FINCCHTA
Finnish Coordinating Center for Health Technology Assessment

UNIVERSITY OF OULU

Digi-HTA Assessment

Monidor solution for the implementation of intravenous fluid therapy

PRODUCT INFORMATION
The Monidor solution consists of a Monidrop® W infusion meter and an IV Screen™ remote monitoring application. The Monidrop® W infusion meter helps the nurse to set the rate of IV drip more easily and accurately than the traditional way. With the IV Screen™ remote monitoring application, the treatment can be checked remotely. Platform: ☒ Android ☐ IOS ☒ MS Windows ☒ Browser ☐ Other Language: ☒ Finnish ☒ Swedish ☒ English ☐ Other Certificates: ☒ CE-marked ☒ Medical device, level Im MDD ☐ US FDA Information security management system: ☐ ISO 27001 ☐ ISO 27701 ☐ Other Quality management system: ☒ ISO 13485 ☐ Other Manufacturer/Distribution: Monidor Oy https://monidor.com/

RECOMMENDATION 26.6.2022
 THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT The product is suitable for monitoring the implementation of intravenous fluid therapy and enables its remote monitoring. The product facilitates the work of nursing staff and its use can prevent complications of intravenous fluid therapy. The recommendation is based on the information provided by the manufacturer.

SUBAREAS OF ASSESSMENT		
Subarea	**Assessment**	Points
Effectiveness	**Promising, but more evidence is needed** A University of Applied Sciences final thesis study has been conducted on the product, and various organisations have carried out pilot monitoring studies during the commissioning of the solution.[1,2,3,4,5,6] In a health economics study, the nursing staff using the product (216 nurses, from 6 hospitals, 15 wards) assessed its effects on routine room visits, the time spent using the product, and its effectiveness in the prevention of complications. 56.3 % of the nursing staff estimate that the product will save employee time. The product reduced routine room visits, saved approximately 5 minutes per shift for healthcare staff, and made it easier to notice when the infusion fluid was coming to an end. The financial evaluation showed that the product recouped itself 2.6 times over.[2] The final thesis study followed the commissioning of the product on two wards in TYKS (Turku University Hospital). The thesis evaluated the benefits of the product through electronic feedback surveys (for every shift) and interviews with staff. The employees assessed that using the product saved them time in the monitoring of intravenous fluid treatment. The employees estimate that the product (drip counter and remote monitoring application) is easy to use. The staff estimated that during commissioning, the product helped to implement fluid therapy and detect abnormalities (incorrect drip rate or cannula blockage). With regard to the thesis, it should be noted that all evaluations were subjective assessments by the staff and no objective measurements were made.[3] **Pilots** In the pilots, the nursing staff have evaluated the use of the product in their normal operations. Based on the pilot studies, the product facilitates the monitoring of IV infusions (drip rate and amount of fluid administered), reduces visits to patient rooms, and	

	reduces adverse events. The reduction of adverse events is a positive thing for all parties. With remote monitoring, changes in drip rate were noticed faster (e.g. clogging of cannula, or significant changes in drip rate). In particular, the staff considered the possibility of remote monitoring as a good option after they had learned to use it.[1,4,5] The nursing staff's assessment of time savings varied widely between organisations and even wards. One reason for this may be the difficulty in estimating time savings, another the differences between wards. Wards with a large number of patients in isolation have benefited more from remote monitoring. In the pilots, the time savings were assessed during a one-week period. Although the product saves time for nursing staff, this time saving accrue from small savings of just minutes per shift and do not allow for staff reductions, for example.[4,5,6] In the organisations that have tracked adverse effects reports during the pilots, there have been no adverse effects notifications about the product.[1] **Literature review** The aim of the literature review was to find similar products and research on them. A similar type of product that would monitor the drip rate and allow remote monitoring was not found in the literature review. In general, it can be said that the implementation of fluid therapy is one of the key actions of nursing. In the implementation of fluid therapy, errors can occur at several points, and they may cause harm to the patient. Various studies have highlighted that the setting of the desired drop rate and remaining at that level is one of the most common points for error.[7,8,9]	
Safety	**Sufficient** The company has processes in place to ensure the safety of its product and to remedy the safety risks encountered during use[1]. The company has a risk management system in accordance with ISO 14971:2012[1]. No adverse events related to the use of the product have been reported either during clinical testing or during use[1].	

	The risk analysis of the product is comprehensive[10]. The product meets the safety standards for medical devices (EN 60601-1)[1,11] The use of the product requires a WiFi connection in the organisation[1]. In situations where the WiFi connection is lost, the Monidrop® W infusion meter will normally measure the infusion and The IV Screen™ remote monitoring application receives a connection error message[1]. When the WiFi connection is established, the status of the service will return to normal[1]. The user organisation should note that Monidrop does not adjust the infusion rate[1,11]. The V track controller can be opened completely, against instructions, in which case the patient receives too much hydration[1]. In these situations, the Monidor solution reduces the negative effects associated with incorrect use of the V track controller by displaying the drip rate and by reporting the drip rate deviation both visually and with sound messages.[1]	
Costs	**Reasonable** The product has a monthly price according to the contract, the amount of which is determined by the number of devices purchased for use. The monthly price includes equipment, maintenance, remote monitoring application and system updates.[1] User training is included in the monthly price of the product.[1] On the basis of the information provided by the manufacturer, it appears that the cost of using the product is reasonable in relation to the benefits to the organisation.[1]	
Data security and data protection	The assessment was carried out using the list of data security and data protection requirements for social welfare and health care procurement and the response material provided by Monidor Oy. **Sufficient** The service meets the most essential requirements. **Risk management and information security testing** Risk management is carried out regularly in conjunction with changes in accordance with the AAMI TIR57 standard. Data security requirements have been integrated into the testing	

process. In addition, third-party software data security scanning has been included as part of the maintenance process.

Log management

The manufacturer utilizes the solutions offered by the cloud service provider to collect and manage logs.

User management

The users' access rights can be restricted. The service supports the federation of identity in Active Directory* at no additional cost. (* Supports two-step authentication)

Equipment

Monidrop devices use WPA2-PSK secure WiFi network. The security of the network for devices is the responsibility of the customer's IT administration and the IT administration should pay attention to the security of the WiFi network used by the device.

Device updates are downloaded over an unencrypted HTTP connection, but the updates are signed and authenticated before the actual update.

The devices are not automatically updated, but the IT administration has the option to update the devices centrally according to their update policies.

The devices are strengthened against physical tampering by removing excess connections and debugging features.

Data protection

Monidor Oy acts as the data processor. The customer acts as a data controller. As a result, the customer organisation owns the register data. The system collects as little personal data as possible to enable it to operate in accordance with the principle of minimizing data collection. The data stored in the cloud service will be kept encrypted in the European Economic Area.

It is the responsibility of the controller to prepare a data protection impact assessment. Monidor assists its clients in this process.

	Other considerations This assessment applies to the cloud service. The service can also be delivered as an on-premise installation. In the on-premise operating model, the client should also take into account the on-premise installation requirements for their organisation. During the purchase phase it is important to always get in touch with the IT management, data security specialist and data protection specialist of your own organisation. Please discuss with them whether this product fulfils your requirements. In addition we recommend that health care districts utilise the European Union Agency for Cybersecurity (ENISA) data security manual for purchases[13]	
Usability and accessibility	**Sufficient** According to the manufacturer's declaration, the product is designed for anyone qualified to work as a healthcare professional in IV therapy[1]. The product has been tested with real user groups and based on their feedback, the product has been further developed[1]. The text content of the product takes into account the professional vocabulary used by healthcare professionals[1]. The company has a process that takes into account customer feedback as part of the continuous development of usability and accessibility[1]. The design of the Monidrop® W infusion meter conforms to the EN standard 62366:2008: Medical devices — Application of usability engineering to medical devices[1]. The company has itself assessed the accessibility of the IV Screen ™ remote monitoring application and it partially meets the WCAG 2.1 Level A and AA requirements[14]. Accessibility gaps are described in the Accessibility Statement[14]. There is an electronic feedback channel for customer feedback and the company will respond to the feedback within 14 days. **General instructions for purchases** The purchasing organisation must take into account the accessibility requirements laid out for digital services and keep in	

	mind that fulfilling the requirements is the responsibility of the service provider[15,16,17]
Other things to consider when using the product	The IV Screen™ remote monitoring application is available on Microsoft Windows and Android platforms[1]. The Monidrop® W infusion meter is battery-powered, battery life approx. 50 hours, charging time 2 hours. It is possible to charge the product during use. **Interoperatibility** The product supports the HL7 FHIR interface[1]. **Technical functionality** The company uses the software lifecycle standard IEC 62304[1] for medical devices software. Product-related error messages are reported either by phone or e-mail to the company[1]. The customer who reports an error, will receive information about the way the error is corrected. According to the company, the product has not been out of use or operating insufficiently due to a failure during the past six months[1]. End users are informed of updates of the IV Screen™ cloud service by email and the updates will be implemented without interruptions that have not occurred so far[1]. The user organisation will not be charged for the updates[1]. **Training and technical support** User training is included in the monthly payment[1]. The training is organised in Finnish or English[1]. To support commissioning, the the company has published a short 2.5-minute user manual video and PDF instructions with pictures based on the video[1]. Customer support phone works on weekdays from 8am to 4pm and email outside office hours[1]. **Distribution** The product is used in a total of 50 wards in approximately 20 hospitals or health centres in Finland[1].
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REFERENCES

1. Digi-HTA questionnaire completed by the manufacturer. Not publicly available.
2. Puolitaival A, Savola M, Tuomainen P, Asseburg C, Lundström T, Soini E. Advantages in Management and Remote Monitoring of Intravenous Therapy: Exploratory Survey and Economic Evaluation of Gravity-Based Infusions in Finland. Adv Ther 2022. DOI:10.1007/s12325-022-02093-6
3. Mällinen O. 2021. Potilaan nesteytyshoidon etävalvonnan pilotti TYKS neurokeskuksessa. Turun ammattikorkeakoulu. Available at: http://urn.fi/URN:NBN:fi:amk-2021061015582 , Accessed on 26.6.2022.
4. KYS infuusiohoidon etävalvonta pilotointi sisätautiosastolla, Not publicly available.
5. PPSHP OYS pilot Monidor-infuusiohoidon etävalvonta, tulokset os 39A-B, Not publicly available.
6. PPSHP OYS pilot Monidor infuusiohoidon etävalvonta, tulokset os 42, Not publicly available.
7. Mousavi M, Khalili H., Dashti-Khavidaki S. 2012. Errors in fluid therapy in medical wards. Int J Clin Pharm. 2012;34(2):374-81. DOI: 10.1007/s11096-012-9620-8
8. Rooker J.C. ja Gorard D.A. 2007. Errors of intravenous fluid infusion rates in medical inpatients. Clin Med 2007;7:482-5
9. Suvanto J. 2015. Laskimonsisäisen nestehoidon toteutus ja kehittämistarpeet. Kyselytutkimus terveydenhuollon ammattihenkilöille laskimonsisäisen nestehoidon toteuttamisesta käsin säätämällä ja tipanlaskijalla. Master's thesis. University of Eastern Finland, School of Medicine, Faculty of Health Sciences.
10. Risk Analysis of Monidrop WLAN, Not publicly available.
11. Monidor W Infusion monitor - Operating manual. Available at: https://monidor.com/D0276_Monidrop%20WLAN%20User%20Manual_1_EN_v3.0.pdf Accessed on 26.6.2022.
12. National Emergency Supply Agency. Cyber Health Project. Information security and data protection requirements for social welfare and healthcare procurements. Available at: https://www.kyberturvallisuuskeskus.fi/en/ncsc-news/instructions-and-guides/information-security-and-data-protection-requirements-social Accessed on 26.6.2022
13. The European Union Agency for Cybersecurity Procurement Guidelines for Cybersecurity in Hospitals. Available at: https://www.enisa.europa.eu/publications/good-practices-for-the-security-of-healthcare-services Accessed on 26.6.2022
14. Monidor accessibility statement. Available at: https://ivscreen.com/accessibility_statement.html Accessed on 26.6.2022
15. Laki digitaalisten palvelujen tarjoamisesta 306/2019 Available (in Finnish and Swedish) at: https://www.finlex.fi/fi/laki/alkup/2019/20190306 Accessed on 26.6.2022

16. Etelä-Suomen aluehallintovirasto, Saavutettavuuden valvonnan yksikkö (Regional State Administrative Agency in Finland). Requirements of the Act on the Provision of Digital Services. https://www.webaccessibility.fi/requirements-of-the-act-on-the-provision-of-digital-services/ Accessed on 26.6.2022
17. Laki julkisista hankinnoista ja käyttöoikeussopimuksista 1397/2016. Available (in Finnish and Swedish) at https://www.finlex.fi/fi/laki/alkup/2016/20161397 Accessed on 26.6.2022.

Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but more evidence is needed	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

Recommendation Scale

Total score	Definition
10	**USE OF THE PRODUCT IS RECOMMENDED** The use of this product is recommended because of strong evidence for its effectiveness. Safety, data security and protection, and usability and accessibility of the product are at an adequate level. The cost of using the product is reasonable.
9	**THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT** An organization considering the deployment of the product should note that **in one key area there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
7-8	**THERE ARE A FEW THINGS TO CONSIDER WHEN USING THE PRODUCT** An organization considering the deployment of the product should note that **in two or three key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
5-6	**THERE ARE MANY THINGS TO CONSIDER WHEN USING THE PRODUCT** An organization considering the deployment of the product should note that **in four or five key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
≤4	**THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT** An organization considering the deployment of the product should note that **there are shortcomings in one or more key areas.** Information about the effectiveness of the product is untrustworthy or of low quality. There may be shortcomings in the product's safety, or information related to it may be unreliable or of low quality. Product costs may be prohibitively high. There could be shortcomings in the product's data security and protection or in usability and accessibility.