

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.

CONFIDENTIAL EXECUTIVE BRIEFING

Department of Defense Health Affairs

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

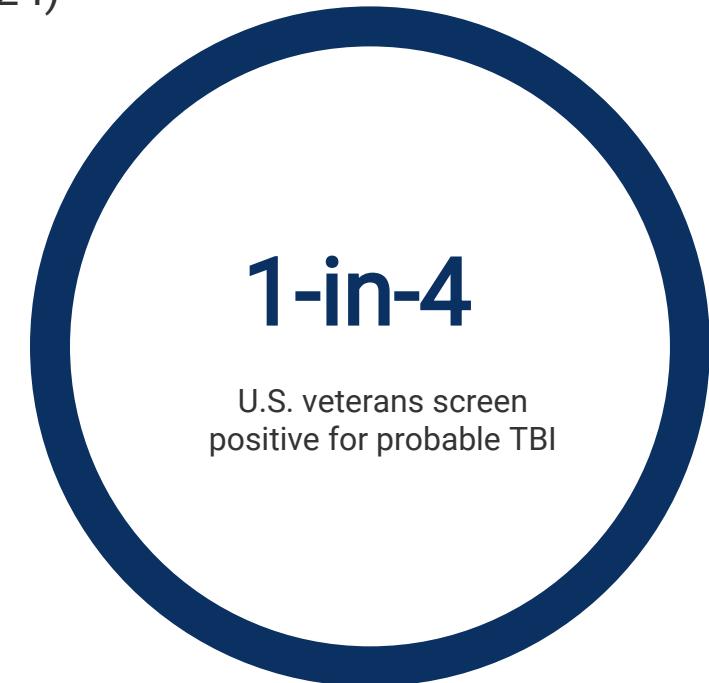
Q&A PERIOD

15 MIN

The Military's Hidden Epidemic: TBI & Concussion

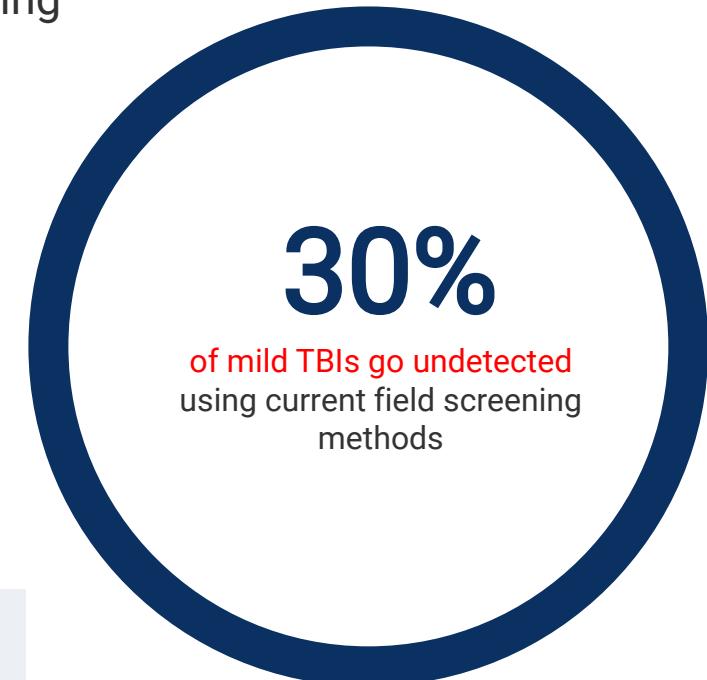
- **458,000+** Service members diagnosed with TBI since 2000 (DoD 2024)
- Majority classified as mild TBI (concussion), often undiagnosed or under-reported
- **54% increased risk** of non-medical readiness after deployment-related TBI
- Only **17%** of TBIs occur in deployed settings – training and garrison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

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



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."

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"

How MySafePass Works



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



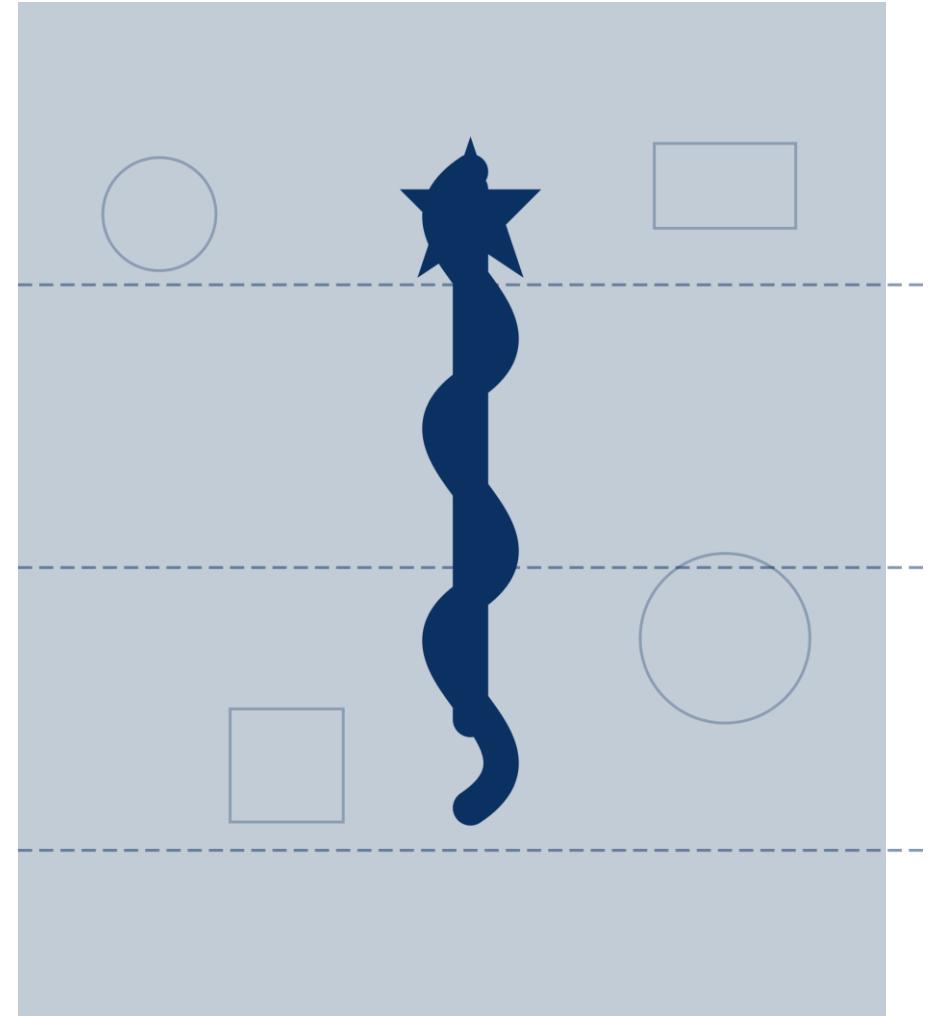
COMBAT
CASUALTY CARE



OPERATIONAL
READINESS



MISSION
CAPABILITY



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Force Readiness: Protecting America's Military Advantage

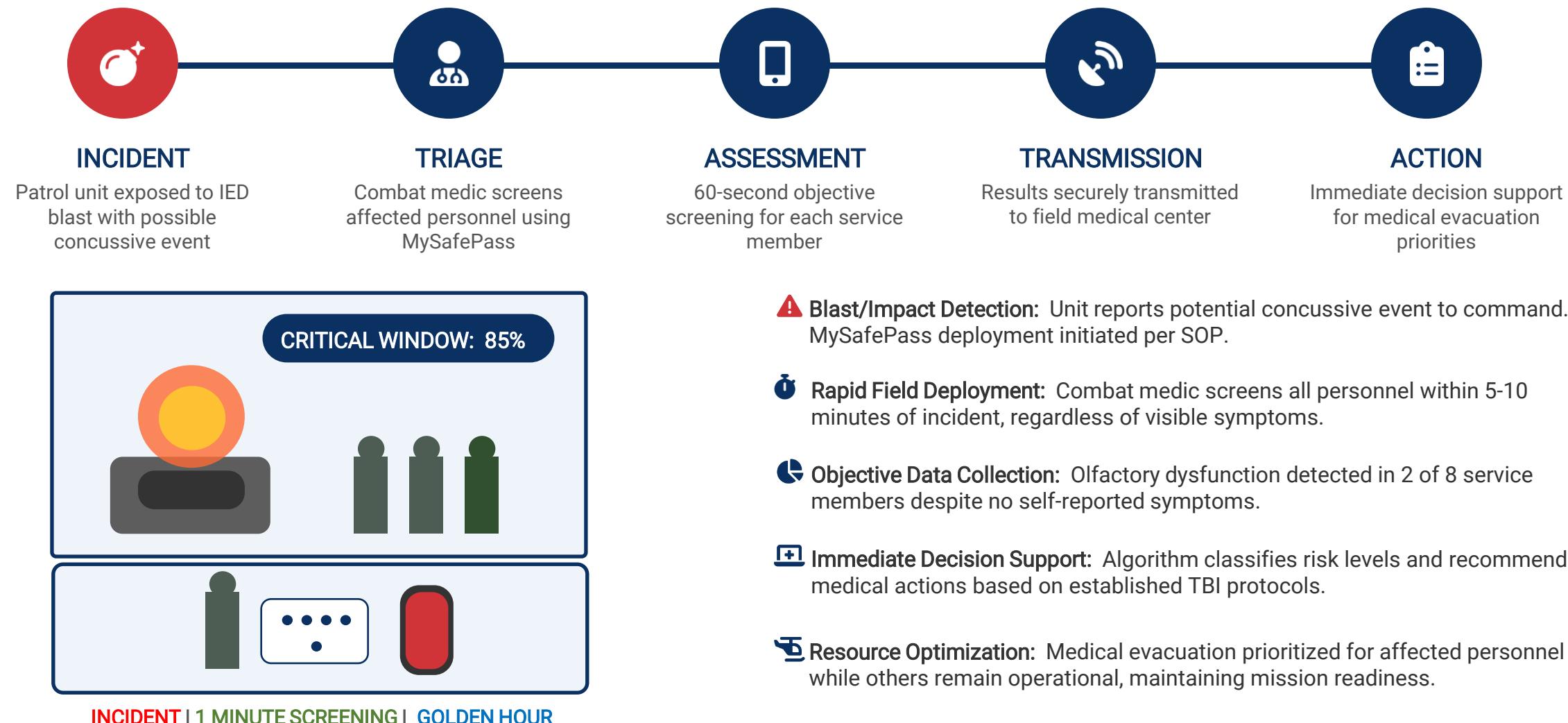
- 🛡️ **Early detection** of TBI prevents force degradation, preserves combat effectiveness
- ✈️ Enables **rapid medical decision support** for immediate return to duty or escalation to higher care
- 👥 **Reduces non-deployable status duration** by identifying mild TBI cases that might otherwise go undetected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

78%

Operational Readiness with
Early TBI Detection

"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

Combat Scenario: Rapid Field Screening Example



Data-Driven Results: Clinical & Military Validation

Figure 1: Olfactory Dysfunction vs Other TBI Biomarkers

90%

Of early-stage TBI cases show olfactory dysfunction prior to other symptoms

Figure 2: TBI Detection Timeline with MySafePass vs Standard Protocol

54%

Reduced non-medical readiness outcomes when early TBI detection protocols are implemented

- "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

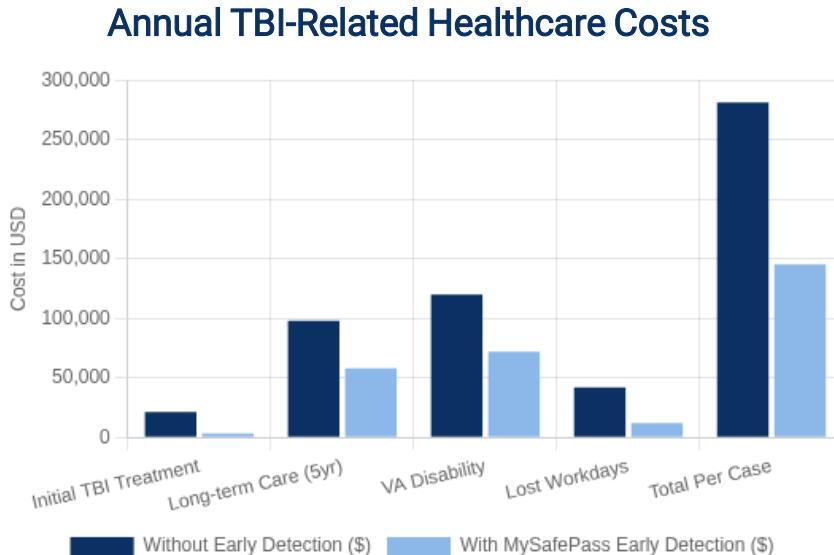
MySafePass Advantage

- ✓ 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

*Military Acute Concussion Evaluation

"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



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

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

GARRISON SCREENING

- rapid mass screening - Test up to 240 personnel per hour with single administrator

FIELD DEPLOYMENT

- digital integration - Works with standard military mobile devices, connects to AHLTA, MEDPROS, and CHCS

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

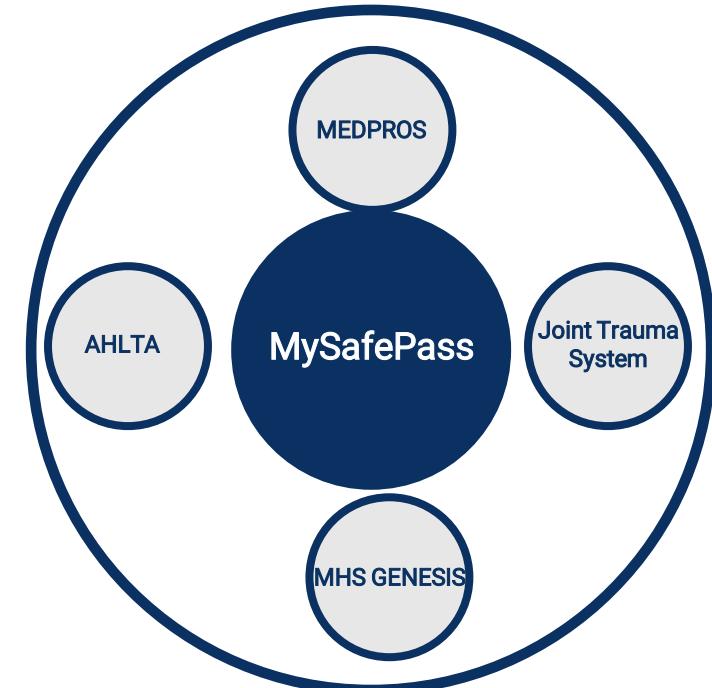
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Integration: Seamless with Military Medicine

- ✓ 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"



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

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

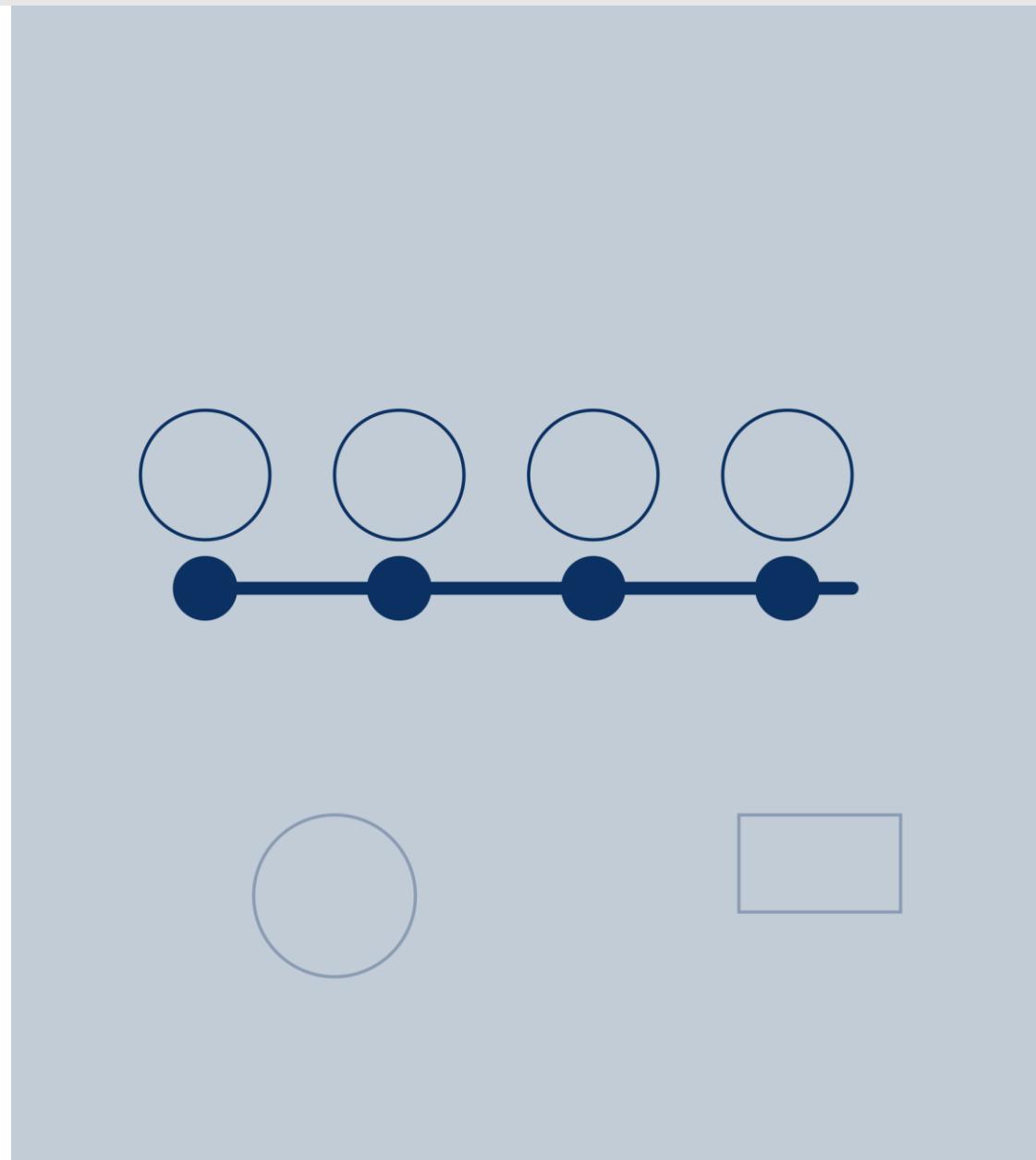


GLOBAL DEPLOYMENT

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

DoD Pilot Program

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

Technical Support

-  MySafePass Defense Team
-  phone
-  email

Research Partnership

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

Procurement Office

-  name
-  phone
-  email

Technology Resources

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

SCAN FOR
SECURE
PORTAL