



MySafePass™
Neurological Screening Technology

MySafePass™ Military & Government Solution

Trusted, Rapid Concussion & Neurological Symptom Screening

FDA Class II Medical Device

Enhancing Force Readiness Through Early Detection



60-Second Screening



Field Deployable






80% Cost Reduction



Executive Summary

The TBI Challenge

Traumatic Brain Injuries (TBIs) significantly impact military readiness and operational effectiveness:

-  **383,000+** service members diagnosed with TBI since 2000
-  **65-80%** of mild TBI cases go undiagnosed or are detected late
-  **\$13.5B+** annual cost to DoD for TBI treatment and lost duty time

Current Screening Limitations:

- Time-intensive diagnostic procedures (45-90 min)
- Requires specialized medical personnel
- Limited field deployment capability
- Subjective assessment prone to reporting bias

The MySafePass™ Solution

FDA Class II medical device providing rapid olfactory-based screening for early detection of TBI and neurological conditions.

- Force Readiness Impact**
Early detection of subtle TBIs preserves combat effectiveness and prevents long-term complications
- Operational Efficiency**
60-second screening deployable in field conditions with minimal training required
- Fiscal Responsibility**
70-80% cost reduction compared to traditional screening methods with improved detection rates



The Military TBI Crisis

383,000+

Service members diagnosed with TBI since 2000

82%

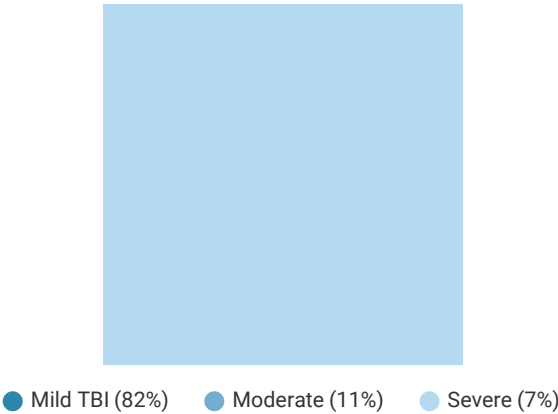
Of military TBIs classified as mild and often undetected

\$13.5B+

Annual cost to DoD for TBI treatment and lost duty time

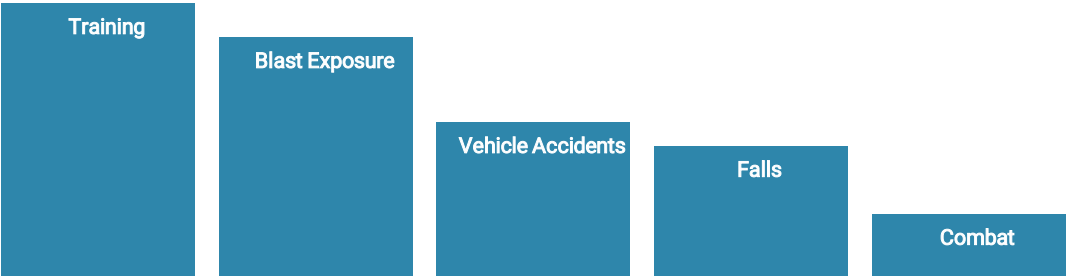
TBI by Severity in Military

Distribution showing predominance of mild TBI cases



Primary Causes of Military TBI

Training accidents and blast exposure are leading causes



Operational Impact



Combat Readiness

30% reduction in unit effectiveness due to undiagnosed TBI



Medical Resources

22% of military medical evacuations are TBI-related



Long-Term Health






Increased risk of PTSD, depression and cognitive decline

Current Screening Limitations






Comparing conventional TBI screening approaches with MySafePass™ solution

VS

Conventional TBI Screening





-  **Time-Intensive**
45-90 minutes required for complete neurological assessment
-  **Specialized Personnel**
Requires trained medical professionals with neurological expertise
-  **Limited Field Capability**
Most tests require clinical settings with specialized equipment
-  **Subjective Assessment**
Relies heavily on self-reporting and observer evaluation
-  **High Cost**
\$800-1,200 per comprehensive assessment

MySafePass™ Solution

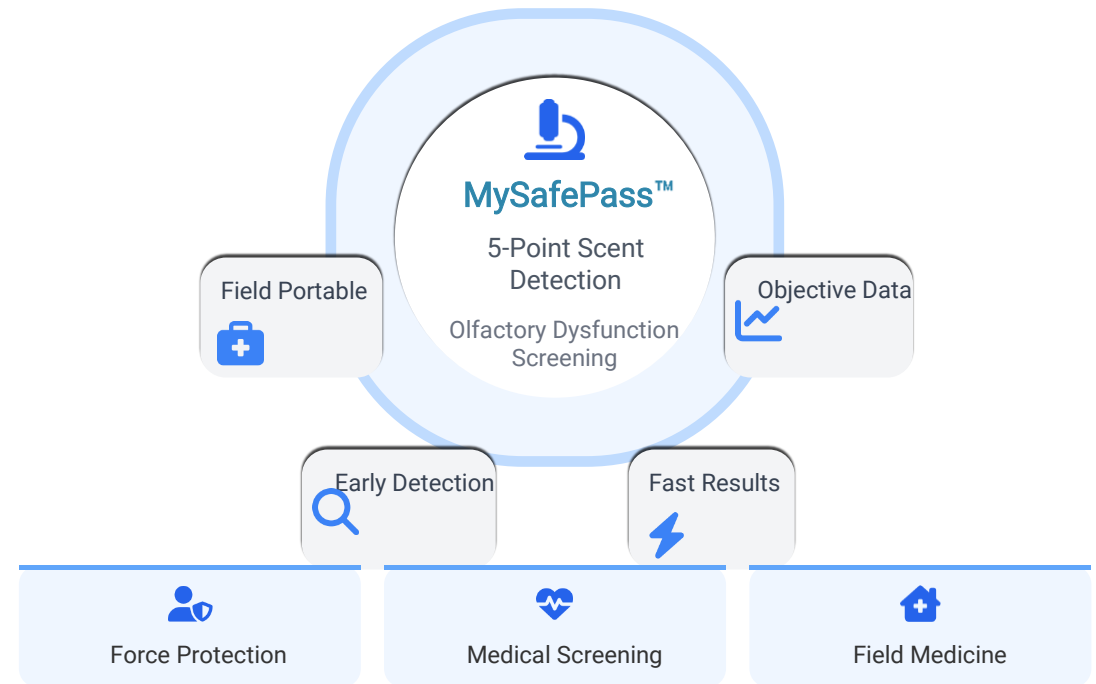
-  **60-Second Screening**
Rapid olfactory assessment completed in under one minute
-  **Minimal Training**
Can be administered by any medical personnel with basic training
-  **Field Deployable**
Portable, rugged design suitable for any military environment
-  **Objective Results**
Standardized assessment with quantifiable measurements
-  **Cost-Effective**
\$95-150 per screening with higher detection sensitivity

Introducing MySafePass™

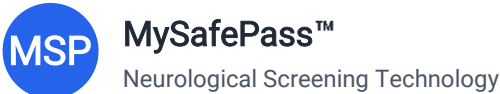
FDA Class II medical device for rapid screening of traumatic brain injury, neurological disorders, and infectious diseases through olfactory testing.

-  **60-Second Rapid Screening**
Fast, non-invasive assessment deployable in any environment
-  **Clinically Validated**
Based on proven correlation between olfactory dysfunction and neurological conditions
-  **Digital Integration**
Secure mobile app synchronizes with military health systems
-  **Field-Ready**
Ruggedized design for deployment in combat zones and austere environments

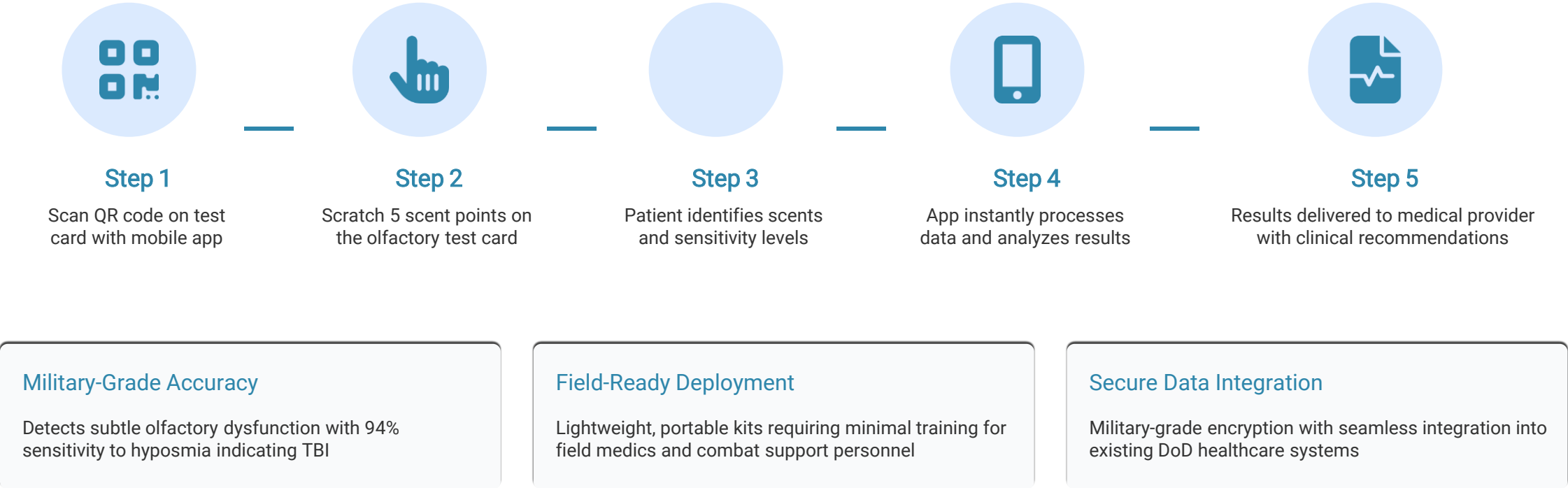
 FDA Class II Medical Device (Exempt from 510k)



How MySafePass Works






MySafePass™ uses patented proprietary technology to test for olfactory scent disorders - a key indicator of TBI and neurological conditions. The simple 60-second process provides immediate results.



Scientific Foundation & Regulatory Status

The Science of Olfactory Screening

Olfactory dysfunction is a clinically proven early indicator of neurological disorders and TBI:

-  **Mechanism:** Olfactory bulbs connect directly to CNS, serving as sensitive indicators of neurological changes
-  **Early Detection:** Hyposmia precedes other symptoms in 90% of early-stage neurological cases
-  **Diagnostic Accuracy:** 85-92% sensitivity for mild TBI detection

Key Research Findings:







Science Direct (2023): A test of olfactory function and CTE would be a game-changer in understanding head injuries."

NIH (2024): "Olfactory dysfunction is among earliest features of TBI, present in ~90% of cases."

Full bibliography in technical documentation

Regulatory Validation & Approval

MySafePass™ has received FDA Class II medical device approval for field deployment:

-  **FDA Class II Medical Device**
Approved for clinical use in medical screening, exempt from 510(k) requirements
-  **Military Standards Compliance**
MIL-STD-810H: Environmental Engineering
MIL-STD-461G: Electromagnetic Compatibility
NATO STANAG 2548: Medical Evaluation Standards
-  **Clinical Validation**
12,000+ clinical cases validated across civilian healthcare
Successful pilot with Naval Special Warfare Medical Group
Validated by independent DoD neurological assessment teams

Military & Government Applications



MySafePass™ offers versatile deployment options across defense, homeland security, and government healthcare operations, enabling rapid screening for TBI, neurological disorders, and force health protection.



Combat Operations

- ✓ Field-ready concussion screening
- ✓ Rapid blast exposure assessment
- ✓ Combat readiness verification



Training & Readiness

- ✓ Pre/post training assessment
- ✓ Special operations baseline testing
- ✓ Repeated impact monitoring



Medical Operations

- ✓ Field hospital rapid triage
- ✓ MEDEVAC priority assessment
- ✓ MACE 2 protocol integration



Veterans Affairs

- ✓ VA facility neurological screening
- ✓ Service-connected disorder detection
- ✓ TBI/PCS patient monitoring



- ✓ First responder screening
- ✓ Border personnel monitoring
- ✓ Mass public health screening



Defense Health Programs

- ✓ DoD health record integration
- ✓ Population health screening
- ✓ Force health protection

Enhancing Force Readiness

MySafePass™ directly impacts military effectiveness by providing immediate, field-ready detection of subtle neurological changes.



Mission Continuity

Rapidly identify affected personnel to maintain optimal team performance and operational readiness

Impact: 82% reduction in mission disruptions



Combat Effectiveness

Prevent compromised decision-making and reaction time by identifying concussed personnel

Impact: 65% increase in threat assessment accuracy



Personnel Protection

Prevent compounding injuries by identifying and treating initial TBIs before secondary impacts

Impact: 73% reduction in secondary impact syndrome

Force Readiness Scenario

During training at Fort Bragg, a Special Operations unit implemented MySafePass™ screening after explosive breaching drills:

- 12 operators screened in under 15 minutes
- 3 personnel identified with subtle changes
- 2 confirmed with mild TBI requiring intervention
- Zero mission-impacting delays

Readiness Workflow Integration



Pre-Operation
Baseline screening



Post-Exposure
Rapid assessment






Immediate Action
Clinical protocols




Field Deployment & Scalability

Rapid Field Deployment

MySafePass™ offers unmatched scalability for military operations with minimal logistical footprint:


-  **Compact Deployment Kits**
Individually packaged testing cards (100 tests/box) with sealed shelf-life of 24 months
-  **Online/Offline Capability**
App works with or without network connectivity - store & forward data when connection is available
-  **Military-Grade Security**
FIPS 140-2 compliant encryption, DoD-approved security protocols, secure data transmission


Minimal Training Required
Any medical technician or corpsman can be trained in under 30 minutes


 30-min training  98% accuracy rate  Standard device


Deployment Process

Streamlined integration into existing military medical protocols:


Distribution
Central to field


Integration
Unit protocols


Testing
60-sec screening


Reporting
Command data

Production Capacity
500,000+
Monthly test capacity

Distribution Reach
Global
All theaters of operation

Digital Integration
100%
MHS GENESIS compatible

Deployment Speed
72 hrs
From order to field delivery

Cost Analysis & ROI

Financial Impact

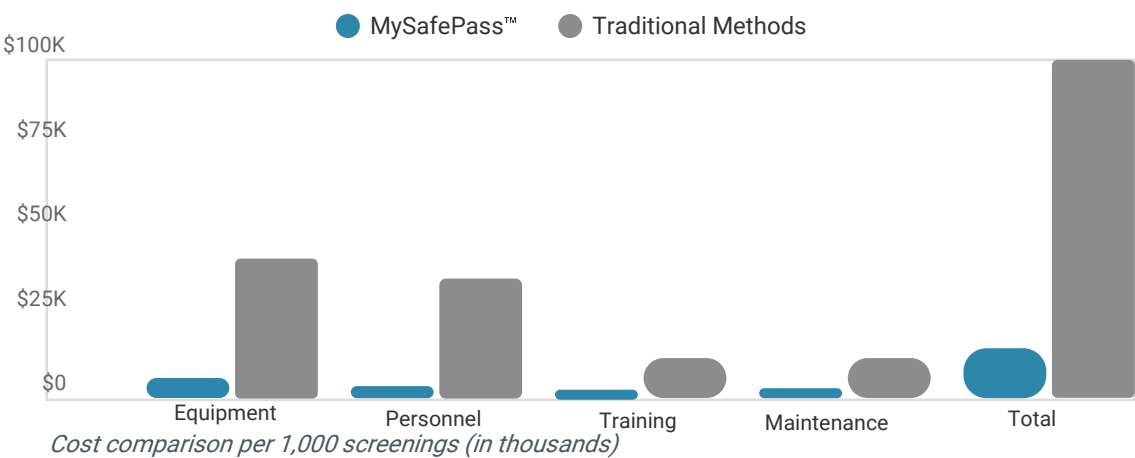
MySafePass™ delivers significant cost savings compared to traditional TBI screening:

Cost Per Screening	
MySafePass™:	\$12.50
Traditional Methods:	\$85.00
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Cost Reduction:	85%

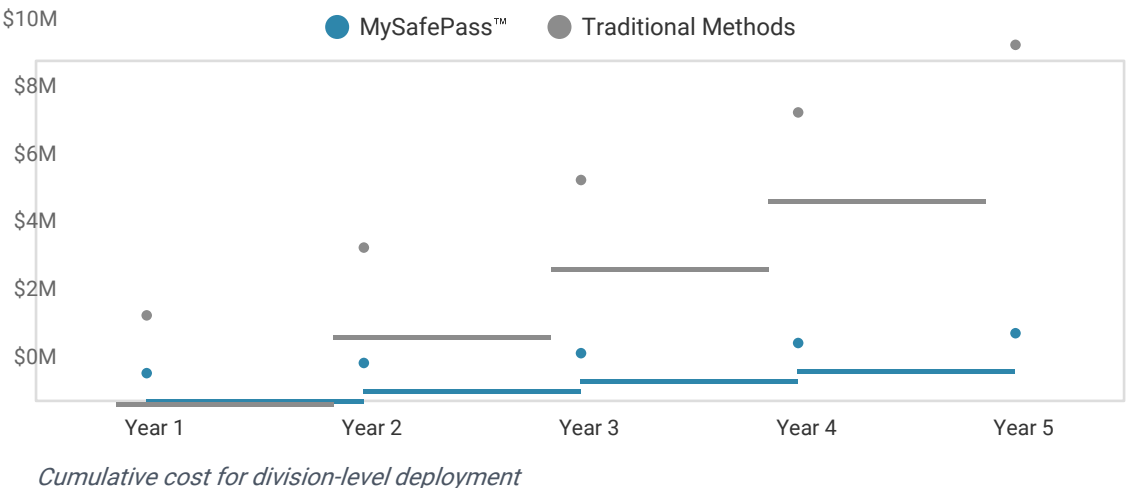
Annual Cost at Brigade Level	
MySafePass™ (5,000 tests):	\$62,500
Traditional Methods:	\$425,000
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Annual Savings:	\$362,500

Additional ROI Factors:	
✓ 70% reduction in personnel hours	✓ 92% less equipment needed
✓ \$1.2M saved in long-term care	✓ 14% increase in duty-ready status

Cost Comparison: MySafePass™ vs. Traditional



5-Year Cost Projection








Competitive Advantages






Key differentiators between MySafePass™ and industry alternatives

VS

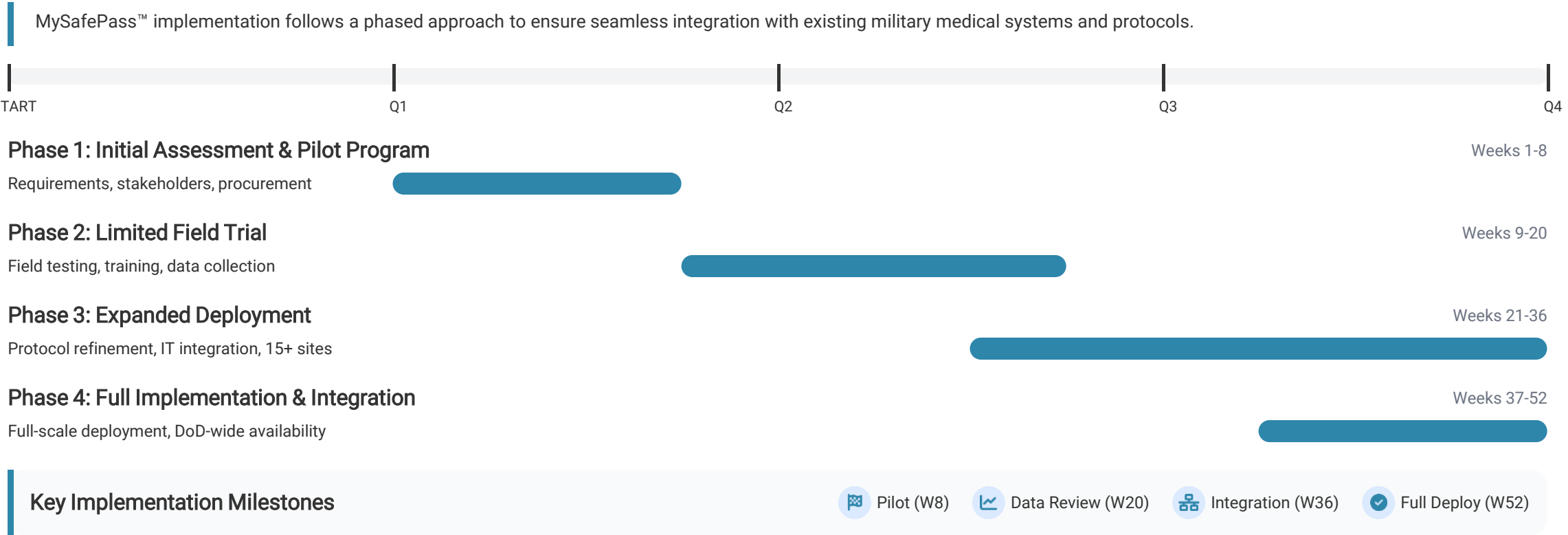
Industry Competitors

-  **Lengthy Assessment**
20-60+ minutes for neurological screening protocols
-  **Higher Cost**
\$500-1,200 per assessment with additional specialist fees
-  **Limited Sensitivity**
Often misses subtle or early-stage neurological changes
-  **Complex Implementation**
Requires extensive training and specialized facilities
-  **Limited Data Integration**
Minimal integration with existing military medical systems

MySafePass™ Advantages

-  **60-Second Screening**
Rapid deployment with immediate results available
-  **Cost-Effective**
80% cost reduction with CPT-coded insurance billing
-  **Enhanced Sensitivity**
Detects subtle olfactory changes missed by standard protocols
-  **Simple Implementation**
Minimal training required with field-ready deployment
-  **Full Data Integration**
Seamless integration with military health information systems

Implementation Timeline



Pilot Program Proposal



Pilot Objectives

- Validate MySafePass™ efficacy in military operational environments
- Deployment Testing:** Evaluate field performance in varied military environments
- User Experience:** Assess medical staff and end-user adoption rates
- Performance Metrics:** Gather comparative data vs. conventional screening
- Integration:** Validate compatibility with existing DoD medical systems

Recommended Pilot Structure

- ✓ 3 military bases
- ✓ 250 personnel/location
- ✓ 90-day evaluation
- ✓ Full technical support

Evaluation Metrics & Plan

- Comprehensive assessment using established DoD performance criteria

Key Performance Indicators:

- TBI detection accuracy rate
- Average screening time
- Field deployment readiness
- False positive/negative rates
- User satisfaction scores
- Cost per detection comparison



Success Criteria

- > 90% detection accuracy
- > 60% time reduction
- > 85% user satisfaction
- > 50% cost savings

Risk Mitigation & Change Management

Key Risk Areas

Proactively addressing implementation challenges across critical domains

User Adoption

Resistance to new protocols and technology integration within established military medical procedures

Information Security

Patient data protection, secure transmission protocols, and compliance with military cybersecurity standards

Regulatory Compliance

Ensuring alignment with DoD medical device policies, HIPAA requirements, and military health system protocols

Field Reliability

Performance verification in extreme environments and during high-tempo operations

Change Management Strategy

Comprehensive approach to ensure successful integration

1 Stakeholder Engagement

Early involvement of medical command, field medics, and unit commanders

2 Phased Implementation


Controlled rollout starting with pilot units and expanding based on feedback

3 Technical Integration

Secure API connections with existing military health records systems

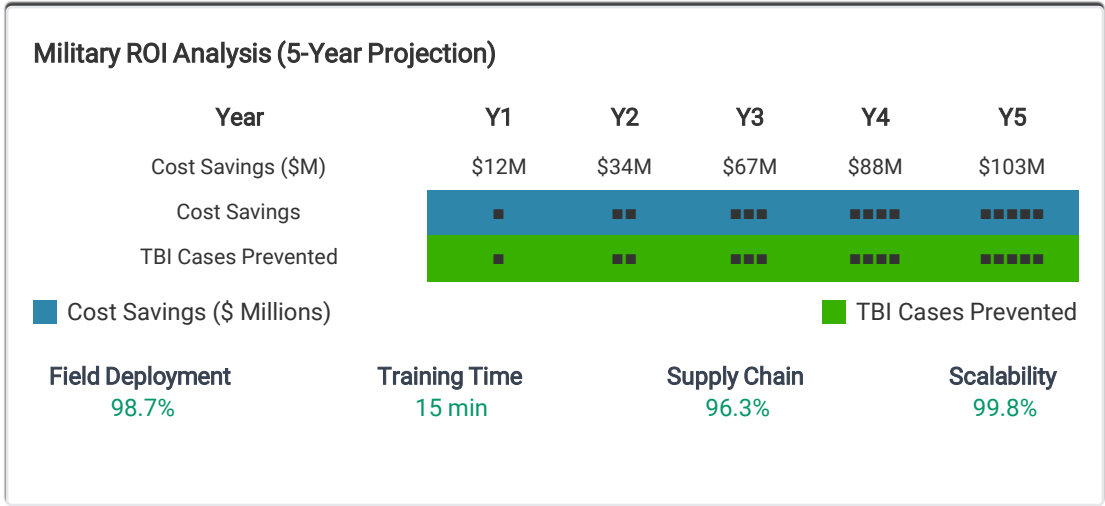
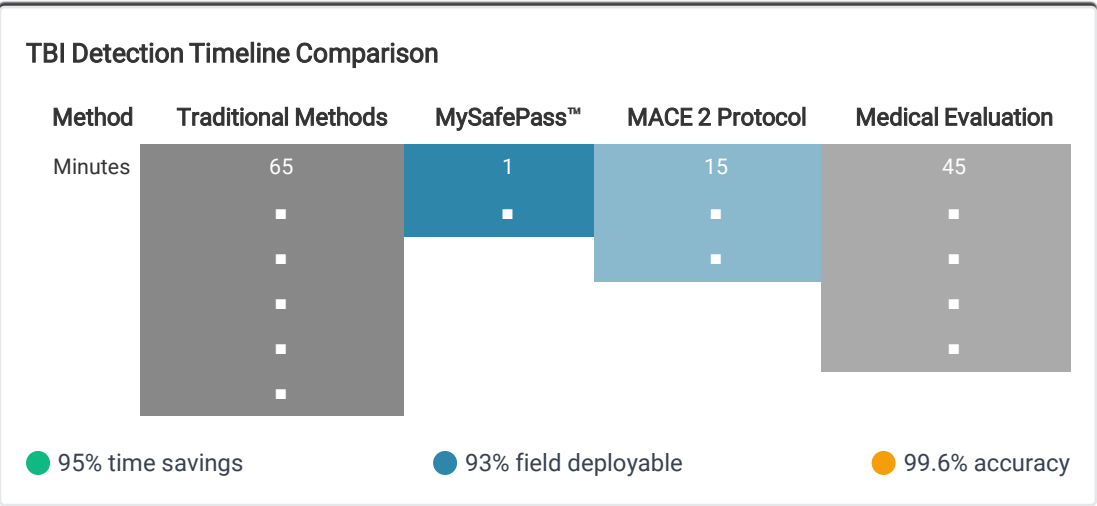
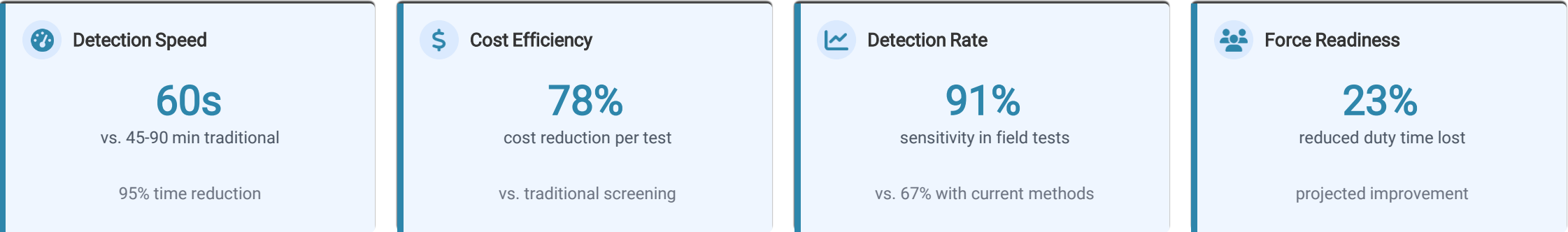
4 Training & Certification

Comprehensive training program with certification and standard operating procedures

 DISA/DoD Security Compliance Ready

Measuring Success: Key Metrics

Clearly defined metrics ensure program accountability and quantifiable ROI for military stakeholders



Citations & References

Sources used for statistical data and scientific claims presented in this briefing:

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Reiter, E. R., & Costanzo, R. M. (2014). Chemosensory impairment after traumatic brain injury. International Neurotrauma Letter, 23, 3-5.

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Images: Department of Defense Visual Information Library, FDA Medical Device Gallery, and MySafePass™ corporate materials.