

Introduction of the NRFit™ Standard for Regional Anesthesia and Algology at a Primary General University Hospital in Belgium: Practical Procedure for a Successful Step-by-Step Introduction

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Abstract

Whilst in modern medicine, the optimisation of treatment administration is based on knowledge not only of pharmacology but also of physiology, patient safety is no less important. ISO standards play a part in this, and as such, ISO 80369-6 (NRFit™ in practice) belongs to a family of standards whose primary aim is to drastically reduce the risk of mis-connection or mis-injection. However, the current uptake of this standard remains limited. The reason for this appears to be that the transition from Luer-type equipment to NRFit™ equipment can pose a problem for many of us. Consequently, driven by a desire to enhance patient safety, we have devised and implemented a structured plan for transitioning to the NRFit™ standard in our practices, taking a holistic approach. In doing so, we have taken into account not only regional anaesthesia but also pain management. Here, we describe the entire preparatory phase, the full methodology of our implementation (from the most theoretical to the most practical aspects), and finally the monitoring of the effectiveness of the standard's implementation. In this context, the main objective was the strictest and most comprehensive application of the NRFit™ standard, as recommended by ISO. At the same time, we had to take into account the specific conditions at our institution, which means that this report cannot be regarded as universally applicable. However, as we have endeavoured to be as comprehensive and informative as possible, our work may serve as a useful guide for those interested in this kind of implementation.

Keywords

Regional, Anaesthesia, NRFit™, ISO80369-6, Safety, Prevention

1. Introduction

Whilst concerns regarding safety in medicine—and more specifically in the day-to-day practice of anaesthesia—have become routine with corresponding guidelines [1]-[3], underpinned in particular by the systematic adherence to ISO standards (simplification, systematisation, standardisation, etc.), the prospect of considering a potential improvement through the implementation of a new standard may itself be a cause for concern. The family of ISO standards concerning the safety of the various categories of connections for the different types of patient access and administration routes aims to reduce, or even eliminate entirely, the risk of misconnection and misadministration of active ingredients at this stage, which could prove fatal to the patient (especially concerning acid tranexamic subarachnoid injection) or leave them with lasting effects or a significant degree of disability that drastically disrupts their life [4]. This was driven by the fact that, in anaesthesia, a medication error occurs in every 20 to 133 procedures, and that 14% of these are linked to an error in the route of administration [5]. Furthermore, the tendency to underreport cases remains significant. Moreover, this is now considered a serious issue, as a survey by the ISMP (Institute for Safe Medication Practices) reveals that 124 clinicians (47.5%) admit to having experienced at least one instance of misconnection; the most common being IV/enteral (39%), but IV/neuraxial comes in second place (22%). Furthermore, it is estimated that 79.1% of these incidents were unreported or their reporting status was inaccurate or unknown [6].

Because cases of misconnections leading to erroneous administrations are still regularly reported in the literature for over ten years [7]-[13] and even presented and discussed on the media [14], that ISO has been led to propose a solution involving the use of a family of non-Luer connections specifically dedicated to each system.

The implementation of this family of standards is now a reality [15] [16], particularly in the fields of urology (ISO 80369-4, green colour-coding for all connectors on all drainage catheters in all body cavities) and gastroenterology (ISO 80369-3, purple colour-coding not only for drainage catheters but also for enteral feeding tubes). Alongside these two standards, the ISO 80369-6 [17] or NRFit™ standard for the nervous system aims to implement, using the same methodology, on the one hand a specific yellow colour code for all connectors and other catheters, and on the other hand specific connectors with a specific design and diameter. The work on the NRFit™ connection aims to prevent the risk of confusion with Luer™ connectors (primarily mainly intravenous but also intramuscular and subcutaneous), whether of the “slip” type (simple cylindrical tube) or “lock” type (cylindrical tube with a screw thread), which represent the most frequent error in this context. Whilst the NRFit™ system has been tested and confirmed by simulation [18], it is recognised as a genuine improvement in risk management and error prevention, it is nevertheless reported that the transition could be complex, costly and significantly time-consuming [19].

Existing since 2016 [17], we think it would be interesting to try to outline the overall situation regarding the NRFit™ standard and its implementation in hospitals. To date, although there are recommendations and encouragement to adopt this safety standard, its uptake remains very patchy. Whilst in some countries, national professional societies—such as in the United Kingdom ([20], upgrade 2025), which pioneered the standard as early as 2016, and in France [17], Australia and New Zealand [21] between 2018 and 2022 - have taken the initiative to publish recommendations, the actual implementation is left to individual or institutional bodies themselves. It must be acknowledged that this approach results in highly variable uptake, the impact of which is impossible to quantify with any certainty. In this instance, we can only speak of a “centre effect” of which we have no real overall picture. Alternatively, the only country that has truly applied a comprehensive and systematic approach remains Japan, which enacted a law through its Ministry of Health as early as 2018 [22]. This legal obligation has required all healthcare institutions in the country (8000 healthcare centres of all sizes, affecting up to more than 100,000 patients in outpatient clinics annually) to phase out the Luer system from 2020 in favour of the NRFit™ system. This large-scale transition has been accompanied by the publication of a specialised checklist by the national PMDA [23]. The article by Yosokama [24] documents this shift in a tertiary-level hospital. However, experiences from larger institutions have not been published to date. This is what has encouraged us to share our experience today.

In that context, this article represents a single-centre quality-improvement or implementation report of our experience on the upgrading of RA and by extension Algo equipment to the NRFit™ standard in the Department of Anaesthesia, Intensive Care and Pain Management at our university hospital in Belgium.

Basically, we had considered both all-manual procedures (strictly manual operations without assistance) and all assisted procedures (whether using an electrical device). The structure of this article reflects this duality.

2. Methods

Erasme Hospital is a 980 beds academic hospital that performs a full range of surgical procedures, primarily on adult patients (10,000 surgical interventions a year, 25,000 to 30,000 hospitalisations a year and 350,000 to 400,000 consultations a year). Local and RA (+/-8500 cases a year including obstetric) and Algo management (+/-5000 cases a year) are practised in accordance with the most recent best practice guidelines [1]-[3]. It is precisely in this context that the implementation of the ISO NRFit™ standard was considered. Our respective preliminary annual consumptions of Luer system pieces are summarized in Appendix 1.

Alternatively, the following points formed part of the rationale behind the development of our NRFit™ implementation plan:

- Whilst the NRFit™ standard was originally designed for neuraxial procedures, we wanted to extend it to cover all procedures performed in RA (infiltrative and infiltrative techniques) and in pain management (neuraxial and periph-

eral) primarily driven by the argument that the risk of misinjection should be minimised as much as possible by incorporating procedures and equipment that were previously unavailable or not in use.

- To try to limit the number of suppliers (if possible, a single supplier), partly for practical reasons relating to discussions and the organisation of implementation, and partly for financial negotiation purposes regarding the optimisation and best possible adjustment of sales prices. Generally, this is made easier by having a single supplier, who is better placed to offer more substantial price adjustments if they cover a wider range of materials.
- Limit the additional costs incurred by changing RA and Algo equipment.
- Consider a single, comprehensive transition covering both RA and Algo for all sites within our institution.

2.1. Comprehensive Approach and Strategy

Based on the above, it must be said that the most important aspect of this type of procedure is careful and thorough preparation during the preliminary phase. The idea of introducing the NRFit™ standard does not arise suddenly but rather develops gradually as one reads various texts and consults other information. The secret to a successful implementation lies in the details and the thoroughness of the preparation phase. Our experience in this area can therefore be summarised in six steps, as set out in Table 1. In our project, we have opted for a single-phase roll-out (all sites on the same day) across all sites where RA and Algo. are used, to minimise the risk of confusion arising from some sites being equipped whilst others are not; particularly as the NRFit™ standard clearly recommends avoiding any coexistence between Luer and non-Luer standards. In our experience, drawing up the preliminary plan (Step 2, in Table 1) mainly involved mapping all the sites affected by the implementation, thereby enabling us to verify the volume of activities (Figure 1).

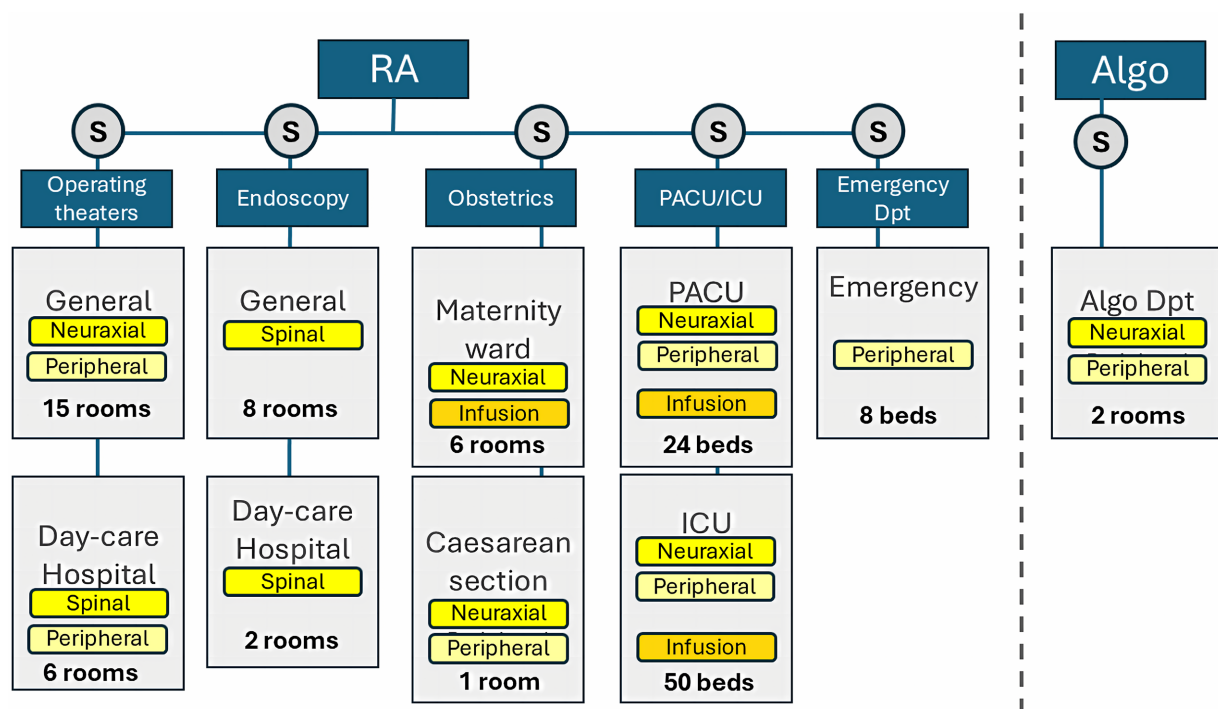
Table 1. Timeline of our NRFit™ experiences summarized at international level (in dark grey on the left), at national level in Belgium (in medium grey in the centre) and at local level within our institution (in light grey on the right). Our local plane follows 6 different steps (on right).

Time line	General-International	National (Belgium)	Local (6 steps)
Preliminary	2010		
	ISO 80369		
	“Small-bore connectors for liquids & gases in healthcare applications” first publication		
	https://www.iso.org/standard/82071.html (2025 upgrade)		
	2013	2013	
	First official ASRA & ESRA statements	National BeSARPP statements	

Continued

Step 1	2016 ISO 80369 “Small-bore connectors for liquids & gases in healthcare applications” official publication https://www.iso.org/standard/82071.html (2025 upgrade)	2016-2017 Informal discussions	2016 Step 1 Preliminary contacts and discussions-Establishment of a working group ¹
	2017 Official NRFit™ recommendations of use in California and UK		2017-2019 Step 2 Stuff planning & market review (general considerations) Preliminary plan ²
Step 2	2018 NRFit™ implementation law publication in Japan	2018-2026 Various scientific meetings and symposiums	2019-2021 Step 3 Stuff planning & market review (final industrial provider selection) Final plan agreements ³ Industrial contracts
	2019 Progressive & variable diffusion in Europe > North America		2021 Step 4 Information, support, training and guidance ⁴
Step 3	2020 Legal deadline for the implementation of NRFit in Japan		2022 Step 5 End of February “Go Live”
Step 4			2022-2026 Step 6 Post-implementation monitoring ⁵
Step 5			
Step 6			

¹To consider, as comprehensively as possible, any potential issues, the working group comprises an anaesthetist, a pharmacist, four nurses specialising in operating theatres and other technical areas, two dedicated administrative staff members, two members of the logistics department and a representative from the selected industrial supplier; ²The first draft of the re-equipment plan mainly involved identifying all the types of neuraxial and peripheral procedures we wished to include. For each of these, the various components were identified. This step took approximatively 6 months but on and off over a period of roughly two years. During this period, we tried to determine who has what, where, and in what volumes to define the potential local champions; ³The final, if not definitive, version of the re-equipment plan consists of a comprehensive and definitive review of all neuraxial and peripheral procedures, including the most accurate possible quantification of the items required to build up replacement stocks. Order fulfilment and stock management took us about six months to build up these stocks; ⁴The information and support provided during this two-months period consisted of six interactive sessions aimed at anaesthetists, nurses and support staff at all the relevant technical sites. These sessions were, first, theoretical presentation of safety aspects and concerns, and second, practical on site. They provided a comprehensive overview and served as an initial training exercise for these staff members; ⁵Monitoring involves recording instances of problems (difficulties in performing AR or Algo techniques), instances of equipment failure in the broadest sense, and, of course, instances of misconnection or misinjection. Monitoring involves tracking and conducting an annual review of the compilation of cases.



Note 1: in general, “Neuraxial” means, at list, epidural and spinal; Note 2: in general, “Spinal” refers to use restricted to the spinal block in the subarachnoid space; Note 3: in general, “Peripheral” refers to peripheral plexus and trunk nerve blocks (single shot and/or catheter); Note 4: Maternity ward, “Neuraxial” means epidural catheter with infusion and/or single shot spinal blocks; Note 5: in general, “Infusion” means continuous infusion with or without boluses using either electrical or mechanical elastomeric pumps adapted to NRFit™; Note 6: Caesarean section “Peripheral” corresponds to the various techniques at the trunk level with most TAP blocks; Note 7: Algo Dpt “Neuraxial” corresponds to epidural algological infiltration (single use); Note 8: combined Epidural/Spinal block is mainly performed in the general operating theatre, the caesarean section room, sometimes in the maternity ward; Note 9: at the top, “S” means “secondary stock” intermediate between the primary central stock and the respective trolleys. These secondary stocks are located within each respective theatre. Consequently, there are 10 secondary stock locations.

Figure 1. Summary of all sites included in the NRFit™ implementation process at our institution. There are 6 different departments corresponding to 10 distinct theatres.

2.2. Overview of Procedures, Analysis of Their Components and Validation Using Random Simulation

Based on the previous mapping (**Figure 1**), all RA and Algo procedures carried out have been reviewed to compile a list of older-generation Luer fittings (Appendix 2). We have matched these items with their equivalent NRFit™ items (Appendix 2). To this, we have added all the accessories required for the proper use of the NRFit™ system (Appendix 2). The next step involves listing all the items required for the successful performance of any type of procedure using the new equipment. Consequently, in accordance with the respective procedure, it will be necessary to compile between 4 and 12 items. Overall, the aim was to determine, firstly, as accurately as possible the scope of application of the new neural connector; secondly, the potential pitfalls that could lead to implementation failure; and finally, and perhaps most importantly, all the specific accessories required for the optimal use of the NRFit™. Finally, once all the lists of equipment required for each procedure had been drawn up, we validated them using randomised simulations: for each

procedure selected at random (using shareware R Randomizer™ via Google Play™ to generate a list of procedures to be tested each time) we used, three independent validators (potential users not directly involved in the project) were asked to review the lists. Each respective procedural list consisted of between 6 and 10 questions relating to the equipment. Each procedural list was validated once 100 per cent agreement had been achieved across all three validators. Each procedure was tested until this objective was met. In practice, the procedures had to be tested between one and four times. Then, when all three lists matched the original list, it was validated. In total, we carried out 87 random validations, with the same success rate for both neuraxial and peripheral techniques.

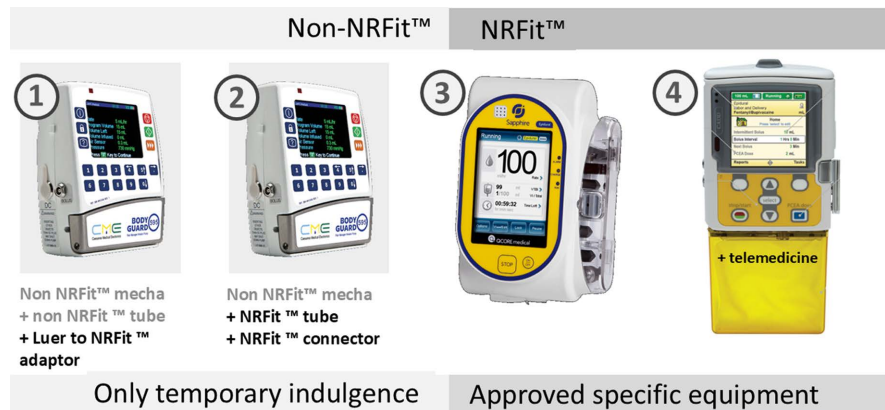
2.3. Stock Build-Up Planning and Preparation/Finalisation of the Implementation Procedure

Once all requirements had been compiled and validated (especially the volumes to be ordered), we were able to select a single supplier, as originally planned. Consequently, our institution was able to negotiate and sign contracts during 2021 (Step 3 in **Table 1**). During these discussions, particular emphasis was placed, on the one hand, on preventing stock-outs (notably the measures envisaged), and, on the other hand, on the lead times for building up the initial stocks on which the implementation process will rely. During this period, our institution's economic and financial department negotiated and signed the supply contracts. In theory, the list prices indicated that the cost associated with the NRFit™ equipment amounted, under our terms, to between 13% and 15%. Taking into account, on the one hand, our loyal partnership over several years and, on the other hand, the fact that our institution was the first in Belgium to take the plunge, our supplier decided not to apply the price increase that would normally have been expected. Thus, as part of a win-win agreement, our implementation was carried out at a constant cost. However, it should be noted that this arrangement is likely to remain exceptional and specific to our institution and our implementation conditions. This context cannot be regarded as standard. It is therefore important to note that the NRFit™ implementation and the associated security measures will incur a cost, the exact figure for which varies from one supplier to another but which, in Europe, appears to be of at least 10 per cent. There is no doubt that this cost of enhanced security will be a factor to be considered in the future decisions made on a centre-by-centre basis.

Once the contracts had been signed, the supplier we selected made a commitment and was able to guarantee that stock would be built up over a two-month period between late 2021 and early 2022. Thus, end of January 2022, the primary and secondary stocks were ready for implementation.

2.4. Infusion and Continuous Administration Systems

With regard to continuous infusion methods, with or without a bolus, three approaches can be considered:



For now, Given that we are currently in a phase of gradual roll-out, and taking into account the costs involved in purchasing new NRFit™-specific pumps, each institution is granted a grace period of unspecified duration (in practice, between one and three years). During this period, it is possible to use a standard, non-NRFit™ pump with a simple connector adapter (solution 1 on the left) at the end of the Luer line, allowing connection to NRFit™ devices. This is, of course, the least reliable option in terms of misinjection. The second option (solution 2) also uses the same type of pump, but beyond the drive roller, the tubing complies with the NRFit standard. The use of this type of device is not satisfactory in the long term. Furthermore, the NRFit™ options (on the right) use devices specifically developed with disposables that are fully compatible with varying levels of electronic features, either comparable to a non-NRFit™ pump (option 3) or incorporating functions such as networking and telemedicine (option 4). The cost of these devices ranges from €1500 to €4000 per pump.

Figure 2. Implementation of electronic pumps. From left to right, the most simple solution to the most expert option.

- The simplest involves using a 50 ml NRFit™ infusion syringe with suitable extension tubes (Appendix 2), utilising a non-specific electric syringe pump as the syringe body is compatible. This solution is generally used during the intraoperative period or, alternatively, in the early postoperative period on a temporary basis for a maximum of a few hours (PACU and ICU).
- The second, intermediate solution, involves the use of elastomeric pumps. In our experience, we have been able to replace our Luer fittings with NRFit™ fittings quite easily. We have even managed to simplify matters by reducing the number of items from two to one. This solution is intended for postoperative use for 24 - 48 hours, either during inpatient hospitalisation or in a day hospital with home care.
- The third option is the most sophisticated and offers the greatest potential: electronic infusion pumps (Figure 2). Whilst for the first two solutions the transition to NRFit™ remains straightforward, with many similarities to single-use items (Appendix 2), the changeover for this equipment is necessarily more complicated and takes longer, primarily due to financial and budgetary constraints. Indeed, the average cost in Europe for such a pump is in the region of €1500 to €4000, depending on the level of complexity and options (particularly telemedicine). Alternatively, there is a temporary workaround involving

adapting non-NRFit™ pumps to make them compatible (**Figure 2**). This involves using either a Luer-to-NRFit™ converter adaptor (the simplest temporary solution) or, a slightly more elaborate option, a semi-NRFit™ connector tubing (**Figure 2**). In this regard, the cost of temporary solutions for converting non-NRFit™ pumps ranges from €30 (front panel sticker) to €200 (replacement of just a few components). This category of equipment is used in post-operative care in the broadest sense (PACU, ICU and patient rooms) and in the maternity ward. In our case, we chose to rule out any interim or temporary solutions, again with the aim of genuinely trying to minimise the risk of incorrect injection or connection. This is our own reasoning and, for us, comes down to a matter of logistics or practical common sense, as the limited number of reported cases has not allowed us to use them as a guide.

To date, with regard to infusion and continuous administration systems, the decision on which option to choose (as mentioned above) can only be determined through discussion on a centre-by-centre basis, depending on local capabilities. Over time, as the number of implementations increases, it should be possible to issue well-reasoned recommendations, even if, ultimately, the use of specifically dedicated equipment remains mandatory.

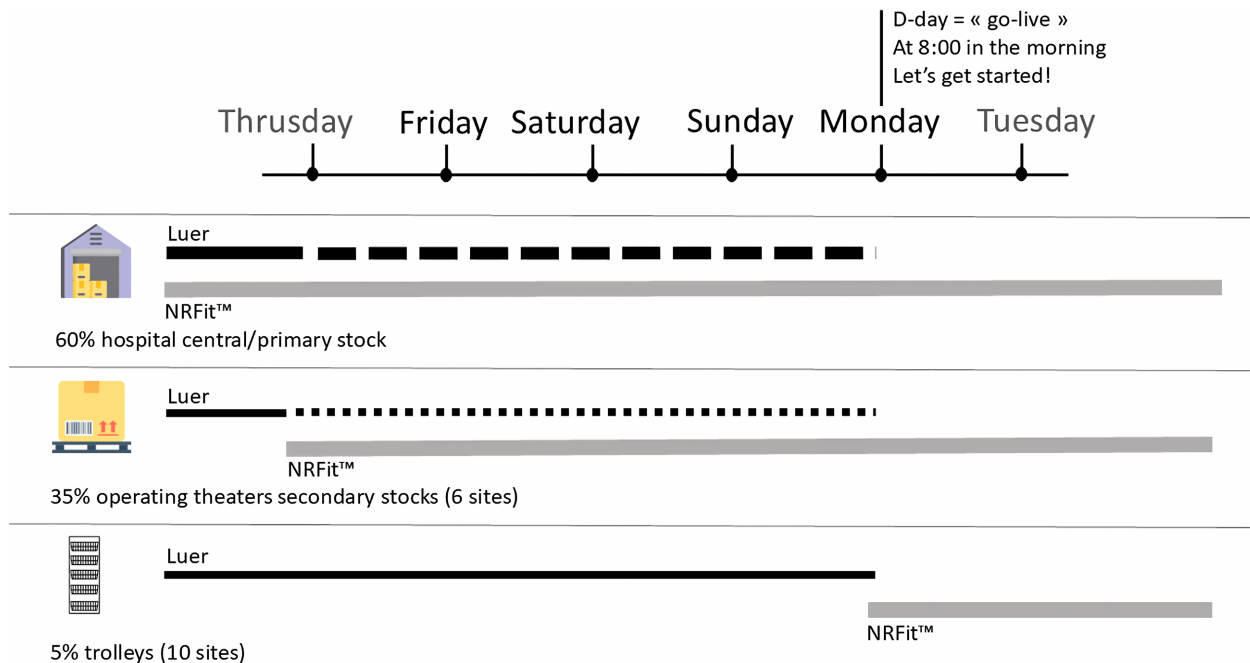
2.5. Information, Support, Training and Guidance

During the financial negotiation phase (Step 3 in **Table 1**), once the supplier had been selected, a series of information and training sessions were organised in collaboration with it (Step 4 in **Table 1**). First, two theoretical seminars (each lasting one hour) were held for members of the various departments concerned (**Figure 1**), followed by four interactive practical sessions aimed not only at doctors but also at paramedical and logistical staff at the various sites (**Figure 1**). During this second type of session, the staff's clear understanding of the new equipment, as well as their ability to interact smoothly without making mistakes (such as omitting steps when reviewing a particular procedure), helped to validate our shift preparations. From that point onwards, the implementation of the NRFit™ standard across all operations at our various sites (**Figure 1**) strictly adhered to all the implementation recommendations for the standard laid down by the ISO. This applies to the fundamental rule of maintaining absolute separation between NRFit™ equipment at all stages of the storage and usage process.

2.6. Go-Live/Implementation Day

After all the preparatory work (Steps 1 to 4 between 2016 and 2021 in **Table 1**), the decisive day arrives: the actual implementation (Step 5, go-live in **Table 1**). With stocks finally established in January 2022, the date was set for 28 February, when all members of the working group were available. In our experience, the roll-out took place over a weekend, from Friday to Monday morning at 8 am (**Figure 3**). The roll-out is based on the replacement of Luer with NRFit across all three stock levels (**Figure 3**). In advance, to manage our stock as effectively as possible,

it was decided to gradually reduce Luer orders over the last two months (January and February) so as not to exceed 20% of the usual stock level at the time of implementation, with the aim of optimising the investment. In addition, a series of equipment take-backs by suppliers were negotiated, again with the same aim in mind.



Our final implementation plan spans a weekend in the broadest sense, from Friday to Monday morning at 8 am (above). It essentially involves the time-based management of the various stock levels. The central or primary stock holds roughly two-thirds of the NRFit equipment (top). This stock has been built up over the last two months. This is where all deliveries have arrived, and from there the various items are distributed to the other stocks. The grey line represents the full NRFit central stock as it has stood for the past few weeks. It will remain this way based on automatic reorder points determined by consumption. At the same time, from Thursday evening onwards, Luer items are gradually being withdrawn until the go-live date, but not below the threshold of 15% of usual stock levels to avoid the risk of an untimely shortage that could compromise clinical activities (black dotted line). All returned Luer items will be concentrated here for subsequent return. Below this, the secondary stocks correspond to the first level of deployment of NRFit items. There are six of these, accounting for roughly one-third of the equipment in question. These local stocks enable items to be made available close to clinical practice sites. At this level, the procedure for removing Luer items is similar from Thursday evening onwards, adhering to the same threshold limit (black dotted line). Here, NRFit items (grey line) are only made available from Friday morning to prevent any uncontrolled use. Finally, at the bottom, the ten operational sites retain and use their Luer items throughout the weekend (where applicable) until Monday at 8 am. At this point, all Luer trolleys and carts (Appendix 3) at the 10 sites are systematically replaced with others containing NRFit items (of comparable composition). From this point onwards, the monitoring period begins.

Figure 3. Final implementation plan for the go-live.

The central stock holds approximately 60% of the equipment that has been gradually collected (Figure 3). From the Thursday before the weekend, Luer items are gradually withdrawn without falling below the threshold of 15% of the usual stock level to avoid any shortages. The recovery process will be finalised on Monday morning. All Luer equipment is concentrated at this level for return. From Thursday onwards, and even earlier, the NRFit™ central stock is operational and

enters the usual replenishment cycle based on consumption from Monday onwards. The secondary stocks (**Figure 3**) are located near each group of usage sites (**Figure 3**). There are six of them (**Figure 1**). These stocks are operational reserves and account for more or less 35% of NRFit™'s supply (**Figure 3**). At these stock locations, Luer equipment is gradually withdrawn from Thursday onwards in the same way as the central stock (**Figure 3**). It is at the secondary stock locations that the trolleys and carts (Appendix 3) used by the 10 respective sites (**Figure 1**) are concentrated over the weekend. To this end, we have converted our Luer regional anaesthesia carts to NRFit™ using specific stickers (Appendix 3).

On the day of implementation at 8 am (**Figure 3**), just before staff (who had been notified of the date in advance) arrived at the sites of use, the Luer trolleys were replaced by the NRFit™ trolleys (with the greatest possible similarity in storage layout, and specific prior training for logistics staff). Then the monitoring begins.

2.7. Post-Implementation Monitoring

From the moment of go-live, we felt it was important to monitor the roll-out of the NRFit implementation as a means of validating the entire process, as mentioned previously [24]. This monitoring (Step 6 in **Table 1**) takes place in two phases. The first involves monitoring the go-live itself, starting on the day itself and continuing over the following days. In our case, the working group decided that one week seemed reasonable. The second aspect consists of long-term monitoring over the following months. Based on our experience, we decided on annual monitoring. We therefore now have reports from 2022 to 2025, with 2026 currently in progress.

2.8. Short-Term Monitoring of the Implementation

This part of the monitoring involved tracking the implementation conditions during the first week, and in particular during the first two days following go-live. The aim was to identify and analyse any incidents that might hinder the smooth progress of the hardware roll-out, which could even lead to the process being halted and a return to Luer hardware being required, as several teams have experienced in recent years. The working group therefore monitored the activities to ensure, on the one hand, the smooth operation of the entire supply chain from the central stock to local stocks at the respective sites, and, on the other hand, the implementation of AR and Algo techniques under optimal conditions with the NRFit equipment during these crucial days. The summary is therefore as follows:

- Forty-six anaesthetists, 68 nurses, 14 midwives, 15 logistics officers, 8 technical assistants, 28 warehouse staff and 1 administrative staff member took part on the first day and during the first week. During this period, the working group had to respond to 9 calls and 4 on-site requests on the first day, and ultimately to 20 calls and 7 requests during the first week.
- The respective activities are summarised in **Table 2**.

- There was only one minor incident: the initial supply of 2 ml syringes was insufficient. The shortfall was immediately made up from the central stock.

Table 2. Short-term monitoring after the go-live. The number of respective techniques carried out on the first day and during the first week without any major incidents or bottlenecks of any kind that might have caused the implementation process to fail.

RA & Algo Procedures	First day	First week
• Neuraxial epidural	12	75
• Neuraxial spinal	12	81
• Neuraxial combined Epid-Spin	1	2
• Neuraxial continuous spinal	2	4
• Peripheral blocks	22	87
• Algo	16	76
TOTAL	65	325

2.9. Long-Term Annual Monitoring

In the longer term, based on annual monitoring from March 2022 to the present day, covering more than 30,000 cases involving AR and AI technologies, no instances of misconnection or misinjection have been recorded. Furthermore, apart from stock-out incidents (one or three per year, mainly concerning accessories) for which we are not responsible (the supplier was responsible and managed to find a suitable solution each time), no NRFitTM-related hardware failures have been reported, apart from a problem with an epidural catheter connector, which is unrelated to the NRFitTM standard. However, this finding must be qualified by the fact that we did not have a systematic system for recording AR and Algo incidents, as is often the case, [4] making it difficult to compare the situation before and after implementation.

3. Conclusions and Perspectives

Of course, safety in our day-to-day practices is essential, and in this respect the ISO 80369-6 standard has a vital role to play. However, it must be acknowledged that the implementation of this standard has not yet been sufficiently widespread. We are still a long way from universal adoption.

Whilst the NRFit implementation project of a certain scale (10 different sites using new-generation equipment) at our university, reported here, can be considered a success, this was only possible under certain conditions that are worth noting.

Firstly, only a detailed plan structured in advance with the collaboration of a multidisciplinary working group can lead to success in this area. In our case, this plan comprises six clearly defined steps (Table 1). In this regard, foresight is the

key element throughout the implementation of the plan. Furthermore, constant communication between the members of the task force is another key element. Finally, the six-step plan seemed to us to be a good compromise, avoiding excessive complexity whilst not being overly simplistic.

Over the period from 2016 to 2022, the task force did not, of course, work on the project full-time. It is nevertheless possible to estimate, even roughly, that we worked on it for between 10 and 15% of the period in question, representing approximately one year. In this respect, the implementation procedure is time-consuming [19]. As time is money, this procedure must be considered to have a significant cost [19], even though, under our circumstances, we avoided the additional cost normally incurred by new hardware. It is in this sense that we can say that security, despite everything, comes at a certain cost.

Choosing a single supplier simplified the task for us during the relevant stages (Table 1), even though this is not a mandatory requirement.

The recommendation that Luer and NrFit standards should never coexist reinforced our belief in a single, coordinated go-live on the same day across all ten of our sites, which proved successful but was dependent on extremely meticulous planning. Preliminary simulations are recommended.

Finally, short-term and long-term monitoring serve very different purposes, but they enable us to validate the implementation and all the work carried out. In this respect, centres that have taken the plunge should assist those planning this type of migration.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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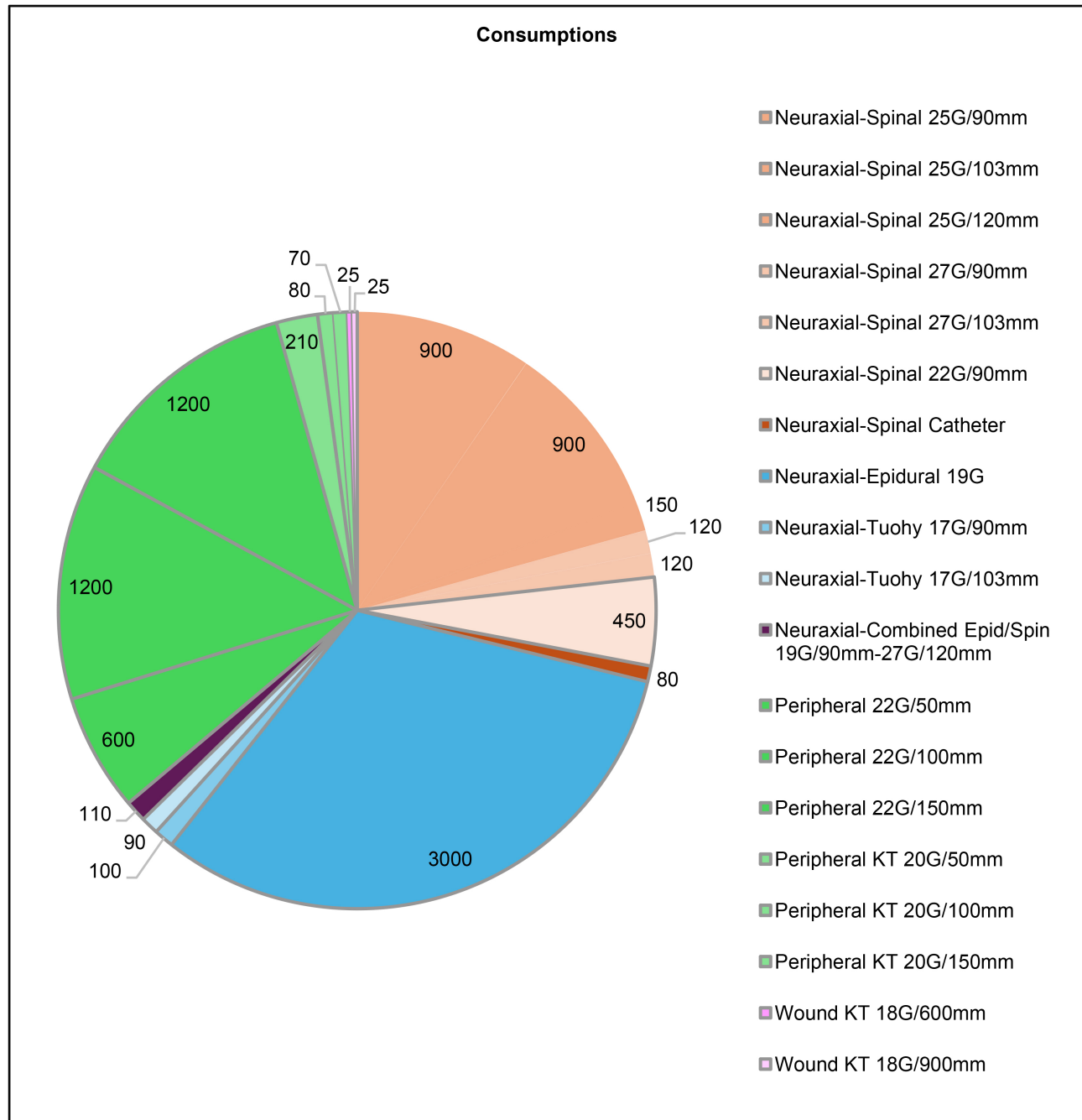
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Appendix & Online Supplementary Files

Appendix 1

Respective annual consumptions of “Neuraxial-Spinal” (shades of orange), “Neuraxial Epidural” (shades of blue), “Neuraxial Combined Epidural/Spinal” (purple) “Peripheral” (shades of green) and “Wound” (shades of pink). The figures given under the five headings are based on the hospital pharmacy’s annual orders. They are primarily indicative. We have considered a possible variation of approximately 10% either way.



Appendix 2

The most comprehensive list possible of the new equipment (on right) that will replace the old (on left). “**N**” indicates new equipment not included in the Luer version. Whilst there is near-total equivalence in most cases, we have had to expand the range of our new equipment, particularly about accessories.

Luer™ System	NRFit™ System
Neuraxial Epidural	
Tuohy needle 19G 90 mm/catheter 20G/filter 0.2 µm	Tuohy needle 20G 90 mm/catheter 21G/filter 0.2 µm
	Epidural blood patch set ¹ N
Neuraxial Spinal	
Sprotte needle 25G 90 mm/103 mm/120 mm	Sprotte needle 25G 90 mm/103 mm/120 mm
Sprotte needle 27G 90 mm/103 mm/120 mm	Sprotte needle 27G 90 mm/103 mm/120 mm
Sprotte needle 22G 90 mm/150 mm	Sprotte needle 22G 90 mm ²
Sprotte needle 21G 90 mm/catheter 23G	Sprotte needle 21G 90 mm/catheter 23G
Neuraxial combined epidural/spinal	
Tuohy needle 19G 90 mm/Sprotte needle 27G 110 mm/ catheter 20G/filter 0.2 µm	Tuohy needle 20G 90mm/Sprotte needle 27G 120 mm/ catheter 21G/filter 0.2 µm ³ N
Peripheral ⁴	
Short bevel needle 21G 50 mm/70 mm/100 mm/120 mm	Short bevel needle 22G 50 mm/80 mm/100 mm ⁵
Short bevel needle 19G 50 mm/100 mm/150 mm/ non-stimulating catheter 22G	Short bevel needle 20G 50 mm/100 mm/150 mm/ non-stimulating catheter 22G
Set wound infiltration catheter needle 19G/catheter 600 mm/900 mm	Set wound infiltration catheter needle 19G/catheter 600 mm/900 mm
Accessories	
Epidural Tuohy needle 17G 90 mm/120 mm	Epidural Tuohy needle 17G 90 mm/120 mm
Epidural catheter 20G/filter 0.2 µm	Epidural catheter 21G/filter 0.2 µm
Injection pressure regulator	Injection pressure regulator
	Large bore filtrating needle (aspiration) N
	Syringes (1 ml/3 ml/5 ml/10 ml/20 ml) N
	Catheter clamping adaptor N
	Filter 0.2 µm + fixation N
	Male/female cap N

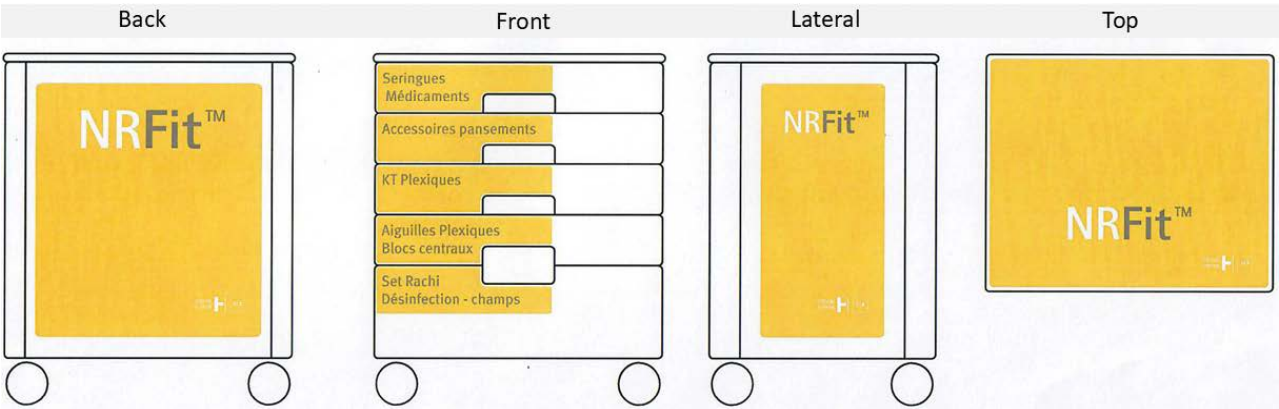
Continued

Infusion	
Elastomeric pump 250 ml/5 ml·h ⁻¹	Adaptative elastomeric pump 350 ml/flexible flow rate
Elastomeric pump 500 ml/10 ml·h ⁻¹	3 ml·h ⁻¹ /5 ml·h ⁻¹ /8 ml·h ⁻¹
Syringe VPC 50 ml	Syringe VPC 50 ml
Syringe VPC extension tube 100 cm	Syringe VPC extension tube 120 cm
Tubing set for electronic pump (spike connector + anti-siphon valve)	Tubing set for electronic pump (spike connector + anti-siphon valve)

Note 1: Until then, we did not have a full set (including the fields and all the accessories). The NRFit™ implementation gave us the opportunity to introduce this type of equipment; Note 2: No long needles in this category could be found; Note 3: Whilst the two sets of sequential anaesthesia equipment are comparable (particularly the docking device system), this is a new item from the selected sole supplier; Note 4: About regional anaesthesia and peripheral anaesthesia, this section covers plexus and nervous trunk techniques for the limbs and the trunk, as well as wound infiltrative techniques; Note 5: As regards the short-bevel needles, it has not been possible to source the same lengths (due to a change of supplier). From a practical point of view, we have reduced the number of needle lengths from four to three (short, medium, long).

Appendix 3

As part of the roll-out of the new NRFit equipment, we are refurbishing our trolleys specifically designed for AR use by applying stickers to all sides to bring them into line with the new standard.



Appendix 4

Key learning points:

- Mis-injection of systemic drugs in regional anaesthesia, especially neuraxial, this may lead to serious and permanent consequences, such as permanent damage or even the patient's death.
- Although every anaesthetist must remain vigilant regarding the medicines they use, the development of a specific connectors approach makes it possible to distinguish local and regional anaesthesia techniques from systemic general anaesthesia.
- The ISO 80369-6 standard, known as NRFit™, has promoted the development

and use of a specific connector system that is radically different from Luer and Luer-Lock connectors, as well as the yellow colour-coding system.

- To minimise the risk of incorrect administration as much as possible, the ISO 80369-6 standard, known as NRFit™, requires the strict separation of equipment (trolleys, trays, disposables, etc.) between regional anaesthesia and systemic anaesthesia (intravenous, subcutaneous, intramuscular, inhalation, etc.).
- Originally developed for central regional anaesthesia (spinal, epidural, combined, etc.), the ISO 80369-6 standard (NRFit™) can be extended to cover all regional anaesthesia techniques (peripheral plexus and nerve block, infiltration, etc.). That has been at the heart of our approach.

Key points:

Question: What methodology should be defined in advance and then applied in order to ensure the optimal implementation and global deployment (single-shot and continuous techniques; neuraxial and peripheral) of NRFit™ devices in a multi-sites academic hospital?

Finding: The formation of a multidisciplinary team (doctors, nurses, pharmacists, logistics staff, administrative staff, etc.) enabled a preliminary analysis to be carried out on a procedure-by-procedure basis. This made it possible to determine our institution's actual needs with precision. On this basis, a series of equipment replacements (two third) as well as the introduction of new equipment were planned for all sites of use. Subsequently, a series of randomised simulations were carried out to test our plans. These simulations proved satisfactory. Finally, a three-part plan enabled the deployment of NRFit™ equipment whilst avoiding any potential failures.

Meaning: A process of switching all Luer or Luer-Lock regional anaesthesia equipment to NRFit™ equipment is entirely feasible but only following a careful and thorough analysis of existing local conditions to minimise the risk of failure the day of the shift.

List of Abbreviations

Algo	Algology
ASRA	American Society of Regional Anesthesia
BeSARPP	Belgian Society of Anesthesiology, Resuscitation, Perioperative Medicine and Pain Management
ESRA	European Society of Regional Anesthesia
ISO	International Organization of Standardization
NRFit™	International Organization of Standardization ISO 80369-6 norm
PMDA	Pharmaceuticals and Medical Devices Agency
RA	Regional Anaesthesia
TAP	Transverse Abdominis Plane