

MySafePass™

# MySafePass: Next-Generation TBI & Neurological Screening for Military Readiness



Executive Briefing for U.S. Department of War Decision Makers

## EXECUTIVE SUMMARY:

MySafePass offers a rapid, objective, field-deployable screening solution for Traumatic Brain Injury (TBI) detection using validated olfactory testing technology. This briefing presents how this FDA Class II medical device can

- enhance force readiness,
- reduce healthcare costs, and
- improve operational capabilities

*through early TBI detection.*

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# AGENDA

- |   |  |        |
|---|--|--------|
| 1 | The TBI Challenge in Military Settings | 5 min  |
| 2 | Introducing MySafePass Technology      | 8 min  |
| 3 | Military Applications                  | 7 min  |
| 4 | Force Readiness & Operational Impact   | 10 min |
| 5 | Data & Case Studies                    | 8 min  |
| 6 | Cost-Benefit Analysis                  | 7 min  |
| 7 | Integration & Deployment               | 6 min  |
| 8 | Next Steps for DoD Adoption            | 5 min  |

TOTAL BRIEFING TIME

56 MIN

Q&A PERIOD

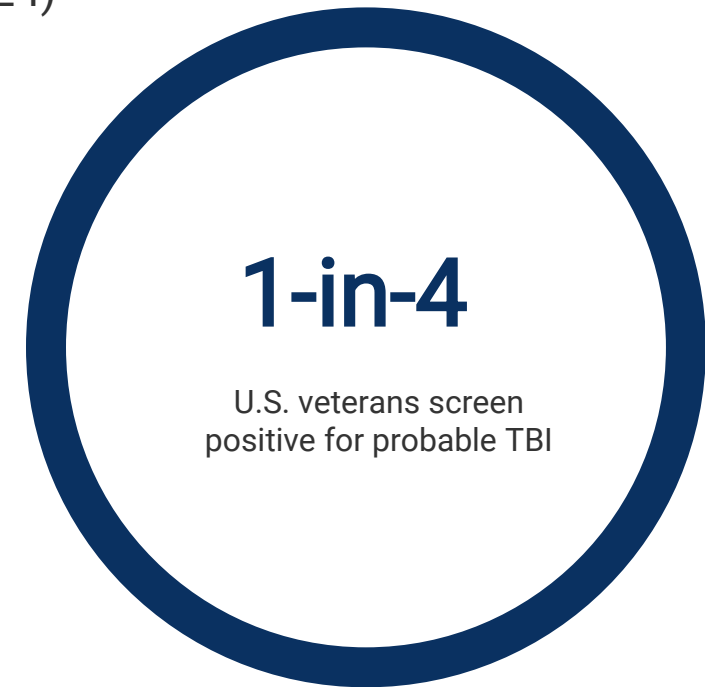
15 MIN

# The Military's Hidden Epidemic: TBI & Concussion

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- **458,000+** Service members diagnosed with TBI since 2000 (DoD 2024)
- Majority classified as mild TBI (concussion), often undiagnosed or under-reported
- **54% increased risk** of non-medical readiness after deployment-related TBI
- Only **17%** of TBIs occur in deployed settings – training and garrison incidents often missed

*"TBI associated with military service, regardless of severity, puts military service members and veterans at risk of long-term adverse outcomes."*



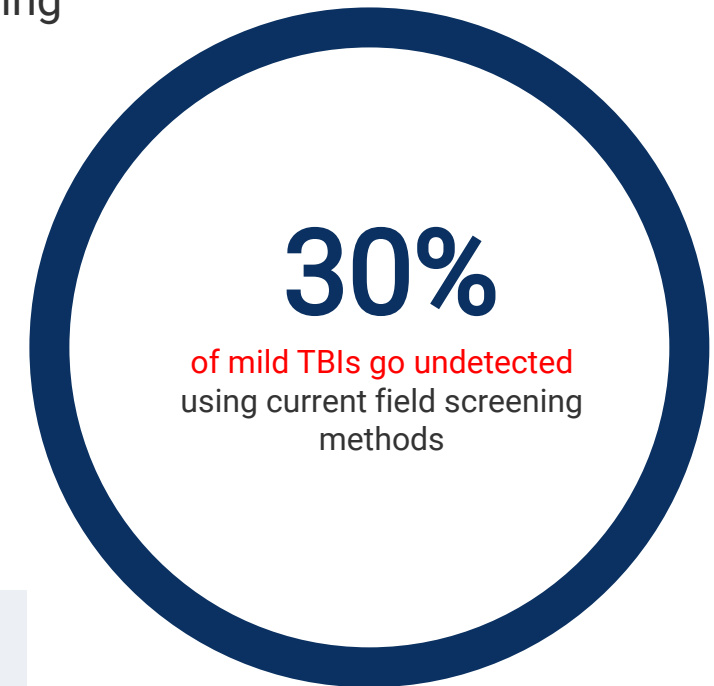
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# Current Screening Protocols & Their Limitations

- **MACE 2** (*Military Acute Concussion Evaluation*) – primary DoD TBI screening tool, but **requires trained medical personnel**
- **Subjective assessment** – relies on self-reporting and observable symptoms that may be minimized by service members
- **Baseline limitations** – most SAC validation studies require baseline scores for comparison, often unavailable in field conditions
- **Deployment gaps:** – current protocols not optimized for forward operating environments or mass casualty scenarios

*"Defense Medical Readiness requires objective, field-deployable tools for rapid TBI screening that can be administered by any trained service member – not just medical personnel."*



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# Introducing MySafePass: Science Behind the Solution

- **FDA Class II** medical device (exempt from 510k) with patent-protected technology
- Rapid **1-minute** olfactory dysfunction screener — identifies subtle scent disorders (hyposmia) that go undetected
- 5-point proprietary scent protocol validated through clinical testing
- Olfactory dysfunction present in **~90%** of early-stage concussion/TBI cases — precedes motor symptoms



**FDA CLASS II  
MEDICAL DEVICE**

*"A test of olfactory function and CTE in real time would be a 'game-changer' in our understanding of repetitive head injuries. A 5-min smell test could objectively track CTE over time."*

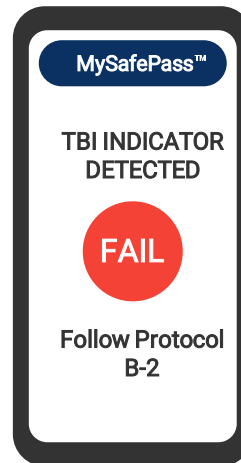
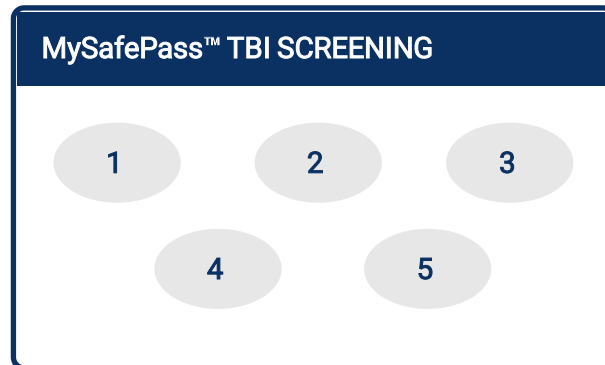
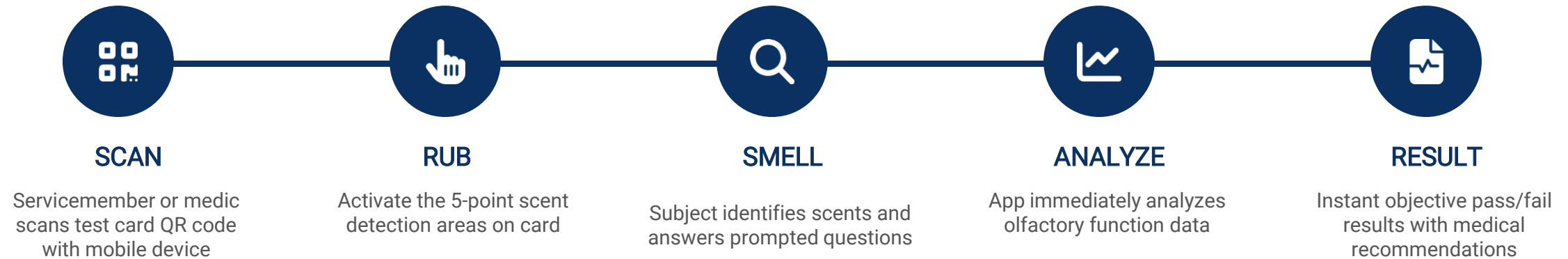
— Journal of World Otorhinolaryngology - Head and Neck Surgery (2018)

**National Institute of Health:** "Olfactory dysfunction is among the earliest features of TBI and present in ~90% of cases"

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# How MySafePass Works



- ✓ **5-point scratch-and-smell scent card** with precisely calibrated odors to test olfactory function
- ✓ **Simple pass/fail objective detection** of olfactory impairment at various sensitivity levels
- ✓ **Mobile app integration** for immediate results, data management and secure transmission to medical systems
- ✓ **Portable and ruggedized** for field deployment in any environment - from FOB to forward positions
- ✓ **-Non-invasive, 60-second process** easily administered by combat medics or unit leaders with minimal training

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# MILITARY APPLICATIONS

## From Garrison to Battlefield: Protecting America's Warfighters

MySafePass provides **rapid, objective TBI screening** across the full spectrum of military operations, enabling commanders to maintain force readiness and safeguard our most valuable asset – our people.



FORCE  
PROTECTION



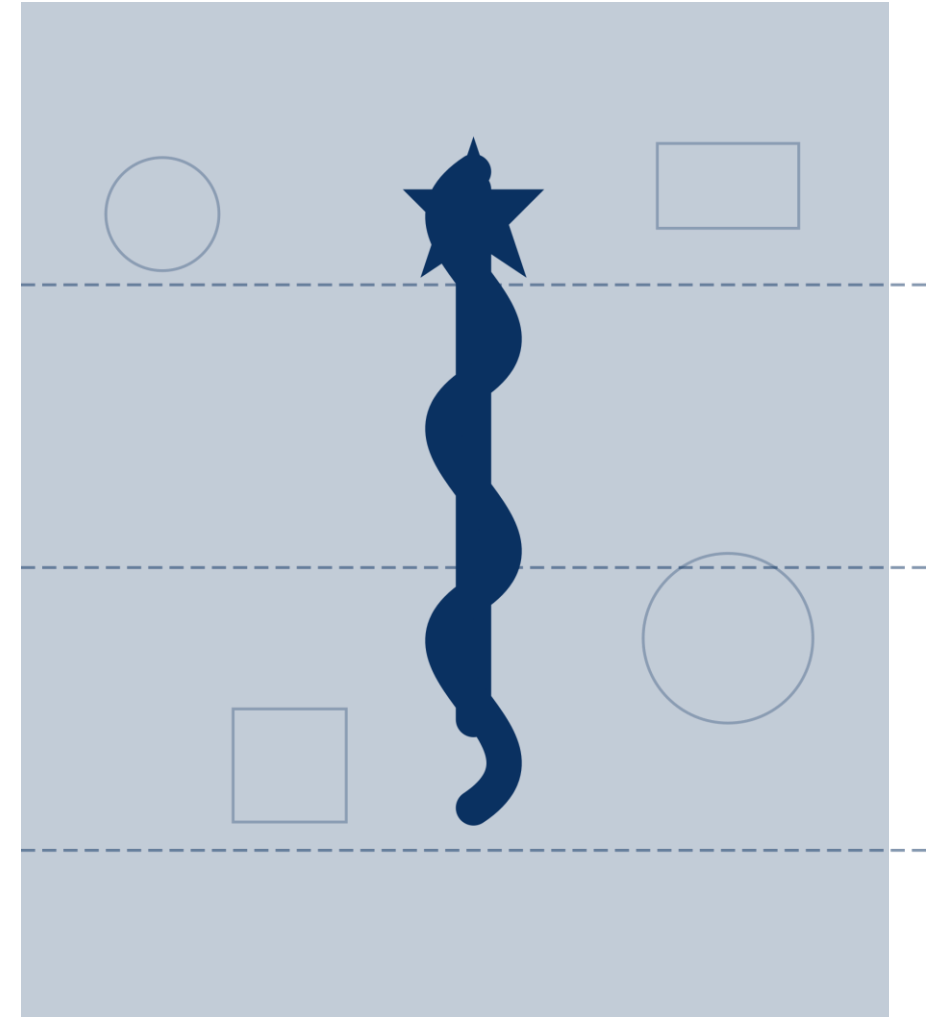
COMBAT  
CASUALTY CARE



OPERATIONAL  
READINESS



MISSION  
CAPABILITY

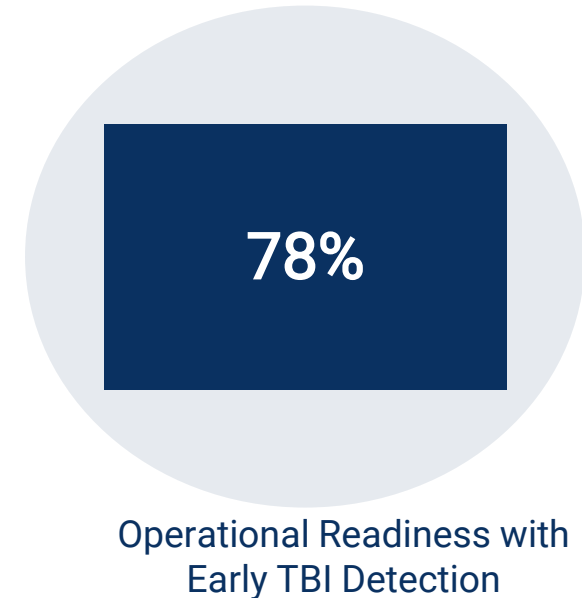


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# Force Readiness: Protecting America's Military Advantage

- 🛡️ **Early detection** of TBI prevents force degradation, preserves combat effectiveness
- ✈️ Enables **rapid medical decision support** for immediate return to duty or escalation to higher care
- 👥 **Reduces non-deployable status duration** by identifying mild TBI cases that might otherwise go undetected
- 📋 Maintains **unit cohesion and operational tempo** through objective, standardized screening



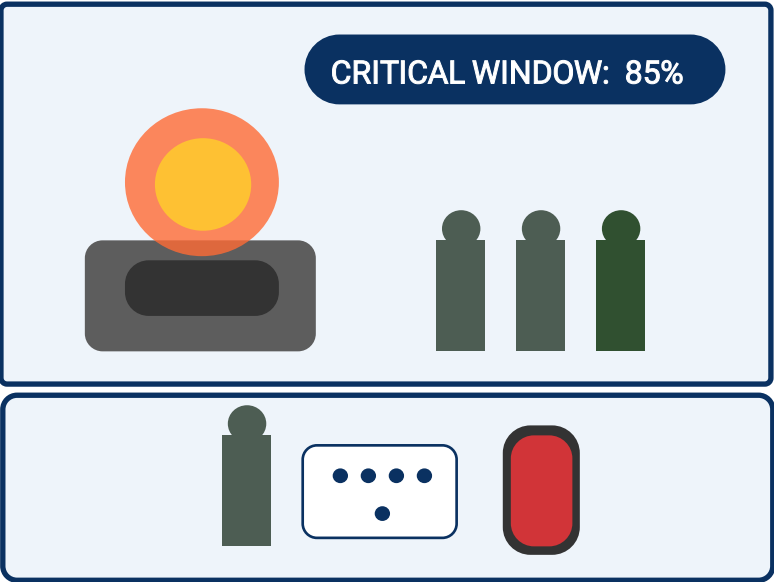
*"This study identified 54% increased odds of 'not medically ready' disposition for military personnel with probable traumatic brain injury following deployment." — Military Health System Research, 2025*

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# Combat Scenario: Rapid Field Screening Example



INCIDENT | 1 MINUTE SCREENING | GOLDEN HOUR

- Blast/Impact Detection:** Unit reports potential concussive event to command. MySafePass deployment initiated per SOP.
- Rapid Field Deployment:** Combat medic screens all personnel within 5-10 minutes of incident, regardless of visible symptoms.
- Objective Data Collection:** Olfactory dysfunction detected in 2 of 8 service members despite no self-reported symptoms.
- Immediate Decision Support:** Algorithm classifies risk levels and recommends medical actions based on established TBI protocols.
- Resource Optimization:** Medical evacuation prioritized for affected personnel while others remain operational, maintaining mission readiness.

# Data-Driven Results: Clinical & Military Validation

Figure 1: Olfactory Dysfunction vs Other TBI Biomarkers

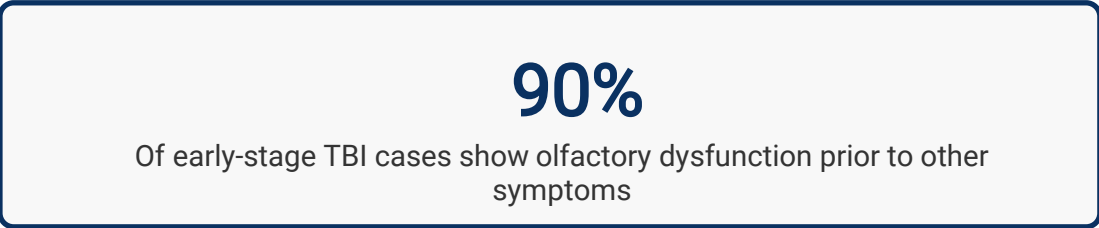
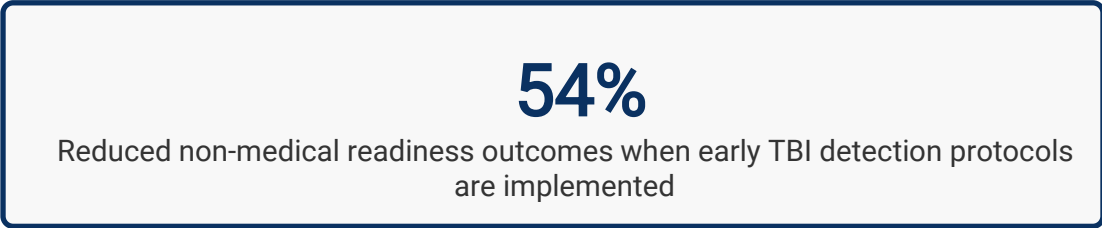


Figure 2: TBI Detection Timeline with MySafePass vs Standard Protocol



- "A test of olfactory function and CTE in real time would be a 'game-changer' in our understanding of repetitive head injuries. A 5-min smell test given by a single technician could objectively track CTE over time."  
*Science Direct (2018) - Journal of World Otorhinolaryngology*
- "Olfactory dysfunction is among the earliest nonmotor features of neurological disorders. Such dysfunction is present in approximately 90% of early-stage cases and can precede the onset of motor symptoms by years."  
*National Institute of Health (2023)*
- "Study identified 54% increased odds of 'not medically ready' disposition for military personnel with probable traumatic brain injury following deployment."  
*Department of Defense Health Affairs DoD Medical Surveillance Monthly Report (2025)*

# Comparative Analysis: MySafePass vs. Current Methods

## MACE 2\* & Current Protocols

- Subjective self-reporting requiring trained medical personnel
- Requires baseline testing for meaningful comparison
- Takes 15-20 minutes to administer properly
- Higher training requirement for field medics
- Limited utility in detecting mild TBI cases with subtle symptoms

*\*Military Acute Concussion Evaluation*

## MySafePass Advantage

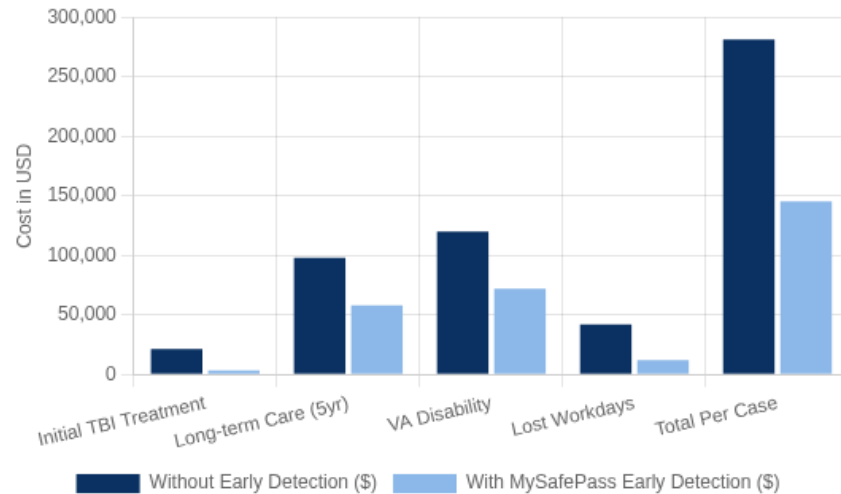
- ✓ Objective, non-biased testing independent of self-reporting **OBJECTIVE**
- ✓ No baseline required - results valid on first use **EFFICIENT**
- ✓ Rapid 60-second testing protocol **FAST**
- ✓ Can be administered by non-medical personnel after brief training **SIMPLE**
- ✓ Detects subtle hyposmia changes indicative of mild TBI **SENSITIVE**

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*"A test of olfactory function and CTE in real time would be a 'game-changer' in our understanding of repetitive head injuries. A 5-min smell test given by a single technician could objectively track CTE over time." — ScienceDirect*

# Cost-Effectiveness: Savings for DoD & VA

Annual TBI-Related Healthcare Costs



**10:1**  
ROI Ratio

- \$ \$19,800 average annual excess TBI-related costs per veteran** according to Veterans Health Administration (2021) study on long-term care
- \$458M+ potential annual savings** based on early detection and intervention across 458,000+ service members diagnosed with TBI since 2000
- 54% reduction in non-deployable status duration** through early detection, reducing downstream medical costs and improving force readiness
- Reduced disability claims and long-term care requirements** through earlier intervention preventing progression of TBI-related conditions

## CURRENT APPROACH

**\$87,634**

Average inpatient cost per TBI patient without early detection

## MySafePass APPROACH





**\$45 - \$75**

Per test with substantial reduction in downstream medical costs

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# Deployment & Scalability: Designed for Military Environments

-  **Compact kits** - Ruggedized carrying case, shelf-stable for 24 months, zero cold chain requirements
-  **Minimal training** - Under 30 minutes for medical technicians, 60 minutes for combat medics
-  **Rapid mass screening** - Test up to 240 personnel per hour with single administrator
-  **Digital integration** - Works with standard military mobile devices, connects to AHLTA, MEDPROS, and CHCS



GARRISON SCREENING

FIELD DEPLOYMENT

COMBAT OPERATIONS

MASS CASUALTY EVENTS

FORWARD AID STATIONS

*"Army tests capability of portable diagnostic devices currently not available for deployed medicine. One of three devices being tested will be selected for field deployment to improve critical response times." - Army.mil*

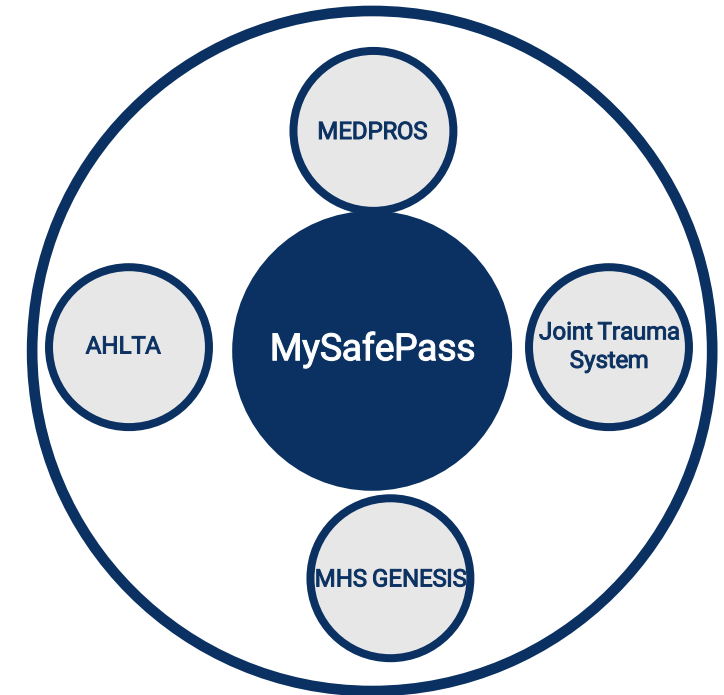
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# Integration: Seamless with Military Medicine

- ✓ **Compatible with Joint Trauma System** and DoD TBI protocols - supports standardized concussion care pathway
- ↔ **Data interoperability** - secure transmission to AHLTA, MHS GENESIS, and MEDPROS readiness tracking systems
- ↻ Supports **Force Health Protection goals** with standardized TBI data collection and reporting
- 👤 Results securely transmit to **electronic medical record (EMR) systems** with automatic documentation

*"Integrates with the Military Health System's care continuum from point-of-injury through treatment facilities and long-term monitoring"*

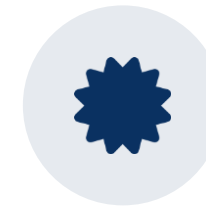


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# Procurement & Regulatory Status

- **FDA Class II Medical Device** (exempt from 510k requirements) – ready for immediate implementation
- Compliant with **DoD Instruction 6430.02** medical materiel standardization requirements for field deployment
- DHA-verified **CPT Codes 92700 r.43 and Z 13.858** for reimbursement and VA/DoD medical record continuity
- Available through **multiple acquisition pathways** : ECAT, GSA, Direct DHA procurement, or Middle Tier Acquisition



**FDA APPROVED**

Class II Medical Device  
Status



**DoD COMPLIANT**

Meets DHA Medical  
Standards



**ACQUISITION READY**

Multiple Procurement  
Pathways

*Patent and Trademark protection secured – manufactured in USA with secure supply chain compliant with Defense Production Act requirements*

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# NEXT STEPS

## Pathway to DoD Adoption and Implementation

MySafePass offers a clear, streamlined pathway to full DoD deployment within 12 months, beginning with strategic pilot programs and leveraging existing acquisition channels to accelerate adoption across all branches.



**PILOT  
PROGRAMS**

90 Days



**ACQUISITION  
APPROVAL**

60 Days



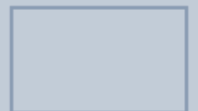
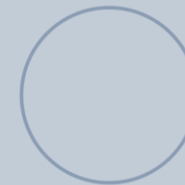
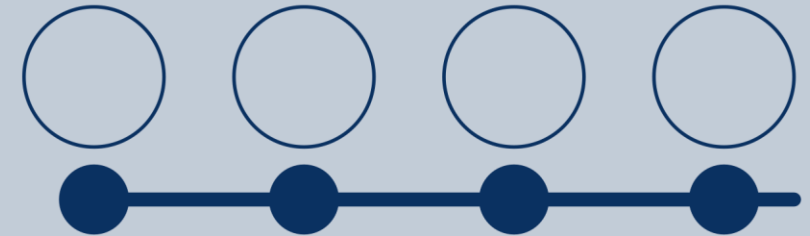
**FORCE-WIDE  
TRAINING**

120 Days



**GLOBAL  
DEPLOYMENT**

90 Days



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# Conclusion: The Case for MySafePass in Defense Health

- TBI remains an **unresolved crisis** affecting military readiness, operational capacity, and long-term veteran health costs
- MySafePass offers **objective, rapid, field-deployable screening** that complements existing protocols while addressing critical gaps
- Implementation provides **immediate ROI through early detection**, reduced disability claims, and improved force health protection
- Seamless integration with **existing military medical systems** ensures minimal disruption to established workflows

**RECOMMEND: Approve pilot program in Q4 2025**



*"A simple 1-minute olfactory screening test administered by field medics could revolutionize our approach to TBI detection and force protection."*

# Appendix / Contact & Further Information

## Scientific References


Doty RL. (2015). "Olfactory dysfunction and its measurement in the clinic." World Journal of Otorhinolaryngology Head and Neck Surgery, 1, 28-33.


Frank ME, et al. (2017). "Recognition of the component odors in mixtures." Chemical Senses, 42, 537-546.


MacGregor AJ, et al. (2025). "The association of deployment-related probable traumatic brain injury with post-deployment medical readiness." Military Medicine, 190(1), e83-e91.

Coldren RL, et al. (2010). "Evaluation of the Military Acute Concussion Evaluation for use in combat operations." Military Medicine, 175(7), 477-481.


### Military Program Director


 name


 phone

 email


### Technical Support


 MySafePass Defense Team


 phone

 email

### Procurement Office

 name

 phone

 email

### DoD Pilot Program

Initial deployment with select units for operational validation and integration testing. 90-day evaluation program available for immediate start.

### Research Partnership

Collaborative research opportunities with military medical institutions to further enhance TBI detection capabilities and protocols.

### Technology Resources

Secure portal access for military personnel to download technical specifications, research papers, and integration documents.

SCAN FOR  
SECURE  
PORTAL