IQSH
Initiative zur Qualitäts - Sicherung der Hilfsmittelversorgung
Alte Dorfstr. 38; 21684 Stade
Email: info@iqsh.eu

BEO MedConsulting Berlin GmbH
c/o Mr Friedrich
Helmholtzstr. 2

10587 Berlin

Release report on evidence of the medical benefit of the antidecubitus lateral positioning system "Ekamove" from the company Ekamed GmbH&Co.KG

I. Product history

In June 2008 we assessed the medical benefit of the antidecubitus lateral positioning system **"DOLUK 30°"**. As part of testing, the product was used with five subjects over a period of three weeks each. The subjects were aged 78-85 years. The subjects had underlying conditions typical of this age group such as various forms of dementia, stroke, heart conditions and osteoporosis. They also had limited mobility and were at varying degrees of decubitus risk. One of the subjects had a category II bedsore (EPUAP).

At the end of the test period there were no negative changes to the skin of the at-risk patients. The category II (EPUAP) decubitus displayed a marked signs of healing. Based on the positive test results, the system was recommended as suitable for use in inpatient and outpatient medical care.

Over the past year the manufacturer has modified the product "DOLUK 30°". It expanded the functions of the control unit. The product was renamed and is now called "Ekamove". The expansion of the functionality of the product "DOLUK 30°" by increasing the maximum weight-bearing to 300 kilograms, the option of programmable positioning variables (time interval, angle of inclination and selection of lateral position) and optimum use of pressure sensors as well as the logging option represent useful medical and

therapeutic product modifications. For many patients, individually adjusted positioning is of major importance for medical and therapeutic success. The product changes mentioned therefore represent a positive expansion of positioning options tailored to the patient.

The lateral recumbent position unit has not been changed. The product is still used in conjunction with a foam mattress. The technical changes involve optimisation of the control unit which does not affect how the system works but allows the user/patient to individually adjust their position. As the medical benefit of the product has already been proven by the report (see Annex) from June 2008, there is no need for re-testing the product on patients.

II. Handling and structure of the test "Ekamove"

The handling and structure of the test item are as per the previous model "DOLUK 30°". This product is likewise a lateral positioning system comprising a lateral recumbent positioning unit and a control unit. According to the manufacturer, the modified system is now suitable for patients weighing up to 300 kilograms.

The angle of inclination, the positioning interval and the control/selection of lateral position can be individually adjusted according to the patient's needs. The system can now be fitted with optional lateral angle sensors as well as a data chip for logging purposes.

Handling of the modified product is straightforward. In the lateral positioning system the lateral recumbent position element under a mattress is filled with air by a pump. Air volume, time interval and choice of side are governed by the control unit. Filling with air on one side creates a slant which then, in conjunction with the mattress, results in a tilted position for the patient.

During testing of the "DOLUK 30° lateral positioning system" the "ekaFlex-S mattress" was used on the system. It has not been modified and still comprises two elements: the mattress insert and a breathable cover. The mattress insert comprises a 7 cm thick cold foam layer and a 5 cm thick viscoelastic layer. The mattress cover is water-repellent, two-way stretchable, breathable and antibacterial. The cover supplied can simply be removed from the mattress insert by means of a zip and washed at max. 95°C.

The control unit of the “Ekamove lateral positioning system” can be wiped down using a standard commercial household cleaner. A disinfectant wipe is also possible.

III. Technical and optical modifications to the lateral positioning system “Ekamove”

Technical and optical modifications have been made to the control unit for the test “Ekamove” under assessment. Firstly the design of the casing has been adapted to the altered adjustment options. Secondly, technical details have changed.

The changes relate to the maximum permissible patient weight and the option to adjust positioning variables.

No changes have been made to the lateral positioning unit.

The changes have had no impact on the medical benefits of the decubitus prophylactic and/or therapeutic effect of the product.

IV. Transferability of the test results for the lateral positioning system “DOLUK 30°” to the lateral positioning system “Ekamove” - Conclusion and recommendation

The test item **“Ekamove”** represents an optically and technically revised version of the previously tested lateral positioning system **“DOLUK 30°”**.
The operating principle of the lateral positioning and/or individually timed pressure relief to promote circulation to the non-weight-bearing areas of tissue and handling are not affected by the product modifications. These involve technical changes to the control unit which represent a useful expansion of the individual positioning options. There has been no change to the lateral positioning unit.

The medical benefit of the lateral positioning system “DOLUK 30°” has already been proven in clinical testing with five subjects over a test period of several months.

Based on the positive results from the previous assessments, the use of comparable components and materials, the assessors deem the test results offering statements on the

medical benefit in respect of the decubitus prophylactic and therapeutic effect to be transferable.

The optical and technical modifications to the test item have no impact on the medically therapeutic benefit of the system. In this respect they have no impact on the already proven decubitus prophylactic and/or therapeutic effect of the product. It may continue to be used for the relevant indications.

The above remarks have shown that the test results are transferable so consequently, we can endorse the use of the lateral positioning system **"Ekamove"** for both outpatients and inpatients.

Stade, 30.03.11

_____
Claudia Kiechle
(Healthcare Administrator)

_____
Marco Möller
(Orthopaedic and Rehabilitation Technician)

Annex:

- Copy of evidence of the medical benefit of the lateral positioning system "DOLUK 30°"
- Copy of the evidence of the medical benefit of the antidecubitus mattress "ekaFlex-S mattress"

IQSH
Initiative zur Qualitäts - Sicherung der Hilfsmittelversorgung
Alte Dorfstr. 38; 21684 Stade
Email: info@iqsh.eu

BEO Berlin
c/o Mr Friedrich
Helmholtzstr. 2

10587 Berlin

Evidence of the medical benefit of the "DOLUK the 30° lateral positioning system" for decubitus prophylaxis and therapy in both models - "manually operated" and "electronically operated" from the company Ekamed OHG

1. The "DOLUK the 30° lateral positioning system" for decubitus prophylaxis and therapy from the company Ekamed OHG was examined. The product is used for decubitus prophylaxis (with moderate to high risk of decubitus according to the Braden Scale) and in treatment of decubitus ulcers (up to Category III according to EPUAP inclusive).

2. Details on the test facility / institution

The experts include a Master of Nursing Science and an orthopaedic and rehabilitation technician. The female expert is a Master of Nursing Science and has specialised for some years in the field of antidecubitus systems. The scope of this work includes advising on product development, evaluating these systems in practice as well as training courses for various players in the healthcare system. The orthopaedic and rehabilitation technician has worked as a consultant on medical products for over 10 years. The scope of this work includes consultancy and concept development in the standard field and customised construction as well as advising on product development and training courses on the subject of orthopaedic appliances.

The medical benefit was examined in various settings in the healthcare system such as hospitals, inpatient and outpatient facilities for geriatric care and at home.

Both models of the 30° lateral positioning system were tested at a care home in Buxtehude. In this large (number of residents < 80) residential facility, disabled people and those in need of nursing care (at all three levels of care) are nursed and cared for.

3. Details of period of use

In recent months we have tested the aid supplied by you and obtained the following results:

Both models of the "DOLUK the 30° lateral positioning system" were tested in conjunction with the antidecubitus foam mattress "ekaFlex-S mattress" (see also report on this from 29.04.2008) from the company Ekamed OHG. The two product models differ in that one is operated manually and the other electronically. With the manual system the patient has to be actively placed in the lateral position by care staff, assisted by the system. The electronic system places the patient in the right and then the left 30° lateral position at a fixed pre-set interval.

Both product models were used over a period of 2 ½ months with five subjects.
The "DOLUK 30° lateral positioning system" was used to prevent and treat decubitus ulcers up to and including Category II (EPUAP).
The subjects were aged 78 - 85 years with varying underlying disorders.
These were common disorders associated with old age such as forms of dementia, stroke, intracranial haemorrhage, stroke (sic) and hypertension.
The subjects had varying degrees of impaired mobility.
The decubitus risk was measured using the Braden Scale. The subjects were assessed to be at varying decubitus risk. All patients were at decubitus risk. One of the five patients had a Category II (EPUAP) pressure sore in the sacral region.

4. Progress of therapy

Subject	**01**	**02**	**03**	**04**	**05**
"DOLUK the 30° lateral positioning system"	**Manually operated**	**Manually operated**	**Manually operated**	**Electronically operated**	**Electronically operated**
Mattress used	**EkaFlex-S mattress**	**EkaFlex-S mattress**	**EkaFlex-S mattress**	**EkaFlex-S mattress**	**EkaFlex-S mattress**
Place of measurement	Buxtehude	Buxtehude		Buxtehude	Buxtehude
Start of observation	09/04/08	30/05/08	21/05/08	30/04/08	21/05/08
End of observation	30/04/08	21/05/08	18/06/08	21/05/08	18/06/08
Age	85	85	78	85	81
Gender	female	female	male	female	female
Diagnosis	Alzheimers, status post stroke; arterial hypertension, hearing loss, carotid stenosis, osteoporosis, status post pneumonia	Depression, dementia, skin cancer, sight loss	Status post intracranial haemorrhage, arterial hypertension; right hemiparesis	Alzheimers, status post stroke; arterial hypertension, hearing loss, carotid stenosis, osteoporosis, status post pneumonia	Osteoporosis, arterial hypertension, dementia, stroke, hearing loss
Weight (kg)	56.1 kg	51.2	73	56.1	58.1
Height (cm)	144	160	178	144	160
Baseline decubitus risk according to Braden	9	18	13	9	12
Closing decubitus risk according to Braden	9	18	13	9	12
Baseline wound category according to EPUAP					II
Baseline wound size					Diameter 1.2 cm - epithelising
Closing wound size					Wound almost closed
Baseline					

wound depth					
Closing wound depth					
Progress of wound					Wound almost closed by end of test period
Decubitus prophylactic effect	positive	positive		positive	positive
Skin status	positive	positive		positive	positive
Comments	Contractures, aged			Contractures, aged	

The wound status of the already epithelising pressure sore (Category II, EPUAP) markedly improved during the test period. The wound diameter decreased and the surface of the decubitus was closed. The skin of the at-risk patients remained intact during the test period. In addition, all patients were turned at the individually required intervals. All patients were mobilised out of bed each day so the 30° lateral positioning system was primarily used at night.

5. Handling

According to information in the instructions for use of the tested product, the 30° lateral positioning system in conjunction with the antidecubitus foam mattress "ekaFlex-S mattress" replaces an existing standard mattress. The 30° lateral positioning system comprises parallel synthetic cushions connected to the operating unit via air hoses.
In the manually operated system the system has to be filled with air using a pump. The air can be manually distributed into the left or right air cushion via a valve on the operating unit. Filling with air on one side creates a slope which, in conjunction with the mattress, results in a tilted position for the patient.

The electronically operated model works along the same lines. Here, the air cushions are automatically filled with air using a pump in the system. Alternately filling the left and right air chamber with air is also controlled by the operating unit.

During testing of both models of the "DOLUK 30° lateral positioning system" the "ekaFlex-S mattress" was used with the system. It comprises two components – the

mattress insert and a breathable cover. The mattress insert comprises a 7 cm thick cold foam layer and a 5 cm thick viscoelastic layer. The mattress cover is water-repellent, two-way stretchable, breathable and antibacterial.

According to the manufacturer, the system is suitable for patients weighing 50 kg to 150 kg.

The cover supplied can simply be removed from the mattress insert by means of a zip and washed at max. 95°C.

Both models of the "DOLUK 30° lateral positioning system" can be wiped down using a standard commercial household cleaner. A disinfectant wipe is also possible.

6. Risk notice

The instructions for use for the "DOLUK 30° lateral positioning system" list both the indications and the contraindications. According to the manufacturer, the system is suitable for decubitus prophylaxis with moderate to high risk of decubitus according to the Braden Scale and in treatment of decubitus ulcers up to and including Category III according to EPUAP. As contraindications the manufacturer lists allergy to foam and weight restrictions on patient weights over 150 kg and below 50 kg as well as non-stable fractures, severe burns, balance disorders and underlying neurological conditions that cause anxiety in the patient.

Under the point "Use" in the instructions for use the manufacturer also points out that sufficient distance of 22 cm must be left between the top of the mattress and the top of the side rail when using the mattress in a hospital bed with side rails. If necessary a bed rail extension should be used.

Also ensure that the mattress used does not slide on the lateral positioning system.

7. Overall assessment

The "DOLUK 30° lateral positioning system", in both the "manual" and "electronically operated" models, was successfully used with five subjects.

The care staff were very positive about the product after several weeks of testing. Users assess it as relatively easy to handle. Based on the positive results and experiences whilst using the test “DOLUK 30° lateral positioning system” in conjunction with the “ekaFlex-S mattress”, the care staff assess the product as suitable for decubitus prophylaxis as well as decubitus therapy. The carers endorse the use of the “DOLUK 30° lateral positioning system” in the treatment of decubitus up to and including Category III according to EPUAP as the positioning intervals of residents have been extended by using the system. Residents can also be positioned using straightforward handgrips due to the well-proportioned surface design of the mattress used.

Based on the test results obtained and the valid line of argument, we can endorse the use of both the “manual” and “electronically operated” models of the “DOLUK 30° lateral positioning system”, both at home and in hospital, with moderate to high risk of decubitus on the Braden Scale and in treatment of decubitus ulcers up to and including Category III (EPUAP), according to the indications listed by the manufacturer.

Stade, 30.06.2008

_____

Claudia Kiechle
(Healthcare Administrator)

_____

Marco Möller
(Orthopaedic and Rehabilitation Technician)

Annex:
Copy of the report on the medical benefit of the “ekaFlex-S mattress” from 29.04.2008