Smartphone-based analysis of biochemical tests for health monitoring support at home

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In the context of home-based healthcare monitoring systems, it is desirable that the results obtained from biochemical tests – tests of various body fluids such as blood and urine – are objective and automatically generated to reduce the number of man-made errors. The authors present the StripTest reader – an innovative smartphone-based interpreter of biochemical tests based on paper-based strip colour using image processing techniques. The working principles of the reader include image acquisition of the colour strip pads using the camera phone, analysing the images within the phone and comparing them with reference colours provided by the manufacturer to obtain the test result. The detection of kidney damage was used as a scenario to illustrate the application of, and test, the StripTest reader. An extensive evaluation using laboratory and human urine samples demonstrates the reader's accuracy and precision of detection, indicating the successful development of a cheap, mobile and smart reader for home-monitoring of kidney functioning, which can facilitate the early detection of health problems and a timely treatment intervention.

1. Introduction: The deployment of home-based healthcare systems, which emerged in the last few years, requires that patient data needs to be collected at least partially in the home environment. Such data collection is partly based on tests of various body fluids such as blood and urine, which are called biochemical tests. Currently, there are a number of home-based biochemical tests, for example, for measuring blood glucose levels and substances in the urine. Such tests are typically use small, paper-based strips with one or more pads containing chemicals that exhibit colour reaction after contact with the fluids of interest. The results are often obtained by semi-quantitative analysis after the quick (within a minute) visual comparison of the colour developed on the pads with those provided by the manufacturer. In the context of healthcare home-monitoring systems, this would require the patient to manually insert the test results, which is error-prone. In addition, elderly or colour-blind people will likely face difficulties in performing a quick visual analysis, which may lead to incorrect results. Hence, fully-automated analysis of biochemical tests would provide needed support in such cases.

Already in the late 1990s the manufacturers of strips, such as Siemens, offered commercial automatic readers for biochemical tests, based on specially designed, and therefore expensive, hardware [1]. The exploitation of modern mobile technology has led to the development of a number of portable readers of biochemical tests, as recently reported in the literature. The phone camera has been used in a number of systems for analysis of paper-based assays of glucose and protein in urine [2] and of pH test strips [3]. The latter system is capable of handling skewed strip placement and partial reflection; the classification of the colour pH values is based on clustering techniques. A mobile, pocket-sized colorimetric reader for the analysis of 10-parameter paper strips was capable of sending data via a smartphone to a healthcare specialist [4]. Immunoassay data are quantified by the system presented in [5] using the open-source computer vision library OpenCV [6] for image processing on a smartphone. Rapid diagnosis of various infectious diseases is performed by another very recently developed reader [7]. The reader is a compact device, which is attached to the existing camera unit of a smartphone and allows various tests to be inserted within. Images of the tests are captured under light-emitting diode (LED)-based illumination and digitally processed on the phone for a diagnostic result and submission to a central server. Other readers that use an energy-demanding, mechanical attachment to the phone are Albumin Tester for analysis of albumin concentrations [8], iTube for food allergen testing [9] and the phone-based *E. coli* detection platform [10]. Despite the quick image processing on the phone, the first two readers use specially designed test and control tubes whose preparation require time.

Mobile readers for rapid diagnostic tests have recently gained attention. One of them uses Google Glass technology to capture images, which are subsequently sent via Wi-Fi to a server for processing [11]. In the context of healthcare this may be critical as the test outcome depends on internet connectivity. The commercial Mobile Assay (mobileassay.com), on the other hand, requires that the user manually places the test under the phone within a specified frame depicted on the phone screen to allow image capture. This implies that the test results are highly dependent on the correct operation by the user. In the context of healthcare applications this can be a challenging task as the users vary in their physical abilities (e.g. vision) and abilities to operate well with technology. A recent review of existing mobile readers is given in [12].

Despite the potential value of the above mentioned automated readers of biochemical tests, there is still a need for cheaper and easier-to-use readers to support home-based healthcare decision-making. Modern mobile devices such as smartphones provide an excellent platform for the development of such readers. In line with current trends, here we present *StripTest* – a novel smartphone-based reader for the quantitative analysis of biochemical tests. The reader contains a mobile application that uses the phone's camera to capture images of pads with colour reaction, then analyses the images and finally compares them with the reference colours provided by the manufacturer to obtain the final test result. The StripTest reader offers the following advantages:

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- Clinically validated quantitative standardised analysis with minimal user intervention and input error.
- Mobile, easy to use and cheap reader as no extra hardware is needed except the smartphone and the strips.
- Automatic contact with a caregiver can be initiated when the test results indicate health risk.
- Easy integration within more comprehensive home-based health monitoring systems.

This research was originally motivated by the development of a home-monitoring system for pregnant women [13]. Crucial for detecting pregnancy complications is urinalysis and in particular, the measurement of protein and creatinine levels in urine by means of a special paper-based stick (dipstick); see Fig. 1 – step ①. We note that the working principles of the reader, as described here, are general and can also be applied to biomedical tests of other body fluids. Preliminary detection methods and experiments with artificial test fluids were reported in [14]. Here we extend not only the image processing and classification methods, but also experimentally demonstrate the clinical usefulness of the StripTest reader. This shows the potential of the reader to facilitate prevention and monitoring healthcare tasks, without requiring costly tests and additional work by the care providers.

2. Method

2.1. Design requirements of mobile readers: To build useful home-based mobile readers of biochemical tests, a number of factors need to be taken into account. First, for colour-based biochemical tests, the surrounding environment conditions such as sunlight and reflection, considerably influence the test results, which requires their control to minimise the variation, for example, by creating a dark environment and using the LED light of the smartphone as the only light source. Secondly, the resolution of the camera plays an important role in this application as well. Thirdly, the reader should have sufficient power to be able to perform fast image processing (object detection and colour analysis) so that instant results are obtained. Finally, the intended users (patients) differ in their abilities and skills in performing and reading the tests. As a consequence, the user's intervention needs to be minimised and well-controlled. Related to these issues is that the automated reader needs to be easy to use. Recent advances in mobile applications allow the use of text-to-speech features that can support visually impaired people.

To maximally account for these design requirements, we developed a simple holder in which the user can place the strip with the phone on top of it. The holder is based on a slight adaptation of the smartphone's box delivered by the manufacturer; see Fig. 1 – steps ③ and ④. This adaptation involves the addition of a plastic base that fits perfectly in the bottom of the phone box. Within this base a space is carved out for the dipstick, so that the position of the dipstick always remains fixed. The plastic material of the base guarantees easy cleaning after use. The holder (i) minimises the user intervention, and (ii) creates a dark environment, effectively eliminating external light influences. The built-in LED of the phone is used to capture image(s) of the dipstick when placed in the holder. An important consideration in this design is that a sufficient distance between the dipstick and the mobile camera is provided, such that focused images are taken, in case the phone does not support 'macro mode' of the camera. Furthermore, although the use of LED may lead to over-exposure of the captured images, by using the same image processing algorithm for both test and reference images, we minimise this effect.

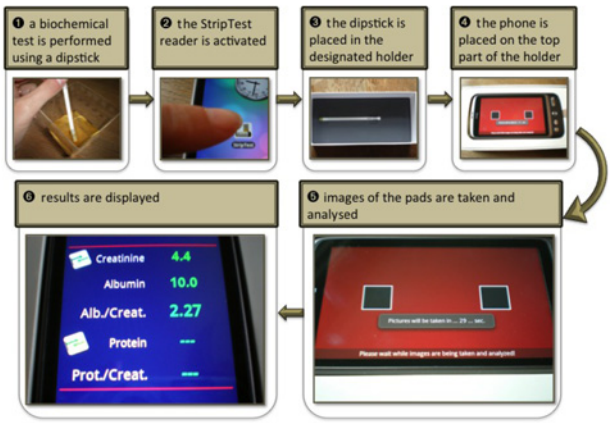

Figure 1 *Scheme of the working principles of the StripTest reader*

2.2. Working principles of the StripTest reader: they are built on the manufacturer's instructions for reading reagent strips:

1. Perform the test.
2. Wait a prescribed time (around a minute) for a biochemical concentration colour to develop on the strip.
3. Compare with the reference colours provided by the manufacturer to classify the test.

The StripTest reader performs steps 2 and 3. The working principles of the StripTest reader are sketched in Fig. 1.

2.2.1 Image acquisition: Once the image acquisition module of the StripTest app is activated, the LED light of the phone is turned on automatically and a specially designed screen appears on the phone. Given the fixed and stable placement of the strip in the holder, this screen contains designated windows, which delineate the borders of pad tests on the strip and correspond to the images to be taken; see Fig. 1 – step ⑤. The position of the designated windows are determined relative to the screen resolution of the phone. In such a way, there is no need to process the whole image to segment the pad(s) and the obtained images are of a small size, making data storage, processing and transfer easy. Given the change of the colour reaction over time, the reading of the pad colour is to be done following the manufacturer's instructions for time t_0. Hence, we designed the image acquisition of the StripTest app to start automatically after t_0 seconds making M subsequent images of the pad, each taken every t seconds. Before image capture, the camera auto-focus is activated. The images are saved on the phone's data storage space.

2.2.2 Image processing: Every image I captured and stored on the phone is analysed in a number of steps, depicted in Fig. 2*a*. First, the acquired image is decoded to a bitmap, which subsequently is used to obtain the red–green–blue (RGB) and cyan–magenta–yellow (CMY) levels in the image. Based on these levels, we next compute a histogram for each basic colour component C – red, green, blue and cyan – and the corresponding component mean μC over the number of pixels N in the image

$$\mu C_I = \frac{1}{N}\sum_{i=1}^{N} C_i$$

Furthermore, we also compute the mean *hue* value of the image μH_I based on the mean values of red, green and blue components

$$\mu H_I = \arctan 2(\sqrt{3}(\mu G_I - \mu B_I), 2\mu R_I - \mu G_I - \mu B_I)$$

Although the choice of the colour components for analysis might depend on the particular biochemical test solutions, we note that the image processing procedure still remains the same. For

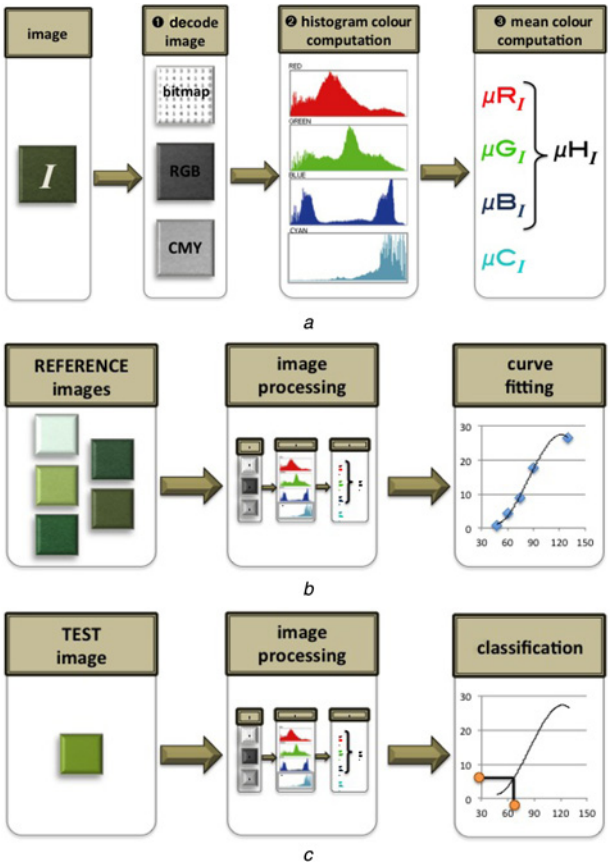

Figure 2 *Scheme of the image processing and classification methods used in the StripTest app*
a Image processing
b Curve fitting of reference images
c Classification of a test image

example, in the current urinalysis application the choice of cyan was determined by the albumin reaction on the pads (from green to blue), whereas the choice of hue was motivated by the creatinine and protein reaction also containing orange or yellow colours.

2.2.3 Test sample classification: Since our analysis follows the manual reading of the biochemical tests, we need to obtain the digital representations of the reference images (pads) provided by the manufacturer, which will subsequently be used for the classification of a test sample. To do so, for each concentration we have a number K of reference images rI, and we apply the same image processing procedure to them, as described above. This results in a set of mean values $\mu C_{rI_j}, j = 1, \ldots, K$, per colour component C. This analysis is performed only once and the obtained mean colour values are saved as vectors in the analysis module. A regression curve is fitted between the mean colour values thus obtained and the respective reference values for the concentration. In such a way, we interpolate between the finite number of reference points and achieve fine quantification of the test results; this is schematically illustrated in Fig. 2*b*. Such one-time analysis can serve as a basis for calibration of the reference colours for other mobile devices and camera settings.

Subsequently, the image processing analysis, as described in Section 2.2.2, is applied to a test sample image tI to obtain the predicted colour values. In combination with the fitted curve for solution and colour, we predict quantitatively the concentration of the substance at the test sample, as illustrated in Fig. 2*c*. We note that although the two images (test and reference) come from different sources, the same image acquisition and processing process is applied to both of them to maximally minimise the colour discrepancies, which is evident by the good diagnostic performance of the analysis as reported in the next Section.

3. Results

3.1. Clinical problem of kidney damage: The clinical problem we focus on for the evaluation of the StripTest app is kidney damage. The kidneys play an important role in the body for filtering wastes from the blood, regulating blood pressure and maintaining salt/water balance. It can therefore be very detrimental if the kidneys are damaged. One such life-threatening condition where kidney damage is observed is, for example, preeclampsia – a pregnancy-related disorder which causes 76 000 mothers and 500 000 babies to die each year worldwide [15]. Other common consequences of malfunctioning kidneys are hypertension, edema (swelling because of the water retention) and anaemia. Kidney damage can be identified by the leakage of proteins from the blood into the urine. When this leakage is abnormally high, the condition is referred to as 'proteinuria'.

3.2. Proteinuria: The diagnosis of proteinuria is only done by laboratory tests. Common tests for detection are the urine reagent strips, which are widely used in the clinic as well as at home. The indicator measured by these tests is the protein-to-creatinine ratio (PCR), which compares the amount of protein and creatinine in a urine sample. Table 1 presents the clinical criteria for classification of proteinuria. Beginning stages of kidney damage, called albuminuria (albumin is the main protein in the blood that leaks easily because of its small size), however, can be diagnosed at protein leakage level between 3.4 and 30 mg/mmol, and for its detection the developed StripTest reader would be especially useful to facilitate a timely intervention and to prevent severe complications.

3.3. Evaluation set-up: Together with the Laboratory for Clinical Chemistry of Radboud University Medical Centre, the Netherlands, a protocol for the laboratory evaluation of the StripTest app was developed. It describes in detail the experimental set-up for: (i) artificially prepared samples and (ii) human urine samples. For both types of samples the reference concentration of a substance is determined in the laboratory, providing the ground-truth values.

The goal of the experiments was to establish how well the StripTest reader can determine the concentrations in terms of accuracy and precision (repeatability). Although the StripTest reader is compared to the laboratory ground-truth values for a thorough analysis, we note that given the ultimate application, namely home-based health monitoring, the accuracy we aim at concerns the correct clinical classification as presented in Table 1.

During the evaluation procedure, we made use of the following commercial urine reagent strips for detection of albuminuria and proteinuria, produced by Siemens: (A) Albustix: 50 strips with 1 pad (protein) and (B) Microalbustix: 25 strips with 2 pads (albumin and creatinine). A set of reference colours for visual comparison is provided by the manufacturer (Fig. 3), which are also used in the StripTest reader for classifying the test sample.

Table 1 Clinical criteria for classification of proteinuria based on the ranges of protein–creatinine ratio

normal	<3.4 mg/mmol
albuminuria	3.4–30 mg/mmol
proteinuria	30–333.3 mg/mmol
severe proteinuria	>333.3 mg/mmol

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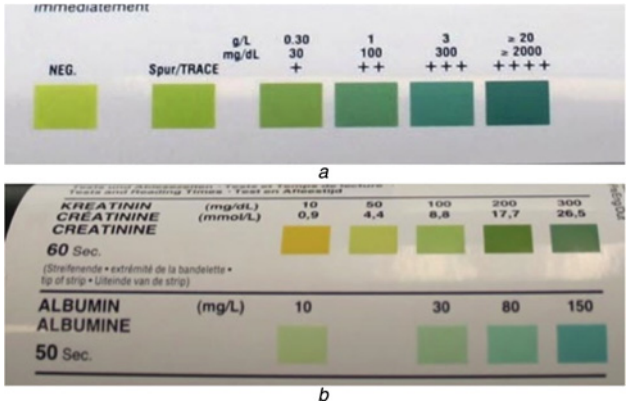

Figure 3 *Reference colours for the Albustix and Microalbustix urine reagent strips*
a Albustix
b Microalbustix

3.4. Implementation issues: The StripTest reader has been fully implemented in Google's open source Android operating system, a running platform for a diversity of smartphones and tablets. The implementation of the user interface and the image processing analysis was straightforward using the standard Android Software Development Kit (SDK). The results presented next are obtained by the reader implemented on an HTC Desire Android smartphone with a 5 megapixel colour camera including auto-focus, macromode and flash. In the current application, four images are being taken starting at 45 s after activating the image acquisition module with each image having dimensions of 96 × 96 pixels and a size of 8 kb.

4. Results and discussion

4.1. Experiments with artificial solution samples: To evaluate the analytical performance of the developed application, test samples were composed at the Laboratory for Clinical Chemistry. Stock solutions of human albumin (200 g/l, Albuman, Sanquin, the Netherlands) and creatinine (30 mmol/l, Merck, Germany) were used to create four different ground-truth-concentrations in the saline (0.9% NaCl); see Table 2. These four solutions were based on the clinical classification of proteinuria (see Table 1). Exact concentrations of the created solutions were verified on clinically validated assays. Creatinine solutions were verified on the Abbott Architect c160000 random access analyser using the enzymatic creatinine assay (Abbott laboratories, IL, USA). Human albumin concentration in the created stocks was verified on the Siemens BNII nephelometer, using anti-human albumin (Q0328, Dako, Glostrup, Denmark).

We used two standard measures – accuracy and precision – to estimate the performance of the StripTest analyser. The accuracy, which measures the correctness of the result based on the ground-truth measurement (see Table 2), is reflected in the bias, which is computed in percentage over a number of repeated tests T as

$$\text{Bias(Sol)} = 100 - \frac{|\text{gt(Sol)} - m_T(\text{Sol})|}{\text{gt(Sol)}}100$$

Table 2 Laboratory concentration samples used in the experiments

Sample S#	Albumin, mg/l	Creatinine, mmol/l	PCR, mg/mmol
S_1	31.3	10	3.13
S_2	125	5	25
S_3	250	2.5	100
S_4	500	1.25	400

where gt and m denote the ground-truth and the mean of a solution concentration Sol.

The analytical performance resembled in the precision on both creatinine and albumin was evaluated using a standard EP5 protocol according to the Clinical and Laboratory Standards Institute (CLSI) guidelines. This reflects the repeatability of the measurement within, and in between, days. For biomedical test applications, the precision is typically measured using the coefficient of variation (CV) computed in percentage over a number of repeated tests T

$$\text{CV(Sol)} = \frac{\sigma_T(\text{Sol})}{m_T(\text{Sol})}100$$

where σ and m denote the standard deviation (std.dev.) and the mean of a solution concentration Sol. To evaluate the precision, for each ground-truth concentration we performed 15 sample tests with the StripTest analyser during the period of 5 days (three samples per day). Both accuracy (reflected in the bias) and precision (reflected in the CV) for each solution – albumin (protein) and creatinine – as well as for the protein-creatinine ratio (PCR) are shown in Table 3.

Results from these experiments confirmed that the protein stick analysis was not very sensitive at low protein concentration, below 31.3 mg/l (limit of quantification; CV = 22%). Both accuracy and precision were highly improved from a concentration of 125 mg/l. Overall the analytical performance for the analysis of creatinine was very good, also at lower concentrations. The PCR was highly accurate in the detection and classification of albuminuria and proteinuria, and indicated some underestimation of classification of severe proteinuria.

4.2. Experiments with human urine samples: To test the accuracy of the StripTest analyser in a clinical setting, we applied it to 110 human urine samples, from which 65 were of diseased (different degrees of kidney failure) individuals and 45 were of healthy individuals. The albumin (protein) value varied between 2 and 8860 mg/l and the creatinine between 1.3 and 29.2 mmol/l, which resulted in samples with a PCR varying between 0.3 mg/mmol (normal condition) and 1080.49 mg/mmol (severe proteinuria).

We first compare the predictions obtained from the StripTest analyser with the coarse classification based on the reference colours from the manufacturer. The latter is obtained by classifying the known concentrations of protein and creatinine for each sample to the closest reference colour and then divide them to obtain the

Table 3 Accuracy and precision of the StripTest reader on the four artificial samples S_i, $i = 1, \ldots, 4$ for a total of 15 samples

Solution Sol	Value	StripTest predicted			
		Mean	Std. dev.	Precision (CV%)	Accuracy (Bias%)
albumin, mg/l	31.3	12.3	2.8	22	39
	125	71.1	9.3	13	57
	250	256.6	41.4	16	103
	500	496.1	38.9	8	99
creatinine, mmol/l	10	8.4	1.4	16	84
	5	3.5	0.6	17	70
	2.5	2.5	0.2	8	100
	1.25	1.9	0.2	8	152
PCR, mg/mmol	$S_1 = 3.13$	1.5	0.2	16	48
	$S_2 = 25$	20.6	2.2	11	82
	$S_3 = 100$	104.4	19.3	18	104
	$S_4 = 400$	263.0	29.4	11	66

Table 4 Summary of the accuracy of the StripTest analyser

Criteria	Number (%) of samples
underestimated	6 (5.4%)
overestimated	13 (11.8%)
clinically important (exact + overestimated)	104 (94.6%)
overall accuracy (±1 pad)	110 (100%)

PCR; we refer to this as a manual classification. The results in terms of R^2 fitted scores for all 110 samples, and are 0.91 and 0.15 for the StripTest analyser and the manual classification, respectively. These scores clearly indicate an improvement by the automatic analyser, indicating that having a finer classification helps in a better detection of protein leakage in the urine.

We next determined the detection capabilities of the analyser for the clinical problem of proteinuria. The first column of Table 5 reports the clinically relevant conditions with the respective ranges of PCR. The second column of the table presents the classification results per condition. Since the Microalbustix strips are only able to detect albumin concentrations up to 150 mg/l we used the following rule to decide when to apply Albustix strips for detection of higher concentrations of protein

$$\begin{array}{lll} \text{IF Det-Alb} < 70\ \text{mg/L} & \text{THEN} & \text{Det-Alb/Det-Creat} \\ & \text{ELSE} & \text{Det-Prot/Det-Creat} \end{array}$$

where Det-Sol is the solution concentration detected by the StripTest analyser. In Table 4, we present a summary of the accuracy.

The under- and over-estimated samples are those whose predicted concentration is less and more than that of the ground-truth, respectively. Note that underestimation may result in missing the timely detection of kidney problems, thus having a worse impact than overestimation from a clinical point. Finally, we observe that the analyser's predictions are always within ±1 pad from the ground-truth, misclassifying mainly the samples with borderline PCR values (see the ranges below the numbers of classified samples in Table 5). This implies good overall accuracy, but to obtain a better insight into the clinical implications of the analyser's results, we look at a number of standard statistical measures, namely sensitivity (the ability of a test to correctly classify an individual as 'diseased'), specificity (the ability of a test to correctly classify an individual as 'diseased-free'), positive and negative predicted values (PPV and NPV). Based on the results from Table 5 we obtain: true positive (TP) = 60, false positive (FP) = 7, true negative (TN) = 38, false negative (FN) = 5 and the clinical performance measures reported in Table 6.

Table 6 Clinical accuracy of the StripTest analyser

Measure	Definition	StripTest result, %
sensitivity	TP/(TP + FN)·100%	92
specificity	TN/(TN + FP)·100%	84
PPV	TP/(TP + FP)·100%	90
NPV	TN/(FN + TN)·100%	88

Both PPV and NPV are comparably high, which indicates good prediction capabilities of the analyser. A high PPV is highly preferable when medical treatment can cause collateral damage. A high NPV is needed if you do not want to miss disease with the test and treatment cannot cause any harm at all. So in our case, 88% of the individuals with a negative result obtained from the StripTest analyser are truly negative while the other 12% have a negative test result but do have some degree of kidney damage. By using a smart algorithm we should focus on these 12%, for example, by repeating the test in the morning (at that time urine is concentrated and traces of protein are more likely to be detected).

4.3. Integration of the StripTest reader within a home-based pregnancy monitoring system: As mentioned earlier, the development of the StripTest reader was originally motivated by the need for performing urinalysis within a home-based pregnancy monitoring system, called eMomCare [13]. This system also contains an Android-based mobile application, which made the integration of the StripTest app straightforward. We performed usability tests with seven pregnant women to obtain insight into the user-friendliness and the technical operation of the eMomCare system and its components, including the StripTest analyser. Each monitoring system was in use for at least 2 weeks, and the pregnant woman was performing urine strip tests every alternative day. The measurements obtained from the StripTest analyser, a blood pressure meter and other clinical information was saved on the smartphone and used by an embedded probabilistic intelligent model [16] to automatically interpret the results and provide a direct feedback to the woman about her current health status and an appropriate advice for action, for example, if the status indicates a slight worsening in the woman's health condition then she is advised to monitor again after some time and if a considerable worsening is detected then the advice is to immediately contact the caregiver.

Using a specially designed questionnaire each user was able to provide her feedback about the use of the system and the various components. Concerning the StripTest analyser there were no technical problems experienced and the use of the automated urinalysis

Table 5 Clinical classification accuracy of the StripTest reader on human urine samples

Protein–creatinine ratio (PCR), mg/mmol		StripTest predicted				Total (110)
		Normal	Albuminuria	Proteinuria	Severe proteinuria	
Ground-truth	normal (≤3.4)	**38**	7 (5 with PCR > 2.1)			45
	albuminuria (3.4–30)	5 (3.8 < PCR < 5.0)	**36**	6 (PCR > 13.0)		47
	proteinuria (30–333.3)			**11**		11
	severe proteinuria (>333.3)			1 (PCR = 388.2)	**6**	7

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was perceived as positive and useful, even for users with limited smartphone experience.

5. Conclusions: We have presented novel research on the development of a fully-automated, laboratory and clinically validated analyser of biochemical tests, called StripTest, using a smartphone and commercial urine strip tests. The design of the proposed analyser minimises the effect of external surrounding factors, including the user's intervention. Except for the phone and the strips, no additional equipment is needed, making the reader cheap and portable. Furthermore, the reader can be easily enhanced with personalised features such as test schedules at preferable times. The results obtained with artificial sample concentrations and human urine samples demonstrated the good detection capabilities of the StripTest analyser, not only for critical health signs such as proteinuria, but also for early health-risk signs such as albuminuria. The image processing and colour analysis implementation of the analyser are Java-based, making it straightforward to integrate it within more comprehensive home-based healthcare monitoring systems. We have done this for the remote monitoring of pregnant women to provide a timely feedback about the woman's current and predicted health status.

In summary, the clinical validation results and application of the StripTest analyser are to have important clinical implications in terms of prevention and timely detection of health problems, adequate treatment intervention, better overall health outcomes and reduced work pressure on caregivers. In turn, this will provide benefits for the healthcare system as a whole by identifying low- and high-risk patients to whom tailored care can be provided and by reducing costs for treating severe health complications and for hospitalisations.

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