Safety and Effectiveness of A Novel Enteral Feeding System: Prospective Study Protocol

NCT06173063

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2.0 Device Description

Device Description

The Mobility+ Enteral Feeding System ("Mobility+ System") is a portable, lightweight, non-electronic, disposable enteral feeding system intended to deliver commercially available liquid nutrition formula to a patient, using a standard extension set (or feeding tube) with an ENFit® connector, in the clinical or home care settings.

The Mobility+ System delivers formula using a simple container system ("Feeding Pouch") that has an internal elastomeric pump, filled by the user with formula, that gradually deflates once enabled. The deflation of the elastomeric pump generates a consistent, low pressure that gently pushes the formula from inside the elastomeric pump through the supplied tubing set ("Giving Set") to the user's extension set (or feeding tube), where the formula enters their digestive system through a surgically placed stoma. The progress of formula delivery is indicated by reductions in Feeding pouch inflation and weight, and completion of formula delivery is indicated by a cessation in formula flow out of the giving-set. Clinicians will consult product labelling to determine which giving-set patients should be guided to use, to provide for their individual flow rate needs. The system can be worn in a bag of choice, or in clothing, that can fit the system without kinking the tubing.
The Mobility+ System is self-contained, portable and does not require an external pump, power source, or IV pole. It is designed to provide the patient greater mobility and overall ease of use. It operates silently, avoiding noises which can prove distracting and sleep disrupting for patients requiring night-time feeding. It offers the overall simplicity of operation of gravity-fed systems without requiring gravity to deliver formula to the patient.

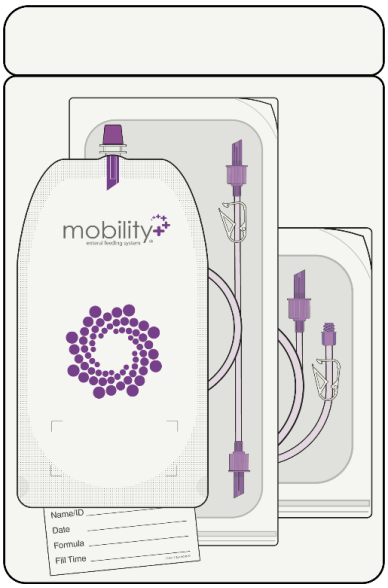

Figure 1: The Mobility+ System. Feeding Pouch (left), Filling Set and Giving Set (right);

The Mobility+ System is single patient use, disposable and intended for use over a 24-hour period. It has three primary components (Figure 1).

Primary components

The Feeding Pouch

The combined pump and reservoir of the Mobility+ System (Figure 2). It consists of a flexible protective sleeve with an internal silicone elastomeric pump.

To fill the Feeding Pouch, the Filling Set is attached to the spout. As the Feeding Pouch is filled with formula, it inflates. This inflation generates the mechanical force used to dispense the formula in a controlled manner, without any external energy source or need for gravity. Once filled, the Filling set is detached from the spout. The Feeding Pouch can hold a maximum of 500 ml of formula and a minimum of 250 ml.

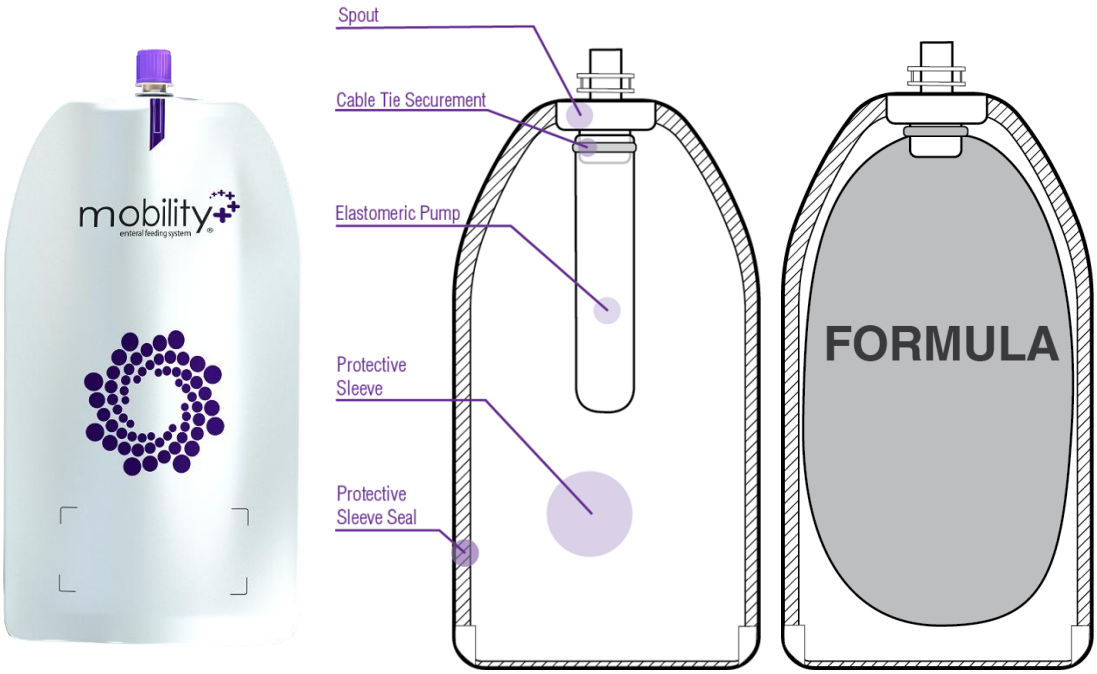

Figure 2: Feeding Pouch (left), Internal Schematics (right, empty & full)

The Filling Set

Tubing that transfers commercially available nutritional formula from its packaging to the Feeding Pouch using ENFit® connectors and a syringe (Figure 3).

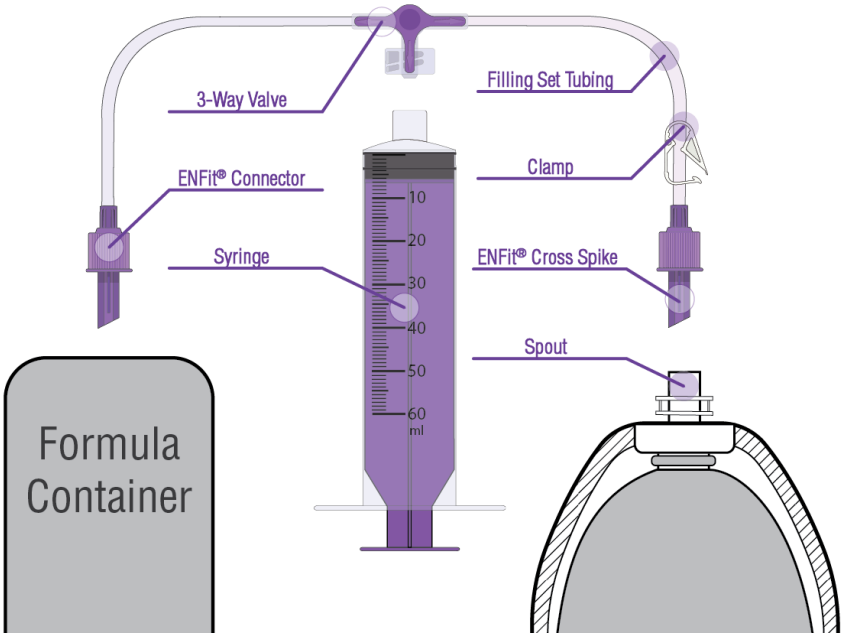

Figure 3: The Filling Set and Syringe

Note: A 60 ml ENFit® syringe (Figure 3) is not included with the Mobility+ System. It is an ancillary device used in the transfer of formula from the formula packaging ('feed container' in Figure 3) to the Feeding Pouch, with the use of the Filling Set.

The Giving Set

Tubing that connects the Feeding Pouch to the ENFit® connector of the user's extension set (or feeding tube), (Figure 4). The Giving Set is available in a variety of lengths to give a range of formula flow rates (Figure 5).
Once the Feeding pouch is filled using the Filling set (figure 3), the Giving Set is attached to the Feeding Pouch with the clamp of the Giving Set tubing closed. Formula flow is enabled by opening the clamp. The system is then primed (allowing the Feeding Pouch to fill the Giving Set tubing with formula to clear air, if any, from the elastomeric pump and the Giving Set tubing itself). The formula flow is disabled by closing the clamp. The Giving Set is attached to the extension set (or feeding tube). The Mobility+ System is now ready. Once again, formula flow is enabled by opening the clamp.

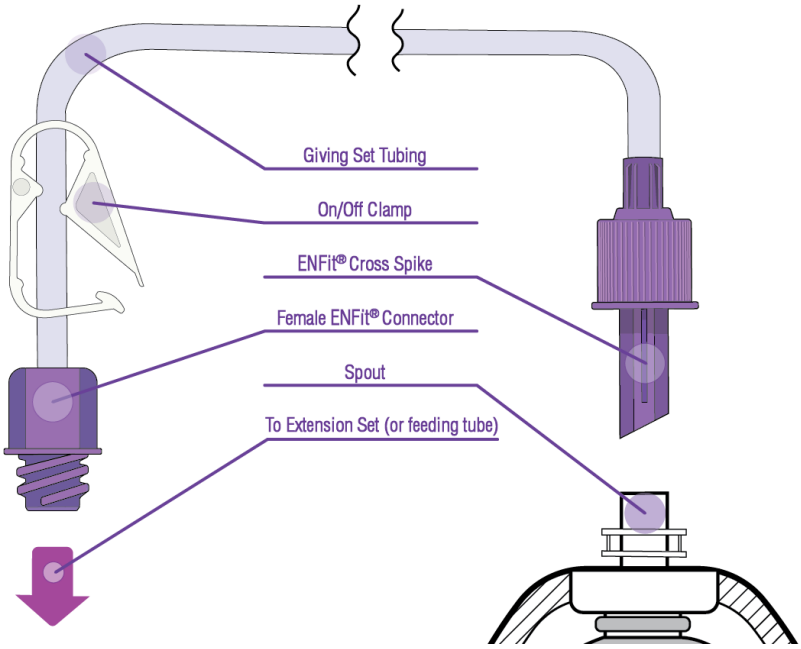

Figure 4: The Giving Set

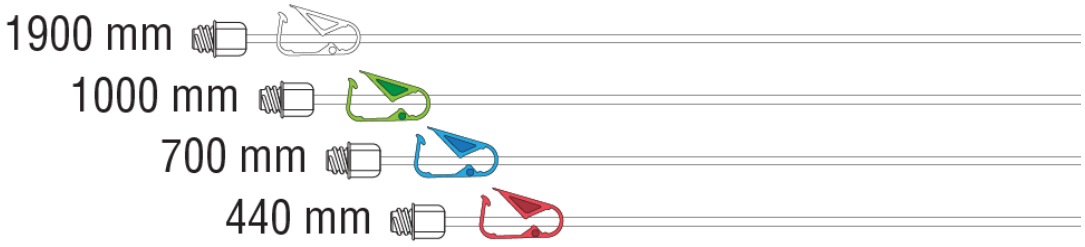

Figure 5: Available Giving Set lengths

The Mobility+ System may be worn in a bag of choice that can fit the filled Feeding Pouch without kinking the Giving Set tubing. The Instructions for Use guides the user to place the spout of the Feeding Pouch within 15cm (6 inches) above or below the user's stoma when feeding.
All connectors in the Mobility+ System comply with the FDA-recognized ENFit® standard (ISO 80369-3 and ISO 18250-3).

2.1 Intended Use and Indications for Use

Intended Use

The Rockfield Medical Devices Mobility+ Enteral Feeding System is intended to deliver liquid nutrition formula to an enteral access device (feeding tube) in users aged 2 years and over.

Indications for Use

The Rockfield Medical Devices Mobility+ Enteral Feeding System is intended to deliver liquid nutrition formula to an enteral access device (feeding tube) in users aged 2 years and over.

3.0 Purpose

The purpose is to evaluate the safety and effectiveness of Mobility+ enteral feeding system via this initial post-market study (510k clearance number K222678) in adults, a subset of the intended use population. This evaluation will be conducted in a prospective, single arm, non-randomized clinical study.

Hypothesis and Objectives

The study hypothesis is that Mobility+ meets its intended use, safely. The objectives are to evaluate the below primary and secondary endpoints, through execution of this protocol:

Endpoint	Detail	How it will be measured
***Primary:* Safety and Effectiveness of Mobility+**	Evaluate participants who have received familiarization training can use device, according to IFU, to allow delivery of liquid nutrition to their feeding tube, in a real-life setting (home), **safely** (i.e. can execute critical device use tasks to allow feeding, without serious adverse events) *and* **with effectiveness** (i.e. using Mobility+ for the majority or all of their feeding sessions i.e. two daily feeds, minimum)	Phone communication and checklist (*Appendix8*)

***Secondary*: Usability of Mobility+**	Evaluate Participant perspectives on mobility, ease of use and tolerance, with their current feeding system(s) and Mobility+	Participant perspectives surveys: Baseline *(Appendix 4)* End of study (*Appendix 7)*
	Evaluate changes in participant Quality of Life (QoL)	QoL survey at baseline *(Appendix 5)* and QoL question at end of study (Appendix 7)
	Estimate if participants consume similar average volume (and kcals) of feed/day during the study, compared to baseline	Collect descriptive data on estimated average feed volume and kcals consumed at baseline *(Appendix 3)* and at end of study *(Appendix 8)*

The outcome will be presented in a study report.

4.0 Scope

The scope is a post-market clinical study with adult users, in line with the scope of identified users as per the Usability Engineering File (DR010), with the Mobility+ system, which includes the 4 REF codes below.

REF code	Product
Mob1- 440	Mobility+ with 440mm Giving Set
Mob1-700	Mobility+ with 700mm Giving Set
Mob1-1000	Mobility+ with 1000mm Giving Set
Mob1-1900	Mobility+ with 1900mm Giving Set

The scope includes use of the Mobility+ via filling the system from feed poured into a container (See IFU Filling Method A) and excludes filling the system from a ready to hang feed bag (Filling Method B, IFU).

ISO 14155 principles are applied in part to this protocol, to suit the clinical developmental stage of Mobility+ and study design, in line with Annex I I.7 ISO 14155:2020.

6.0 Appendix List

Appendix 1: Screening Log
Appendix 2: Screening questionnaire
Appendix 3: Demographics questionnaire
Appendix 4: Participant perspectives baseline survey
Appendix 5: QoL survey
Appendix 6: Phone communication check sheet – Trial days
Appendix 7: Participant perspectives outcome survey
Appendix 8: Phone communication check sheet (Study Day 7 and 14)
Appendix 9: Adverse event classifications
Appendix 10: Adverse events logging method
Appendix 11: Participant familiarization training
Appendix 12: Participant familiarization training record
Appendix 13: Operator training record
Appendix 14: Evidence of expert review

7.0 Definitions

Term	Description
User	Person interaction with medical device
Operator	Operators are study staff who have self-trained in the use of Mobility+ and who have received training in the execution of this Protocol by the sponsor, Rockfield Medical Devices. Study staff in this study comprise advanced nursing practitioners, registered dietitians, researchers and principal investigator.
Participant	Individual who is or becomes a participant in a clinical investigation, as a recipient of the investigational device. *Note that 'participants' in this study are users of the device who are being enterally fed in clinical settings or who are feeding at home (as per Usability Engineering File DR010).*
Investigational medical device	Medical device being assessed for clinical performance, effectiveness, or safety in a clinical investigation
Clinical effectiveness	Achievement of a clinically significant intended result in a defined portion of the target population when the investigational medical device is used within its intended uses and according to its instructions for use, as determined by documented scientific evidence
Malfunction	Failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use
Principal Investigator	Qualified person responsible for conducting the clinical investigation at an investigation site
Use error (ISO 14155:2020)	User action or lack of action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. Note: Use error includes inability of the user to complete a task.
Adverse event (AE) (ISO 14155:2020)	Untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated
Serious adverse	adverse event that led to any of the following

effect (SAE)	a) Death b) Serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following: 1) A life-threatening illness or injury, or 2) A permanent impairment of a body structure or a body function including chronic diseases, or 3) In-patient or prolonged hospitalization, or 4) Medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function, c) Fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment
Adverse device effect (ADE)	Adverse event related to the use of an investigational medical device.
Serious adverse device effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event
Unanticipated serious adverse device effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment *Note:* Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment
Serious public health threat	Serious public health threat, means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time
Stock-Keeping Unit (SKU)	A Stock-Keeping Unit is a number (and sometimes letters) that is assigned to a product for the purpose of inventory management and ease or tracking

8.0 Methods

8.1 General Methodology

The study duration will allow 25 participants to use the Mobility+ system for their feeding sessions over the course of 14 consecutive days, following an initial 7-day period where participants have time to trial and get used to the new system. As determined by the PI, five to seven pre-intervention days (During 'Trial days' 1 to 7), with a minimum of 5, is time to allow participants to become familiar with a new feeding system (i.e., Mobility+) and 14 days (Study Day 1 through Day 14 inclusive) is the time required to effectively assess safety and effectiveness of Mobility+(as outlined in **Appendix 8**).

The environment is Mayo Clinic Setting at study outset for the clinic visits where participants will be screened, consented, and enrolled. Participants' homes are the setting for the 21-day study duration.

Mobility+ Devices will be built by a process detailed within a Mobility+ Work Instruction, from within a quality management system. The work instruction will be in place at the time of Mobility+ production runs occurring before execution of this protocol.

8.2 Equipment

Component description	**Name**
Mobility+ device	Mobility+ Enteral Feeding System
ENFit Syringe.	Reusable, 60ml ENFit syringe
Generic cross body bags to wear Mobility+ in	Off the shelf brand

8.3 Participants

This is a first in human post-market clinical study to evaluate the Mobility+ system, being carried out following market approval (i.e., FDA clearance). 25 participants will be enrolled to ensure data can be obtained for 20 participants (the expected drop-out rate is estimated at ~20%), as this is considered appropriate for a post-market clinical study on a low-risk device and will add meaningful data to device risk management files. If more than 5 participants drop out, re-recruitment will aim to bring the sample size up to 20.

Recruitment will aim to obtain a mix of female and male participants who meet the inclusion criteria. Screening questions will be used by operators during the recruitment process to ensure participants are eligible (See **Appendix 1 and Appendix 2**).

8.4 Inclusion and Exclusion Criteria

Inclusion criteria	1. Participants with Gastrostomy (G) tube or Jejunostomy (J) tubes 2. Participant must require enteral tube feeding every day, as determined at the time of study enrolment 3. Participant must use commercially available enteral formula with standard enteral feeding system(s) (gravity bag, bolus, pump or combination(s)), for some or all of their tube feeds, for daytime *or* day and night-time feeding 4. Participant must be EN dependent i.e., 500 ml minimum daily feed intake from EN 5. Participants must be able to swap from current system to Mobility+ for a minimum of two daily feeds per day for duration of study (Study days 1 -14) 6. Participant must be >= 18 to reflect the subset of the intended use population being evaluated 7. Participant must be willing to participate in the study and provide consent). 8. Participants must have been on an enteral feeding regime for a minimum of 10 weeks 9. Participants clinical functional capacity is adequate as determined by operator clinical judgement, to enable them to participate fully in the study 10. Participants are suitable candidates for using Mobility+ as determined by operator clinical judgement on participant enteral feeding needs (as per prescription) and alignment with Mobility+ Flow Rate Guide (see Giving Set SKU decision tree for prescribing Mobility+ *Figure 6*)
Exclusion Criteria	1. Participants who do not use commercially available enteral formula for some or all their formula needs 2. Participants unable/unwilling to provide consent 3. Participants whose enteral feeding needs do not match the offering of the Mobility+, as determined by operator clinical judgement (see Decision Tree for prescribing Mobility+ *Figure 6*)

	4. Participants who have inadequate clinical functional capacity, as determined by operator clinical judgement to participate fully in the study e.g. neuromuscular or neurodegenerative disorders, or developmental delay. 5. Participants with very limited mobility, as determined by operator clinical opinion

Note: In considering functional capacity, the operator will consider the ability to conduct critical tasks associated with successful use of Mobility+ (i.e. removal of protective caps; connecting filling set to pouch in correct orientation; operating clamps; orientating 3-way valve; pushing syringes of feed into pouch; disconnecting tubing (filling and giving sets); connecting giving set to extension set or feeding tube; wearing Mobility+ and coiled tubing on the body; Sit, walk, and stand while wearing Mobility+)

8.5 Study Measurements

The study measurements which will be taken are detailed in Table 3 below:

Table 3: Study measurements

Baseline measurements:	• Demographics *(Appendix 3)* • Average volume and Kcals of feed consumed / day *(Appendix 3*) • Quality of life measure *(Appendix 5)* • Participant perspectives on mobility, ease of use (current system(s)) and feeding intolerance symptoms *(Appendix 4)*
Trial days	• Tubing SKU check (*Appendix 6)*
Interim survey questions (Study Day 7)	• Tubing SKU check, safety and effectiveness check, compliance and calorie intake check *(Appendix 8)*
End of study measurements (Study Day 14):	• Quality of life question *(Appendix 7)* • Participant perspectives on mobility and ease of use of Mobility+ system (*Appendix 7)* • Note of tubing SKU used, safety and effectiveness check, compliance and calorie intake check, General end of study questions (wearing, wellbeing, future use etc.) *(Appendix 7)*

8.6 Compliance

Phone communication surveys on Study days 7 and 14 will collect information on the amount participants are using, to capture if they are using Mobility+ for a minimum of 2 daily feeds (**Appendix 8**).

Note: In some cases, participants may not comply fully with their enteral feeding regime due to issues unrelated to the study or feeding system. At screening, potential participants will be asked how often they skip or cut-short feeding sessions to determine if general compliance with enteral nutrition (EN) feeding may be an issue. Questions on compliance will also be asked on Study Days 7 and Day 14 (See **Appendix 8**). Poor compliance (participants who take less than two daily feeds using Mobility+), should it occur, will be reported in the study results and sub analyses will be conducted on participants who met the criteria.

8.7 Selection of giving set tubing SKUs

During eligibility screening, patient e-medical records will be reviewed to allow operators to determine if the Mobility+ system is suitable for potential participants based on the enteral nutrition formula the person uses, their **estimated** flow rate needs (mls/hour), and the information in the Mobility+ Flow Rate Guide (FRG) on indicative flow rates achieved with various formula and tubing SKU combinations. *Note: The process of healthcare professionals using the FRG to allow selection of an appropriate tubing SKU is validated by expert review .*

Operators will use FRG and the potential participant's enteral feeding regimen prescription to estimate which giving –set tubing SKU (from four available options) best suits the participant's needs, with the approach being to pick the SKU which will provide a flow rate that is slightly slower than the participant's estimated flow rate. The operator will refer to the Decision Tree for Prescribing Mobility+ (see **Figure 6**) when deciding if the potential participant should be invited for a clinic visit.

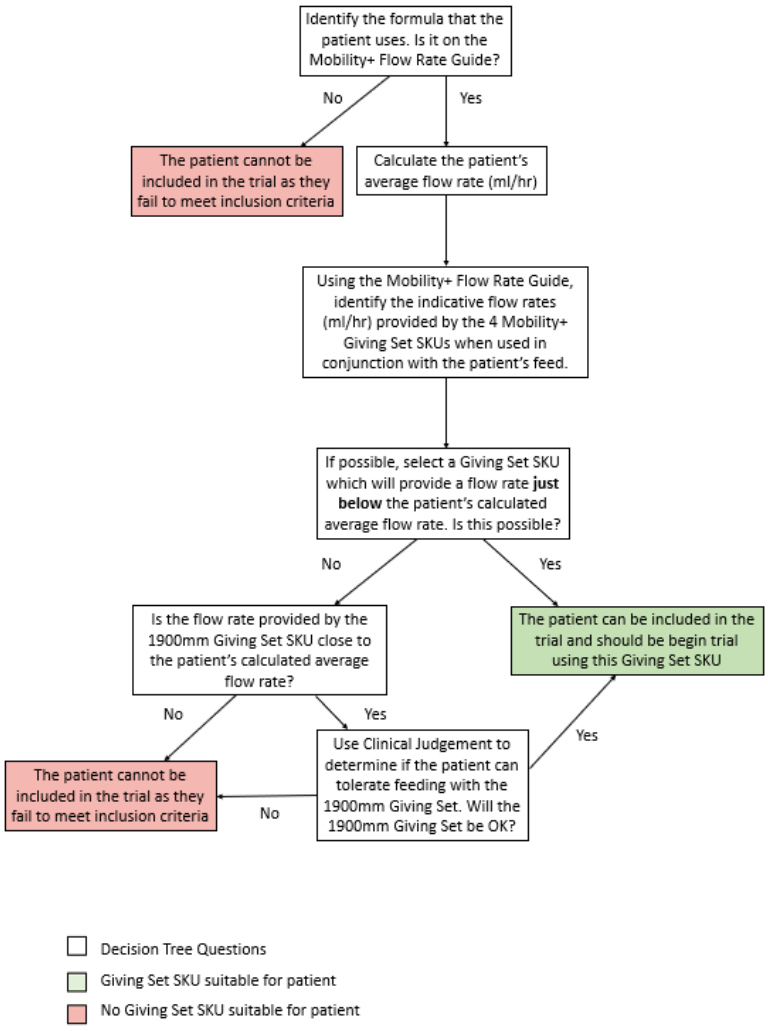

Figure 6: Decision Tree for prescribing Mobility+

During the clinic visit, the operator will administer the screening questionnaire (**Appendix 2**) which will allow the operator to gauge the participant's **calculated average flow rate**. The operator will then use the participant's calculated average flow rate, the FRG and Decision Tree for Prescribing Mobility+ (see **Figure 6)** to make a final decision on which giving set SKU the participant will begin the trial period with. As per the Decision Tree for Prescribing Mobility+, the operator will prescribe the giving set SKU which provides a flow rate slower than the participant's calculated average flow rate and exercise caution when prescribing the 1900mm for use in the trial. This reduces the likelihood of the participant starting the trial with flow rates that are too high, and reduces the risks associated with this e.g. nausea and vomiting, among others. The trial period will allow time for an assessment on whether this initially selected tubing SKU is the best-fit for the participant to continue to use for the study days.

Participants will be made aware at enrollment that operators who are licensed to prescribe enteral feeding systems may advise changes to the giving-set tubing SKU they use, throughout the study, should clinical and participant factors necessitate this.

During phone communications in the trial period days, the operator will advise the participant about what, if any, changes to make to the tubing SKU they are using, which will be logged (**Appendix 6**). If necessary, participants will be advised by the operator to move to tubing SKUs which provide faster or slower flow rates as tolerated (See Phone Communication Decision Tree Figure 7), until the participant has their optimum tubing SKU selected by the end of the trial period, for use during the study days. The participant will then ideally continue with the selected tubing SKU for the duration of the study days.

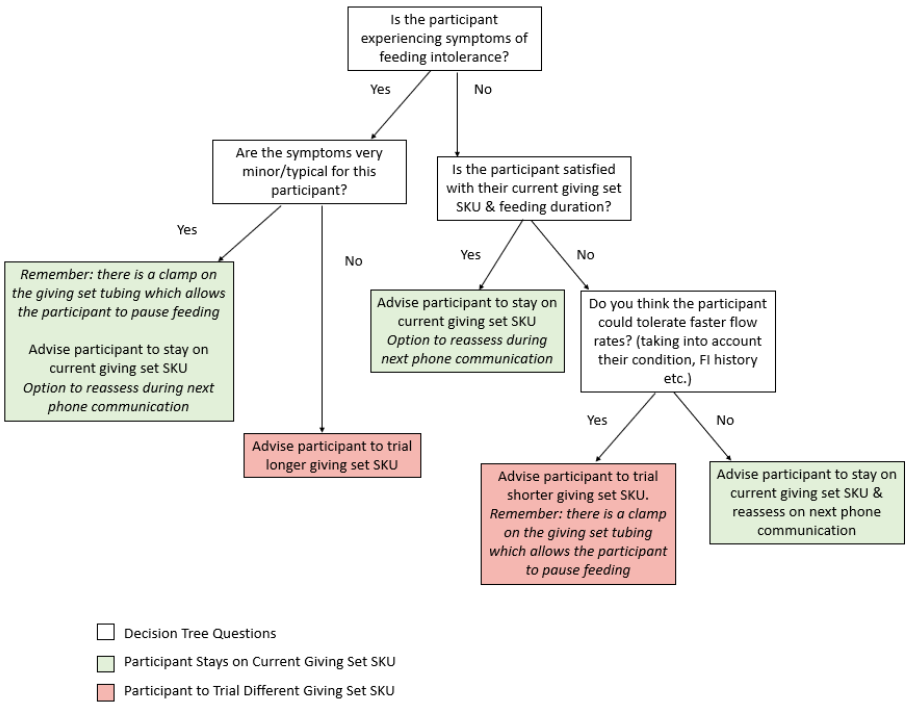

Figure 7: Phone Communication Decision Tree

However, on study Day 7 operators will discuss the tubing SKU being used with the participant and advise if any changes need to be made. Any changes made to the SKU being used will be logged by the operator (**Appendix 6)**. On study day 14 (at outcome), operators will log the SKU that participants finished the trial with.

Participants will be supplied with devices, tubing SKUs and other consumables necessary, for trial period and study days.

Table 4 and **Figure 8** below summarizes the study schedule and the subsequent text details what occurs at screening and baseline visit, and in the pre-intervention and intervention phases.

Note: Operators will, if applicable, log reports on 1) surveys/phone communications that subjects fail to respond to (including reasons), and 2) participants withdrawn (including reason for withdrawal)

8.8 Study Schedule and Flow

Table 4. Study Schedule

	Pre intervention	**Intervention Phase (21 consecutive days)**														
Day	Clinic Visit	**Trial Days 1 to 7**	Study Day 1	Study Day 2	Study Day 3	Study Day 4	Study Day 5	Study Day 6	Study Day 7	Study Day 8	Study Day 9	Study Day 10	Study Day 11	Study Day 12	Study Day 13	Outcome Study Day 14
Clinic visit	X															
Phone Communication		X (days 1,3,5)							X							X
Participant info sheet	X															
Screening Questionnaire	X															
Giving Set Tubing Selection	X															
Consent & data privacy, Enrolment	X															
Record Demographics	X															
Familiarization Training	X															
Device First clinical use		X														
Participant perspectives survey	X															X
- QoLmeasure	X															X
Estimate EN intake (kcals & volume)	X								X							X

	Pre intervention	**Intervention Phase (21 consecutive days)**														
Day	Clinic Visit	**Trial Days 1 to 7**	Study Day 1	Study Day 2	Study Day 3	Study Day 4	Study Day 5	Study Day 6	Study Day 7	Study Day 8	Study Day 9	Study Day 10	Study Day 11	Study Day 12	Study Day 13	Outcome Study Day 14
Clinic visit	X															
Phone Communication		X (days 1,3,5)							X							X
General End of Study Questions																X

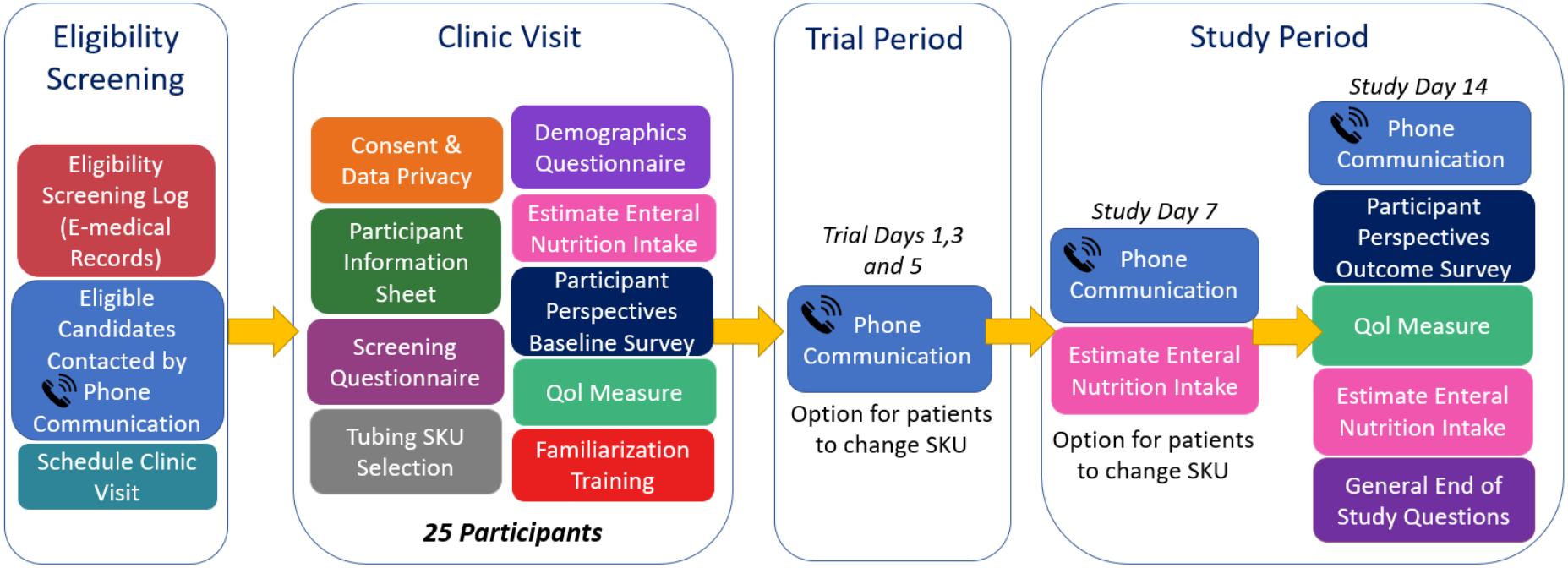

Figure 8. Study Flow Chart

8.9 Screening

- Conduct eligibility screening using the eligibility screening log (see **Appendix 1**) and information from patients' electronic medical records. Ensure that the candidate meets the study inclusion criteria. Check if the candidate's enteral nutrition formula is listed on the Mobility+ FRG.

- Develop an understanding of the candidate's flow rate needs. Information on flow rates may be listed in patient electronic medical records or determined based on information such as patient diagnosis, feeding method and type of feeding tube. Where necessary, consult with other study staff (e.g dietitian) to determine a patient's estimated flow rate range and maximum flow rate likely to be tolerated.

- Consult FRG and use the Giving Set SKU decision tree for prescribing Mobility+ (see **Figure 6**) to estimate a suitable giving set SKU for candidates. Note, if the indicative flow rates in the FRG are not suitable for the candidate, they are not eligible for inclusion in the study.

- Assess whether a candidate's mobility and clinical functional capacity are adequate to allow them to participate in the trial.

- Contact eligible candidates by phone and give them a brief description of the clinical trial. Schedule a clinic visit with candidates that are interested in participating in the trial.

8.10 Clinic Visit

The following activities are carried out during the clinic visit.:

- Provide the information sheet to the participant. Obtain informed consent verbally and via e-signature, and agreement with data privacy policy[SW1].
- Officially enroll participant.
- Administer the screening questionnaire (**Appendix 2**) to confirm participant eligibility
- Revisit the FRG and Decision Tree for Prescribing Mobility+, and use the additional information generated through the screening questionnaire to make a final decision on the appropriate giving-set tubing SKU (**Appendix 2**) for participants to begin the trial period with.
- Advise participant that operators (licensed to prescribe) may change the giving-set tubing SKU participants are to use, during the trial and or study days, if clinical and participant factors indicate this is needed (e.g. participant reflux may necessitate a change to slower flow rate, or participant finding feeding times too long may necessitate a change to a faster flow rate)
- Answer any queries
- Record the demographic data including calorie intake (**Appendix 3**).

- Administer the participant perspectives baseline survey (**Appendix 4**) and quality of life survey (**Appendix 5**).
- Provide familiarization training as per **Appendix 11.**
- Provide necessary consumables.

8.11 Phone Communication

1. Pre-intervention phase – Trial days

Phone communication on **Trial Days 1; 3 and 5**: Participant is contacted by telephone to ensure the participant is becoming familiar with using the device including the most appropriate giving-set tubing SKU. (**Appendix 6)**.

2. Intervention phase – Study days

- Phone communication - Study **Day 7**: Participant is contacted by telephone to ensure they are successfully and safely feeding with an appropriate tubing SKU, and check compliance and calorie intake (**Appendix 8**).
- Phone communication -Study **Day 14**: Participant is contacted by telephone to ensure participant is successfully and safely feeding with an appropriate tubing SKU, and check compliance and calorie intake. Operator also evaluates self-perceived wellbeing, mobility, wearing methods, and longer-term device use wishes (**Appendix 8**) Administer participant perspectives outcome survey, including question on QoL (**Appendix 7**)

Note: Regarding disposal – as per IFU, devices are disposed of alongside normal waste.

8.12 Training

Participants will be familiarized with how to use Mobility+ by the trained operator (**Appendix 11**).

Operators will log completion of familiarization training (**Appendix 12**). The operator advises the participant that the first 7 days of the use during the study are effectively a trial period to enhance comfort and familiarity with the system, before the 14-day intervention phase (Study Day 1 through Study Day 14) of the study.

Operators are to self-train in the use of Mobility+ (as detailed in DR010) and be trained in the execution of this Protocol by the sponsor, Rockfield Medical Devices (**Appendix 14**), before study execution. The sponsor will be available to provide continuous training to the operators throughout the duration of the study, as necessary.

Participants will be provided with the contact phone number of the Operator in case of questions or concerns.

8.13 Monitoring

PI will monitor participants experience of feeding with Mobility+ during the study as per schedule of phone communications in **Table 4** Study Schedule, and as outlined in **Appendices 6 and 9** Should any adverse events or health threats become known to the operator via phone communications or otherwise, the operator will proceed to assess these as per **Appendices 9 and 10**. Furthermore, participant hospitalization for any reason during the trial days or study days will necessitate the ceasing of a participant's participation in this study (**Appendices 6 and 8**).

9.0 Risk Benefit

Risks associated with the investigational device and its use have been estimated in accordance with ISO 14971 prior to the development of this protocol. As part of ongoing risk management processes throughout the lifecycle of the device, and in line with SOP004, FMEA (Failure modes effects analysis) has been used to evaluate risks that may occur through use of the device and controls have been implemented to reduce risk to acceptable levels. Residual risks are deemed reduced as far as possible and are communicated in device labelling and other mitigation activities as per sponsor Risk documents. Benefits associated with the device outweigh risks. Risk benefit will be updated in risk management files (FMEA and Mobility+ Risk Management Report) following completion of the study report.

10.0 Safety Evaluation and Reporting

Safety evaluation and reporting will take place in line with Rockfield Medical Devices Quality Management System and SOPs on feedback and complaint management (SOP022 Customer Complaint Process Management).

The Principal Investigator (PI) undertakes to follow their institutes Institutional Review Board (IRB) policies regarding safety evaluation and reporting, and record AE's, SAE's, device deficiencies (including those which could lead to SADEs) and serious health threats, conduct an assessment on these, and report them to the IRB within 24 hours if the matter is considered serious, detailing the determination and action taken.

The PI also undertakes to report serious matters in a timely manner (within 24 hours) to the sponsor as per **Appendix 10,** following which the sponsor will review if the PIs assessment, determination, and actions are appropriate. The sponsor will also follow the sponsors relevant procedure on reporting (SOP022) and data outputs will be reviewed as part of SOP024.

11.0 Data Collection and Analysis

11.1 Data Collection

Data from screening, surveys and phone communications will be collected by operators and input directly into the Mayo Clinic Electronic Data Capture (Redcap) system.

11.2 Data Analysis

Table 5 below details how data from the surveys will be analyzed.

Table 5: Details of how measurements will be analyzed

Measurement	General details on purpose of analysis	Specific details on analysis
Participant perspective surveys	Feeding system surveys at baseline and end of study, to assess participant perspectives on feeding system specific parameters and the impact of converting from usual system(s) to Mobility+	Surveys consist of 16 five-point Likert scale type questions, where rating options either range from very difficult to very easy, or strongly disagree to strongly agree. The ratings are assigned a point scoring system, whereby the most negative option (i.e. very difficult or strongly disagree) is assigned 0 points and the most positive option (i.e. very easy or strongly agree) is assigned 4, meaning the total possible maximum score is 64 points. As participants are asked to complete these surveys at baseline and at study end, the **overall score obtained with** their usual systems can be compared to the overall score obtained after using Mobility+. Scores for **individual** questions can also be compared.
QoL measures (QoI survey at baseline and QoL question at end of study)	A simple QoL measure will be used at baseline to gauge participants overall QoL using a scale previously published (See Appendix 5) accompanied by a simple question evaluating if self-perceived QoL has changed, at end of study	Determine baseline QoL Evaluate any changes to QoL in the second week of study

General End of Study Questions	This survey is designed to assess changes in participants perceived wellbeing and mobility from study start – where they used their usual feeding system – to study end with Mobility+. It will also capture additional information on Mobility+ usage patterns and consumer demand for Mobility+.	The survey consists of 9 simple questions which predominantly assess change in participants perceived wellbeing and mobility with Mobility+ versus their usual systems. The questions are mostly Likert scale type questions where answer options range from “much better” to “much worse”. Additional questions assess the importance of mobility to the participant, how the participant wore the Mobility+ and if the participant would like to use the Mobility+ again, among others. Data collected will supplement QoI and participant perspectives data.

12.0 Data management

A validated Electronic Data Capture system will be used at the study site, which complies with all relevant local and national rules.

13.0 Maintain Records

Records shall be maintained in accordance with SOP002 Control of Records Procedure.

14.0 Appendices

Appendix 1

Eligibility-Screening Log

Date:		
Operator(s) ID:		
Questions:	**Answers:**	
All answers to the following questions must be **'YES'** for a candidate to be deemed eligible for this Study.		
1. Is the candidate at least 18 years of age?	**YES** ☐	**NO** ☐
2. Do they have a gastrostomy tube or jejunostomy tube?	**YES** ☐	**NO** ☐
3. Do they use a standard enteral feeding system (gravity bag, enteral nutrition pump, bolus or combination(s)?	**YES** ☐	**NO** ☐
4. Have they been on an enteral feeding regime for greater than or equal to 10 weeks?	**YES** ☐	**NO** ☐
5. Do they currently require greater than or equal to 500ml enteral nutrition **every day**?	**YES** ☐	**NO** ☐
6. Do they tube feed either during the **day** or **day and night**?	**YES** ☐	**NO** ☐
7. Is their clinical functional capacity adequate to enable them to participate fully in the study? (Determined by operator clinical judgement)	**YES** ☐	**NO** ☐
8. Is the patient mobile? (Determined by operator clinical opinion)	**YES** ☐	**NO** ☐
9. Do they currently use a commercially available enteral formula that is listed on the Mobility+ Flow Rate Guide?	**YES** ☐	**NO** ☐

Appendix 2

Screening Questionnaire

(Operator asks the Participant these questions)

Participant ID:		
Date:		
Operator(s) ID:		
Questions:		**Answers:**
1. What type of feeding system(s) do you use? **GRAVITY BAG** ☐ **PUMP** ☐ **SYRINGE/BOLUS** ☐ **COMBINATION** ☐		
If **COMBINATION,** please give detail ……		
2. What is the name of the enteral feed you use?	**Brand:** ……	**Type:** ……
3. Do you feed during the day, at night or a combination of both? **DAY** ☐ **NIGHT** ☐ **COMBINATION** ☐		
4. What volume (and kcals) of enteral nutrition do you typically consume over a 24 hour period?	……. mls	…… kcals
5. How many feeding sessions do you have per day? ……..		
6. How many hours do you typically infuse for over a 24 hour period?	…… hours	……. minutes
7. What flow rate do you typically use (*i.e. per feeding, what ml of formula do you provide over how many minutes*)? **0-50ml/hr** ☐ **50-100ml/hr** ☐ **100-150ml/hr** ☐ **150-200ml/hr** ☐ **>200ml/hr** ☐ **UNSURE*** ☐		
***Calculated Average Flow Rate:** ……		
8. How many full feeding sessions do you miss a day?	**0 1 2 3 4 Other**	
9. How many feeding sessions do you cut short each day?	**0 1 2 3 4 Other**	
10. Are you able to swap from your current system to Mobility+ for a minimum of two daily feeds (operator calculates this volume using	**YES** ☐	**NO** ☐

answer to Q.4 and Q.5) for a trial period of 5 -7 days, followed by 14 consecutive study days? *Note to operator: minimum device fill is 250ml *(as per precautions in IFU)*		
Operator Facing Questions		
11. Is the subject a suitable candidate for using Mobility+ based on their enteral feeding needs and alignment to the Mobility+ Flow Rate Guide (*See giving set SKU decision tree for prescribing Mobility+* **Figure 6**)	**YES** ☐	**NO** ☐

The candidates feed and flow rate needs mean the most appropriate tubing SKU to start them on during trial days is:

440mm	**700mm**	**1000mm**	**1900mm**
RED	**BLUE**	**GREEN**	**WHITE**
☐	☐	☐	☐

Appendix 3
Demographics questionnaire
(Operator asks the Participant these questions where these elements are not already captured from Electronic Medical Records)

Questions:	**Answers:**	
Are you male/female?	**Male** ☐	**Female** ☐
What is your age?	…… (years)	
What is your height (cm)?	…… cm	
What is your weight (kg)?	…… kg	
What is your diagnosis? Note: Operator selects a standard pathophysiological mechanism from list	☐ **Malignancy**	
	☐ **Mechanical Obstruction**	
	☐ **GI Dysmotility**	
	☐ **Hepato-biliary/Pancreatic**	
	☐ **Mucosal Disease**	
	☐ **Trauma/Injury**	
	☐ **Neuro-degenerative Disease**	
	☐ **Short Bowel Syndrome**	
	☐ **Functional Disorder**	
	☐ **Bariatric Surgery**	
	☐ **Congenital/Developmental**	
Are you working or studying (or both)?	**Yes, I work, study or both** ☐	**No, I neither work or study** ☐
Which type of feeding tube do you have?	**G-tube** ☐	**J-tube** ☐

Appendix 4

Participant perspectives baseline survey

Participant perspectives of *current* feeding system: Usability, mobility and ease of use

(Operator asks the Participant these questions)

During use of your current feeding system, how do you find these activities?	**Very Difficult**	**Difficult**	**Neutral**	**Easy**	**Very Easy**
Moving from one room to another room					
Going up and down stairs					
Short walk (e.g., one block)					
Long walk (e.g., several blocks)					
Travelling in car/public transport					
Moderate intensity physical activities, such as: - Moving a table - Pushing a vacuum - Bowling - Playing golf					
Other daily activities (e.g., lifting or carrying groceries, household chores)					
Ability to sleep					
Socializing with friends/family					

During use of your current feeding system, how do you find working/ studying or both? Please log as N/A if participant does neither.	**Very Difficult**	**Difficult**	**Neutral**	**Easy**	**Very Easy**	**N/A**

Note to operator: When scoring this questionnaire, assign points using the legend below. Very Difficult = 0 points, Somewhat Difficult = 1, Neutral = 2, Somewhat Easy = 3 and Very Easy = 4					
Thinking about your overall experience with your current system, how strongly do you	**Strongly Disagree**	**Some-what Disagree**	**Neutral**	**Some-what Agree**	**Strongly Agree**

agree or disagree with the following statements?					
My current system is easy to use					
My current system is easy to carry					
The noise level of my current system during use (including alarms) is acceptable					
My current system allows me to feed discreetly					
I am satisfied with the overall performance of my current system					

Note to operator: When scoring this questionnaire, assign points using the legend below. Strongly Disagree = 0 points, Somewhat Disagree = 1, Neutral = 2, Somewhat Agree = 3 and Strongly Agree = 4				
Do you experience any of the following symptoms of feed intolerance while using your current feeding system?				
Gas/Bloating?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Abdominal Pain?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Diarrhea?	☐ Yes			
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	☐ No
Constipation?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Nausea/Vomiting?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Mild ☐	Mild ☐	
Reflux?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Mild ☐	Mild ☐	

Appendix 5

QoL survey

(Operator asks the Participant these questions)

Reference: Elfadil OM, Patel A, Abdelmagid M, et al. 1117929 - Mental Health Among Enteral Feeding Patients and Caregivers: Is Home Enteral Nutrition Overwhelming? Nutrition and Metabolism Research Oral Paper Session Abstracts. ASPEN Nutrition Science & Practice Conference: March 26-29, 2022 (Seattle, WA). JPEN J Parenter Enteral Nutr. 2022 Mar;46 (S1) https://aspenjournals.onlinelibrary.wiley.com/doi/full/10.1002/jpen.2344

Rate your quality of life	Excellent	Good	Neutral	Bad	Very Bad

Appendix 6
Phone Communication check sheet – Trial days

(Operator to use this check sheet to log tubing SKU and changes)

Tubing SKU check			
Trial Day 1: SKU that participant is using:			
440mm **RED** ☐	**700mm** **BLUE** ☐	**1000mm** **GREEN** ☐	**1900mm** **WHITE** ☐
Select one:	**Stay on this SKU** ☐	**Trial _____ SKU** ☐	
Reason for changing:			
Trial Day 3: SKU that participant is using:			
440mm **RED** ☐	**700mm** **BLUE** ☐	**1000mm** **GREEN** ☐	**1900mm** **WHITE** ☐
Select one:	**Stay on this SKU** ☐	**Trial _____ SKU** ☐	
Reason for changing:			
Trial Day 5: SKU that participant is using:			
440mm **RED** ☐	**700mm** **BLUE** ☐	**1000mm** **GREEN** ☐	**1900mm** **WHITE** ☐
Select one:	**Stay on this SKU** ☐	**Trial _____ SKU** ☐	
Reason for changing:			
Have you been admitted to hospital in the last 5 days/during this trial period?	☐ Yes	☐ No	
Note to operator: Confirm you have reminded participant of the day they will begin the 14 day study period	☐ Yes	☐ No	

Appendix 7

Participant perspectives outcome survey

Participant perspectives of *Mobility+* feeding system: Usability, mobility, and ease of use, including general end of study questions

(Operator asks the Participant these questions)

During use of the Mobility+ system, how do you find these activities?	**Very Difficult**	**Difficult**	**Neutral**	**Easy**	**Very Easy**
Moving from one room to another room					
Going up and down stairs					
Short walk (e.g., one block)					
Long walk (e.g., several blocks)					
Travelling in car/public transport					
Moderate intensity physical activities, such as: - Moving a table - Pushing a vacuum - Bowling - Playing golf					
Other daily activities (e.g., lifting or carrying groceries, household chores)					
Ability to sleep					
Socializing with friends/family					

During use of the Mobility+ system, how did you find working/ studying or both? Please log N/A if participant does neither	Very Difficult	Difficult	Neutral	Easy	Very Easy	N/A

Note to operator: When scoring this questionnaire, assign points using the legend below. Very Difficult = 0 points, Somewhat Difficult = 1, Neutral = 2, Somewhat Easy = 3 and Very Easy = 4					
Thinking about your overall					

experience with the Mobility+ system, how strongly do you agree or disagree with the following statements?	**Strongly Disagree**	**Some-what Disagree**	**Neutral**	**Some-what Agree**	**Strongly Agree**
The Mobility+ system is easy to use					
The Mobility+ system is easy to carry					
The silent nature of The Mobility+ system during use is acceptable					
The Mobility+ allows me to feed discreetly					
I am satisfied with the overall performance of the Mobility+ system					
Note to operator: When scoring this questionnaire, assign points using the legend below. Strongly Disagree = 0 points, Somewhat Disagree = 1, Neutral = 2, Somewhat Agree = 3 and Strongly Agree = 4					

Do you experience any of the following symptoms of feed intolerance while on your current feeding system?				
Gas/Bloating?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Abdominal Pain?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Diarrhea?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Constipation?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Nausea/Vomiting?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Reflux?	☐ Yes			☐ No
If yes, is it mild, moderate, or severe?	Mild ☐	Moderate ☐	Severe ☐	
Have you been admitted to hospital since you last received phone communication?	☐ Yes			☐ No
General End of Study Questions:				

When answering the following questions, consider how **the last 14 days with Mobility+** have been compared to an average week of using the feeding system that you had **before you started this study**. Please try to answer based **solely on your experience with the Mobility+** in the last two weeks and not on external factors that may have positively/negatively impacted your week of using the Mobility+

How do you feel your overall Quality of Life has been during the last 2 weeks of using Mobility+?

Excellent	Good	Neutral	Bad	Very Bad
☐	☐	☐	☐	☐

How mobile have you been in your everyday activities during the last 2 weeks of using Mobility+, compared to before you started the study?

Much Better	Somewhat Better	About the Same	Somewhat Worse	Much Worse
☐	☐	☐	☐	☐

How do you rate the importance of being mobile in your everyday activities to your overall wellbeing?

Very Important	Somewhat important	Not important at all
☐	☐	☐

How strongly do you agree with the following statement? I would like to use the Mobility+ again.

Strongly Agree	Somewhat Agree	Neutral	Somewhat Disagree	Strongly Disagree
☐	☐	☐	☐	☐

If you would like to use Mobility+ again, how often would you like to use it?

Every Day	Every Week	Every Month
☐	☐	☐

Think about your overall wellbeing if you used Mobility+ for SOME/ALL of your tube feeding needs, in the long term. How would your wellbeing be then, compared to now?

Much Better	Somewhat Better	About the Same	Somewhat Worse	Much Worse
☐	☐	☐	☐	☐

Would you pay out of pocket for the Mobility+?	YES	NO
	☐	☐

How did you choose to wear the Mobility+ system?

☐ **Crossbody bag**
☐ **Handbag**
☐ **Backpack**
☐ **In clothing**
☐ **Clipped onto belt/clothing**
☐ **Other (Detail): ……**

Appendix 8

Appendix 8 - Phone communication check sheet (Study Day 7 and 14) - ***(Operator asks the Participant these questions)***

Day 7

Day 7			
Questions:		**Answers:**	
Day 7 Safety & Effectiveness Check			
Are you able to use Mobility+ to successfully and safely provide enteral feeding?		**YES** ☐	**NO** ☐
Day 7 Compliance & Calorie Intake Check			
Consider your feed intake over the last 3 days (i.e. Study day 4, 5, 6).			
Questions:		**Answers:**	
What volume of enteral nutrition did you consume on average per day (i.e. over 24 hr)?		**Volume Mobility+** ……mls	**Volume Other System** ……mls
How many hours did you typically infuse for, on average/day?		…… hours	…… minutes
How many feedings **did you intend to** take using **Mobility+,** on average / day?		**……feedings**	
How many feedings **were you able to take** using **Mobility+,** on average / day?		**……feedings**	
What was the average volume of enteral nutrition that you consumed per feeding with Mobility+?		……mls	
What time of the day did you provide feedings with Mobility+?		**Morning** ☐ **Afternoon** ☐ **Evening** ☐ **Night-time** ☐	
Operator facing question:	On average, did the participant take at least two daily feeds with Mobility+?	**YES** ☐	**NO** ☐
	If no, why not?	**……**	
Day 7 Tubing SKU check			
Study Day 7: SKU that participant is using: **440mm RED** ☐ **700mm BLUE** ☐ **1000mm GREEN** ☐ **1900mm WHITE** ☐			

Select one:	**Stay on this SKU** ☐	**Trial _____ SKU** ☐
Reason for changing:	**Intolerance** ☐ **Taking too long to feed** ☐ **Abdominal discomfort** ☐ **Unable to tolerate feed** ☐	

Day 14

Day 14 Tubing SKU Check			
What giving set tubing are you using?			
440mm RED ☐	**700mm BLUE** ☐	**1000mm GREEN** ☐	**1900mm WHITE** ☐

Day 14 Safety & Effectiveness Check		
Are you able to use Mobility+ to successfully and safely provide enteral feeding?	**YES** ☐	**NO** ☐

Day 14 Compliance & Calorie Intake Check		
Consider your feed intake over the last 3 days (i.e., Study Day 11, 12, 13).		
What volume of enteral nutrition did you consume on average per day (i.e. over 24 hr)	**Volume** .....mls	**Volume Other System** .....mls
How many hours did you typically infuse for, on average/day?	..... hours	..... minutes

How many feedings **did you intend to** take using Mobility+, on average / day?	**.....feedings**
How many feedings **were you able to take** using Mobility+, on average / day?	**.....feedings**
What was the average volume of enteral nutrition that you consumed per feeding with Mobility+?	.....mls
What time of the day did you provide feedings with Mobility+?	**Morning** ☐ **Afternoon** ☐ **Evening** ☐ **Night-time** ☐

Operator facing question:	On average, did the participant take at least two daily feeds with Mobility+?	**YES** ☐	**NO** ☐
	If no, why not?	……	

Appendix 9
Adverse event classifications

The below figures from ISO 14155:2020 highlight the process to be followed to determine if an AE or device deficiency is one of the below:

- AE
- SAE
- ADE
- SADE
- ASADE
- USADE
- Device deficiency with SADE potential
- Device deficiency without SADE potential

Table F.1 — Categories of adverse events

Adverse events	Non-device-related	Device- or investigational procedure-related	
Non-serious	Adverse event (AE)[a] (3.2)	Adverse device effect (ADE)[c] (3.1)	
Serious	Serious adverse event (SAE)[b] (3.45)	Serious adverse device effect (SADE) (3.44)	
		Anticipated	**Unanticipated**
		Anticipated serious adverse device effect (ASADE)[c] (3.1, Note 1 to entry)	Unanticipated serious adverse device effect (USADE) (3.51)

[a] Includes all categories.
[b] Includes all categories that are serious.
[c] Includes all categories that are related to the device or the investigational procedure.

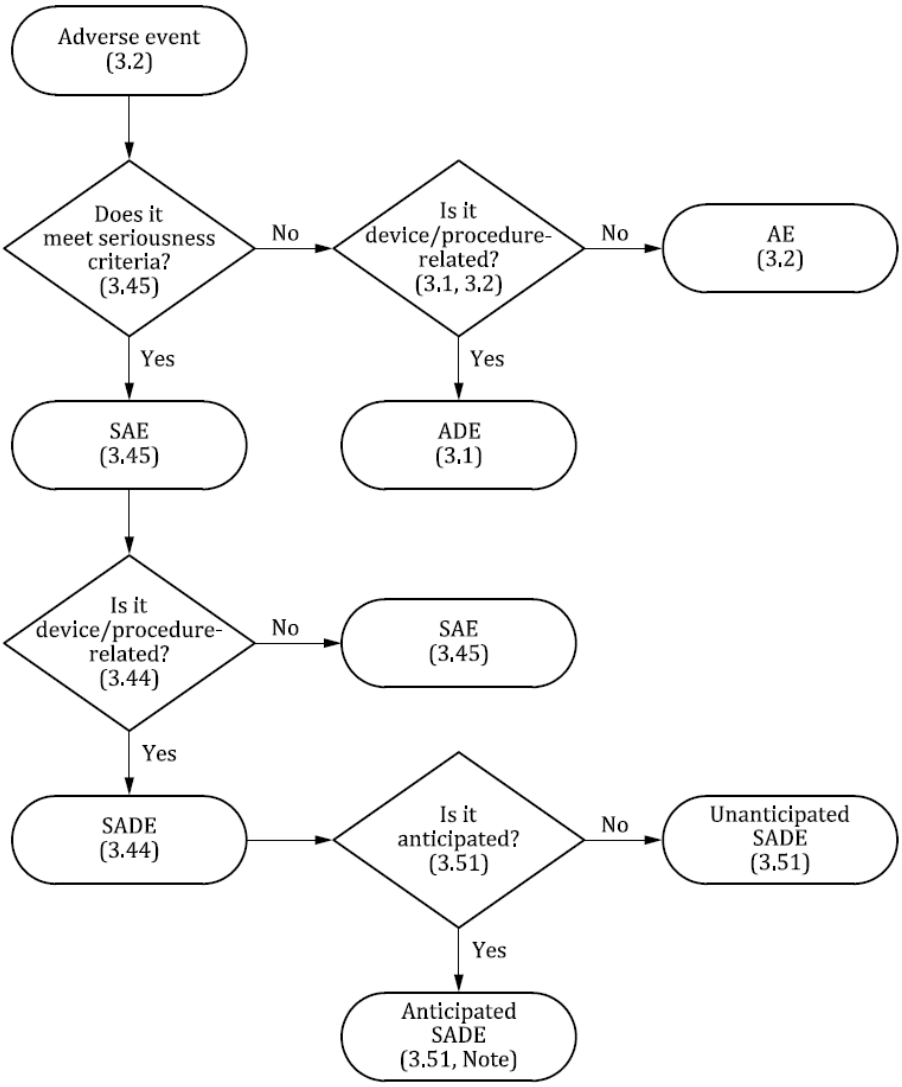

Figure F.1 — Adverse events categorization chart

The flowchart below on device deficiencies should only be used in case the device deficiency is not associated with an adverse event.

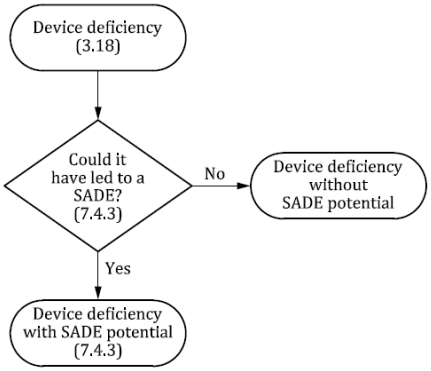

Figure F.2 — Device deficiency categorization chart

Appendix 10
Adverse Events Logging Method

The PI undertakes to report serious matters in a timely manner (within 24 hours) to the sponsor including details on the below:

- Participant ID
- Operator ID
- Incident date and time
- Incident details Incident category
- PI assessment details
- Determination
- Action
- Time PI reported assessment to Sponsor

Appendix 11
Participant Familiarization Training

This familiarization training matches typical training provided for new users of new enteral feeding systems on discharge and consists of a 1:1 demonstration of the system, including bringing attention to the labelling of the system, to minimize the potential for user errors to occur during unsupervised home use . Participants will attend a short 1:1 training session with a trained operator where they will be trained on Filling Method A (Filling from feed poured into a container), flushing, feeding, and wearing, as below. The setting will be a room in a clinical environment.

- Provide participant with Instructions for Use (IFU) booklet, a Mobility+ feeding pouch, giving set tubing, filling-set tubing, an ENFIT syringe and a cross-body bag
- Inform participant of the option to consult an instructional video, which can be accessed via smart device by scanning QR code on the IFU

Filling

- Demonstrate **Filling Method A** steps by filling a pouch with some water or formula.

Feeding

- Demonstrate 'feeding' by letting the Feeding Pouch (with giving-set attached) deliver some of its contents into a beaker.
- Explain the Feeding pouch deflates and reduces in weight as liquid feed is delivered , and the feed session is finished when no more liquid flows out of the tubing
- Advise the participant they can hold their Feeding pouch at times during feeding, to get used to feeling the pouch deflating and reducing in weight

Flushing

- Take the participant through the flushing section of the IFU

Wearing

- Show the participant the IFU guidance on how to loosely coil the giving set tubing and advise them to place the giving set tubing in the bag/clothing they choose to wear the system in (without kinking the tubing).

Hazards

- Ensure the participant is aware of the warning statement and precautions in the IFU

Notes:

- Extension set tubing may be left outside any bag/clothing the device is being worn in
- The Feeding Pouch is not to be squeezed during set up or use. The only time it is appropriate to squeeze the pouch is during flushing

Appendix 12
Participant familiarization training record

Date……..
Participant ID/……
Operator ID……..

Familiarization training was conducted and the participant was taken through filling (filling method A), feeding, flushing, and wearing, as per the Instructions for Use, and given opportunity to execute the steps necessary for them to use the Mobility+ system at home to obtain their necessary nutrition.

Participant Signature ……

Operator signature ……..

Appendix 13
Operator training record

Date……..
Operator ID……..

Operator self- training on use of Mobility+ device was conducted.

Operator was trained in execution of this study protocol (CLP001) by the sponsor Rockfield Medical Devices.

Operator signature ……..

Sponsor signature .....

Appendix 14

Evidence of Expert review

The below specially developed surveys and other study tools are the subject of expert review, which will be recorded in the format of a short report/letter.

Surveys being expertly reviewed for validation:

Participant perspectives surveys:

- Participant perspectives baseline survey (Appendix 4)
- Participant perspectives outcome survey (Appendix 7)

Tools being expertly reviewed for general suitability for use:

- Quality of Life measure (Appendix 5)
- Mobility+ flow rate guide (See LA030 attached to protocol)
- Phone communication check sheets (Trial days – Appendix 6)
- Phone communication check sheets (Study days 7 and 14 - Appendix 8)
- General end of study questions (end of Appendix 7)
- Giving set decision trees (Figures 6 and 7