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Onboard Tagging for Smart Medical Devices

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***Abstract*—Most medical devices are 'dumb:' their role is to acquire, display, and forward data. They make few if any operational decisions based on those data. Onboard tagging is a means whereby a device can embed information about itself, its data, and the sensibility of those data into its data stream. This diagnostic add-on offers a move toward 'smart' devices that will have the ability to affect changes in operational modes based on onboard contextual decision making, such as decisions to avoid needless wireless transmission of corrupt data. This paper presents a description of three types of onboard tags that relate to device hardware (type I tag), signal statistics (type II tag), and signal viability for the intended application (type III tag). A custom wireless pulse oximeter is presented as a use case to show how type II and III tags that convey photoplethysmogram (PPG) statistics and usability specifiers can be calculated and embedded into the data stream without degrading performance.**

***Keywords*—onboard tagging, real-time embedded system, photoplethysmogram, pulse oximetry**

I. Motivation

Medical devices can be categorized according to their 'intelligence quotient.' Most medical devices are 'dumb:' they leave data interpretation to a clinician or host system, although they may locally display these data and provide notifications that, e.g., indicate whether parameters go out of range or whether measurements have been correctly acquired. These devices are easier to regulate because their functional state spaces are limited and predictable.

Alternatively, a 'smart' device might make contextual decisions based upon acquired data, including changes in how those data are processed or alterations to its operational state. A smart device might also change its modes given remote commands. Such devices would be clinically useful but difficult to verify and regulate since their operational state spaces would be significantly larger and more complex. Devices that control other devices add a further layer of complexity and are not a feature of most systems slated for FDA regulation. Note that devices that simply offer more features are not necessarily 'smart' (though they may be marketed that way) – contextual decisions must play a role.

To further the dialogue regarding how the medical community might move from dumb to smart devices, it is valuable to specify basic issues that drive the use of dumb devices. These include 1) hardware limitations (e.g., a low-power wearable device may host a microcontroller but offer limited processing, storage, and communication resources), 2) software and algorithm hurdles (e.g., besides the obvious resource limitations, a clinically-effective expert system on a small medical device requires broad collaborations), and 3) the need for clinical verification and validation, including FDA approval.

Efforts have been made to improve the intelligence level of some formerly dumb medical devices. For instance, most commercial pulse oximeters can indicate the presence of motion artifact through an alarm. In that case, front panel readouts for heart rate and blood oxygen saturation will not update until valid data recommence. Various research efforts have focused on the detection and reduction of motion artifact, primarily within the context of the viability of the pulsatile photoplethysmogram (PPG) [1]. However, most of these algorithms are computationally complex relative to the normal physiologic parameter extraction process and would be a challenge to implement on a resource-limited device.

Even a standardized 'motion detected' indicator in a pulse oximeter data stream is a good step forward towards a 'smart' pulse oximeter. While some manufacturers utilize this feature, it is customized for their device and often used only internally in the machine. This kind of indicator is referred to as a 'tag' in this paper, as tags have wide use in other daily contexts. For example, a price tag describes a commodity's price, manufacturer, category, etc. Blogging or video blogging services such as YouTube use tags on entries to classify, search, and share information.

The term 'tag' as defined here similarly provides concise but meaningful information to a medical device as well as to other devices that receive its data. Any meaningful tag must be sensible and keep the device's original functionality and data intact. A tag should update with newly acquired data, meaning it should only be valid for a specific data segment (see Fig. 1). Such properties help to ensure, within reason, that a new device which employs tags is "substantially equivalent" to, e.g., a formerly approved device, allowing a 510(k) mechanism for U.S. device approval [2].

This paper discusses onboard tagging technology, which if standardized can improve medical devices and the healthcare services they provide. For devices with limited hardware and battery resources, onboard tagging promises advantages due to its light-weight computational requirement and its potential to optimize transmission time as well as the data that are sent to a host system.

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II. Onboard Tagging Technology

This section addresses the need for onboard/real-time tags, the types of tags one might employ, the information they can convey, and some suitable tag formats. The assumption is that tags mark the original data stream provided by a medical device, as in Fig. 1. Once data frames accumulate to form a data segment with a predetermined length, a tag will be appended to the end of the segment.

Fig. 1. Tags embedded in an original data stream.

A. *Onboard and Real-Time Tags*

An 'onboard' tag implies that the tagging procedure is performed on the device and does not depend on external resources (human or machine) such as the receiver. Onboard tagging should be emphasized for these reasons:

- The receiver or host system cannot be guaranteed to be active, available, or capable enough to provide assistance, especially in the case of mobile devices.
- A device should know its data best, and a data point or segment is ideally processed right after being sampled, e.g., even prior to being packed into a data frame.
- A device is immediately improved if it can indicate characteristics of its current data and/or make independent decisions based on these tags, e.g., automated sleep control.
- For low-power, wearable/mobile devices, wireless data transmissions are the primary consumers of battery power. Tags can help a device to 1) process its own data with a goal of sending processed parameters instead of raw data over the telemetry link and/or 2) decide when transmissions should be avoided, such as cases where invalid data are undesired and their transmission would unnecessarily reduce battery life.

New tags can be created or updated as physiologic data are acquired and therefore should be attached directly to these data streams by the medical devices that provide the real-time data processing and transmission. This clearly requires that onboard tagging also be performed in real time. The following are other reasons why onboard tagging can or should be accomplished in real time:

- Tags are a condensed information set. They require few processing and storage resources compared to the routine tasks of a medical device.
- Old tags become irrelevant when new data emerge.
- Delayed tags offer limited correlation value when compared against current data segments.

B. *Tag Type and Content*

While medical devices may record numerous pieces of information in tag form, tags fall into three broad categories (Table I). Clearly, the stakeholders in column two may change depending upon the care scenario and device type.

TABLE I
Tag Types

Type	Interested Group	Primary Content of Interest
I	Device Designer	Hardware, algorithm, and data states
II	Signal Analyzer	Signal character and statistics
III	End User	Alerts, physiologic indices, & data quality

Type I tags indicate whether the device is functioning as designed. Such a tag could describe an internal system error, a system variable, a data sampling state, a control flow state, etc.; a role much like the information provided to a firmware developer when debugging a prototype. System level tags within this group could serve multiple usage roles. For example, a tag that represents a hardware failure state could also serve as a warning for an end user or clinician.

Type II tags focus on the signals themselves. Devices such as 12-lead ECGs have multiple signal channels, and each channel can have separate tags. Typical tags in this category may mark easy-to-discern statistical features related to one data segment, e.g., extreme values (valley and peak), amplitude (peak-to-valley excursion), number of cycles (amplitude swings), rising time (a counter may increment by one when a current data point is larger than the previous point), falling time (counterpart of rising time), etc. Looking at the extreme values as an example, if a tag indicates a certain number of lower-bound and/or upper-bound values for the given sampling range (e.g., a 10-bit ADC has the sampling range of [0, 1023] digitization levels), then the tagged signal segment is saturated to some level.

Type III tags speak to clinical data viability and are a user friendly version of type I and type II tags. For an end user that has little or no professional knowledge regarding device design or signal interpretation, type III tags make it easy for them to understand what is happening to the device and the measurement data. For example, if a power source voltage goes below a threshold and generates a type I tag, then a second type III tag like "low battery" could be created as an alert. In another instance, a type II cycle-count tag may change abruptly compared to prior tags, presenting an apparent inconsistency, so a type III tag may be used to note that the current value has low reliability, the current signal quality is poor, or a longer measurement time is required.

A type III tag offers a higher level description of type I and II tags. It should arguably not be directly attached to the original data stream since it carries indirect information. A digital event log would be a more appropriate repository for these tags. As implied earlier, a transformation mechanism on the device would be responsible for presenting Type III tags to a common user. If the transformation process equates to a task such as the interpretation of raw data to create a physiologic index, then a prudent verification and validation procedure should be performed in advance.

C. *Tag Format and Indices*

Since tags accompany the data stream, and new tags apply

only to the current data segment, it is sensible to look at the data frame structure first. To give this discussion context, a custom pulse oximeter [3] that employs serial communication is used as an example throughout this section. For this device, a data frame that contains one data point for each of four channels is laid out in Fig. 2. The first eight bytes define the data frame header, the last two bytes (17-18) are the tail, and the middle bytes (9-16) are the payload.

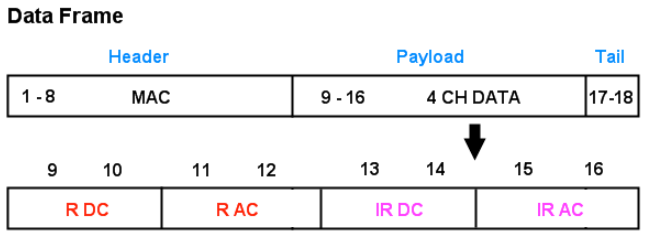

Fig. 2. Data frame structure for a custom pulse oximeter that employs serial communication (R: red channel; IR: near-infrared channel; AC & DC: pulsatile and baseline samples). The frame length is 18 bytes, with the first 8 bytes assigned to a unique MAC address, the next 8 bytes assigned to the four signal channels, and the last two bytes appended for frame integrity.

A similar structure is adopted for a tag frame (see Fig. 3). A tag frame header is an eight-byte MAC address, except it is not the real device MAC address. A preset virtual MAC (VMAC) is uniformly assigned to all tag frames. When the system detects a VMAC sequence, it knows the frame is a tag frame that holds tags for the current data segment.

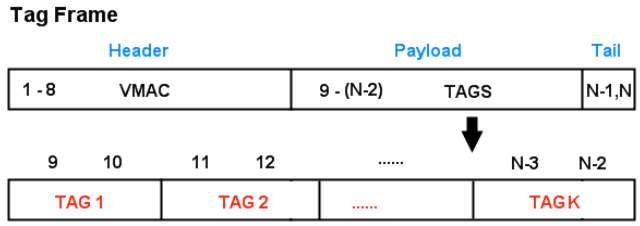

Fig. 3. Tag frame structure for a custom pulse oximeter. The frame length is N bytes containing K tags.

The tag frame length of N bytes is not fixed – it depends on how many tags the frame conveys. If we use a uniform tag size of 2 bytes, a tag frame holding K tags has a length of

$$N = 2K + 10 \tag{1}$$

bytes, where $2K$ bytes is the payload size and the remaining 10 bytes hold the header (8 bytes) and the tail (2 bytes).

One issue regards the length of time a tag is active and the rate at which tags are assigned. Two indices, *tag active time* and *tag density* are introduced here. Tag active time denotes the duration for which a tag is active – usually one data segment. E.g., if a tag frame is yielded after each three-second data segment, *tag active time* = 3 seconds and *tag delay* = 1.5 sec (the average reporting delay over a three-second moving segment). Tag density is defined as

$$\text{Tag Density} = \frac{\text{Tag Frame \#}}{\text{Data Frame \#}} \tag{2}$$

For example, if the data frame rate (sampling frequency) is 240 Hz and the tag active time is 3 seconds, then the *tag density* = 1/720 = 0.14%. Tag density is important. A high tag density can lead to over-reporting and unnecessarily high bandwidth requirements, whereas a low tag density can increase the tag delay and make it more difficult for a system to respond to data anomalies in 'real time.'

III. A Use Case for Onboard Tagging

A use case is a good way to illustrate onboard tagging. The custom pulse oximeter is again employed for that purpose. Here, the goal is to smarten this formerly 'dumb' device so that it can identify three items: 1) PPGs corrupted by motion artifact, 2) data affected by signal saturation, and 3) clean, usable PPGs versus non-saturated data that do not exhibit meaningful pulsatile wave shapes [4]. Such results are useful for either the host system (e.g., to improve the integrity and usability of the associated electronic health records) or the device itself (e.g., to maximize its battery life by identifying segments of data that need not be transmitted over the wireless link because they are not useful anyway).

A. *Use Case Tag Selection*

Since this use case is focused on the PPG signal, four type II (signal statistics) tags were chosen as in Table II. A series of experiments was conducted to find the tag that relates most closely to signal quality [4]. For instance, 200 segments of clean, motion-free PPG data from 20 different subjects (10 three-second segments each) were used to evaluate the performance of Tag 3: rising time count. This parameter represents the number of sample-to-sample value increases in a three-second data segment that has been decimated from 240 Hz to 30 Hz, yielding 90 decimated samples per segment. Fig. 4 contains Tag 3 statistics from the 20 subjects, where each bar height is the average rising time count for the individual's 10 segments, and the line at the top of each bar is the corresponding standard deviation.

TABLE II
Four Type II Tags Picked For a Custom Pulse Oximeter

Tag	Content	Relation
1	Baseline (*DC channel) variation count	Motion
2	PPG extreme value count	Saturation
3	PPG rising time count	Shape
4	PPG falling time count	Shape

*DC level is assumed to be constant in some pulse oximeter designs or adjustable according to the subject's vascular profile and perfusion level, as in the custom pulse oximeter employed here.

For Tag 3, the average bar height is 28, and the maximum standard deviation is less than 4. Similar statistical results for Tag 4 (falling time count) yield an average of 60 and a standard deviation that is also less than 4. The ratio of Tag 3 to Tag 4 is consistent with the traditional metric that the diastolic interval is roughly two times longer than the systolic interval in normal heart activity. As a side note, each segment is three seconds long, i.e., *tag active time* = 3 seconds, a duration that normally corresponds to less than four cardiac cycles for an adult at rest.

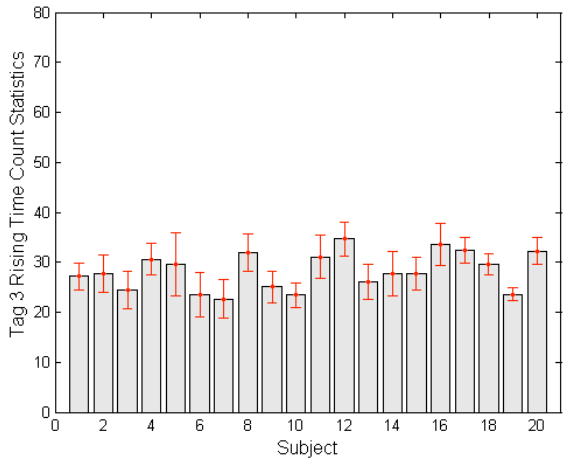

Fig. 4. Tag 3 (rising time count) statistics for 20 subjects.

B. *Use Case Firmware Implementation*

Onboard tagging implementation is an extra code block in the ten-step firmware flow that produces a single data frame. All code blocks reside in the timer interrupt routine, which drives the steps forward (step 1 to step 2, step 2 to step 3, … step 10 to step 1, etc.). The first nine steps preserve the original pulse oximeter functionality, including channel switching, analog-to-digital conversion, data frame packing, and wireless transmission. The last step implements the tagging service, which is triggered right after a new data point/frame is available rather than merely at the end of a segment. Hence, it gives the tagging algorithm a relatively large amount of total computation time without delaying the continuous data acquisition process.

C. *Use Case Decision-Making and Tag Transformation*

To extend onboard tagging technology for this use case, a three-step hierarchical approach is adopted to generate user friendly type III tags from the aforementioned type II tags via the following assessments: 1) motion status, 2) saturation status, and 3) signal quality (see Fig. 5).

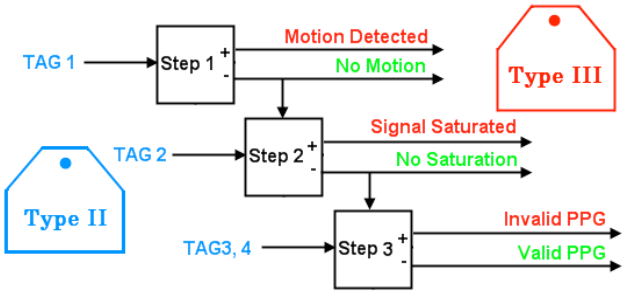

Fig. 5. Three-step hierarchical approach to tag transformation.

In Step 1, motion is detected based only on Tag 1. (Each step uses Bayesian hypothesis testing.) If 'No Motion' is present, Tag 2 is used to decide the signal saturation status. The Step 2 decision rule couches the decision in terms of whether the signal can pass through to the next step. For example, a pure ambient noise signal can easily walk through the first two steps; however, the Step 3 decision rule that deduces morphological information from Tags 3 and 4 will reject the noise signal and disqualify other non-PPG signals. A data segment passing through the entire hierarchy is tagged 'No Motion,' 'No Saturation,' and 'Valid PPG.' Since the decision-making process only involves threshold comparisons with these type II tags, the type III tags are created right after the type II tags.

Type II tags typically demonstrate 100% accuracy, whereas type III tags are usually accompanied by different levels of error, depending on the correlation between the two tag types and the transformation method employed. A 99% accuracy was achieved for these type III tags using a Bayesian hypothesis testing approach [4].

IV. Conclusion

This paper presented a description of onboard tagging technology as a means to embed information about medical device hardware (type I tag), signal samples (type II tag), and signal viability (type III tag) in the data stream itself. A use case addressing a custom pulse oximeter demonstrated that type II tags can be embedded in a data stream and then be used to calculate type III tags that are also embedded in the data stream. Further, these tags can be inserted seamlessly in the firmware flow without incurring a computation load that affects device performance.

References

[1] R. Krishnan, B. Natarajan, and S. Warren, "Two-Stage Approach for Detection and Reduction of Motion Artifacts in Photoplethysmographic Data," *IEEE Transactions on Biomedical Engineering,* vol. 57, pp. 1867-1876, 2010.

[2] U.S. Food and Drug Administration (FDA), "Premarket Notification (510k)," 2011, http://www.fda.gov/MedicalDevices.

[3] K. Li and S. Warren, "A Wireless Reflectance Pulse Oximeter Suitable for Wearable and Surface-Integratable Designs That Produces Unfiltered Photoplethysmograms," *IEEE Transactions on Biomedical Circuits and Systems,* submitted for publication.

[4] K. Li, S. Warren, and B. Natarajan, "Onboard Tagging for Real-Time Quality Assessment of Photoplethysmograms Acquired by a Wireless Reflectance Pulse Oximeter," *IEEE Transactions on Biomedical Circuits and Systems,* to be published.