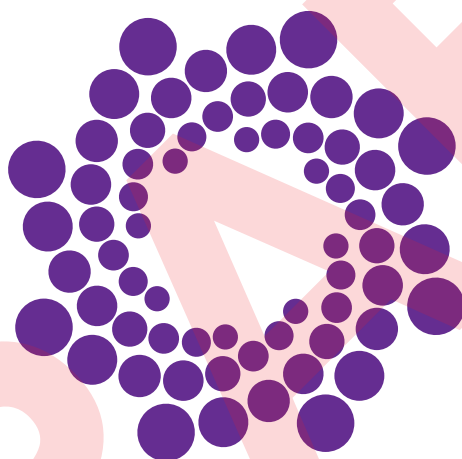




mobility[®]
enteral feeding system



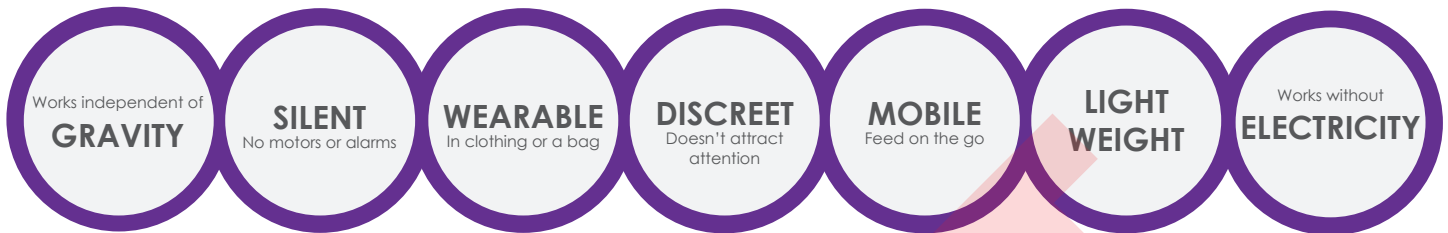
CLINICIAN GUIDE



ABOUT MOBILITY+™

The Mobility+ Enteral Feeding System (Mobility+) is mobile, lightweight and silent. It delivers enteral nutrition without the need for electricity, batteries, or gravity which allows for discreet feeding at home or on the go.

Designed for homecare patients, Mobility+ is designed to allow tube feeders greater mobility and freedom while tube feeding.



OUR STORY

Rockfield Medical Devices was founded by a tube feeder who, from his personal experience with home enteral nutrition, recognized the need for a more mobile tube feeding system. To learn more about our story and our team, visit <https://test.rockfieldmd.eu/>

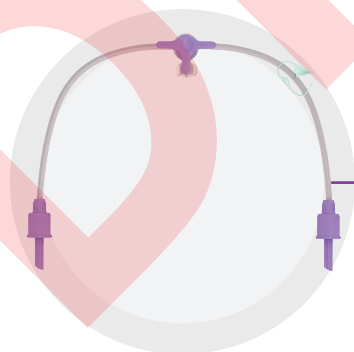


MOBILITY+ COMPONENTS



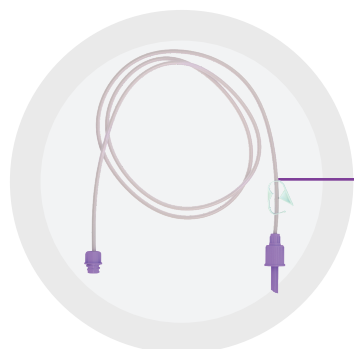
THE FEEDING POUCH

The Feeding Pouch can be filled with 250-500ml of enteral nutrition formula. Inside is an elastomeric pump. When the Feeding Pouch is filled, the internal elastomer expands (or inflates like a balloon). When the Giving Set is attached, the elastomer begins to contract (deflate), delivering formula in a controlled manner.



THE FILLING SET

The Feeding Pouch is filled with formula using the Filling Set and a 60ml ENFit® Syringe. Detailed filling instructions can be found in the Mobility+ Instructions for Use.



THE GIVING SET

The Giving Set connects directly to the feeding tube for delivery of formula using an ENFit® luer. Feeding rates differ depending on the length of Mobility+ feeding set selected. Shorter sets deliver the formula faster and longer sets deliver the formula more slowly. There are 4 different lengths available to choose from (see page 2, Mobility+ Giving Set Length).



IS MOBILITY+ A SUITABLE FIT FOR YOUR PATIENT?

Indications for Use

The Rockfield Medical Devices Mobility+ Enteral Feeding System is intended for use by individuals, over 2 years of age, who receive all or part of their daily calorific intake through gastrostomy or jejunostomy feeding tube

Intended Patient Population

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 and who receive all or part of their daily calorific intake through:

- JEJ - Surgical jejunostomy,
- PEJ - Percutaneous endoscopic jejunostomy,
- RIJ - Radiologically inserted jejunostomy,
- PEG- Percutaneous endoscopic gastrostomy and
- RIG- Radiologically inserted gastrostomy.

Additional points to consider include:

- Dexterity and hand strength
- Desire to be ambulatory/more mobile
- Desire to feed discreetly
- The patient does not require a high degree of flow rate accuracy

Contraindications

- Not for NG (Nasogastric) feeding or TPN (total parenteral nutrition).
- Not for drug/medication delivery

MOBILITY+ FLOW RATES

Before prescribing, read the information below.

Mobility+ Giving Set Length

The Mobility+ giving set is available in four different lengths which can be identified by their clamp colour as shown in Figure 1 - White (1900mm), Green (1000mm), Blue (700mm) & Red (440mm). The shortest giving set (Red) provides the fastest flow rates. The longest giving set (White) provides the slowest flow rates. Patients may need to change between the various giving sets to find the one they need to suit their flow rate requirements.

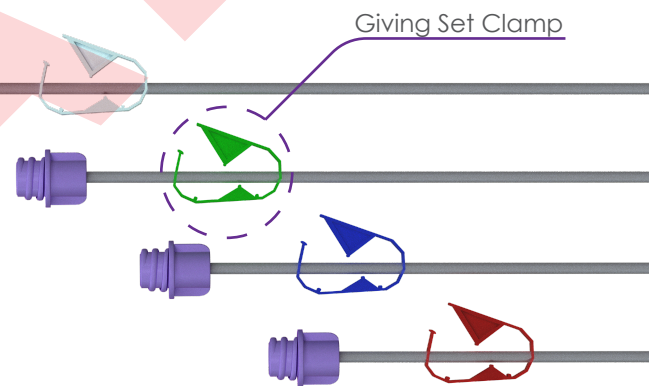


Figure 1. Giving Set Lengths

Formula Used

Each enteral nutrition formula behaves differently in Mobility+, due to differences in their composition and viscosity. In general, formulas that are of low viscosity (thin, runny or water-like consistency) flow faster through Mobility+, while formulas that are of high viscosity (thick or honey-like consistency) flow more slowly through Mobility+.

Average Flow Rate (ml/hour)

The flow of enteral nutrition formula out of Mobility+ is highest at the beginning of the feeding session, and lowest at the end of the feeding session (see Figure 2). Average flow rate (ml/hr) is calculated based on the time taken for 90% of 500g of formula to be delivered.

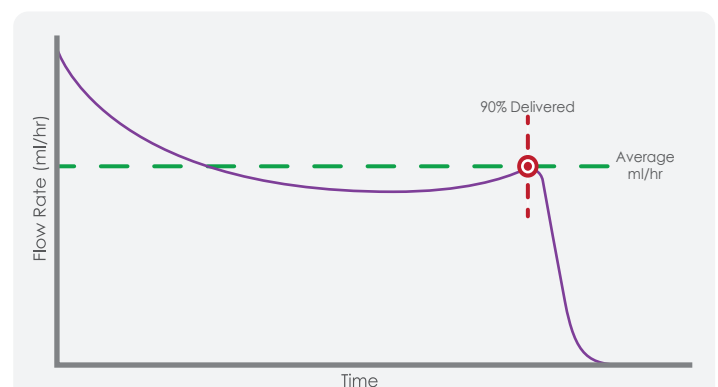


Figure 2. Mobility+ Flow Rate Curve

Flow Rate Guide (See pages 4-6)

The purpose of the Flow Rate Guide is to help shorten the trial-and-error process involved in finding the optimal Giving Set length for your patient.

The Flow Rate Guide displays Mobility+ flow rates in 11 groups (A-K), from slowest to fastest.

These groups (A-K) are for guidance purposes only. Actual flow rates may fall outside of the ranges indicated for each group due to a variety of factors (see next page).

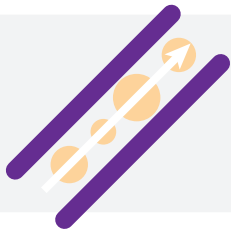


FACTORS AFFECTING FLOW RATE

For the Flow Rate Guide shown in the following pages, the Mobility+ was tested under the following controlled conditions:

- Using a single batch of each formula listed
- The formula and environmental temperature were maintained at 20-24°C (room temperature)
- The Mobility+ was positioned at stoma height
- The Mobility+ was filled with 500g of formula
- Tests were initiated immediately after filling

In everyday use conditions, several factors, listed below, may affect Mobility+ flow rates.

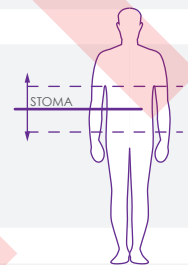


FORMULA VARIABILITY

Flow rates may be impacted by formula manufacturing variables with ingredients as well as formula temperature while feeding (as described below).

MOBILITY+ POUCH POSITIONING (HEIGHT)

If Mobility+ is positioned below stoma height, (e.g. worn in a fanny pack on the waist) flow rates may be slower. If Mobility+ is positioned above stoma height (e.g. in a backpack) flow rates may be faster. Mobility+ should not be worn greater than ± 15 centimetres above or below the stoma site.

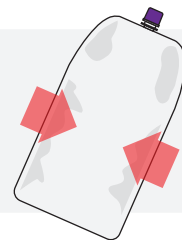


TEMPERATURE

Environmental temperatures higher than 24°C (room temperature) may result in faster flow rates, while lower temperatures may result in slower flow rates. Mobility+ should not be used in environmental temperatures above 35°C or below 15°C. Using refrigerated formula will result in slower flow rates.

EXTERNAL PRESSURE

External pressure such as squeezing or laying on Mobility+ may result in faster flow rates.

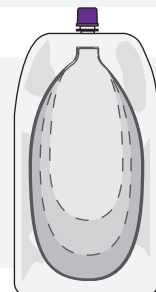


MULTIPLE USE

Mobility+ can be re-used multiple times within 24 hours once components are flushed between use (as per instructions for use). Flow rates may be slower with multiple use.

FILL VOLUME

Do not fill Mobility+ with less than its minimum fill volume of 250ml or more than its maximum fill volume of 500ml. The lower the fill volume of the Mobility+ the quicker the delivery time will be.





Mobility+ Enteral Feeding System Flow Rate Guide (EU)

The Flow Rate Guide displays Mobility+ flow rates in 11 groups (A-K), from slowest to fastest. These groupings are for guidance purposes only. Actual flow rates may fall outside of the ranges indicated for each group due to a variety of factors.

FLOW	SLOW										FAST
GROUP	A	B	C	D	E	F	G	H	I	J	K
Approx flow rate (ml/hr)	<40	41-70	71-100	101-130	131-180	181-250	251-350	351-600	601-1000	1001-1500	>1500
Approx Delivery time (hh:mm)	>12:00	12:00 - 07:00	07:00 - 05:00	05:00 - 03:45	03:45 - 02:45	02:45 - 02:00	02:00 - 01:30	01:30 - 00:45	00:45 - 00:30	00:30-00:20	<00:20
* Not suitable for use											

NESTLÉ®

GIVING SET CLAMP COLOUR	1900mm (WHITE)	1000mm (GREEN)	700mm (BLUE)	440mm (RED)
PEPTAMEN® HN	C	G	H	I
PEPTAMEN® AF	D	G	H	I
PEPTAMEN® (VANILLA)	C	E	G	H
PEPTAMEN® (NEUTRAL FLAVOUR)	F	H	I	J
PEPTAMEN® JR PHGG	H	I	J	K
PEPTAMEN® JR 1.5	F	H	I	J
PEPTAMEN® JR 0.6	C	F	G	H
PEPTAMEN® JR ADVANCE	*	B	C	E
PEPTAMEN® JR LIQUID	H	I	J	K
COMPLEAT® PEDIATRIC	G	I	I	K

ABBOTT®

GIVING SET CLAMP COLOR	1900mm (WHITE)	1000mm (GREEN)	700mm (BLUE)	440mm (RED)
JEVITY®	B	C	E	F
JEVITY® PLUS	A	C	E	F
JEVITY® 1.5	C	E	F	H



FLOW	SLOW										FAST
GROUP	A	B	C	D	E	F	G	H	I	J	K
Approx flow rate (ml/hr)	<40	41-70	71-100	101-130	131-180	181-250	251-350	351-600	601-1000	1001-1500	>1500
Approx Delivery time (hh:mm)	>12:00	12:00 - 07:00	07:00 - 05:00	05:00 - 03:45	03:45 - 02:45	02:45 - 02:00	02:00 - 01:30	01:30 - 00:45	00:45 - 00:30	00:30-00:20	<00:20

* Not suitable for use

ABBOTT®

GIVING SET CLAMP COLOUR	1900mm (WHITE)	1000mm (GREEN)	700mm (BLUE)	440mm (RED)
JEVITY® PROMOTE	A	B	C	E
JEVITY® PLUS HP	H	I	J	K
TWOCAL®	E	G	H	H
TWOCAL® BOLUS	E	G	H	I
OSMOLITE®	C	E	F	G
OSMOLITE® PLUS	C	F	G	H
OSMOLITE® HP	D	G	H	I
OSMOLITE® 1.5	D	G	H	I

FRESENIUS KABI®

GIVING SET CLAMP COLOUR	1900mm (WHITE)	1000mm (GREEN)	700mm (BLUE)	440mm (RED)
FRESUBIN® COMPLETE	E	G	H	I
FRESUBIN® ENERGY	D	F	H	H
FRESUBIN® ENERGY FIBRE	E	H	I	I
FRESUBIN® HP ENERGY	B	E	G	H
FRESUBIN® HP ENERGY FIBRE	E	G	H	I
FRESUBIN® ORIGINAL	F	H	H	J
FRESUBIN® ORIGINAL FIBRE	D	F	G	H



FLOW	SLOW										FAST
GROUP	A	B	C	D	E	F	G	H	I	J	K
Approx flow rate (ml/hr)	<40	41-70	71-100	101-130	131-180	181-250	251-350	351-600	601-1000	1001-1500	>1500
Approx Delivery time (hh:mm)	>12:00	12:00 - 07:00	07:00 - 05:00	05:00 - 03:45	03:45 - 02:45	02:45 - 02:00	02:00 - 01:30	01:30 - 00:45	00:45 - 00:30	00:30-00:20	<00:20
✱ Not suitable for use											

NUTRICIA®

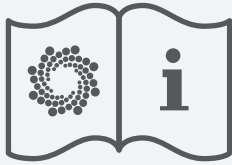
GIVING SET CLAMP COLOUR		1900mm (WHITE)	1000mm (GREEN)	700mm (BLUE)	440mm (RED)
NUTRISON® ENERGY MULTI FIBRE 1.5		E	G	H	I
NUTRISON® ENERGY FIBRE 1.5		D	F	H	H
NUTRISON® ADVANCED PROTISON 1.28		E	H	I	I
NUTRISON® PROTEIN INTENSE 1.26		B	E	G	H
NUTRISON® ADVANCED CUBISON 1.0		E	G	H	I



ONLINE RESOURCES

All resources related to Mobility+ are available to download from our website, including:

INSTRUCTIONS FOR USE



INSTRUCTIONAL VIDEO



FLOW RATE GUIDE

	1	2	3	4
1	●	●	●	●
2	●	●	●	●
3	●	●	●	●
4	●	●	●	●
5	●	●	●	●
6	●	●	●	●
7	●	●	●	●
8	●	●	●	●
9	●	●	●	●
10	●	●	●	●

To ensure you can use Mobility+ effectively, self-train on how to use the device with the instructional videos or by reading the Instructions for Use.

AVAILABLE AT THE QR CODE



For communications regarding the device, you can contact us by calling (+353) 91 763 000, by scanning the QR code or by visiting: <https://test.rockfieldmd.eu/contact>

HOW TO DEMONSTRATE THE MOBILITY+ TO USERS/CAREGIVERS

SUPPLIES NEEDED:

- Instructions for use
- Mobility+ Enteral Feeding System
- 60ml ENFit® syringe

FILLING

- Demonstrate filling method steps by filling Mobility+ with some formula or water.

FEEDING

- Demonstrate 'feeding' by letting the Feeding Pouch (with Giving Set attached) deliver some of its contents into a cup.
- Explain that the Feeding Pouch deflates and reduces in weight as formula is delivered.
- Explain that the feeding session is finished when the Feeding Pouch is deflated (no more formula flows out of the Giving Set).

FLUSHING MOBILITY+ SYSTEM

- Take the user/caregiver through the flushing section of the instructions.

WEARING

- Show the user/caregiver the guidelines on 'How to wear Mobility+' in the instructions for use booklet

HAZARDS

- Direct the user/caregiver to warning and precautions section of the Instructions for use booklet.

