# USABILITY STUDY FOR A NOVEL INTRAVENOUS AND SUBCUTANEOUS SYRINGE INFUSION SYSTEM

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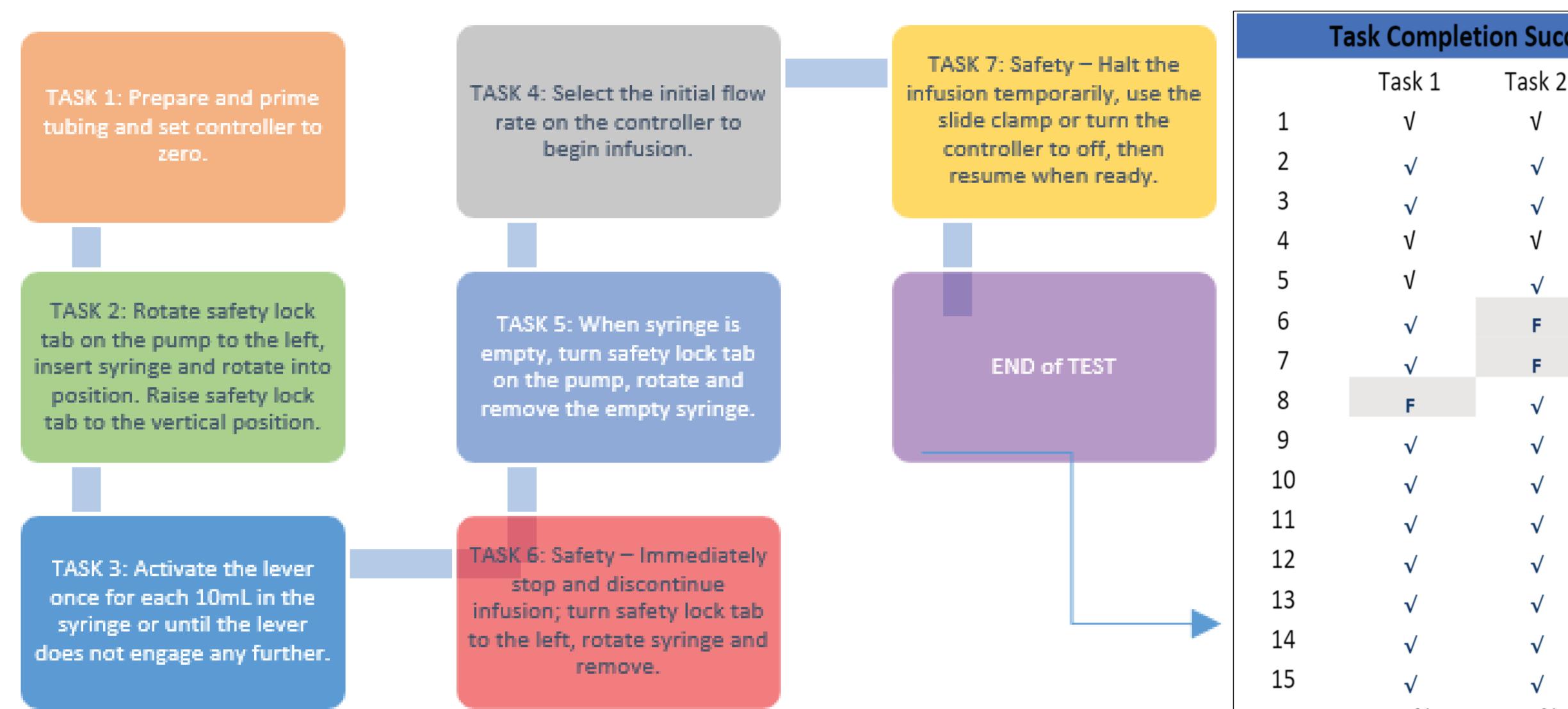
### AIM

To perform a usability study for a new syringe driver infusion system to make subcutaneous infusion easier for patients and nurses and to prove the system's effectiveness.

## INTRODUCTION

While intravenous and subcutaneous routes of medication therapy have primarily been used for the infusion of medications in the hospital and clinic, they are also used in the home where patients perform their own infusion, or the infusion is performed by a caregiver/home care nurse. Common medications given in the home setting include intravenous antibiotics and subcutaneous immunoglobulin. Adults and pediatric patients without systemic symptoms are frequently treated for diseases such as bone and joint infections, staphylococcal bacteremia, endocarditis, lung infections, soft tissue infections, neurological disorders, cancer, and immunodeficiency diseases.

The company performed a pre-market usability study to gauge user experiences with a novel infusion system for intravenous and subcutaneous use. User feedback on infusion effectiveness, efficiency, controllability, customizability, and consistency provides invaluable data, which is used to assess the ease of use, safety, and identify additional user needs.



Task Completion Success and Failure Rates- Caregiver Demonstrations											
	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7				
1	٧	V	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
2	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
3	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	$\checkmark$				
4	٧	V	√	√	$\checkmark$	$\checkmark$	$\checkmark$				
5	٧	√	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
6	$\checkmark$	F	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
7	√	F	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
8	F	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
9	$\checkmark$										
10	$\checkmark$										
11	$\checkmark$										
12	$\checkmark$										
13	$\checkmark$										
14	$\checkmark$										
15	$\checkmark$										
	93%	87%	100%	100%	100%	100%	100%				

Figure 1. Usability study tasks.

### DISCUSSION

The study was performed with two groups: 16 nurses and 15 caregivers ages 12 - 82. The nurses included a combination of registered nurses with varying degrees of education, from 3-year prepared nurses to an expert doctoral prepared nurse. The lay persons varied from high school education to college with some post graduate work. One participant was an adolescent. Both groups were trained on the Insignis Syringe Infusion System and asked to return-demonstrate the infusion process. In addition, to assess retention and trainability, post-demonstration nurses took a 90-minute break and were asked afterwards to demonstrate how they would train a caregiver. 100% of nurses indicated the infusion system was: "very easy" or "somewhat easy" to train and prepare, "convenient" to use," and was more satisfactory to use than other infusion systems. Other descriptor words included: "accessible," "clear," "easy to use," "effective," "reliable," "understandable," "useful," "fast," and "efficient."

## CONCLUSION & CLINICAL RELEVANCE

It is imperative that a medical device performs reliably and achieves its intended use effectively. The end user must easily understand how to infuse safely, whether in the home or in a hospital setting. For home infusions, users need a simple, easy-to-use, infusion system. The system's compact design, versatility, and portability further aid in providing the patient with an improved quality of life. The usability study demonstrated the infusion system was effective, simple, easy to use and to teach, and the majority of participants ranked the system an "A" or "B." Benefits of an easy-to-teach and easy-to-use system may include a reduction of infusion resources including training time and costs.

DEMOGRAPHICS										
		Caregivers/Lay persons								
ID	Age	Sex	Education	ID	Age	Sex	Education			
ML1	31	F	BSN	GJ1	36	M	HS			
VC2	33	F	BSN	MC2	46	F	HS			
KS3	25	F	BSN	LW3	51	F	HS			
RH4	39	F	BSN	CB4	19	M	HS			
LB5	25	F	MSN	RX5	78	F	HS			
M6	31	F	BSN	SS8	80	F	ASSOC			
BS7	41	F	ASSOC	FS7	54	F	BS			
BS8	33	F	BSN	ID8	44	F	BS			
RS9	51	F	BSN	AC9	26	F	QUIT HS			
JU10	32	F	BSN	CG1	34	M	HS			
JB11	35	F	BSN	CG2	37	F	BS			
LR12	44	F	TECH SCH	CG3	40	F	HS			
BK13	32	F	BSN	CG4	39	F	HS			
N1	66	F	AND	CG5	67	М	BS+			
N2	37	F	BSN	*CG6	12	М	MIDDLE			
*N3	59	F	PHD	STUDY #1 COLOR CODE		STUDY #2 COLOR CODE				

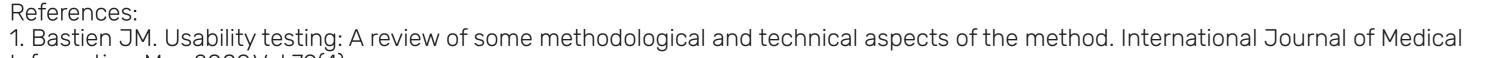
Figure 2. Demographics overview.







Figure 3. Nurses and caregivers demonstrating the infusion system.



<sup>2.</sup> Guidance for Industry and FDA Staff. US Department of Health and Human Services Food and Drug Administration Center for Devices and 3. Keenan HL, Duke SL, Wharrad HJ, Doody GA, Patel RS. Usability: An introduction to and literature review of usability testing for educational resources in radiation oncology. Tech Innov Patient Support Radiat Oncol. 2022 Sep 17;24:67-72. doi: 10.1016/j.tipsro.2022.09.001. PMID:

<sup>4.</sup> Sather S, Lawyer J. An ISO 14155:2020 Primer - Good Clinical Practice For Medical Device Trials. Guest Column, February 2, 2021





