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Diagnostic sample transport via pneumatic tube systems: data logger and their algorithms are sensitive to transport effects

https://doi.org/10.1515/cclm-2023-0632 Received June 16, 2023; accepted October 4, 2023; published online October 16, 2023

Abstract

Objectives: Many hospitals use pneumatic tube systems (PTS) for transport of diagnostic samples. Continuous monitoring of PTS and evaluation prior to clinical use is recommended. Data loggers with specifically developed algorithms have been suggested as an additional tool in PTS evaluation. We compared two different data loggers.

Methods: Transport types – courier, conventional (cPTS) and innovative PTS (iPTS) – were monitored using two data loggers (MSR145[®] logger, CiK Solutions GmbH, Karlsruhe, Germany, and a prototype developed at the University Medicine Greifswald). Data loggers differ in algorithm, recording frequencies and limit of acceleration detection. Samples from apparently healthy volunteers were split among the transport types and results for 37 laboratory measurands were compared.

Results: For each logger specific arbitrary units were calculated. Area-under-the-curve (AUC)-values (MSR145 $^{\oplus}$) were lowest for courier and highest for iPTS and increased

with increasing recording frequencies. Stress (St)-values (prototype logger) were obtained in kmsu (1,000*mechanical stress unit) and were highest for iPTS as well. Statistical differences between laboratory measurement results of transport types were observed for three measurands sensitive for hemolysis.

Conclusions: The statistical, but not clinical, differences in the results for hemolysis sensitive measurands may be regarded as an early sign of preanalytical impairment. Both data loggers record this important interval of beginning mechanical stress with a high resolution indicating their potential to facilitate early detection of preanalytical impairment. Further studies should identify suitable recording frequencies. Currently, evaluation and monitoring of diagnostic sample transport should not only rely on data loggers but also include diagnostic samples.

Keywords: algorithm; data logger; diagnostic sample transport monitoring; pneumatic tube system; preanalytical phase

Introduction

Various pneumatic tube systems (PTS) are used in hospitals around the world to transport diagnostic samples [1]. PTS are capable to reduce turn-around-time and to improve preanalytical workflows to accelerate result-oriented patient treatment [2–5]. In addition to conventional PTS (cPTS) utilizing cartridges, innovative PTS (iPTS) directly send unpacked samples into a bulk loader of laboratory automation systems.

Validation of each new PTS is mandatory to ensure that the quality of diagnostic samples is not impaired. Hemolysis is one of the most frequent and severe preanalytical error [6]. It affects numerous measurands [1, 7–9]. Hemolysis can occur due to a disease (*in vivo* hemolysis) or due to sample collection and sample handling (*in vitro* hemolysis). *In vitro* hemolysis does not reflect the patients' status and, consequently, bears a risk for patients if altered results are released. In contrast, *in vivo* hemolysis, e.g. due to infectious diseases, hereditary disorders, drugs, valvular transplant or

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immune-mediated, reflects the patients' status and needs to be identified, for example by measuring haptoglobin and hemopexin [10, 11]. Especially, as in-vitro hemolysis can be induced by a number of pre-analytical processes, such as repeated fist closing or prolonged tourniquet application during blood withdrawal, it is important to investigate transportation systems separately [7, 12, 13]. A widely used practice is to collect diagnostic samples from healthy volunteers. Samples are split among transport types considered: the gold standard, often courier and the transport type in question.

It is recommended to evaluate PTS after installation and on a regular basis thereafter [13]. To identify alternative ways for validation the use of data loggers has been proposed [13, 14]. During transport, the data logger collects information on acceleration in three axes. Specific algorithms are used to predict the effects of sample transport on the integrity of the diagnostic sample. For algorithm development, original diagnostic samples are inevitable as for example described by Streichert et al. who used a commercial data logger [13]. Furthermore, an improved data logger prototype was developed at the University Medicine Greifswald, including an improved algorithm [15].

In our study, we evaluated two different data loggers and their respective algorithms and compared the outcome with measurement results from diagnostic samples. The investigated transport types encompassed courier, cPTS and iPTS.

Materials and methods

Data loggers and algorithms

Two loggers were investigated: the commercially available product MSR145[®] (CiK Solutions GmbH, Karlsruhe, Germany) and a prototype developed at the University Medicine Greifswald [15].

MSR145® measures temperature, humidity, pressure and acceleration and has been used in previous studies [4, 13, 16]. Its dimensions are $18\times14\times62$ mm weighing 18 g. MSR145 $^{\tiny \circledR}$ cannot be used in a tube with a smaller inner pipe diameter, for example in the iPTS used in this study. Therefore, the logger was removed from its original housing and placed into a sample tube to fit iPTS. The MSR145® logger measures acceleration in x, y and z-axis for up to 16 g at a maximum sampling rate of 50 Hz. With the help of the MSR Reader (Version 5.28.00), the collected data are transferred to a computer via a USB port and displayed graphically with the MSR Viewer (Version 5.20.07; Supplementary Figure S1). The areaunder-the-curve (AUC) values from MSR145® logger data were calculated as described by Streichert et al. [13]. Briefly, acceleration in the x, y and z directions and the absolute vector sums were determined using data analysis software (R software version 3.2.4) [13]. The AUC algorithm was based on measurements with a frequency of 10 Hz. In this study, we measured at 50 Hz. In order to achieve a better comparability with

previous studies, every 5th value of the 50 Hz AUC values was used to mimic 10 Hz recording. This was done for all readings. Afterwards, the average was calculated from these five 10 Hz AUC values.

The data logger prototype matches the geometry and weight of a transported blood sample (Supplementary Figure S2). It measures acceleration in x, y and z-axis for up to 200 g at a maximum sampling rate of 1,600 Hz. Its dimensions are $31.1 \times 10 \times 6.5$ mm with a weight of 10.6 g. The prototype logger was placed in an empty BD Vacutainer® EDTA 2 mL sample tube [15]. After recording, data was transferred to a computer via USB port. The data logger prototype software visualizes the acceleration measurements (Supplementary Figure S3) and introduces a stress (St)-value given in m/s²=kmsu (1,000*mechanical stress unit) [15]. In contrast to the previously described AUC value, the St only cumulates changes of acceleration that a blood sample experiences over time rather than acceleration alone. Therefore, areas of constant acceleration do not cause an increase in the St-value, which in turn is the case when applying AUC.

Transport types

Three transport types were investigated: courier, cPTS and iPTS. In courier transport a designated person performed the transport (~300 m), the route included stairs and elevators.

The cPTS (Aerocom® GmbH, Schwaebisch Gmuend, Germany) allows targeted distribution between connected wards and other targets. Data loggers were treated in the same way as diagnostic samples: wrapping with blister foil according to the local SOP before packing into a cPTS carrier. Likewise, data loggers and samples were unpacked in the laboratory. The distance between the selected sending station and the laboratory was approximately 350 m.

The iPTS (Tempus600[®], Sarstedt ApS, Bording, Denmark) connects two end points, e.g. a ward with the laboratory. In this study, the distance was approximately 300 m, connecting a ward with the bulk loader of the laboratory [4]. Data loggers were transported immediately after study samples and collected from the bulk loader immediately upon arrival.

Samples

In 2016 and 2017, non-fasting venous blood sample sets were collected from 60 apparently healthy volunteers at the University Medicine Greifswald. On these days all logger runs were performed as well. For blood collection, a BD Vacutainer® Safety-Lok™system (Becton Dickinson GmbH, Heidelberg, Germany) was used employing the following tube types:

- 1.8 mL sodium citrate BD Vacutainer® tube for coagulation measurands,
- 4.5 mL lithium heparin BD Vacutainer® PSTTM II tube with an inert polymer separator gel for clinical chemistry measureands,
- 2 mL K₂EDTA BD Vacutainer® tube for hematology measurands.

Written informed consent was obtained from the participants (Local Ethical Approval BB 100-15 of the Ethic Commission of the University Medicine Greifswald). Due to volume restriction imposed by the local Ethics Committee (max. 20 mL) it was not possible to collect all three tube types three times per volunteer (one set of hematology, coagulation and clinical chemistry for each transport type). Instead of the requested nine tubes, each volunteer donated six tubes in the following

combinations: (1) three tubes lithium heparin for clinical chemistry and three tubes K₂EDTA for hematological analyses (total 19.5 mL), (2) three tubes for clinical chemistry and three sodium citrate tubes for coagulation (18.9 mL), or (3) three tubes for coagulation and three tubes for hematology (11.4 mL). The selection was made randomly. Anonymized samples were thoroughly mixed and transported to the laboratory either by courier, cPTS or iPTS. Thus, for each volunteer, three sample sets, each consisting of two tubes, were sent separately to the laboratory via these different types of transport.

Laboratory measurements

In the laboratory all samples were processed by an automation system and conveyed to the respective analyser. Lithium heparin and citrate tubes were centrifuged for 5 min at 3,280 g (ROTANTA 460 Robotic, Andreas Hettich GmbH & Co. KG, Tuttlingen, Germany).

Measureands are given in Supplementary Table S1; hematological analyses were measured using Sysmex XN (Sysmex Deutschland GmbH, Norderstedt, Germany), coagulation measurands were determined with Sysmex CS 5100 (Siemens Healthineers AG, Erlangen, Germany) and clinical chemistry analyses were done on a Dimension Vista 1,500 system (Siemens Healthineers AG, Erlangen, Germany). All instruments were operated according to the manufacturers' recommendations and according to the German Rili-BAEK [17].

Statistical analyses

During the study, the two different data loggers were used once per day for each way of transport: courier, iPTS or cPTS. To compare the arbitrary units, namely AUC and St, during each way of transport, we visualized the distribution of measured stress values using boxplots. Because of repeated measurements, a mixed model was estimated in order to analyze the association between the way of transport (exposure) and the respective arbitrary unit (outcome) recorded by the data loggers.

For all measurands, the number of results as well as medians (25 %-; 75 %-quartile) for each way of transport are given. Friedman test was used to statistically compare the measured median between the different ways of transport. Furthermore, the distribution of measurement values depending on the way of transport was visualized using boxplots. Wilcoxon signed-rank test was used to compare if the measures of central tendency between each combination of two transport ways were statistically different. The relative difference between courier transport and iPTS or cPTS was calculated for each measurement, respectively. The distribution of relative measurement differences was displayed as median (25 %-; 75 %-quartile) for each measurand. When a measurement of one transport type for a subject was declared invalid, the corresponding measurements of the other two transport types were also re-coded into missing values to allow statistical comparisons across transport types.

Statistical significance was assumed at a p-value <0.05. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

The loggers rotated evenly between courier, cPTS and iPTS resulting in one recording per transport type for each study day. Recorded average transport times were 4:00 min, 1:49 min and 0:30 min for courier, cPTS and iPTS, respectively. Recordings of g-forces in all three axes were displayed in graphs as shown in Supplementary Figure S1 (MSR145[®] logger) and Supplementary Figure S3 (prototype logger). The maximum g-force for each logger (16 g for MSR145® logger and 200 g for prototype logger) was achieved in all runs with iPTS.

During eight study days, two different data loggers were carried once a day using each transport type. The distribution of the measured stress values during each transport type are displayed using boxplots (n=8).

Each logger calculated its own arbitrary unit to indicate the impact of transport. AUC-values in arbitrary units from the MSR145® logger for 10 Hz ranged from 0 to 6 for courier transport, from 158 to 213 for cPTS and from 311 to 415 for iPTS. For 50 Hz, the AUC for courier transport ranged from 1 to 29, for cPTS from 757 to 928 and for iPTS from 1,455 to 1,745. St-values for the prototype logger ranged from 296 to 403 kmsu for courier transport, from 301 to 586 kmsu for cPTS and from 1,334 to 1,569 kmsu for iPTS. All calculated

Table 1: Overview of measured stress values determined with different data loggers and during different ways of transport with calculated mean and standard deviation.

Date	Transport type	AUC (10 Hz)	AUC (50 Hz)	St (1,600 Hz)
1	Courier	6	29	296
1	cPTS	185	886	529
1	iPTS	324	1,457	1,372
2	Courier	0	0	381
2	cPTS	157	757	454
2	iPTS	316	1,561	1,380
3	Courier	5	24	373
3	cPTS	193	928	436
3	iPTS	324	1,521	1,342
4	Courier	0	0	363
4	cPTS	181	891	403
4	iPTS	320	1,540	1,397
5	Courier	0	2	377
5	cPTS	213	872	387
5	iPTS	415	1745	1,427
6	Courier	0	0	348
6	cPTS	181	845	479
6	iPTS	339	1,534	1,393
7	Courier	0	1	396
7	cPTS	181	888	586
7	iPTS	311	1,529	1,334
8	Courier	1	4	403
8	cPTS	158	803	301
8	iPTS	311	1,455	1,569
Mean, SD	Courier	2 (3)	8 (12)	367 (34)
Mean, SD	cPTS	181 (18)	859 (55)	447 (88)
Mean, SD	iPTS	333 (35)	1,543 (90)	1,402 (74)

AUC- and St-values are given in Table 1. The distribution of AUC- and St-values for each transport type are visualized in Figure 1.

During eight study days, two different data loggers were carried once a day using each transport type. The measured stress values during each day and each transport type are displayed in this Table, as well as calculated mean and standard deviation.

Compared to courier, cPTS and iPTS showed higher AUC- and St-values, respectively. Among the PTS-transports, iPTS gave higher AUC- and St-values than cPTS. When having raised the recording frequency from 10 to 50 Hz in the MSR145[®] logger, the AUC-values increased for cPTS and iPTS, but were more pronounced for iPTS.

Median AUC-values for courier transport were 0 for 10 Hz and 2 for 50 Hz, for cPTS 181 and 879 arbitrary units and for iPTS 322 and 1,531 arbitrary units, respectively. The median St-value of the data logger prototype in iPTS showed higher values than the ones of the other two types of transport. The median St was 375 kmsu for courier transport, 445 kmsu for cPTS and 1,387 kmsu for iPTS.

A mixed model was used to analyze the association between the transport type and AUC- as well as St-values. The results are presented in Table 2. Both algorithms identified, independent of the recording frequency, transport via iPTS as significantly more stressful than courier transport. Based on both frequencies of the MSR145® logger, the results further showed that the transport via cPTS is significantly more stressful than courier transport. In contrast, no statistically significant difference between these two transport types could be found in the results of the data logger prototype.

During eight study days, two different data loggers were carried once a day using each transport type. Because of repeated measurements, a mixed model was used to analyze the association between transport type (exposure) and the respective stress value (outcome).

A total of 16 (0.4%) measurements were invalid due to low sample volume or lipemia. Supplementary Table S1 displays the number of valid measurements as well as median (25%-; 75%-quartile) of each measurand depending on the transport type. Friedman test showed that the median results between the three transport types were statistically

Table 2: Association between transport type and stress value determined by the used data loggers.

Logger	Stress value	Transport type	Estimate	StdErr	p-Value
MSR145 [®] logger	AUC (10 Hz)	Courier	Reference group		
		cPTS iPTS	179.68 331.00	9.35 9.35	<0.01 <0.01
MSR145 [®] logger	AUC (50 Hz)	Courier	Reference group		
		cPTS iPTS	851.22 1,535.13	30.57 30.57	<0.01 <0.01
Data logger prototype	St (1600 Hz)	Courier	Reference group		
		cPTS iPTS	79.94 1,034.87	40.81 40.81	0.07 <0.01

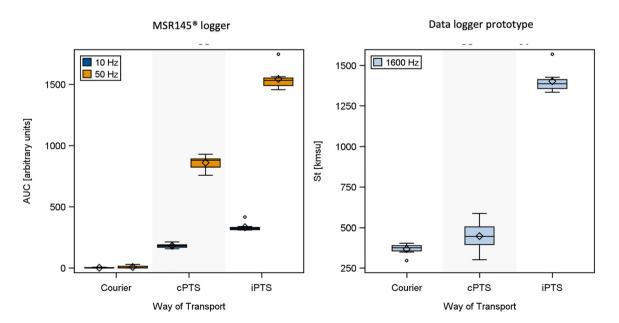


Figure 1: Distribution of established stress values separated by data logger and way of transport.

different for only three of the investigated measurands: free hemoglobin (fHb), lactate-dehydrogenase (LDH) and thyrotropin (TSH).

A more detailed view on the distribution of the measurement values for the hemolysis sensitive measurands fHb, LDH, ASAT and potassium separated by transport type is given in Figure 2. For all other measurands, these measurement distributions are visualized in Supplementary Figures S4 and S5. Regarding the hemolysis-sensitive measurands, only for potassium no significant statistical differences in measurement values between transport types were observed. The measurement values for ASAT and LDH differed significantly when comparing both PTS transport types with courier transport, but not between each other. fHb measurements were significantly elevated in both PTS transport types, with higher results in iPTS.

Distribution of measurement values for the different laboratory measurands was visualized with boxplots. The number of samples measured after each transport type is shown at the left corner of each Figure. Wilcoxon signedrank test was used for group comparisons. The corresponding p-values are displayed in the Figure.

Furthermore, for each sample and measurand the difference between courier transport and iPTS or cPTS was calculated, respectively (Supplementary Table S2). We observed that the relative difference in measurement values between transport types was less than 5 % for all but one of the 37 measurands. The only exception is the hemolysis sensitive measurand fHb, which was higher in both PTS types compared to courier transport.

Discussion

This study evaluated the ability of two data loggers and their respective algorithms to monitor the quality of diagnostic sample transport.

The results from hematology, coagulation and clinical chemistry were well comparable between all investigated transport types, with the relative differences not exceeding 5%, except for fHb. The hemolysis sensitive measurands fHb, LDH and ASAT showed statistically significant differences between transport types. From a clinical point of view, these differences can be regarded as negligible. As shown by the median and 25 %-; 75 %-quartile for courier, cPTS and iPTS (Supplementary Table S1), the measurement results were clearly comparable between transport types. For example, the median concentration of ASAT was

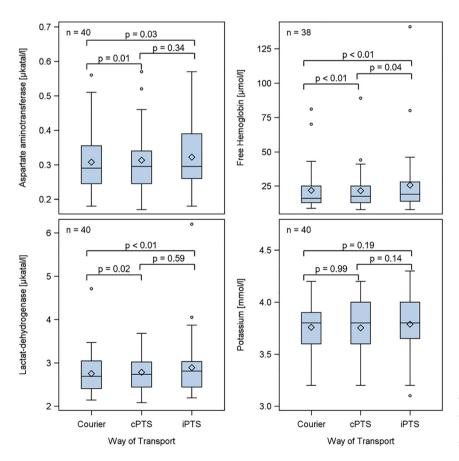


Figure 2: Distribution of measurement values for the laboratory measurands aspartate aminotransferase, potassium, lactate-dehydrogenase and free hemoglobin separated by transport type.

0.29 µkat/L for courier transport and 0.30 µkat/L for both PTS types. Likewise, median potassium concentration did not differ by transport type (3.80 mmol/L for all three transport types) and medians for courier, cPTS and iPTS transports for fHb (16.0, 17.5 and 19 μ mol/L) and LDH (2.69, 2.74 and 2.81 µkat/L) were very similar from a clinical perspective. One measurand, TSH, which is not known to be particularly affected by hemolysis, also showed a statistically significant difference depending on the transport type, but this can also be regarded as clinically irrelevant as shown by comparing the median concentration of each transport type (courier: 1.61 mU/L, cPTS: 1.56 mU/L, iPTS: 1.55 mU/L).

Overall, the impact of any of the two PTS transport types on measurement results was low. At the same time, both investigated data loggers showed differences between the cPTS and iPTS: AUC and St were considerably higher in iPTS. For the AUC recorded at 10 Hz, the values for both cPTS and iPTS remained below 500 arbitrary units, as suggested by Streichert et al. as a threshold to indicate a beginning impact on diagnostic samples [13]. A previous evaluation of the iPTS used in this study employing patient samples and the MSR145® logger also confirmed AUC values below the suggested 500 arbitrary units when using the 10 Hz AUC-results [4]. At a frequency of 50 Hz, the AUC in PTS increased considerably, reaching values up to 1,500 arbitrary units in the present study, with iPTS showing higher AUC than cPTS (Figure 1). This demonstrates the impact of the recording frequency on the algorithms.

In comparison, the St was recorded at a considerable higher frequency of 1,600 Hz. Since algorithms and units differed, a comparison could only be descriptive: both algorithms showed differences between courier and PTS transport, which is reasonable since courier transport over short distances is regarded as an established standard with very low acceleration forces.

The investigated data loggers seem to detect the stress on the diagnostic sample earlier than the analytical quality and consequently patient safety is affected. This is highly desirable, since tools in monitoring transport, that are capable to serve as an early warning system to allow enough scope of action for corrective measures, are needed. With an increasing recording frequency from 10 to 50 Hz, the difference between courier and PTS transport became more pronounced when AUC was used (Figure 1, Table 2). To our knowledge, the AUC was used in three studies with 10 Hz [4, 13, 16]. Further three studies used the AUC concept with different frequency or without reporting the recording frequency [14, 18, 19]. One study reported a possible impact of the reported frequency [19]. Considering our findings on the impact of recording frequencies,

further investigations should be conducted to evaluate at which recording frequency a steady state is reached and results are reliable.

Strengths and limitations

Due to the lack of measurement replicates, it was not possible to statistically test the reproducibility of the logger data. However, as shown in Figure 1 and Table 1 the data were quite densely distributed around the mean, suggesting good reproducibility. Our study investigated only one set of representative transport routes within one hospital and was limited to 60 healthy volunteers. The sample sets had to be rotated due to limitations in blood volume allowed by ethical approval. Even though 37 measurands were included in this study, they could not represent the full spectrum of laboratory examinations. Explicitly, the study did not aim to investigate the transport of red blood cell concentrates or similar blood products. Also, only three widely used sample tube types were investigated. Despite these limitations, the study elucidated the potential of data loggers and their respective algorithms as early warning tools in monitoring sample transport.

Conclusions

Both, AUC and St, showed differences between the cPTS and iPTS, with St emphasizing these differences more clearly. The statistical, but not clinical, differences in the results for fHb, LDH and ASAT may be regarded as an early sign of preanalytical impairment of diagnostic blood samples. Results from data loggers - calculated by different algorithms record this important interval of beginning mechanical stress with a high resolution, demonstrating that they are sensitive to transport effects. Thus, the investigated data loggers and their respective algorithms AUC and St have the potential to identify mechanical stress on a diagnostic sample before analytical and consequently clinical impairment occurs. They may be used for continuous monitoring of PTS transport and early detection of preanalytical impairment of blood samples. Further studies should investigate the continuous increase of stress on diagnostic samples using both types of loggers and algorithms until the analytical, and thus clinical, impact can be measured. These kinds of studies could help to identify reliable thresholds for AUC and St.

Currently, evaluation and monitoring of diagnostic sample transport should not only rely on data loggers, but should include both, diagnostic samples and data loggers, with appropriate algorithms.

Research ethics: Local Ethical Approval BB 100-15 of the Ethic Commission of the University Medicine Greifswald.

Informed consent: Informed consent was obtained from all individuals included in this study.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Competing interests: The authors state no conflict of interest.

Research funding: None declared.

Data availability: The raw data can be obtained on request from the corresponding author.

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Supplementary Material: This article contains supplementary material (https://doi.org/10.1515/cclm-2023-0632).