Gustav Eriksson

Head of Environmental department

KAROLINSKA
University Hospital

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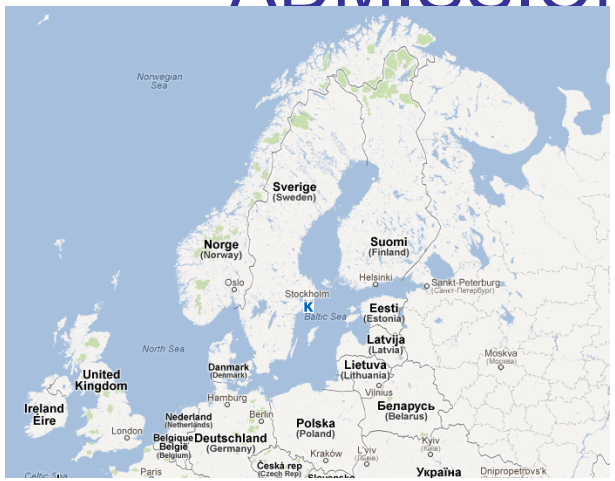
With financial support
from EU's Life+ programme

KAROLINSKA
University Hospital

1,700
HOSPITAL BEDS

108,400
ADMISSIONS

6,000
ADMISSIONS
OF PATIENTS FROM OTHER
COUNTIES OR COUNTRIES



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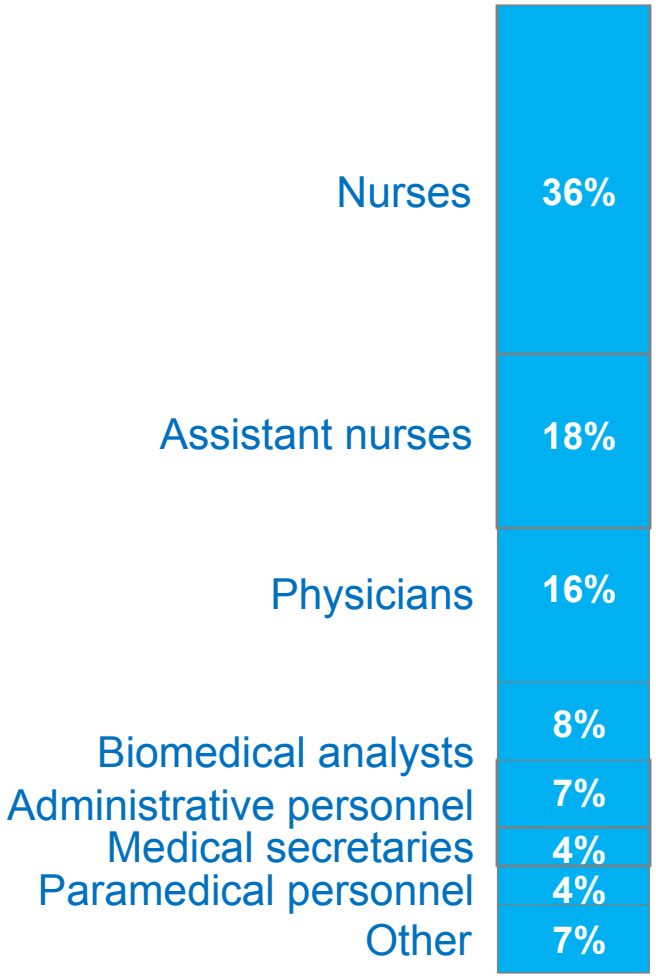
KAROLINSKA
University Hospital

15,300
EMPLOYEES

SALES SEK
15.7
BILLION



January 2014

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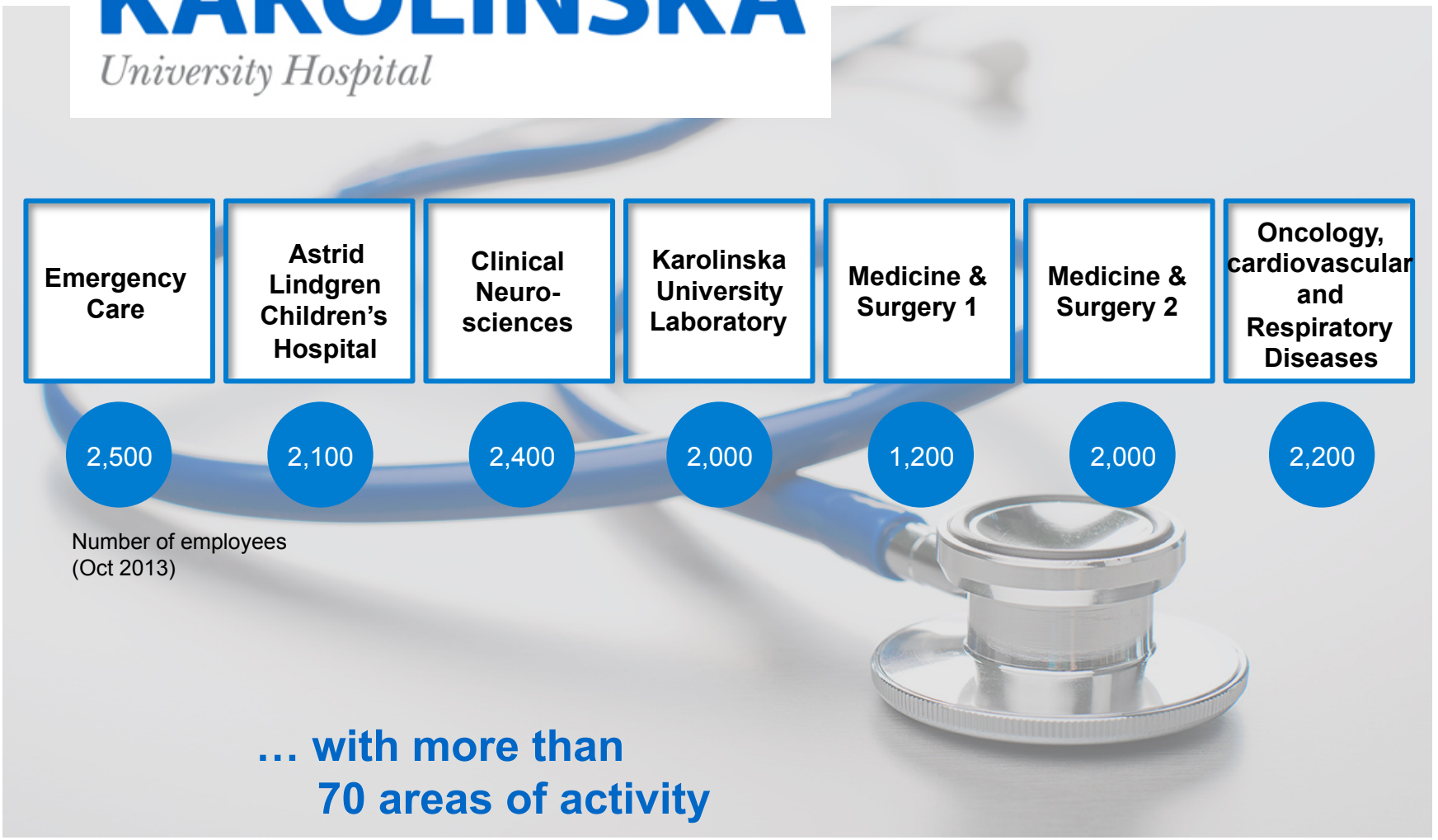
KAROLINSKA
University Hospital



Emergency Care	Astrid Lindgren Children's Hospital	Clinical Neuro-sciences	Karolinska University Laboratory	Medicine & Surgery 1	Medicine & Surgery 2	Oncology, cardiovascular and Respiratory Diseases
2,500	2,100	2,400	2,000	1,200	2,000	2,200

Number of employees
(Oct 2013)

… with more than 70 areas of activity

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KAROLINSKA
University Laboratory

- We carry out nearly 20 million tests per year to about 40 000 customers.
- We are divided into eight clinics
- We conduct accredited operations at the Karolinska University Hospital and close to 70 sampling units and a number of outlets for blood donors.
- Using 80 000 blodbags per year
- Our customers are located throughout the country in all categories of health care providers, including private and public companies and institutions.
- We are as a part of Karolinska university hospital certified according to the environmental standard ISO 14001.

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KAROLINSKA – ONE OF THE WORLDS MOST ENVIRONMENTALLY ADAPTED HOSPITALS

ISO 14001:2004 CERTIFICATION™
Intertek

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DEHP is classified as a reproductive toxic

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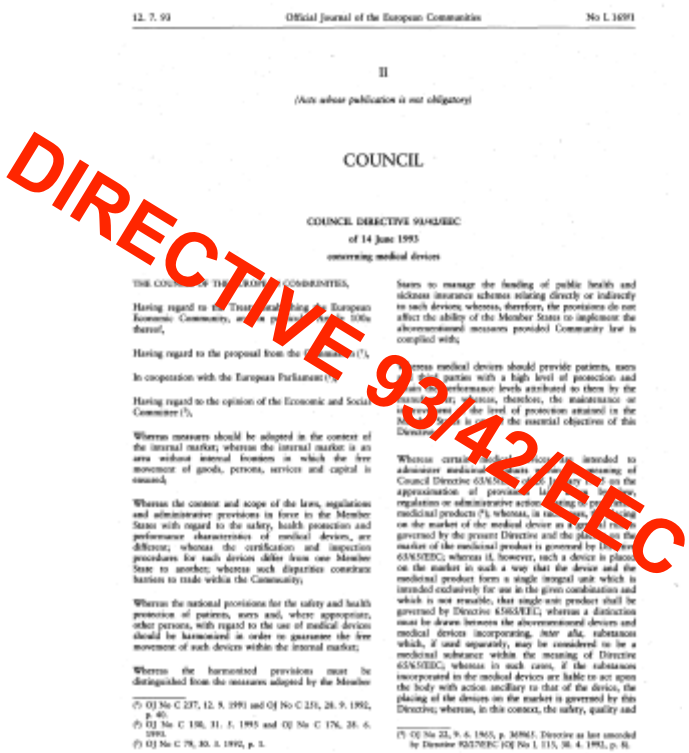
DEHP's risks are emphasized in the directive for medical devices



12. 7. 93 Official Journal of the European Communities No L 169/1

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

DIRECTIVE 93/42/EEC

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices, are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas medical devices should provide patients, users and other parties with a high level of protection and should achieve performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

Whereas certain [illegible] intended to administer medicinal [illegible] meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products (4); whereas, in fact, the placing on the market of the medical device as a [illegible] is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC; whereas if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-use product shall be governed by Directive 65/65/EEC; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, *inter alia*, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC; whereas in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive; whereas, in this context, the safety, quality and

(1) OJ No C 237, 12. 9. 1991 and OJ No C 231, 28. 9. 1991, p. 40.
(2) OJ No C 150, 31. 5. 1993 and OJ No C 176, 28. 6. 1993.
(3) OJ No C 79, 30. 3. 1992, p. 3.

(4) OJ No 22, 9. 2. 1965, p. 369/65. Directive as last amended by Directive 92/27/EEC (OJ No L 113, 30. 4. 1992, p. 8).

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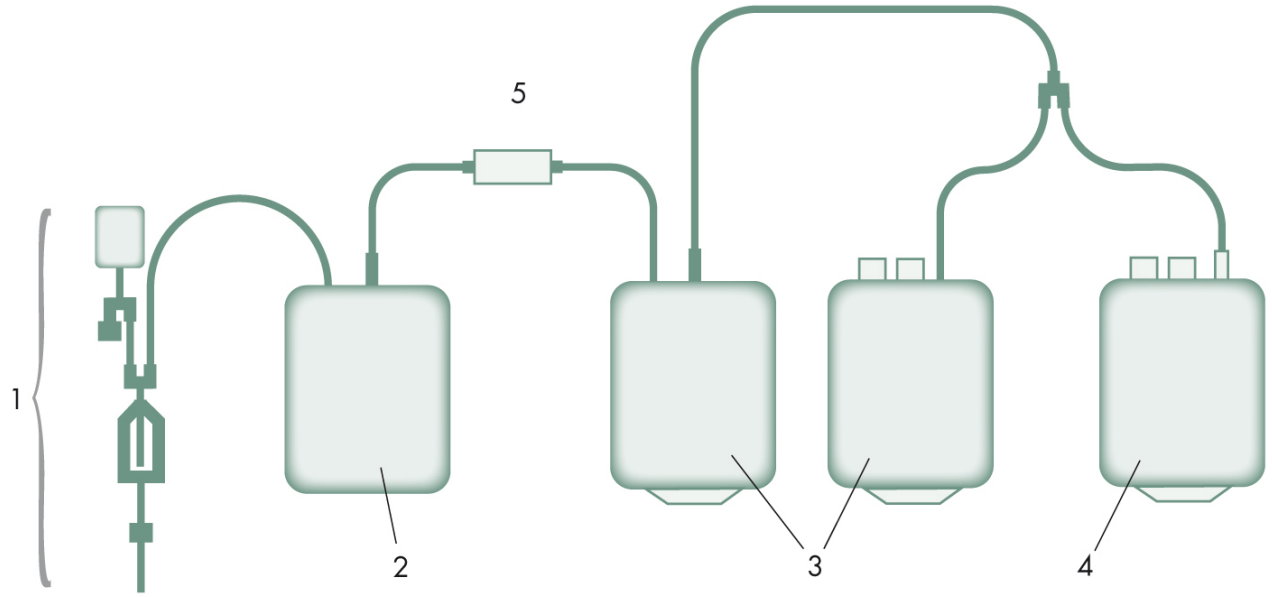
PVC needs plasticizer to become soft



KEY
1. Sampling device
2. Collection bag
3. Empty transfer bag
4. Transfer bag with additive solution
5. Leucocyte filter

Most bags for red blood cells consist of 30-40% DEHP

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Waste and production problems - Globally

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- Who can predict the consequences of new plasticizers?
- We demand PVC-free blood bags out of precaution

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