Review of Medical Device Connectivity in Neurocritical Care

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Abstract

Background: Multimodal monitoring is the standard of care in neuroscience intensive care units (neuro-ICUs) and it has led to the creation of a data-rich environment. However, a “plug-and-play” interoperable approach is not yet available for medical devices in neuro-ICUs and this has hindered the creation and adoption of valuable informatics tools such as clinical decision support.

Objective: This paper presents a review of the characteristics of the device interfaces that have been examined by Moberg Research, Inc. for the development of their platform for neurocritical care data integration.

Methods: Neurocritical care device interfaces were reviewed by answering a series of questions designed to describe the adherence to specifications, the acceptance of standards, the overall quality of the protocols and to uncover potential pitfalls.

Results: A total of 26 devices interfaces were examined in this process; 2 were discarded because of their analog nature. Device manufacturers did not provide protocol specification documents for 2 of the 24 device interfaces. In the case of device interfaces for which protocol specifications were provided, an unexpected degree of deviation was encountered. 18% of the protocol implementations exhibited a behavior substantially different from what expected based on the specifications. A large number (32%) exhibited undocumented behaviors. Out of the 24 examined protocol implementations, 3 did not provide a protocol version field in the output and only one was based on an existing communication and nomenclature standard. No form of identification for the device source and/or data types was included in the protocol for 29% of the investigated devices. One device did not specify the units either in the protocol specification or in the transmitted data. While some device
protocols provided checksums or at least parity bits, 54% of the devices did not provide either.

**Conclusions:** The results of this review revealed a lack of adherence to published/provided specifications, creating significant barriers to the development of connected, interoperable systems. Almost no data standardization was implemented in the analyzed protocols and many lacked transmission error detection schemes or source identification. These barriers impose a high degree of technological overhead for those who want to implement a connected neuro-ICU, making the development of custom interfaces costly and, ultimately, stifling innovation. Additionally, well-designed, standardized and documented device interfaces would reduce the risk of data misinterpretation and systematic medical errors.

In order to reduce the currently identified barriers to connectivity, it is our recommendation that medical device manufacturers provide a well-designed and documented communication protocol for their devices. We also anticipate that our research will lead to the development of "best practices" that manufacturers could follow in the absence of widely adopted standards applicable to neurocritical care.

**Introduction**

Neurocritical care is a medical discipline that deals with complex neurosurgical, neurological and medical problems in critically ill patients who suffered acquired brain injuries, including traumatic brain injury, stroke or subarachnoid hemorrhage.

In most neuroscience intensive care units (neuro-ICUs), multimodal monitoring is routinely performed and has become a standard of care. Multimodal monitoring is defined as the continuous, simultaneous evaluation of cerebral function and vital signs from multiple modalities in a single patient, with the goal of avoiding or mitigating secondary brain insults [1-4]. Monitored physiological parameters include, for example, intracranial pressure (ICP), partial pressure of brain tissue oxygen (PbtO2), cerebral blood perfusion, heart rate, mean arterial pressure, and respiration rate. The increase in the number of monitored modalities has led to the creation of a data-rich environment, where information extraction and consolidated review is still sub-optimal [5, 6]. A significant limitation of informatics in current Neuro ICUs is the highly proprietary nature of the data collected by the multiple stand-alone devices. Whereas in consumer electronics an
interoperable, "plug-and-play" approach is expected from all devices, this is not true in the neurocritical care environment, which contains numerous barriers to the integration of data collected by multiple sources for the extraction of meaningful information [7]. The barriers to meaningful integration of the information collected by stand-alone devices has hindered the development of advanced data displays, which are recommended in order to support the cognitive process of clinicians while avoiding adverse effects on clinical decision-making [5]. Likewise, bedside data analytics would provide clinical decision support and enhance awareness of patient status but, today, can only be implemented in institutions that have developed their own unique data infrastructure and are rarely scalable or adaptable for routine care. Informatics tools in neurocritical care cannot, in fact, solely rely on the sparse data collected by electronic medical records, but need high-resolution data streams that can only be provided by medical devices directly.

Moberg Research, Inc. has developed a unique platform for neurocritical care data integration: the Component Neuromonitoring System (CNS). It consists of a series of hardware and software solutions to provide the simultaneous, time-synchronized integration of data collected by multiple stand-alone devices used in the neuro-ICU. This paper presents a review of the characteristics of the device interfaces that have been examined for the development of the CNS.

Methods

The device interfaces examined in the development of the CNS for use in neuro-ICUs were reviewed by answering a series of questions designed to describe the adherence to specifications, the acceptance of standards, the overall quality of the communication protocols and to uncover potential pitfalls.

1. Adherence to specifications

   1.1. How many device interfaces were not accompanied by protocol specification documents from the manufacturer?

   1.2. How many protocol implementations deviated from the manufacturer’s specifications?
1.3. How many protocol implementations exhibited a behavior substantially different from what was expected based on the manufacturer’s specifications?

1.4. How many protocol implementations exhibited undocumented behaviors?

1.5. How many devices exhibited error conditions that were not explicitly mentioned or clearly identified in the communication protocol?

1.6. How many protocol implementations did not provide a version field in the output?

2. Acceptance rate for standards

2.1. How many protocols either followed or were based on existing communication standards?

2.2. How many protocols either followed or were based on an existing standard nomenclature?

3. Quality of the protocol

3.1. How many protocols did not include identification of the source device and/or data types?

3.2. How many protocols did not specify units for the transmitted data or identify the units in the output data packets?

3.3. How many protocols did not provide checksums or parity?

Sources of the data were Protocol Specification Documents provided by the manufacturers of the medical devices for which Moberg Research, Inc. developed interfaces and Device Definition Documents produced in the development phase.

Percentages were rounded to the nearest integer.

Results

A total of 26 device interfaces were examined in this process. Two of the 26 device interfaces were discarded from further investigation because of their analog nature. Any subsequent protocol examination was performed only on the 24 digital interfaces.

First, adherence to protocol specification was investigated (Table 1). Manufacturers did not provide protocol specification documents for some the device interfaces (2 out of 24). In the case of device interfaces for which protocol specifications were provided, a high degree of deviation was encountered. For example, many protocol implementations did not output data at the interval described in the specifications: for the vast majority of devices, the
protocol specification implied a regular output interval while their implementation exhibited a high degree of irregularity; though sometimes the average output interval was accurate over time, other implementations wandered unpredictably. About 1 out of 5 (18%) of the protocol implementations exhibited at least one behavior substantially different from what was expected based on the specifications. Additionally, a large number of protocol implementations (7 out of 22) exhibited undocumented behaviors. As an example, the protocol specification for one of the devices provided details about how to obtain trend data but did not specify how the high-resolution waveforms are transmitted. Out of the 24 examined protocol implementations, 3 did not provide a protocol version field in the output. We then examined the rate of adherence to standards (Table 2). Out of the 24 device interfaces investigated in this study, only one was based on an existing communication standard and standard nomenclature (IEEE 11073). Some deviations from the accepted standard were implemented, however, to accommodate some nomenclature needs specific to neurocritical care.

**Table 1. Summary of results for questions related to adherence to specifications.**

<table>
<thead>
<tr>
<th>Question</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 How many device interfaces were not accompanied by protocol specification documents from the manufacturer?</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>1.2 How many protocol implementations deviated from the manufacturer’s specifications?</td>
<td>22</td>
<td>100% a</td>
</tr>
<tr>
<td>1.3 How many protocol implementations exhibited a behavior substantially different from what was expected based on the manufacturer’s specifications?</td>
<td>4</td>
<td>18% a</td>
</tr>
<tr>
<td>1.4 How many protocol implementations exhibited undocumented behaviors?</td>
<td>7</td>
<td>32% a</td>
</tr>
<tr>
<td>1.5 How many devices exhibited error conditions that were not explicitly mentioned in the communication protocol?</td>
<td>1</td>
<td>5% a</td>
</tr>
<tr>
<td>1.6 How many protocol implementations did not provide a protocol version field in the output?</td>
<td>3</td>
<td>13%</td>
</tr>
</tbody>
</table>

aPercentages for these results were calculated considering only the protocols for which specifications were provided (N=22).
Table 2. Summary of results for questions related to acceptance rate for standards.

<table>
<thead>
<tr>
<th>Question</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 How many protocols either followed or were based on existing communication standards?</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>2.2 How many protocols either followed or were based on an existing standard nomenclature?</td>
<td>1</td>
<td>4%</td>
</tr>
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Finally, we examined the quality of the protocols (Table 3). We identified the following aspects as important: identification of source device and/or data types; specification of units; presence of checks to identify data transmission errors. No form of identification for the device source and/or data types was included in the protocol implementation for 29% of the investigated devices. One device did not specify the units either in the protocol specification or in the transmitted data; yet it allowed the units of the output values to be changed on the fly in response to user control actions. While some device protocols provided checksums or at least parity bits, 54% of the devices did not provide either.

Table 3. Summary of results for questions related to the quality of the protocol.

<table>
<thead>
<tr>
<th>Question</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 How many protocols did not include identification of the source device and/or data types?</td>
<td>7</td>
<td>29%</td>
</tr>
<tr>
<td>3.2 How many protocols did not specify units for the transmitted data or identify the units in the output data packets?</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>3.3 How many protocols did not provide checksums or parity?</td>
<td>13</td>
<td>54%</td>
</tr>
</tbody>
</table>

Discussion

This study was designed to review the characteristics of device interfaces used in neuro-ICUs and that have been encountered during the development of a platform for neurocritical care data integration. The results revealed a lack of adherence to published/provided specifications, creating significant barriers to the development of connected, interoperable systems. Although
manufacturers seeking FDA approval are required to provide documentation regarding their device specifications, the protocol implementation is not examined for adherence to such specifications. The widespread presence of additional behaviors that were unaccounted for and the lack of version control in some protocol implementations was also a reason of concern. Due to the lack of a protocol version field in the output, slight variations to the protocol could go undetected by the receiving devices, creating the potential for incoming data to be misinterpreted. Almost no data standardization was implemented in the analyzed protocols. Although currently accepted standards would require the addition of nomenclature specific to neurocritical care, the lack of data standardization imposes a technological overhead for those institutions that want to implement clinical decision support tools based on the data collected in their neuro-ICUs. Finally, we observed that many protocols did not provide transmission error detection schemes and did not include identification of the source device or data type. As a consequence, data misinterpretation or incorrect parsing of the received data are possible hazards, potentially leading to delayed or incorrect treatment of patients.

Overall, a variety of barriers to the creation of a connected environment in neuro-ICUs have been identified. It is acknowledged that an initial effort would be required of device manufacturers in order to provide a well-designed, standardized and documented data stream from their device. However, a push towards seamless connectivity would create additional value. Currently, custom interfaces need to be developed by any manufacturer or institution that wants to connect to external medical devices: this requires highly skilled labor, is expensive, and poses a high risk in terms of data interpretation reliability. Ultimately, these high connectivity costs stifle innovation and new technologies are slow to reach the market. Furthermore, it has been recognized that seamless medical device connectivity could improve quality of care through the reduction of adverse events due to safety interlocks [8-10]. Similarly, it would increase the overall effectiveness of care, thus shortening the length of stay, and it would also increase the productivity of clinicians due to decreased time spent manually entering information [8].
Conclusions

Moberg Research, Inc. has developed multiple interfaces for the connection and the integration of data from a variety of medical devices used in neuro-ICUs. Based on the results of this review, we have confirmed that there is no widely adopted standard for medical device communications, resulting in a plethora of custom protocols. Additionally, data outputs from medical devices have been historically only of interest to researchers: this explains why the examined communication protocols are frequently not well engineered, not well supported, and sometimes erroneous in their operation. Without a standard to meet or a single organization to certify quality of a communications protocol, the job of testing these systems sits on the shoulders of the hospitals. However, there are no test tools or standard test methods specifically designed for medical devices connected to hospital information systems, potentially leading to errors that result in patient morbidity and mortality. It is our hope that, in lieu of adopted standards for medical device connectivity, the industry will develop and adopt “best practices” for these interfaces.

Acknowledgements

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Conflicts of Interest

The authors are affiliated with Moberg Research, Inc., a medical device manufacturer.

Abbreviations

Neuro-ICU: Neuroscience Intensive Care Unit

References


8. The value of medical device interoperability. West Health Institute, 2013.
