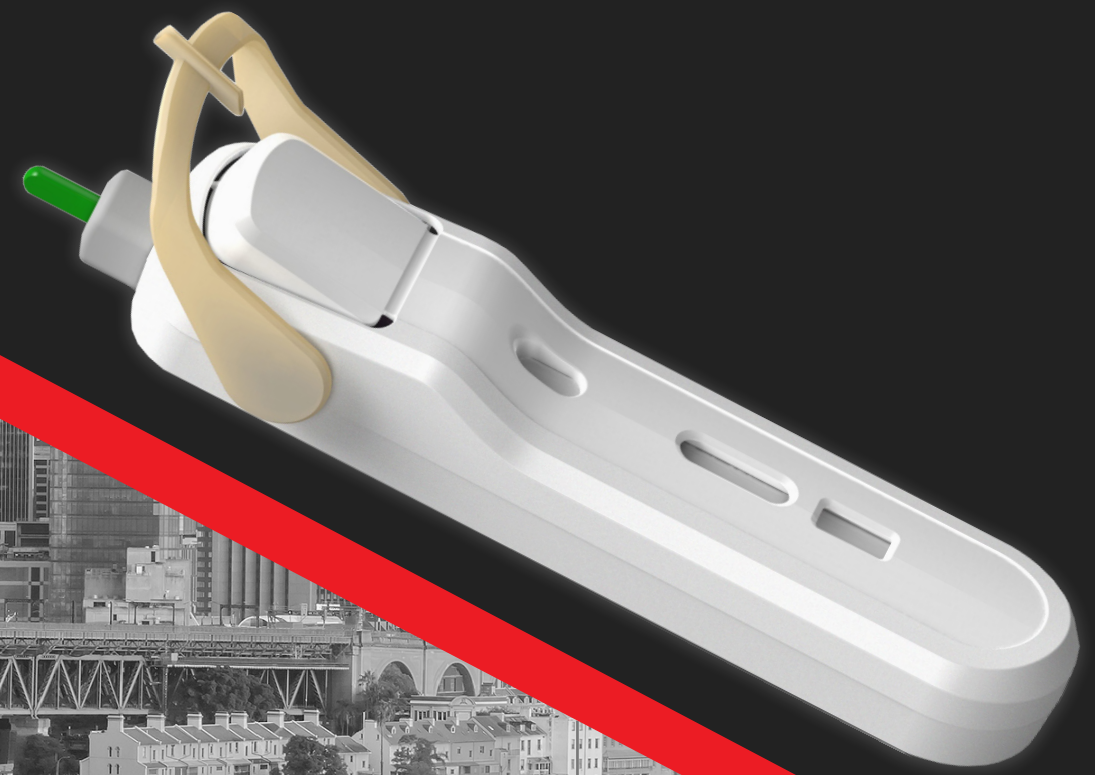


PASCAL USABILITY STUDY

Ergonomie
Laboratories

2022



AIM, SCOPE, ACRONYMS & DEFINITIONS

AIM

To gather valuable insights on preferences between Atomo's all-in-one Pascal platform or a commercially available, CE marked, multi-component generic RDT kit.

The study sought to identify the unique design features of Pascal that set it apart from multi-component RDT kits and determine its improved performance in terms of functionality and ease of use.

SCOPE

This formative usability study was conducted by an independent third party, Ergonomie Australia, by surveying 50 lay-users of varying demographics from within the Greater Sydney area.

ACRONYMS

BCU - Blood collection Unit

IFU - Instructions for Use

RDT - Rapid Diagnostic Test

DEFINITIONS

Omission - Failing to execute steps.

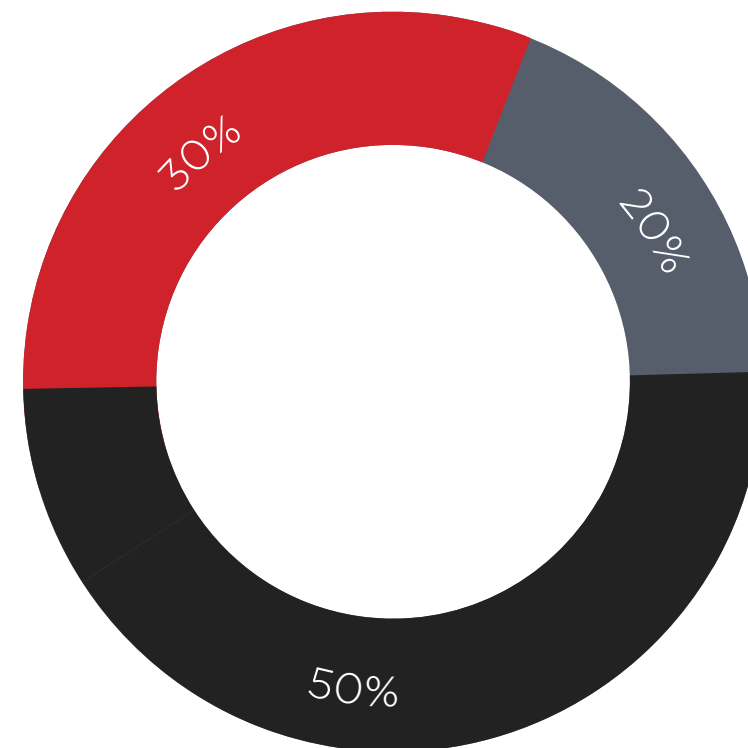
Commission - Incorrectly executing steps.





PARTICIPANTS

50 adult participants from the general public in the Greater Sydney area with no medical background were recruited to take part in this study. These individuals represented a diverse range of ages, with 25 participants between 18-40 years, 15 between 41-55 years, and 10 between 56-65 years.



■ 41-55 YEARS

■ 18-40 YEARS

■ 55-65 YEARS

LOCATION & ENVIRONMENT

Our data collection sessions took place in the state-of-the-art

Ergonomie Usability Laboratory, located in Sydney, Australia.

The facility is equipped with advanced technology to ensure the

highest quality data collection possible.



ATOMORAPID™ PASCAL

VS.



MULTI-COMPONENT RDT

MATERIALS USED

This user study focused on the Pascal Platform, developed by Atomo Diagnostics and compared it to a commercially available multi-component RDT similar to that shown. The IFUs for both the Pascal Device and the multi-component kit are shown in the appendix of this report.



STUDY DESIGN

The approach involved both quantitative and qualitative research techniques to ensure a comprehensive assessment of the two devices. During the test session, participants were also timed to assess speed of completion of each test. The order of these tests was randomised between participant sessions to ensure an equal balance.

PROCEDURES

To ensure that the study reflected real-world usage scenarios, participants were not given any training before attempting the tests. Instead, they watched a brief instructional video before each timed trial which demonstrated how to use the device. They were also provided with the IFU for each device and were allowed to refer to them as needed throughout.

Facilitators would not assist participants unless absolutely necessary for task completion. Help would not be provided until the participant had spent at least two minutes attempting to complete a subtask and had reached an impasse. If assistance was required, the facilitator would provide progressive levels of guidance to help the participant progress and complete the test.



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DATA COLLECTION METHODOLOGY

During the data collection sessions, facilitators utilised various techniques to measure and record both qualitative and quantitative data. These techniques included observing participants during testing, conducting retrospective video analysis (if necessary), collecting written feedback from participants through questionnaires presented after each task, and transcribing participant data from the final interview questions conducted after all tasks were completed.

QUANTITATIVE DATA

Research techniques were used to observe how participants interacted with the devices and identify any issues encountered while following the provided IFUs. All errors and difficulties were documented and categorised based on the specific procedural step involved.

	PRIORITY TASK	PASCAL PRIORITY TASK	MULTI-COMPONENT PRIORITY TASK
01	<ul style="list-style-type: none">• Lance Finger	<ul style="list-style-type: none">• Twist and remove green sterility tab• Press grey button firmly	<ul style="list-style-type: none">• Twist and remove protective cap of lancet• Press lancet to finger
02	<ul style="list-style-type: none">• Collect Blood Sample and Accurately Deliver	<ul style="list-style-type: none">• Fill BCU• Rotate BCU to transfer blood	<ul style="list-style-type: none">• Collect blood with pipette• Fill to line• Place blood in specimen well
03	<ul style="list-style-type: none">• Apply Buffer	<ul style="list-style-type: none">• Push button to apply buffer	<ul style="list-style-type: none">• Remove cap from bottle• Apply correct number of buffer drops to cassette well

During the usability test, we collected data on the following use issues:

Difficulties: These were instances where participants encountered challenges in performing a task correctly, which were noted by observing behaviours such as self-correction, facilitator assistance, multiple attempts, participant comments, and facial expressions indicating confusion or frustration.

Failures/Errors: These were instances where participants did not correctly or completely perform a critical task or sub-task, performed a task incorrectly or omitted a task/sub-task.



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IFU REFERENCES

Only a handful of participants needed to watch the Pascal video more than once, while a significantly larger number needed to re-watch the multi-component video to complete the test process. The highest number of views for the Pascal video by a single participant was just two, while for the multi-component video, one participant viewed it five times, and four others watched it more than three times.

TASK TIME

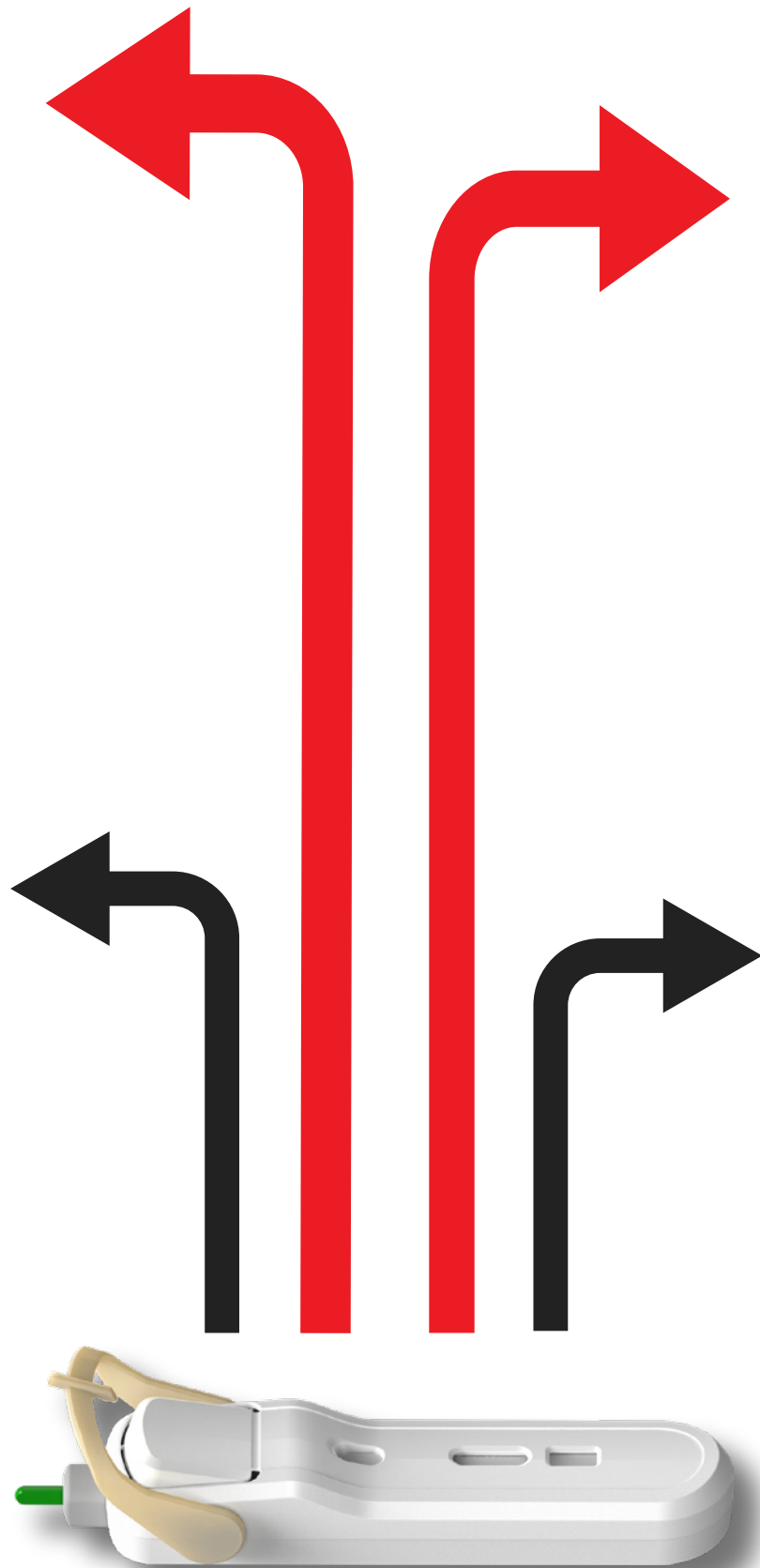
It is noteworthy that participants took almost three minutes longer on average to complete the multi-component test. This suggests that the Pascal RDT, along with its accompanying instructions, offers an easier and more efficient process for self-test blood sampling at home.

DEVICE ERROR RATE

Table 2 demonstrates that the Pascal device had a much lower error rate compared to the multi-component device, particularly in the blood collection, transfer, and buffer application steps.

TASK VALIDITY

The Pascal had a test validity rate of 96%, while the multi-component RDT had a test validity rate of only 42%. Notably, 29 out of 50 multi-component tests were observed to be invalid by the facilitators. In contrast, only two Pascal tests were considered invalid.



PRIORITY TASK	PASCAL ERROR RATE	MULTI-COMPONENT ERROR RATE
Remove Sterility Tab	0%	8%
Press Lancet to Finger	2%	4%
Collect Blood	0%	42%
Fill Blood	4%	42%
Transfer Sample to Test	0%	16%
Apply Buffer	0%	16%

TABLE 1: ERROR RATE FOR PRIORITY TASKS

FAILURE MODE	PASCAL COUNT	MULTI-COMPONENT COUNT
Incorrect Blood Volume	2	21
Incorrect Buffer Liquid Volume	0	5
Incorrect Blood Volume & Incorrect Buffer Liquid	0	3
Total Failures	2/50	29/50
Total Validity	96%	42%
Total Failures	4%	58%

TABLE 2: FAILURES RESULTING IN AN INVALID TEST



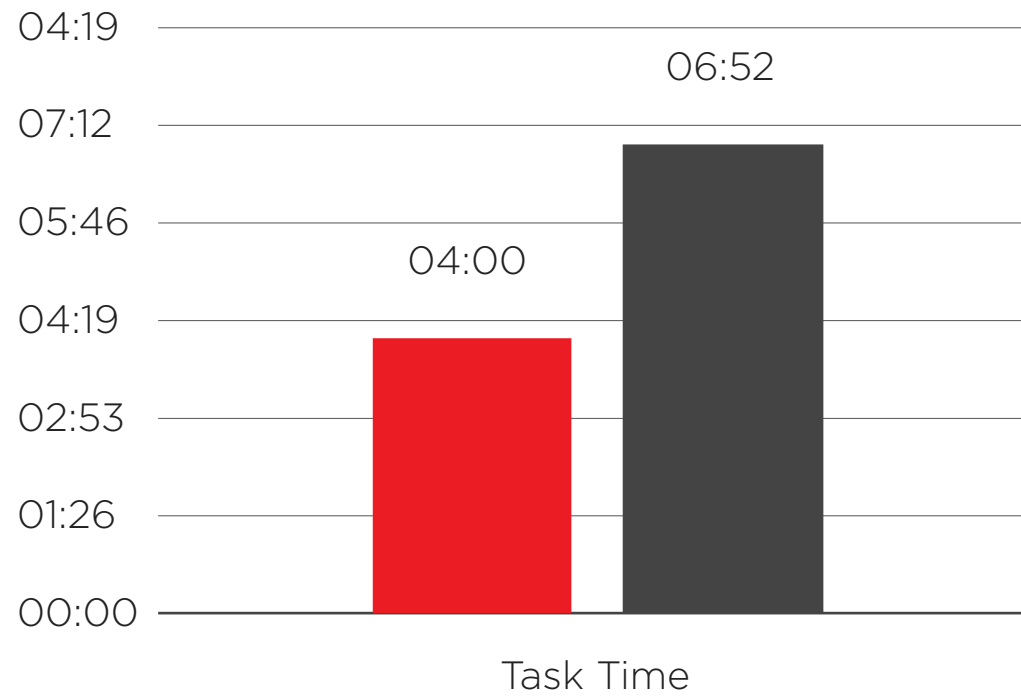


CHART 1: AVERAGE TASK TIME TO COMPLETION

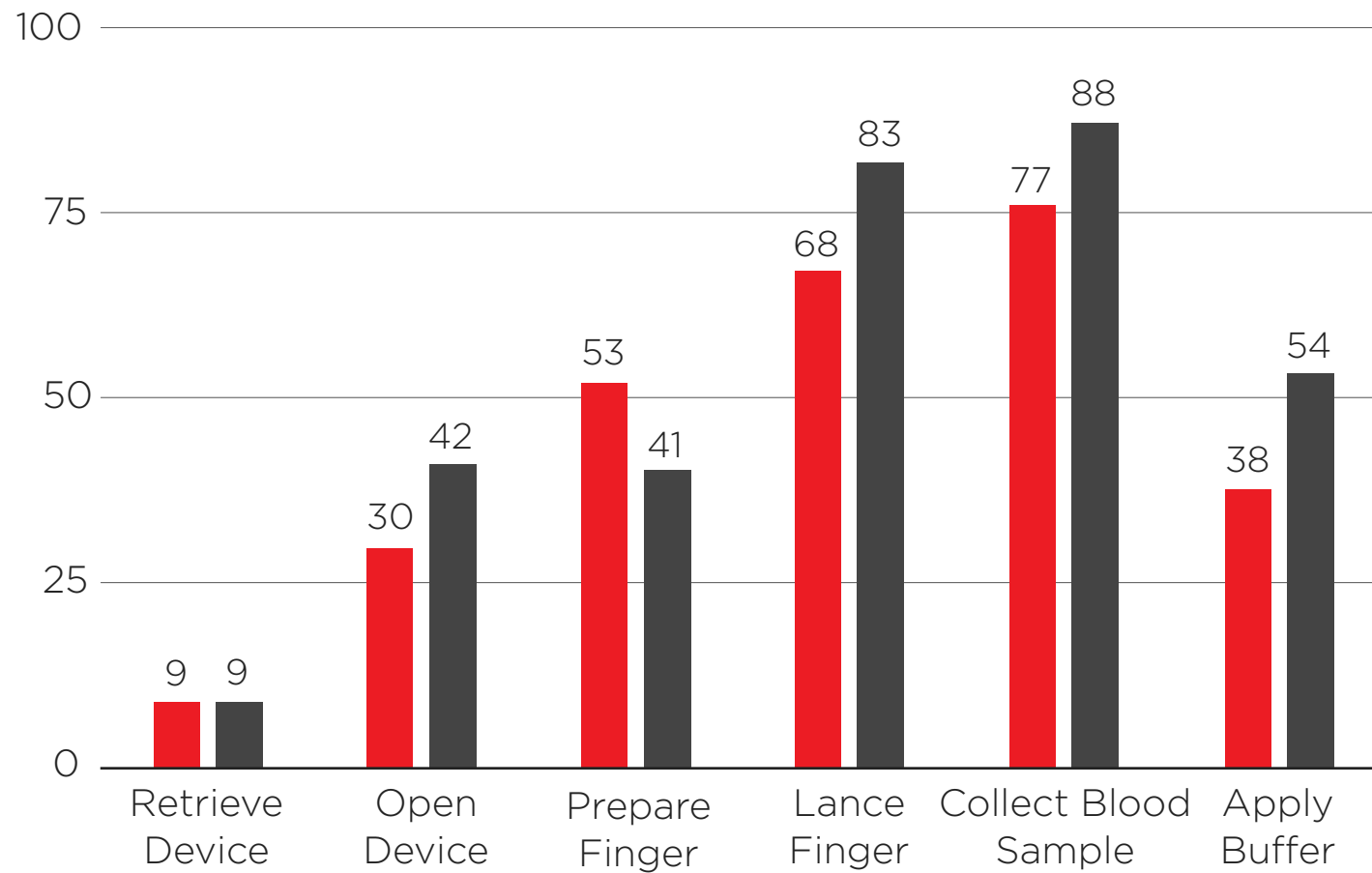
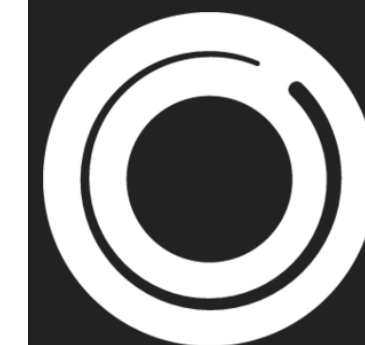
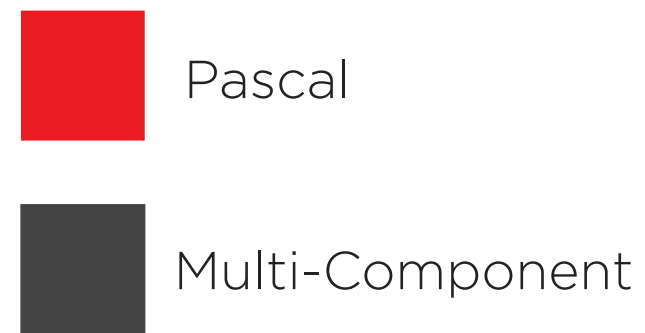


CHART 2: IFU REFERENCES WHEN COMPLETING RDT TEST



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QUALITATIVE DATA



90%

90% of participants found the Pascal test easier to use than a multi-component test kit

98%

98% of participants successfully activated the lancet on Pascal

96%

96% test validity (confirmed test result regardless of positive or negative outcomes) for Pascal

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CONCLUSIONS

The study's findings demonstrate that the Pascal RDT outperformed the multi-component RDT in several key areas, including higher test validity rates (96% for Pascal vs. 58% for multi-component), faster task completion times (4 minutes for Pascal vs. 6 minutes 52 seconds for multi-component), and significantly fewer critical errors made (3 for Pascal vs. 64 for multi-component). Participants also required fewer references to the Pascal IFU compared to the multi-component IFU.

90% of study participants found the Pascal RDT easier to use than the multi-component test kit. The Pascal RDT's superior performance and ease of use make it a promising option for individuals seeking reliable and efficient at-home blood testing.



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