



AmDTx Clinical Safety Case Report

Mobio Interactive Pte Ltd

Published 2020-07-18

Document filename: MI Clinical Safety Case Report	
Directorate / Programme	Project: AmDTx
Document Reference	CRM-CSCR
Director	Bechara Saab
Owner	Mark Thoburn
Authors: Mark Thoburn, Ramya Loganathan, Avetis Muradyan, Bechara Saab	2020-06-01

Document Management

Revision History

Version	Date	Summary of Changes
0.1	2020-06-01	Draft 1
1.0	2020-07-18	Reviewed and approved

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Mark Thoburn	Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer	2020-07-18	1.0
Bechara Saab	Chief Scientist	2020-07-18	1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Mark Thoburn	Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer	2020-07-18	1.0

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Doc Reference Number	Title	Version
1	CRM-CRMS	Clinical Risk Management System (CRMS)	1.0
2	CRM-CSHL	Clinical Safety Hazard Log	1.0
3	CRM-CA	MI CRMS Compliance Assessment (DCB0129)	1.0
4	CRM-CRMS	MI CRMS Compliance Assessment	1.0
5	CRM-CSCR	AmDTx Clinical Safety Case Report	1.0
6	CRM-CRMS	MI Clinical Risk Management System	1.0
7	DPIA	Am DPIA 20191215	20191215
8	CLA	AmDTx Code Level Assessment-20200127	20200127

Contents

Introduction	4
System Definition / Overview	4
Clinical Risk Management System	5
Clinical Risk Analysis	5
Clinical Risk Evaluation	6
Clinical Risk Control	6
Hazard Log	6
Test Issues	6
Summary Safety Statement	6
Quality Assurance and Document Approval	6
Configuration Control / Management	6

Introduction

The purpose of the Clinical Safety Case Report (and associated Hazard Log) is to identify, assess and manage clinical safety hazards arising from the creation and implementation of AmDTx in health care settings, including the use of Am as a preventative stress management tool with healthy populations at risk for chronic stress and mental illness.

With this document, MI demonstrates that associated hazards related to the use of AmDTx have been identified and managed, where possible, to ensure they do not give rise to unacceptable risks to patients and delivery of care. and phase of lifecycle it relates to.

System Definition / Overview

Program Overview:

AmDTx is a mobile app that administers psychotherapy, primarily in the form of mindfulness meditation, through audio recordings. The app allows users to self-assess their mood and stress, and log personal comments. Users' computer vision stress assessments inform the personalisation of their training.

As **AmDTx** app allows the user to view stress measures, this falls in scope of DCB0129, as there could be adverse effects of this information displaying incorrectly.

Version number:

- 1.9.10

Clinical environment Where **Am** is deployed:

- Available for download within the general population worldwide

Description of existing systems Am interfaces with:

- n/a

Number of users and patients using AmDTx:

- Between 300 and 1000 Weekly Active Users (WAUs)

Clinical Risk Management System

1. Description of AmDTx' clinical risk management system:

See MI's Clinical Risk Management System

2. Identification of key personnel, their roles and responsibilities;

- Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer: Mark Thoburn
- Security Officer: Ramya Loganathan
- Chief Scientist: Dr. Bechara Saab
- Chief technology Officer: Avetis Muradyan

3. Identification of clinical risk management governance structure (a formally documented set of systems and procedures to control and govern IT clinical risks).

The risk management of AmDTx is governed through systems and procedures detailed in the following documents. Together, these documents constitute the Clinical Risk Management policy for AmDTx.

- Clinical Risk Management
- AmDTx Clinical Safety Hazard Log
- MI Clinical Risk Management Plan
- MI CRMS Compliance Assessment (DCB0129)
- AmDTx Clinical Safety Case Report.docx
- MI Clinical Risk Management System (CRMS).docx
- Am DPIA 20191215
- AmDTx Code Level Assessment-20200127

Clinical Risk Analysis

Not all computer vision stress measures in Am are accurate. Users may misinterpret an inaccurate measure and respond adversely.

- In the case of an inaccurate measure of high stress (when the user's stress is actually low), the user may experience stress or anxiety as a result of seeing the measurement.
- In the case of a low stress measurement (when the user's stress is actually high), the user may fail to appropriately manage their stress.

Clinical Risk Evaluation

MI effectively communicates to users that unique objective measures of stress in AmDTx may be inaccurate, and that users should monitor stress measure trends instead.

Additionally, users of AmDTx are informed that regular training with Am, regardless of stress reports, is required to develop robust stress management skills and to strengthen stress resilience.

A core curriculum of stress training is available to Am users for free at all times.

As a result, MI assesses the use of AmDTx as:

- Risk: Level 1
- Severity Classification: Minor

Clinical Risk Control

- No further action is required at this time

Hazard Log

- See **AmDTx** Clinical Safety Hazard Log

Test Issues

- n/a

Summary Safety Statement

- AmDTx is a mobile application supporting stress management and stress resilience via pre-recorded audio psychotherapy. AmDTx is safe to use as intended, presenting no significant risk to end users.

Quality Assurance and Document Approval

- See: Clinical Risk Management Compliance Assessment.

Configuration Control / Management

Configuration Control of AmDTx is managed via Bitbucket (<https://bitbucket.org/>), a third-party code repository, which maintains the following certifications:

- SOC II
- SOC III
- PCI DSS
- ISO/IEC 27001
- ISO/IEC 27018
- GDPR