

Ucollect

Wearable and innovative solution to collect urine samples from senior citizens for health and care purposes

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Report about evaluation and results of testing

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Preface

This document describes the results of evaluation and testing under the research project "Wearable and innovative solution to collect urine samples from senior citizens for health and care purposes (Ucollect)", which is funded under the AAL 2020 "Healthy Aging with the Support of Digital Solutions" grant program under project number aal-2020-7-19-SCP. Overall, the Ucollect project will deliver the following listed documents:

- D1.1 Joint data protection agreement, signed by all partner
- D1.2 Final report
- D2.1 Prototype of a user-friendly device for collecting urine
- D2.2 Report about evaluation and results of testing
- D2.3 Dissemination report
- D3.1 Quantitative market research
- D3.2 Individual business cases industrial partners
- D3.3 Total Cost Ownership analysis

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1 General overview about the evaluation and testing in the project

From the very beginning, the general research design of the project was planned to consist of three phases: an inspiration phase, in which first ideas and criteria were gathered, an intensive phase of designing and developing the prototype and, finally, the evaluation phase (figure 1). Two of these phases include tasks of field research, evaluating and testing: the inspiration and the evaluation phase.

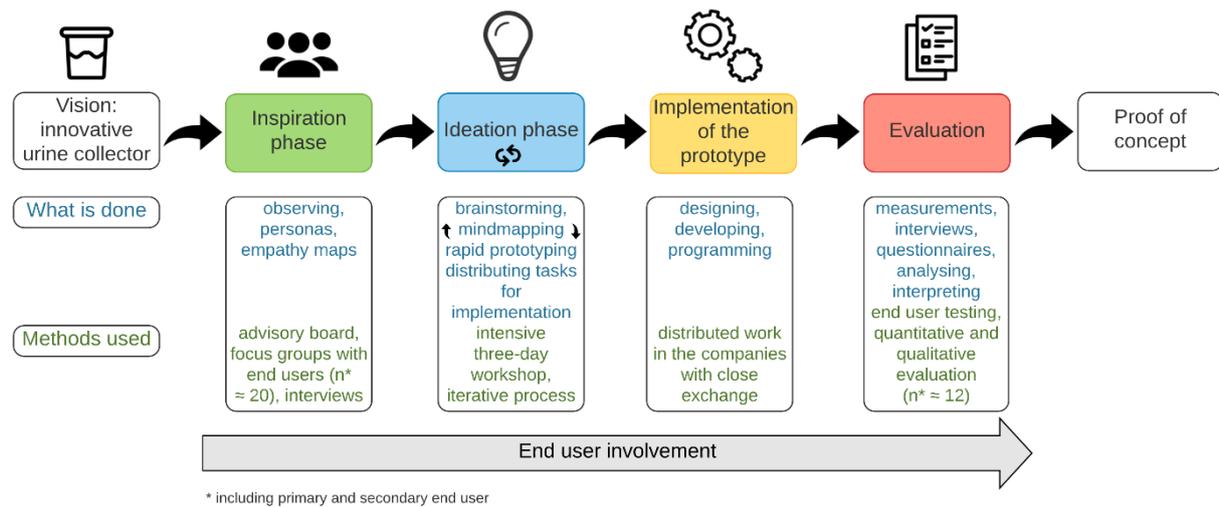


Figure 1: Research design of the project.

The research design also oriented towards human centred design, which means that the interests of both, primary and secondary users are always safeguarded during the development of the product. That was the reason for the elaborate research design, including several waves of survey and continuous involvement of the user. The consortium partners have invested a lot in this. The idea of the human centred design is shown in figure 2.

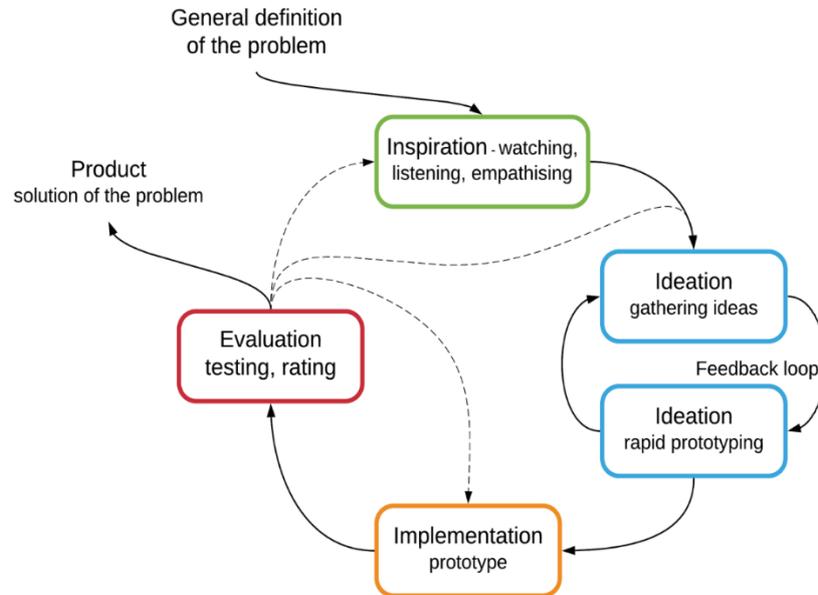


Figure 2: Human Centred Design, Trommelschläger et al. 2018.

2 Inspiration Phase

As mentioned before, the inspiration phase was an important part of the research work, in order to meet the requirements of the human centred design. The aim in this phase was to gather needs and expectations on a product, designed for the collection of urine, by both, the primary users (mostly older adults) and secondary users (professional and family caregivers). In addition, we expected the results to be helpful to define technical requirements and to clarify, how far we could go with our technical possibilities and where limits were set.

Furthermore, we asked for advice from the projects advisory board, consisting of specialists in urology, laboratories specialising on the analysis of urine, and nursing.

The methods used were a focus-group-interview (Flick 2007) with caregivers/secondary end users and guideline-interviews with primary end-users (both: self-reliant and chronic-ill). The question-guideline for both, the interviews and the focus group were constructed by researchers of the consortium. The interviews and the group-interview were recorded and transcribed. We translated the original danish texts into English and analyzed them using the software MAXQDA. We also managed to fulfill the methodological requirement of intercoder reliability, which means that two persons read the interviews and inductively formed categories out of them. We then searched for matches and differences and managed to build a system of categories, which we used in a second round for the analysis. The results of this process are what we present you today. The analysis of the qualitative data gathered, oriented to the specifications of the content analysis (Mayring 2015). The advisory board was asked to fill out a questionnaire.

We successfully conducted a focus group with ten caregivers, some with low working experience of 2 years, some with the working experience of 30 years of work (mean=17years) and interviews with 4

elderly persons in the age between 68 and 81, From which two live at home (both 68 years old), and two live in assisted living circumstances.

2.1 Results from the interviews with the older adults

Acceptance of technology is always an issue when the new technology should be applied on older adults. In most cases, older adults are less interested in new technologies and have less access to it in comparison to younger people. In the literature there can be found several explanations for this phenomenon. However, there are also technologies, of which older adults are “early adopters”, as it is for example the case with e-bikes. But in most cases, they do not see the need for technical inventions (Friebe et al. 2014; Selwyn 2016). Some passages in the interviews went in this direction. This lack of technology-acceptance (more or less a question of habitus) becomes clearly visible, when they say, that it is okay, as it is, when they deny to need help and cannot imagine an alternative way. It is often the case, when they say, that they are making the “best out of their situation” and don’t think, that there can be any improvements. In the focus-group interview, there was a similar passage: one participant warned us to make the planned product as suitable for seniors as possible. Even the wrong colour could lead to the result, that people don’t use it (the participant recommended white for any pants, nappies or whatever).

When self-reliant seniors have to give a urine sample, they simply go to the toilet and pee in a cup. It is hardly thinkable how any technological improvement could be made in their cases. However, there is still some potential for technological improvement as for exemplifying in the time-management and the organization and planning of the whole process. Due to the high time pressure of the caregivers, they can only stay for a short amount of time, which generates stress. The clear differentiation between the two groups of older adults, the ones who are self-reliant and the ones who need help, is of course not always possible.

In the group of older adults who are still largely independent, there are also those who need assistance with a usable urine collection (for example, washing before sampling). When they go to the toilet to collect, they often do not collect midstream urine. Urine collection is not going optimally, but from the nurse's point of view, it is at least working (in some cases, with help from relatives).

Another difficulty mentioned was, that, sometimes, wrong diagnosis was made. When caregivers suspect a urinary tract infection (UTI), they are also supposed to take the sample. Sometimes it happens that they take urine samples from clients and later it figures out that they were wrong and actually the client is not sick. When they have really bad luck, it can also happen that they trigger a urine tract infection with the catheters. The differentiation between self-reliant and non-self-reliant users remains important, because in the caregiver’s point of view nobody, who doesn’t really have to, likes to wear a diaper. One of them gets to the heart of it: “I also think that if I can go to the toilet by myself and I'm not a diaper user [...] and I have to run around with a diaper to pick up urine [others interrupt but mumble] I think that would be degrading.” (R8) Clients, who do not wear a diaper normally are mobile enough to take the urine-sample by themselves or at least with little help.

On the other hand, there are those, who need more help with the collection of urine. It may be the case, that they are bedridden, in a wheelchair, have to wear nappies ore other devices. For them, there are of course many emotional aspects concerning the collection of urine. For example, it is very degrading to wear diapers. A woman described, that she is often wet at night, which she feels is very

annoying. Also, she feels, that she has to explain the reason, why she is incontinent. It seems important to her to explain the reason, that the incontinence comes from a blood clot, that she had.

It can be quite difficult to get clean, not contaminated mid-stream urine from clients with chronic illness. They always need help in every situation. When we develop a device that is supposed to be used by the clients themselves (like a nappy) than there will occur several problems with hygiene, as some respondents mentioned. Contamination with stool is a problem. The urine-incontinence often comes along with an incontinence of stool. If you are wearing a diaper for a longer time, you have to be aware not to get wounds. Getting bedsores and decubitus is also an issue, that the project consortium has to keep in mind.

2.2 Results from the focus-group-interview with the caregivers

Caregivers, no matter of which profession exactly, feel to never have enough time. The number of samples, they have to take from their clients differs and can reach from once a week to once or twice a month. Their service plan is tight/ densely packed. So, they only have the time for things they actually find in their nursing plan. Any additional task thwarts their plan. For example, when they get suspicious a client could have a UTI during their visit, they have to do a bunch of things afterwards. For that reason, it would be best for them, if the developed device could save them some time or could ease up the whole process. One example for such a time saving device from the focus-group was an alarm function included in the collector, so that they get an information, when the urine has been collected.

Sometimes the caregivers are able to make an appointment with their clients: When you succeeded the urine collection, call this number and then we will come and collect it and bring it to the lab. When they do so, they cannot monitor the quality of the urine sample taken, which is a disadvantage.

The collected urine somehow must go to the laboratory or to the doctor. In some cases, the caregivers transport it. The challenge is, that the sample should be cooled. So, this can be a problem for the caregivers, when they are on tour.

Not every caregiver has the same responsibilities. For example, not everyone is allowed to take a quick test.

The caregivers plead for a disposable solution, in which they see several advantages, as for example concerning hygiene, avoiding of cleaning and so on.

In summary the results of this first round of interrogations already raised a few issues that needed to be addressed further in the course of the project:

- Technology acceptance
- Stress and other problems
- Emotional aspects (degrading and limiting social life)
- Hygienic issues
- Organizational issues for clients and caregivers (planning with demented persons)

The consortium met to a sprint workshop, in which they further elaborated and prioritized these requirements. As an international consortium we met online and resolved that task using the online white board “miro board”, which served us well in the further course of the project, see figure 3.

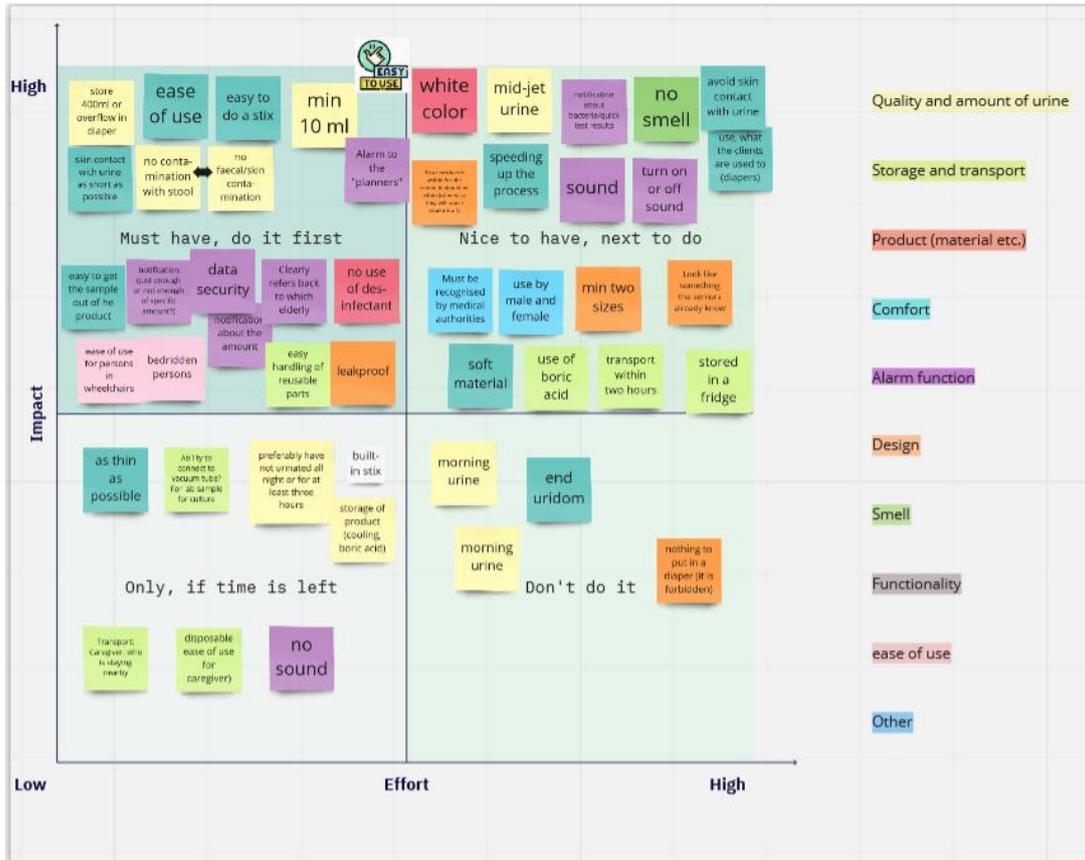


Figure 3: Working on the requirements for the product on miro-board.

It was on this occasion and knowing about the results from the inspiration phase, that the consortium decided to design a device only for women, as the need for a solution is much higher for women due to a higher risk of getting incontinent in older age. Besides, there already exists a portable solution for men called uridom.

3 Evaluation Phase

In the last third of the project the prototype (hereinafter referred as “Ucollector”) came into use and we tested it in different settings. As planned, we conducted laboratory tests, field tests and evaluated the results, thereby following the guideline for evaluations provided by Rossi & Freeman 1993. They define evaluation as a “systematic application of empirical research methods to evaluate concepts, implementation and effectiveness of (social) interventions”. The effectiveness is supposed to be tested in the laboratory tests, but also in the field test. As the device is still far from be implemented in the setting of caring, the evaluation mainly concerns the proof of concept.

3.1 Laboratory tests

3.1.1 Research questions:

- To what extent is it possible to collect urine with the prototypes developed in the project that is suitable for further medical analysis in the laboratory?
- To what extent is it possible to collect urine that is not contaminated with faeces and skin with the prototypes developed in the project?

- Is the quality of the urine sample collected with the prototype comparable to conventional urine samples?

3.1.2 Hypotheses

- H1: The quantity of urine collected is sufficient for medical analysis
- H2: The quality of the collected urine meets medical requirements and has little to no contamination with faeces and skin particles
- H3: There is no difference between the urine sample collected with the prototype and a urine sample collected with the conventional method

Conduct of the laboratory tests

Six urine samples from six adult persons/ or two samples per person (if possible, at least one person with stool incontinence), three of which collected with the Ucollector, three with conventional methods will be analysed in the laboratory (blinded).

The following Indicators/ Outcome parameters were measured:

- No difference between samples
- Quality of urine
- No contamination with faeces
- No contamination with skin particles
- Fulfilment of further requirements for medical analysis

3.1.3 Results: Summary of the lab test in Brønderslev – September 2021

There was taken 6 blinded urine samples. Here is shown, which sample is taken by which method:

Urine sample number	Collected by	Was the urine collection a success?
1	Ucollector	Yes
2	Ordinary method	Yes
3	Ucollector	No – not after 4 trials
4	Ordinary method	Yes
5	Ucollector	No – not enough urine ran inside the collector
6	Ordinary method	Yes

3 older adults gave both a urine sample via the Ucollector and via the ordinary method. Data about the older adults are:

- Sample 1 + 2 = Not faeces incontinent
- Sample 3 + 4 = Not faeces incontinent
- Sample 5 + 6 = Not faeces incontinent

The feedback from the 3 seniors:

Question	Yes	No
Was the Ucollector comfortable for you to wear?	3	
Was the Ucollector a worthy way for you to collect urine?	3	
Do you have suggestions for improvement of the collector?		3

Notes:

- One older adult said that she couldn't feel the Ucollector, when it was applied on her
- The same person said that it would have been a worthy way to collect urine, if it had succeeded in the first attempt

The feedback from the caregivers:

Question	Yes	No
Was the handling of the Ucollector easy?	2	2

(Note: One caregiver answered both "yes" and "no" to this question)

If no, why was the handling not easy?

- It is easy enough. The problem might be, if it is placed too far back – then urine might not reach correctly
- The senior is a very large/heavy woman and therefore it was very difficult to place the Ucollector correctly. I tried 4 times – all 4 times, it failed

Question	Yes	No
Was the Ucollector fitted to collect urine?	1	2

If no, why was it not fitted to collect urine?

- It (the urine) runs beside the hole, so there is not enough urine (in the Ucollector)
- It was a success when the senior stood up/walked around – then she peed normally.
- (It is) easy to apply – easy to take off – easy to take the urine from
- It is too short for a large/heavy woman.
- The Ucollector was wet, but not enough urine was gathered inside the collector

Question	Yes	No
Do you have any suggestions for improvement?	1	2

- An indicator, that shows, it (the Ucollector) is filled
- Maybe a change of color when there is a UTI
- A bigger hole, that the urine can run into
- When you are sitting on it (the Ucollector), you might press out the urine through the hole, where you are supposed to take the dipstick
- The gel in the hole could be a bit thinner
- Maybe a small edge around the hole

Further feedback from the caregivers:

After the lab tests, we called both caregivers to get further feedback from them. Here is, what they said:

- The Ucollector can also be applied, while the senior is laying down
- The Ucollector works fine when the senior is a “normal size” person
- The heavy senior is normally sitting down all day. The Ucollector was applied, while she was laying down, but it might get shoved as she sat up (maybe by the thighs). The Ucollector seemed too small for her. The Ucollector was difficult to replace/adjust, as the senior sat up, because of her size. The caregiver tried 4 times (with 4 different urinations) and used 2 Ucollectors – none of the tried succeeded even though the Ucollector got wet – no (or just a little) urine was inside the collector. Maybe the hole is too small.
- The size of the urination must be big to get a successful sample, as the product is at this moment
- The Ucollector worked perfectly for one of the seniors, but didn’t work at all for the second senior (this caregiver had 2 different seniors to get samples from)

- The Ucollector is easier to handle than expected when it was presented at the first time. It is like a panty liner.
- Maybe there should be a stick-function on the back of the Ucollector, so that I can stick to the diaper as a panty liner does

Results from the examination of the urine

All the urine samples were analyzed by the laboratory. Here are the results:

Sample number	Collection method	Results
1	Ucollector	10^5 E-coli + 10^4 contaminations from skin- and mucous membranes bacteria
2	Ordinary method	10^5 E-coli
3	Ucollector	Urine sample did not succeed
4	Ordinary method	10^4 - 10^5 proteus species + 10^4 - 10^5 contaminations from skin- and mucous membranes bacteria
5	Ucollector	Urine sample did not succeed
6	Ordinary method	10^3 - 10^4 E-coli + 10^3 - 10^4 contaminations from skin- and mucous membranes bacteria

3.1.4 Summary:

- There was enterobacteria in all the 4 urine samples
- There was admixture of skin- and mucous membranes bacteria in all the samples
- The Medical Laboratory Technologist wonders, why there are so many e-coli bacteria in sample 1 and 2. It could be, because of a bad urine collection or an asymptomatic UTI. If the urine sample is a mid-jet urine, collected the right way, there shouldn't be this much e-coli bacteria in the urine.

To compare the numbers in the results: If a patient has symptoms of a UTI and the urine sample is a mid-jet urine collected the right way, there limit for a UTI is 10^3 for e-coli and 10^4 for proteus. This information is just for us internally in the project – the laboratory doesn't want to be mentioned in our project – nor this information of the limits of the bacteria.

3.1.5 Results from the laboratory tests in Eindhoven – 1 December 2021

We tested with three instead of four people, because of a positive corona in the fourth test person. The test persons were volunteers, without any need for care. The testing was done on Wednesday 1 December at 1.30 pm and the material was taken to the laboratory at 3.30 pm, see figure 4. The research is done by Drs. Etienne Michielsen, Clinical Chemist at Diagnostiek voor U in Eindhoven.

- We agreed with the lab that we would supply 2 tubes of urine, obtained from the Ucollector, and a sample of the same urine stream in a sterile urine jar.

- The urine is withdrawn from the 1st tube with the needle supplied by Ucollect and the 2nd tube with its own sterile needle.
- The laboratory examines the supplied urine samples and can compare the contamination from the Ucollector with the sample from the urine jar.
- It is also examined for skin cells, the presence of contamination such as faeces and it is checked whether the material from which the Ucollector is made is protein-binding.
- An unused Ucollector is also tested with contaminated urine, which has already been tested in the laboratory for comparison.



Figure 4: Pictures taken from the laboratory test in the Netherlands.

Person A

Determination	Ordinary urine (2021120102)	Urine from device (2021120101)	
Strip (Clinitek)			
Specific gravity	1,02	1,02	kg/L
pH	6,5	7	
glucose	trace	trace	
protein	trace	neg	
keto substances	trace	trace	
erythrocytes	neg	neg	
Leukocyte esterase	neg	1+	
nitrite	neg	neg	
Urine screening (UF4000)			
bacteria	179	704	/μL
leukocytes	-	-	
gram stain	gram positive	gram positive	
urine cultures	non-pathogenic flora : 10e3-10e4 /mL	non-pathogenic flora : 10e3-10e4 /mL	
Urine Chemistry (Atellica)			
albumin	9,5	6,1	mg/L
creatinine	13	13	mmol/L

On strip negative on protein, but 6.1 mg/L albumin...

On strip negative on protein, but 6.1 mg/L albumin...

Lots of bacteria...

Possible contamination of the urine...

Fairly big difference in alb-creat ratio

albumin-creatinine ratio	0,7	2,1	mg/mm ol	
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Person B

Determination	Ordinary urine(2021120 104)	Urine from device(2021120 103)		
Strip (Clinitek)				
Specific gravity	1,025	>=1,030	kg/L	
pH	6	6		
glucose	neg	neg		On strip negative on protein, but 31 mg/L albumin...
protein	neg	neg		
keto substances	neg	neg		
erythrocytes	1+	trace		
Leukocyte esterase	neg	1+		1+ leukocytes, but ++ in the flow cytometry. Exactly different from 1
nitrite	neg	neg		
Urine screening (UF4000)				
bacteria	72	718	/μL	Lots of bacteria...
leukocytes	+	++		
gram stain	ntb	gram positive		
urine cultures	non-pathogenic flora :10e4-10e5 /mL	non-pathogenic flora : 10e3-10e4 /mL		Possible contamination of the urine...
Urine Chemistry (Atellica)				
albumin	3,2	31	mg/L	Fairly big difference in alb-creat ratio

creatinine	11	14	mmol/L	
albumin-creatinine ratio	0,3	2,3	mg/mmol	

3.2 Field tests

3.2.1 Research questions

- Does the Ucollector reduce the amount of time collecting urine?
- Does the Ucollector reduce the amount of steps collecting urine?
- Is the success rate of urine collection higher than before? Does the Ucollector reduce the amount of failed urine collections?
- How easy is the handling of the Ucollector from the caregivers point of view?
- How reliably does the sensor report the total amount of urine to the care givers?
- How comfortable do you find wearing the UCollector?
- Do you experience Ucollect as a worthy way to collect urine?
- What are the costs of urine collection with the Ucollector and to what extent is urine collection more expensive than the previous average cost of 12,58 EUR/ 15,10 EUR (3,08 EUR since this is what they are payed for)?

3.2.2 Hypotheses

- H1: The average time taken to collect the urine sample of 10-15 ml with the Ucollector is less than the 16.5 minutes recorded so far (excluding end-user waiting times).
- H2: The number of subtasks to be carried out for the collection of the urine sample of 10-15 ml is smaller/equal compared to the subtasks determined so far (approx. 11 subtasks).
- H3: The caregivers find the handling of the Ucollector at least rather easy on a five-point scale from very difficult to very easy.
- H4: The end users find the Ucollector at least rather comfortable on a five-point scale from very comfortable to very uncomfortable.
- H5: The reliability of the total amount of urine detected by the sensor is at least 90%.
- H6: More than 50% of end users experience the Ucollector as a worthy way to collect urine.
- H7: The calculated costs for urine collection with the Ucollector are less than or equal to the previous average costs of 12,58 EUR/ 15,10 EUR/ 3,08 EUR.

3.2.3 Summary of the field test in Brønderslev – November 2021

Sample number	Collected by	Results
1		
2	Ucollector	10 ⁴ proteus species + 10 ⁴ contaminations from skin- and mucous membranes bacteria
3	Ucollector	10 ² – 10 ³ contaminations from skin- and mucous membranes bacteria
4	Ucollector	10 ³ – 10 ⁴ enterococci + 10 ³ – 10 ⁴ contaminations from skin- and mucous membranes bacteria
5	Ucollector	10 ⁵ E-coli
6	Control urine	10 ⁴ contaminations from skin- and mucous membranes bacteria
7		
8		

9	-	
10	-	
11	Control urine	10 ³ contaminations from skin- and mucous membranes bacteria
12	-	
13	Ucollector	10 ⁴ – 10 ⁵ contaminations from skin- and mucous membranes bacteria
14	-	
15		
16		

Explanation of the results:

- Sample number 2: the amount of pathogen bacteria would require a treatment for UTI according to the hospital
- Sample number 3: Not many skin- and mucous membranes (almost the least that can be measured)
- Sample number 4: If this patient has had symptoms, there would be indication for treatment.
- Sample number 5: There is no contamination of skin bacteria, so the sample is perfect collected. However, the amount of pathogen bacteria requires a treatment for UTI according to the hospital.
- Sample number 2 + 4 + 6 + 11 + 13: Bad collected samples because of the amount of skin bacteria. There are no pathogen bacteria in the sample 6 + 11 + 13.
- The skin- and mucous membranes bacteria that are present in the urine samples are NOT from handling/making the Ucollector – it's from the genitals.
- To compare the numbers in the results: If a patient has symptoms of a UTI and the urine sample is a mid-jet urine collected the right way, there limit for a UTI is 10³ for e-coli and 10⁴ for proteus. This information is just for us internally in the project – the hospital doesn't want to be mentioned in our project – nor this information of the limits of the bacteria.

3.2.4 Oral feedback from the caregivers:

The sample collection:

- Sample number 2: The caregiver forgot to put on the sensor before applying the Ucollector on the senior. She then applied the sensor and there was no problem with connecting. The app showed, the collector was full with 10 ml. urine, but there was only 8 ml. in the collector.
- Sample number 3: The caregiver tried on the Ucollector herself. Everything worked fine.
- Sample number 4: The caregiver tried on the Ucollector herself. Everything worked fine.
- Sample number 5: The senior peed, when the caregiver cleaned her. Therefore it took a bit longer to collect the urine. The collector sat, where it was supposed to, but all the urine ran beside the hole in the collector. Almost nothing ran inside the collector – only 2 ml.
- Sample number 6: control urine from the caregiver
- Sample number 9: The senior pees several times. After 1 hour the caregiver scrolls down on the transfer app, but then the image disappears and she doesn't know how to get the data

back. She can see on the Nurseapp, that it doesn't seem to be disconnected, but nothing shows on the transferapp. Even though the senior pees a lot, no urine goes inside the collector. The collector has moved around and even though the collector is placed correctly again, no urine goes inside the collector.

- Sample number 10: The collector was placed correctly but the senior called after 45 minutes, that she must go to the toilet (for feces), so she wanted to take the Ucollector off. When the caregiver arrived at the seniors home, the senior had taken the collector off, but there was feces on it. Therefore, there was on urine sent to the lab.
- Sample number 11: control urine from the caregiver.
- Sample number 12: This senior is a large woman. The caregiver placed the collector correctly on the senior and then used 20 minutes to pair the sensor and the app. The senior has a large urination, but nothing goes inside the collector. When the caregiver has to fill out the form in the app, the images "jumps" around and the text disappears.
- Sample number 13: Everything worked perfectly. However, there were some problems with the form, so the caregiver isn't sure, the information was sent. There were some troubles with the network in some parts of Denmark that day – maybe that had an impact.
- Sample number 14: The caregiver wasn't informed, that the senior had an appointment at the hospital that day, so she couldn't place the Ucollector on the senior. However, the senior returned later and was then encouraged to drink a lot and after 30 minutes, the collector was placed on the senior. After wearing the collector for 30 minutes, the senior wants to take it off, because the senior can't pee anymore. There has been a small urination, but nothing is inside the collector. Also, in this case there were some difficulties with the form and closing the test.

3.2.5 Overall feedback:

- It's not possible to withdraw urine from the Ucollectors with an extender (a stud?) on the urine sample glass. The hole in the collector is too small for this. This is the way, the caregivers normally get the urine in the sample glass, see fig. 5.
- It's not possible to do a dip stick test directly in the collector, because the hole in the collector is too small, see fig. 5.
- It's not possible to penetrate the Ucollector with a needle/syringe to withdraw the urine without breaking/bending the needle
- So overall the collector is too stiff to get the extender/stud, the dip stick and needle inside/through.
- The app uses a lot of power from the caregivers' phones, which is a problem
- The collector – as it is at this point – is OK, but there is room for improvements. The apps/the technics is too time consuming.
- One of the caregivers experienced, that the images "jumped" every time she had to fill in the name/address/info which made it difficult to stay patient and be sure, that everything was typed in correctly
- Both caregivers tried on the Ucollector and said, it comfortable to wear. They sat down and stood up but couldn't feel it at all. No senior has complained that it was uncomfortable to wear.
- There are not that many seniors in Brønderslev, that could benefit from the Ucollector. The more complexed seniors live in nursing homes.

- Because the collector is so stiff and the caregivers have to be aware not to get the sensor wet, the collector can be unhandy and unhygienic to handle.

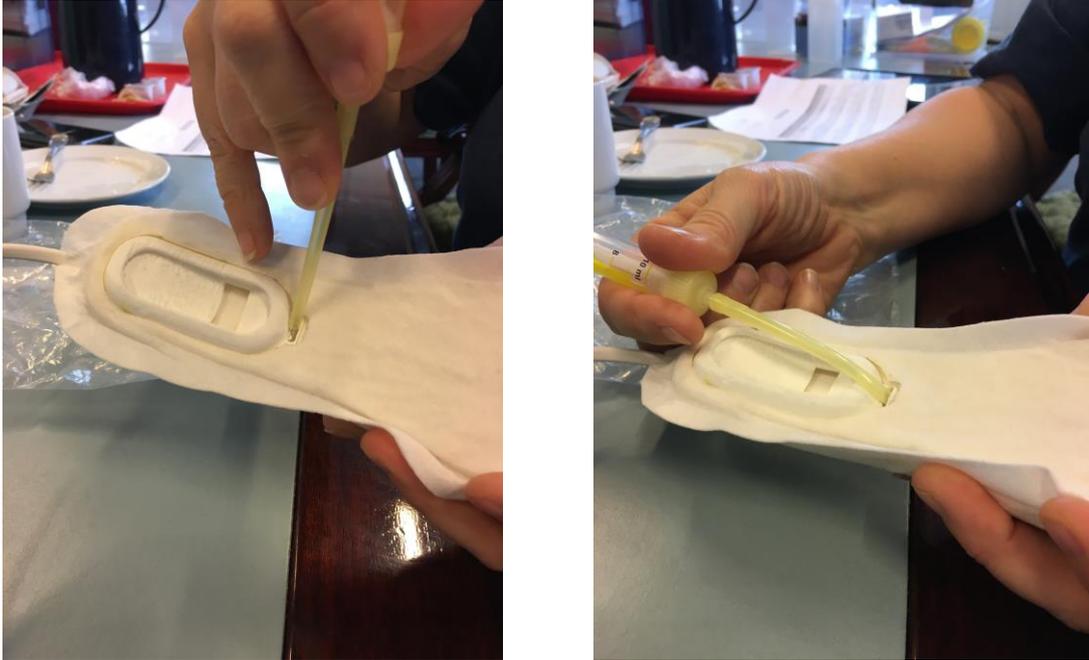


Figure 5: Pictures taken from the field test in Brønderslev.

3.2.6 Suggestions for improvements:

- If the textile on the Ucollector could absorb the urine, the urine collection would succeed more often. Maybe not all the textiles should be able to absorb – maybe just half (to be sure, that no feces bacteria got mixed with the urine).
- The hole in the collector is more wide/bigger, so that's possible to do a dip stick and withdraw the urine
- The Ucollector should be made of more flexible material
- The bottom should have a double-sided tape, so that the Ucollector can be fixed to the diaper and not slide, when the senior moved around
- The collector should be longer to be easier to fixate on the senior. Its's not necessary to make the "hole" inside the collector bigger so that it can hold more urine. It's only to make it easier to fixate the collector on the senior.
- If the collector is meant for larger seniors also, the cord must be longer
- A notification with a sound (on the caregiver's phone) when the collector is full is desirable.

All five test persons agreed, that the Ucollector was both a worthy and comfortable way to collect urine.

4 Conclusion and Management Summary

Testing and evaluating was part of the projects since its start in April 2021. We successfully conducted various interrogations, field and laboratory tests and documented the results in a transparent way.

The first round of interrogations consisted of interviews with possible users of the Ucollector. We also made a focus-group-interview with a group of danish caregivers. These interviews helped us to focus the development process by elaborating requirements for the device.

The two second rounds of tests, one in the laboratory, one in the field were made in order to get first results about the usability and the possibilities of the developed concept. The time between these two rounds was spend into development work.

4.1 Requirements, elaborated from the interviews:

- Technology acceptance: The device must be easily acceptable for the users. Issues of technic-acceptance and the digital divide between the generations must be kept in mind.
- The differentiation between several groups of potential users (people, who have to make urine samples): there are those, who are mostly independent and can make the urine sample by themselves (or at least with only a little bit of help). Then, there is the group of people who do need help taking a urine sample. Each group has different needs and expectations.
- Anyway, there is potential for both groups of potential users: for self-reliant and non-self-reliant users and the differentiation between these two groups remains important, because in the caregiver's point of view nobody, who doesn't really have to, likes to wear a diaper. The device is of most value for people that actually have to wear any form of diaper.
- It is important to collect the mid-stream urine for laboratory testing, which can be quite difficult, especially from clients with chronical illness. The technical device needs to solve these problems.
- Organization: For the caregivers a reduction of stress/improvement of the care process would be of highest value. A solution with which the clients could be left alone for a while, so that they could make other tasks in the meanwhile and then return after a signal from the device was promising for them.
- Hygiene: In matter of hygiene the caregivers plead for a disposable solution, because the process of washing was seen as too complicated. Washing could easily consume the amount of time won by improving the whole process of urine sampling and take the whole thing at absurdum.

4.2 Results of the laboratory test

Eight blinded urine samples should be analysed in the laboratory, four taken in an ordinary way, four using the Ucollector. We assumed, that if the laboratory wouldn't be able to find any differences between the two ways, the urine-collection by Ucollector is a proper way and the Ucollector capable of collecting mid-stream-urine.

Unfortunately, there occurred some problems with the collection of urine with two of the Ucollectors in Denmark, so only one probe actually was analysed in the danish laboratory.

On the other hand, this gained some interesting knowledge about the usability of the Ucollector for us, especially concerning with heavier people (the Ucollector seemed to be too small, so that the urine ran besides and not in it). In doing so, we already anticipated some of the results of the field tests.

At least, the results from the laboratory analysis in Denmark could not show differences between the three probes from ordinary collection and the one from the Ucollector. All four were contaminated with enterobacteria and an admixture of skin- and mucous membranes bacteria, so that even the

medical laboratory technologist wondered. In his opinion this could only occur because of a bad urine collection or an asymptomatic UTI. And he mentioned, that if the urine sample is a mid-jet urine, collected the right way, there shouldn't be this much e-coli bacteria in it.

The laboratory test in the Netherlands showed a much higher bacteria contamination of the urine sample, taken with the Ucollector, than in the ordinary sample.

So, in summary, the collection for the laboratory was hardly a success and in future some more laboratory analysis should be planned in order to gain the security that the concept really works out.

4.3 Results from the field tests

For the field tests we concentrated on practical issues: is it practicable? Does it reduce the amount of time of urine collection? Can urine be collected in a successful way?

We therefor asked five persons in care, some of them already helped us during the interviews and were, in a way, part of the whole project like this. Five urine samples were taken with the Ucollector and another analysis of the sampled urine was made to see, if there was a contamination with skin bacteria etc.

The results showed, that two of the five samples were actually quite good and useful, the other three were not. In their cases the contamination with either pathogen bacteria, skin membranes and bacteria were too high, but corresponding tests with ordinary collected samples showed, that the skin- and mucous membranes bacteria, that were present in the urine samples, were not from handling with the Ucollector, but from the genitals instead.

In the handling and organization of the samples some other issues occurred, for instance some technical problems showed up, especially in the cooperation between Ucollector and the App (for example it once did not show the correct number of milliliters of collected urine), but nothing serious.

All in all, the device could fulfill its purpose in a comfortable and suitable way and the collection of urine worked in most cases very fine.

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