EVALUATION IN ACCORDANCE WITH ISC-TA-EB-0253 ANNEX A STATEMENT OF WORK

Artificially Intelligent Monitoring System (AIMS)

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EXECUTIVE SUMMARY

BACKGROUND

The Artificially Intelligent Monitoring System (AIMS) is an autonomous, artificially intelligent, platform technology designed to prevent healthcare associated infections (HAIs) caused by improper hand hygiene that is wholly owned by Lumenix.

EVALUATION APPROACH

We conducted an independent evaluation of AIMS as part of the Innovative Solutions Canada – Testing Stream. The evaluation involving 20 AIMS units was conducted in two sites within The Ottawa Hospital (TOH) between 26th May 2020 and 23rd June 2020 by a team led by Dr Jeremy Grimshaw from the Clinical Epidemiology Program of the Ottawa Hospital Research Institute (the research arm of TOH).

The evaluation included 6 objectives involving 29 test procedures addressing 29 key performance indicators (KPIs) identified in the Statement of Work (SOW) (Table 1). Multiple experiments were conducted for each AIMS unit for each KPI. Units were considered *fully compliant* with a KPI if a unit passed all related experiments, *partially compliant* if a unit passed some of the related experiments and *non-compliant* if a unit failed all relevant experiments. Overall compliance with each key performance indicator was then assessed.

RESULTS

The AIMS system met all Objectives and KPIs specified in the SOW. After multiple experiments were performed on each unit, the AIMS system was fully compliant in 92.9% of KPIs, partially compliant in 4.5% KPIs, and non-compliant in 2.6% KPIs. Causes of non-compliance were identified by the evaluation team and the Contractor's technical staff.

CONCLUSION

The AIMS system exceeded expectations. We assess the Innovation to have passed the TRL7 level and to be ready for field testing at the TRL8 level in the hospital's operational environment. In the few instances where some AIMS units were partially or non-compliant, there were clear reasons for this that should be easily addressed during further operational testing and development of the AIMS system.

EVALUATION OF THE ARTIFICIALLY INTELLIGENT MONITORING SYSTEM (AIMS)

INTRODUCTION

The Ottawa Hospital (TOH) was the Testing Organization for the evaluation which was undertaken by Dr. Grimshaw and colleagues from the Ottawa Hospital Research Institute (the research arm of TOH).

TOH was responsible for:

- Conducting a 4-week test of the Innovation in collaboration with Contractor technical staff in a clinical setting (i.e., ICU, ED, patient bedroom) with the following characteristics:
  - Fixed patient location, such as a bed or infant warmer;
  - Fixed location for sink in field of view of sensor;
  - Fixed location of wall mounted dispenser in field of view of sensor;
  - Ingress/egress point in field of view of sensor;
  - Clinical (or care) staff engaging in routine care tasks; engineering support staff engaging in module specific test tasks; and
  - Wireless connectivity.
- Composing a design of experiments (DOE) in conjunction with Contractor Technical staff to enumerate real-world variables for each of the test procedures (i.e. variations in position, setting, light level, etc.);
- Conducting all tests enumerated in the DOE in conjunction with Contractor technical staff;
- Independently verifying the outcome of each test and correlate them with their associated KPIs;
- Ensuring the Innovation can be physically mounted to the ceiling of the clinical space where the test is being conducted:
  - Mounting frame and hardware included by Contractor; and
  - Optional mounting plate for drop ceilings/acoustic tile provided by Contractor as required.
- Ensuring the clinical space can provide the following electrical requirements:
  - 120V AC junction box; and
  - Installation of 5V AC/DC converter (included by Contractor).
- Ensuring internet access is available for the Innovation, as the Innovation is ethernet enabled.
- Ensuring that the Innovation is installed in an orientation that provides an unobstructed view of the patient and the hand hygiene equipment, such as wall mounted sanitizer dispensers or sinks.

OBJECTIVES OF EVALUATION

The objectives of the evaluation were specified in the Statement of Work (Table 1).

Table 1. Evaluation objectives as specified in the Statement of Work

Sequence	Objective Detail
O1	Confirm Innovation's ability to send and receive data and commands while operating on Testing Organization's network
O2	Confirm Innovation's ability to detect hand washing events in each of the installed environments
O3	Confirm Innovation's ability to apply timely warnings to prevent breaches of hand hygiene policy
O4	Confirm Innovation's ability to accurately detect instances of physical contact with a patient (HAND STATE = DIRTY) in Testing Organization's operational setting
O5	Confirm the Innovation properly submits data to user portal and dashboards
O6	Confirm user portal responds to user queries

EVALUATION APPROACH

Setting

TOH is Canada's largest academic hospital providing quaternary, tertiary and secondary care services on three sites to 1.3 million citizens in Eastern Ontario. It has 1,224 beds, and sees over 60,000 patient admissions, and 1.125 million ambulatory care visits per year.

The evaluation was conducted in two clinical areas within TOH including: ***6 East*** **-** an inpatient Malignant Hematology unit at The General Campus with 28 bed spaces (involving 8 AIMS units); and ***Module H*** **-** the Thrombosis and Benign Hematology Clinic at The General Campus of The Ottawa Hospital with 13 single patient rooms (involving 12 AIMS units).

Evaluation team

Dr Jeremy Grimshaw, Senior Scientist in the Clinical Epidemiology Program of the Ottawa Hospital Research Institute, Professor in the Department of Medicine, University of Ottawa and Canada Research Chair in Health Knowledge transfer and Uptake was responsible for the detailed design, conduct and analysis of the evaluation (with senior staff) from his team. This report documents the methods and results of the evaluation.

Design of experiments

In conjunction with Lumenix technical staff, we designed experiments for each test procedure to assess performance of AIMS against the specified key performance indicators (KPIs) (Table 2). We created detailed operating procedures for each experiment (see Appendix 1). For some KPIs, experiments assessed whether the AIMS units were compliant eg whether events triggered an appropriate response on the unit (by physical observation of the unit) and whether the client portal (dashboard) was compliant in logging events (by observing the dashboard). For some KPIs, we conducted multiple experiments for each AIMS unit. All experiments were conducted independently and Lumenix staff were not present during these.

For each KPI, AIMS units were considered *fully compliant* with a KPI if a unit passed all related experiments, *partially compliant* if a unit passed some of the related experiments and *non-compliant* if a unit failed all related experiments. Overall compliance with each key performance indicator (KPI) was then assessed. The causes of partial or non-compliance were identified by the evaluation team and Contractor's technical staff.

The evaluation was conducted over a 4-week period between 26th May and 23rd June 2020.

Table 2 Test procedures and Key Indicators

	Test Procedure	Key Performance Indicator
O1	Innovation networking testing: 1. Power-on and confirm device establishes connection with Contractor client portal 2. Confirm device responds to application launch commands 3. Toggle parameters (sound: on/mute; lights: on/off, IR emitter: on/off; etc.) using the client portal. Confirm device acknowledges and responds appropriately 4. Query system status: ID, active state, temperature, CPU utilization 5. Confirm logging events 6. Confirm messages are being published by Innovation to client portal 7. Confirm user management system publishes updates 8. Send deactivation signal 9. Send power down signal 10. Send reboot signal	1. Innovation subscribes to Contractor client topics 2. Innovation device transitions from idle to active state 3. Commands are acknowledged and Innovation responds by performing action 4. Innovation returns specified queried data 5. Log files contain accurate record of all events performed by system 6. Client portal displays time-stamped messages corresponding to system events 7. User actions (enter, exit, hand washing, warnings, violations, etc.) trigger messages to be published 8. Innovation system transitions from active to idle on receiving deactivation signal 9. Innovation system powers down on receiving power-off command 10. Innovation system reboots on receiving reboot command
O2	Hand Hygiene Event detection: 1. Innovation tracks users entering field of view 2. Innovation detects user proximity to hand hygiene equipment 3. Innovation detects user interaction with hand hygiene equipment 4. Innovation determines that a user has washed hands based on Contractor acceptability criterion 5. Hand hygiene event is logged and reported	1. Entry event logged and time-stamped 2. User proximity to hand hygiene equipment acknowledged through visual indication (light pattern) 3. User interaction with hand hygiene equipment acknowledged through visual indication (light pattern) 4. User hand washed state acknowledged through published message and log event 5. Confirm log report and messages appropriately generated

O3	Provide timely warning to prevent breach of hand hygiene policy: 1. User enters field without washing hands 2. User's hands come in close proximity to the patient, but do not touch the patient 3. Innovation predicts possible violation of hand hygiene policy and emits audible and visible warning	1. User entry logged and time-stamped with handstate=dirty 2. AIMS does not register touch violation 3. AIMS emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal
O4	Innovation detects violation of hand hygiene policy: 1. User enters field and does not wash hands 2. User approaches patient and hands come in close proximity 3. User touches patient in full view of the Innovation 4. Innovation detects violation and documents the event	1. User entry logged and time-stamped with handstate=dirty 2. Innovation emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal 3. Innovation provides visual acknowledgement of hand hygiene policy violation, logs and time-stamps event, and message appears in client portal 4. Confirm log entry and message portal entry exists for this violation
O5	Client portal displays Innovation system information: 1. Client portal home page contains aggregated information from all active Innovation units 2. Client portal allows access to "dashboards" for each deployed Innovation unit (active and inactive) 3. Active Innovation units publish data in real-time and can be queried 4. Inactive Innovation units provide information on current status only	1. Home page contains accurate list of deployed Innovation devices, aggregated statistics on Innovation detections, links to individual dashboards 2. Hyperlinks for each Innovation unit bring user to Innovation dashboard for each deployed unit 3. Up-to-date information is displayed on the dashboard of each active Innovation unit 4. Inactive units display their inactive status
O6	Client portal permits queries by event type over specified date range: 1. Clients can access the Innovation database through the query feature. Queries can be submitted by selecting a date range from a dropdown calendar and event types can be selected by checking radio boxes. 2. The query is submitted. 3. Client can download data in .csv format	1. Query feature allows date and event-type selection. 2. The requested data is returned by the Innovation database 3. Data is compiled into .csv format and is sent to client's browser.

RESULTS

Overall results

The AIMS system met all of the Objectives and KPIs specified in the SOW. After multiple experiments were performed on each unit, the AIMS system was fully compliant in 92.9% of KPIs, partially compliant in 4.5% KPIs, and non-compliant in 2.6% KPIs.

In the few instances where AIMS units were partially or non-compliant, there were clear reasons for this that should be easily addressed during further operational testing and development of the AIMS system (see Appendix 2 for further details). Four AIMs units were subject to a third-party software bug that prevented power up. The third-party confirmed that this was a new bug and that they were actively working to correct this. Non-compliance with hand hygiene detection, proximity to a patient with unclean hands (and initiating audible/visual prompt) and violation detection were uncommon, and the result of calibration and field of vision adjustments that should be easily resolvable.

Results by Key Performance Indicator

Table 3 Summary of Key Performance Indicator compliance across AIMS units

Key performance indicator	Units Tested	Full	Partial	Non-Compliant
O1 Innovation networking testing				
O1.1 Innovation subscribes to Contractor client topics	20	16	-	4
O1.2 Innovation device transitions from idle to active state	20	20	-	-
O1.3 Commands are acknowledged and Innovation responds by performing action	12	9	3	-
O1.4 Innovation returns specified queried data	20	20	-	-
O1.5 Log files contain accurate record of all events performed by system	17	17	-	-
O1.6 Client portal displays time-stamped messages corresponding to system events	17	17	-	-
O1.7 User actions (enter, exit, hand washing, warnings, violations, etc.) trigger messages to be published	17	17	-	-
O1.8 Innovation system transitions from active to idle on receiving deactivation signal	20	20	-	-
O1.9 Innovation system powers down on receiving power-off command	20	20	-	-
O1.10 Innovation system reboots on receiving reboot command	16	16	-	-
O2 Hand hygiene event detection				
O2.1 Entry event logged and time-stamped	17	17	-	-
O2.2 User proximity to hand hygiene equipment acknowledged through visual indication (light pattern)	12	10	2	-

Key performance indicator	Units Tested	Full	Partial	Non-Compliant
O2.3 Innovation detects user interaction with hand hygiene equipment User interaction with hand hygiene equipment acknowledged through visual indication (light pattern)	12	10	2	-
O2.4 User hand washed state acknowledged through published message and log event	12	10	2	-
O2.5 Confirm log report and messages appropriately generated	17	15	2	-
O3 Provide timely warning to prevent breach of hand hygiene policy				
O3.1 User entry logged and time-stamped with handstate=dirty	15	15	-	-
O3.2 AIMS does not register touch violation	15	11	3	1
O3.3 AIMS emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal	15	11	3	1
O4 Innovation detects violation of hand hygiene policy				
O4.1 User entry logged and time-stamped with handstate=dirty	15	15	-	-
O4.2 Innovation emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal	15	12	1	2
O4.3 Innovation provides visual acknowledgement of hand hygiene policy violation, logs and time-stamps event, and message appears in client portal	15	12	1	2
O4.4 Confirm log entry and message portal entry exists for this violation	15	12	1	2
O5 Client portal displays Innovation system information				
O5.1 Home page contains accurate list of deployed Innovation devices, aggregated statistics on Innovation detections, links to individual dashboards	1	-	1	-
O5.2 Hyperlinks for each Innovation unit bring user to Innovation dashboard for each deployed unit	20	20	-	-
O5.3 p-to-date information is displayed on the dashboard of each active Innovation unit	17	17	-	-
O5.4 Inactive units display their inactive status	20	20	-	-
O6 Client portal permits queries by event type over specified date range				
O6.1 Query feature allows date and event-type selection.	17	17	-	-
O6.2 The requested data is returned by the Innovation database	17	17	-	-
O6.3 Data is compiled into .csv format and is sent to client's browser.	17	17	-	-

SUMMARY AND CONCLUSIONS

The AIMS system exceeded expectations. We assess the Innovation to have passed the TRL7 level and to be ready for field testing at the TRL8 level in the hospital's operational environment.

After multiple experiments were performed on each unit, the AIMS system was fully compliant in 92.9% of KPIs, partially compliant in 4.5% KPIs, and non-compliant in 2.6% KPIs. In the few instances where AIMS units were partially or non-compliant, there were clear reasons for this that should be easily addressed during further operational testing and development of the AIMS system.

Appendix 1 Detailed description of evaluation procedures

	Test Procedure	Key Performance Indicator	Evaluation (OHRI)
O1	Innovation networking testing: 1. Power-on and confirm device establishes connection with Contractor client portal 2. Confirm device responds to application launch commands 3. Toggle parameters (sound: on/mute; lights: on/off, IR emitter: on/off; etc.) using the client portal. Confirm device acknowledges and responds appropriately 4. Query system status: ID, active state, temperature, CPU utilization 5. Confirm logging events 6. Confirm messages are being published by Innovation to client portal 7. Confirm user management system publishes updates 8. Send deactivation signal 9. Send power down signal 10. Send reboot signal	1. Innovation subscribes to Contractor client topics 2. Innovation device transitions from idle to active state 3. Commands are acknowledged and Innovation responds by performing action 4. Innovation returns specified queried data 5. Log files contain accurate record of all events performed by system 6. Client portal displays time-stamped messages corresponding to system events 7. User actions (enter, exit, hand washing, warnings, violations, etc.) trigger messages to be published 8. Innovation system transitions from active to idle on receiving deactivation signal 9. Innovation system powers down on receiving power-off command 10. Innovation system reboots on receiving reboot command	1. N units: All circuits on H and 6E Location: Both Test procedure: Power down through dashboard. Turn breaker off. Turn unit on through dashboard. Turn breaker on. Observe number of units physically for signs of being o. Observe registration on the dashboard (From black circle to crescent moon). 2. N units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test procedure: Switch unit to idle (turn off detection mode). Switch unit to active (turn on detection mode). Observe if eye has red light in it. Dashboard – detection mode toggle should appear green. 3. N Units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test procedure: Ensure unit is active. Change parameter. Physically observe sound for sound/on, light signal, IR glow. Dashboard-toggle characteristics 4. N Units: All Location: Both (dashboard observation) Test procedure: Review dashboard. 5. N units: 12 for physical observation. All for dashboard observation Location: H (physical observation); Both (dashboard observation) Procedure: Module H-Observe different events (entering, exiting, hand hygiene)

	Test Procedure	Key Performance Indicator	Evaluation (OHRI)
			6E-Observe dashboard for time-stamped messages of events. 6. N Units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test Procedure: Module H-Observe different events (entering, exiting, hand hygiene) and if time-stamped message is logged in dashboard. 6E-Observe dashboard for time-stamped messages of events. 7. N Units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test Procedure: Module H-Simultaneously observe in person and on dashboard for events on activity log as they are occurring (when person enters, exits, has a warning, has a violation). 6E-Observe dashboard for event logs. 8. N Units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test Procedure: Toggle detection mode off. Observe if unit goes idle. On dashboard changes from green circle to crescent moon (if sound and lights are off). 9. N Units: 12 for physical observation. All for dashboard observation. Location: H (physical observation); Both (dashboard observation) Test Procedure: On dashboard, toggle unit to power off. Observe if system is off on dashboard and physically on unit. 10. N Units: 12 for physical observation. All for dashboard observation

	Test Procedure	Key Performance Indicator	Evaluation (OHRI)
			Location: H (physical observation); Both (dashboard observation) Test Procedure: Click reboot. Observe dashboard and physical unit to see/hear unit reboot.
O2	Hand Hygiene Event detection: 1. Innovation tracks users entering field of view 2. Innovation detects user proximity to hand hygiene equipment 3. Innovation detects user interaction with hand hygiene equipment 4. Innovation determines that a user has washed hands based on Contractor acceptability criterion 5. Hand hygiene event is logged and reported	1. Entry event logged and time-stamped 2. User proximity to hand hygiene equipment acknowledged through visual indication (light pattern) 3. User interaction with hand hygiene equipment acknowledged through visual indication (light pattern) 4. User hand washed state acknowledged through published message and log event 5. Confirm log report and messages appropriately generated	1. N Units: 12 for physical observation. All for client portal observation Location: H (physical observation); Both (client portal observation) Test Procedure: Module H-Observe user walking into room. Check client portal to see if entrance is recognized and logged. 6E-Observe node page for each unit and confirm if entrances are being logged. 2. N Units: 12 for physical observation. Location: Module H Test Procedure: Observe if light pattern commences when user is in proximity to hand hygiene equipment (sink). 3. N Units: 12 for physical observation. Location: Module H Test Procedure: Observe user interacting with hand hygiene equipment (sink) and if unit acknowledges this with pulsing blue light. 4. N Units: 12 for physical observation. Location: Module H Test Procedure: Observe duration of time person interacts with hand hygiene equipment (sink) and if unit indicates completion with a blue sliding light. 5. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Module H-Observe user conducting hand hygiene according to criterion and if this is registered on the client portal. 6E-Observe client portal for hand hygiene event logs.

	Test Procedure	Key Performance Indicator	Evaluation (OHRI)
O3	Provide timely warning to prevent breach of hand hygiene policy: 1. User enters field without washing hands 2. User's hands come in close proximity to the patient, but do not touch the patient 3. Innovation predicts possible violation of hand hygiene policy and emits audible and visible warning	1. User entry logged and time-stamped with handstate=dirty 2. AIMS does not register touch violation 3. AIMS emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal	1. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Observe person entering room and if this is registered on the client portal. 2. N Units: 12 for physical observation. Location: Module H Test Procedure: Observe user approaching patient. Unit should not trigger a violation event. 3. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Observe user approaching patient. Unit should emit audible and visual warning if sound and lights are ON. Client portal should log a warning event.
O4	Innovation detects violation of hand hygiene policy: 1. User enters field and does not wash hands 2. User approaches patient and hands come in close proximity 3. User touches patient in full view of the Innovation 4. Innovation detects violation and documents the event	1. User entry logged and time-stamped with handstate=dirty 2. Innovation emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal 3. Innovation provides visual acknowledgement of hand hygiene policy violation, logs and time-stamps event, and message appears in client portal 4. Confirm log entry and message portal entry exists for this violation	1. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Observe user entering room and if this is registered on the client portal. 2. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Observe user coming close to patient. Unit emits audible warning, displays unique colour pattern, and logs/time-stamps warning. Warning appears on message center in client portal. 3. N Units: 12 for physical observation. Location: Module H Test Procedure: Observe person touching patient. Unit should provide visual notification of violation. Client portal should register violation.

	Test Procedure	Key Performance Indicator	Evaluation (OHRI)
			4. N Units: 12 for physical observation. All for client portal observation. Location: Both Test Procedure: Observe dashboard for violation message.
O5	Client portal displays Innovation system information: 1. Client portal home page contains aggregated information from all active Innovation units 2. Client portal allows access to "dashboards" for each deployed Innovation unit (active and inactive) 3. Active Innovation units publish data in real-time and can be queried[6] 4. Inactive Innovation units provide information on current status only	1. Home page contains accurate list of deployed Innovation devices, aggregated statistics on Innovation detections, links to individual dashboards 2. Hyperlinks for each Innovation unit bring user to Innovation dashboard for each deployed unit 3. Up-to-date information is displayed on the dashboard of each active Innovation unit 4. Inactive units display their inactive status	1. N Units: All units Location: Both Test Procedure: Observe client portal home page for list of units, aggregated statistics. 2. N Units: All units Location: Both Test Procedure: Interact with client portal and ensure links to each individual unit work. 3. N Units: All units Location: Both Test Procedure: Observe client portal for each unit and ensure capturing live data. 4. N Units: All units Location: Both Test Procedure: Observe client portal for each unit while detection mode is off. Toggle should show off and no events should be captured.
O6	Client portal permits queries by event type over specified date range: 1. Clients can access the Innovation database through the query feature. Queries can be submitted by selecting a date range from a dropdown calendar and event types can be selected by checking radio boxes. 2. The query is submitted. 3. Client can download data in .csv format	1. Query feature allows date and event-type selection 2. The requested data is returned by the Innovation database 3. Data is compiled into .csv format and is sent to client's browser	1. N Units: All units Location: Both-Client portal only Test Procedure: Enter dates in search bar on client portal and click search. 2. N Units: All units Location: Both-Client portal only Test Procedure: Choosing event types should return appropriate data. 3. N Units: All Location: Both-Client portal only Test Procedure: Click download results and ensure that .CSV file opens and contains appropriate data.

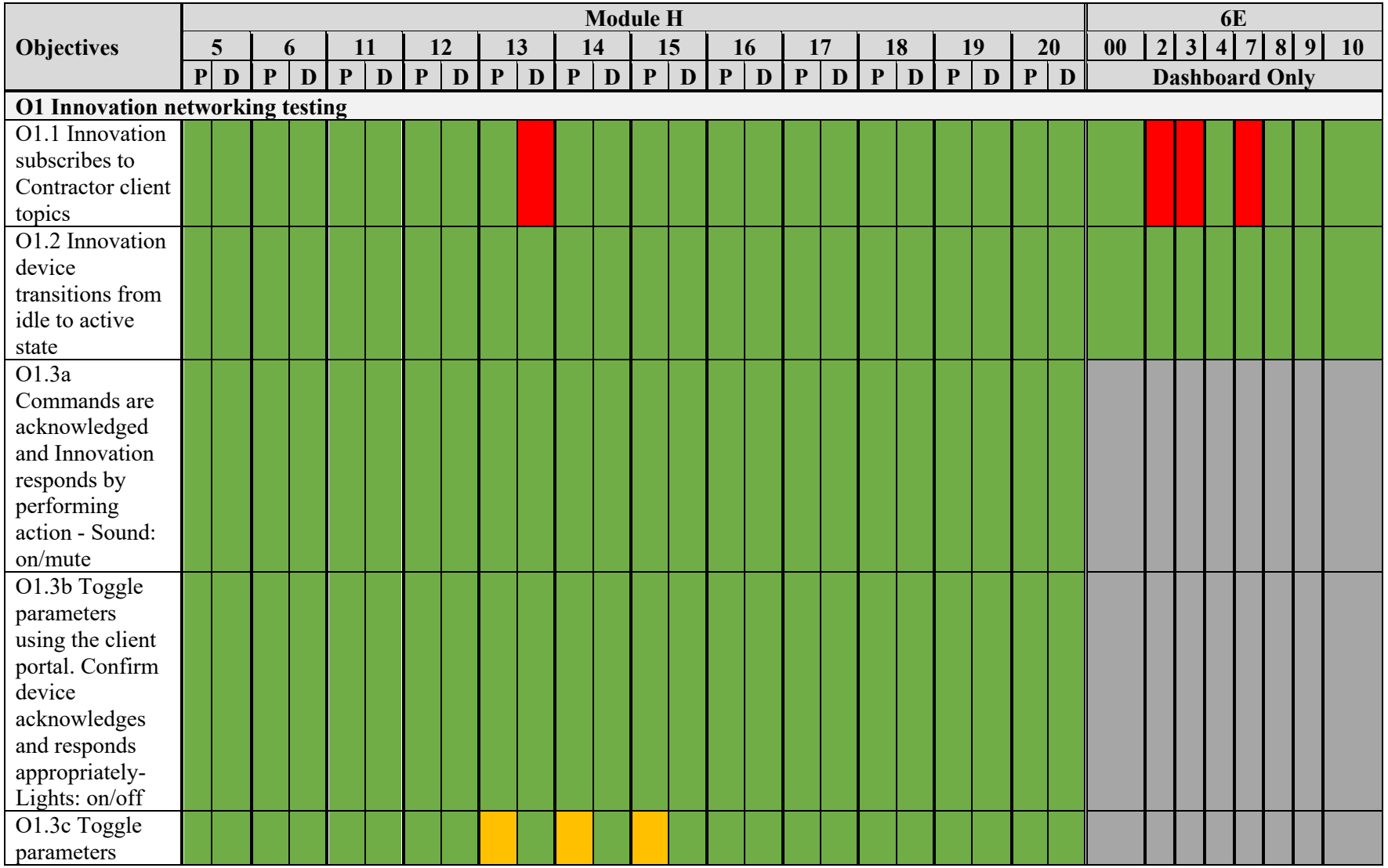
APPENDIX 2 DETAILED RESULTS BY KPI AND UNIT TESTED

In this Appendix we provided the detailed results of experiments by KPI and unit tested. Detailed notes are provided after Appendix Table 2

Legend

Fully Compliant with KPI	
Partially Compliant with KPI	
Non-Compliant with KPI	
Not Applicable (units not tested for specific KPI)	
Physical Observation of unit for light/sound/IR signals	P
Dashboard Observation	D

Objective 1 - Confirm Innovation's ability to send and receive data and commands while operating on Testing Organization's network



Objectives	Module H																								6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
using the client portal. Confirm device acknowledges and responds appropriately-IR emitter: on/off																																
O1.4 Innovation returns specified queried data																																
O1.5 Log files contain accurate record of all events performed by system																																
O1.6 Client portal displays time-stamped messages corresponding to system events																																
O1.7 User actions (enter, exit, hand washing, warnings, violations, etc.) trigger messages to be published																																
O1.8 Innovation system																																

Objectives	Module H																								6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
transitions from active to idle on receiving deactivation signal																																
O1.9 Innovation system powers down on receiving power-off command																																
O1.10 Innovation system reboots on receiving reboot command																																

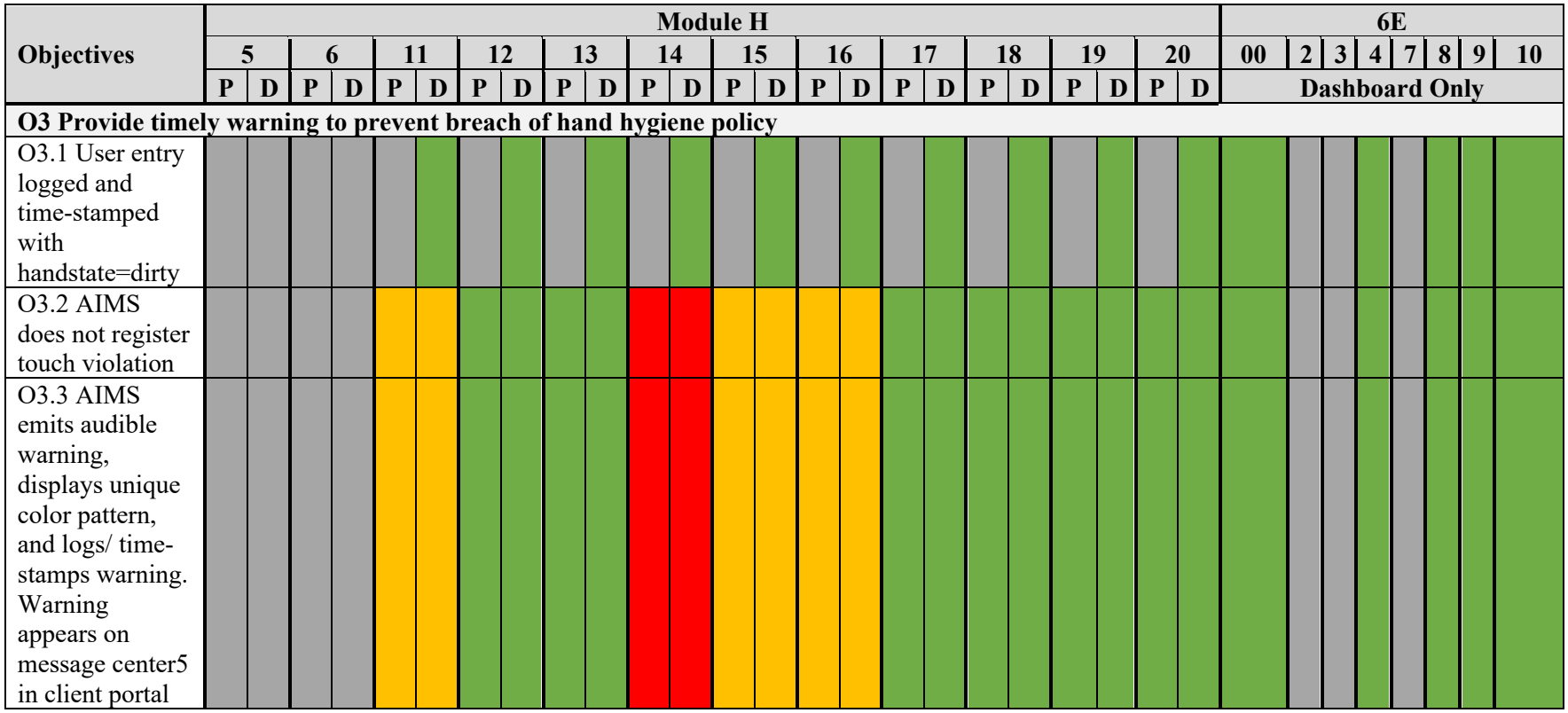
1.1 Innovation subscribes to Contractor client topics - 20 were tested. 16 units were fully compliant and 4 were non-compliant. Four units did not power up due to a third-party software bug issue and were classified as non-compliant. Lumenix technical staff contacted the third-party to request that bug was resolved. For the three affected units on 6E this meant that we were unable to conduct test procedures on 1.5-1.7, 2.1, 2.5, 3.1-3.3, 4.1-4.4, 5.3, 6.1-6.3.
1.2 Innovation device transitions from idle to active state - 20 units were tested and 20 units were fully compliant.
1.3 Commands are acknowledged and Innovation responds by performing action – 12 units were tested, 9 were fully compliant and 3 were non-compliant. These experiments required physical observation of the AIMS units and so were conducted on 12 units in Module H. Twelve were fully compliant for the experiments involving sound and light signals. Nine were fully compliant fir the experiments involving toggling the IR signal and three were non-compliant as the dashboard toggle was reversed (ie. dashboard said the IR was on when it was off and vice versa).
1.4 Innovation returns specified queried data - 20 units were tested and 20 units were fully compliant.
1.5 Log files contain accurate record of all events performed by system - 17 units were tested and 17 units were fully compliant. We were unable to test the three units that were non-compliant in 1.01 from the third-party bug issues.
1.6 Client portal displays time-stamped messages corresponding to system events -17 units were tested and 17 units were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues.
1.7 User actions (enter, exit, hand washing, warnings, violations, etc.) trigger messages to be published - 17 units were tested and 17 units were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues.
1.8 Innovation system transitions from active to idle on receiving deactivation signal – 20 units were tested and 20 units were fully compliant.
1.9 Innovation system powers down on receiving power-off command – 20 units were tested and 20 units were fully compliant.
1.10 Innovation system reboots on receiving reboot command - 16 units were tested and 16 units were fully compliant. Luminex technical staff advised against sending reboot signals to four units that we not in the ON state.

Objective 2 - Confirm Innovation's ability to detect hand washing events in each of the installed environments

Objectives	Module H																						6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
appropriately generated																														

2.1 Entry event logged and time-stamped - 17 units were tested and 17 units were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues.
2.2 User proximity to hand hygiene equipment acknowledged through visual indication (light pattern); 2.3 User interaction with hand hygiene equipment acknowledged through visual indication (light pattern); *2.4 User hand washed state acknowledged through published message and log event*; *2.5 Confirm log report and messages appropriately generated* – 12 units were tested; 10 were fully compliant and 2 were partially compliant. Partially compliance was due to the units not consistently acknowledging proximity to the hand hygiene equipment (sink). This was the result of calibration and field of vision adjustments that should be easily resolvable.

Objective 3 - Confirm Innovation's ability to apply timely warnings to prevent breaches of hand hygiene policy



3.1 User entry logged and time-stamped with handstate=dirty - 15 units were tested and 15 units were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues and two units in Module H that did not have a bed area (representing a patient) calibrated into the AIMS system.
3.2 AIMS does not register touch violation; 3.3 AIMS emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal - 15 units were tested; 11 were fully compliant three were partially compliant, and one was non-compliant. Partial compliance was due to violations being registered when no touch occurred and non-compliance was due to a unit not capturing or registering warnings. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues and two units in Module H that did not have a bed area (representing the patient) calibrated into the AIMS system. This was the result of calibration and field of vision adjustments that should be easily resolvable.

Objective 4 - Confirm Innovation's ability to accurately detect instances of physical contact with a patient (HAND STATE = DIRTY) in Testing Organization's operational setting

Objectives	Module H																						6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
O4 Innovation detects violation of hand hygiene policy																																
O4.1 User entry logged and time-stamped with handstate=dirty																																
O4.2 Innovation emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal																																
O4.3 Innovation provides visual acknowledgement of hand hygiene policy violation, logs and time-stamps event, and message appears in client portal																																

Objectives	Module H																						6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
O4.4 Confirm log entry and message portal entry exists for this violation																														

4.1 User entry logged and time-stamped with handstate=dirty - 15 units were tested and 15 were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues and two units in Module H that did not have a bed area (representing a patient) calibrated into the AIMS system

4.2 Innovation emits audible warning, displays unique color pattern, and logs/ time-stamps warning. Warning appears on message center in client portal; 4.3 Innovation provides visual acknowledgement of hand hygiene policy violation, logs and time-stamps event, and message appears in client portal; 4.44 Confirm log entry and message portal entry exists for this violation - 15 units were tested; 12 units were fully compliant, 1 unit was partially compliant, and 2 units were non-compliant. Partial compliance was due to registering touch violations before they occurred and noncompliance was due to not registering touch violations or being very difficult to induce a touch violation. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues and two units in Module H that did not have a bed area (representing a patient) calibrated into the AIMS system. This was the result of calibration and field of vision adjustments that should be easily resolvable.

Objective 5 - Confirm the Innovation properly submits data to user portal and dashboards

Objectives	Overall Score
O5 Client portal displays Innovation system information	
O5.1 Home page contains accurate list of deployed Innovation devices, aggregated statistics on Innovation detections, links to individual dashboards	

Objectives	Module H																								6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
O5 Client portal displays Innovation system information																																
O5.2 Hyperlinks for each Innovation unit bring user to Innovation dashboard for each deployed unit																																
O5.3 Up-to-date information is displayed on the dashboard of each active Innovation unit																																
O5.4 Inactive units display their inactive status																																

5.1 Home page contains accurate list of deployed Innovation devices, aggregated statistics on Innovation detections, links to individual dashboards -This was an overall test (not broken down by unit) with a score of partial compliance as the aggregated information was presented however the weekly histogram did not register events from days that were known to have had logged events.
5.2 Hyperlinks for each Innovation unit bring user to Innovation dashboard for each deployed unit – 20 units were tested and 20 units were fully compliant.
5.3 Up-to-date information is displayed on the dashboard of each active Innovation unit - 17 units were tested and 17 were fully compliant. We were unable to test the three units that were non-compliant in 1.1 from the third-party bug issues.
5.4 Inactive units display their inactive status – 20 units were tested and 20 were fully compliant.

Objective 6 - Confirm user portal responds to user queries

Objectives	Module H																								6E							
	5		6		11		12		13		14		15		16		17		18		19		20		00	2	3	4	7	8	9	10
	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	P	D	Dashboard Only							
O6 Client portal permits queries by event type over specified date range																																
O6.1 Query feature allows date and event-type selection																																
O6.2 The requested data is returned by the Innovation database																																
O6.3 Data is compiled into .csv format and is sent to client's browser																																

6.1 Query feature allows date and event-type selection – 20 units were tested and 20 were fully compliant.
6.2 The requested data is returned by the Innovation database – 20 units were tested and 20 were fully compliant.
6.3 Data is compiled into .csv format and is sent to client's browser - 20 units were tested and 20 were fully compliant.