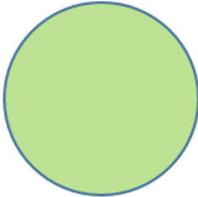


## Digi-HTA Recommendation

### Evondos Medication Dispensing Service

PRODUCT AND ITS INTENDED PURPOSE	
<p>Evondos® Service includes the Evondos E300 medicine dispensing robot and the Evondos remote care system.</p> <p>The aim of using the service is to improve the administration of medication in home care. The Evondos E300 medicine dispensing robot gives the dose distribution sachets to the customer at the time marked on it. With the Evondos remote care system, home care staff can monitor the administration of the client's medication in real time. Home care personnel will get a notification if the medicine is not taken. The remote care system can be used to send short messages to the customer.<sup>1</sup></p> <p>The device has a CE-mark. It is a Class I medical device (Medical Device Directive (MDD) 93/42/EEC).<sup>1</sup></p> <p>The company does not have a certified quality management system (QMS). It has its own QMS that describes the required processes according to Medical Device Directive (MDD) Class I, e.g. product traceability and adverse event handling. Evondos will be certified using the ISO 13485 quality system as part of the Medical Devices Regulation (MDR) compliance process.<sup>1</sup></p>	
RECOMMENDATION	
Date of The Recommendation	21.11.2019
	<p>Evondos® Service (the Evondos E300 medicine dispensing robot and Evondos remote care system combined) can enhance medication regimen compliance and bring flexibility to the organization of the home care service. The device and associated remote care system may not be suitable for all home care clients.</p> <p>Research evidence on the benefits of the device is scarce.</p>

SUB AREAS OF ASSESSMENT		
Effectiveness	<p>Only one peer-reviewed study on the device was available. It focused on the safety of the device as well as its usability. According to the study, 97.7-99.0 % of the dose distribution sachets were taken from the device at the right time.<sup>2</sup> In addition, the use of the service had been studied in a few theses at different levels<sup>3,4,5</sup> and in the final report of the IkäOTe project<sup>7</sup>. The theses focused on the experience of using the service from the perspective of home care staff<sup>3,4</sup> and the customer value that the service provided to home care.<sup>4,5</sup></p> <p>The IkäOTe project investigated the impact of the service on perceived quality of life. The study group comprised only nine people, so the result could not be generalized. The project showed that end user choice had a major impact on whether the use of the service achieved benefits.<sup>6</sup> The second sub-project of the project aimed to estimate cost-effectiveness, but, due to the small size of the group, it could not be done.<sup>7</sup></p> <p>There are several medicine dispensing devices on the market that use sound and light to remind taking a drug. They have been studied in terms of safety, effectiveness, and patient satisfaction. The use of medicine dispensing devices would appear to improve adherence to medication regimens so that medications are almost completely taken at the right time.<sup>8-11</sup></p> <p>Adherence to a medication regimen can improve a client's health and prevent complications.<sup>11</sup> Studies on the long-term effects of drug delivery devices on the overall well-being of clients would be necessary.</p>	
Safety	<p>The safety of the device was examined in one study. The study did not reveal any safety deficiencies.<sup>2</sup></p> <p>The company constantly monitors the device's safety. Potential safety risks have been considered in the device's design, and related precautions have been implemented. For example, missed medicines are stored inside the device so that the customer cannot take them later, thus avoiding an overdose.<sup>1</sup></p> <p>The company's risk analysis is comprehensive.<sup>12</sup></p>	
Cost	<p>The cost of the service to the home care provider consists of an annual leasing fee of € 2,400-2,900 / device / year. The equipment remains the property of the manufacturer. Annual costs also include necessary maintenance and software updates.<sup>1</sup></p> <p>The home care provider can decide the cost of using the service for a home care client.<sup>1</sup></p> <p>The home care provider can achieve cost savings after the introduction of the service, if the number of visits is reduced and, thus, the human resources can be minimized.<sup>3</sup> On the other hand, the service can increase the cost of home care if the number of visits does not decrease.<sup>7</sup> The introduction of the service may make it possible to postpone home care visits from peak times (mornings and evenings) to another time. This can bring flexibility to home care operations and, in some situations, savings in human resources.<sup>3,4,5</sup></p>	

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	<p>The use of the service may affect the home care customer's fees for home care services, depending on the service's effect on the number of visits and the duration of the visits, as well as the possible usage fee.</p>	
<p>Data Security and Protection</p>	<p>The supplier's answers demonstrate a good understanding of data security and data protection issues. They have been considered in crafting a high-quality solution. From the perspective of data security and protection, the risks of the solution are minimized.</p> <p>However, it is a good idea for the organization considering the procurement to also specify its level of security and protection requirements in the invitation to tender or as an annex to the contract. The data security and protection requirements of the Northern Ostrobothnia Hospital district (PPSHP) have been used in this assessment.<sup>13</sup></p>	
<p>Usability and Accessibility</p>	<p>The usability and accessibility of the service are sufficient. Special user groups (e.g. users with hearing, visual, and functional disabilities) have been taken into account in the design of the device's usability. The service may not be suitable for people with delusions or in the later stages of dementia.<sup>1</sup></p> <p>The application available to home care workers is available on several different operating systems.<sup>1</sup></p>	
<p>Other Things to Consider When Using This Product</p>	<p><b>Interoperability</b></p> <p>The device supports integration with other types of software. The home care provider can deploy these as needed.<sup>1</sup></p> <p><b>Technical Stability and Product Support</b></p> <p>The manufacturer has defined processes for monitoring technical stability and responding to faults as required. Home care providers have spare equipment in the event of a malfunction in the medicine dispensing robot. The manufacturer is responsible for the technical functionality of the device; product support for the service is available 24/7/365.<sup>1</sup></p> <p><b>Training and Other Available Recommendations for the Product</b></p> <p>The device manufacturer provides mandatory training (for a fee) for administrators the home care provider nominates to train other home care workers. Home care staff will instruct clients in the use of the device and be present in medication-taking situations as needed until they learn how to use it.<sup>1</sup></p> <p>In connection with the alerts that the remote care system sends, it is advisable for the home care provider to draw up an action plan that takes into account, say, how alarm checks or extra home visits are arranged.</p> <p>The use of the device is recommended in Norway as part of the organization of home care.<sup>14</sup></p>	
<p>References</p>	<p>1 Digi-HTA, information provided by manufacturer. Not publicly available.</p> <p>2 Rantanen et al 2017. An In-Home Advanced Robotic System to Manage Elderly Home-care Patients' Medications: A Pilot Safety and Usability Study. <i>Clinical Therapeutics</i> 2017;39(5): 1054-61. DOI:10.1016/j.clinthera.2017.03.020</p>	

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	<p>3 Setälä 2018. Assessment of the Evondos Service in the City of Lohja's Home Care- what effects can be achieved by investing in health technology? (English abstract). Master Thesis. Turku University of Applied Science</p> <p>4 Mäkelä 2016. EHealth solutions' customer value to public home care organizations. Master of Science Thesis. (English abstract). Tampere University of Technology</p> <p>5 Tiitola 2018. Value assessment and communication with a management accounting approach in home care: case study with a technology service provider. Master of Science Thesis. Tampere University of Technology</p> <p>6 Kärnä, Kauppila ja Pihlainen 2017. Lääkeautomaattikokeilu ja koettu elämänlaatu, in Kauppila et al. 2017 (Eds.) Teknologia ikäihmisen tuenäketterän kokeilukulttuurin ytimessä. IkäOTe - Ikääntyvien oppiminen ja hyvinvointiteknologia -hanke. (In Finnish only). Grano Oy, Jyväskylä.</p> <p>7 Karttunen 2017. Lääkeautomaattikokeilu kustannusten näkökulmasta, in Kauppila et al. 2017 (Eds.) Teknologia ikäihmisen tuenäketterän kokeilukulttuurin ytimessä. IkäOTe - Ikääntyvien oppiminen ja hyvinvointiteknologia -hanke. (In Finnish only). Grano Oy, Jyväskylä.</p> <p>8 Hannink et al 2019. A Randomized controlled efficacy study of the Medico medication dispenser in Parkinson's disease. BMC Geriatrics 2019; 19:273-280. DOI 10.1186/s12877-019-1292-y</p> <p>9 Hoffmann et al 2018. Enhanced Adherence in Patients Using an Automated Home Medication Dispenser. Journal of Healthcare Quality 2018;40(4):194-200. DOI 10.1097/JHQ000000000000097</p> <p>10 Marek et al 2013. Nurce Care Coordination and Technology Effects on Health Status of Frail Elderly via Enhanced Self-management of Medication: Randomized Clinical Trial to Test Efficacy.</p> <p>11 Henriksson et al 2016. A Prospective Randomized Trial of the Effect of Using an Electronic Monitoring Drug Dispensing Device to Improve Adherence and Compliance. Transplantation 2016;100:203-209. DOI 10.1097/TP.0000000000000971</p> <p>12 Risk management report, not publicly available.</p> <p>13 The data security and protection requirements of the Northern Ostrobothnia Hospital district (PPSHP, the National Emergency Supply Agency's Cyber Health project 2018-2019, University of Tampere Jari Seppälä). Available from:  <a href="https://www.kyberturvallisuuskeskus.fi/en/ncsc-news/instructions-and-guides/information-security-and-data-protection-requirements-social">https://www.kyberturvallisuuskeskus.fi/en/ncsc-news/instructions-and-guides/information-security-and-data-protection-requirements-social</a>  Cited 16.12.2019</p> <p>14 Helsedirektoratet 2017. Andre gevinstrealiseringsrapport med anbefalinger - Nasjonalt velferdsteknologiprogram. IS-2557. ISBN-nr. 978-82-8081-485-2. Available from:  <a href="https://www.helsedirektoratet.no/rapporter/gevinstrealiseringsrapporter-nasjonalt-velferdsteknologiprogram">https://www.helsedirektoratet.no/rapporter/gevinstrealiseringsrapporter-nasjonalt-velferdsteknologiprogram</a>  Cited 21.11.2019</p>
Assessment Team	<p>Petra Falkenbach, Senior Planning Officer, FinCCHTA</p> <p>Eerika Syrjänen, Lead Designer, IT Department, Northern Ostrobothnia Hospital District</p> <p>Anssi Huhtala, Information Security Designer, IT Department, Northern Ostrobothnia Hospital District</p>

Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but the information is scarce	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	<p>USE OF THE PRODUCT IS RECOMMENDED</p> <p>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.</p>
9	<p>THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT</p> <p>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.</p>
7-8	<p>THERE ARE A FEW THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>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.</p>
5-6	<p>THERE ARE MANY THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>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.</p>
≤4	<p>THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>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.</p>