developed, and the company is now validating this technology through two key pre-hospital studies that will guide its refinement toward a commercial-grade device.

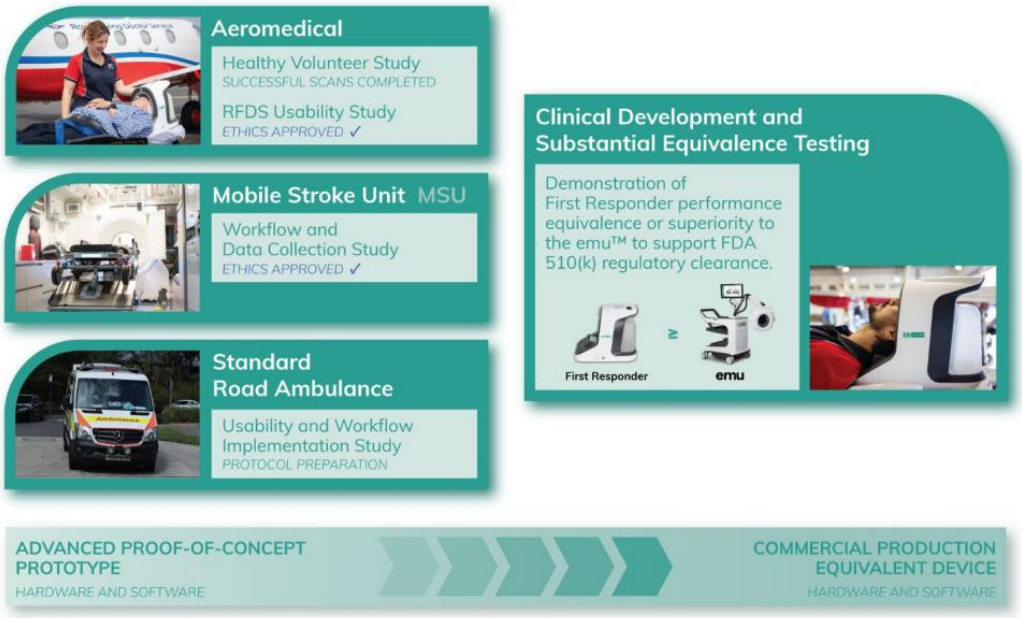
- **Aeromedical Feasibility Study (RFDS)** – EMVision has initiated a feasibility, usability, and workflow study in collaboration with the Royal Flying Doctor Service and partners to ensure the First Responder unit can be seamlessly integrated into aeromedical retrieval workflows. This single-arm study will evaluate the scanner's usability, reliability, and functionality in-flight, as well as its impact on emergency workflow metrics, without impeding patient care. Ethics approval is in place, with patient recruitment on track to commence in the current quarter (3Q 2025) and initial results expected by the following quarter. The outcomes will indicate how well the device fits into air ambulance operations and inform any design or workflow adjustments needed for commercial deployment.

- **Mobile Stroke Unit (MSU) Study (Melbourne)** – A second ethics-approved study is set to deploy the First Responder scanner on Australia's only Mobile Stroke Unit in Melbourne. This study will evaluate the device's use during actual pre-hospital stroke responses, examining how it performs alongside standard care. Importantly, the MSU's onboard CT scanner will provide contemporaneous ground-truth imaging; paired EMVision scan and CT data from suspected stroke patients will be collected to further develop and validate the device's diagnostic algorithms. This trial is slated to begin later in 3Q 2025, with an initial phase focusing on workflow integration and a follow-up phase gathering patient imaging data. Insights from the MSU study will directly feed into the First Responder's commercial design, ensuring the final product meets the rigors of

on-scene stroke diagnosis while refining its accuracy against gold-standard CT results.

Data and user feedback from these First Responder programs are pivotal for EMVision's commercialization strategy. The studies will guide final hardware/software tweaks and confirm that the scanner can operate effectively in real-world emergency settings, de-risking its transition to a market-ready version. Moreover, the clinical data (including the paired CT comparisons) will support EMVision's planned FDA 510(k) submission by establishing substantial equivalence and demonstrating the device's safety and effectiveness in the field.

Figure 17: Development pathway and current validation studies for EMVision's First Responder scanner, supporting eventual 510(k) submission. Source: EMVision company presentation (July 2025).



Competitive Landscape

A diverse array of companies, from established med-tech giants to venture-backed startups, are racing to bring diagnostic capabilities out of the centralized radiology department and directly to the patient's bedside or the pre-hospital scene. However, to view this landscape as a single, monolithic race is to misunderstand the market.

EMVision's success does not hinge on replacing the high-resolution anatomical detail of conventional CT and MRI. Rather, its commercial viability is predicated on its ability to dominate specific, high-value clinical niches that are poorly served by existing or emerging competitors. Emu™ is not designed to be a better MRI or CT, it is designed to create an entirely new category of routine, radiation-free neurological monitoring that is currently impossible. Similarly, the First Responder is not intended to be a better MSU. It is engineered to be the first economically scalable solution that can democratize the proven clinical benefits of effective pre-hospital screening.

This section addresses the critical question: upon securing regulatory clearance, will EMVision's unique value proposition be compelling enough to drive commercial adoption in a crowded and rapidly evolving market?

The Bedside Battleground

The in-hospital market for point-of-care neuroimaging is driven by two primary needs: first, the need for rapid, definitive diagnosis in critically ill patients without the risks of transport; and second, the need for safe, frequent monitoring to detect subtle

neurological changes over time. While several technologies are vying for this space, they are optimized for one need at the expense of the other.

The Low-Field MRI Challenger: Hyperfine's Swoop

Hyperfine's Swoop system is arguably the most prominent and ideologically similar competitor to the emu™. Swoop is a portable, ultra-low-field (0.064 Tesla) MRI. "Ultra-low-field" means that it operates with a relatively low magnetic field strength. This is achieved using a permanent magnet design which has profound practical advantages: it requires no specialized cooling systems (cryogens), extra power infrastructure, or purpose-built radiofrequency (RF) shielded rooms, allowing it to be plugged into a standard electrical outlet.

Its low magnetic field strength significantly reduces the risk of projectile incidents compared to high-field MRI. While it still generates a magnetic field with a 5-gauss safety contour that must be respected, it can operate in the presence of common ICU equipment like ventilators and IV pumps positioned outside this line. Furthermore, the specific absorption rate (SAR), a measure of RF energy absorbed by the body, is well below safety thresholds, mitigating the risk of patient heating.

Swoop is FDA-cleared for brain imaging of patients of all ages and can produce several standard diagnostic sequences, including T1-weighted, T2-weighted, Fluid-Attenuated Inversion Recovery (FLAIR), and Diffusion-Weighted Imaging (DWI) with an Apparent Diffusion Coefficient (ADC) map. This multi-sequence capability is a key differentiator.

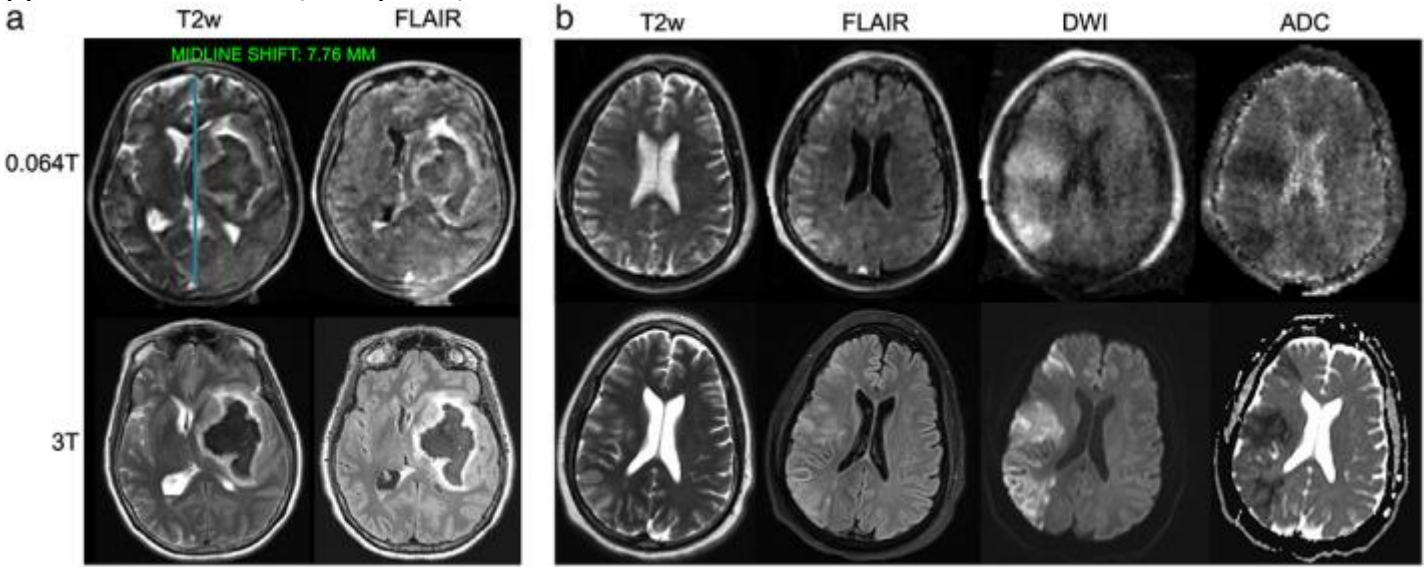
However, weighing 635kg, Swoop's portability is more theoretical than practical – restricting it largely to intra-ward settings. Scan times average around 30 minutes, which is a significant improvement over the multi-hour process of transporting a patient to a fixed MRI but remains a considerable time commitment, especially in consideration of stroke triage and the ED applicability.

Figure 18: Hyperfine swoop. Source: Hyperfine website.

Clinically, it provides structural images suitable for detecting significant strokes and hydrocephalus but struggles with subtle pathologies, such as small haemorrhages under 1mL. These limitations are reiterated in the published clinical literature: a pivotal study published in *Science Advances* – "Portable, low-field magnetic resonance imaging enables highly accessible and dynamic bedside evaluation of ischemic stroke" – involving 50 confirmed ischaemic stroke patients reported 90% sensitivity. However, in the 5 patients incorrectly diagnosed, infarct sizes were as large as 10mm (as captured on high-field MRI DWI sequences). For reference, small-vessel occlusion ischaemic strokes ("lacunar infarcts") are often 10mm. A study *Nature Communications* – "Portable, bedside, low-field magnetic resonance imaging for evaluation of intracerebral haemorrhage" – found that Swoop correctly detected intracerebral haemorrhage in 45 of 56 cases, yielding a sensitivity of 80.4%. A key technological limitation is that the system currently lacks vessel imaging (angiography) and dedicated haemorrhage-sensitive sequences like susceptibility-weighted imaging, which are standard components of a conventional stroke workup.

The capital cost is estimated at US$250,000, which is significantly less than conventional MRI (routinely above US$1.5 million), but higher than the US$175k anticipated launch price of emu™. The key question in this competitive dynamic is: will the reliance on traditional imaging modalities adapt when a fit-for-purpose alternative becomes available? While Swoop's commercial availability gives it a head start, its physical heft and clinical limitations leave ample room for emu™'s radically lighter and more agile solution. We assert that emu™ provides a superior value proposition for both triage (ED) and neuromonitoring (ICU).

Figure 19: Comparison of low-field (0.064T) and high-field (3T) MRI in patients with brain pathology (a) and healthy individuals (b). Source: Weizman et al., *Sci Rep.* 2022;12:22284.



Panel (a) shows T2-weighted and FLAIR images demonstrating a brain lesion with associated midline shift (7.76 mm) at both 0.064T and 3T field strengths. Panel (b) displays T2w, FLAIR, DWI, and ADC sequences in a healthy subject, again comparing 0.064T (top row) and 3T (bottom row). Notably, the image clarity and contrast are substantially higher at 3T, with improved delineation of anatomical structures and pathology. This superior resolution at 3T significantly enhances diagnostic confidence and the ability to detect and characterize subtle or early abnormalities.

CT on Wheels

While portable MRI represents a novel approach, the more established competitors in point-of-care imaging are the portable CT (pCT) scanner manufacturers. Companies like Siemens Healthineers (SOMATOM On.site), Samsung subsidiary NeuroLogica (OmniTom and CereTom), and Xoran Technologies (xCAT) have developed CT scanners that can be brought directly to the patient's bedside in the ICU, ED, or operating room.

These devices are true mobile CT scanners, offering the gold standard in neuroimaging for acute stroke. They can perform not just non-contrast head CTs to rule out hemorrhage, but also advanced imaging like CT Angiography (CTA) and CT Perfusion (CTP). The Siemens SOMATOM On.site, for example, delivers image quality comparable to stationary scanners and features a unique self-shielded, telescopic gantry to minimize radiation exposure to nearby staff and patients. Similarly, NeuroLogica's OmniTom Elite is a 16-slice, battery-powered unit that can be moved throughout the hospital and charged from a standard wall outlet.

The primary value proposition of portable CT is the elimination of risky and time-consuming intrahospital transport. This directly addresses a major bottleneck in critical care, allowing for rapid diagnosis of neurological emergencies at the bedside. These systems are already deployed in hospitals and are a direct competitor to any new point-of-care diagnostic device. However, their fundamental limitation is the use of ionizing radiation. This makes them ideal for a one-off, definitive diagnostic scan but entirely unsuitable for the high-frequency, routine monitoring that constitutes Emu™'s core value proposition. A clinician would not order a CT scan every six hours on a post-operative patient due to radiation concerns, but this is precisely the use case Emu™ is designed to fill.

EMV's Positioning

EMVision's Emu™ is positioned not as a direct competitor to Swoop on image quality, but as the creator of a new clinical capability: (i) rapid triage for stroke in ED and (ii) routine, high-frequency neurological monitoring. This approach targets distinct and arguably more pervasive problems in diagnosis and critical care.

In ED, Emu™'s ability to provide a "bleed or no bleed" answer in minutes (with 92% sensitivity and 85% specificity per pilot data) allows the stroke team to move from a reactive to a proactive stance, preparing tPA or neurosurgery pathways long before the confirmatory CT is complete. A portable CT offers a definitive answer but still involves radiation and may be a shared resource. Moreover, at over 700kg, just because a CT is put on wheels doesn't make it "portable". Moreover, Mobile CT/MRI units tend to sit around hospitals like paper weights due to lack of radiographer availability. Swoop, with its ~30-minute scan time, is less suited for this initial, rapid-fire triage role where every minute counts.

The clinical need for Emu™ in ICU is clearly defined: to overcome the "Sedation Paradox", where intubated patients cannot be serially examined, and to eliminate the significant clinical and logistical risks of intrahospital transport for conventional imaging. Emu™'s key attributes – speed (scans in minutes), safety (no ionizing radiation or strong magnetic fields), and portability (a form factor akin to a cart-based ultrasound) – are purpose-built for this monitoring use case. This enables a screening cadence, such as a scan every six hours for a post-cardiac surgery patient, that is simply impossible to achieve with any MRI or CT technology, portable or otherwise. By enabling routine surveillance, Emu™ has the potential to prevent a small number of the catastrophic, high-cost secondary events, which could generate immense savings in long-term care, rehabilitation, and ICU length of stay. This represents a more complex but potentially much larger health-economic argument for adoption.

It's worth noting that these devices are not necessarily mutually exclusive: a large, comprehensive stroke center could justify owning all three. However, for hospitals prioritizing workflow efficiency, proactive surveillance, and rapid, radiation-free ED triage, Emu™ presents a unique and compelling value proposition.

Figure 20: Comparative overview of portable neuroimaging technologies across key operational and clinical dimensions. Source: Internal analysis, incorporating manufacturer specifications and market data.

Feature	EMVision Emu™	Hyperfine Swoop	Portable CT (e.g., SOMATOM On.site)
Technology	Electromagnetic Imaging	Ultra-Low-Field (0.064T) MRI	Computed Tomography (X-ray)
Primary Use Case	Rapid Triage, Patient Management & High-Frequency Monitoring	Preliminary Bedside Diagnosis	Definitive Bedside Diagnosis
Diagnostic Output	Bleed/No-Bleed, Clot/No-Clot	T1, T2, FLAIR, DWI sequences	High-resolution anatomical images (CT, CTA, CTP)
Speed (Scan Acquisition)	< 5 minutes	~30 minutes	< 5 minutes
Safety Profile	No ionizing radiation	No ionizing radiation, low magnetic field (5-gauss line)	Ionizing radiation, requires shielding
Physical Footprint	Ultrasound-cart size	~630 kg, requires clear pathway	Wheeled, self-propelled units, typically > 700kg
Capital Cost (Est.)	~US$175,000	~US$250,000	Varies, generally higher than pMRI at > US$1m

Inadequacies of Prehospital Stroke Diagnostics

Diagnostic Blindness – The Failure of Clinical Scales

In the absence of imaging, paramedics are forced to rely on a variety of clinical assessment scales to identify potential stroke victims. These include the Cincinnati Prehospital Stroke Scale (CPSS/FAST), the Los Angeles Motor Scale (LAMS), the Rapid Arterial Occlusion Evaluation Scale (RACE), and the Vision, Aphasia, Neglect (VAN)

assessment. While simple and rapid to administer, their diagnostic performance is highly variable and often suboptimal.

For example, the Cincinnati Pre-hospital Stroke Scale (CPSS) is a three-point, yes/no screen that asks paramedics to look for facial droop, arm drift and slurred speech; if any one sign is abnormal the patient is tagged "stroke-positive." That simplicity makes it fast (<30 seconds) and reasonably sensitive (~75-90% for typical anterior-circulation events), yet the very same minimalism exposes its flaws. CPSS all but ignores posterior-circulation red flags (ataxia, vertigo, diplopia), so recognition of those strokes can plunge below 35%. It offers no severity gradation or large-vessel-occlusion prediction, leaving paramedics blind to which patients need direct routing to a thrombectomy hub. Specificity swings wildly – from ~60% when one sign triggers activation to >90 % when all three are required – fuelling costly over-triage or, conversely, missed cases. Performance is also operator- and language-dependent, degrades without regular training, and has never been validated for paediatrics or transient ischaemic attack. In short, while CPSS (and similar mnemonics) brought stroke triage into the ambulance, its binary, anterior-centric design is no longer fit for purpose in an era that demands rapid, high-precision classification to unlock reperfusion therapies.

Multiple studies have highlighted the deficiencies of scales. A study comparing 7 scales in patients with suspected stroke found sensitivities ranging from a low of 38% for the LAMS to a high of 84% for MedPACS, with specificities hovering in a poor 28-34% range for most scales. Given that differentiating stroke vs non-stroke, and haemorrhagic vs ischaemic is of critical importance, scales in isolation are not sufficient to inform effective triage, transfer and certainly not treatment decision making.

MSUs – The Status Quo

The limited diagnostic utility of scales is bettered by the mobile stroke unit (MSU). MSUs are specialized ambulances equipped designed to facilitate immediate, comprehensive, stroke evaluation and treatment at the patient's location – a "mini ED on wheels". They are equipped with CT, lab testing equipment and telemedicine technology, allowing for real-time consultations with remote stroke specialists. A typical MSU team consists of paramedics, a stroke physician, and a neuroradiologist or radiographer.

The primary advantage of MSUs is their ability to drastically reduce the time from symptom onset to definitive diagnosis and treatment. MSUs achieve this by collapsing the traditional sequential steps of conventional stroke management (prehospital transport, hospital arrival, in-hospital diagnosis, treatment) into a single, integrated prehospital process.

- Diagnosis Time: for intracerebral hemorrhage (ICH) patients, brain imaging and diagnosis were performed in a median of 39 minutes after MSU dispatch, compared to 57 minutes with conventional ambulance transport, an 18-minute reduction.

- Therapy Decision: a randomized controlled trial showed that MSUs reduced the median time from emergency alarm to therapy decision by 41 minutes (35 minutes for MSU vs. 76 minutes for control).

- tPA Administration: MSUs are associated with a median reduction of 31 minutes in onset-to-intravenous thrombolysis (IVT) times compared to usual care. The BEST-MSU trial reported a median time of 72 minutes for tPA administration in the MSU group versus 108 minutes in the EMS group, a 36-minute reduction.

- "Golden Hour" Treatment: MSUs significantly increase the proportion of patients receiving tPA within the critical "golden hour" (60 minutes of symptom onset). The PHANTOM-S study observed a 6-fold higher rate (31.0% with MSU vs. 4.9% with conventional care), and the BEST-MSU data showed a 10-fold increase (33% with MSU vs. 3% with conventional EMS). Overall, tPA administration rates are higher with MSUs (33% vs. 21% for usual care).

The expedited care provided by MSUs directly translates to superior clinical outcomes. MSU use is associated with an approximately 65% increase in the odds of achieving an excellent outcome (Modified Rankine Scale (mRS) score of 0 to 1 at 90 days). The BEST-MSU trial reported that 55.0% of MSU patients achieved an mRS score of 0-1 at 90 days, compared to 44.4% in the EMS group. An Australian meta-analysis found MSU patients had more than double the odds of achieving non-disability (mRS 0-1) within 90-180 days post-stroke. The same study also reported the MSU group halved the mortality rate.

While establishing and operating an MSU involves significant initial investment, robust analyses demonstrate their cost effectiveness. An MSU program can cost approximately A$1.5 million to launch and A$0.8 to A$1.5 million per annum to run. However, this upfront expenditure is offset by substantial reductions in downstream stroke-related healthcare costs, primarily due to fewer rehospitalizations, decreased long-term acute care visits, and reduced reliance on nursing facility services. Studies show an incremental cost-effectiveness ratio (ICER) of US$33,537 per quality-adjusted life year (QALY), which is well below the commonly accepted US willingness-to-pay threshold. The economic efficiency improves with a higher volume of patients treated annually. MSUs also contribute to cost-effectiveness by accurately diagnosing "stroke mimic" patients, preventing unnecessary hospital admissions and diagnostic tests.

EMVision is posed to be a disruptor: the First Responder device is engineered to resolve the accuracy-versus-portability dilemma. The custom-built, reinforced ambulances required for an MSU house 500+ kilogram CT machines and a power generator, adding weight and cost. For dense urban environments, MSUs seem rather impractical; for remote areas, they are entirely infeasible. Both First Responder and emu™ are positioned to address the critical issues. First Responder is approximately 12kg, making it suitable for deployment, via a backpack, in any standard ambulance or aeromedical service.

The Next-Generation CT Challenger: Micro-X

While most innovation has focused on non-radiation-based technologies to solve the MSU scalability problem, ASX-listing company Micro-X is tackling the issue by fundamentally redesigning the CT scanner itself. Micro-X is developing a lightweight, mobile head CT scanner that weighs only 70kg (154 lbs). This dramatic size and weight reduction is achieved by replacing the traditional, heavy rotating gantry with an array of miniature, stationary x-ray tubes that fire sequentially. The company's goal is to create a scanner compact enough to fit into standard road and air ambulances, delivering diagnostic-quality CT imaging to determine stroke type before reaching the hospital. This directly addresses the cost and complexity barriers of current MSUs, positioning it as a direct competitor to EMVision's First Responder in the race to create a scalable pre-hospital diagnostic solution.

Figure 21: Micro-x's Head CT. Source: Micro-x website.

Micro-X is at an earlier stage of development, with plans to commence human clinical trials in Australia in 2025. While its approach could solve the scalability problem, it still relies on ionizing radiation. This remains a key differentiator for EMVision's First

Responder, which is radiation-free. Moreover, a major limitation of Head CT is that it would theoretically require a radiographer in every ambulance to operate it, However, if Micro-X can deliver on its promise of a truly portable, affordable CT scanner, it would represent a significant competitive threat by offering the existing gold-standard imaging modality in a scalable format.

Electromagnetic Competition: Medfield Diagnostics
Previously considered the most advanced direct competitor, this Swedish company developed the Strokefinder, a microwave-based device using an eight-antenna array to differentiate stroke types. The technology was undergoing a significant and closely watched pre-hospital trial with NSW Ambulance in Australia, the first of its kind globally. Earlier hospital-based studies had shown promising but mixed results; one study reported 100% sensitivity for detecting chronic subdural hematomas but at the cost of 25% false positives (75% specificity), while another noted accuracy over 90% for hemorrhagic stroke but a lower accuracy of around 65% for ischemic stroke. However, Medfield Diagnostics filed for bankruptcy in June 2024. This event has effectively removed a primary competitor from the landscape, creating a clearer path to market for EMVision. The company's closure leaves the future of its technology and the final outcomes of its trials uncertain, removing what was anticipated to be a major clinical benchmark for the pre-hospital microwave imaging category.

Alternative Approaches: Answering a Different Question
A critical distinction in the pre-hospital market is that not all triage tools are created equal because they answer different clinical questions. Several technologies are focused solely on detecting Large Vessel Occlusion (LVO), which is a secondary, albeit important, part of the diagnostic puzzle.

- **EEG-based Triage (TrianecT StrokePointer):** Developed from the AI-STROKE project in Amsterdam, this technology uses a dry-electrode EEG cap and AI to detect brain activity patterns indicative of an LVO stroke. However, EEG is fundamentally incapable of differentiating an ischemic stroke from a hemorrhagic one. A paramedic using this device would still not know if it is safe to administer thrombolytic therapy. Its sole function is to guide transport decisions to a thrombectomy-capable center.

- **Blood-based Biomarkers (ABCDx LVOCheck):** This Swiss startup is developing a point-of-care lateral flow test that measures blood biomarkers (e.g., H-FABP, NT-proBNP) to identify LVO strokes in under 15 minutes from a finger prick. Like EEG, this is an LVO detection tool that provides no information on the presence of a bleed, making it insufficient as a standalone pre-hospital diagnostic solution.

There is a clear hierarchy of needs in pre-hospital stroke diagnosis. The primary, non-negotiable decision point is the differentiation of haemorrhagic versus ischaemic stroke, as this determines eligibility for thrombolysis. The secondary decision point is the detection of LVO in ischemic patients to guide transport. Technologies like EEG and biomarkers only address the secondary question, providing a piece of the puzzle but failing to solve the core diagnostic dilemma. EMVision's First Responder, by aiming to answer the primary "bleed vs not" and “clot vs not” questions, is positioned to be a more fundamental and indispensable tool, placing it higher in the clinical value chain.

The Investor Verdict: A Scalable Solution to the Right Question
The pre-hospital market is not a race to simply provide any data, but to provide the right data in a scalable format. The MSU model proved the clinical value of getting the right data (a CT scan) but failed on scalability due to its immense cost. LVO detectors are potentially scalable but provide incomplete data.

EMVision's First Responder is positioned at the intersection of clinical relevance, safety, and economic scalability. It aims to answer the most critical pre-hospital question ("bleed or no bleed?") at a price point (~US$60-70k) that allows for mass deployment in

existing ambulance fleets. Its radiation-free technology offers a significant safety advantage over CT-based solutions. Emerging competitors like Micro-X are also targeting the scalability problem with innovative CT technology, but they remain in earlier development stages and cannot mitigate the inherent issue of ionizing radiation. EMVision's combination of solving the right problem with a safe and economically viable solution gives it a clear path to widespread commercial adoption and market leadership in the pre-hospital diagnostic space.

Figure 22: Competitive landscape of pre-hospital stroke diagnostic technologies. Various sources.

Technology	Company (Product)	Diagnostic Goal	Key Advantage	Key Limitation/Risk
Electromagnetic Imaging	EMVision (First Responder)	Differentiate Bleed vs. Clot	Answers the primary clinical question; scalable; radiation-free	Clinical accuracy in pre-hospital setting not yet proven in a large-scale trial
Microwave Imaging	Medfield (Strokefinder)	Differentiate Bleed vs. Clot	First-mover in pre-hospital trials, setting the benchmark	Early data suggests lower accuracy for ischemic stroke; trial results pending
Next-Gen Portable CT	Micro-X (Head CT)	Differentiate Bleed vs. Clot	Gold-standard imaging in a potentially scalable format	Early stage of development; uses ionizing radiation
EEG	TrianecT (StrokePointer)	Detect LVO	Potentially very fast and low-cost	Cannot rule out haemorrhage; addresses a secondary clinical question
Biomarker	ABCDx (LVOCheck)	Detect LVO	Simple, finger-prick test	Cannot rule out haemorrhage; requires validation in large trials
Mobile CT	Mobile Stroke Unit (MSU)	Full CT/CTA diagnosis	Gold-standard imaging	Prohibitively expensive and complex; not scalable

Tailwinds

Regulatory Accelerants

Expedited FDA Clearance Pathways

Emvision may be eligible for Breakthrough Device Designation, a program offering priority FDA review and intensive guidance, accelerating time-to-market for devices that address life-threatening conditions like stroke. To qualify, devices must meet two criteria: first, they must provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions; second, they must represent breakthrough technology, have no approved alternatives, offer significant advantages over existing alternatives, or their availability must be in the best interest of patients. Currently, the average review time for breakthrough devices seeking de Novo classification is 312 days versus 390 days for standard reviews. While not attained as of yet, we anticipate EMVision's emu™ and First Responder Devices will be eligible.

In 2024, CMS established the TCET (Transitional Coverage for Emerging Technologies) pathway, a program specifically designed to accelerate patient access to beneficial medical products while health economic data is being generated. The pathway is limited to certain Breathrough devices and can accommodate up to five devices annually. Under TCET, CMS will fast-track national coverage determinations (NCDs), aiming to finalize coverage within 6 months of FDA approval. This greatly reduces the reimbursement lag that historically plagued new devices.

CMS Payment Reforms

Medicare has also revised payment rules to incentivise innovative device development. For inpatient settings. New Technology Add-On Payments (NTAP) no longer require upfront evidence of 'substantial clinical improvement' for Breakthrough devices: a 2-year waiver of that criterion allows companies to gather real-world data post launch of

product. For EMVision, emu™ could immediately qualify for NTAP, providing up to 65% add-on payment of its cost to hospitals. This represents a fundamental shift in reimbursement policy that is highly favourable to EMVision should a future Breakthrough designation be obtained.

In outpatient settings under the Hospital Outpatient Prospective Payment System (OPPS), CMS created a similar pass-through payment pathway. Breakthrough devices are deemed “new and not substantially similar” to existing technologies, thereby automatically meeting key criteria for temporary additional payments. When Emu™ is FDA-cleared, hospitals can get extra Medicare reimbursement for using the device, lowering financial barriers to adoption. Notably, CMS has never denied a Breakthrough-designated device’s application for add-on payments to date, while only approving 26% in traditional pathway applications.

Breakthrough device designation would be transformative for EMVision.

Streamlined Australian Pathways

The TGA offers a Priority Review Pathway for breakthrough devices, analogous to the FDA program. EMVision can seek “priority determination” to jump to the front of the queue for Australian approval since Emu™ targets an unmet need with novel technology. Notably, if EMVision secures FDA or CE approval, the TGA can leverage those reviews (via comparable overseas regulator mechanisms) to fast-track Australian market entry. Additionally, Australian R&D incentives have de-risked development: EMVision received nearly A$3M in cash rebates last year under Australia’s 43.5% R&D Tax Incentive.

Favourable Reimbursement Dynamics

The foundational economic argument for EMVision's technology is rooted in a simple, brutal reality: the downstream costs of stroke-related disability create a powerful, system-wide incentive for payers and providers to invest in upfront diagnostic technologies that can mitigate these long-term burdens. This is not about a simple fee-for-service transaction but a strategic investment in cost avoidance. The purchase of a US$175,000 Emu™ scanner is not merely a capital outlay; it is an insurance policy against the multi-hundred-thousand-dollar lifetime cost of a severely disabled stroke survivor. The financial calculus shifts from "How much does the device cost?" to "How much does it save?". By enabling faster diagnosis and treatment, the technology directly interrupts the cascade of events that leads from acute injury to chronic disability and its associated economic devastation. This powerful incentive to shift spending from expensive, long-term chronic care to effective, upfront acute intervention forms the bedrock of the reimbursement case for EMVision.

CPT Code Reimbursement

EMVision is likely to pursue a novel Current Procedural Terminology (CPT) code, initially a category III code. These codes are specifically designed for new and emerging technologies to allow for data collection and assessment while they are being integrated into clinical practice. Securing a Category III code is a critical milestone for several reasons. First, it establishes a formal mechanism for hospitals to bill for the procedure, moving it out of the unlisted, unbillable category. Second, it allows for the systematic tracking of the technology's utilization, which is essential data for demonstrating widespread use to payers. While payment under a Category III code is at the discretion of individual Medicare contractors and private payers and does not have a nationally set fee schedule, its existence is the necessary first step toward permanent reimbursement. The application process for a Category III code has a lower evidence threshold and a faster review cycle than for a permanent code, making it an ideal entry point for an innovative technology like emu™.

EMVision can leverage the accumulated evidence of clinical use, safety, and efficacy to apply for a permanent Category I CPT code. A Category I code signifies that the American Medical Association (AMA) CPT Editorial Panel recognizes the procedure as a

well-established standard of care, performed by numerous professionals across the country. Achieving Category I status is the ultimate goal, as it establishes a unique, permanent code with a nationally recognized payment rate under the Medicare Physician Fee Schedule, ensuring predictable and consistent reimbursement for providers.

This "category creation" strategy would stand in stark contrast to the approach taken by competitors like Hyperfine, which utilizes the existing CPT code 70551 for its *Swoop* portable MRI scanner – a code for a standard brain MRI without contrast. By seeking a new code, EMVision is not asking payers, "Is this as good as a CT or MRI?" Instead, it is asking, "What is the value of a new procedure that can be performed in minutes at the bedside, without radiation, and with the frequency required for effective monitoring?" This reframes the value proposition entirely. While using an existing code like Hyperfine does may offer a faster path to initial billing, it forces a direct comparison on metrics like image quality and resolution, where a low-field MRI may be at a disadvantage against conventional high-field systems.

Aligning Emu™ with Hospital Financial Imperatives

In the modern US healthcare landscape, a device's value is measured less by the fee generated for its use and more by its impact on the total episode-of-care costs and quality metrics. Emu™ is perfectly aligned with the financial incentives of value-based care (VBC), making it a strategic asset for hospitals, not just a line-item expense.

The healthcare system is undergoing a fundamental shift away from traditional fee-for-service payment, which rewards volume, toward VBC models like Accountable Care Organizations (ACOs) and bundled payments. In these models, provider organizations are held financially accountable for both the quality and the total cost of care for a patient or population. They are rewarded with shared savings for delivering high-quality, efficient care and penalized for poor outcomes, costly complications, and readmissions.

Take the example of frequent post-operative neurological monitoring checks in ICU using emu™. This function allows for detection of neurological deterioration early, allowing for intervention that prevents catastrophic outcomes. This directly avoids the immense costs of extended ICU stays, complex follow-on care, and long-term disability – costs that are borne by the hospital under VBC arrangements. Furthermore, by improving stroke care and preventing secondary injuries, the device helps lower 30-day readmission rates, a critical quality metric tied to significant financial penalties and rewards.

The financial case for the Emu™ is therefore exponentially stronger for a hospital operating under a risk-based or VBC contract. In a fee-for-service world, the purchasing decision is a simple transaction: Revenue (CPT code) - Cost (device + consumables). In a value-based world, the equation becomes: Revenue (CPT code) + Shared Savings (from lower total costs) + Avoided Penalties (for readmissions/complications) - Cost (device + consumables). The "Shared Savings" and "Avoided Penalties" components can easily dwarf the direct CPT reimbursement. Preventing a single severe post-operative stroke could save a hospital hundreds of thousands of dollars in an episode of care, a saving in which the hospital shares. This transforms the Emu™ from a potential cost center into a profit-driving, risk-mitigation tool, fundamentally changing the purchasing calculus for hospital administration.

Figure 23: US reimbursement mechanisms relevant to EMVision's deployment in hospital settings. Source: various sources.

Mechanism	System	Use Case	Purpose	Financial Impact for Hospital
Category III CPT Code	AMA	ED & ICU	Track emerging tech, enable billing, collect data for Cat I	Discretionary payment; enables billing but revenue is uncertain.
Category I CPT Code	AMA	ED & ICU	Standard of care, permanent code	Established, predictable national payment rate.
NTAP	Medicare IPPS	ICU	Subsidize cost of new inpatient tech	Up to 65% add-on payment, de-risks capital purchase.
Transitional Pass-Through	Medicare OPPS	ED	Subsidize cost of new outpatient tech	Additional payment to cover device cost above APC rate, de-risks use in ED.
Value-Based Incentives	CMS / Private Payers	ED & ICU	Reward quality and cost reduction	Shared savings and avoided penalties from better outcomes, reduced LOS, and fewer complications.

Unlocking New Payment Models: First Responder & the ET3 Precedent

The CMS Emergency Triage, Treat, and Transport (ET3) model, despite its early termination in 2023, serves as a critical precedent and a roadmap for the future of EMS reimbursement. This voluntary payment model was designed to break the mould of fee-for-transport by creating new payment mechanisms for two key interventions: (i) transport to an alternative destination (TAD), such as an urgent care clinic or physician's office, and (ii) treatment in place (TIP), often facilitated by a telehealth consultation. The explicit goal was to improve quality and lower Medicare costs by avoiding unnecessary, high-cost ED visits for low-acuity conditions. The model's final evaluation report validated this premise, finding an average savings of over $500 per intervention compared to an ED visit.

The model was ultimately ended due to lower-than-expected participation and intervention volume. This outcome was not a failure of the payment concept but a reflection of a critical missing component: diagnostic certainty. ET3 created the billing codes and payment pathways but failed to address the core clinical barrier for paramedics on the front line: the fear of incorrectly triaging a serious condition like a stroke without definitive diagnostic information. Faced with an ambiguous clinical presentation and armed only with imprecise clinical scales, a paramedic faces immense potential liability for a decision to treat-in-place or transport to a lower-acuity facility. The default, safe, and legally defensible decision is always to transport to the ED. This diagnostic uncertainty was a primary driver of the low utilization of the TIP and TAD pathways, preventing the model from generating sufficient volume and data.

The First Responder device could well have been the missing technological key that solved this problem. Imagine the same scenario, but the paramedic is equipped with the First Responder. A quick scan provides an objective data point: "no bleed." This information is relayed to the remote telehealth physician. Suddenly, the decision to treat a presumed stroke mimic or other low-acuity condition in place is no longer a guess based on subjective symptoms; it is a data-driven clinical judgment. This dramatically reduces clinical risk and liability, empowering the EMS team to confidently use the alternative payment pathways that CMS has already demonstrated a clear willingness to create and fund. The First Responder is the enabling technology that makes future ET3-like models clinically safe and therefore economically viable and scalable.

Precedent Approvals Supporting Smaller Form-Factor Imaging

Hyperfine's Swoop portable MRI system received its first FDA clearance in 2020 and CE Mark certification (for Europe) in 2023. Swoop is the first portable MRI scanner and is used for neuroimaging at bedside. In mid-2024, the Positrigo's NeuroLF ultra-compact brain PET scanner received FDA clearance. This system allows patients to be scanned in a seated position rather than a whole-body PET tunnel. These approvals underscore a regulatory willingness to approve smaller, targeted imaging systems focused on a single organ. NeuroLF also received CE Mark certification following FDA clearance. See the "Competition" section of this report for more in-depth analysis on these devices, but, in

essence, if a seated PET device can pass muster, a lightweight microwave-based scanner should likewise be approvable provided clinical performance and reliability can be demonstrated.

Public Sector Funding & Support

EMVision has already tapped significant non-dilutive funding at home, with A$25m in non-dilutive funding secured since inception. The company was awarded a A$5 million federal government grant under the modern manufacturing initiative (MMI) to establish production of emu™. This grant validates the government's support for local medtech manufacturing and specifically recognizes EMVision's technology as strategically important. Moreover, in June this year, the Company was awarded an Australian Government Industry Growth Program (IGP) Commercialisation and Growth Grant of $5 million. It provides non-dilutive funding to accelerate the global commercialisation of the First Responder device. Grant payments are being paid quarterly in advanced, based on forecast eligible expenditure, adjusted for unspent amounts from previous payments.

EMVision is also a core partner in the Australian Stroke Alliance, a consortium that in 2021 won a landmark A$40m grant from the Medical Research Future Fund's Frontier Health Program. Through this, EMVision has received roughly A$8m, funding R&D. Such government backing not only provides capital but also serves as an external endorsement (making future grant or contract applications more credible).

Looking ahead, EMVision's technology aligns with priorities of major funding agencies abroad. For example, the US Department of Defense (DARPA and military medical research programs) has interest in portable diagnostics for battlefield and austere environments – a portable brain scanner for traumatic brain injury in the field could attract DoD grants or procurement. The Biomedical Advanced Research and Development Authority (BARDA) and NIH have also funded projects in emergency and point-of-care imaging in the past (e.g. portable ultrasound initiatives); a case could be made for stroke being a public health emergency where earlier diagnosis improves outcomes. In Europe, Horizon Europe and country-level innovation grants (like the EU EIC Accelerator or Germany's healthcare innovation funds) are potential sources, especially since EMVision would help address stroke care disparities, a noted EU focus.

While not yet realized, these represent *optionality*: EMVision may be eligible to compete for or partner on such grants given the emu™ and First Responder compelling use-cases. Any future public-sector awards would further propel validation and adoption – for instance, a US NIH-funded study could accelerate FDA clearance of expanded indications and payer acceptance.

Structural & Societal Tailwinds

Rural Healthcare Access Initiatives

Both in the US and Australia, there is a policy drive to close urban-rural healthcare gaps. Stroke care, as outlined in the "Delayed Diagnosis, Irreversible Damage" section of this report, is a prime example: patients in remote areas suffer worse outcomes due to lesser diagnostic and treatment capabilities. EMVision will directly address this gap, initially with Emu™ placed in small rural centres, and then with the First Responder device perfect for ambulance and aeroplane. In the US, some states and CMS programs provide bonus payments or infrastructure funds for telestroke and mobile stroke unit (MSU) programs.

CMS has become a powerful enabler of telestroke and MSU programs in rural America, transforming the economics of early stroke care in precisely the settings where EMVision's devices are most valuable. Following legislative reforms such as the Bipartisan Budget Act of 2018, CMS eliminated geographic restrictions for acute-stroke telehealth, allowing rural hospitals, critical access facilities, and even MSUs to bill for specialist consults via a dedicated "G0" modifier. These sites also receive a facility-

originating fee for hosting the consult, creating direct reimbursement pathways for rural deployments. Critically, CMS explicitly recognises MSUs as eligible originating sites and supplements Medicare payments for rural ambulance transports by up to 22.6%, easing the capital burden of equipping vehicles with diagnostic technology. For rural hospitals operating under Method II, telehealth services attract 101% of cost, further boosting reimbursement. With telehealth waivers extended through at least 2025 and bipartisan support for permanent policy change, CMS is clearly incentivising decentralised, image-enabled stroke care. This structure creates a significant tailwind for EMVision: both Emu™ and the First Responder scanner align with CMS's operational and funding priorities, making them commercially viable solutions for underserved communities.

In Australia, this momentum is exemplified by the 30/60/90 National Stroke Targets, developed by the Australian Stroke Coalition and endorsed by leading national health bodies. These targets aim for: (i) door-to-needle thrombolysis within 60 minutes, (ii) door-to-puncture times for endovascular thrombectomy within 30 minutes (transfers) or 90 minutes (primary presenters), and (iii) access to certified stroke unit care for over 90% of stroke patients by 2030. Crucially, the action plan identifies the need for system-wide mapping of all hospitals into functional categories – from Comprehensive Stroke Centres to Telestroke-enabled hospitals – and explicitly promotes the use of telestroke, streamlined triage, and prehospital solutions to meet these access goals in regional and remote communities.

Decentralization & Hospital-at-Home

Governments' responses to the COVID-19 pandemic accelerated a paradigm shift toward decentralizing care – treating patients outside of crowded hospitals when safe to do so. The CMS created the "Acute Hospital Care at Home" waiver program, now adopted by 315+ hospitals across 37 states. The program brough diagnostics to the patient. In theory, the First Responder device could assess a suspected stroke patient at home rather than being rushed to a tertiary centre for CT. The continuing expansion of this program means there is growing reimbursement and operational support. DispatchHealth, for example, a company providing this service, carry 'in-home imaging' equipment as part of their acute care kits. Even beyond formal programs, the pandemic taught hospitals the value of bedside imaging as a means to avoid moving infectious or unstable patients. Emu™, which can be sanitized and moved from room to room, aligns with infection control and the patient-centric care trend that administrators now prioritise.

Aging Population & Stroke Burden

Demographic trends are increasing the addressable market for stroke diagnostics. Ageing populations across western countries correlates to increasing prevalence of stroke: stroke incidence rises sharply with age. This creates urgency for healthcare systems to improve stroke outcomes – a pressure coming from payors (to reduce long-term indirect costs) and from political bodies focused on elderly welfare. There is also growing public awareness and advocacy around stroke, for instance, the American Heart Association's goal to improve cardiovascular health, which includes improving stroke response times. These forces translate into a tailwind: stakeholders are seeking tools that can improve outcomes. Emu™'s ability to distinguish between stroke and non-stroke, ischaemic vs haemorrhagic at the point-of-care is the exact kind of innovation that can improve standard of care.

Headwinds

An investment thesis predicated on disruption must also acknowledge the formidable barriers to that disruption.

Translating Potential to Proof

The clinical utility of a point-of-care stroke diagnostic device is ultimately judged by its accuracy, particularly relative to the established gold standard regardless of workflow benefits. As discussed, the pilot study showed the algorithm achieved 92% sensitivity and 85% specificity for the detection of intracranial haemorrhage. Modern multi-detector CT scanners, when performed within 6 hours of headache onset, demonstrate a sensitivity of 98.7% and a specificity of 99.9% for ruling out aneurysmal subarachnoid haemorrhage. The performance of AI-augmented CT interpretation software is similarly high, with some systems achieving sensitivity of 98% and specificity of 99.7% for intracranial haemorrhage detection. Against this benchmark, EMVision's current performance presents two critical clinical challenges: the risk of false negatives and the disruption of false positives.

A 92% sensitivity implies a false-negative rate of 8%: for every 100 patients with haemorrhage, the device could fail to detect 8 of these. The consequence of such an error is catastrophic. Emergency physicians operate in a high-stakes environment where patient safety is paramount: a diagnostic tool with a meaningful risk of a catastrophic false negative would be deemed clinically intolerable for making a definitive treatment decision ahead of a confirmatory CT scan. This reality fundamentally challenges the device's most aggressive value proposition – enabling treatment initiation before a CT scan – and likely relegates it to a more modest role as a probabilistic triage or "early warning" tool, a less powerful and less compelling proposition for clinicians.

Conversely, a specificity of 85% implies a false-positive rate of 15%: for every 100 patients without a brain bleed, 15 would be incorrectly flagged as positive for haemorrhage. As this would immediately indicate the need for confirmatory CT, there are fewer downsides to false positives. The main issue would be the cost to the payor for the confirmatory CT. Regardless, a device that frequently "cries wolf" risks creating more diagnostic confusion and workflow friction than it resolves, which can quickly lead to alert fatigue and erode clinician trust, ultimately resulting in poor adoption.

Navigating Regulatory Pathways

The De Novo pathway, while offering a more streamlined process than a full Premarket Approval (PMA) application, is still a rigorous and time-consuming gauntlet. The average review time for a De Novo request by a breakthrough device is 312 days , and this clock can be stopped at any time if the FDA issues an "Additional Information" request, placing the submission on hold indefinitely while the company scrambles to address deficiencies, burning precious cash and time.

A note on BDT

While EMVision has not secured Breakthrough Device Designation for Emu™ nor First Responder as of yet, it's important to note that this label can be a double-edged sword. While it is a powerful tool for attracting investor attention and can facilitate more frequent communication with the FDA, it can also lead to increased agency scrutiny. Companies have reported that the enhanced interaction can result in FDA suggestions for more extensive clinical trials, larger patient cohorts, or additional documentation, potentially increasing the time and cost of development.

More importantly however, there is a significant "breakthrough mirage" to consider. Furthermore, there is a significant "breakthrough mirage" to consider. The designation itself is not a strong predictor of ultimate market authorization. As of June 2023, the FDA had granted 831 Breakthrough designations, but only 77 of these had translated into a marketing authorization – a conversion rate of less than 10%. This disparity suggests that while many devices show initial promise, they often fail to generate the required evidence during pivotal trials. Recent research has also raised concerns that some breakthrough-designated devices are authorized based on limited evidence, such as surrogate endpoints, with required post-market studies being frequently delayed or

failing to confirm clinical benefit. This creates a risk that even if EMVision achieves authorization, sophisticated payers and hospital Value Analysis Committees may discount the "Breakthrough" label and demand more robust, outcome-based evidence before granting reimbursement or purchasing the device.

The AI Generalizability Challenge

The diagnostic power of both the emu™ and First Responder devices is predicated on the performance of their AI-powered algorithms. A fundamental and well-documented challenge for all medical AI is generalizability – the ability of an algorithm trained on a specific dataset to maintain its performance when exposed to the "messy," heterogeneous data of the real world.

Emu™ will be operated by numerous users with varying levels of training and experience. It will be used on patients of diverse ages, body habitus, and clinical acuities, some of whom may be agitated or unable to remain still. While it is likely that the pilot and validation studies included scans in chaotic, fast-moving environments, the true utility and robustness of a medical AI system can only be ascertained through large-scale, prospective studies in real-world settings, where performance is often lower than in retrospective analyses. A significant drop-off in real-world performance would not only undermine the device's clinical utility but could also rapidly erode clinician trust.

Reimbursement Labyrinth

EMVision's ability to scale likely hinges on obtaining reimbursement across various jurisdictions. In the US, we expect the company to pursue a dedicated Cat III CPT code and leverage transitional add-on payments while working toward a permanent Cat I CPT code. This is a well-trodden path.

The initial step, securing a Category III CPT code, is designed to facilitate data collection for emerging technologies. However, these codes are explicitly temporary and do not have nationally assigned payment rates or relative value units (RVUs). Reimbursement is left to the discretion of local Medicare Administrative Contractors (MACs) and private payers, who are often reluctant to pay for services they deem experimental or lacking definitive evidence of clinical utility. A hospital purchasing a US$175,000 emu™ device faces significant financial risk if reimbursement for its use is uncertain or non-existent.

To bridge this gap, the Centers for Medicare & Medicaid Services (CMS) offers temporary add-on payments for qualifying new technologies: New Technology Add-on Payments (NTAP) for the inpatient setting and Transitional Pass-Through (TPT) payments for the outpatient setting. While these programs can significantly de-risk initial hospital adoption by providing supplemental reimbursement for 2 to 3 years, they are not a long-term solution. They are temporary by design, intended only to provide a financial bridge while the company gathers the real-world evidence needed to justify permanent reimbursement.

This creates the single greatest commercialization risk for EMVision: the "payment cliff." The ultimate goal is to convert the temporary Category III code to a permanent Category I code. However, this transition is notoriously difficult and has a low historical success rate. The CPT Editorial Panel requires robust evidence of widespread clinical use and proven efficacy to grant Category I status. If EMVision fails to achieve this conversion before its NTAP and TPT payments expire, hospitals will lose the supplemental reimbursement that made the device economically viable. This would effectively pull the financial rug out from under the company's commercial model, likely causing sales to collapse.

Value Analysis Committees & Protracted Sales Cycles

Selling high-dollar capital equipment into the hospital market is a notoriously long, complex, and resource-intensive process. Sales cycles for such equipment routinely average 12 to 24 months and can, in some cases, extend for years. This protracted

timeline means EMVision will be burning significant cash immediately after launch before recognizing meaningful revenue, placing further strain on financial runway.

The primary gatekeeper for new technology adoption in modern health systems is not the individual physician champion, but the multi-disciplinary Value Analysis Committee (VAC). These committees are comprised of clinicians, nurses, supply chain managers, financial analysts, and hospital administrators. Their mandate is to conduct a systematic, evidence-based evaluation of any new product to ensure it provides the highest standard of care at the lowest possible overall cost.

VACs are unmoved by marketing claims or even physician preference. They demand hard data. To gain approval, EMVision will need to assemble a comprehensive dossier of evidence of both clinical superiority and economic value relative to the existing standard of care. This requires a level of evidence that often goes far beyond what is needed for FDA clearance. The committee will scrutinize the pivotal trial data, but they will also demand a robust health economic analysis. EMVision will need to build a convincing financial model demonstrating that the US$175,000 investment in an emu™ device will generate a clear return for the hospital, through mechanisms such as reduced length of stay, prevention of costly complications, or improved workflow efficiency leading to lower labour costs.

Overcoming Institutional Inertia & Workflow Disruption

he intended use environments for EMVision's devices – the Emergency Department, ICU, and pre-hospital settings – are high-pressure, time-critical ecosystems that are notoriously resistant to changes that disrupt established, life-saving workflows.

The implementation of new technology in these settings faces a host of human-factor barriers, including the high cognitive load on already overworked staff, resistance to abandoning familiar techniques, insufficient time for training, and high employee turnover rates. The ED, in particular, is often characterized by overcrowding and staff burnout, making it a challenging environment for introducing novel tools.

This "last mile" adoption problem is a critical, non-financial headwind. A device that is perceived by nurses and physicians as being complex to set up, requiring cumbersome integration with the electronic health record (EHR), or generating ambiguous results that add to diagnostic uncertainty will not be used, regardless of its theoretical benefits. If emu™ is seen as an additional burden in the frantic first minutes of a "Code Stroke" activation, rather than a seamless and intuitive solution, it risks gathering dust in a corner. Therefore, EMVision’s success depends not only on technical merits, but equally, its ability to design a product and an implementation process that integrates flawlessly into the existing reality.

Forecasts & Market Model Assumptions

Regulatory Approval

Emu™

Critical to our valuation is forecasting the timeline to market entry. We anticipate EMVision will lodge an FDA de novo application for emu™ by the end of FY26 on the back of pivotal validation study finalisation in Q3 FY26 (early calendar year 2026). The company outline in recent marketing materials the study is expected to take 6 to 12 months; and commencement of the study was announced in late March 2025. We allow a quarter to ready final dossier materials for submission.

The De Novo pathway is specifically designed for novel medical devices that are low-to-moderate risk but have no existing, legally marketed predicate device to which they can

claim substantial equivalence. As the emu™ represents a new class of point-of-care electromagnetic brain imaging technology, it must undergo this process. The De Novo pathway involves a rigorous review of clinical performance data to establish a new device classification, ensuring both safety and effectiveness.

We anticipate TGA approval of emu™ will follow in FY28. The TGA's approval process for medical devices allows for the leveraging of assessments from comparable overseas regulators, with the FDA being a primary example. A successful De Novo clearance from the FDA provides a comprehensive dossier of clinical and technical evidence that can significantly streamline and de-risk the TGA application, as the Australian regulator can use the FDA's rigorous review to inform its own decision. This strong bearing often accelerates the local approval timeline.

First Responder

Following the successful De Novo clearance of the emu™, we forecast that the miniaturized First Responder device will achieve FDA clearance via the more streamlined 510(k) pathway. The 510(k) process does not require the same level of novel clinical data as a De Novo submission. Instead, its primary purpose is to demonstrate that a new device is "substantially equivalent" in terms of intended use, technological characteristics, and performance to a legally marketed predicate device.

emu™'s De Novo clearance is the critical enabler for this strategy. Once cleared, the emu™ itself becomes the predicate device. The First Responder, which utilizes the same core electromagnetic imaging technology for the same fundamental purpose of stroke classification, can then be submitted as a subsequent-generation device. This allows EMVision to leverage the emu™'s established safety and effectiveness profile, making the regulatory journey for the First Responder significantly faster and less capital-intensive. TGA approval is expected to follow shortly after the FDA's 510(k) clearance.

While other jurisdictions represent future opportunities, our forecasts focus exclusively on these initial core markets.

Commercialisation

US Market Entry

Following de Novo clearance, we model the full commercial launch of emu™ in the US commencing in FY28. Our model assumes the company will employ a direct sales strategy. While capital intensive (sales teams in multiple jurisdictions selling a novel device – a category often burdened with a long sales cycle and little early success). While capital-intensive, a direct sales approach allows EMV to control the commercial narrative, capture higher margins, and build direct relationships with key opinion leaders, which is essential for a disruptive technology.

A plausible alternative commercial pathway is the distribution partner model. After an initial period of direct selling (e.g. the first three years post-launch), EMVision could opt to partner with an established medical device distributor. This strategy would allow EMV to leverage the partner's extensive sales infrastructure, existing hospital relationships, and sophisticated distribution network. Such a partnership could potentially accelerate sales growth beyond what a nascent direct sales team could achieve independently.

However, this approach comes with a significant trade-off: margin compression. A distribution partner would command a substantial portion of the revenue, reducing EMVision's profitability on each unit sold. While this could be offset by higher sales volumes, it represents a fundamental shift in the business model's financial dynamics. Moreover, emu™ would be one of many devices the partner is contracted to sell. If emu™ sales are slow, the distributor’s sales team are disincentivised from pushing emu™ and would likely opt rather to push a different device in the portfolio. For these reasons, while we acknowledge a future distribution deal as a strategic possibility, our valuation remains conservatively based on the direct sales model, which the company is currently pursuing.

Other Jurisdictions

Following TGA approval in FY28, we anticipate a launch into Australia at the start of FY29. While a relatively small market in comparison to the US, we believe the company is incentivised to commercialise emu™ in Australia: the company can leverage the relationships built with key opinion leaders and hospitals fostered through Australian-based R&D; Australia suffers from a similar rural-urban disparity in stroke diagnostic access and stroke outcomes as the US.

While highly likely the Company pursues commercial launches on other jurisdictions, namely Europe, Canada and Japan, we omit this potential from our initial modelling: EMV is yet to conduct any development work in Europe, Canada and Japan. Additionally, we sought to refrain from over-speculating, and rather

Market Penetration: The S-Curve Adoption Model

To forecast the rate of market adoption for the Emu™ device, we employ a logistic growth model, commonly known as an S-curve. This is the standard framework for modelling the diffusion of new technologies into a market. It realistically captures the typical adoption lifecycle: a slow initial phase driven by innovators early adopters, followed by a steep acceleration as the technology gains mainstream acceptance, and finally a tapering of growth as the primary target market approaches saturation.

The specific shape of our projected adoption curve is defined by three key parameters:

- **10-Year Market Potential (L):** we assume that over the initial 10-year commercialisation wave, EMVision will achieve a peak market penetration of 35% of the Primary TAM (3,409 units) in the US and 35% of the primary TAM in Australia (312 units). We purposefully limit the scope of the 10-year market potential to the primary TAM in each of our two core markets: this segment, comprising advanced stroke centers (CSCs, PSCs) and underserved rural hospitals (CAHs), represents the most immediate and compelling use cases. Advanced centers have a critical need for high-frequency ICU monitoring to prevent costly secondary injuries, while rural hospitals require a rapid ED triage tool where no other imaging is available. This focus on the highest-need facilities is a pragmatic approach to initial market entry. Furthermore, as detailed in the TAM section, the high patient volumes and multiple critical care nodes (ED, Neuro-ICU, Stroke Ward) within a single CSC or PSC justify the purchase of multiple units per facility, forming the foundation of our market potential estimates.

  For First Responder, we calculate an L-figure differently. We apply a 15% potential to the Road Ambulance TAM and an 80% potential to the Air Ambulance TAM (collectively, L = 11,102 units). The bifurcated assumption for the First Responder reflects different adoption dynamics. The slow global uptake of Mobile Stroke Units (MSUs) over the last decade sets a precedent for caution in the road ambulance market. These environments operate on highly optimized, time-sensitive workflows, making them historically slower to adopt new technologies that may disrupt established protocols. In contrast, the aeromedical environment is more conducive to adoption. Longer transport times, the higher acuity of patients being airlifted, and a greater capacity to incorporate a new diagnostic step make the First Responder a more immediately impactful and justifiable investment for air ambulance fleets, supporting our higher 80% penetration assumption in that segment.

- **Growth Rate Coefficient (k):** this coefficient determine the steepness of the adoption curve once sales begin. We model a steep slope in the US for emu™ (k = 0.8), justified by the traditionally slow adoption of novel technologies (particularly given this is de novo rather than 510(k)) and then strong adoption after the initial slow period as (i) Emu™ delivers on its value proposition, enabling increasing visibility from potential buyers year on year, and (i)

advanced centres are pressured to adopt technologies that improve outcomes and efficiency.

A more gradual lope is assumed for the Australian emu™ market (k = 0.6), reflecting the smaller market size and potentially longer procurement cycles. A k-value results in a relatively larger number of 1st year sales. This is justified by the commercial launch and existing sales of emu™ in the US in the year prior resulting in market visibility in Australia. For the First Responder (k = 0.7), we assume a moderate growth rate between the two emu™ markets. This balances the clear clinical need, validated by the MSU model, against the significant operational challenges of training thousands of paramedics and integrating the device into established pre-hospital protocols.

- **Inflection Year (t_0):** This is the point of maximum adoption velocity, where sales growth is at its fastest. For the US and Australian emu™ markets, we model the inflection point in year 8 and 7, respectively. These timelines provide a realistic runway for the necessary catalysts of mainstream adoption: market seeding with early innovators, the publication of real-world clinical and health-economic data, and the initial inclusion of the technology in clinical guidelines.

  The inflection point for the First Responder is modelled to occur in Year 8 post-launch. Its adoption is heavily dependent on the prior success of the in-hospital emu™. Once the foundational technology is clinically validated, trusted by physicians, and has established reimbursement pathways, the case for its pre-hospital extension becomes significantly more compelling for EMS agencies and medical directors, triggering its accelerated uptake.

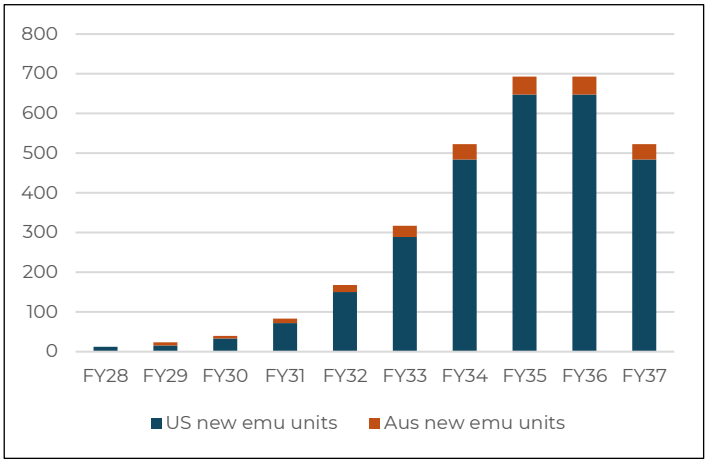
  The timing of these adoption curves, particularly the acceleration around years 6-8, is strategically aligned with the anticipated maturation of the reimbursement landscape. The transition from a temporary Category III CPT code to a permanent Category I code, which we anticipate around year 5, is a critical catalyst. A Category I code signifies that the technology is an established standard of care and, most importantly, provides hospitals with predictable, national reimbursement rates. This removes the financial uncertainty and perceived risk associated with the discretionary payments under a Category III code, thereby unlocking budget approvals and driving the widespread mainstream adoption reflected in our model's inflection points. This effect is visible in our forecasts, where new First Responder sales, for example, jump from 575 units in year 5 to 985 in year 6, and emu™ sales in the US show a similar rapid acceleration post-year 5.

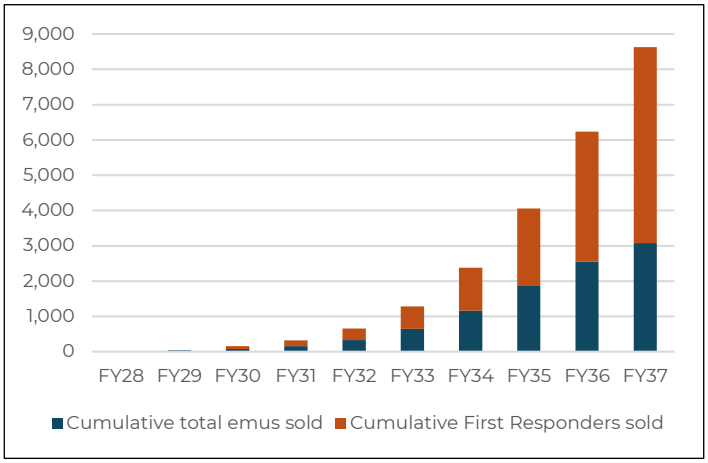
Cumulative units sold (y) in each category (e.g. emu™ sales in US) are calculated as the 10-year market potential divided by the exponent of negative growth coefficient x (current year minus inflection year):

$$y = {}^{L}/_{e^{-k(t-t_0)}}$$

Figure 24: Projected unit sales for EMVision's Emu™ and First Responder devices (FY28–FY37). Source: Evolution Capital's forecasts.

	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35	FY36	FY37
US new emu™ units	13	15	33	72	150	289	484	648	648	484
% of Primary Market 10yr potential	*0.4%*	*0.8%*	*1.8%*	*3.9%*	*8.3%*	*16.8%*	*31.0%*	*50.0%*	*69.0%*	*83.2%*
% of Total US TAM	*0.1%*	*0.2%*	*0.5%*	*1.0%*	*2.1%*	*4.2%*	*7.8%*	*12.6%*	*17.4%*	*21.0%*
Aus new emu™ units	0	8	6	11	18	28	38	45	45	38
Total new emu™ units	13	24	40	83	168	317	523	693	693	523
Cumulative total emu™s sold	**13**	**36**	**76**	**159**	**328**	**645**	**1,167**	**1,860**	**2,553**	**3,076**
First Responder new units			82	82	161	311	575	985	1488	1867
Cumulative First Responders sold			**82**	**164**	**325**	**636**	**1211**	**2196**	**3684**	**5551**
% of Primary Market 10yr potential			*0.7%*	*1.5%*	*2.9%*	*5.7%*	*10.9%*	*19.8%*	*33.2%*	*50.0%*
% of TAM			*0.1%*	*0.2%*	*0.4%*	*0.9%*	*1.6%*	*3.0%*	*5.0%*	*7.5%*





Pricing & Utilization

As per Company publicly disclosed guidance, we assume an initial launch price of emu™ in both the US and Australia at US$175,000 per unit. We forecast a price increase to US$185k in FY33 to account for inflation, the device's established value in the market, and the greater IRR required by EMVision as a result of continued R&D post-launch. We expect First Responder to be launched at US$60k per unit with a forecasted price increase to US$70k in FY33.

Recurring revenue is a key long-term value driver, directly tied to the growing installed base of devices.

- **Service contracts:** we model an annual service and maintenance fee of 10% of the unit's sale price. To account for rising service costs and value, a 2% annual price inflator is applied to these contracts. We model an 80% sale year service attachment rate (i.e. 80% of units purchased have a corresponding service contract purchased). To this, we apply a 7.5% service attachment growth rate, up to a peak service attachment rate of 95%. (i.e. in the subsequent year, 86% of the devices sold in the prior year will have an attaching service contract. In the year after that, 86% x 107.5% ≈ 92.5% of those devices will have an attaching service contract. The following year, 95% of those devices will be covered by service).

- **Consumables:** per Company guidance, we forecast consumables (e.g. single use, disposable head caps) per unit to be priced at US$25 for emu™ and US$50 for First Responder.

Scan volume drives consumables revenue. Our utilisation forecasts are built on a conservative, phased ramp-up per unit sale. In the US, we forecast that each emu™ will be used 200 times per year. This reflects the initial phase where hospitals are integrating the new technology into their clinical workflows. We forecast utilization to ramp up over 4 years to a peak of 450 scans per unit per annum. Each new device sold is used in year

1 of operation at the lower threshold to account for the likelihood that a new sale is to a hospital without an existing emu™ (and therefore there is an integration and adjustment period). This is supported by the TAM analysis under the section "Total Addressable Market for Emu™".

Figure 25: Projected US Emu™ device utilization and scan volume (FY28–FY37). Source: Evolution Capital's forecasts.

	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35	FY36	FY37
Cumulative units sold in US	13	28	61	134	284	573	1,057	1,705	2,352	2,836
Total scans p.a. (000s)	1.3	5.3	13.6	29.8	64.3	134.0	262.8	467.7	734.6	1,009.7
% utilization of primary TAM potential	*27%*	*51%*	*59%*	*60%*	*61%*	*63%*	*67%*	*74%*	*84%*	*95%*
Avg. scans p.a. per unit in the field	*100*	*190*	*221*	*223*	*227*	*234*	*249*	*274*	*312*	*356*

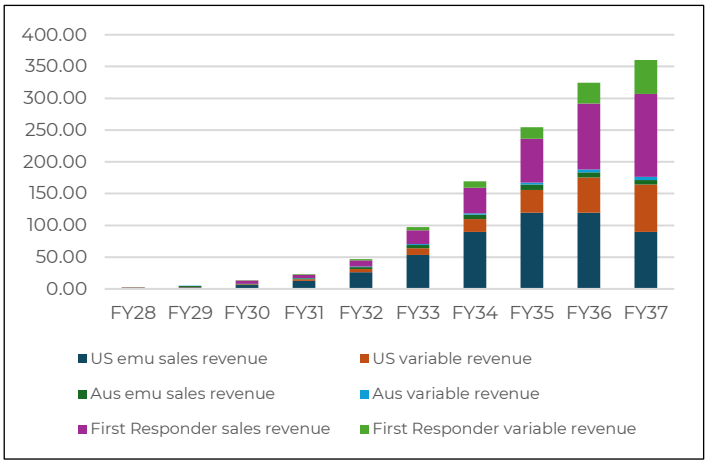
Based on the estimated TAMs of (i) primary US market emu™ units (9,740), and (ii) total scans per annum for these units (3.63m), we estimate the % utilization of primary TAM potential. For instance, in FY28, there are only 13 emu™s in the field. To this we apply a sales delay factor of 0.5 to account for the likelihood of sales being spread out over the course of the fiscal year. Given it is the first year of use for these units, they are presumed to be used 200 times each: 200 x 0.5 = 100 ("avg. scan p.a. per unit in the field"); 100 x 13 ≈ 1,300 scans; 1,300 scans / (13 / 9,740 units) x 3.63M scans = 27% utilization. I.e. with 13 units in the field, a possible 4,687 scans are possible for that year and the devices in the field performed 1,300, being 27% of what would be expected at full capacity and precedent scan volume requirements (based on ED visits for suspected stroke, and ICU uses for neuromonitoring).

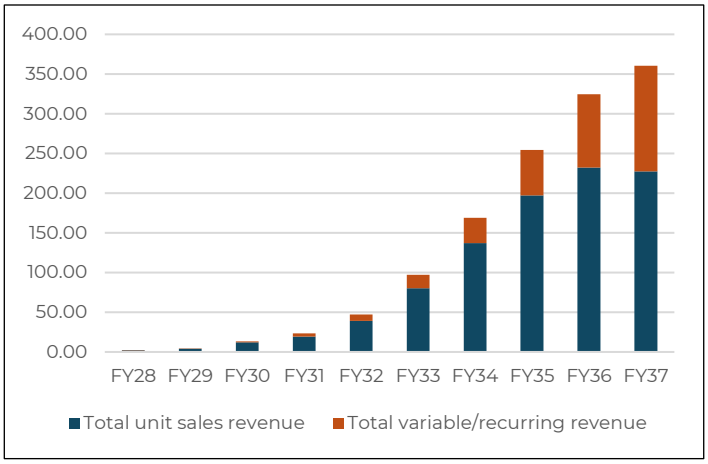
Revenue

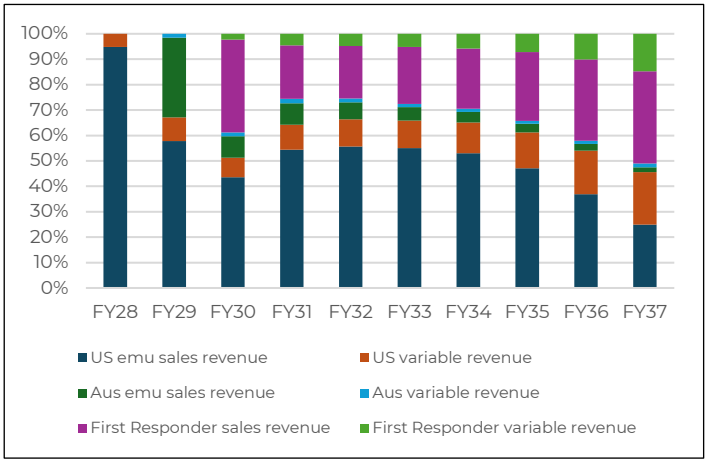
The market penetration & utilization profiles result in modest early revenue (c.US$2.3m in FY28 and c.US$4.6m in FY29), growing rapidly as unit sales drive upward toward the inflection year for US emu™ sales (c.US$254.5m in FY35). In the latter years of the forecasted period, as more recurring revenue is generated on the back of service and consumables revenue, a more sustainable long-term revenue profile mix is achieved (i.e. the topline is less reliant on unit sales).

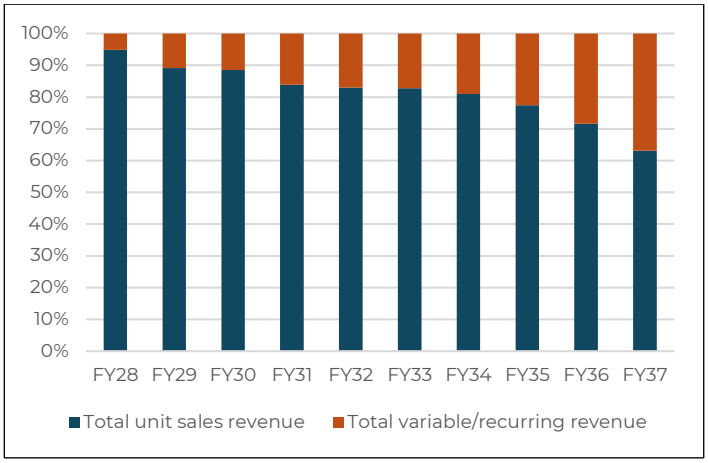
Figure 26: Forecast revenue composition from EMVision's device and recurring revenue streams (FY28–FY37). Source: Evolution Capital's analysis.

(All in US$M)	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35	FY36	FY37
US emu™ sales revenue	2.20	2.67	5.86	12.64	26.25	53.49	89.58	119.81	119.81	89.58
US variable revenue	0.12	0.43	1.03	2.30	5.01	10.49	20.52	36.06	55.43	74.46
Aus emu™ sales revenue		1.45	1.14	1.95	3.20	5.16	7.08	8.39	8.39	7.08
Aus variable revenue		0.07	0.21	0.41	0.72	1.22	1.96	2.95	4.09	5.22
First Responder sales revenue			4.92	4.92	9.68	21.77	40.23	68.94	104.13	130.70
First Responder variable revenue			0.30	1.04	2.29	4.97	9.71	18.31	32.55	53.20
Total unit sales revenue	**2.20**	**4.12**	**11.92**	**19.50**	**39.14**	**80.42**	**136.90**	**197.15**	**232.33**	**227.36**
Total variable/recurring revenue	**0.12**	**0.50**	**1.55**	**3.75**	**8.01**	**16.68**	**32.19**	**57.32**	**92.07**	**132.88**









Graph 1 (top left): Total Revenue broken down by source; **Graph 2 (top right):** Total Revenue broken down into two categories – total unit sales revenue and total variable/recurring revenue. Revenue is forecasted to grow slowly as EMV gains market visibility in early commercialisation years before growing more rapidly toward the end of the forecasted period to over US$350m in FY37; **Graph 3 (bottom left):** Total revenue mix. Highlights unit sales of emu™ and first responder dominate the mix in the in their respective launch years. As the Company grows, variable revenue becomes a greater share of the mix; **Graph 4 (bottom right):** Revenue mix by unit sales and variable revenue. Simply depicts unit the revenue mix maturing as more units are in the field generating consumables and service revenue.

Cost Profile

COGS

We forecast the gross margin on hardware sales to begin at a conservative 45% in the first year of commercialisation (FY28). This reflects the initial costs associated with scaling up manufacturing and establishing a supply chain. As production volumes increase, we project the margin to expand steadily to a mature, long-term rate of 60% by FY31. This improvement is driven by economies of scale, including bulk purchasing of components and manufacturing process efficiencies. A 60% margin is a suitable and sustainable target, consistent with established, specialized medical device companies that benefit from proprietary technology and intellectual property.

As for consumables and service margins, we forecast high and stable margins for these recurring revenue streams: consumables margin of 85% and service margin of 80%. hese high margins are justifiable and typical for this business model. The single-use consumables (e.g., head caps) are low-cost to produce at scale but are essential for every scan, creating a high-margin, recurring revenue model. Similarly, service contracts primarily consist of labour and software support with limited parts replacement, allowing for high profitability.

The combination of these factors results in a robust blended gross margin that expands from approximately 47% at the start of commercialisation to nearly 67% by the end of the forecast period, as equipment margins improve and the high-margin recurring revenue streams constitute a larger portion of the overall revenue mix.

Operating Expenditure & Leverage

In the initial commercial years, R&D spending remains high relative to revenue. This is necessary to fund the continued refinement of the device hardware and AI algorithms, as well as to conduct essential post-approval clinical studies to support expanded indications and secure reimbursement in global markets.

- **R&D Expenditure:** In the years prior to commercialisation, we anticipate R&D expense ramping up from FY25. After US launch, as revenue grows, we forecast R&D expense to decline from 250% of revenue in FY28 to a sustainable long-term rate of 6% of revenue. This reflects the shift in focus from development to high growth.

- **SG&A Expenditure:** Sales, General & Administrative expenses are also forecast to be very high relative to early revenues. This is a direct result of the company's strategic decision to pursue a direct sales model, which requires a significant upfront investment in building a specialized sales force, marketing infrastructure, and administrative support before substantial revenues are generated. As the top line scales, we model SG&A to decrease from over 400% of revenue in FY28 to a mature rate of 30% of revenue by the end of the forecasted period. With scale and growing market visibility and reputation, a proportionately smaller amount is required to be spent on salespeople.

This opex profile results in a first positive operating income year in FY32. Operating income margin begins at roughly 26% in FY32, rising to roughly 34% by the end of the forecasted period as R&D and SG&A expense as a percentage of revenue comes down.

Figure 27: Projected income statement highlights for EMVision (FY25–FY37). Source: Evolution Capital's analysis.

	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35	FY36	FY37	Terminal
Total Revenue				2.3	4.6	13.5	23.3	47.1	97.1	169.1	254.5	324.4	360.2	
Total COGS			1.4	1.2	3.6	5.9	8.7	17.1	35.2	60.6	89.3	109.7	115.1	
Gross margin				46.9%	-14.4%	51.4%	58.2%	60.4%	61.2%	62.1%	63.3%	64.8%	66.9%	*69.5%*
% R&D of Revs				250%	100%	20%	15%	10%	8%	6%	6%	6%	6%	*6.0%*
R&D Expense (US$M)	5.5	5.5	6.0	5.8	4.6	2.7	3.5	4.7	7.8	10.1	15.3	19.5	21.6	*21.8*
% SG&A of Revs				400%	250%	100%	60%	30%	30%	30%	30%	30%	30%	*30%*
SG&A Expense (US$M)	6.0	6.0	6.5	9.3	11.6	13.5	14.0	14.1	29.1	50.7	76.3	97.3	108.1	*109.1*
Total Opex (US$M)	**11.5**	**11.5**	**13.9**	**16.3**	**19.7**	**22.1**	**26.2**	**36.0**	**72.1**	**121.5**	**180.9**	**226.5**	**244.8**	*238.2*
Operating Income (US$M)	**-9.5**	**-9.1**	**-11.5**	**-11.4**	**-12.6**	**-6.6**	**-1.8**	**12.7**	**27.0**	**50.9**	**77.9**	**104.5**	**123.9**	*134.8*
Operating Margin %	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*26.1%*	*27.3%*	*29.5%*	*30.1%*	*31.6%*	*33.6%*	*36.1%*
Operating Income (A$M)	-14.2	-13.7	-17.2	-17.0	-18.9	-9.9	-2.6	19.0	40.5	76.4	116.9	156.8	185.9	*202.2*

Valuation

Our $2.92 price target is derived from our 12-year forward DCF model, which incorporates the sales of emu™ and First Responder in in the US and Australian markets. In Figure 28 below, we include a summary of our operational performance forecasts.

Our DCF model incorporates the following components:

- **Equity parameters:** we apply a calculated WACC of 14.6%. We use a 4.25% risk-free rate, base don prevailing yields for long-term Australian treasury bonds; an 8% equity risk premium (reflecting the speculative nature of EMV as an early-stage, pre-cash flow, R&D focused investment); and a beta of 1.29, derived from a 5-year monthly regression of EMV's returns against the ASX200 index. We incorporate 0% target leverage.

- **Risk-adjustment:** we apply a 65% Probability of Success (PoS) factor to the present value of our forecasted FCFF to account for the risk that future cash flows may not materialise. This blended PoS factor reflects the key commercial and regulatory hurdles that EMVision must overcome. The product of individual probabilities (85% x 85% x 90% ≈ 65%) forms our blended 65% PoS factor.

    i. **Regulatory Approval** (p = 85%): this is the most critical near-term hurdle. This probability reflects the risk that EMV's devices are not cleared by the FDA in the US or TGA in Australia.

    ii. **Favourable Reimbursement** (p = 85%): this factor accounts for the dual risk that the devices may not be assigned reimbursement codes (e.g.

dedicated CPT Cat III), and that even if the codes are assigned, they may not be at a level that sufficiently incentivises hospitals to both purchase and consequently use the devices. Securing adequate reimbursement is fundamental to the commercial case of the Company.

iii. **Successful Commercial Adoption** (p = 90%): this reflects execution risk associated with market entry. This includes the risk that early commercial efforts with direct sales teams are unsuccessful, physician adoption is slower than anticipated, or that the devices are not easily integrated into hospital workflows, thereby jeopardising the company's path to profitability.

Figure 28: EMVision DCF valuation model. Source: Evolution Capital's analysis.

	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	FY33	FY34	FY35	FY36	FY37
Emu™ Cap. Equipment Rev. (US$M)	-	-	-	2.2	4.1	7.0	14.6	29.5	58.7	96.7	128.2	128.2	96.7
Emu™ Variable Revenue (US$M)	-	-	-	0.1	0.5	1.2	2.7	5.7	11.7	22.5	39.0	59.5	79.7
FR Cap. Equipment Rev. (US$M)	-	-	-	-	-	4.9	4.9	9.7	21.8	40.2	68.9	104.1	130.7
FR Variable Revenue (US$M)	-	-	-	-	-	0.3	1.0	2.3	5.0	9.7	18.3	32.6	53.2
Total Revenue (US$M)	**2.0**	**2.4**	**2.4**	**4.9**	**7.1**	**15.5**	**24.4**	**48.7**	**99.2**	**172.5**	**258.9**	**331.0**	**368.7**
Total COGS (US$M)	-	-	-1.4	-1.2	-3.6	-5.9	-8.7	-17.1	-35.2	-60.6	-89.3	-109.7	-115.1
Total OPEX (inc. COGS) (US$M)	-11.5	-11.5	-13.9	-16.3	-19.7	-22.1	-26.2	-36.0	-72.1	-121.5	-180.9	-226.5	-244.8
Operating Income (A$M, fixed AUD/USD = 1.5)	**-14.2**	**-13.7**	**-17.2**	**-17.0**	**-18.9**	**-9.9**	**-2.6**	**19.0**	**40.5**	**76.4**	**116.9**	**156.8**	**185.9**
Operating Margin	*0%*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*26%*	*27%*	*30%*	*30%*	*32%*
(+) D&A	0.4	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
ΔWC	-2.1	-0.1	0.9	0.1	-0.0	-1.2	1.6	3.1	8.0	9.8	10.7	4.5	-2.9
Capex & Other	-0.1	-0.1	-0.1	-0.1	-0.1	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2
FCFF (A$M)	-7.8	-12.6	-15.7	-15.3	-15.2	-9.5	-3.7	17.6	35.8	70.0	63.0	66.3	51.2
Discounted FCFF (A$M)	**-7.8**	**-11.0**	**-11.9**	**-10.2**	**-8.8**	**-4.8**	**-1.6**	**6.8**	**12.1**	**20.6**	**16.2**	**14.8**	**10.0**

Inputs	
Beta	1.29
Risk Free Rate	4.25%
Equity Risk Premium	0.08
Re	14.6%
Rd	15.0%
Target Leverage	0%
WACC	**14.6%**
Approval	85%
Reimbursement	85%
Commercialisation	90%
Blended PoS	**65%**

DCF Calculation	**A$m**
Cumulative PV	24.2
LT Growth Rate	3%
Terminal Value	1,798
PV of TV	351.3
PoS	65%
Enterprise Value	244.1
Equity Value	260.1
Diluted SOI	89.0
Fair Valuation	**$2.92**
Unrisked Fair Val	$4.40

Our unrisked fair valuation for EMV is $4.40 per share. As EMvision successfully navigates each PoS-related hurdle listed above, the associated risk diminishes. Upon receiving FDA clearance, the PoS would be revised upward by almost entirely removing the regulatory risk component, thereby increasing our valuation, all else being equal. Subsequent confirmation of favourable reimbursement and evidence of successful market uptake would further de-risk the company and unlock the full, un-risked valuation over time.

Sensitivity Analysis

Sensitivity - DCF Inputs

LT Growth Rate \ WACC	12.6%	13.6%	14.6%	15.6%	16.6%
2.0%	3.88	3.22	2.70	2.27	1.92
2.5%	4.07	3.36	2.80	2.36	1.99
3.0%	4.28	3.52	2.92	2.45	2.06
3.5%	4.51	3.69	3.05	2.55	2.14
4.0%	4.77	3.88	3.19	2.65	2.22

The valuation is sensitive to small changes in both the WACC and the Terminal Growth Rate. This is typical for long-horizon DCF models where the present value of the terminal value, which is heavily influenced by these two inputs, represents a significant portion of the total enterprise value. Nonetheless, a highly conservative scenario such as 16.6% WACC, 2.5% terminal growth yields a favourable fair valuation.

Sensitivity - PoS & WACC

Probability of Success Factor \ WACC	12.6%	13.6%	14.6%	15.6%	16.6%
55%	3.65	3.01	2.50	2.10	1.77
60%	3.96	3.26	2.71	2.27	1.92
65%	4.28	3.52	2.92	2.45	2.06
70%	4.60	3.78	3.13	2.62	2.21
75%	4.91	4.03	3.35	2.80	2.35

The valuation is highly sensitive to the Probability of Success (PoS) factor, which directly adjusts the final value for key regulatory and commercial risks. This table highlights the significant de-risking and valuation uplift that would occur as the company successfully achieves its milestones.

Sensitivity - US Emu™ Adoption

US Inflection Point \ US Growth Rate Coefficient	0.70	0.75	0.80	0.85	0.90
6	2.46	2.69	2.78	2.93	3.05
7	2.76	2.91	2.93	3.01	3.07
8	2.78	2.86	2.92	2.97	2.99
9	2.68	2.73	2.78	2.81	2.83
10	2.45	2.50	2.53	2.56	2.58

The fair valuation is mildly sensitive to variation in s-curve inputs. A steeper adoption curve, combined with an earlier inflection point yields a higher fair valuation – this would reflect minimal unit sales in the first couple of years but very steep ramp up in sales in years 3-6 post-commercialisation. This would bring positive FCFF earlier in the forecasted period, and as earlier FCFF is discounted less than later FCFF, a greater positive contribution to final enterprise value occurs. In general, the longer it takes to reach the inflection year, the lower the val. Worth mentioning is that one of the model's limitations lowers fair val with inflection in year 6. This is due to the higher expected proportional spending on R&D and SG&A in this year: more revenues = a disproportionate relative increase in R&D and SG&A expenditure.

Sensitivity - Aus Emu™ Adoption

Aus Inflection Point \ Aus Growth Rate Coefficient	0.50	0.55	0.60	0.65	0.70
5	2.81	2.84	2.80	2.82	2.83
6	2.83	2.85	2.87	2.89	2.90
7	2.89	2.91	2.92	2.93	2.94
8	2.93	2.94	2.96	2.97	2.98
9	2.95	2.97	2.98	2.99	2.99

In contrast to the US market, the valuation is largely insensitive to the adoption speed of the emu™ in Australia. Because Australian sales represent a small fraction of the total revenue forecast, even significant changes in the adoption curve have a minimal impact on the overall valuation.

Sensitivity – Market Potential for Emu™

Aus 10yr Market Potential (% of Primary TAM) \ US 10yr Market Potential (% of Primary TAM)	25%	30%	35%	40%	45%
25%	2.40	2.65	2.93	3.21	3.49
30%	2.40	2.64	2.93	3.21	3.49
35%	2.39	2.64	2.92	3.21	3.49
40%	2.39	2.64	2.92	3.20	3.48
45%	2.39	2.63	2.92	3.20	3.48

The fair valuation is very sensitive to EMV's ability to penetrate the primary market for the emu™ in the US. A bear case is < 20% penetration into the primary TAM of 9,740 units across 3,100 hospitals over the 10-year initial commercialisation phase. Over 40% represents a bull case. Conversely, because Australian sales account for a small percentage of the overall forecast, variations in the 10-year market penetration in Australia have an almost negligible effect on the fair valuation.

Sensitivity - First Responder Penetration & Potential

Growth Rate Coefficient \ 10yr Market Potential (% of Primary Road TAM)	5%	10%	15%	20%	25%
0.5	2.22	2.39	2.62	2.78	2.97
0.6	2.30	2.53	2.76	3.05	3.27
0.7	2.37	2.64	2.92	3.20	3.52
0.8	2.42	2.74	3.05	3.37	3.69
0.9	2.47	2.82	3.17	3.52	3.87

The valuation is also highly sensitive to the long-term market penetration and adoption speed of the First Responder device. As this product represents a major source of revenue in the later years of the forecast, both the ultimate size of the installed base and the speed at which it is achieved are key drivers of value.

Expansion Opportunities

Europe & ROW Sales

A key component of the long-term investment case is the significant valuation upside that is not captured in our base-case model, which conservatively forecasts sales only in the US and Australian markets. The addressable market in Europe (Germany, France,

UK) and the Rest of World (ROW) is immense, representing a combined potential for over 91,000 emu™ units and 112,000 First Responder units, per the Company's estimates. These regions face similar healthcare pressures to the US, including aging populations and disparities in rural and urban access to acute stroke care, creating a clear and compelling need for EMVision's point-of-care solutions. Capturing even a small fraction of this vast international market would dramatically increase the company's long-term revenue potential and require a significant upward revision of our fair valuation.

Secondary Indication: Traumatic Brain Injury (TBI)
Further valuation expansion is possible through the pursuit of additional clinical indications beyond stroke. The company has identified Traumatic Brain Injury (TBI) as a high-value second target, a condition affecting 50 to 60 million people globally each year with an estimated annual economic cost exceeding US$400 billion. Currently, initial TBI assessment often relies on subjective neurological scales, creating a diagnostic gap that EMVision's technology is perfectly suited to fill. The development of both the emu™ and First Responder devices for the rapid, non-invasive assessment and monitoring of TBI would open up an entirely new, multi-billion-dollar market. This would not only provide a major new revenue stream but also diversify the company's clinical focus, offering another powerful vector for significant, long-term valuation growth.

M&A Landscape

The strategic endgame for EMVision is likely an acquisition by a major medtech player, even though we do not factor M&A into our valuation model. In our view, EMVision's portable neuroimaging technology (the Emu™ and First Responder devices) represents a must-have innovation for large medical device companies with imaging or neurodiagnostic franchises.

The primary catalyst for substantive M&A interest will be commercial validation – a potential acquirer will require clear, real-world evidence of market acceptance and successful integration into existing workflows in ICU and ED. By this time, a meaningful installed base will exist, and the recurring revenue stream from single-use consumables will demonstrate a predictable and attractive growth trajectory, fundamentally de-risking the asset for a strategic buyer. This de-risking is crucial, transforming the 'bet' from venture-style to immediately value-accretive for the buyer.

In short, while not baked into our base case, a takeout by a well-established player is a high-probability outcome (3+ years after commercial launch) if EMVision executes to plan.

Figure 29: Precedent M&A transactions in diagnostic and imaging technologies. Source: various sources.

Date	Acquirer / Target	Upfront (US$M)	Total (TEV) (US$M)	Target LTM Revenue (US$M)	TEV / LTM Rev	Stage / Key Technology
Apr 2024	Johnson & Johnson / Shockwave Medical	13,100	13,100	730.2	17.9x	Commercial / Intravascular Lithotripsy (IVL) for calcified artery disease
Rationale: Move to significantly enhance J&J's medtech cardiovascular portfolio and compliment its existing businesses - Biosense Webster in electrophysiology and Abiomed in heart recovery – creating a formidable presence in interventional cardiology.						
Jan 2025	Stryker / Inari Medical	4,900	4,900	603	8.1x	Commercial / Mechanical Thrombectomy for venous thromboembolism (VTE)
Rationale: To enter the venous thromboembolism market with its innovative catheter-based systems designed to mechanically remove large blood clots from veins and lungs.						
June 2024	Boston Scientific / Silk Road medical	1,160	1,160	191.4	6.1x	Commercial / Transcarotid Artery Revascularisation (TCAR) for stroke prevention
Rationale: Adding a unique, revolutionary TCAR platform. Foundation likely as strategic imperative to secure a leading and clinically differentiated technology in the large and growing market for stroke prevention.						
Dec 2020	Philips / BioTelemetry	2,800	2,800	450	2.9x	Commercial / Remote cardiac diagnostics and monitoring
Rationale: Expand Philips presence in the rapidly growing remote patient monitoring market, leveraging BioTelemetry's leadership in remote cardiac diagnostics.						
Jul 2020	Medtronic / Medicrea	155	155	35	4.3x	Commercial / AI-driven surgical planning & personalized spinal implants
Rationale: Strengthened Medtronic's position in AI-enabled spine surgery by adding patient-specific implant tech and predictive planning software, bolstering its robotic and imaging-guided surgery ecosystem.						
Sep 2019	Stryker / Mobius Imaging	370	500	Unknown	n/a	Commercial / Mobile diagnostic CT imaging system
Rationale: Instant entry into intra-operative imaging, augmenting Stryker's spine surgery toolkit with a mobile CT scanner to pair with its implants and navigation systems.						
Dec 2019	Fujifilm / Hitachi	1,640	1,640	1,310	1.3x	Commercial / Traditional diagnostic imaging business
Rationale: Catapulted Fujifilm into the top tier of imaging OEMs by adding CT and MRI modalities – a synergistic move to compete head-on with GE, Siemens and Philips in diagnostic imaging. On the back of US$1.8bn decline in revenues for Fujifilm.						
Sep 2021	GE Healthcare / BK Medical	1,450	1,450	165	8.8x	Commercial / Active Imaging intraoperative ultrasound platform
Rationale: Expanded GE's ultrasound business from diagnostics into real-time surgical visualization, enabling intraoperative imaging in neuro and other surgeries and complementing its precision health strategy.						

Corporate Items

Capital Management

We estimate EMVision's cash position at the end of FY25 (June 30, 2025) to be approximately A$10.6 million. As a pre-revenue company with significant development and commercialisation milestones ahead, we anticipate the company will need to raise additional capital to fund its growth trajectory. These funds will be critical for financing ongoing R&D programs, supporting SG&A expenditure related to global regulatory submissions and the build-out of a direct sales force, and for the initial purchase of inventory ahead of commercial launch.

Our financial model forecasts two future capital raises to ensure the company remains adequately funded through to profitability. We project an initial A$20 million raise in late FY26, followed by a further A$42 million raise in FY28. We have assumed both raises are conducted at the current market price of A$1.70 per share.

It is important to note that EMVision has demonstrated an ability to attract strategic capital. In February 2024, the company secured a A$15.3 million investment from Keysight Technologies (NYS: KEYS) at a price of A$2.05 per share. Keysight, a core supplier of the Vector Network Analysers (VNAs) central to EMVision's technology, is now a substantial shareholder with an 8.7% stake, providing a strong external validation of the company's technology and commercial prospects.

Potentially Dilutive Securities

We have taken a conservative approach to future dilution. Our model assumes no further issuance of performance rights and no additional share-based compensation

beyond what is already disclosed. We forecast that all outstanding in-the-money (ITM) options will be exercised by holders in the final year prior to their expiry and have factored this into our fully diluted share count.

Share Registry

The company's co-founder and CEO, Scott Kirkland, is the second-largest shareholder with a 5.0% stake. Other notable shareholders include co-founder Ryan Laws (3.7%) and UniQuest Pty Limited (1.4%), the commercialisation arm of the University of Queensland where the core technology was developed. The Board of Directors collectively holds a significant interest in the company, totalling 9.6% of the shares on issue, demonstrating strong alignment with shareholder interests.

Figure 30: Share Registry. Source: Iress.

	LATEST BALANCE	31/07/2025
Rank	**Ranking Shareholder Name**	**Percentage Held**
1	Keysight Technologies, Inc.	8.72
2	Scott Kirkland	5.00
3	Ryan Laws	3.68
4	John Keep	2.42
5	Jrn Starcevich Investrnents Pty Ltd	1.44
6	UniQuest Pty Limited	1.40
7	Emma Waldon	1.36
8	Walsh Prestige Pty Ltd	1.23
9	Stuart Crozier	1.22
10	Vincent O'sullivan	1.18
11	Martin Kolev	1.17
12	Geoffrey Richard Pocock	1.00
13	Pak Lim Kong	0.95
14	Wakil Family Group Pty Ltd	0.93
15	Hillridge Proprietary Ltd.	0.88
16	Pit2 co Pty Ltd	0.87
17	Angelique Brown	0.84
18	Paul Brown	0.84
19	Tony Keane	0.70
20	Philip Dubois	0.60

Appendix
Financial Forecasts

Income Statement					
A$'000s	**FY24a**	**FY25e**	**FY26e**	**FY27e**	**FY28e**
Revenue	-	-	-	-	3.48
Other Income	11.22	6.84	4.39	3.59	3.92
Total Revenue	**11.22**	**6.84**	**4.39**	**3.59**	**7.39**
Operating expenses	-13.07	-17.25	-17.25	-18.75	-22.59
EBITDA	**-1.85**	**-10.41**	**-12.86**	**-15.16**	**-15.20**
D&A	-0.41	-0.44	-0.27	-0.21	-0.21
EBIT	**-2.26**	**-10.85**	**-13.13**	**-15.37**	**-15.41**
Net Interest	0.23	0.64	0.21	0.45	0.14
NPBT	**-2.03**	**-10.21**	**-12.92**	**-14.92**	**-15.28**
Tax expense	-0.70	-	-	-	-
Discontinued operations	-	-	-	-	-
NPAT	**-2.73**	**-10.21**	**-12.92**	**-14.92**	**-15.28**

Balance Sheet					
A$'000s	**FY24a**	**FY25e**	**FY26e**	**FY27e**	**FY28e**
Cash	18.60	10.59	22.43	6.77	32.84
Receivables	0.02	-	-	-	-
Inventory	-	-	-	0.53	0.50
R&D Incentive Receivable	2.78	2.39	2.39	2.61	2.52
Other	0.47	0.06	-	-	-
Current assets	**21.87**	**13.04**	**24.82**	**9.91**	**35.86**
Intangibles	0.65	0.61	0.57	0.52	0.48
PPE	0.24	0.27	0.30	0.34	0.37
Other	1.22	-	-	-	-
Non-current assets	2.10	0.88	0.87	0.86	0.85
Total Assets	**23.97**	**13.92**	**25.69**	**10.77**	**36.71**
	-	-	-	-	0.00
Payables & Accrued Liabilities	0.93	1.23	1.23	1.33	1.60
Borrowings	0.82	0.82	0.82	0.82	0.82
Lease Liabilities	0.25	0.09	-	-	-
Other	1.42	-	-	-	-
Current liabilities	**3.41**	**2.13**	**2.05**	**2.15**	**2.43**
Borrowings	1.77	1.94	2.22	2.60	3.10
Other liability	0.27	1.54	1.50	1.02	0.09
Non current liabilities	**2.04**	**3.48**	**3.72**	**3.62**	**3.19**
Total Liabilities	**5.46**	**5.62**	**5.77**	**5.77**	**5.62**
Net Assets	**18.52**	**8.30**	**19.92**	**5.00**	**31.09**
	-	-	-	-	0.00
Contributed Equity	41.57	41.57	66.11	66.11	107.48
Retained earnings	-26.52	-36.73	-48.98	-63.91	-79.18
Reserves/Other	3.46	3.46	2.80	2.80	2.80
Total Equity	**18.52**	**8.30**	**19.92**	**5.00**	**31.09**

Statement of Cashflows					
A$'000s	**FY24a**	**FY25e**	**FY26e**	**FY27e**	**FY28e**
Net profit for period	-2.73	-10.21	-12.92	-14.92	-15.28
Depreciation & Amortisation	0.41	0.44	0.27	0.21	0.21
Changes in working capital	-4.65	-2.10	-0.15	0.86	0.15
Other	0.98	0.11	0.10	0.11	0.12
Operating cash flow	**-5.99**	**-7.57**	**-12.40**	**-15.46**	**-15.09**
Payments for PPE	-0.12	-0.20	-0.20	-0.20	-0.20
Other payments	-0.19	-	-	-	-
Proceeds from asset sale	-	-	-	-	-
Investing cash flow	**-0.30**	**-0.20**	**-0.20**	**-0.20**	**-0.20**
Equity raised, net of costs	15.25	-	24.54	-	41.37
Net borrowings	-	-	-	-	-
Lease repayments	-0.24	-0.24	-0.09	-	-
Other	-0.00	-	-	-	-
Financing cash flow	**15.00**	**-0.24**	**24.44**	**-**	**41.37**
Free cash flow	**-6.29**	**-7.77**	**-12.60**	**-15.66**	**-15.29**
Net cash flow	**8.71**	**-8.01**	**11.84**	**-15.66**	**26.08**
Effects of exchange rate					
Cash year end	18.60	10.59	22.43	6.77	32.84

Investment Fundamentals					
	FY24a	**FY25e**	**FY26e**	**FY27e**	**FY28e**
Liquidity					
Current Ratio	6.4	6.1	12.1	4.6	14.8
Quick Ratio	1.0	1.1	1.2	1.5	1.2
Solvency					
Debt to Equity	0.2	0.5	0.2	0.9	0.1
Debt to Assets	0.1	0.3	0.2	0.4	0.1
LT Debt to Assets	0.1	0.1	0.1	0.2	0.1
Profitability					
Net Margin	n/a	n/a	n/a	n/a	n/a
ROA	-11%	-73%	-50%	-139%	-42%
ROE	-15%	-123%	-65%	-298%	-49%
Valuation					
P/E	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	n/a	n/a	n/a	n/a	n/a
P/B	0.0	0.0	0.0	0.0	0.0

Key Risks

Clinical trial risk: EMVision's technology is still in the clinical validation stage and its success hinges on positive trial outcomes. Ongoing pivotal studies must demonstrate that the Emu™™ scanner can accurately differentiate stroke types and improve diagnostic speed. Any failure to meet efficacy or safety endpoints – for example, if sensitivity or specificity falls below targeted levels – would delay regulatory submissions and could diminish confidence in the platform. Unfavorable or inconclusive trial results may necessitate additional costly studies, or could even halt the development of the device.

Regulatory approval risk: There is no guarantee that EMVision will obtain timely regulatory clearances for its novel brain scanner. The company plans to seek FDA De Novo approval (and corresponding approvals in other jurisdictions), a process that can be rigorous and protracted. Regulators may request further data or larger trials, and any unexpected compliance issues could emerge during the review. A delay in or failure to secure FDA or TGA approval would significantly set back the commercialization timeline. Even if approvals are eventually obtained, they might come with restrictive labels or requirements (e.g. post-market studies) that add cost and complexity.

Commercialisation and adoption risk: Even with regulatory clearance, EMVision's portable scanner must achieve adoption in a conservative healthcare market. Hospitals and emergency services are accustomed to proven CT/MRI imaging for stroke; persuading them to integrate a new electromagnetic device may be challenging. Uptake could be slower than forecast if clinicians are skeptical of a new modality or if integrating the device into emergency workflows proves difficult. The company's market entry strategy (initial direct sales into stroke centers and later expansion) carries execution risk – early missteps in demonstrating clinical value or training users could curb momentum. If EMVision cannot clearly show improved patient outcomes or cost-effectiveness in real-world settings, hospitals may limit purchases or usage of the devices, impacting future revenue.

Competition risk: EMVision faces a rapidly evolving competitive landscape in acute stroke diagnosis. Traditional solutions like hospital CT scans remain the gold standard, and mobile stroke units with on-board CT have proven clinical benefit (though at high cost). In addition, several emerging technologies aim to address the same need. For example, portable low-field MRI systems have demonstrated the ability to detect brain hemorrhages at the bedside and at least one competitor is developing a compact, lightweight CT scanner for ambulances. Other startups are exploring ultrasound or microwave-based diagnostics. There is a risk that a competing product reaches the market first or offers superior accuracy or ease-of-use, which could diminish EMVision's market opportunity. Larger medical device companies could also invest in this space, leveraging their resources to outcompete EMVision.

Intellectual property risk: While EMVision has built a patent portfolio around its electromagnetic imaging technology, its competitive moat is not assured. The company has acquired full ownership of its core IP, but there is a risk that existing patents might be circumvented or challenged by competitors. Likewise, EMVision must ensure it has freedom to operate globally – any unforeseen third-party patents covering similar technology could result in legal disputes or the need for licensing. If EMVision's patents do not provide broad enough protection, or if they expire before the technology achieves wide adoption, competitors could develop similar devices, eroding EMVision's advantage. Defending intellectual property can also be costly for a small company, potentially straining financial resources.

Reimbursement and economic risk: The commercial success of EMVision's devices will depend on securing adequate reimbursement in key markets. As a new category of medical device, there is a risk that government and private payors will not promptly assign reimbursement codes or coverage for the scanner's use. Even if codes are obtained, they may come with low payment rates that fail to incentivize hospitals to invest in the technology. A slow or unfavorable reimbursement outcome, especially in the United States, would make it difficult for hospitals to justify purchasing the equipment or charging for its use, limiting uptake. Demonstrating clear health-economic benefits (such as reduced disability or savings from avoided patient transfers) will be crucial; failure to do so could result in hospitals perceiving the device as too costly or optional.

Funding and financial risk: EMVision is a pre-revenue company and will require additional capital to reach its development and commercial milestones. We estimate the company's cash balance will be approximately A$10 million by the end of FY25, which is insufficient to complete pivotal trials, regulatory filings, and product launch. The business is not yet generating cash flow, so it will likely need to raise significant funds through equity or partnerships. There is a risk that market conditions or project setbacks could impede EMVision's ability to secure funding when needed, or that such capital may only be available on dilutive terms. If fresh funding is delayed or unavailable, the company might be forced to slow its R&D programs, seek strategic alternatives, or in a worst-case scenario, could run out of cash. Investors should also note that future government grants or non-dilutive funding, while helpful, are not guaranteed and typically require the company to meet certain milestones.

Key personnel and talent risk: EMVision's success is heavily dependent on a small team of specialized executives, engineers and clinicians. The company's co-founder/CEO and its technical leaders (including the Chief Technology Officer and Chief Scientific Officer) possess deep domain expertise and drive strategic execution. Losing any of these key individuals could disrupt development timelines or deprive the company of critical know-how. Furthermore, as EMVision transitions from R&D into manufacturing and sales, it must attract and retain talent in areas like quality manufacturing, regulatory affairs, and commercial sales. There is a risk that the company may struggle to hire the necessary skilled personnel or that it might face retention challenges in a competitive medtech labour market. Any difficulties in building out the team could hamper product refinement, regulatory compliance, or the rollout to customers.

Operational and scale-up risk: Transitioning from prototype to commercial product will test EMVision's operational capabilities. The manufacturing of a complex medical device must meet strict quality and regulatory standards (e.g. ISO 13485, FDA QSR), and scaling up production can expose challenges in supply chain and quality control. As a relatively small organization, EMVision may encounter production bottlenecks or supplier issues (for specialized components and electronics) that delay device availability. Any unforeseen technical hurdles in final product engineering, or failures to manufacture units reliably at scale, could increase costs and postpone revenues. Additionally, building a global distribution and support network for a capital equipment device is non-trivial – logistics, servicing, and user training infrastructure will be needed. If EMVision underestimates these requirements, the initial launch may face execution issues that impact the company's reputation and customer confidence.

Market and macro-environment risk: Broader healthcare and economic conditions could also affect EMVision. Hospital capital budgets are often constrained; if economic conditions worsen or healthcare providers face financial pressure, they may defer purchasing new equipment like EMVision's scanner. Changes in healthcare policy or stroke care protocols could influence demand – for instance, if telemedicine or centralized stroke centers expand, the perceived need for point-of-care devices might evolve. The company is also exposed to foreign exchange and international market risks as it plans to operate in multiple regions (fluctuating currencies or trade barriers could impact costs and pricing). Finally, investor sentiment toward high-risk, pre-revenue medtech companies can be volatile. Any shift in risk appetite in equity markets could affect EMVision's valuation and its ability to raise capital on favourable terms.

Board & Management

Scott Kirkland – CEO & MD
Scott is the co-founder of EMVision Medical Devices Ltd. Scott has held several senior sales positions, including Head of Client Sales at Quantcast, a US-based technology company, prior to founding Kirkland Capital, targeting emerging technologies. Scott oversees EMVision's corporate affairs, commercial strategy and business development efforts. Scott is also charged with optimising the company's capital requirements, including further non-dilutive financing and grants. Scott is a member of the Australian Institute of Company Directors.

John Keep – Chairman
John has extensive experience in managing both start-ups and enterprise level businesses. As CEO of Queensland Diagnostic Imaging, John grew the business to become the state's leading private imaging group and led the successful trade sale of the group to Mayne Pharma for $109 million.

Dr Philip Dubois – NED
Dr. Dubois is an imaging executive and neuroradiologist. Dr. Dubois is previously Non-executive Director of Sonic Healthcare (ASX:SHL), former CEO of their imaging division and served as Executive Director from 2001 to 2020. He is also the founder and former CEO and Chairman of Queensland X-Ray. Dr Dubois is currently an Associate Professor of Radiology at the University of Queensland Medical School. He has served on

numerous government and radiology group bodies, including the councils of the Royal Australian and New Zealand College of Radiologists and the Australian Medical Association, and as Vice-President of the Australian Diagnostic Imaging Association.

Tony Keane – NED
Tony is an experienced Business and Finance executive with an extensive background in banking & business management and is actively involved in the business community through Non-Executive Director roles and finance advisory consultancies. He is Chairman of National Storage Holdings Ltd (ASX:NSR), a $3bn+ National Storage REIT. He is also an Advisory Board member for several private companies. Tony previously held numerous roles with a major trading bank principally in business, corporate and institutional banking. He has a Bachelor of Science (Mathematics) degree and a Graduate Diploma in Corporate Finance, is a Fellow of the Financial Services Institute of Australasia, and a Graduate of the Australian Institute of Company Directors.

Patryk Kania – NED
Patryk is a medical device executive with over 20 years of commercialization and leadership experience in medical devices, pharma, and health technologies working across the US, Europe and APAC, within sales and marketing management, and general management roles. Currently, Patryk is CEO and President USA of Field Orthopaedics Ltd., and has previously held senior roles at Smith+Nephew, Abbott, J&J Medical and Roche.

Carmel Monaghan – NED
Ms Monaghan is an accomplished healthcare leader being the Chief Executive Officer of Ramsay Healthcare Australia (ASX:RHC) since 2020. Ramsay is a leading private health operator with over 70 hospitals and 35,000 staff. Ms Monaghan has worked across hospital, corporate and global positions at Ramsay for almost three decades. Prior to her appointment as CEO of Ramsay Australia, Ms Monaghan was the Group Chief of Staff of Ramsay's global operations, gaining extensive experience and a comprehensive understanding of health care operations and strategy both in Australia and overseas. Ms Monaghan also served as the Group Head of Marketing and Public Affairs, driving marketing, brand and communications strategy, during which the group grew to become one of the leading private healthcare operators globally.

Forough Khandan - CTO
Ms Khandan has over 17 years' experience in the development of regulated products in numerous industries including automotive and medical devices. Before EMVision, she was Program Manager at Nanosonics (ASX:NAN), reporting directly to the CTO, where she led a large multi-disciplined team of engineers and scientists across the business. During her 9-year tenure at Nanosonics, Forough successfully planned and executed highly complex new technology and product development programs and was key in leading activities required to define, develop, and deliver Nanosonics' new products including the second generation of trophon device from prototype to after-market release.

Prof. Stuart Crozier – CSO
Co-inventor of EMVision's underlying technology, Professor Stuart Crozier is also the former Director of Biomedical Engineering at the University of Queensland. Professor Crozier's advancements in MRI technology have been used in billions of scans around the world and are now central to 65% of all MRI machines manufactured since 1997. Professor Crozier brings a wealth of experience in developing and commercialising medical imaging systems.

Intellectual Property

EMVision has established a robust intellectual property portfolio to protect its novel technology and create a durable competitive advantage. The portfolio is built around 14 patent families, with over 60 patent applications pending globally. This strategy has already secured key patents in the United States, including for the core 'Tomographic

Imaging System and Process' (US Patent No. 11,548,386) and its application in 'Stroke Monitoring' (US Patent No. 12,048,507), both granted in July 2024. Further protection for the 'Wearable antenna assembly for electromagnetic head imaging' (US Patent No. 12,186,065) was granted in January 2025. With the earliest of these foundational patents not expiring until 2038, EMVision has a long runway for commercial exclusivity.

In addition to patents, EMVision holds four design registrations and two trademarks, further strengthening its competitive moat. This comprehensive IP foundation is critical for defending the company's market position against potential competitors and is a key asset that underpins the long-term value of the company.

Evolution Capital Ratings System

Recommendation Structure	• **Buy:** The stock is expected to generate a total return of >10% over a 12-month horizon. For stocks classified as 'Speculative', a total return of >30% is expected. • **Hold:** The stock is expected to generate a total return between -10% and +10% over a 12-month horizon. • **Sell:** The stock is expected to generate a total return of <-10% over a 12-month horizon.
Risk Qualifier	• **Speculative ('Spec'):** This qualifier is applied to stocks that bear significantly above-average risk. These can be pre-cash flow companies with nil or prospective operations, companies with only forecast cash flows, and/or those with a stressed balance sheet. Investments in these stocks may carry a high level of capital risk and the potential for material loss.
Other Ratings:	• **Under Review (UR):** The rating and price target have been temporarily suppressed due to market events or other short-term reasons to allow the analyst to more fully consider their view. • **Suspended (S):** Coverage of the stock has been suspended due to market events or other reasons that make coverage impracticable. The previous rating and price target should no longer be relied upon. • **Not Covered (NC):** Evolution Capital does not cover this company and provides no investment view.

Expected total return represents the upside or downside differential between the current share price and the price target, plus the expected next 12-month dividend yield for the company. Price targets are based on a 12-month time frame.

Disclaimer & Disclosures

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