

AWARD NUMBER: W81XWH1990005

TITLE: Assessment of Psychological and Physiological Effects of Augmented Reality: Development of the Dual-Adaptation Protocol for Augmented Reality (DAPAR)

PRINCIPAL INVESTIGATOR: Dr. Kay Stanney

PERFORMING ORGANIZATION: Design Interactive

REPORT DATE: April 25, 2020

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Design Interactive, Inc. 3504 Lake Lynda Dr, Ste 400 Orlando, FL 32817			8. PERFORMING ORGANIZATION REPORT 2018-677-002		
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14. ABSTRACT The Dual-Adaptation Protocol for Augmented Reality (DAPAR) effort seeks to assess the physiological impact of AR exposure and develop usage protocols that have potential to minimize physiological maladaptations associated with AR exposure. This is being accomplished by conducting a human subjects study that assesses physiological effects of AR medical training simulations using different displays (i.e., tablet versus HoloLens versus Magic Leap) and different exposure protocols (i.e., protracted versus repeated, intermittent exposure with breaks). Results from the assessment will be used to evaluate the physiological impact of AR exposure and develop dual-adaptation protocols, design guidelines, usability criteria, and best practices guides to help ensure AR is safe and effective to use for military medical training.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER	19a. NAME OF RESPONSIBLE PERSON
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Annual Technical Status Report for

Assessment of Psychological and Physiological Effects of Augmented Reality: Development of the Dual-Adaptation Protocol for
Augmented Reality (DAPAR)
Research Project No. MTEC 2018-677-002
EGS# MT190005
Reporting Period: 01 MAY '19 – 25 APR '20

MTEC Research Project Awardee

Dr. Kay Stanney, Principal Investigator & Program Manager
Claire Hughes, Project Manager
Deirdre Maietta, Project Management Officer
Dr. Cali Fidopiastis, Chief Scientist
Peyton Bailey, Research Associate
Nicole Taranta, Data Scientist
Lindsey Lee, Research Intern
Jack Reckmeyer, Research Intern

Research Project Technical POC

Claire Hughes
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Submitted: April 25, 2020



1. Project Status

a. Accomplishments

Objective 1: Human Subjects Study Planning

- Milestone 1: Award Executed with MTEC
 - Complete 5/1/2019
- Milestone 2: Kickoff Meeting, Project Planning, and Stakeholder Brainstorm
 - Complete 5/16/2019
- Milestone 3: Quarterly Report 1 (April – June)
 - Complete 7/25/2019
- Milestone 4: Develop Human Subjects Study Protocol
 - Complete 08/01/2019
- Milestone 5: IRB/HRPO Submitted
 - Complete 10/23/2019
- Milestone 6: Administrative Review to Approve Continuation to Objective 2
 - Complete 10/17/2019
- Milestone 7: Quarterly Report 2 (July – September)
 - Complete 10/25/2019
- Milestone 8: Experimental Equipment Set up and Tested
 - Complete 11/15/2019
- Milestone 9: Pilot Testing Complete
 - Complete 12/02/2019
- Milestone 10: Quarterly Report 3 (October – December)
 - Complete 1/25/2020
- Milestone 11: Data Collection Set 1
 - Complete 3/6/2020
- Milestone 13: Annual Report 1
 - Completed 4/25/2020

b. Reportable Outcomes

N/A

c. Progress Detail

Objective 1: Human Subjects Study Planning

Objective 1 resulted in a human subjects study plan that is ready for study execution and is now complete. The following milestones were completed during this reporting period:

- Milestone 2: Kickoff Meeting, Project Planning, and Stakeholder Brainstorm: Complete
 - Stakeholder requirements were gathered, and project planning occurred at the kickoff meeting on 5/16/2019.
 - Literature review was completed 6/30/2019.
- Milestone 3: Quarterly Report 1 (April – June): Complete
 - A quarterly report was generated for April – June and was submitted to MTEC on 7/25/2019.
- Milestone 4: Develop Human Subjects Study Protocol: Complete

- Study design was prepared, completed, and submitted on 8/1/2019.
- Milestone 5: IRB/HRPO Submitted: Complete
 - IRB submission was made to Copernicus IRB and approval was received in September 2019 and subsequently, HRPO submission was prepared, with submission to HRPO on 10/23/2019.
 - HRPO Approval was received 1/10/2020.
- Milestone 6: Administrative Review to Approve Continuation to Objective 2: Complete
 - A meeting was held with DI's Senior Vice President of Shared Services Karen Gibbons to review the IRB approved protocol and approve continuation to Objective 2. This meeting resulted in administrative approval to commence study activities, and a signed copy of this report was submitted to MTEC on 10/17/2019.
- Milestone 7: Quarterly Report 2 (July – September): Complete
 - A quarterly report was generated for July – September and submitted to MTEC on 10/25/2019.

Objective 2: Human Study Assessment Execution

Objective 2 will result in an assessment of how AR exposure impacts human physiological state. The following milestones have been completed toward this objective during this reporting period:

- Milestone 8: Experimental Lab Set up and Tested: Complete
 - The experimental lab has been set up with all necessary equipment. A report describing the set up and testing that has been completed was submitted to MTEC on 11/15/2019. This report included photographs of the different experimental stations that are being utilized throughout the study, as well as a description of each station and its purpose.
- Milestone 9: Pilot Testing: Complete
 - The pilot study was completed between 11/25/2019 and 11/27/2019. A report on the process results and data collection was generated and submitted to MTEC on 12/2/2019. Due to the delay in HRPO approval, in order to maintain the proposed study schedule, we determined that additional lab space and an additional set of equipment needed to be purchased and set up so that we can run four (4) participants per day instead of the planned two (2) participants per day.
- Milestone 10: Quarterly Report 3 (October – December); Complete
 - A quarterly report was generated for October – December and submitted to MTEC on 1/25/2020.
- Milestone 11: Data Collection Set 1: Complete
 - Data collection set 1 was completed between 2/26/20 and 3/5/20. A report detailing the first data collection was submitted to MTEC on 3/6/20.
- Milestone 13: Annual Report 1: Complete
 - An annual report was generated for May 2019 – April 2020 and submitted to MTEC on 4/25/2020.

2. Future Plans

During the next quarter, the following Milestones are planned:

Objective 2: Human Study Assessment Execution

- Milestone 12: Data Collection Set 2
- Milestone 14: Quarterly Report 4 (April – June)

3. Problems / Issues

a. Current Problems / Issues

- HRPO approval delay caused a delay to study initiation, which required additional lab space to be acquired to support running four (4) participants per day instead of the proposed (2) participants per day; this was at incurred additional cost. This additional cost may be able to be compensated for, as discussed at the 4/9/2020 IPR, by eliminating experimental conditions (i.e., 2-day break conditions) should other intermittent protocols (i.e., 30-minute break conditions) prove affective in driving habituation.
- The outbreak of COVID-19 has delayed data collection, but at this time has not impacted any scheduled milestones. We will continue to monitor the situation and report any impacts.

b. Anticipated Problems / Issues

The outbreak of COVID-19 has delayed data collection, but at this time has not impacted any scheduled milestones. We will continue to monitor the situation and report any impacts.

4. Financial Health

The project is financially on track.

5. Personnel Effort

Personnel	Role	Percent Effort
Kay Stanney, PhD	Program Manager	5%
Kay Stanney, PhD	Principal Investigator	5%
Claire Hughes	Project Manager	22%
Deirdre Maietta	Project Management Officer	7%
Cali Fidopiastis, PhD	Chief Scientist	5%
Peyton Bailey	Research Associate	16%
Nicole Taranta	Data Scientist	16%
Lindsey Lee	Research Intern	12%
Jack Reckmeyer	Research Intern	12%

6. Protocol and Activity Status

a. Human Use Regulatory Protocols

TOTAL PROTOCOLS: One (1) human subjects research protocol will be required to complete the Statement of Work.

PROTOCOLS:

Protocol [HRPO Assigned Number]: E01199.1a

Title: Assessment of Psychological and Physiological Effects of Augmented Reality (APPEAR): Development of Dual-Adaptation Protocol for Augmented Reality (DAPAR)

Target required for clinical significance: N/A

Target approved for clinical significance: N/A

Submitted to and Approved by:

- Copernicus Group Independent Review Board; Approved 10/11/2019
- U.S. Army Medical Research and Development Command Human Research Protection Office; Approved 01/10/2020

STATUS:

- Recruitment: 53
- Enrollment: 42
- Excluded after Informed Consent: 11
- Drop Out during Experiment: 0
- Administrative, Technical, Logistical Issues: None

b. Use of Human Cadavers for RDT&E, Education or Training

TOTAL ACTIVITIES: No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).

ACTIVITIES: N/A

c. Animal Use Regulatory Protocols

TOTAL PROTOCOLS: No animal use research will be performed to complete the Statement of Work.

PROTOCOLS: N/A

STATUS: N/A

Annual Business Status Report for

Assessment of Psychological and Physiological Effects of Augmented Reality: Development of the Dual-Adaptation Protocol for Augmented Reality (DAPAR)
Research Project No. MTEC 2018-677-002
EGS# MT190005
Reporting Period: 01 MAY '19 – 25 APR '20

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Research Project Technical POC

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407-706-0977
Email address: Claire.Hughes@designinteractive.net

Submitted: April 25, 2020



1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Program Manager	5%
Principal Investigator	5%
Project Manager	22%
Project Management Officer	7%
Chief Scientist	5%
Research Associate	16%
Data Scientist	16%
Research Intern	12%
Research Intern	12%

2. CURRENT EXPENDITURES

A. Cost Reimbursable Contracts: N/A

B. Fixed Priced Contracts:

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1	Award Executed with MTEC	5/1/2019	\$0
2	Kickoff Meeting, Project Planning, and Stakeholder Brainstorm	5/24/2019	\$50,000
3	Quarterly Report 1 (April-June)	7/25/2019	\$0
4	Study Design Complete	8/1/2019	\$100,000
5	IRB Submitted	9/2/2019	\$100,000
6	Administrative Review to Approve Continuation to Task/Objective 2	10/18/2019	\$58,664
7	Quarterly Report 2 (July - September)	10/25/2019	\$0
8	Experimental Equipment Set Up and Tested	11/15/2019	\$100,000
9	Pilot Testing Complete	12/5/2019	\$150,000
10	Quarterly Report 3 (October – December)	1/25/2020	\$0
11	Data Collection Set 1 Complete	5/1/2020	\$100,000
13	Annual Report 1	4/25/2020	\$0

	Total Expenditures		\$658,664.00
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C. Cost Share Contributions: N/A

3. STATUS OF MILESTONES

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	Award Executed with MTEC	5/1/2019	100%	100%
2	Kickoff Meeting, Project Planning, and Stakeholder Brainstorm	5/24/2019	100%	100%
3	Quarterly Report 1 (April – June)	7/25/2019	100%	100%
4	Study Design Complete	8/1/2019	100%	100%
5	IRB Submitted	9/2/2019	100%	100%
6	Administrative Review to Approve Continuation to Task/Objective 2	10/18/2019	100%	100%
7	Quarterly Report 2 (July – September)	10/25/2019	100%	100%
8	Experimental Equipment Set Up and Tested	11/15/2019	100%	100%
9	Pilot Testing Complete	12/5/2019	100%	100%
10	Quarterly Report 3 (October – December)	1/25/2020	100%	100%
11	Data Collection Set 1 Complete	5/1/2020	100%	100%
12	Data Collection Set 2 Complete	5/1/2020	90%	90%
13	Annual Report 1	4/25/2020	100%	100%
14	Quarterly Report 4 (April – June)	7/25/2020	0%	0%
15	Data Collection Set 3 Complete	8/20/2020	0%	0%
16	Quarterly Reports 5 (July – September)	10/25/2020	0%	0%
17	Data Collection Complete	10/30/2020	0%	0%
18	Quarterly Report 6 (October – December)	1/25/2021	0%	0%
19	Data Analysis Complete	3/1/2021	0%	0%
20	Out Brief and Report Results	4/30/2021	0%	0%
21	Final Technical and Business Status Report	4/30/2021	0%	0%

4. DEVIATION FROM PROJECT PLAN

- Modification 1 was approved on December 19, 2019 moving Milestone 11 from 2/3/2020 to 5/1/2020 due to a delay in HRPO approval.
- Modification 2 was approved on March 12, 2020 adding the HRPO Approval Memorandum as Attachment C to the contract.
- Modification 3 was unilaterally approved by MTEC on April 1, 2020 to increase the incremental funding to \$1,249,999.