



Voxyvi: A system for long-term audio and video acquisitions in neonatal intensive care units



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ABSTRACT

Background: In the European Union, 300,000 newborn babies are born prematurely every year. Their care is ensured in Neonatal Intensive Care Units (NICU) where vital signs are constantly monitored. In addition, other descriptors such as motion, facial and vocal activities have been shown to be essential to assess neurobehavioral development.

Aim: In the scope of the European project Digi-NewB, we aimed to develop and evaluate a new audio-video device designed to non-invasively acquire multi-modal data (audio, video and thermal images), while fitting the wide variety of bedding environment in NICU.

Methods: Firstly, a multimodal system and associated software and guidelines to collect data in neonatal intensive care unit were proposed. Secondly, methods for post-evaluation of the acquisition phase were developed, including the study of clinician feedback and a qualitative analysis of the data.

Results: The deployment of 19 acquisition devices in six French hospitals allowed to record more than 500 newborns of different gestational and postmenstrual ages. After the acquisition phase, clinical feedback was mostly positive. In addition, quality of more than 300 recordings was inspected and showed that 77% of the data is exploitable. In depth, the percentage of sole presence of the newborn was estimated at 62% within recordings.

Conclusions: This study demonstrates that audio-video acquisitions are feasible on a large scale in real life in NICU. The experience also allowed us to make a clear observation of the requirements and challenges that will have to be overcome in order to set up audio-video monitoring methods.

1. Introduction

A newborn is considered premature when he/she is born before a Gestational Age (GA) of 37 complete weeks. In the European Union, 8% of the births are premature and around 6.5% of the newborns have a birth weight of fewer than 2500 g [1], which lead to more than 300,000 premature infants hospitalized each year.

Premature newborns have several immature functions such as digestive, cardiorespiratory, immunological or neurological and thus, receive specialized care in Neonatal Intensive Care Units (NICU). During this period, they are equipped with several medical devices depending on the severity of their immaturity, such as intubation for respiratory assistance, intravenous infusion and catheter for food support. In the meantime, their health status is continuously monitored, especially regarding cardiac and respiratory activities.

In a more punctual manner, their neurobehavioral maturation is also assessed, mainly through sleep evaluation since sleep mechanism has been shown to evolve with increasing age [2].

To this end, observations of various components, such as motor, vocal or facial activities of the newborn, are made by trained nurses [3]. In addition to newborn development, these elements have also been shown to be relevant for the detection of various neurological impairments [4–6]. However, such observations are time consuming and thus only a small part of newborns benefits from this follow-up.

In the light of these observations, the European Union's Horizon 2020 project Digi-NewB has been conducted [7]. With the ambition to propose non-invasive strategies, our team aims to produce new indices helping to evaluate neurobehavioral development but also to diagnose neonatal sepsis, known to be associated with an atonic behavior of preterm newborns [8,9]. Among the non-invasive techniques, the use of

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cameras associated with microphones seems to be one of the most relevant to provide a behavioral characterization close to the observation made by clinicians.

During the last decades, several features extracted from audio or video data have been proven to be relevant indicators of newborn conditions regarding a large scope of clinical situations [10]. Hence, Black and White (BW) cameras were used for motion analyses in order to detect cerebral palsy [11] or neonatal seizures [12] but also to estimate physiological signals such as cardiac pulse [13] or respiratory [14] rates. The last two points were also investigated with color cameras [15–17]. Recently, cameras have also been used as a complement to ElectroEncephaloGraphy (EEG) for the study of neonatal seizures events [18–20]. Concerning audio analyses, two types of microphones have been used: unidirectional for cry analysis [21] or omnidirectional to study NICU acoustic environments [22]. In addition, thermal cameras were also employed to investigate the temperature of the baby [23] or respiratory rate [24]. Combination of audio and video data was rarely investigated. To date, only two studies integrating audio and video processing, have, to our knowledge, been published [25,26]. In [25], a contact-less system for audio-video infant monitoring was proposed and used to process motion and cries separately. Recently, we proposed a semi-automatic approach combining for the first time audio and video analyses for the estimation of sleep states in preterm newborns [26].

However, for all these works, solutions to settle cameras and microphones in NICU were not clearly addressed although this point is essential to move towards an integration of this new type of monitoring in care routine [10]. In fact, studies dealing with preterm newborns were mainly conducted on short recordings, on relatively small databases and under controlled conditions (specific experimental setup with e.g., uncovered newborns, recording by daylight illumination). No author recorded newborns lying in incubators in a night environment, particularly common in NICU. In addition, no author proposes to record preterm newborns all along their hospitalization in order to

automatically assess their neurobehavioral evolution with evolving PostMenstrual Age (PMA).

This study was conducted with three main objectives: to design and evaluate the integration of a new multimodal system in NICU, to identify the percentages of usable data in long audio-video recordings and to report challenges that will have to be overcome to move towards automatic processing of long audio-video recordings.

This paper is divided into three main sections. The first section presents the acquisition system (named Voxyvi) in terms of hardware, software and solutions for deployment in NICU. It is supplemented by methods to evaluate clinical adoption and data quality after the acquisition phase. Then, the first part of the results section is devoted to the evaluation of the integration of this new system through clinician feedback and the collected database description. It is followed by a data qualitative analysis about the usability of the collected data. To finish, a discussion section is reported where challenges and potential solutions to implement fully-automated monitoring solutions are proposed.

2. Methods

In this section, the design of the acquisition system and propositions to integrate such system in the care organization of NICU are firstly presented. Secondly, the methods used to assess the usability of the system and the quality of the collected data are introduced.

2.1. Design and integration of the acquisition system

The Voxyvi acquisition system is composed of hardware and software parts: the audio-video device and the local computer unit which provides an interface, computing capabilities and data recording. This architecture is depicted in Fig. 1.

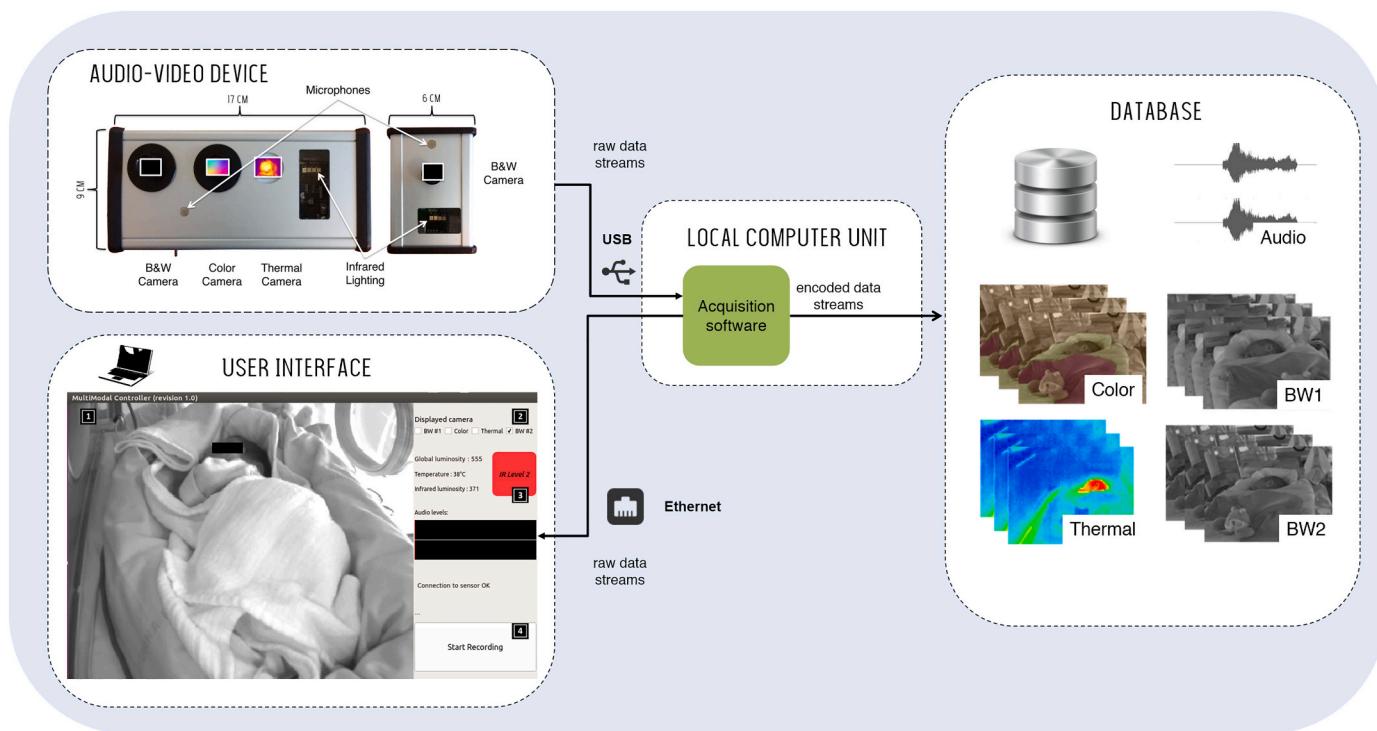


Fig. 1. Voxyvi acquisition system. A two-housing device allows to record several audio-video modalities (infrared BW, color, and thermal cameras, microphones). The audio-video device is connected via USB to a local computer unit that manages interfacing and data recording. The interface allows the visualization of the raw streams and the launching of a recording session. Recordings are stored locally and/or on an external hard drive disk.

2.1.1. Audio-video device

The audio-video device is composed of two housings (see Fig. 1): a main housing ($17 \times 9 \times 4$ cm) that is self-dependent and a secondary housing ($6 \times 9 \times 4$ cm) provided to enable acquisition with a second view (since newborns usually lay on one side).

In the main housing, three video components marketed by FLIR are embedded. First, a small BW infrared camera ($44 \times 34 \times 24.4$ mm) with a resolution of 752×480 pixels was chosen (FMVU-03MTM-CS). Associated with an infrared illumination by LEDs, it provides clear images day or night. The second video component is the equivalent color camera (FMVU-03MTC-CS). The last one is a thermal camera (60×80 pixels) with up to 8.6 fps capturing capability with a size of $8.5 \times 11.7 \times 5.6$ mm. Regarding acoustic, an omnidirectional microphone (FG-23329-P07) marketed by Knowles Acoustics is integrated. The second housing only embeds an infrared BW camera with its associated infrared illumination and a microphone.

Additional technical concerns were addressed. First, to protect the preterm infant's eyes, the maximum near-infrared radiation must be limited to 10 mW/cm^2 [27]. In our case, with the housing placed at least at 30 cm from the newborns' eyes, a total illumination of $29.4 \mu\text{W/cm}^2$ is guaranteed. Secondly, in incubators, the temperature can reach 40°C and the humidity rate up to 90%. Thus, the housings are waterproof and machined in aluminum. To control humidity infiltration, an indicator has been integrated in each housing. From our instructions, the housings have been manufactured by a company specialized in electronic integration.

2.1.2. Local computer unit

The audio-video device is connected to a local computer unit using a USB connection. The software requirements are fulfilled by an Intel Next Unit of Computing (NUC), a mini-computer of $12 \times 11 \times 5$ cm. Two main tasks, described below, are managed by the Voxyvi acquisition software running on the NUC: interfacing and data recording. The software also allows the housings to be switched off/on by clinicians during acquisition without using the interface since it is an important feature to enhance the acceptance of the video system by caregivers [28].

2.1.2.1. User interface. The graphic configuration interface (Fig. 1) allows the visualization of the raw streams captured by the audio-video device and the launching of a recording session. To access the interface, a laptop is connected by Ethernet to the NUC. All video streams can be visualized by selecting the corresponding check box. Other information such as the global luminosity, the temperature or sensor connection status are transmitted in order to control the device before launching the acquisition. A "Start Recording" button is used to launch the recording session. When recording is in progress, the laptop can be disconnected and removed from the room to reduce equipment clutter. To end the recording session, it is sufficient to simply stop the NUC.

2.1.2.2. Data recording format. Recordings are stored locally but Voxyvi also allows saving data on an external hard drive disk connected to the NUC. Each stream is recorded under a unique session directory. Moreover, in order to limit file corruption and data loss, recordings are split into multiple records of 30 min. The encoding formats were also carefully chosen in order to keep a good compromise between data quality and file sizes: video streams are recorded at 25 fps with MPEG-4 encoding, under AVC container, thermal images are saved as binary files at 4 fps and each audio stream is integrated as a channel of a stereo.

wav file at 24 kHz.

2.1.3. Integration in neonatal intensive care unit

In this part, we first focus on the positioning of the Voxyvi acquisition system in order to fit the various types of bedrooms and beds encountered in NICUs. Furthermore, to ensure the following of newborns along their hospitalization, the system had to be installed and uninstalled by clinicians frequently. Thus, a particular attention has been paid to medical staff training.

2.1.3.1. Positioning of the audio-video device. The newborn safety is the most important requirement. To ensure a non-invasive integration, it must not require direct interaction with the newborn meaning that it should fit the environment without modifying it (i.e., no additional electrodes, no need to move the newborn from a location to another). Meanwhile, the device should not disturb the medical staff work in terms of manipulation and congestion. As the specific care of premature newborns implies different kinds of beds (e.g., closed beds like incubators or open beds such as radiant warmer beds and cradles) corresponding to the newborn needs, we designed a flowchart to adapt safely and efficiently the device to each newborn environment (Fig. 2). Two main strategies were proposed.

First of all, an outside positioning is not relevant for closed beds notably because the sounds of the baby will be attenuated but also, fog and water droplets can appear on the walls of the incubators when the humidity level and temperature are high and this can damage the resulting video quality. Thus, the use of a support slipped under the mattress has been proposed. It was placed at the bed end since medical staff and parents rarely approach the newborns by this side of the incubator. The support relies on a base made of a stainless steel acting as a counterweight. To adapt the system position regarding height, the rail is also fixed on two telescopic tubes (max. height 250 mm, min. height 154 mm, diameter 27/20 mm).

For open beds, the same positioning would affect nursing and security of the newborn. Hence, the second strategy is to hang the housings as the other medical devices in the room i.e., using bars or masts. For that purpose, clamps (Manfrotto REF035), with an operational domain on sections comprised between 15 and 55 mm, were provided. In that context, the wide variety of possibilities of hanging can lead to safety issues if clamps are poorly anchored. To manage this critical situation, security lanyards were integrated. However, the study of the room environments showed that in some rooms neither bars nor masts are available in the room. In that case, the housing can be hung on a mobile and ballasted mast usually used for subcutaneous infusion. The main issue implied by this solution is to be sure that the bed will remain in the field of view. To overcome this difficulty, the location of the bed is marked on the floor and medical staff and parents are aware to replace the bed in this position. For security, data standardization and infrared lighting reasons, the distance between the bed and the housings was kept between 30 and 80 cm.

Before launching the acquisition phase of the project, several safety risks were identified and studied in real-life conditions on open and closed beds using a baby doll. They are reported in Appendix A. From there, the protocol for camera positioning has been approved by the Biomedical Engineering Department of CHU Rennes. In addition, a sterilization protocol was established by the Hygiene department of CHU Rennes. It specifies that all the equipment (i.e., wires, housings, clamps or support) must be cleaned with disinfectant wipes at the same time as the bed and at each transfer to another room.

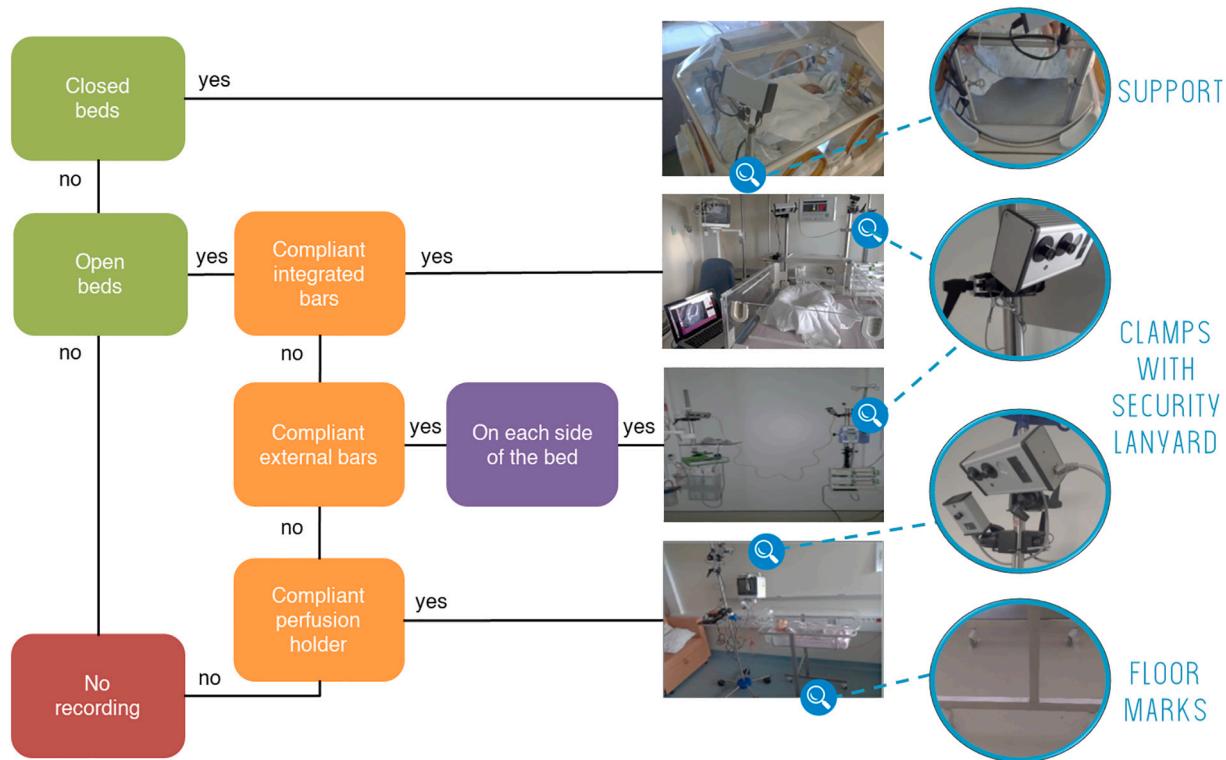


Fig. 2. Flowchart for audio-video device positioning in NICU.

2.1.3.2. Training. The system being exclusively used by clinicians and in a heavy workload context, it had to be user-friendly, meaning that this new equipment had to be easy to appropriate. As a result, training in the use of the system and technical support have been introduced.

First of all, an exhaustive user manual has been provided to each hospital. It was presented during a day of training conducted in each center. It contains all the previous mentioned requirements (positioning, orientation, access to the interface, device sterilization) but also a step by step description of the connection between the different components of the system. To facilitate the installation of the system in rooms, summarized sheets have been given and wires have been marked with different colors. Technical support details have also been communicated and allowed a personalized follow-up of difficulties.

Moreover, signage has been added to the system in order to alert each person (e.g., parents, nurses or cleaners) to the security precautions. As an example, in case of mobile elements (e.g., beds, perfusion holders) the device should not in any way be placed overhead newborns. The corresponding signage was stuck on the back of the main housing.

2.2. Post-acquisition evaluation

We now focus on methods devoted after the acquisition phase, in order to evaluate clinical adoption and video data quality. For this purpose, first a survey was designed and proposed to clinicians to gather their feedback. Secondly, we proposed several approaches to assess data quality in terms of usability. Finally, a paragraph dedicated to statistical analysis methods that have been applied to discuss several hypothesis is proposed.

2.2.1. Gathering clinician feedback

The objective was to gather feedback of clinician which were responsible for the acquisition progress in each hospital center. A set of questions has been constructed by a working group composed of industrials, clinicians and researchers (survey is reported in Appendix B). Four aspects of the system were targeted: installation, interface, training and care integration. For each point, overall questions were first asked (e.g., how long do you take to install the system?). Then, for each category, agreements with several proposals were retrieved on a 4-level Likert scale (Agree, Quite Agree, Quite Disagree and Disagree). The survey was anonymous and was proposed online using SurveyMonkey.

2.2.2. Data qualitative analysis

In order to give an overview of the data quality and the usability of such database, data had to be investigated. The most informative modality in terms of quality is the video since it provides information that has repercussions on all the other modalities. Thus, efforts have been concentrated on this modality.

First, an image for each 30-minute length video file was automatically extracted and stored. A set of images was thus extracted for each recording. Then, we proposed an annotation tool to read and annotate the data. It was developed using QT designer and Python. The interface is presented in Fig. 3.

The three videos (BW1, BW2 and Color) are displayed and the user can pass through the several images of the recording using the left and right buttons. For annotation purpose, two main video classes were identified: the ones to be kept ("Add" button on the interface) for further processing and the ones to discard ("Discard" button). In case of the video to be kept, two additional annotations are made i.e., the best



Fig. 3. Annotation tool for video quality investigation.

camera to use between BW1, BW2 and Color and the type of bed: open or closed. For the second class, we provided a list of non-exclusive reasons, induced by the real conditions of NICU, that can be checked to explain the video to be discarded:

- Mother: when the mother is in the field of view of each camera all along the recording;
- Phototherapy: when phototherapy is performed;
- IR: when the infra-red illumination is not sufficient or cut by a room element (i.e., tablet, device) at the forefront;
- Protocol: when the recording protocol is not respected;
- Framing: when all cameras are badly oriented;
- Other: when another reason justifies the discard.

To go one step further, we applied the deep learning approach presented in [29] to get an automatic annotation of percentages of periods of sole presence of the baby, periods of adults in the camera field and absence of the newborn from bed. In addition to giving us information about periods of analysable video, the identification of periods of presence of adults allows us to identify parts of soundtracks that are potentially impacted by adult voices or noises from their activity. In a similar way, it is also informative about periods that are not relevant for thermal camera analysis.

2.2.3. Statistical analyses

Statistical analyses were performed using the libraries pingouin and scipy.stats in Python 3.7.3. They were performed in order to give insights on the following questions:

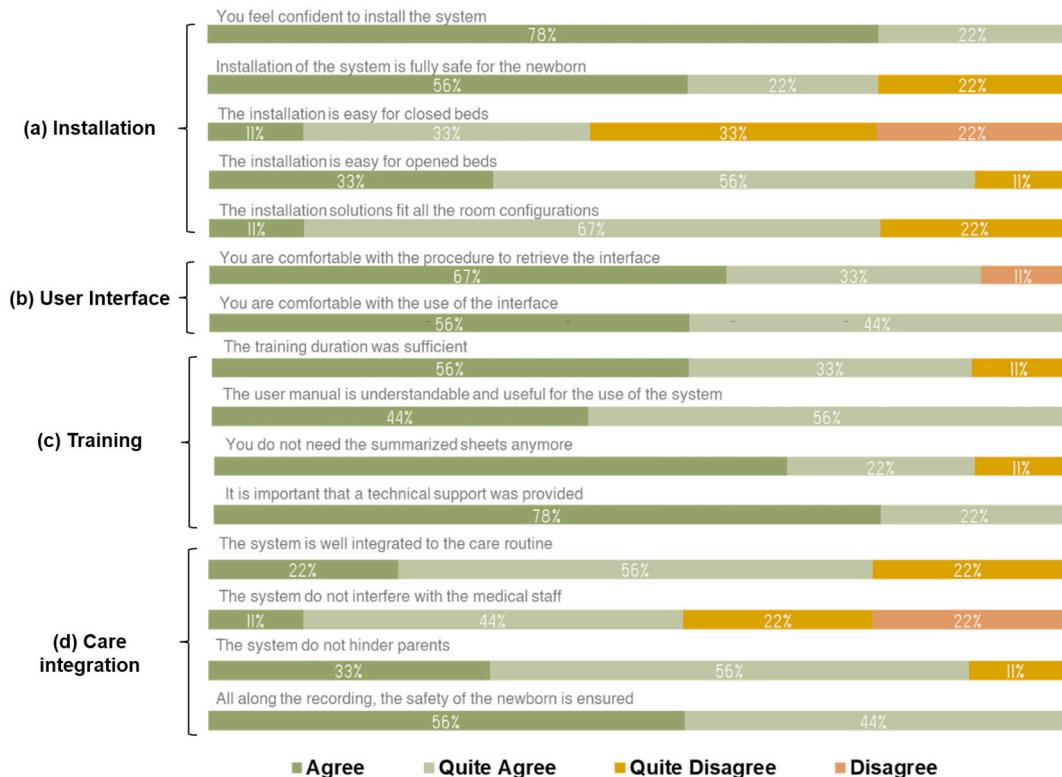


Fig. 4. Clinician feedback regarding installation (a), interface (b), training (c) and care integration (d) on a 4-level scale (Agree, Quite Agree, Quite Disagree and Disagree).

- To what extent do the clinicians' responses agree? Intraclass Correlation Coefficients (ICC) and 95% confident intervals were computed to measure consistency in the ratings of the survey. Since our survey was fully-crossed, a two-way mixed effect model was considered. Clinician was treated as a fixed effect. In our study, the mean ICC(3, k) is studied [30,31].
- Are the data qualitative percentages dependent on the hospital? Hospital distributions of the qualitative percentages (e.g., percentage of sole presence of the newborn) were compared using non-parametric and unpaired Kruskal-Wallis test [32]. The significance level was set at 0.05.
- Are the data qualitative percentages dependent on the age of the newborn? Pearson's correlations between postmenstrual age and qualitative percentages were also computed in order to discuss the influence of the newborn age on the quantity of usable data [33].

3. Results

In this section, results are provided from two angles. First, the evaluation of system integration is carried out using clinician feedback and the database that resulted from this work. Second, the quality of the collected data is analyzed.

3.1. Evaluation of the system integration

3.1.1. Clinician feedback

The survey was answered by nine clinicians with different profiles (five pediatric nurses, two research nurses, one nurse and one clinical research associate). For the purpose of brevity, a set of 15 main questions was extracted and collected answers are reported in Fig. 4. A good to excellent consistency between the raters' answers was obtained with an ICC(3, $k=9$) of 0.90 and a confidence interval of 0.80–0.96.

3.1.1.1. Installation. Clinicians reported that the installation of the system lasted between 15 and 30 min and was mostly achieved by one person. Then, collected answers (Fig. 4(a)) showed that all clinicians feel confident to install the system and mostly consider its installation as fully safe for the newborn. Installation on open-bed was evaluated positively by all clinicians except for one of them. Reversely, the installation reveals challenging on closed beds for 55% of the clinicians. They reported that it was mainly caused by the difficulty to orient the housings in incubators which is not encountered for open beds. However, clinicians mostly consider that the installation solutions fit all room configurations of their units.

3.1.1.2. User interface. The user interface is fully satisfactory since, as reported in Fig. 4(b), almost all clinicians are comfortable with the proposed use of the laptop to retrieve the interface. In addition, they are satisfied with the use of the interface (e.g., stream visualizations, start/stop a recording session).

3.1.1.3. Training. The training was also evaluated (Fig. 4(c)). Once again, the overall evaluation is positive. In fact, respondents mostly declare that the one-day training was sufficient to take control of the system and that the supplied user manual was understandable and useful. In fact, they globally do not need to refer it and to the summarized sheets anymore. In addition, the importance of providing a technical support all along the acquisition progress is underlined by all participants.

Table 1

Sepsis and maturation database details in terms of inclusion criteria, recording protocols and numbers. GA stands for Gestational Age in weeks (w), PRM for Premature Rupture of the Membranes.

	Inclusion criteria	Recording protocol	Nb	Tot
Sepsis	GA < 32 w	3 to 10 consecutive early days of life	273	
	26 < GA < 32 w and PRM	3 early days of life and 17 h every 10 days	113	428
	GA > 37 w and maternal risk factors [34]	6 h after the first 24 h of life	42	
	Extremely preterm (GA < 28 w)		100	
Maturation	Very preterm (28 ≤ GA < 32 w)		145	
	Late preterm (32 ≤ GA < 37 w)	Between 15 and 24 h every 10 days	104	416
	Early-term (37 ≤ GA < 39 w)		24	
	Full-term (GA > 39 w)		43	

3.1.1.4. Care integration. Finally, and undoubtedly the most important point for future considerations, integration of the system in the care routine was evaluated by participants. Answers are reported in Fig. 4(d) and show that 78% of clinicians think that the system, in its current form, is quite well integrated to the daily care routine. However, 44% of the clinicians raised concerns regarding the system interference with medical staff. Indeed, they reported that the system is cumbersome in case of sensitive medical gestures such as the setup of a central catheter, especially in closed beds. Reversely, the system did not hinder the parents and the safety of the newborns is ensured all along with recording sessions.

3.1.2. The resulting database

One goal of the Digi-NewB project was to construct an extensive database regarding two clinical targets: the evaluation of the sepsis risk in newborns and of the newborn neurobehavioral development. This study received ethics approval from the Ouest IV Ethics Committee (reference number 34/16) and one of the parents of each newborn gave its signed agreement to take part to the study. Afterwards, 19 acquisition devices were deployed in six French hospitals: 4 in Rennes in November 2016, 4 in Angers in April 2017, 3 in Nantes in June 2017, 3 in Brest in December 2017, 3 in Tours in December 2017 and 2 in Poitiers in December 2017. Hence, 594 newborns were included along the four years of the project. These inclusions are detailed in Table 1.

Regarding the sepsis objective, a total of 428 newborns were recorded. Among them, 58 newborns actually contracted an infection. Recording protocols depends on the sepsis population but was ranging from hours to days in the early days of life, sometimes followed by recording every 10 days. Long recordings have been scheduled to cover the entire period during which they are most likely to contract sepsis (i.e., in practice, mostly up to a few days after catheter removal).

For the maturation objective, a recording of at least 15 h every 10 days until the discharge was required. A group of 250 non-sepsis newborns of the infection protocol was included. It was supplemented by 166 newborns, given a total of 416 newborns. This population is distributed between five categories of GA: 100 extremely (under 28 weeks GA), 145 very (28 to 32 weeks GA) and 104 late preterm (32 to 37 weeks GA), 24 early term (37 to 39 weeks GA) and 43 full-term (above 39 weeks GA) newborns. Hence, the diversity in the populations led to a

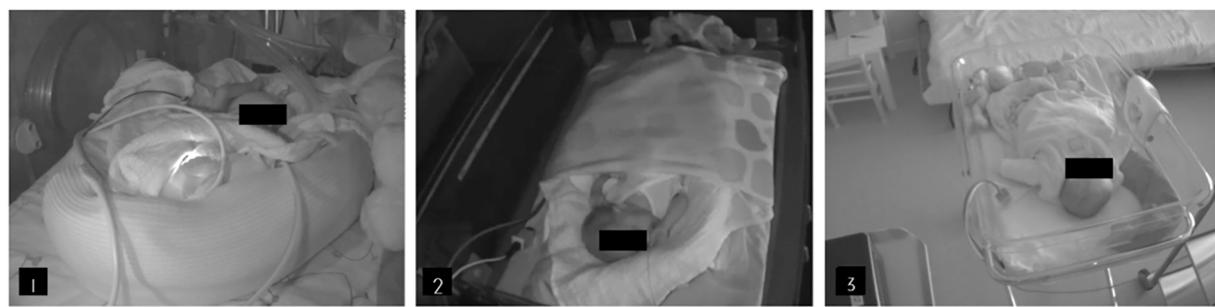


Fig. 5. Illustration of videos recorded for an incubator (1), a radiant warmer bed (2) and a cradle (3).

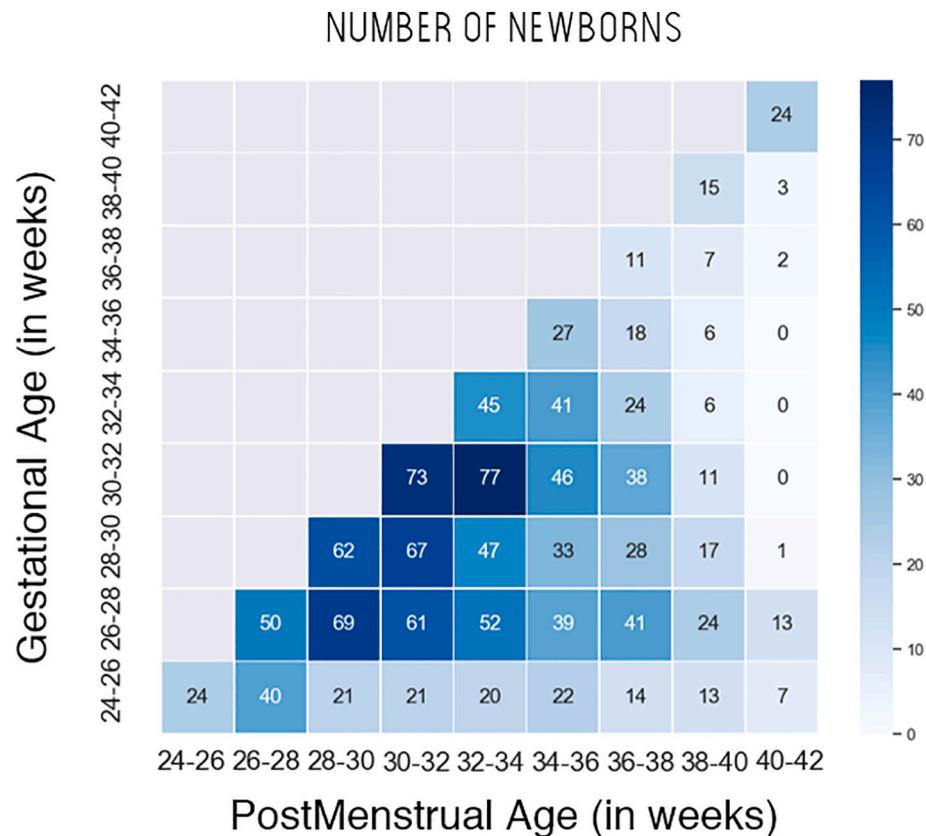


Fig. 6. Overview of the database contents by postmenstrual age (PMA) and gestational age (GA) in terms of number of babies.

large variety in the collected images, notably due to the multiplicity of bedding environments (Fig. 5). Neurological outcomes are not known yet but an Age & Stages Questionnaire is expected to be collected for each newborn in the coming years [35] (Fig. 5).

The whole database is composed of 2658 recording sessions with a total duration of 63,404 h (approximately 7 years). In Fig. 6, the database content in terms of number of newborns is represented within a 2-weeks granularity regarding postmenstrual and gestational ages. Hence, we can see that we succeeded to collect data at different stages of the hospitalization. In fact, a significant number of babies is obtained in each PMA/GA intervals, up to 77 for 32–34 weeks PMA/30–32 weeks GA with a median value of 24 babies. A few newborns were recorded

between 40 and 42 weeks PMA intervals since the discharge home usually occurred earlier. Recording sessions lasted between 1 and 413 h, with a median duration of 18 h. According to the inclusion protocols (Table 1), recordings were longer (up to hundreds of hours) in the early days of life of extremely and very premature newborns (due to the sepsis protocol) than for older newborns (about 20 h) mostly recorded for the maturation protocol. In addition to that, newborns have been recorded several times in relation to their evolving PMA. As a result, the median number of recordings per newborn regarding each category is, 6 for extremely preterm, 3 for very preterm, 2 for late preterm, 1 for early term and full-term newborns.

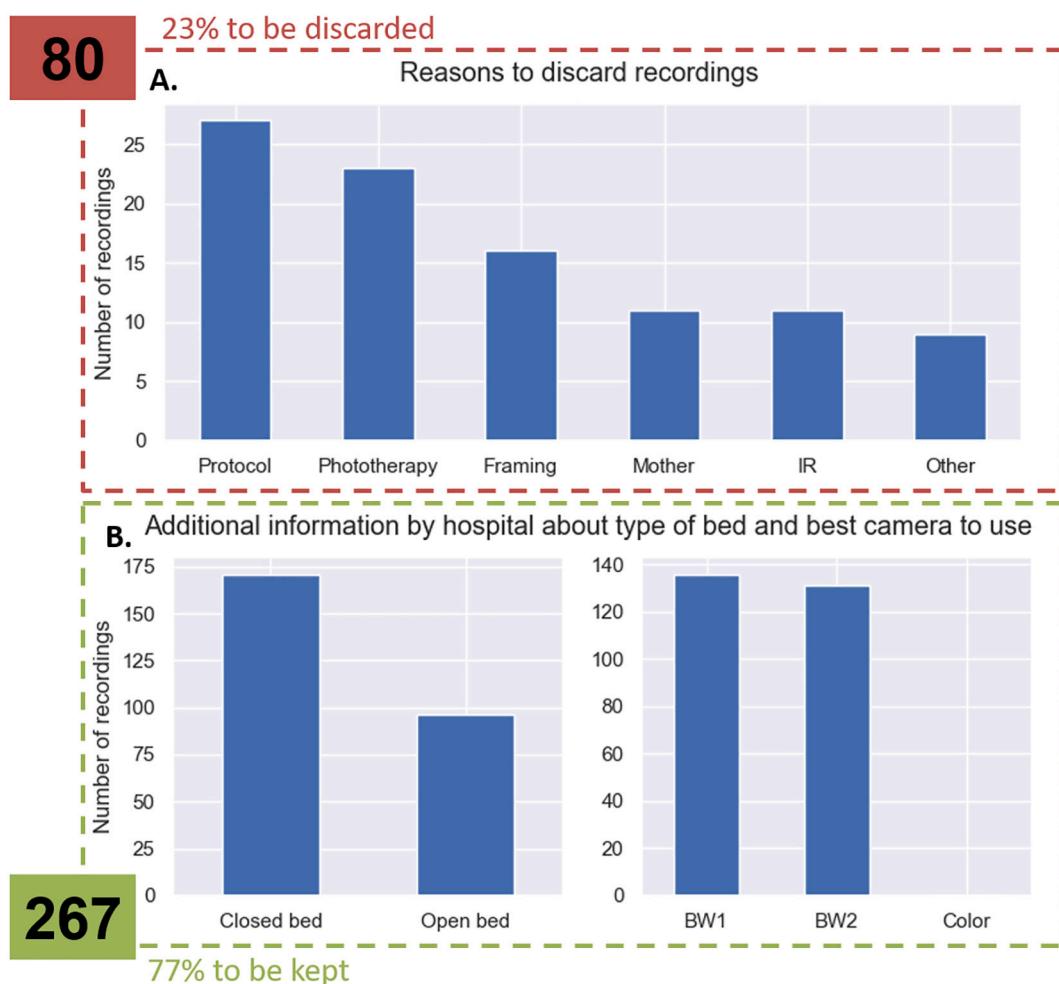


Fig. 7. Outcomes of the visual annotation of 347 recordings of extremely premature newborns.

3.2. Qualitative data analysis

In this section, different points highlighted by the experience of this work are reported. For that purpose, 347 recordings of 96 extremely premature newborns were visually inspected by one annotator using the tool described in Section 2.2.2. We chose to focus on this population since they go through all the room configurations. Results are presented in two steps. First, an overall data quality analysis was performed recording by recording. Then, the data quality within recordings is assessed.

3.2.1. Overall analysis

First, several malfunctions during acquisitions have been raised up by clinicians to the technical support. Further investigations conducted by the housing manufacturer revealed that the power supply showed weakness in a stressful environment such as in NICU. This resulted in unexpected stops of acquisition sessions. Although this problem was corrected, several recordings were impacted and data is missing regarding the inclusion objectives. Furthermore, some recordings were stopped by the medical staff during interventions and were not restarted.

Secondly, difficulties that were observed during data analysis are reported. Results are provided in Fig. 7. Among the 347 recordings, 77% revealed to be exploitable against 23% of non-exploitable data.

Regarding non-exploitable data (Fig. 7A.), the most impacting events are the non-respect of the protocol. In one hospital, the protocol regarding the positioning of the device for open beds was not followed i.e., the support was used instead of clamps. In this configuration, newborns were not entirely visible. We also observed that beds were sometimes moved and not replaced at the marked spots on the floor, leading to unusable recordings. Secondly, 23 recordings were not exploitable because of phototherapy that is used to treat babies which contracted jaundice. These sessions last a few hours and the induced flashing degrades the entire image. Then, bad framing of both housing was noticed in 16 recordings. At the fourth position comes equally dysfunctional IR illumination (11 recordings) due to device malfunctions or to elements placed in front of the camera cutting the lightening and mother sleeping in a bed next to the newborns' bed (11 recordings), constantly in the field of view due to the transparency of the cradle. The last point was only observed for older newborns and in three hospitals. To finish, some marginal situations (9 recordings) had been observed as for example in one hospital where they practice co-bedding for twin

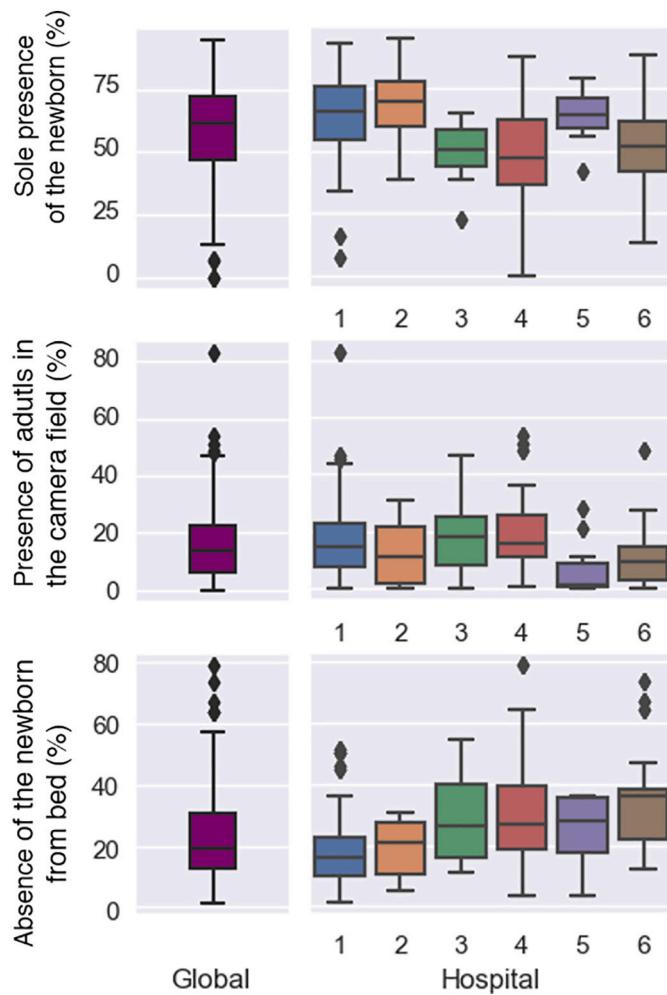


Fig. 8. Percentages of sole presence of newborns, presence of adults in the camera field and absence of newborns from bed globally (left) and in each hospital (right).

babies.

On the other hand, a larger amount of data remains exploitable (77%). Further annotations regarding recording to be kept are reported in Fig. 7B. Closed (171 recordings) and open (96 recordings) beds have both a non-negligible occurrence, it was therefore necessary to provide acquisition methods adapted to these two situations. Secondly, having two housings filming different points of view has been non-negligible to obtain quality images, i.e., the best images come from both BW1 (136 recordings) and BW2 (131 recordings) independently of each hospital. Reversely, color video recordings were not reliable all along sessions and thus were never selected.

3.2.2. In-depth analysis

Firstly, the 267 reliable recordings identified in the previous paragraph were automatically processed in order to retrieve percentages of sole presence of the newborn, of presence of adults in the camera field and of absence of the newborn from bed. At the end, a quite high percentage of the video data concerns periods sole presence of the newborns, i.e., a median percentage of 62% is obtained. Globally, the

resulting median percentage of unusable periods due to adult interventions is 33% where 14% are coming from presence of adults in the camera field and 19% are due to the absence of the newborn from the bed. In fact, babies experience a lot of manipulations either from medical staff or from parents. They are notably taken out bed over quite long periods for feeding or “skin-to-skin” with parents. Results are reported in regard to each hospital in Fig. 8 where different distributions are observed. These inter-hospitals differences have been confirmed by Kruskal-Wallis tests. Indeed, higher percentages of sole presence of the newborn are observed in hospitals 1, 2 and 5. Others have lower percentages due to higher percentages of adults in the camera field (hospitals 3 and 4) and higher percentages of absence of the newborn from bed (hospitals 3, 4 and 6).

To go further, correlations between PMA and the three above percentages were computed. It resulted in weak correlations between PMA and sole presence of the newborn (-0.11), and between PMA and absence of the newborn (-0.11) but in a slightly higher one between PMA and presence of adults in the camera field (0.35).

Other elements, difficult to quantify, have been identified. The first point is that babies are usually well covered, sometimes so much so that it is difficult to see the newborn under the blanket. We have also observed that they can be very congested by respiratory assistance equipment. Another difficulty may lie in pulse-oximetry, used to continuously measure blood oxygenation. It induces a flashing that impacts a part of the image. Some of these situations can impact video streams as well as audio recordings. On this subject, we also noticed that other babies can be recorded when they are in the same room, or even in a close one due to the high level of their cries. This difficulty is in addition to the many sources of noise already present in NICU such as alarms, adults voices, background noises coming from adults' activity (e.g., doors opening/closing, packaging friction, water flowing from the tap) as well as from devices (e.g., ventilatory support airflow, bed adjustment noises).

To finish, thermal images are also impacted by real conditions since beds can include heating by the mattress, especially in an incubator. Then, the resulting temperature is homogeneous in the major part of the image, making difficult to identify regions of interest. In addition, most of the time, the environment is very dark. This results into a very few periods of usability of the color video.

4. Discussion

In this paper, we proposed a new audio-video acquisition system, designed to fit a wide variety of NICU environments, i.e., several hospitals, several room configurations, from incubators to cradles. For this purpose, two types of mounting (support and clamps) have been proposed and guidelines regarding the system installation have been given. Additionally, we provided several supports (e.g., user manual, signage, training) to ensure security of the newborns and acceptance of the system by clinicians. As a consequence, a high number of newborns has been recorded during the past four years, in six French hospitals. For the first time, a large number of babies in each preterm category has been recorded at several PMA, resulting into a total of more than seven years of recordings.

With regard to clinician feedback, evaluation of the system regarding installation, user interface, training and care integration was globally very positive. Clinicians confirmed that the newborn safety is ensured all along the process. In fact, the main challenge, which was to propose a system that fits most of the NICU configurations, is quite successful although solutions to reduce the device size and the number of wires are

needed. For that purpose, once best clinical descriptors will be retained, the number of sensors may be significantly decreased.

A qualitative data analysis has been driven. Firstly, we estimated that 77% of the data is usable. Secondly, on reliable recordings, periods of sole presence of the newborn were quantified and represented more than 60% of the time. This study also highlighted that care habits are different from one hospital to another. These findings concern all types of recorded data (video, audio and thermal images) except for color camera since we have shown that its use was not reliable for continuous monitoring. To go further, the qualitative analysis of thermal images will have to be deepened by working on the recalibration of the data. However, it is also possible that the resolution of our thermal camera model was too low.

As we saw in the introduction, many studies have been proposed to evaluate the health condition of newborns using audio and video data [10]. However, none of them was applied to continuous and real-life data, limiting the clinical transfer of these methods. Our study revealed the highly restrictive acquisition environment of the NICUs and allows to identify several requirements that are reported in 8. Recently, a few systems have nevertheless been applied in NICUs [17,36,37]. For incubators, some authors proposed to mount camera on the top-wall [17,37]. There are several limitations to such a positioning. First of all, as we have mentioned, fog on the walls of the incubators can affect the quality of the video. Also, the wires connecting the camera to the local computer unit can hinder the opening of the incubators allowing the upper cover to be lifted and thus hinder the interventions of the carers, especially in case of reanimation. Similarly, we have observed that in order to provide a dark environment for the newborn, blankets can be placed on the incubators. If they are removed in the case of an emergency intervention, this could easily get caught in the system. Finally, the use of a trolley to support the camera for closed beds [17,37] or open beds [36], as when no bar or mast were available in our study, may be a burden for carers and parents as it limits the space available in rooms that are often already congested. The best solution to overcome these problems would be to integrate the cameras into the design of the beds.

Additionally, this work is the basis to enhance the robustness of algorithms to real context. In that sense, a few algorithms have been recently proposed to deal with these inescapable difficulties such as the automatic detection of periods of presence of adults in the camera field [38] or the baby absence situation for video recordings of toddlers performed at home [39]. Recently, deep learning approaches proposed to tackle both problems by identifying periods of sole presence of the baby in incubators either using color [17,40] or infrared BW [29] videos. Other points will have to be addressed such as the correction of the flashing induced by phototherapy or pulse-oximetry. Both events can impact video analyses and an automatic detection of these events will be necessary to move towards a fully automated solution for monitoring. In the meantime, the fact that babies are well covered with a blanket would also have to be taken into account in analyses. This has been partly addressed in [40] where authors proposed the automatic segmentation of the region of the newborn's skin through the use of a CNN network. About audio analyses, the automatic selection of cries among other sounds existing in NICU has been tackled (e.g., alarms, adult voices) [41,42], but it remains an open issue. Furthermore, once the cries are extracted, a classification of the cries would have to be performed to identify which baby produced them (in case of multiple beds in the room). Deep learning approaches seem appropriate and powerful enough to manage all these difficulties. The high variety of the collected data is well suited for pursuing this type of strategy. Indeed, processing methods must be developed by integrating the hospitals diversity (types

of beds, room environments, number of newborns in the same room, care organization...). Thus, multi-centric databases must be studied, especially for the implementation of machine learning techniques. In addition, robust strategies to manage missing data are needed, being aware that in some hospitals and/or some recordings less data may be available making more challenging to compare extracted clinical descriptors (e.g., number of neonatal seizures) between recordings.

Clinically, so far, the system was only used to collect data. Later, it may be integrated in daily care as a piece of monitoring equipment. In that sense, we already started a new project that aims to measure the impact of video monitoring on health care organization. A system integrating motion analysis will be studied and deployed in two NICUs. Video streams and motion series will be sent back constantly to the central monitoring room so that nurses have access to it. From there, individualized care routine may be provided so as not to disturb the newborn sleep. Broadly, the proposed system can be used in a large scope of clinical objectives such as the detection of epileptic seizures or the evaluation of other neural impairments (e.g., cerebral palsy). One could imagine integrate the Voxyvi system into video-EEG systems which are already being used in the framework of neonatal seizure analysis [18–20] in order to multiply the multimodal strength of the system. In the meantime, we are beginning to see the emergence of commercial products for video streaming of newborns either in NICU [43] or at home [44]. Although, in NICU, the system is only designed to allow parents to visualize their baby outside the hospital, at home the system includes wake/sleep analyses. Thus, we may also imagine an audio/video health monitoring including processing algorithms and whose images would be accessible to parents.

On the other hand, the use of audio and video recordings can raise ethical questions. Caregivers and parents perceive audio and video in care as useful and acceptable provided that measures are taken to ensure informed consent, data protection and to limit the negative impact for caregivers [45,46]. It is a shared observation with several studies that were conducted within the purpose to allow parents to visualize their baby outside the NICU [28,47–49]. Particularly, it was shown that it offers an important solution to periods of enforced parent-infant separation in the early post-natal period [49] and reduces family stress [47]. However, it can enhance caregivers stress and workload because of the constant oversight of parents [28,48]. Indeed, privacy, data protection and impact on caregivers should be considered for the acceptance of a new monitoring system integrating audio and video analyses in NICU.

5. Conclusion

In this paper, a study about audio-video monitoring in NICU was made. We proposed a new system as well as adaptive integration solutions validated in real conditions by clinicians in six hospital centres. We assessed the quality of the data obtained and drew up guidelines for future works, both for system design and for the automation of data analysis. Indeed, it is an inevitable step to direct efforts and thus to propose effective solutions to improve the care of newborns.

Availability of data and materials

In accordance with French policy, the data will be shared in a near future through the health-data-hub (<https://www.health-data-hub.fr/>) where it will be fully available and in respect of French regulation.

CRediT authorship contribution statement

S. Cabon: Conceptualization, Methodology, Software, Validation,

Formal analysis, Writing – original draft, Writing – review & editing. **F. Porée:** Conceptualization, Methodology, Writing – review & editing. **G. Cuffel:** Methodology, Software, Validation, Writing – original draft. **O. Rosec:** Conceptualization, Resources, Supervision. **F. Geslin:** Validation, Investigation. **P. Pladys:** Conceptualization, Methodology, Resources, Project administration, Funding acquisition. **A. Simon:** Conceptualization, Methodology, Writing – review & editing. **G. Carraud:** Conceptualization, Methodology, Writing – review & editing, Project administration, Funding acquisition.

Declaration of competing interest

We declare that we participated in the design, execution, and analysis of the paper by Cabon and colleagues entitled “Voxyvi: A system for

long-term audio and video acquisitions in neonatal intensive care units”, that we have seen and approved the final version and that it has neither been published nor submitted elsewhere. We also declare that we have no conflict of interest, other than any noted in the covering letter to the editor.

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Appendix A. Security tests

Risk	Test summary	Additional precaution
Tilting of the support in direction of the newborn.	Mechanically impossible.	None.
Tilting of the support outside the bed due to clinical intervention.	Only possible in the event of a very hectic resuscitation procedure, dangerousness for the material only.	Caregivers were warned not to pay attention to the system if immediate intervention was required. In case they did, they were taught how to remove it quickly.
Badly anchored housings on the support.	The cameras fall into the bed. The child's cocoon is placed much higher. The newborn can't be touched if distance is respected.	The safety distance between the camera and the bottom of the cocoon (>15cm) must be respected. Double clamping check.
Badly anchored housings on the clamps.	The security lanyard forces the camera to fall along the mast. It does not swing towards the newborn.	The safety distance between the camera and the newborn (>25cm) must be respected. Signage was installed on the housing.
Water infiltration in the housing due to high humidity rate in incubator.	Three full days of recording at humidity rate of 91% and temperature at 40°C showed no infiltration.	A security chip has been placed in both housing, it changes colour in case of infiltration. Regular verification requested.
Control of housing external temperature.	Three full days of recording at humidity rate of 91% and temperature at 40°C showed that the external temperature of the housings was stagnant at 43°C.	None.

Fig. A.9. Summary of the conducted security tests.

Appendix B. English version of the survey

Evaluation of the integration of Voxyvi in Neonatology services

- 1** In which hospital do you practice ?
- Rennes
 - Nantes
 - Poitiers
 - Brest
 - Angers
 - Tours
- 2** Are you currently employed as a pediatric nurse?
- Yes
 - No

- 3** Have you ever worked as a pediatric nurse in a neonatal unit before Digi-NewB?
- Yes
 - No

4 Mounting

	Agree	Quite agree	Quite disagree	Disagree
You are comfortable during the assembly of the system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The color-coded cable markings are useful when installing the system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The assembly of the system is safe for the newborn.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The system is easy to install for closed beds .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The system is easy to install for open beds .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The system's hanging solutions are adapted to the configurations you encounter in services.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cameras are easy to adjust for closed beds .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cameras are easy to adjust for open beds .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You are comfortable when removing the system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The disassembly of the system is done in complete safety for the newborn.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is useful to place marks on the ground to remind the positioning of the mobile elements.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Do you have any details to provide?

- 5** How long does it take you to install the system?
- Between 0 and 15 minutes
 - Between 15 and 30 minutes
 - Between 30 and 45 minutes
 - More than 45 minutes
- 6** How do you install it
- Unassisted.
 - With the help of your partner Digi-NewB.
 - With the help of the nurse in charge of the newborn.

Do you have any further details to add on these subjects?

7	Interface	Agree	Quite agree	Quite disagree	Disagree
		O	O	O	O
	You are comfortable with how to access the interface (from the laptop)	O	O	O	O

You are comfortable with the system interface (start a recording, switching between cameras...)

Do you have any details to provide?

8	Training	Agree	Quite agree	Quite disagree	Disagree
		O	O	O	O
	The duration of training in the use of the system was sufficient.	O	O	O	O
	The user manual is understandable and useful for the use of the device.	O	O	O	O
	You regularly refer to the user manual.	O	O	O	O
	You do not need the summarized sheets anymore.	O	O	O	O
	It is important that a technical support was provided.	O	O	O	O

Do you have any details to provide?

9	Integration into the medical routine	Agree	Quite agree	Quite disagree	Disagree
		O	O	O	O
	The system is well integrated to the care routine.	O	O	O	O
	The system do not interfere with the medical staff.	O	O	O	O
	The system do not hinder parents.	O	O	O	O
	All along the recording, the safety of the newborn is ensured	O	O	O	O
	In the case of an installation with a perfusion holder or a mobile bed, the signage allows others (parents, nursery nurses...) to respect the safety instructions never to place the camera above the newborn.	O	O	O	O

Do you have any details to provide?

10 Do you have any suggestions for improvement in the use or installation of the device?

- Yes
 - No
-

. (continued).

Appendix C. Requirements specifications

Requirements	Type	Description	Priority	Supplementary notes	Our solutions	Perspectives
ENR1	Environment	Recording data in a dark environment	MUST HAVE	To ensure a dark environment, a blanket can be placed over the incubator	Infrared cameras for video data Inside positioning for incubator	Better resolution, increase IR illumination, integration of the device in the bed design
ENR2	Environment	Recording data for a humidity rate up to 80% and temperature up to 40°C	MUST HAVE	Induces fog and water droplets on the walls of the incubator	Positioning inside, choice of robust electronic components, tests in real conditions	Integration of the device in the bed design
ENR3	Environment	Adaptability to bed brands	MUST HAVE	Incubators, radiant warmer, cradle, several sizes, neonatal incubator with bonnet opening upwards...	Two types of mountings adapted to open and closed beds	Integration of the device in the bed design
ENR4	Environment	Adaptability to the rooms	MUST HAVE	Small, wide, with multiple babies, clustered	Minimizing the device size, avoid adding a cumbersome new element by adapting to existing hanging solutions when possible	Integration of the device in the bed design
ENR5	Environment	Adaptability to the hospital	MUST HAVE		Exhaustive inventory of configurations, bed brands and clinical routine of six french hospitals	Increase the number of hospitals, carry out international studies
CR1	Clinical routine	Ensuring security	MUST HAVE	During several phases: visits, clinical intervention, cleaning, installing, recording and removing	Security lanyard, signage, training, careful positioning	Integration of the device in the bed design
CR2	Clinical routine	Not disturbing the care	MUST HAVE		Careful positioning, training	Integration of the system as a standard monitoring system such as electrophysiological monitor
CR3	Clinical routine	No impact on the health/development of the newborn	MUST HAVE	Non invasive, washable system, no additional noise	Non-invasive modalities, sterilization protocol, no sound emitted	Production of a system to medical standard
CR4	Clinical routine	Compliance with clinical standards	MUST HAVE		Validation of protocols by local clinical authorities: Hygiene department, Biomedical Engineering Department, Comité de Protection des Personnes (CPP)	Production of a system to medical standards, CE marking
CR5	Clinical routine	No increase of the complexity of clinician work	MUST HAVE	Heavy workload context	Training, limit the number of manipulations, user friendliness	Integration of the device in the bed design
ETR1	Ethical	Have the agreement of the parents	MUST HAVE		Comité de Protection des Personnes (CPP) validation, signing of an agreement	Production of a system to medical standards, CE marking
ETR2	Ethical	Have the agreement of clinicians	MUST HAVE		Confidentiality of the data	Ensuring the confidentiality of the data and protection of clinicians
ETR3	Ethical	Reduce the amount of data to be stored	SHOULD HAVE		Careful choice of recording codecs and formats	Designing online algorithms, not keeping the data after a certain period of time
DR1	Data analysis	Integrating analyses in the system	SHOULD HAVE	Shows the interest of such a device to clinician, provides additional elements for the monitoring of newborns	None in this study	Integration of motion analyses, cry analyses, respiratory analyses, cardiac analyses, neonatal seizure detection...
DR2	Data analysis	Robust to real conditions processing	SHOULD HAVE	Identify unreliable periods, take into account the difficulty of conditions: several babies in the same room, babies very covered, respiratory assistance...	None in this study	Adults detection, cry extraction, phototherapy detection...
DR3	Data analysis	Choice of relevant modalities	SHOULD HAVE		Color, microphone, B&W cameras, thermal camera	Identification of those that are not useful in order to reduce the system's dimensions
DR4	Data analysis	Propose a multimodal system	SHOULD HAVE	Take advantage of multimodal analyses, integrate several elements into a single system to limit space requirements	Design of a housing integrating several modalities	Coupling with EEG video systems, with web video systems for parents, with electrophysiological monitoring systems
DR5	Data analysis	Ensuring data quality	MUST HAVE		Positioning protocol, device orientation protocol	Designing a fixed device that does not need to be manipulated

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