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Economic study on the impact of reprocessing of single-use medical devices in Belgium

Authors:

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I. Economic considerations on the reprocessing of single use medical devices

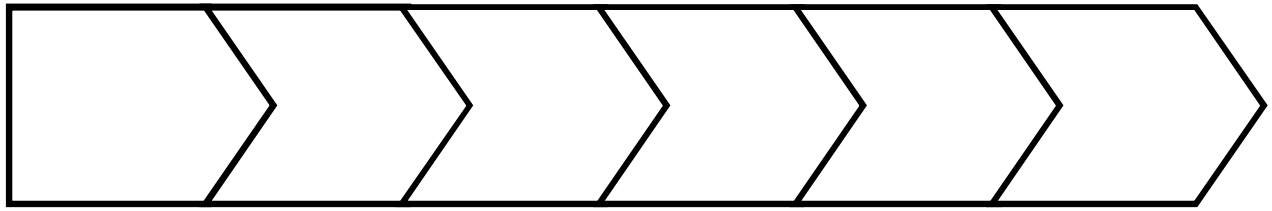
- to reduce their expenses

- various other costs and considerations need to be taken into account

II. Methodology for costs calculation

III. Cost calculation model for the reprocessing of single-use medical devices

Activity Based Costing



1. Defining the cost objects
2. Identifying activities
3. Determining activities per cost object, identifying activity dirver (cost driver)
4. Registering activities
5. Allocating costs to activities
6. Determining cost per cost object (product)

1. Identifying cost object
5 productgroups of single-use medical devices

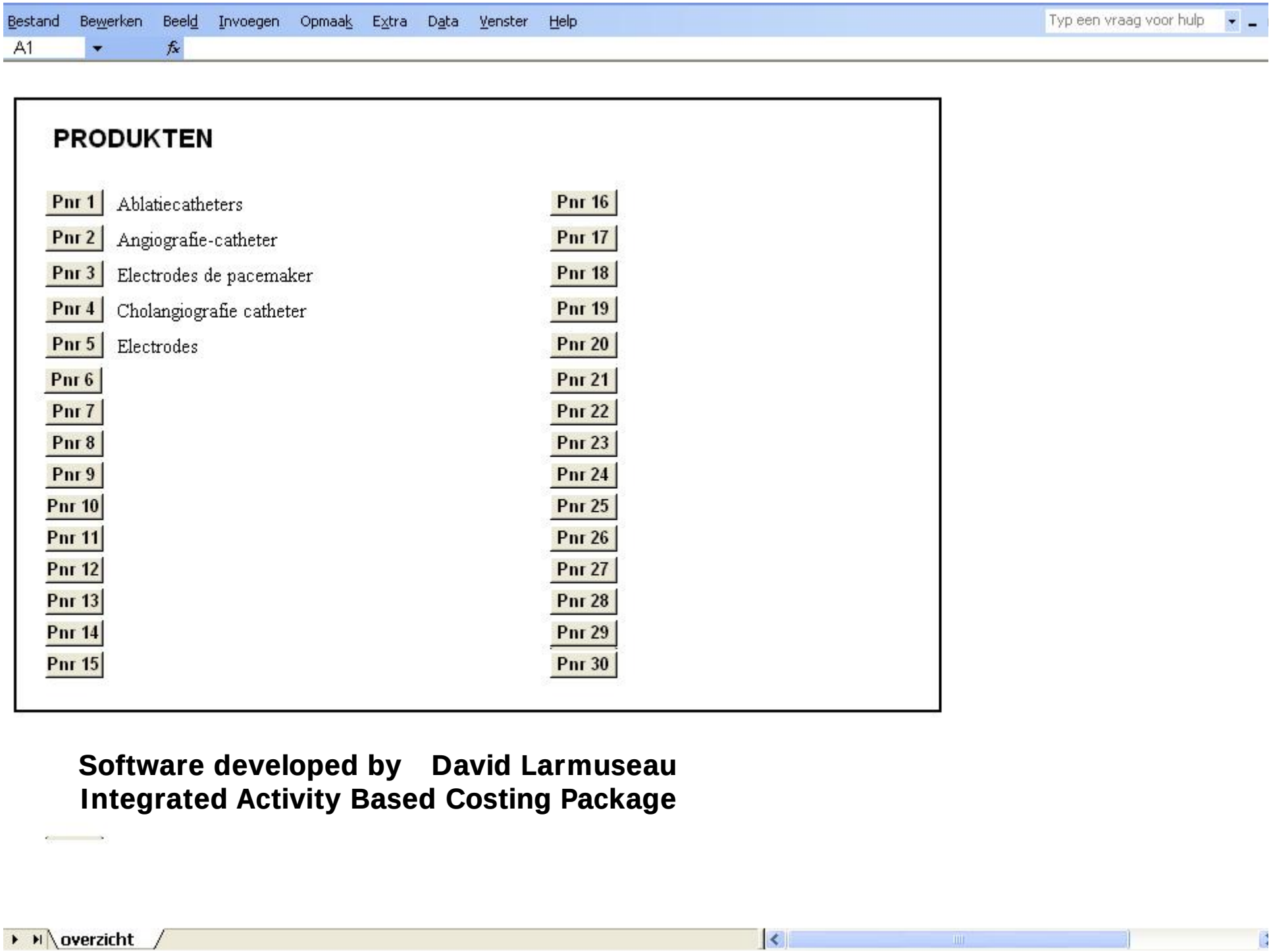
A. Cardiac ablation catheters

B. Angiography catheters

C. Cholangiography catheters

D. Pacemaker electrodes

E. Electrode catheters


Bestand Bewerken Beeld Invoegen Opmaak Extra Data Venster Help
Typ een vraag voor hulp
A1
PRODUKTEN
Pnr 1 Ablatiecatheters
Pnr 2 Angiografie-catheter
Pnr 3 Electrodes de pacemaker
Pnr 4 Cholangiografie catheter
Pnr 5 Electrodes
Pnr 6
Pnr 7
Pnr 8
Pnr 9
Pnr 10
Pnr 11
Pnr 12
Pnr 13
Pnr 14
Pnr 15
Pnr 16
Pnr 17
Pnr 18
Pnr 19
Pnr 20
Pnr 21
Pnr 22
Pnr 23
Pnr 24
Pnr 25
Pnr 26
Pnr 27
Pnr 28
Pnr 29
Pnr 30
Software developed by David Larmuseau
Integrated Activity Based Costing Package
overzicht

2. Identifying activities

1. Collection, protection, packaging and storage of the devices to be treated

2. Transfer to the reprocessor

3. Reception by the reprocessor

4. Cleaning, disinfecting

5. Sterilisation process

6. Post-sterilisation product validation

7. Releasing the devices

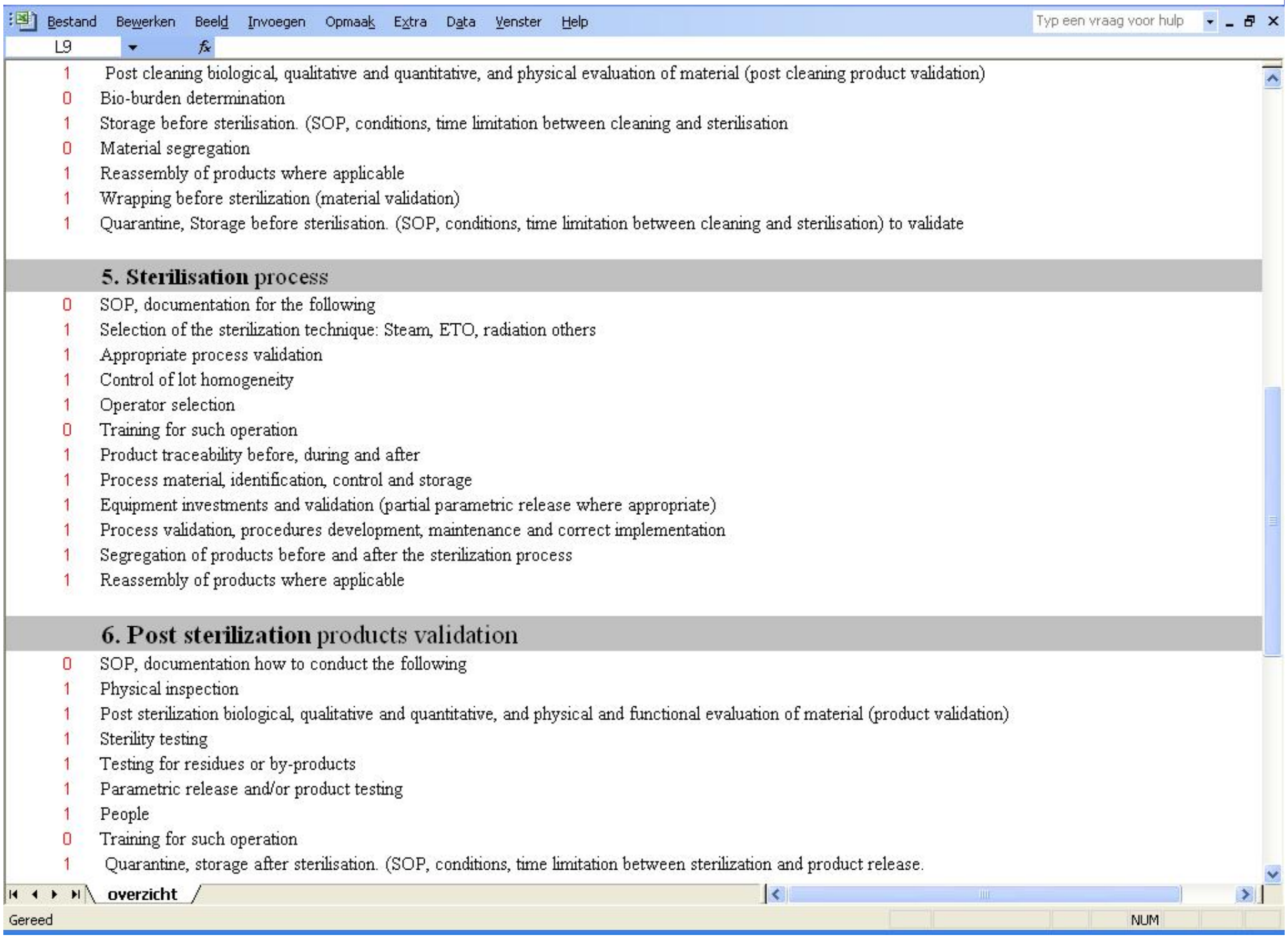
8. Transfer to end-user

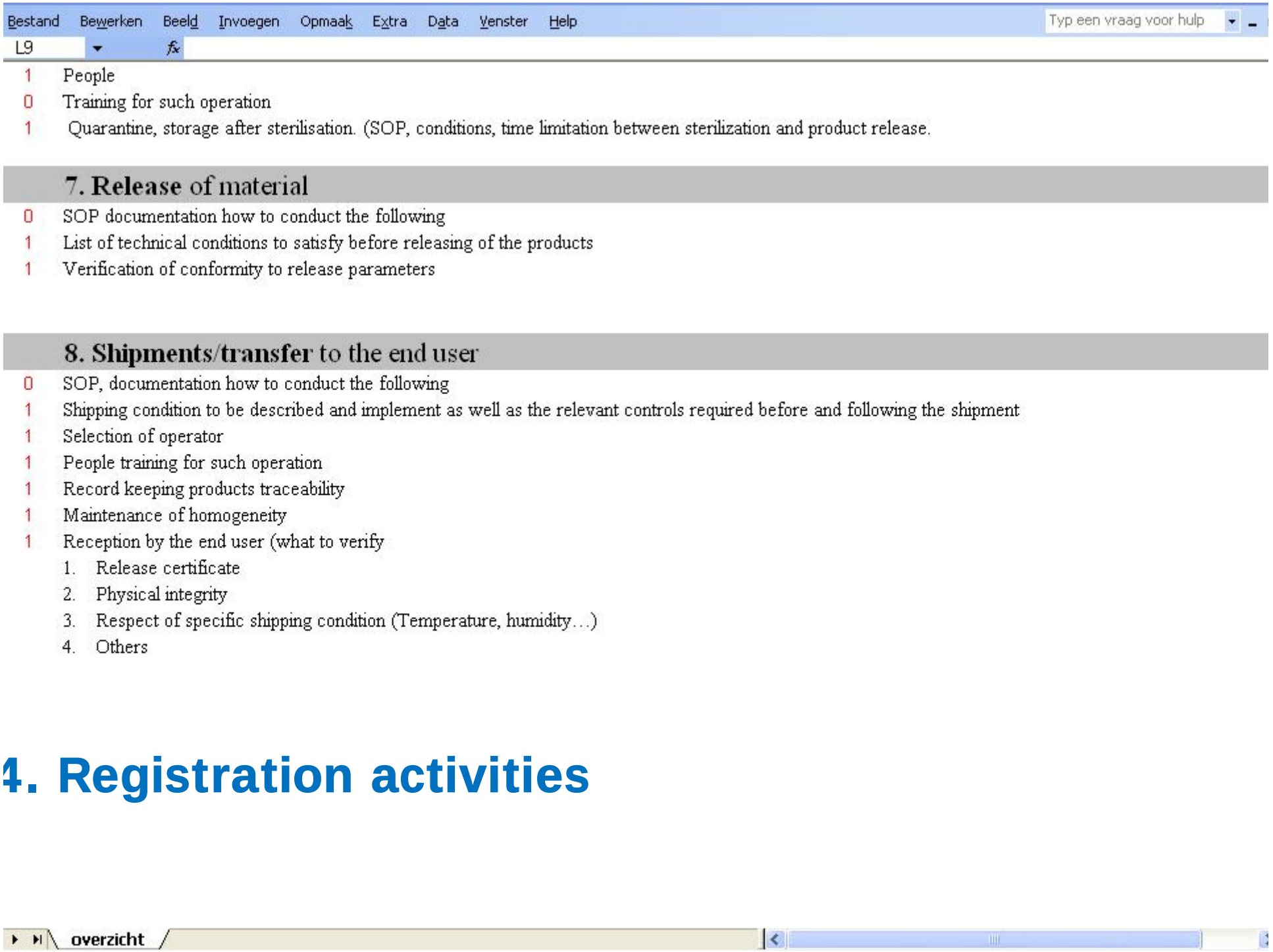
3. Determining activities per cost object

L9 fx

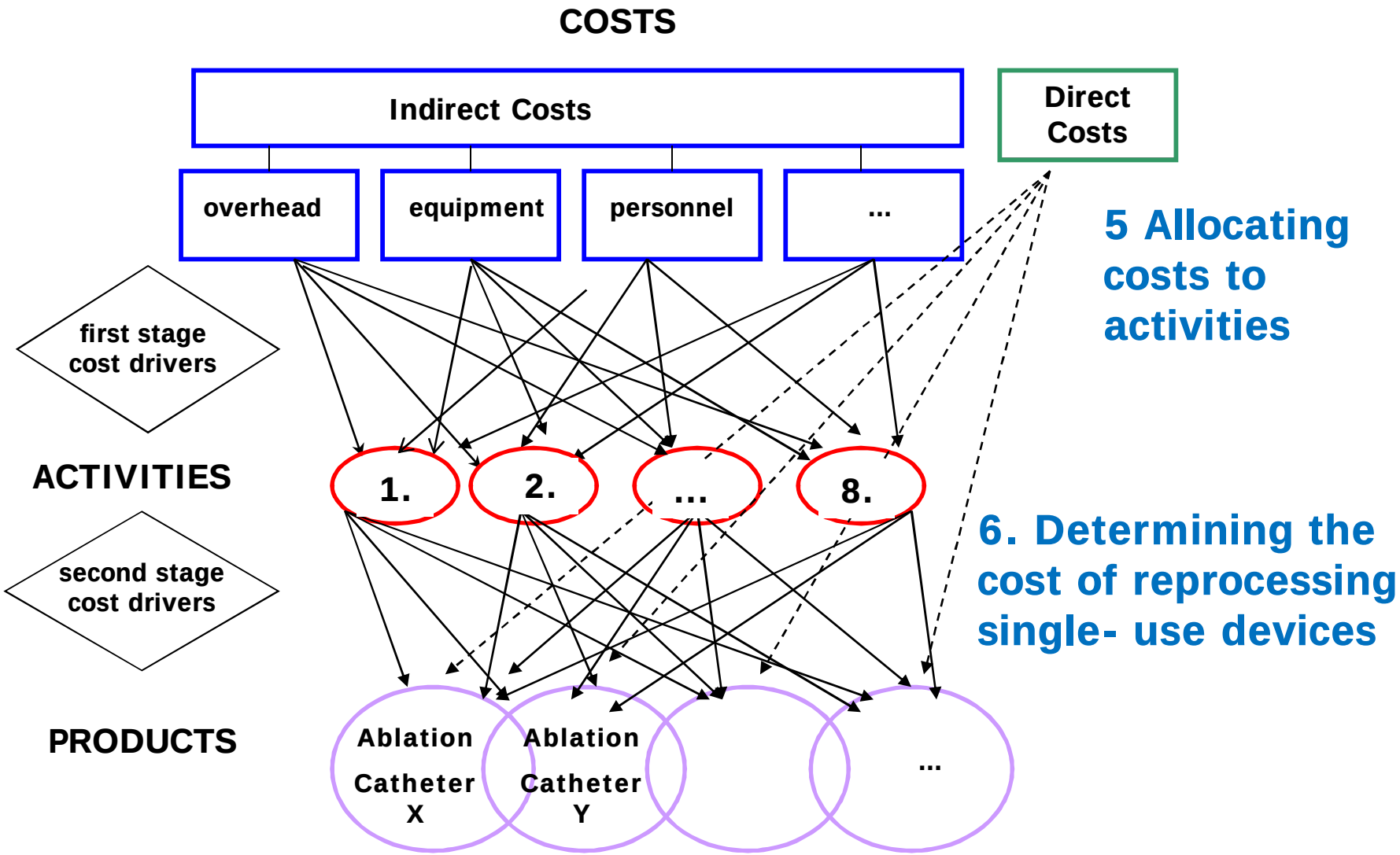
ABLATION CATHETER

YES =1	
	1. Collection, protection, wrapping, storage, preservation of the material to be treated
1	SOP, documentation, how to conduct the following:
1	People selection and training
1	Definition and selection of wrapping material or containers (investment) and methodology
1	Record keeping products traceability
1	Material segregation
1	Constitution and maintenance of homogeneous lots (sorting)
1	Protection of personnel and environment
	2. **Shipments**/transfer to the reprocessor
1	SOP to be developed maintained and implemented describing the shipping conditions as appropriate as well as the relevant controls required
1	People selection and for such operation
1	Record keeping products traceability
1	Maintenance of homogeneity
1	Protection of personnel and environment
	3. Reception by the reprocessor
1	SOP defining reception conditions, verifications, physical control to performed
1	Record keeping products traceability
1	Inspection
0	Release for further processing
	4. Cleaning disinfections
0	SOP, documentation for the following
1	Qualitative and quantitative biological evaluation, physical inspection (product validation)
1	Control of lot homogenity
1	Operator selection


Bestand Bewerken Beeld Invoegen Opmaak Extra Data Venster Help
Typ een vraag voor hulp
L9
1 Post cleaning biological, qualitative and quantitative, and physical evaluation of material (post cleaning product validation)
0 Bio-burden determination
1 Storage before sterilisation. (SOP, conditions, time limitation between cleaning and sterilisation
0 Material segregation
1 Reassembly of products where applicable
1 Wrapping before sterilization (material validation)
1 Quarantine, Storage before sterilisation. (SOP, conditions, time limitation between cleaning and sterilisation) to validate
5. Sterilisation process
0 SOP, documentation for the following
1 Selection of the sterilization technique: Steam, ETO, radiation others
1 Appropriate process validation
1 Control of lot homogeneity
1 Operator selection
0 Training for such operation
1 Product traceability before, during and after
1 Process material, identification, control and storage
1 Equipment investments and validation (partial parametric release where appropriate)
1 Process validation, procedures development, maintenance and correct implementation
1 Segregation of products before and after the sterilization process
1 Reassembly of products where applicable
6. Post sterilization products validation
0 SOP, documentation how to conduct the following
1 Physical inspection
1 Post sterilization biological, qualitative and quantitative, and physical and functional evaluation of material (product validation)
1 Sterility testing
1 Testing for residues or by-products
1 Parametric release and/or product testing
1 People
0 Training for such operation
1 Quarantine, storage after sterilisation. (SOP, conditions, time limitation between sterilization and product release.
overzicht
Gereed
NUM



4. Registration activities


COSTS
Indirect Costs
Direct Costs
overhead
equipment
personnel
...
first stage cost drivers
ACTIVITIES
1.
2.
...
8.
second stage cost drivers
PRODUCTS
Ablation Catheter X
Ablation Catheter Y
...
5 Allocating costs to activities
6. Determining the cost of reprocessing single- use devices

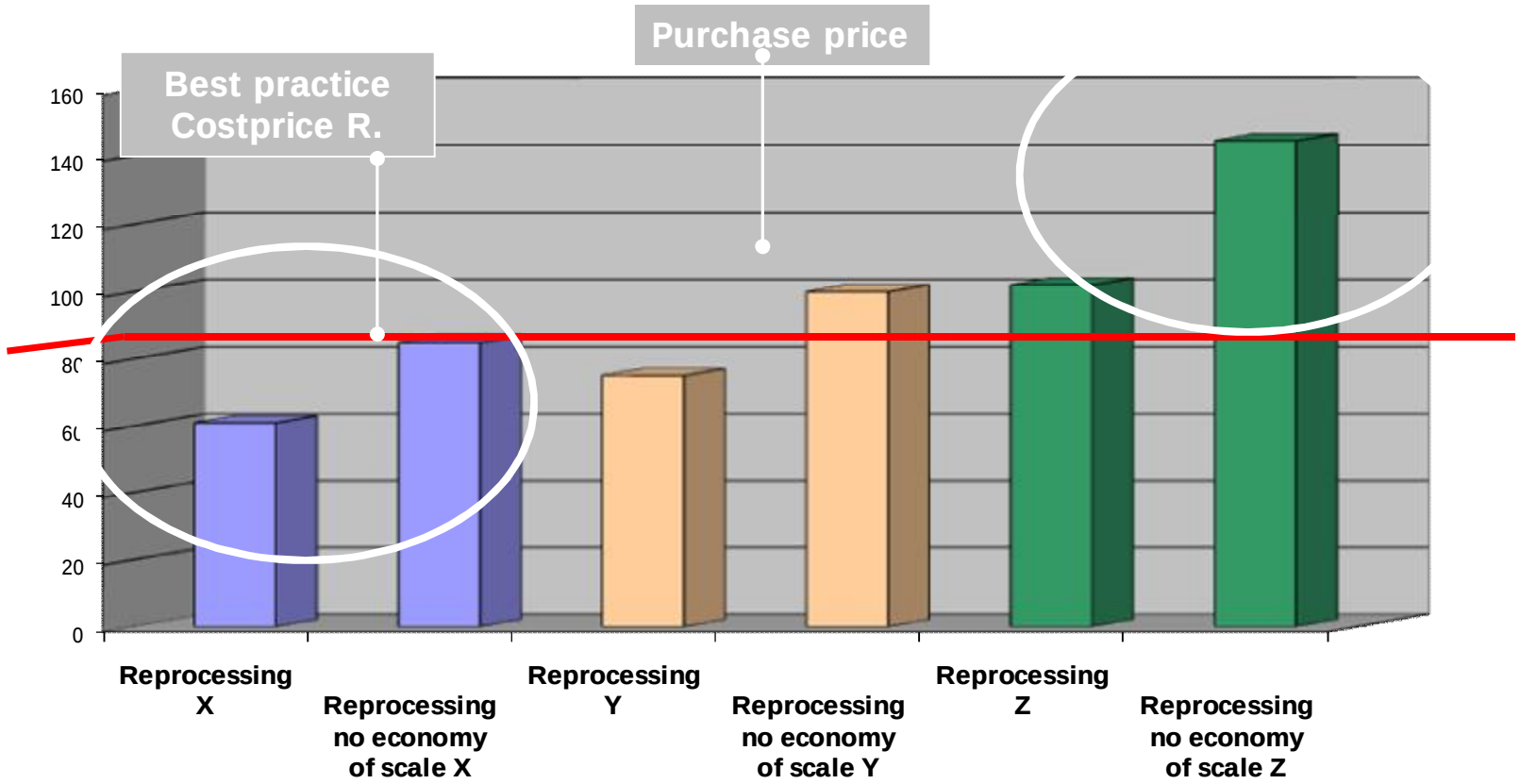
IV. Results of the study

Risk analysis

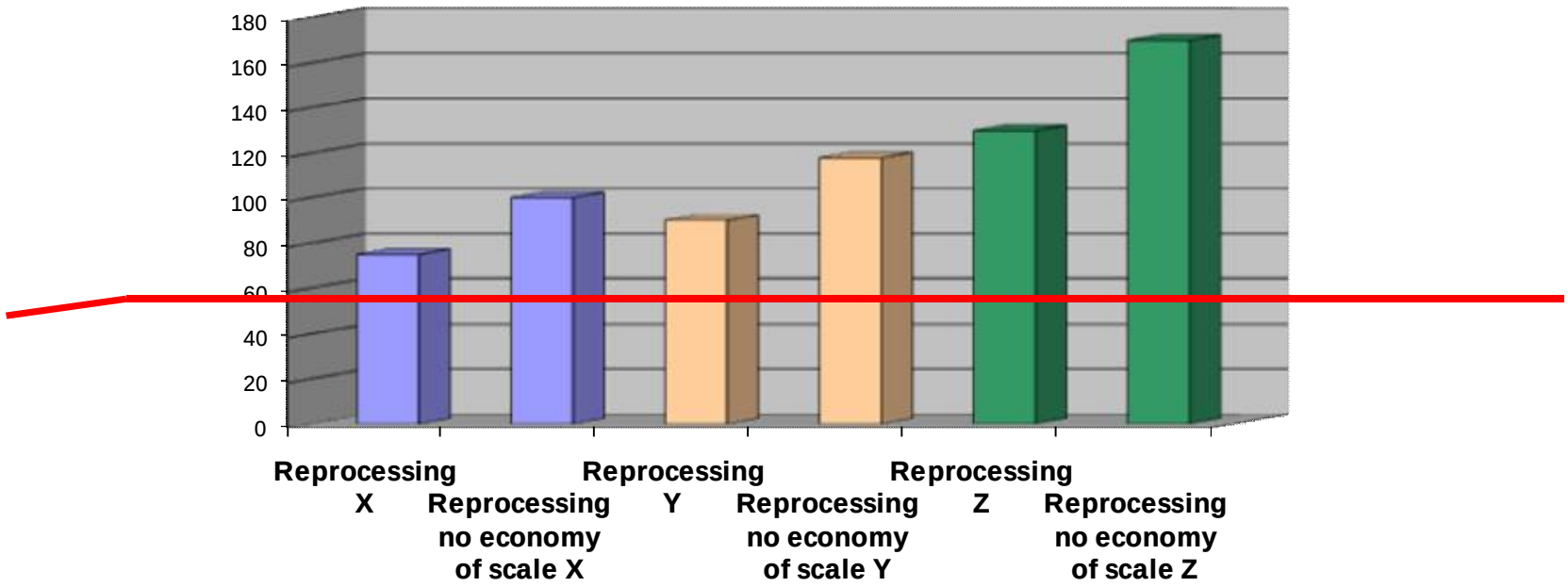
1/5.000 patients die
due to the reprocessing of single-use medical devices

Dr. C. Suetens
European CDC

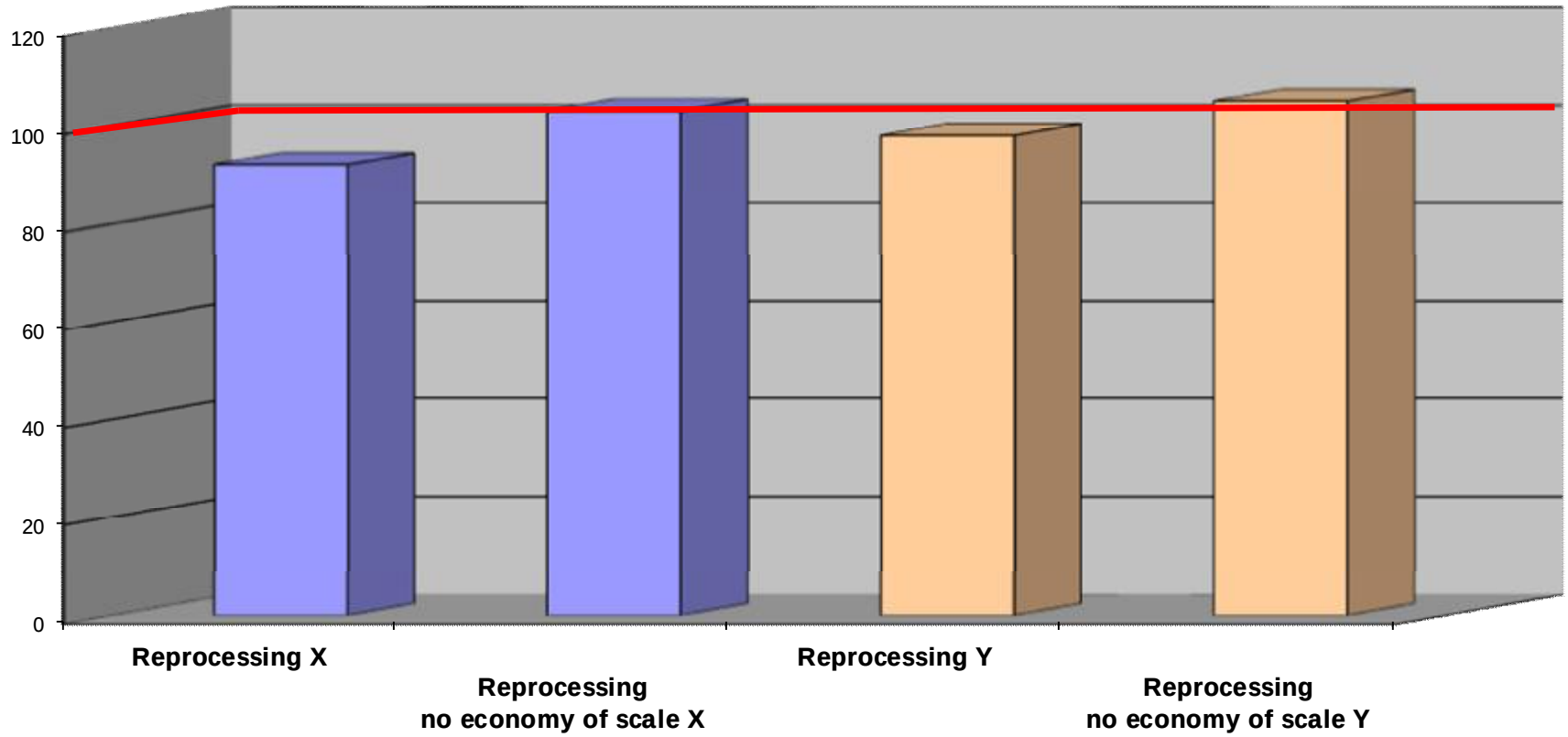
A.1Cost price of reprocessing compared to buying new ablation catheters (in %)



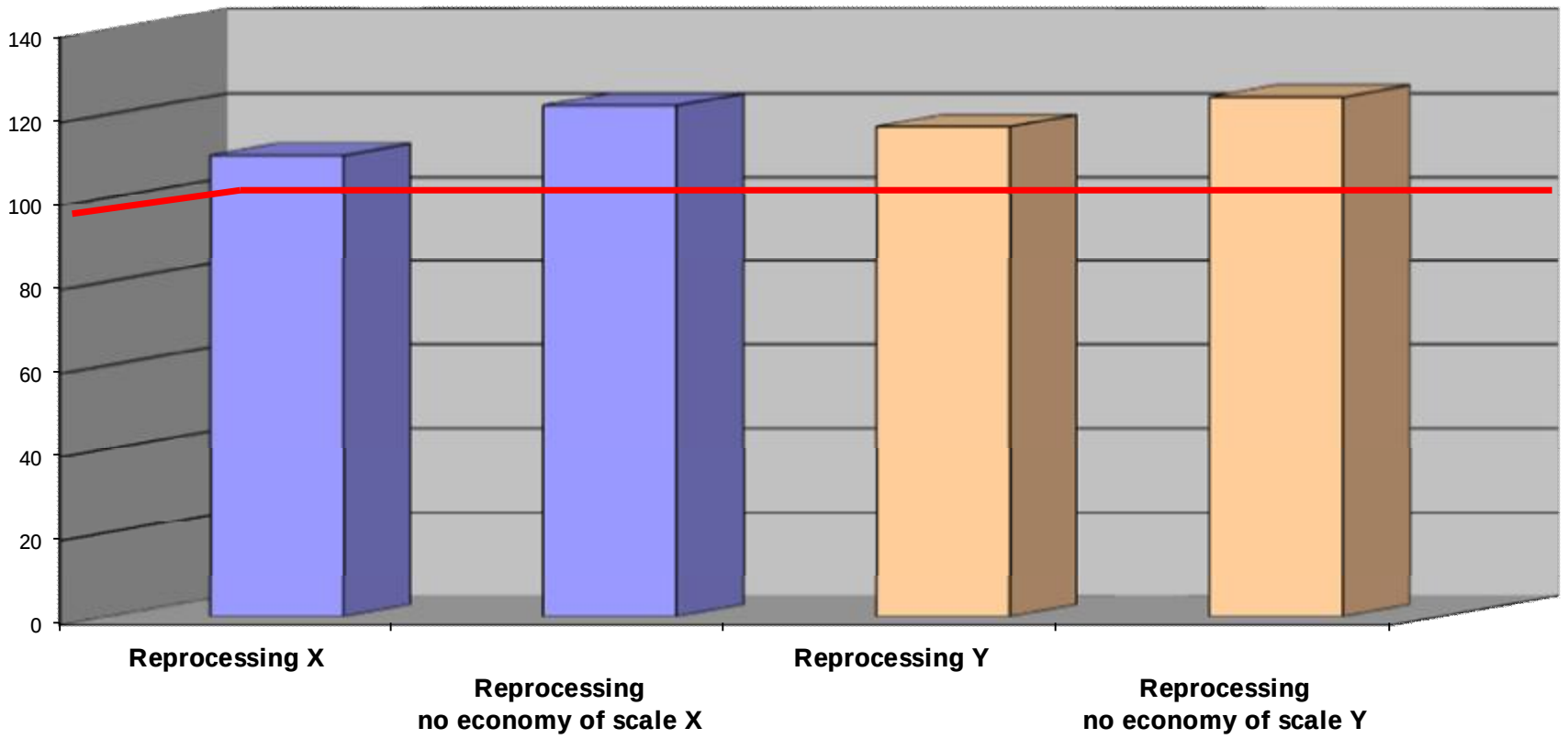
A.2 Cost of reprocessing including risk compared to purchase of ablation catheter (in %)



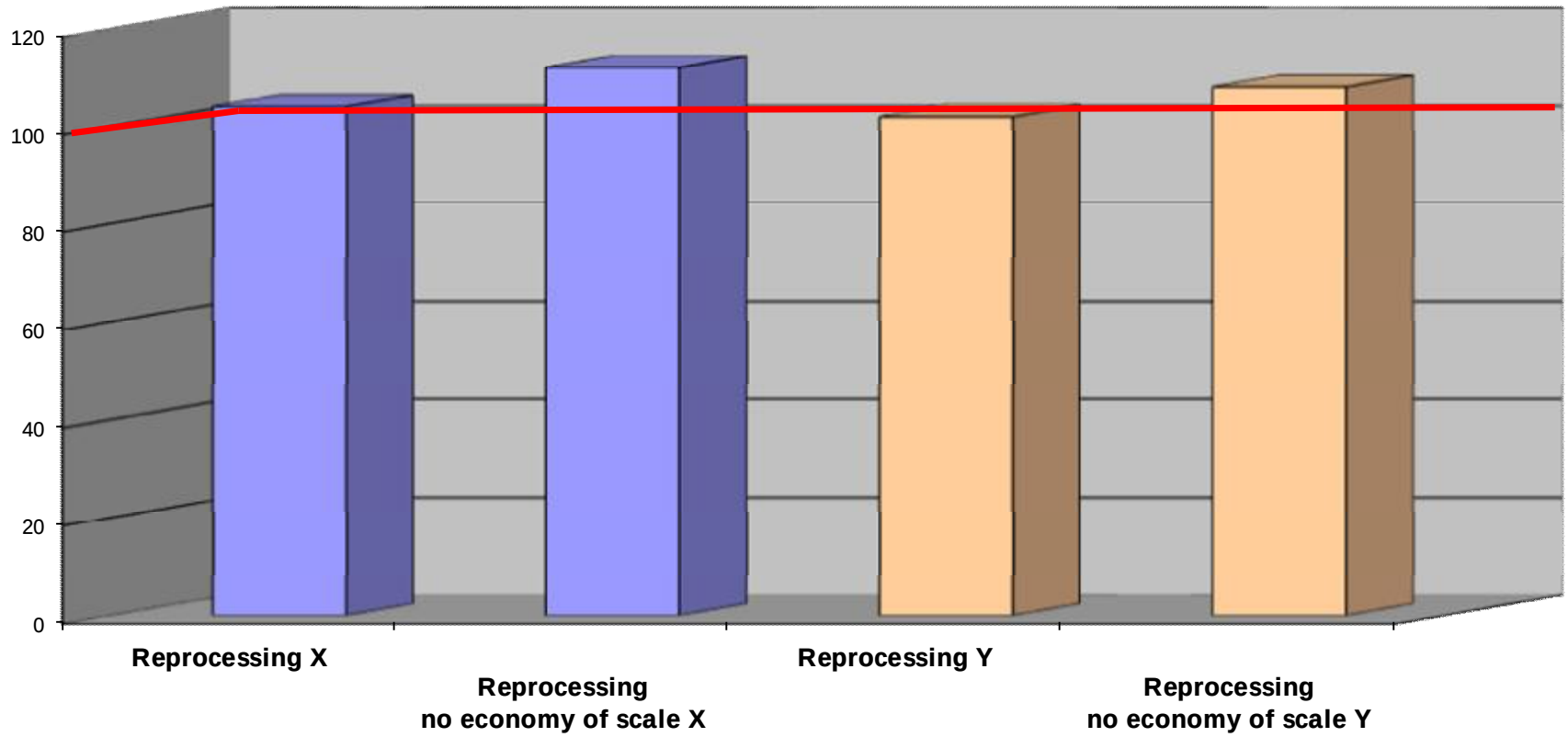
B.1 Cost price of reprocessing compared with the purchase of angiography catheters (in %)



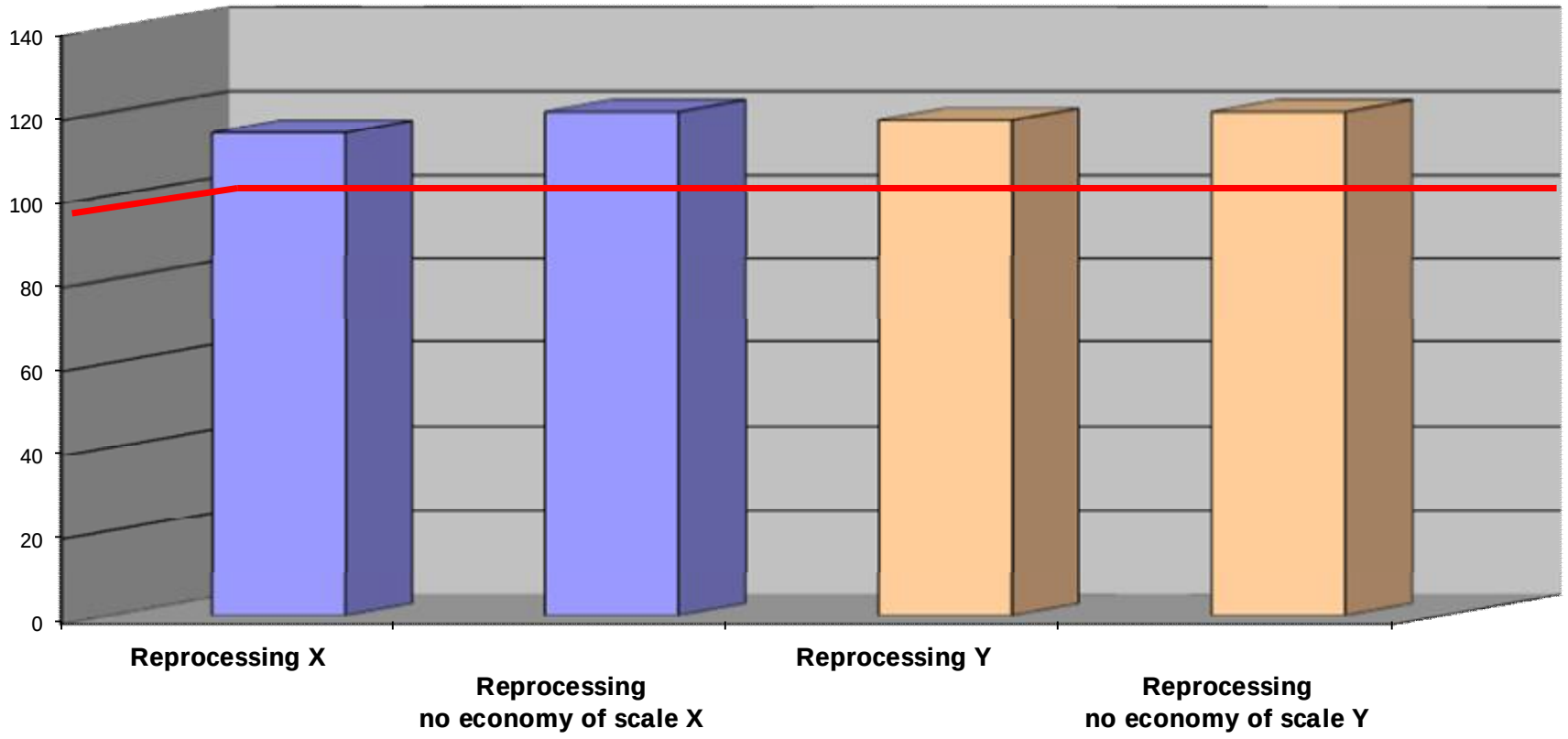
B.2 Cost of reprocessing incl. risk compared with the purchase of angiography catheters (in %)



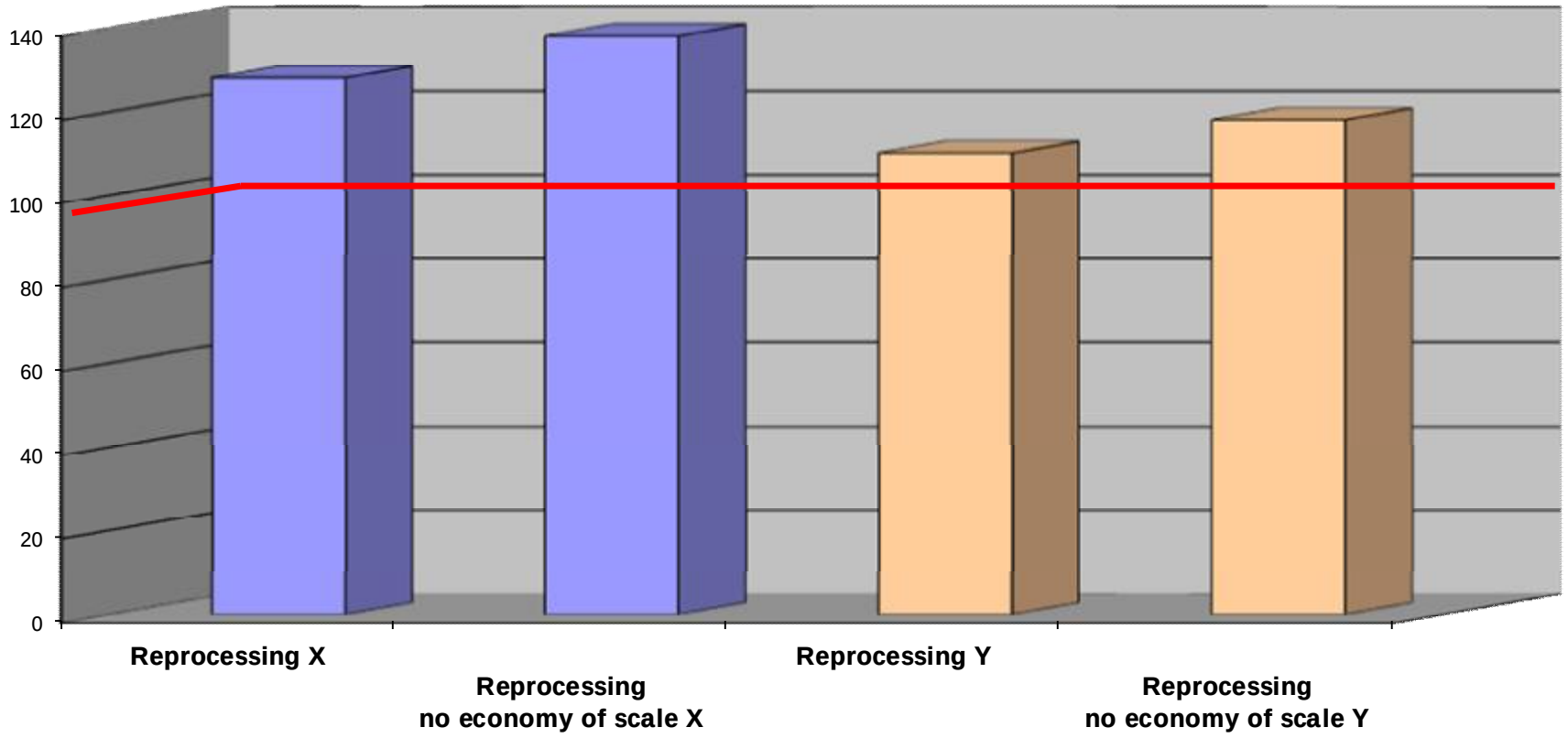
C.1 Cost price of reprocessing compared to purchase of cholangiography catheters (in %)



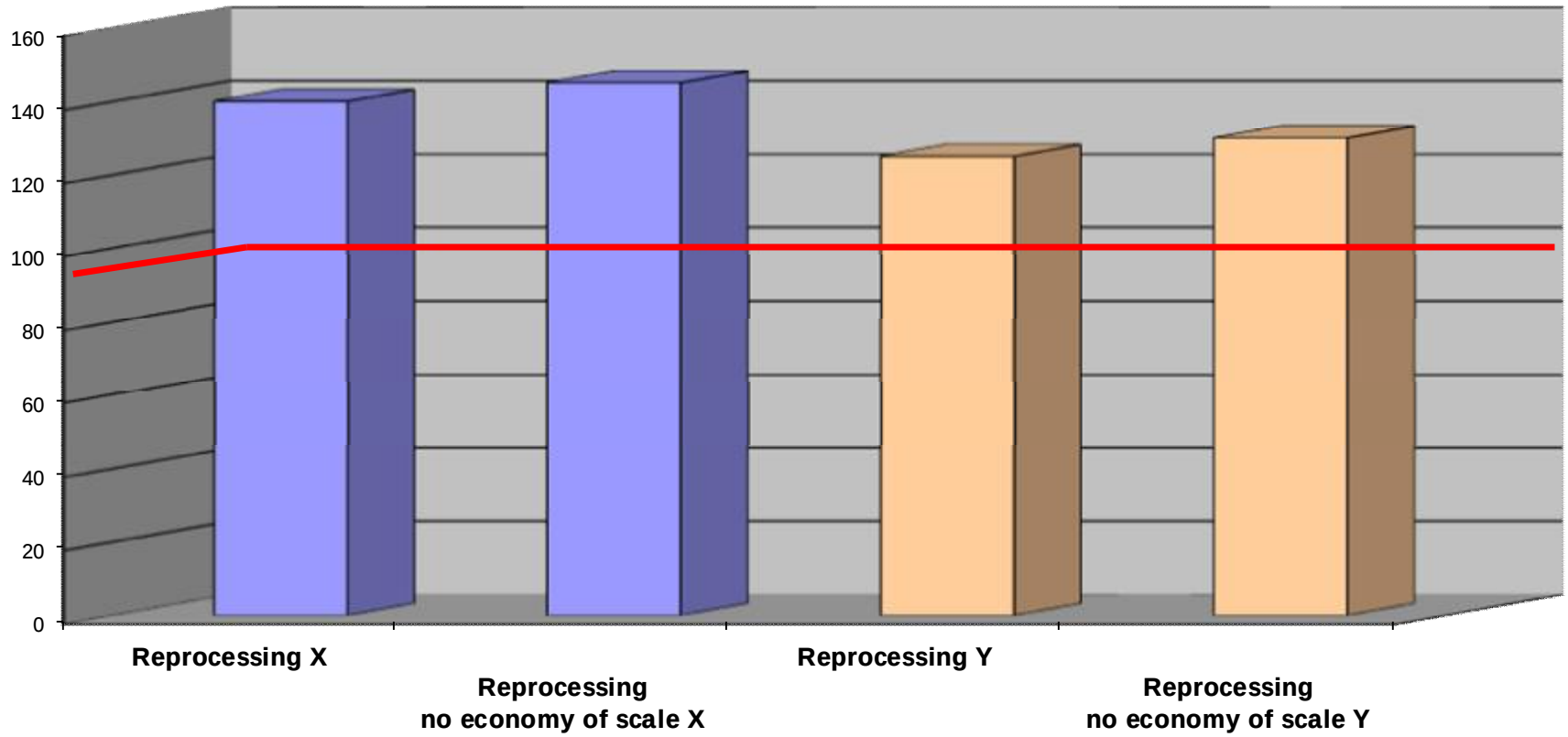
C.2 Cost of reprocessing incl. risk compared with purchase of cholangiography catheter (in %)



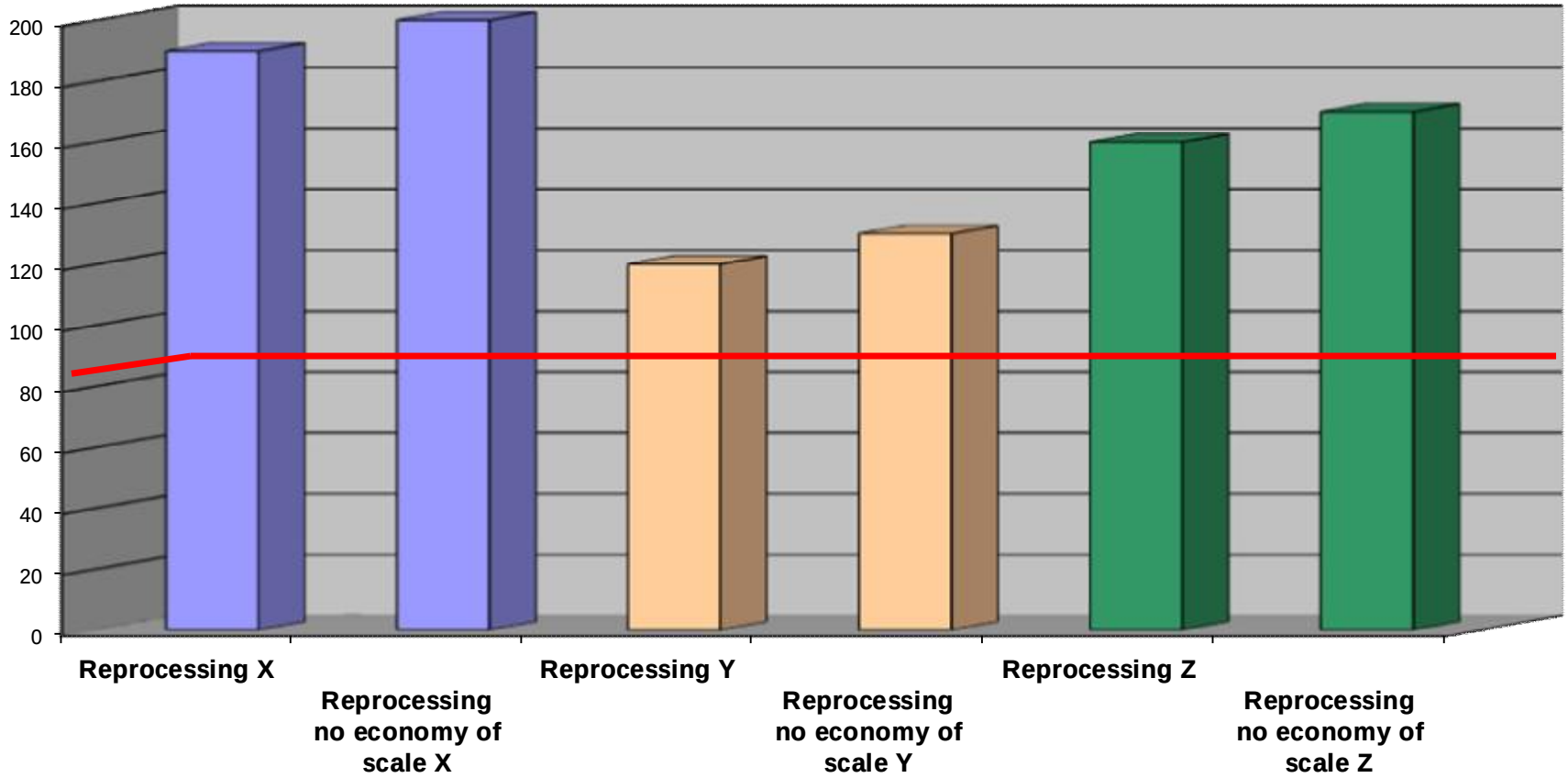
D.1 Cost of reprocessing compared with purchase of pacemaker electrodes (in %)



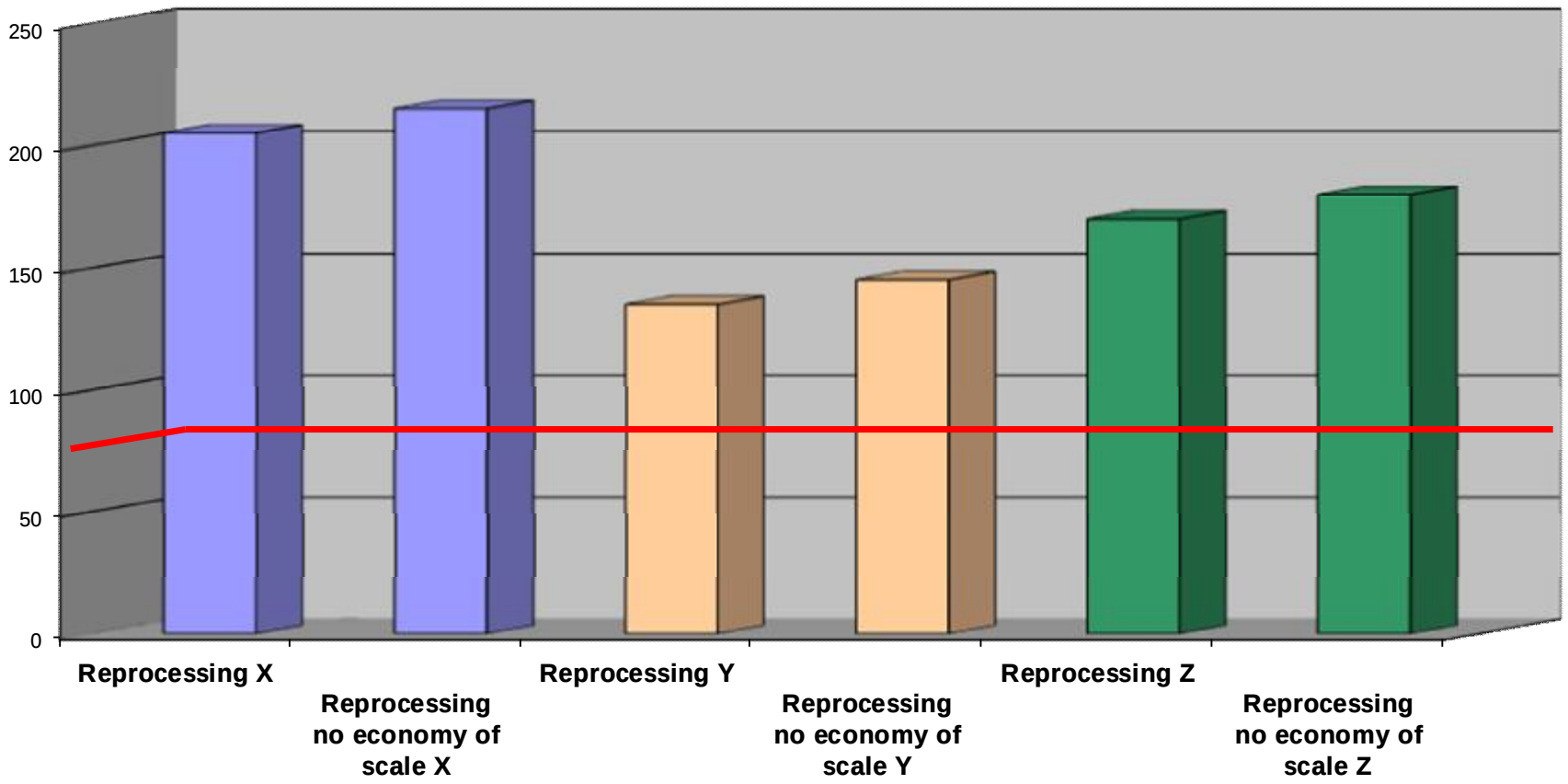
D.2 Cost of reprocessing incl. risk compared with purchase of pacemaker electrodes (in %)



E.1 Cost of reprocessing compared with purchase of electrodes (in %)



E.2 Cost of reprocessing incl. risk compared with the purchase of electrodes (in %)



CONCLUSION

there is a significant difference between the mean purchase price of medical devices by hospitals and the cost price of reprocessing medical devices conform the state-of-the-art.

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