

Clinical Nutrition

Short Guide



Clinical Nutrition

Introduction

B. Braun Melsungen AG is a family-owned company offering outstanding products and process-oriented services to the healthcare industry worldwide. We strive to be a strong and reliable partner; for both people and markets and to grow from our own strength. Our recipe for success is based on progress, founded on a long tradition in business for over 160 years.



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Short Guide

Clinical nutrition is of central importance for our ability to handle diseases in general, infections, surgery and trauma in particular.

The objective of nutrition therapy is improved patient outcome by

- avoiding malnutrition
- maintaining body tissue and functioning plasma protein stores
- preventing macro- and micronutrient deficiency

In recent years the range of adapted products has increased. This is a practical guide about how to support your patients with adequate nutrition using B. Braun TPN (Total Parenteral Nutrition) solutions. There is a lot more to be found on our nutrition site, www.nutrition-partner.com.



Nutritional assessment

Nutritional status can be assessed by using different methods.

Examples:

- BW – Body Weight (kg)
- H – Height (m)
- BMI – Body Mass Index = kg BW/m^2
- MUST – Malnutrition Universal Screening Tool
- SGA – Subjective Global Assessment

How to use these methods, please see p. 17-19

Estimation of nutritional status

Well nourished	Malnourished	Risk for malnutrition
Weight loss <5 % in 6 months	Weight loss >5 % in 6 months	Weight loss >10 % in 6 months
No/small loss of percutaneous fat	Moderate loss of percutaneous fat	Severe loss of percutaneous fat
Appetite satisfactory	Reduced intake food	Severe loss of muscle mass
S-Albumin >35 g/l	S-Albumin <35 g/l	S-Albumin <30 g/l, oedema

Note: Albumin can be low for other reasons than malnutrition, for example due to inflammatory influence, due to burn injury after fluid resuscitation etc.

* Total Parenteral Nutrition

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Recommended supply:

Requirements	Basal	Moderate	Severe
Fluid (ml per kg/day)	20-40 ^{a)}	20-40 ^{a)}	20-40 ^{a)}
Amino acids (g per kg/day)	1,0 ^{b)}	1,0-1,25 ^{b)}	1,5 ^{b,c,d)}
Glucose (minimal intake g/per day)	100 ^{e)}	100 ^{e)}	100 ^{e)}
Lipids g/kg/day	0,5-1,0	1,0-1,5	1,5-2,0
Total energy (kcal)	20-25 ^{a)}	20-30 ^{a)}	30-35 ^{a)}
Electrolytes, trace elements, vitamins	Enough to cover needs		

a) ASPEN in JPEN 22 (1998) 49-66

b) W. Behrendt et al., Infusionstherapie 17 (1990) 32-39

c) O. Pitkänen et al., Clinical Nutrition 10 (1991) 258-265

d) J. Larsson et al., Br. J. Surg. 77 (1990) 413-416

e) J. L. Gamble, Harvey Lectures 42 (1947) 247-273

Energy expenditure (EE) estimation/calculation

When longer periods of supportive nutrition are needed

(> 1 week), the Harris-Benedict formula should be used to calculate the basal energy needs. The actual energy expenditure will normally be higher and can be estimated by multiplying the EE with the activity/injury factor.

Formula:

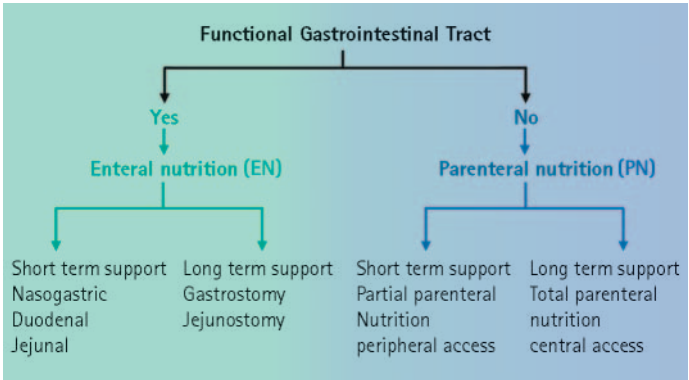
Man: $66 + 13.7 \times BW + 5 \times \text{height} - 6.8 \times \text{age}$

Woman: $655 + 9.6 \times BW + 1.8 \times \text{height} - 4.7 \times \text{age}$

Enteral or parenteral route – Strategy

Use the enteral route if possible. Register and document the energy intake. Prescribe energy meals for the individual patient. Take note of all possible non-nutrition dependant energy sources, for example Propofol-®Lipuro.

Note: Intensive care patients often have gut dysfunction. If this is the case, use the parenteral route.



Guideline:

If the oral intake is insufficient:

1. Adjust the diet. Prescribe parenteral or enteral supplement.

If this does not work:

2. Give enteral nutrition via tube, with free supply orally if possible. Be observant of the energy goal, adjusting the enteral nutrition according to the patient's basic disease and actual need.

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If the energy goal is still not reached, despite enteral nutrition via tube:

3. Give parenteral nutrition up to the goal. Choose NuTRIflex® Lipid peri.

If enteral nutrition is contraindicated, or if it does not work optimally for other reasons:

4. Give total parenteral nutrition - TPN! Choose NuTRIflex® Lipid. To select an appropriate version, please see page 15.



Parenteral nutrition

No patient should have insufficient intake of energy and substrates in modern hospital care treatment. The parenteral route can be used successfully when other alternatives of nourishment are difficult or impossible. Nowadays, fully adequate nutrition can be performed by giving total parenteral nutrition (TPN). The regimen can be individualized to cover different needs. In the short term we can compensate for disturbances in the longer term we can maintain nutritional balance.

Practical approach to estimate individual needs

Early intervention is important to prevent malnutrition. In the already malnourished patient nutritional support is used to replete body tissues and restore organ function.

1. A well nourished patient initially should get glucose with electrolytes postoperatively, minimum 100 - 150 g/day (obligatory daily requirement).

Recommended product: Glucose 10% with electrolytes.

If oral or enteral intake of more than 2-3 days is expected as non-viable, start TPN immediately.

2. An undernourished or severely stressed patient should get total parenteral nutrition as soon as his condition allows, i.e. when dehydration and circulatory disturbances are revoked and supplied substances can be taken up by the body cells.

3. Malnourished/starving patients should get careful nutrition as early as possible under monitoring of electrolyte balance (special care with potassium, phosphate, magnesium. Depleted patients need substantially more than normal patients; they become anabolic with nutrition and build up intracellular mass. If it is possible to measure energy balance, start with 50 % of estimated/calculated needs. Do not advance too rapidly due to risk of re-feeding syndrome!

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Venous access

- For short term parenteral nutrition (PN) use the peripheral route. Give amino acids, glucose and fat simultaneously. Glucose solutions >10 % are not possible, because of hyperosmolarity.

*Recommended products: NuTRIflex® Lipid peri
Vasofix®*

- For longer periods of PN a CVC-Central Venous Catheter is advised.

*Recommended products: NuTRIflex® Lipid peri or plus
Certofix®, Cavafix®*

- For long term treatment, for example home-TPN, use an implantable port system.

*Recommended product: Celsite® ST301 H subcutaneous port
with high flow catheter.*

See also our Internet site www.cvc-partner.com



Considerations during intensive care, kidney failure, liver failure

Nutrition to the intensive care patient

Intensive care patients are a very heterogeneous group as far as underlying disease, age and nutrition status is concerned. Therefore, the treatment should focus on the organ systems and how to avoid side effects by careful monitoring of the patient.

Examples:

- Measure energy release by indirect calorimetry or estimate according to Harris-Benedict formula.
- Try to reach the energy goal by using TPN or a combination of PN and EN.
- Give all components continuously over 18-24 hours.
- Monitor carefully blood glucose (B-glucose), Serum-urea (S-urea) and triglycerides.
- If B-glucose > 6 mmol/l: give insulin. To reduce glucose load, use LGN - Low Glucose Nutrition with NuTRIflex® lipid peri.
- If triglycerides > 5 mmol/l: use Lipoplus®*, Lipofundin® MCT/LCT** and/or reduce infusion rate.
- If S-urea > 20 mmol/l and increasing trend, reduce amino acid infusion rate. If > 40 mmol/l, use hemofiltration/hemodialysis.
- Use balanced lipid emulsions such as Lipoplus®*, Lipofundin® MCT/LCT**.

Nutrition during acute renal failure

Typical metabolic complications are for example:

- Increased catabolism
- Decreased glucose tolerance
- Slow lipid elimination

* additional trade name: Lipidem®

** additional trade names: Medialipide®, Vasolipid®

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- Disturbed protein metabolism
- Risk for fluid retention
- Risk for electrolyte disturbance

Try to achieve a balanced, complete nutrition. Use dialysis to manage fluid and electrolyte balance and to render adequate nutrition possible. Measure energy expenditure (EE) by indirect calorimetry (if available). If this is not possible, calculate energy according to Harris-Benedict's formula + 25%. Use a balanced amino acid solution and calculate ca 1,25 g of amino acids (AA)/kg per day. S-urea should be >30 mmol/l.

Product proposal: Nutriflex® special or NuTRIflex® Lipid special.

Nutrition during acute liver failure

Typical complications are for example:

- Increased catabolism
- Decreased glucose tolerance
- Insulin resistance
- Accelerated lipid elimination
- Disturbed protein metabolism

Acute liver diseases, hepatitis and intoxication, can produce an increased risk for hypoglycemia. Measure energy expenditure (EE) by indirect calorimetry (if available). If this is not possible, calculate energy according to Harris-Benedict's formula + 25%. Use a balanced amino acid solution and calculate ca 1.25 g of AA/kg per day.

Product proposal: Aminoplasmal® Hepa.

During acute failure (incipient liver coma) the nutrition is basically carbohydrates given parenterally.

Complications – trouble shooting

Complications	Possible cause	Action
Tachycardia, fever, chest pain, confusion	Infection, re-feeding	Exclude infection reduce infusion rate
Hyperglycemia > 8 mmol/l	Too high glucose infusion, insulin resistance	Reduce glucose load, consider insulin
Increased urea	Low energy supply or high amino acid supply or impaired kidney function	Reduce amino acid load, increase energy supply
Hypertriglyceridemia, (> 5 mmol 8 h after infusion)	Low ability to break down lipids	Reduce lipid load, use MCT/LCT emulsion
Hypercapnia (pCO ₂ > 6,5)	Impaired ventilation capacity, too high glucose rate?	
Blood vessel pain	Thrombophlebitis or hyperosmolar solution or large potassium addition	Change catheter site, consider a CVC
Obstruction of CVC	Precipitation, incompatibilities, thrombus, fat deposition	Irrigate catheter with 45% ethanol or similiar
Sepsis	Bacterial contamination	Remove catheter, cultivate from peripheral blood or catheter, give antibiotics.

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Follow-up

- *Fluid balance:* To be monitored with all patients. Do not accept rapid weight gains! Try to maintain fluid balance, or keep it slightly negative. Give diuretics if necessary.
- *Body weight:* Should be monitored daily with intensive care patients, 2-4 times/week for others. Rapid changes are correlated to fluid balance.
- *Protein analysis:* Can be of value to follow some plasma proteins during long term treatment (for example S-prealbumin, S-transferrin).
- *B-glucose and S-urea:* Hyperglycemia should be avoided! If B-glucose is high you should first consider to lower supply of glucose. If supply is adequate, consider insulin therapy.
- If the urea value is increasing assess energy supply. If supply is adequate, assess kidney function. With normal kidney function and adequate energy intake the amino acid supply should be adjusted until S-urea is normalised.
- *Temperature:* Increased body temperature can be a sign of infection. If this is excluded the energy intake should be assessed (thermogenesis does not increase body temperature).
- *Lung function:* High supply of glucose leads to ventilatory stress. A large amount of carbon dioxide must be ventilated per energy unit. Use lipid as alternative substrate.
- *Liver function:* Parenteral nutrition can cause an increase in S-Alk phosphatase and S-bilirubin, particularly in combination with intestine rest. Liver function values should be checked once a week during PN.

The NuTRIflex® System

The NuTRIflex® system is adapted for nutritional support to patients with various diseases and requirements. Our products have got specific pharmacological properties such as the amino acid profile, MCT/LCT lipid emulsion, carbohydrate/lipid ratios, glucose concentrations, anti-oxidants, electrolytes.

In order to fulfil the nutritional goal there are several options. To reduce work load and costs choose NuTRIflex® Lipid solutions in three-chamber bags, which include the MCT/LCT lipid emulsion.

For more flexibility choose a combination of Nutriflex® two-chamber bag with Lipoplus®*, Lipofundin® MCT/LCT** emulsions, and/or in combination with Propofol-®Lipuro.

Guide to select suitable NuTRIflex® Lipid version

BW kg	Basal requirement (ml)	Increased requirement (ml)	Increased requirement with fluid restriction (ml)
45	peri 1250	plus 1875	special 1250
50	peri 1875	plus 1875	special 1250
55	peri 1875	plus 1875	special 1250
60	peri 1875	plus 1875	special 1250
65	peri 1875	plus 2500	special 1875
70	peri 2500	plus 2500	special 1875
75	peri 2500	plus 2500	special 1875
80	peri 2500	plus 2500	special 1875

* additional trade name: Lipidem®

** additional trade names: Medialipide®, Vasolipid®

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Appendix 1:

Table of content NuTRiflex® Lipid

NuTRiflex® Lipid 3-chamber bag									
	peri			plus			special		
Volume ml	1250	1875	2500	1250	1875	2500	1250	1875	2500
Amino acids g	40	60	80	48	72	96	72	108	144
Nitrogen g	5,7	8,6	11,4	7	10	14	10	15	20
Glucose g	80	120	160	150	225	300	180	270	360
Lipids g	50	75	100	50	75	100	50	75	100
Total energy kcal	955	1435	1910	1265	1900	2530	1475	2215	2950
Osmolarity mOsm/l	840	840	840	1215	1215	1215	1545	1545	1545
Electrolytes mmol									
Sodium	50	75	100	50	75	100	67	100,5	134
Potassium	30	45	60	35	52,5	70	47	70,5	94
Calcium	3	4,5	6	4	6	8	5,3	8	10,6
Magnesium	3	4,5	6	4	6	8	5,3	8	10,6
Phosphate *)	7,5	11,3	15	15	22,5	30	20	30	40
Chloride	48	72	96	45	67,5	90	60	90	120
Acetate	40	60	80	45	67,5	90	60	90	120
Zinc	0,03	0,045	0,06	0,03	0,045	0,06	0,04	0,06	0,08
Versions "plus" and "special" are available w/o electrolytes. For additives, see max. content.									
*) Phosphate from lipid emulsion not included.									
Max additives mmol									
Sodium+potassium	160	240	320	155	232,5	310	133	199,5	266
Calcium	7	10,5	14	6	9	12	4,7	7	9,4
Magnesium	7	10,5	14	6	9	12	4,7	7	9,4
Phosphate (organic)	20	30	40	20	30	40	20	30	40
Max content mmol									
Sodium+potassium	240	360	480	240	360	480	247	370,5	494
Calcium	10	15	20	10	15	20	10	15	20
Magnesium	10	15	20	10	15	20	10	15	20
Phosphate	27,5	41,25	55	35	52,5	70	40	60	80
Other additives									
Tracutil® trace elements ml	10	10	10	10	10	10	10	10	10

*) Vitamins and trace elements should be added just prior to use! See manufacturer's recommendation

Storage after mixing: Store at 2-8 °C for at least 4 days + 48 hours at max 25 °C.

Dosage: peri and plus: max 40 ml/kg BW/d special: max 35 ml/kg BW/d

Note: NuTRiflex® plus and special are also available without electrolytes (country specific).

*) Phosphate from lipid emulsion not included.

Appendix 2:
Body Mass Index

$$BMI = \frac{\text{Bodyweight (kg)}}{(\text{Height in m})^2}$$

Weight (kg)	Overweight																												Ideal weight
	43	42	41	40	39	38	37	36	35	35	34	33	33	32	32	31	31	30	30	29	28	28	27	27	26	26			
100	43	42	41	40	39	38	37	36	35	35	34	33	33	32	32	31	31	30	30	29	28	28	27	27	26	26			
99	43	42	41	40	39	38	37	36	35	34	33	33	32	32	31	31	30	29	29	28	28	27	27	26	26	25			
98	42	41	40	39	38	37	36	35	34	34	33	32	32	31	30	30	29	28	28	27	27	26	26	25	25	25			
97	42	41	40	39	38	37	36	35	34	34	33	32	32	31	30	29	29	28	28	27	27	26	26	25	25	25			
96	42	40	39	38	38	37	36	35	34	33	32	32	31	30	30	29	28	28	27	27	26	26	25	25	24	24			
95	41	40	39	38	37	36	35	34	34	33	32	31	31	30	29	29	28	27	27	26	26	25	25	25	24	24			
94	41	40	39	38	37	36	35	34	33	33	32	31	30	30	29	28	28	27	27	26	26	25	25	24	24	24			
93	40	39	38	37	36	35	35	34	33	32	31	31	30	29	29	28	28	27	27	26	26	25	25	24	24	24			
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91	39	38	37	36	36	35	34	33	32	31	31	30	29	29	28	27	27	26	26	25	25	25	24	24	24	23			
90	39	38	37	36	35	34	33	33	32	31	30	30	29	28	28	27	27	26	25	25	25	24	24	23	23	23			
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65	28	27	27	26	25	25	24	24	23	22	22	22	21	21	21	20	20	19	19	19	18	18	18	17	17	17			
64	28	27	26	26	25	24	24	23	23	22	22	22	21	21	20	20	19	19	19	18	18	18	17	17	17	16			
63	27	27	26	25	25	24	23	23	22	22	22	21	21	20	20	19	19	19	19	18	18	17	17	17	16	16			
62	27	26	25	25	24	24	23	23	22	22	22	21	21	20	20	19	19	18	18	18	17	17	17	16	16	16			
61	26	26	25	24	24	23	23	22	22	22	21	21	20	20	19	19	18	18	18	17	17	17	16	16	16	16			
60	26	25	25	24	23	23	22	22	22	21	21	20	20	19	19	19	18	18	17	17	17	16	16	16	16	15			
59	26	25	24	24	23	22	22	22	21	21	20	20	19	19	19	18	18	17	17	17	16	16	16	15	15	15			
58	25	24	24	23	23	22	22	22	21	21	20	20	19	19	18	18	18	17	17	16	16	16	15	15	15	15			
57	25	24	23	23	22	22	21	21	20	20	19	19	19	18	18	18	17	17	16	16	16	15	15	15	15	15			
56	24	24	23	22	22	22	21	21	20	20	19	19	18	18	18	17	17	17	16	16	16	15	15	15	15	14			
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52	23	22	21	21	20	20	19	19	18	18	18	17	17	16	16	16	16	15	15	15	14	14	14	14	14	13			
51	22	22	21	20	20	19	19	19	18	18	17	17	16	16	16	15	15	15	15	14	14	14	14	14	13	13			
50	22	21	21	20	20	19	19	18	18	17	17	17	16	16	16	15	15	15	14	14	14	14	13	13	13	13			

1.52 1.54 1.56 1.58 1.60 1.62 1.64 1.66 1.68 1.70 1.72 1.74 1.76 1.78 1.80 1.82 1.84 1.86 1.88 1.90 1.92 1.94 1.96 1.98

Height (m)

Appendix 3:

MUST – Malnutrition Universal Screening Tool

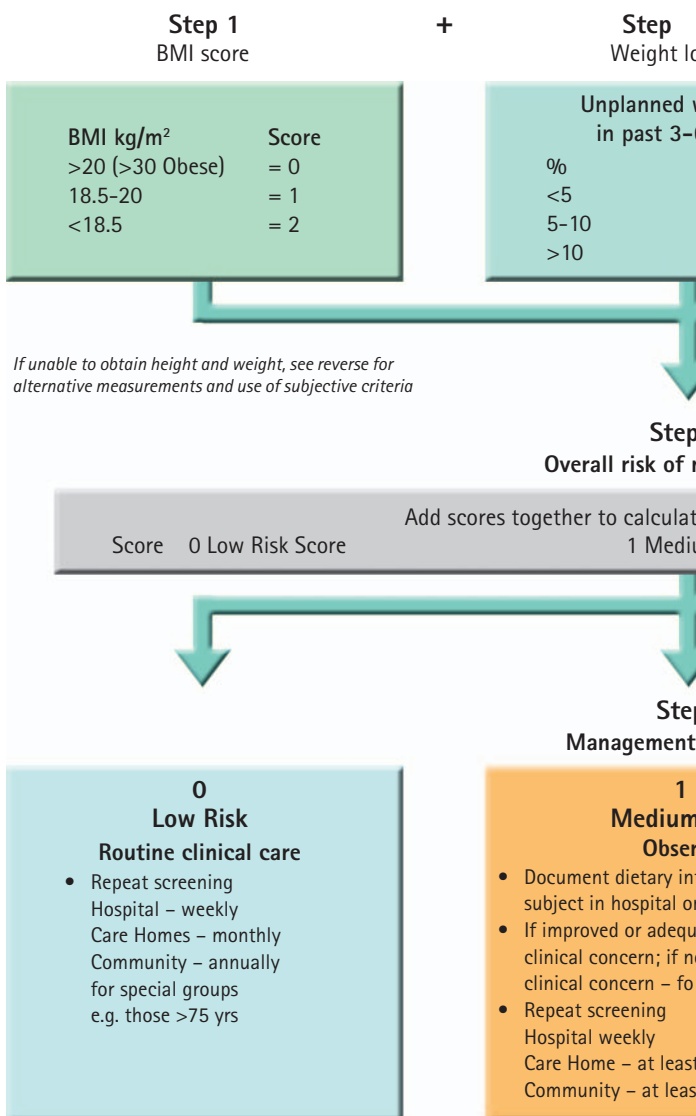
- Step 1.** Measure height and weight to get a BMI score using chart (page 17).
- Step 2.** Note percentage unplanned weight loss and score using tables provided.
- Step 3.** Establish acute disease effect and score.
- Step 4.** Add scores from steps 1, 2, and 3 together to obtain overall risk of malnutrition.
- Step 5.** Use management guidelines and/or local policy to develop care plan.

For further information please see www.bapen.org.uk



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Malnutrition Universal S



Screening Tool (MUST)

Step 2
Loss score

Weight loss
6 months
Score
= 0
= 1
= 2

+

Step 3
Acute disease effect score

If patient is acutely ill and there has been or is likely to be no nutritional intake for >5 days
Score 2

Step 4
Malnutrition

Overall risk of malnutrition
Low risk

Score 2 or more High Risk

Step 5
Guidelines

Low Risk
Guidelines

Intake for 3 days if
in care home
adequate intake – little
no improvement –
follow local policy

Review monthly
Review every 2-3 months

**2 or more
High Risk
Treat***

- Refer to dietitian, Nutritional Support Team or implement local policy
- Improve and increase overall nutritional intake
- Monitor and review care plan
Hospital – weekly
Care Home – monthly
Community – monthly

* Unless detrimental or no benefit is expected from nutritional support e.g. imminent death.

Appendix 4:

SGA – Subjective Global Assessment of Nutritional Status

Anamnesia

Weight change during the last 6 months

- Reduced
- No change
- Increased

Lost weight in kg _____

Lost weight in % _____

Weight change during the last 2 weeks

- Reduced
- No change
- Increased

Change of nutritional intake (compared to normal)

- Yes
- No

Change during no. of weeks _____

Type of change:

- Suboptimal, firm food consistency
- Good liquid diet
- Hypocaloric liquid diet
- Starvation
- Increased intake

Gastrointestinal symptoms (remaining after >2 weeks)

- Nausea
- Vomiting
- Loss of appetite
- Diarrhea

Physical capacity

- Unchanged
- Reduced
- Increased

Reduced functional capacity during no. of weeks _____

Type of reduced functional capacity:

- Manages less than normal
- Ambulatory, but lack of strength
- In bed

Physical examination

Specify for each sign:

0 = normal, 1 = light, 2 = moderate, 3 = serious

- Loss of subcutaneous fat (triceps, chest)
- Loss of muscle mass (quadriceps femoris, deltoideus)
- Ankle edema
- Sacral edema
- Ascites

SGA

- A. Well nourished
- B. Malnourished
- C. Severely malnourished

SGA - Subjective Global Assessment of Nutritional Status, A. S. Detsky et al. (1987)

Short Guide

Appendix 5:

FAQ – NuTRIflex® Lipid

About the NuTRIflex® Lipid concept

Q: What does it mean, peri, plus, special?

A: The names refer to the concentration. „peri“ can be infused into a peripheral vein, „plus“ and „special“ must be administered via a CVC. „Special“ is a highly concentrated version indicated for fluid-restricted patients and/or patients with severe metabolic stress.

Q: What is the content of the different chambers?

A: The lower chamber contains amino acids and electrolytes, the upper left chamber contains glucose, phosphate and zinc, and the upper right chamber lipids.

About the bag design

Q: Why is the NuTRIflex® Lipid bag designed with one lower and two upper chambers?

A: This feature allows for a mixture of the lipid-free compartments, and for visual inspection while additions are made. Before admixture of the lipid check aqueous solution.

Q: What is the maximum volume which can be added to the NuTRIflex® Lipid bag?

A: The total volume after additives have been made can be up to 4.000 ml.

About the bag material

Q: The bag is relatively stiff. Why?

A: Amino acids need good protection from oxygen. The plastic foil has got superior characteristics which is a guarantee for high quality during the entire shelf life.

Q: What kind of plastic material is used for the bag?

A: Co-extruded three-layer film. Inner (binding) layer polypropylene, middle layer polypropylene, outer layer polyamid.

Q: What is the small piece in the space between inner and outer bag?

A: An oxygen absorber. It protects the solutions from oxidation.

Q: Is there any PVC or latex in the bag?

A: No.

Q: Where and how do you dispose of the bag?

A: Incineration of the bag produces CO₂ and water.

About additives

Q: Can you add vitamins and trace elements? Sodium, potassium, phosphate, magnesium?

A: Yes. For more information on additives, please contact your local B. Braun subsidiary.

About mixing

Q: In which order should you mix the different chambers?

A. Mixing sequence without additives:

1. Start by pressing the upper left chamber to mix with the lower chamber.
2. Press the lipid-containing chamber the last. Make this sequence your standard routine. Should you do it the other way around the mixture can be used anyway.

B. Mixing sequence with additives:

1. Start by pressing the upper left chamber (glucose) to mix with the lower chamber (amino acid).

Short Guide

2. Add electrolytes and trace elements via the additive port. Add calcium (as calcium gluconate) the last. Make sure the solution is clear.
3. Finally, open the peel seal of the lipid chamber. Lipid-soluble vitamins can now be added.

Q: For how long can you store the bag?

- A. With overwrap at room temperature: 2 years.
- B. Without overwrap at room temperature: 48 hours protected from light.
- C. After mixing the chambers: Cold store at 2 - 8°C for a minimum of 4 days + 48 hours at 25°C.
- D. After addition of supplements: For immediate use. Infusion should be finished within 48 hours*). For pharmacy compounding, see E below.
- E. Pharmacy compounding: After addition of supplements under aseptic conditions, i.e. using laminar flow hood and validated methods, tested regimens**) can be stored at 2 - 8°C for a minimum of 4 days + 48 hours at 25°C in terms of physico-chemical stability.

Q: For how long can you store a bag with over wrap without light protection?

- A: The bag should be protected from light, but a few weeks in daylight at ward level is acceptable.

Infusion rate

Q: How fast can you infuse NuTRiflex® Lipid?

- A: The maximum infusion rate is 40 ml/kg BW ("special" 35 ml/kg BW). For a patient weighing 70 kg this corresponds to 175 ml/h ("special" 119 ml/h).

*) In some countries 24 hours. Please see local guideline.

**) Please contact your local B. Braun office for tested regimens.

Product Description

Clinical Nutrition

NuTRiflex® Lipid

Composition

NuTRiflex® Lipid (mixed and ready for use 1250 ml)

Active ingredients

	NuTRiflex® Lipid peri	NuTRiflex® Lipid plus	NuTRiflex® Lipid plus without electrolytes	NuTRiflex® Lipid special	NuTRiflex® Lipid special without electrolytes
Isoleucine	2.34 g	2.82 g	2.82 g	4.105 g	4.10 g
Leucine	3.13 g	3.76 g	3.76 g	5.48 g	5.48 g
Lysinehydrate	-	-	3.065 g	-	4.47 g
△ Lysine	-	-	2.73 g	-	3.98 g
Lysine hydro- chloride	2.84 g	3.41 g	-	4.975 g	-
△ Lysine	2.26 g	2.73 g	-	3.98 g	-
Methionine	1.96 g	2.35 g	2.35 g	3.42 g	3.42 g
Phenylalanine	3.51 g	4.21 g	4.21 g	6.145 g	6.145 g
Threonine	1.82 g	2.18 g	2.18 g	3.175 g	3.175 g
Tryptophan	0.57 g	0.68 g	0.68 g	1.00 g	1.00 g
Valine	2.60 g	3.12 g	3.12 g	4.505 g	4.505 g
Arginine	2.70 g	3.24 g	3.24 g	4.725 g	4.725 g
Histidine	1.69 g	2.03 g	-	2.96 g	-
hydrochloride monohydrate					
△ Histidine	1.25 g	1.50 g	1.50 g	2.19 g	2.19 g
Alanine	4.85 g	5.82 g	5.82 g	8.49 g	8.49 g
Aspartic acid	1.50 g	1.80 g	1.80 g	2.625 g	2.625 g
Glutamic acid	3.50 g	4.21 g	4.21 g	6.135 g	6.135 g
Glycine	1.65 g	1.98 g	1.98 g	2.89 g	2.89 g
(△ aminoacetic acid)					
Proline	3.40 g	4.08 g	4.08 g	5.95 g	5.95 g
Serine	3.00 g	3.60 g	3.60 g	5.25 g	5.25 g
Glucose mono- hydrate	88.0 g	165.0 g	165.0 g	198.0 g	198.0 g
△ Anhydrous glucose	80.0 g	150.0 g	150.0 g	180.0 g	180.0 g
Soya bean oil	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g
Medium chain triglycerides	25.0 g	25.0 g	25.0 g	25.0 g	25.0 g
Sodium dihydrogen phosphate dihydrate	1.170 g	2.34 g	-	3.120 g	-
Sodium hydroxide	0.800 g	0.976 g	-	1.464 g	-
Sodium chloride	1.081 g	0.503 g	-	0.473 g	-
Sodium ace- tate trihydrate	0.544 g	0.277 g	-	0.313 g	-
Potassium acetate	2.943 g	3.434 g	-	4.611 g	-
Magnesium acetate tetra- hydrate	0.644 g	0.858 g	-	1.137 g	-
Calcium chlo- ride dihydrate	0.441 g	0.588 g	-	0.779 g	-
Zinc acetate di-hydrate	6.6 mg	6.58 mg	-	8.78 mg	-
Total amino acids	40 g	48 g	48 g	70 g	70 g
Total nitrogen	5.7 g	6.8 g	6.8 g	10 g	10 g
Total glucose	80 g	150 g	150 g	180 g	180 g
Total lipids	50 g	50 g	50 g	50 g	50 g
Total energy (KJ/Kcal)	4000/955	5300/1265	5300/1265	6175/1475	6175/1475
Non-Protein energy (KJ/Kcal)	3330/795	4500/1075	4500/1075	5005/1195	5005/1195
Osmolality (mOsm/kg)	920	1540	1350	2090	1840
Osmolarity (theoret.) (mOsm/l)	840	1215	1055	1545	1330

Product Description

	NuTRIflex® Lipid peri	NuTRIflex® Lipid plus	NuTRIflex® Lipid plus without electrolytes	NuTRIflex® Lipid special	NuTRIflex® Lipid special without electrolytes
Electrolytes:	mmol	mmol	–	mmol	–
Sodium	50	50	–	67	–
Potassium	30	35	–	47	–
Calcium	3.0	4.0	–	5.3	–
Magnesium	3.0	4.0	–	5.3	–
Zinc	0.03	0.03	–	0.04	–
Chloride	48	45	–	60	–
Phosphate	7.5	15	–	20	–
Acetate	40	45	–	60	–

Indications

When oral or enteral feeding is not possible, insufficient or contraindicated.

Contraindications

Acute shock, acute phase of myocardial and cerebral infarction, severe disorders of blood coagulation, acute thrombo-embolism or fat embolism, irreversible liver damage, intrahepatic cholestasis, severe uraemia when dialysis facilities are not available, disorders of lipid metabolism such as pathological hyperlipaemia and conditions associated with triglyceride accumulation during parenteral nutrition, inborn errors of amino acid metabolism, untreated or complicated diabetes mellitus, especially in the presence of coma related to keto-acidosis or diabetic precoma.

These infusions should not be given to neonates and infants up to the age of 24 months.

Precautions

Should be administered with caution to patients with cardiac or renal dysfunction. Disorders of the fluid, electrolyte, and acid-base balance, e. g., overhydration, hyperkalaemia, acidosis, should be corrected before administration. Too rapid infusion can cause fluid overloading resulting in overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity.

Give with caution in conditions of impaired lipid metabolism as in renal insufficiency, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (if hypertriglyceridaemic), sepsis and in conditions of altered amino acid metabolism.

As with other solutions containing glucose, administration of NuTRIflex® Lipid formulations may lead to hyperglycaemia. Blood glucose levels should be monitored and the rate of infusion adjusted or insulin should be administered if hyperglycaemia occurs.

The patient's capacity to eliminate the infused fat from the circulation should be monitored. Especially where the product is administered for extended periods of time, the patient's haemogram, blood coagulation, liver function, and platelet count should be regularly monitored.

In patients suspected to have disorders of fat metabolism, fasting lipaemia should be excluded. In the case of fasting hypertriglyceridaemia the administration of fat is contraindicated. Likewise, hypertriglyceridaemia 12 hours after fat infusion indicates disorders of fat metabolism.

Fluid, electrolyte, and acid-base balance should be monitored.

As with all parenteral solutions administered through a peripheral/central venous catheter, strict aseptic precautions should be taken. Care should be taken to avoid complications of catheterisation including air embolism and venous thrombosis.

Undesirable effects

Undesirable effects related to the components of NuTRIflex® Lipid peri, NuTRIflex® Lipid plus, NuTRIflex® Lipid plus without electrolytes, NuTRIflex® Lipid special and NuTRIflex® Lipid special without electrolytes are rare. Those that do occur are usually reversible and subside when therapy is discontinued.

Nausea or vomiting may occasionally occur. In the event of a forced infusion an osmotic diuresis might occur as a result of the high osmolality.

During infusion in very rare cases the amino acids might cause hyperazotaemia and acidosis.

Immediate (acute) reactions related to the lipid are dyspnoea, cyanosis, allergic reactions, hyperlipaemia, hypercoagulability of the blood, nausea, vomiting, headache, flushing, hyperthermia, sweating, chills, sleepiness, chest and back pain. The infusion should be stopped in these cases. The infusion can be resumed after the disappearance of the symptoms and/or the elevated serum triglyceride levels with reduced dose and/or reduced infusion rate. Close monitoring of the patient's general condition and his/her plasma triglyceride levels is recommended.

Subject to medical prescription.

B. Braun Melsungen AG
D-34209 Melsungen

Lipofundin® MCT/LCT**Composition**

1000 ml emulsion contain

	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%
Soybean oil	50.0 g	100.0 g
Medium-chain Triglycerides	50.0 g	100.0 g
Glycerol, Egg Lecithin, all-rac- α -tocopherol, sodium oleate, water for injections		
Content of essential fatty acids:		
Linoleic acid	24.0 - 29.0 g/l	48.0 - 58.0 g/l
α -Linolenic acid	2.5 - 5.5 g/l	5.0 - 11.0 g/l
Caloric value:	4280 kJ/l = 1022 kcal/l	7990 kJ/l = 1908 kcal/l
Theoretical osmolarity	345 mOsm/l	380 mOsm/l
Titration acidity or alkalinity (to pH 7.4)	< 0.5 mmol/l	< 0.5 mmol/l
pH:	6.5-8.8	6.5-8.5

Pharmaceutical form

Emulsion for infusion

Pharmaco-therapeutic group

Fat emulsion for calorie supply and supply of essential fatty acids

Indications

Calorie supply including a readily metabolisable fat component (MCT); Supply of essential fatty acids and fluid in the setting of total parenteral nutrition

Contraindications

Lipofundin® MCT/LCT must not be administered in the following conditions:

Severe blood coagulation disorders, states of shock and collapse, acute thrombo-embolism, fat embolism, severe septicaemia accompanied by acidosis and hypoxia, acute phases of myocardial infarction and stroke, keto-acidotic coma, decompensated diabetic metabolism or unstable metabolism.

The administration of Lipofundin® MCT/LCT is also contra-indicated if serum triglycerides accumulate in the following conditions:

Disorders of lipid metabolism, liver diseases, disorders of the reticulo-endothelial system, haemorrhagic necrotising pancreatitis.

General contra-indications for parenteral nutrition:

Acidoses of various origin, uncorrected disturbances of the electrolyte and fluid balances (such as hypotonic dehydration, hypokalaemia, hyperhydration), intrahepatic cholestasis.

Special warnings and precautions for use

Hypersensitivity reactions to one of the ingredients of Lipofundin® MCT/LCT, (e.g. traces of protein in soya oil or egg lecithin), are extremely rare, however, these cannot be totally excluded for sensitised patients. Therefore particular caution should be observed when Lipofundin® MCT/LCT (or fat emulsions in general) are to be administered to such patients. If fat is to be administered in high doses every day there should be controls of serum triglycerides and, if necessary, of blood sugar, acid base and electrolyte status after the first day of infusion and then at suitable intervals.

The water balance and/or body weight should be monitored daily. Because alterations in the blood cell counts may be symptoms of overdose, monitoring of the blood cell counts is advisable. In the case of patients suspected to have disturbances of lipid metabolism fasting hyperlipaemia should be excluded by determination of the serum triglyceride concentration. If during infusion the serum triglyceride concentrations exceed 3 mmol/l in adults and 1.7 mmol/l in children the infusion rate must be reduced or the infusion must be stopped. Serum triglyceride concentrations exceeding above values 12 hours after the lipid infusion has been stopped also indicates disturbance of lipid metabolism. Fat administration should also be interrupted if there is a marked increase of the blood glucose concentration during fat infusion. Using fat emulsions as the only calorie source may provoke metabolic acidosis. Simultaneous carbohydrate infusions will prevent those complications. Therefore, fat infusions should always be accompanied by infusions of sufficient amounts of carbohydrate containing solutions.

Vitamin E may have an influence on the effect of vitamin K in the synthesis of coagulation factors. Therefore, in patients receiving oral anticoagulants and suspected to have vitamin K deficiency, monitoring of the coagulation status is recommended.

Pregnancy and lactation

The safety of Lipofundin® MCT/LCT during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Interactions

Interactions with other medicaments are not known so far.

Lipofundin® MCT/LCT must not be used as vehicle solutions for electrolyte concentrates or other medicaments. Uncontrolled mixing with other infusion solutions should also be avoided because adequate stability of the emulsion would no longer be guaranteed.

Combined regimes are only to be used for parenteral nutrition after their pharmaceutical compatibility has been controlled and guaranteed.

Admixture of alcohol containing injections or infusion solutions must be strictly avoided.

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Product Description

Lipoplus® 200 mg/ml

Composition

1000 ml of emulsion contains:

Medium-chain triglycerides:	100.0 g
Soybean oil, refined:	80.0 g
Omega-3-acid triglycerides:	20.0 g

Essential fatty acid content per liter:

Linoleic acid (omega-6):	48.0 - 58.0 g
Alpha-linolenic acid (omega-3):	5.0 - 11.0 g
Eicosa-pentaenoic acid and docosahexaenoic acid:	8.6 - 17.2 g

Caloric content per liter:

7,900 kJ = 1,910 kcal

Osmolality:

approx. 410 mOsm/kg

Titration acidity or alkalinity (to pH 7.4):

less than 0.5 mmol/l NaOH or HCl

pH:

6.5 - 8.5

Indications

Source of calories and essential omega-6 fatty acids and omega-3 fatty acids as a component of a parenteral nutrition regimen for adults.

Contraindications

Lipoplus® must not be used in any of the following conditions:

- Severe hyperlipidemia
- Serious blood clotting disorders
- Acidosis
- Intrahepatic cholestasis
- Severe liver failure
- Severe kidney failure
- Acute phase of myocardial infarction or stroke
- Acute thromboembolic disease, fat embolism
- Known hypersensitivity to egg, fish, or soybean protein

The following conditions are general contraindications to parenteral nutrition.

- Unstable hemodynamic status with compromised vital functions (conditions of collapse and shock)
- Fluid overload
- Acute pulmonary edema

Special warnings and precautions for use

Before infusing a fat emulsion together with other solutions via a Y connector or bypass set, the compatibility of these fluids should be checked, especially when co-administering carrier solutions to which drugs have been added. Particular caution should be exercised when co-infusing solutions that contain divalent electrolytes (such as calcium).

The emulsion should always be brought to room temperature prior to infusion.

If filters are used, these must be permeable to fat emulsions.

Serum triglycerides should be monitored during the infusion of Lipoplus®. In patients with suspected disorders of lipid metabolism, fasting lipemia should be ruled out before the start of the infusion. Hypertriglyceridemia 12 hours after the administration of fat is also indicative of abnormal lipid metabolism.

Transient hypertriglyceridemia or elevated blood glucose levels may arise from the patient's metabolic status. If the plasma triglyceride concentration rises to more than 3 mmol/l during administration of the fat emulsion, it is recommended to reduce the infusion rate. If the plasma triglyceride concentration still remains higher than 3 mmol/l, the infusion should be stopped until the plasma triglyceride concentration normalizes.

Electrolytes, water balance or body weight, acid-base balance, blood glucose levels, and, during long-term administration, blood counts, coagulation status, and liver function should be monitored.

There is as yet no clinical experience of the use of Lipoplus® in children, and there is only limited experience of its use in patients with diabetes mellitus or renal impairment.

There is as yet only limited experience of the use of Lipoplus® for periods longer than seven days.

Caution should be exercised in patients with conditions associated with impaired lipid metabolism, such as renal insufficiency, uncontrolled diabetes mellitus, pancreatitis, hepatic insufficiency, hypo-thyroidism (in the presence of hypertriglyceridemia), and sepsis.

Lipids may interfere with certain laboratory tests (such as bilirubin, lactate dehydrogenase, oxygen saturation) when the blood sample is taken before the lipids have been eliminated from the bloodstream. In most patients this takes 5 to 6 hours beyond the end of the infusion.

The use of fat emulsions as the sole source of calories may give rise to metabolic acidosis. This may be avoided by the concurrent infusion of carbohydrates. It is therefore recommended to infuse an adequate quantity of intravenous carbohydrates or an amino acid solution containing carbohydrates along with the fat emulsion.

Vitamin E can interfere with the effect of vitamin K in clotting factor synthesis. This should be borne in mind in patients with blood clotting disorders or suspected vitamin K deficiency.

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