Support of hospital processes with UDI numbers and GS1 standards

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GOKVI
Gottsegen National Cardiovascular Center

GS1 Hungary

Hungary

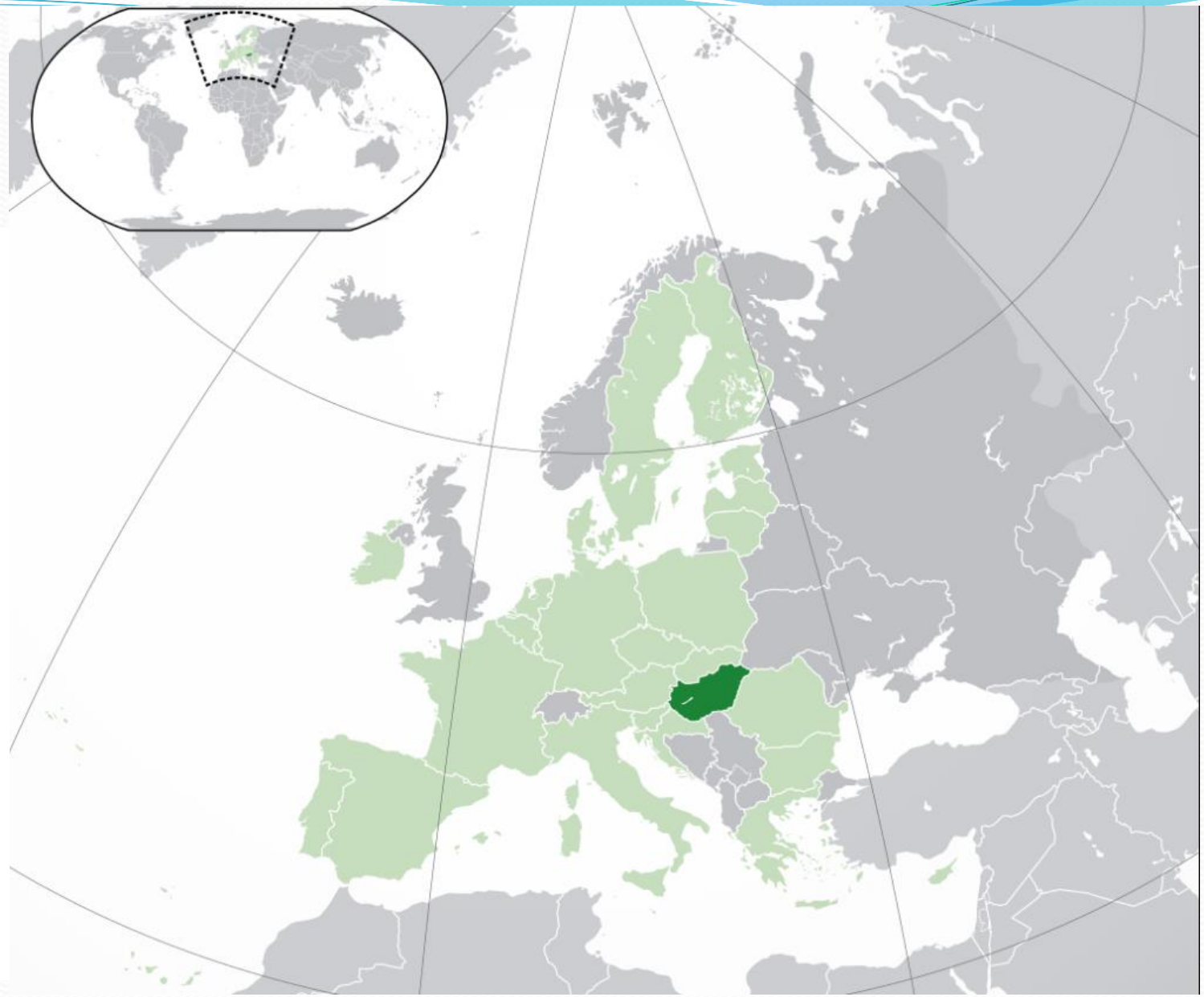
93 thousands km²

10 million inhabitants

EU In the EU since 2004

4,9 % of GDP spends on healthcare sector

169 hospitals including 94 state hospitals – 70.782 beds



Source: http://www.neak.gov.hu/, 2022. EGVE Conference (presentations of Zsuzsanna Selyem and Árpád Kovács)

Hospital Facts &Data

The task of the György Gottsegen National Cardiovascular Institute (Budapest) is the complex cardiovascular examination, non-invasive and invasive therapy of the entire spectrum of cardiovascular diseases for both children and adults, including interventional cardiology, electrophysiology, cardiac surgery and heart transplantation, as well as vascular surgery. Our primary task is the prevention of cardiovascular diseases and the monitoring of cardiology diseases. The Institute serves an average of 9,000 inpatients and 90,500 outpatients annually on 282 beds and 28 specialized outpatient clinics.

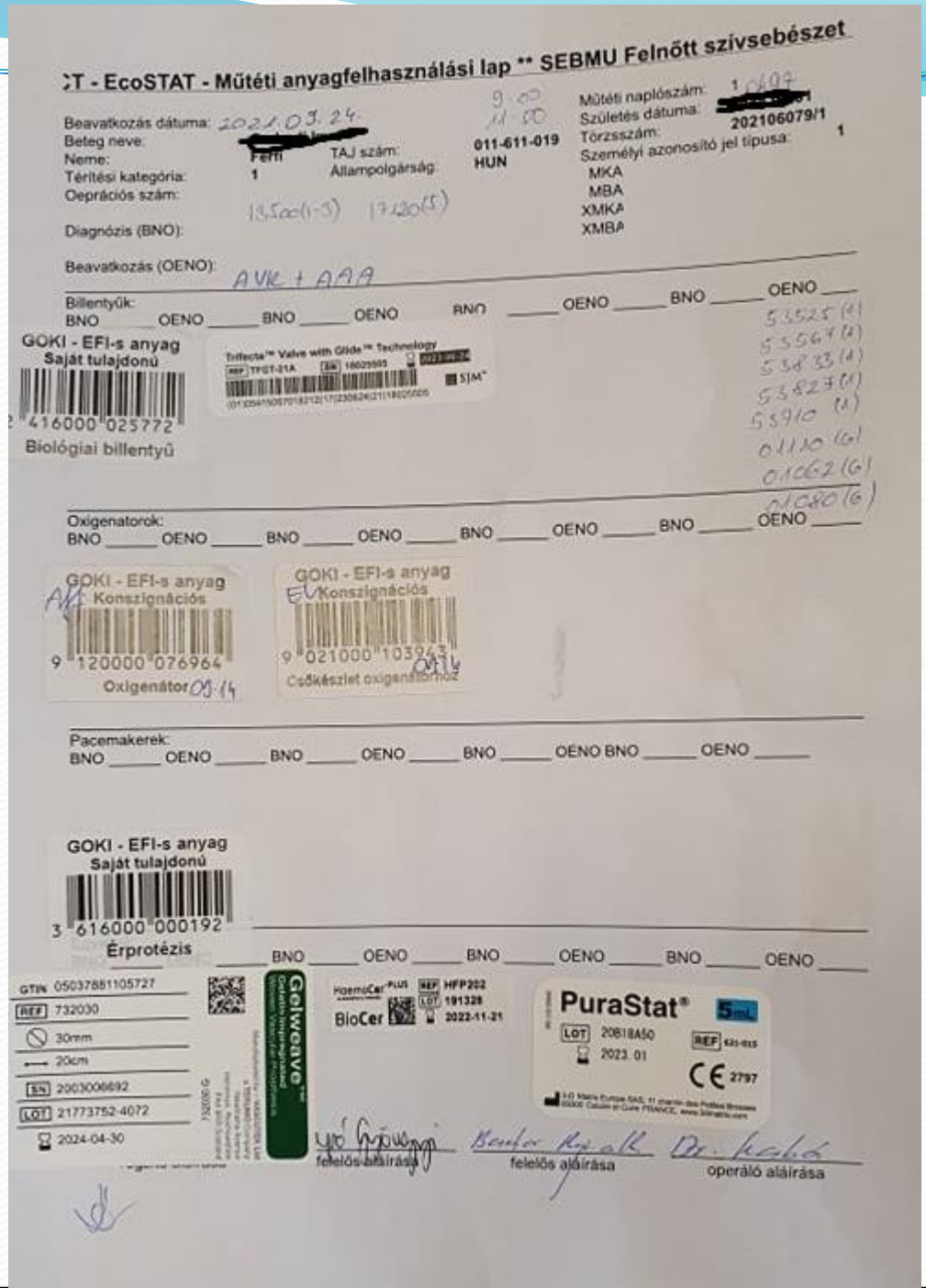
During diagnostic procedures and heart surgeries performed at the Institute, we use very expensive and special equipment. Since only a part of the performed surgeries can be planned in advance, a wide variety of tools must be kept in stock. When choosing tools, we strive to use good quality and modern technology, which is why the inventory value of these tools is very high. In order to ensure an optimal stock, the most expedient solution is to operate a consignment warehouse, where the goal is to ensure a permanent stock in such a way that the used equipment can be replaced almost immediately at the rate of use.

Material and device identification in the beginning

- We have been using different types of barcodes for product identification for more than 20 years. In the past, we couldn't get manufacturers and suppliers to use uniform barcodes on their products.

- The barcode was specified and manufactured according to our own internal plans.

Surgical material consumption sheet



CT - EcoSTAT - Műtéti anyagfelhasználási lap ** SEBMU Felnőtt szívsebészet

Beavatkozás dátuma: 2021.03.24.
Beteg neve: [redacted]
Neme: Férfi
Térítési kategória: 1
Oeprációs szám:
Diagnózis (BNO):
TAJ szám: 011-611-019
Állampolgárság: HUN
Műtéti naplószám: 1[redacted]
Születés dátuma: [redacted]
Törzsszám: 202106079/1
Személyi azonosító jel típusa: 1
MKA
MBA
XMKA
XMBA

Beavatkozás (OENO): AVR + AAA

Billentyűk:
BNO ____ OENO ____ BNO ____ OENO ____ BNO ____ OENO ____ BNO ____ OENO ____

GOKI - EFI-s anyag
Saját tulajdonú
416000 025772
Biológiai billentyű

Trifecta™ Valve with Glide™ Technology
REF TFGT-21A SN 18025555 SJM

Oxigenatorok:
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GOKI - EFI-s anyag
Konszignációs
9 120000 076964
Oxigenátor

GOKI - EFI-s anyag
Konszignációs
9 021000 103943
Csőkészlet oxigenátorhoz

Pacemakerek:
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GOKI - EFI-s anyag
Saját tulajdonú
3 616000 000192
Érprotézis

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Gelweave™

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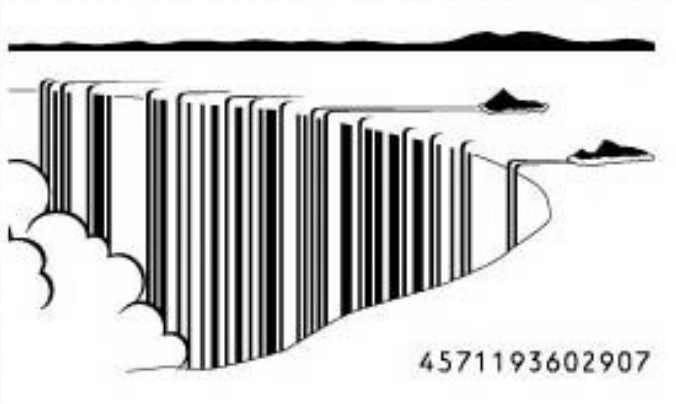
BioCer

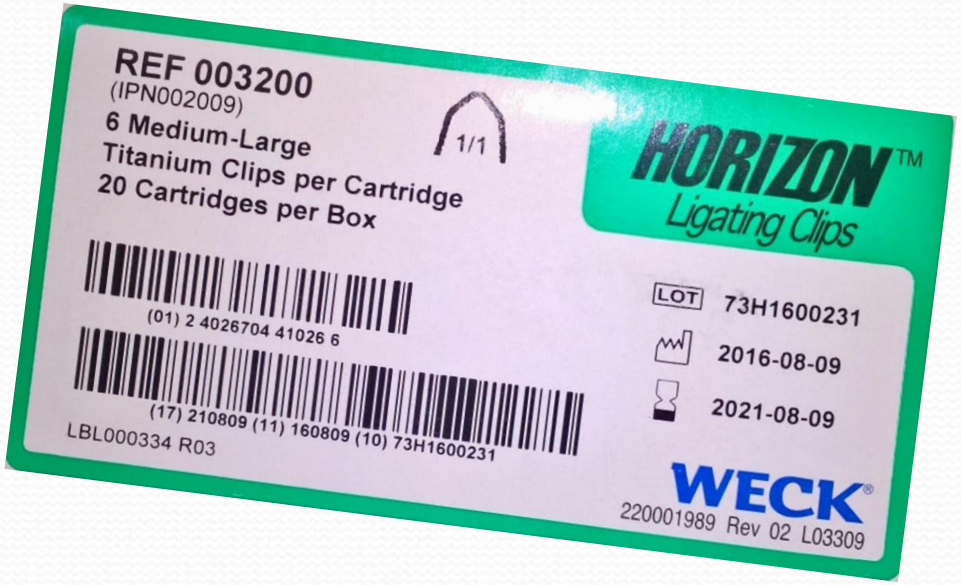
PuraStat® 5mL
LOT 20818A50 2023 01
REF 421-015
CE 2797

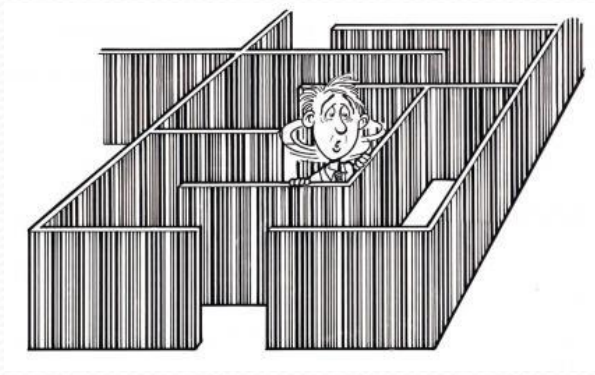
felelős aláírása
felelős aláírása
operáló aláírása

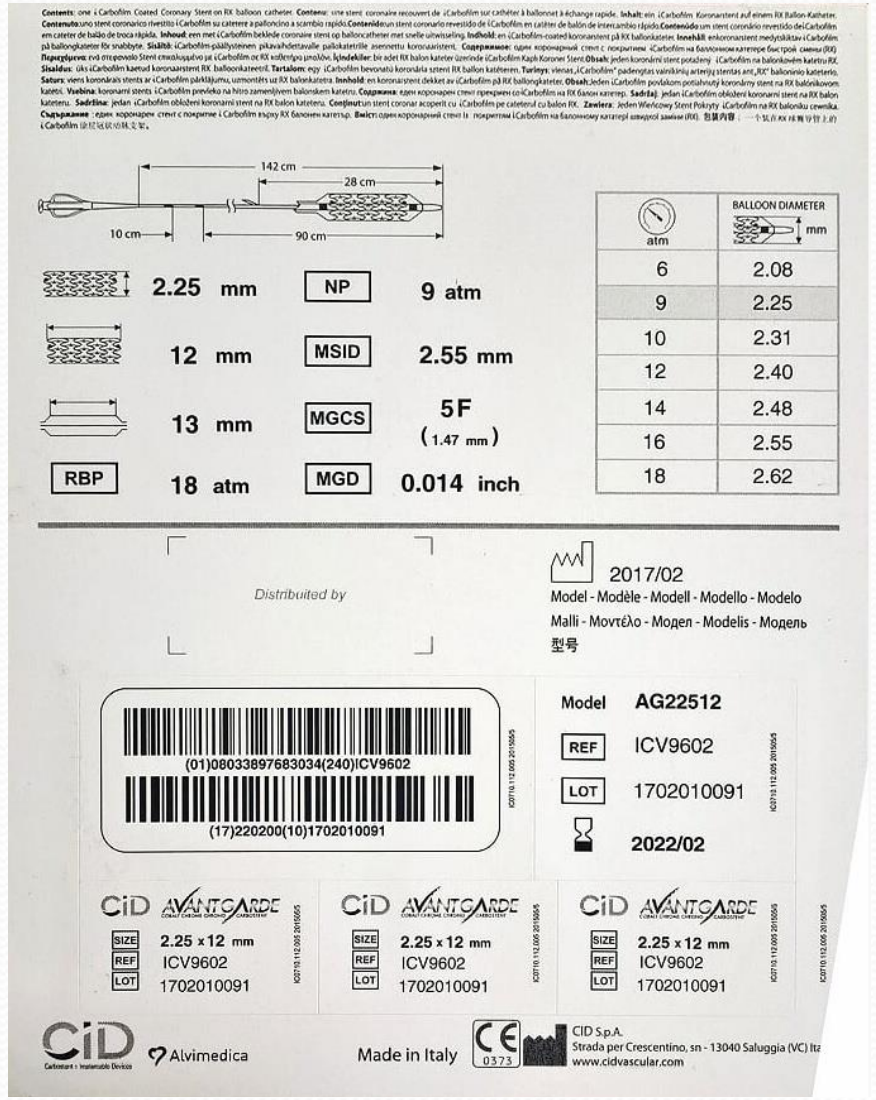
- *By using the barcode created according to the internal plans, it was possible to identify and select only the products from the article body.*
- *Additional data related to the product selected using the barcode scanner (production number, LOT number, production date, expiration date, unique identifier) had to be recorded manually in each case when the receipt was prepared.*
- *This work process contained a lot of possibilities for error and required a lot of time.*



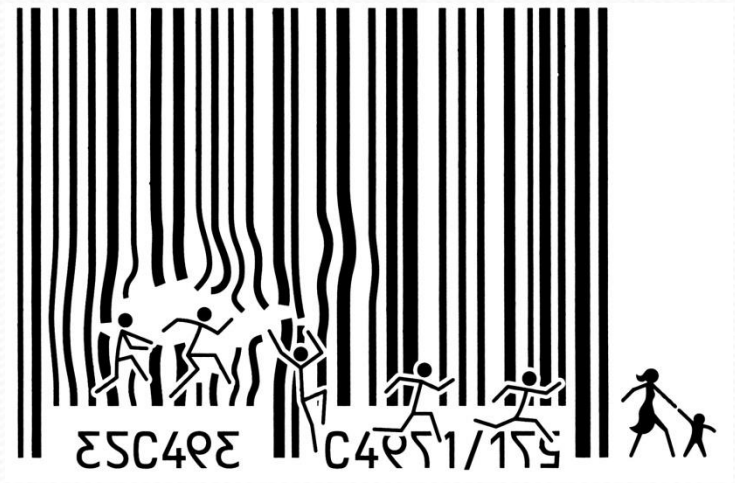
- 6-8 years ago, product distributors started to replace old product identification barcodes with a new type of barcode.
- At that time, distributors were not yet familiar with the structure of the GS1 standard.
- They knew nothing about barcode technology.

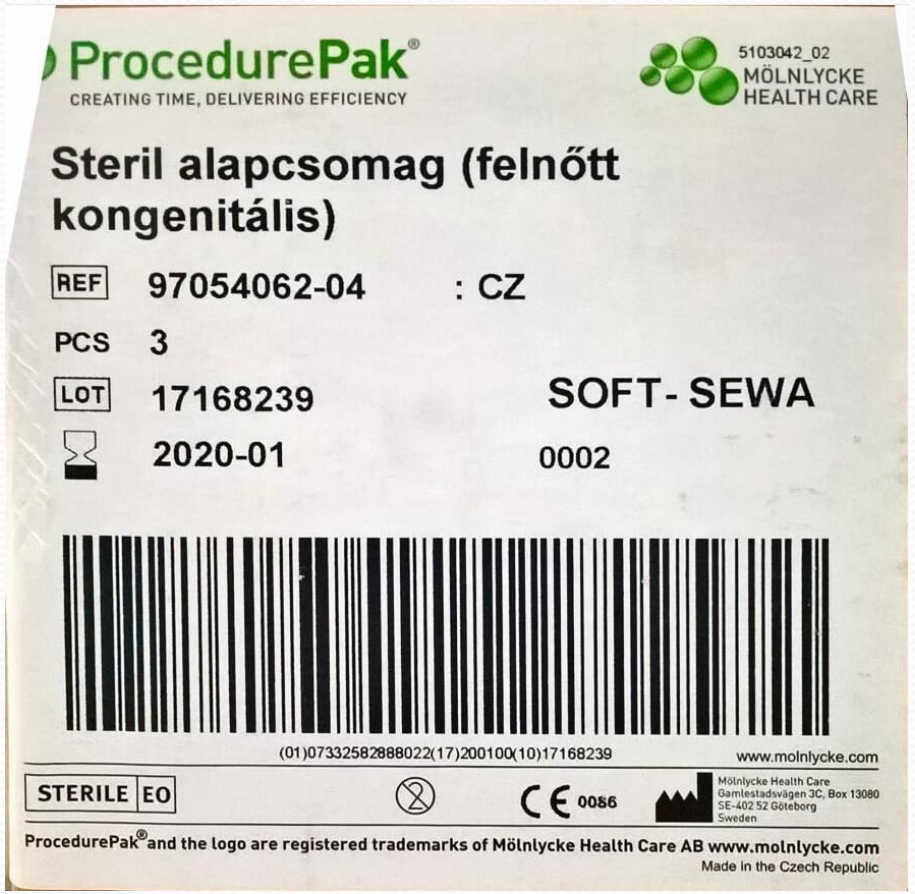






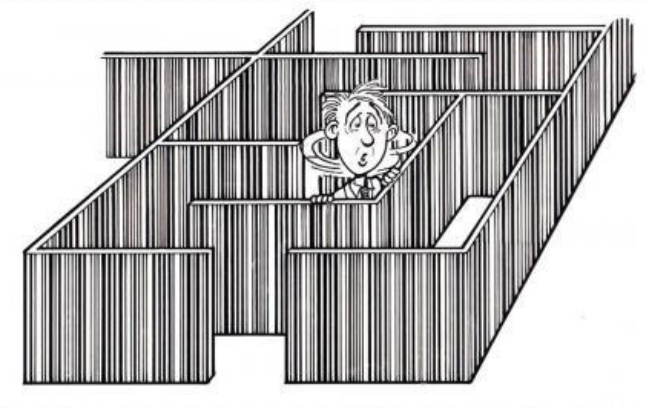
- With the appearance of one- and two-dimensional barcodes, our previous product identification system became unusable.
- Again, manual data entry had to be used.





Getting to know the standard and barcodes

- Getting to know the GS1 standard,
- Interpretation of the technical parameters included in the standard, (data content identifiers -AI, group separators -GS),
- Getting to know the databases related to the parameters,
- Interpretation of fixed and variable length technological data defining the structure of GS1 barcodes,
- Separation of various collective packaging units of the product (may vary by manufacturer),
- Correspondence of unique and various collection packages.



The UDI system - Unique Device Identification

- The Unique Device Identification System aims to provide a globally harmonized framework for the identification of medical devices in order to significantly improve the quality of care, ensure patient safety and make business processes more efficient.
- The introduction of the UDI system is an international process, which is required in the European Union by Regulations 745/2017 (MDR) and 746/2017 (IVDR), while in the USA by the US FDA, Final Rule (09/24/2013) legal documents .
- The aim of the EU Regulations is to guarantee the safe use of medical devices in two ways:
  - strengthening the rules for the market distribution of devices
  - by tightening the control of traded assets.

- *We have established professional contact with the specialists from GS1 Hungary*

- *At the same time, the development and transformation of the software had to be planned together with the developers of the economic system.*

- *The development had to be carried out in such a way that the software changes and new data entry screens did not interfere with the daily routine and working methods used in other hospitals.*

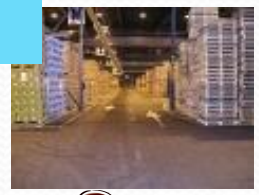
Stock images

The process

Supplier

Consumption advice

Consignment warehouse



Consignment store

Central warehouse

Automated receipt generation

Inbound flow and warehouse stocking

Recording data: surgical material consumption

- **Receipt to the consignment warehouse (Economic system - inventory module - receipt)**
  - *Enter the standard data required to prepare the receipt (supplier's name; delivery note number; date of receipt).*
  - *Scanning the barcode of the product to be received using a barcode reader.*
  - *After scanning, the system records the additional data in the appropriate data field.*
  - *After that, you only have to enter the amount to be received and the receipt can be closed*
  - *The stock has been purchased. The system manages the barcode of the product's collective packaging.*

- ***Material release from consignment warehouse to consignment manual warehouse (operating room)***

  The release to the manual warehouse is actually a transfer between warehouses, where the material is transferred from the warehouse to the operating room for use.
  - *After opening the release receipt, you only need to enter the name of the transferring and receiving warehouse.*
  - *It is necessary to scan the barcode of the products to be issued.*
  - *After entering the quantity, the receipt is ready.*

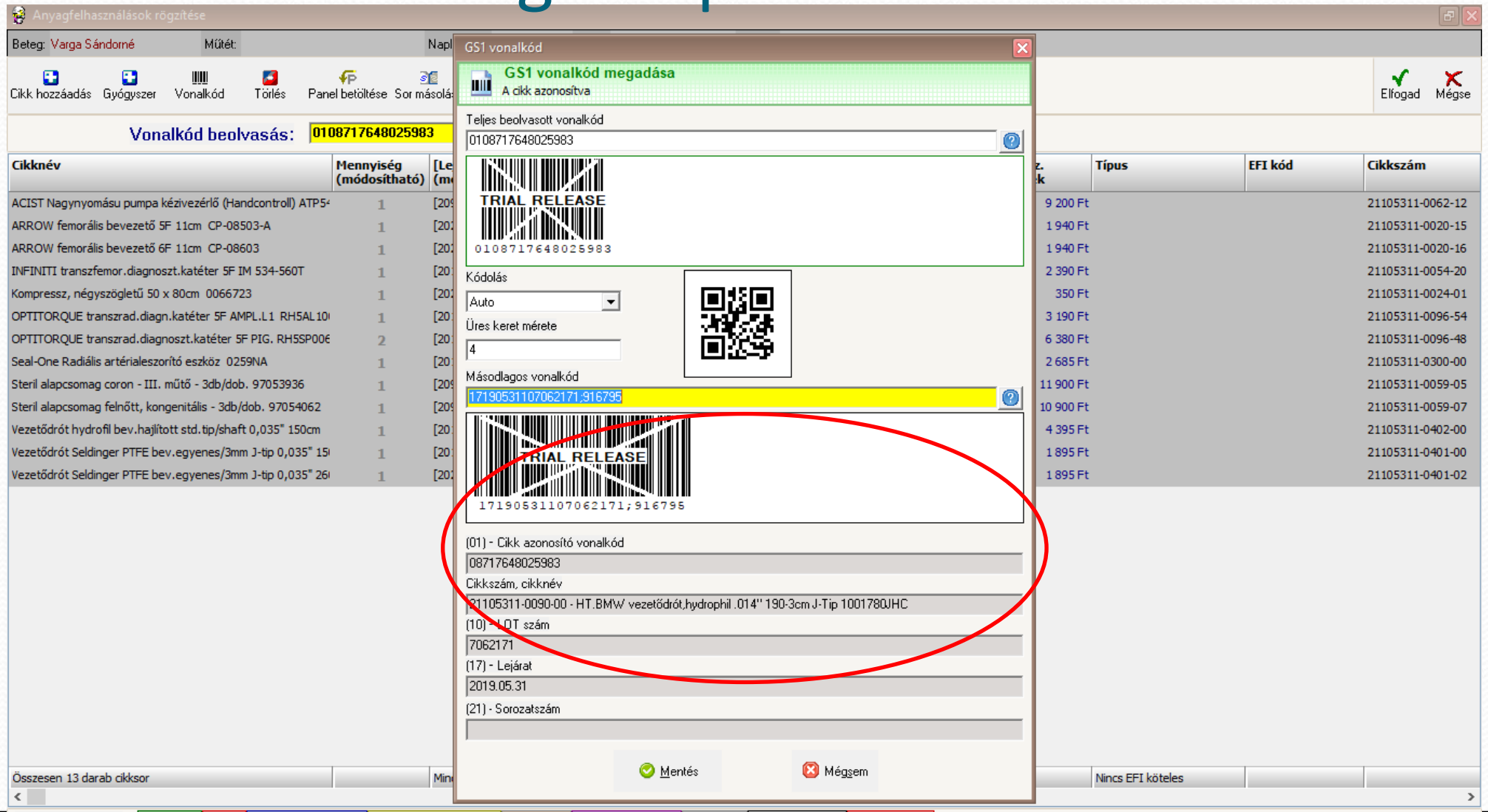
- ***Material release from consignment warehouse for direct use***

  Materials for direct use are those that are used for more than one patient (e.g. cooling gas for ablation, contrast material syringe). Therefore, it is not possible to attach it to the patient.
  - When preparing the receipt, the name of the transferring warehouse and the user department must be entered.
  - Then the bar code of the product to be used is read.
  - The amount used is specified.
  - After the data entry, the economic system generates two additional receipts so that the use is passed through the billing system and the central warehouse's registration system.
  - An automatic receipt is also created, so that the value of material consumption is written off from the budget of the department.

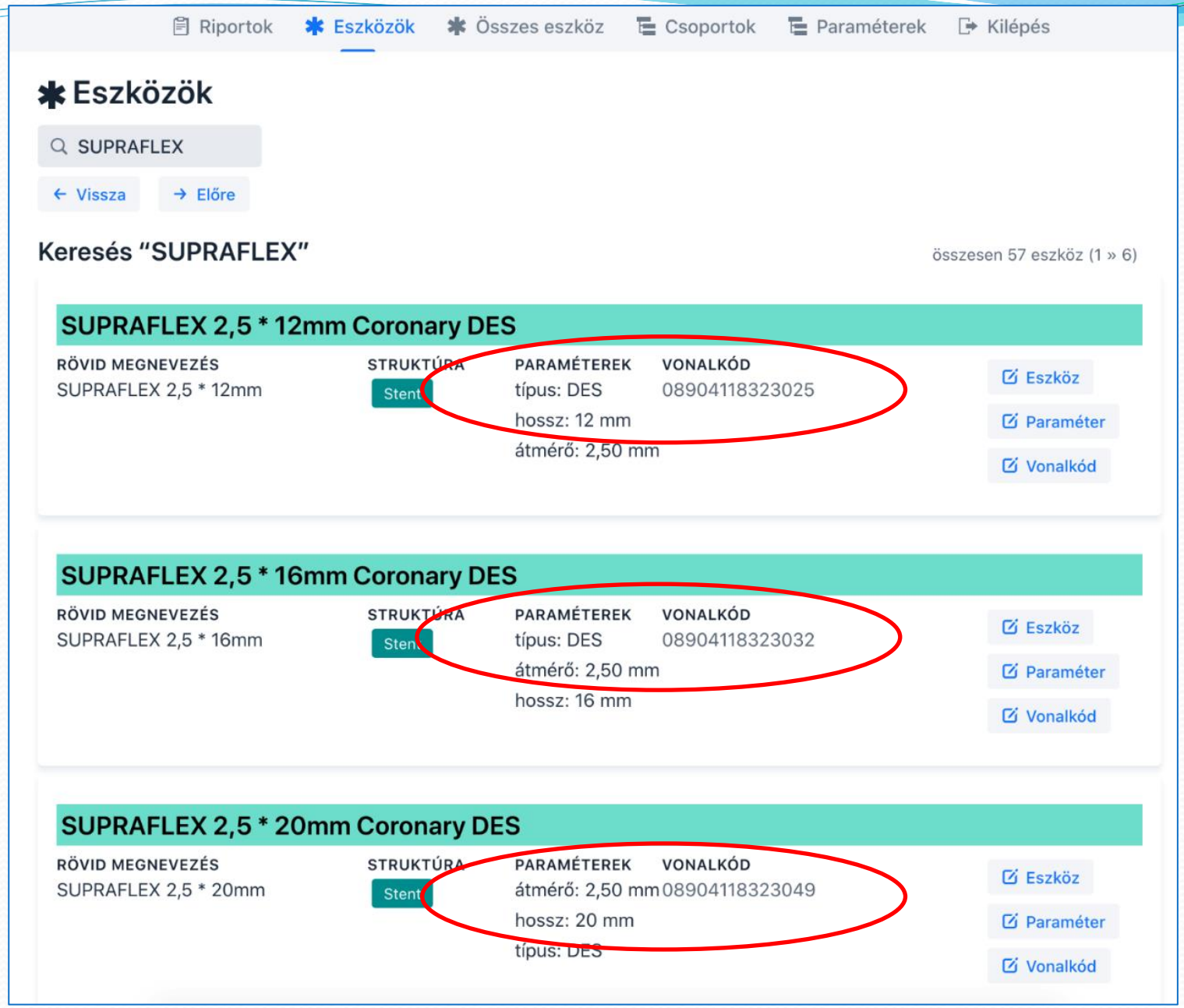
Recording patient-related medical device usage

- *The patient's data must be selected in the surgery module of the economic system.*
- *After that, the bar code of the materials used during the intervention must be scanned using a bar code scanner and the amount used must be entered.*
- *On the basis of the recorded receipts, the receipt is prepared for each supplier (according to the product owner), which forms the basis of invoicing.*

Inbound flow to the consignment warehouse using the product barcode



Creating surgical documentation using barcodes


Riportok
Eszközök
Összes eszköz
Csoportok
Paraméterek
Kilépés
Eszközök
SUPRAFLEX
Vissza
Előre
Keresés "SUPRAFLEX"
összesen 57 eszköz (1 » 6)
SUPRAFLEX 2,5 * 12mm Coronary DES
RÖVID MEGNEVEZÉS
SUPRAFLEX 2,5 * 12mm
STRUKTÚRA
Stent
PARAMÉTEREK
típus: DES
hossz: 12 mm
átmérő: 2,50 mm
VONALKÓD
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Eszköz
Paraméter
Vonalkód
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RÖVID MEGNEVEZÉS
SUPRAFLEX 2,5 * 16mm
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Stent
PARAMÉTEREK
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átmérő: 2,50 mm
hossz: 16 mm
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Eszköz
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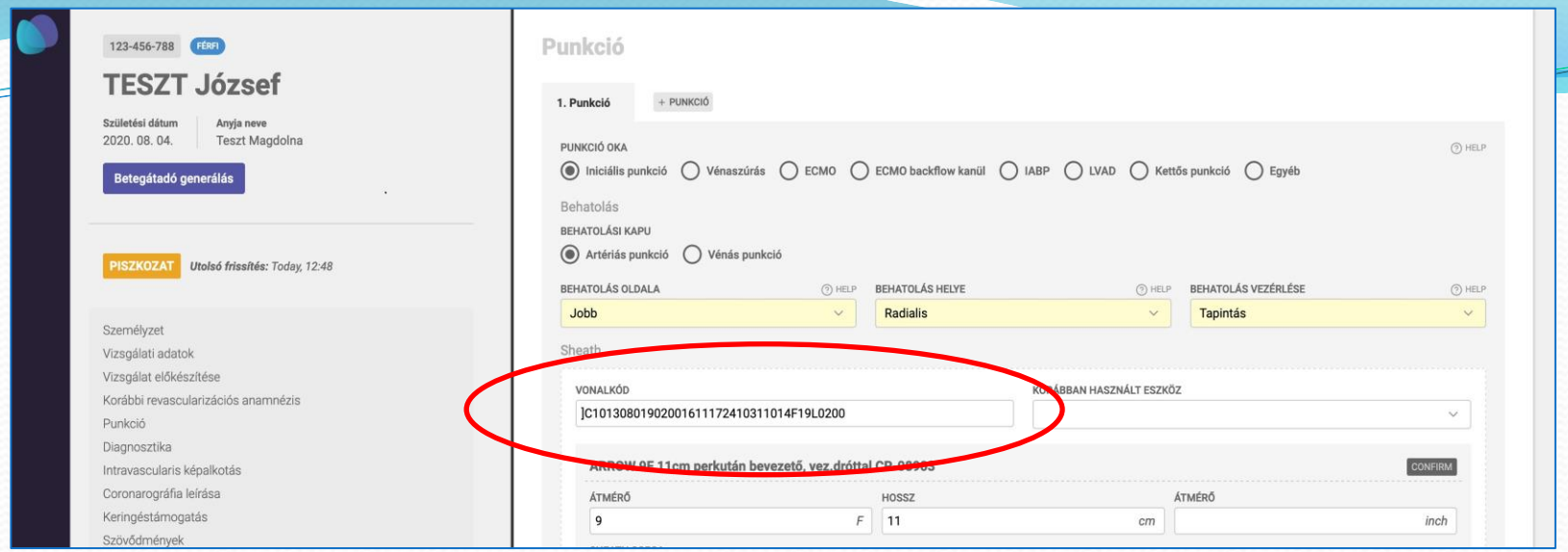
Paraméter
Vonalkód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TESZT József
Születési dátum
2020. 08. 04.
Anyja neve
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PISZKOZAT
Utolsó frissítés: Today, 12:48
Személyzet
Vizsgálati adatok
Vizsgálat előkészítése
Korábbi revascularizációs anamnézis
Punkció
Diagnosztika
Intravascularis képalkotás
Coronarográfia leírása
Keringéstámogatás
Szövődmények
Punkció
1. Punkció
+ PUNKCIÓ
PUNKCIÓ OKA
HELP
Iniciális punkció
Vénaszúrás
ECMO
ECMO backflow kanül
IABP
LVAD
Kettős punkció
Egyéb
Behatolás
BEHATOLÁSI KAPU
Artériás punkció
Vénás punkció
BEHATOLÁS OLDALA
HELP
Jobb
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Radialis
BEHATOLÁS VEZÉRLÉSE
HELP
Tapintás
Sheath
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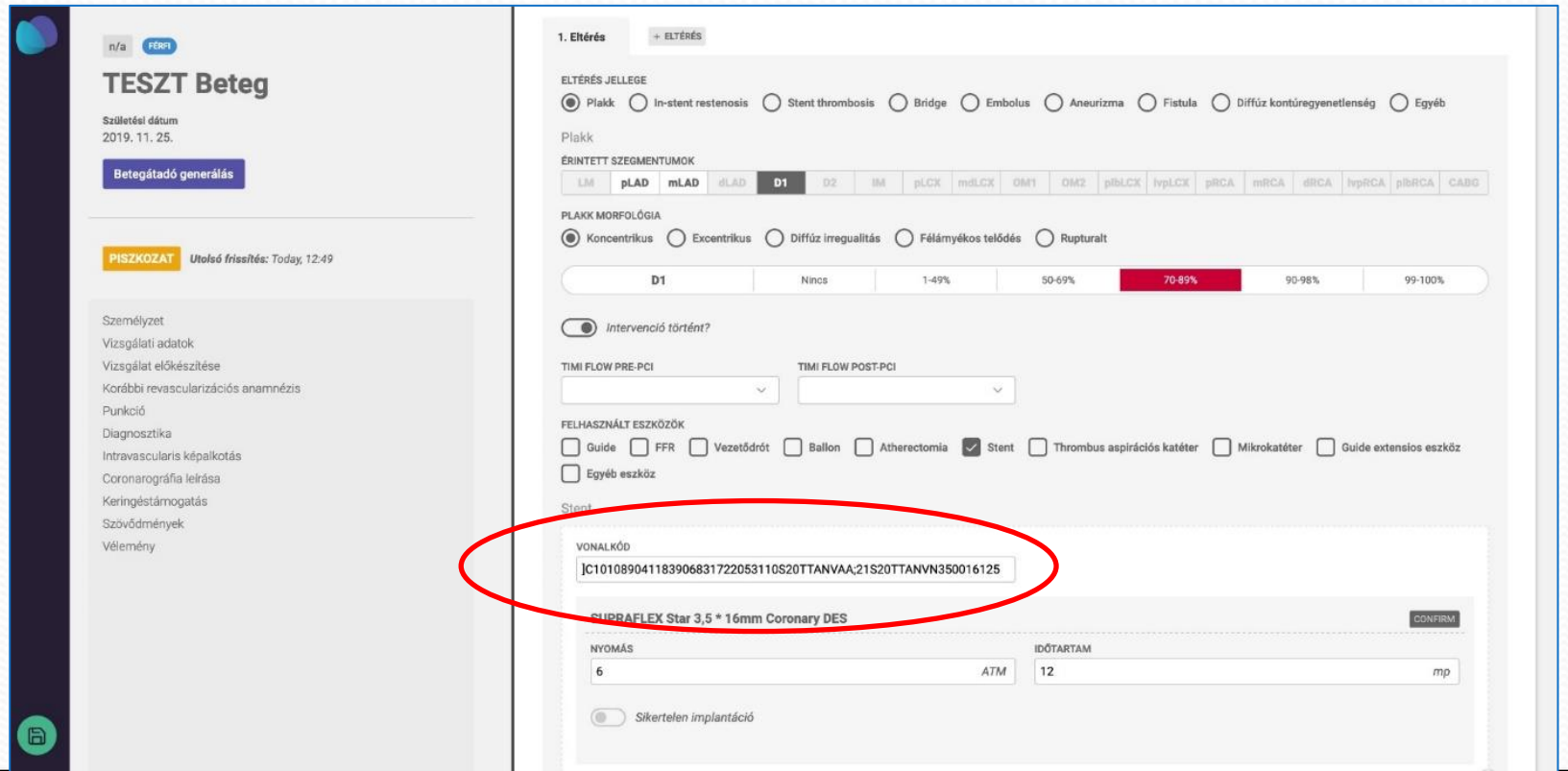
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Személyzet
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Vizsgálat előkészítése
Korábbi revascularizációs anamnézis
Punkció
Diagnosztika
Intravascularis képalkotás
Coronarográfia leírása
Keringéstámogatás
Szövődmények
Vélemény
1. Eltérés
+ ELTÉRÉS
ELTÉRÉS JELLEGE
Plakk
In-stent restenosis
Stent thrombosis
Bridge
Embolus
Aneurizma
Fistula
Diffúz kontúregyenetlenség
Egyéb
Plakk
ÉRINTETT SZEGMENTUMOK
LM
pLAD
mLAD
dLAD
D1
D2
IM
pLCX
mdLCX
OM1
OM2
plbLCX
lvpLCX
pRCA
mRCA
dRCA
lvpRCA
plbRCA
CABG
PLAKK MORFOLÓGIA
Koncentrikus
Excentrikus
Diffúz irregularitás
Félárnyékos telődés
Rupturalt
D1
Nincs
1-49%
50-69%
70-89%
90-98%
99-100%
Intervenció történt?
TIMI FLOW PRE-PCI
TIMI FLOW POST-PCI
FELHASZNÁLT ESZKÖZÖK
Guide
FFR
Vezetődrót
Ballon
Atherectomia
Stent
Thrombus aspirációs katéter
Mikrokatéter
Guide extensios eszköz
Egyéb eszköz
Stent
VONALKÓD
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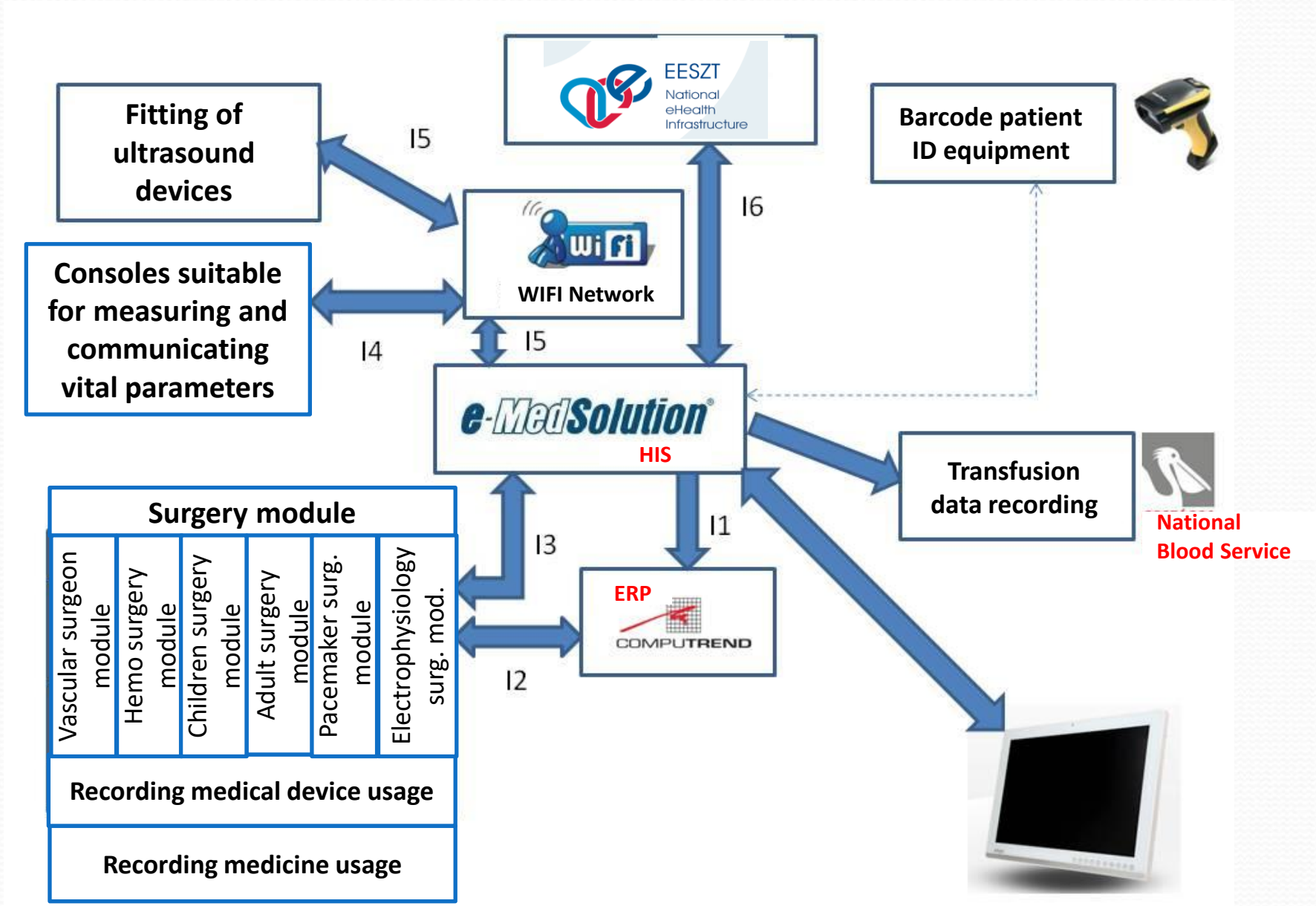
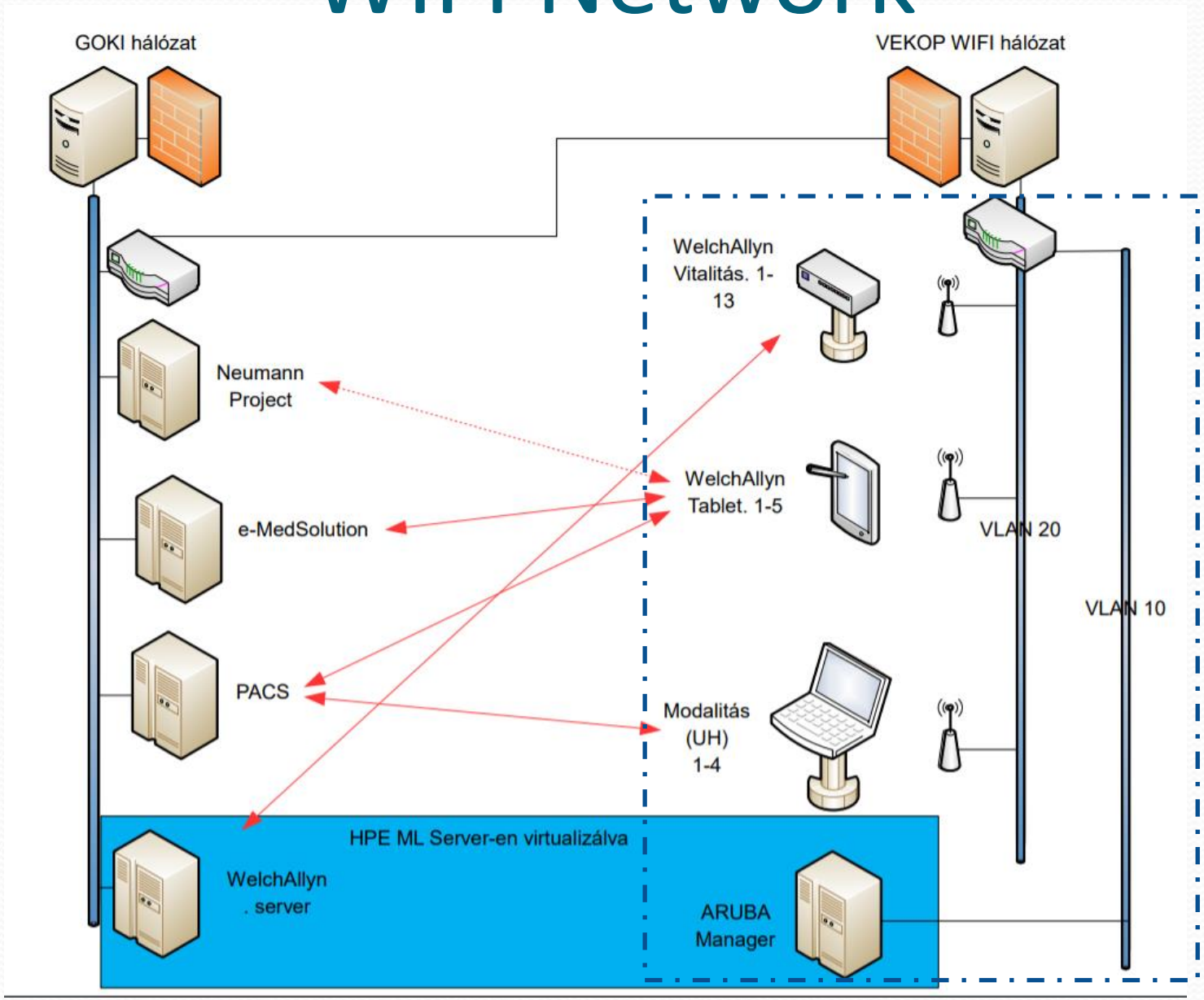
ATM
IDŐTARTAM
12
mp
Sikertelen implantáció


EESZT
National eHealth Infrastructure
Fitting of ultrasound devices
I5
Barcode patient ID equipment
I6
Consoles suitable for measuring and communicating vital parameters
WIFI Network
I4
I5
e-MedSolution
HIS
Transfusion data recording
National Blood Service
Surgery module
Vascular surgeon module
Hemo surgery module
Children surgery module
Adult surgery module
Pacemaker surg. module
Electrophysiology surg. mod.
I3
I1
ERP
COMPUTREND
I2
Recording medical device usage
Recording medicine usage

WIFI Network



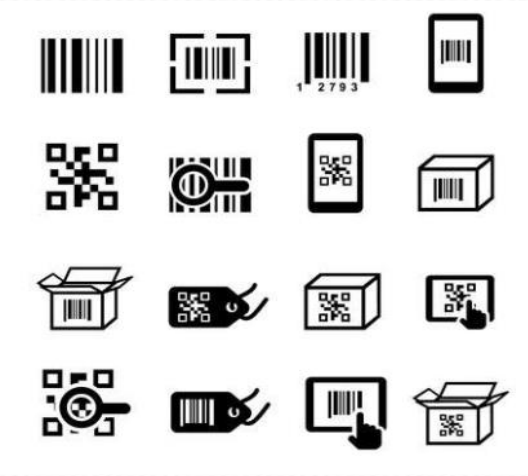
Devices

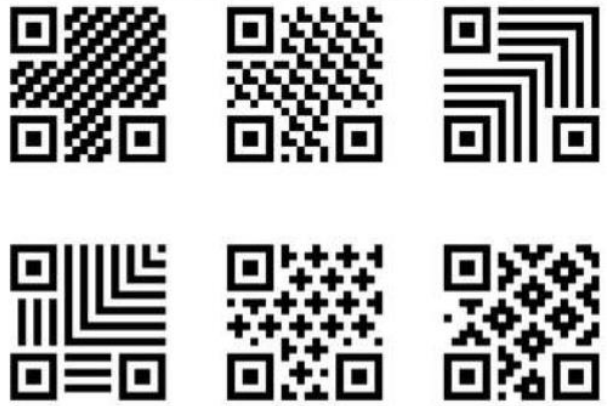
g

Barcode usage during patient care

Project goals I.

- Identification of inpatients based on wristbands and follow-up within the hospital (patient admission, transfer, discharge, operations, diagnostic tests,...).
- Implementation of barcode patient identification in wards and nurses desks.
- Fast and error-free data entry of the materials and preparations used with the help of barcode devices (e.g. blood preparations).
- Fitting wireless barcode reading devices in workplaces relevant to care. Improving patient care management in all patient care and diagnostic workplaces.
- The freedom of data entry can be increased by using a Wi-Fi network.





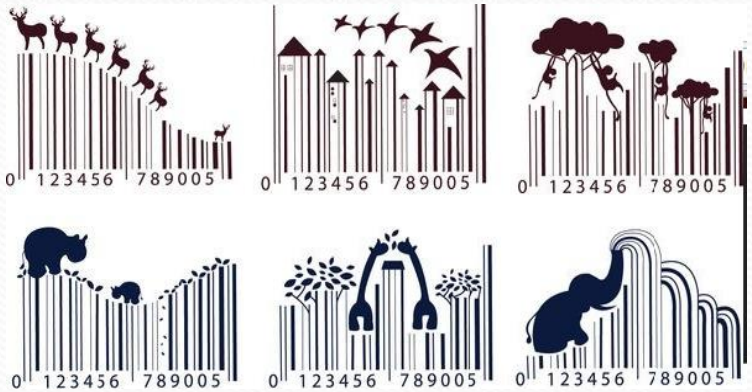
Project goals II.

- Measuring the vital parameters of inpatients and transferring the data to the HIS system via a Wi-Fi network.
- The patients' vital parameters (temperature, saturation, pulse, blood pressure) are stored in the database of the HIS system, so they can be directly part of the patient documentation.
- With the establishment of the Wi-Fi network, it is possible to transfer the ultrasound examinations of patients carried out at the bedside and in the operating room to the PACS system. We connected existing ultrasound devices to a Wi-Fi network.
- We want to improve patient safety by installing bedside patient identification in special medical places with specifically designed tablet devices for medical purposes.
- A lot of blood and blood products are used during surgical interventions at GOKVI. With the creation of a central transfusion workplace, it is possible to record administered blood products and record them in the patients’ documentation.

Patient wristbands

Patient identification in practice

- identification based on personal data
- identification based on a barcode wristband
- identification based on a central patient ID
- identification based on ambulatory diary serial number
- identification based on inpatient case identification number
- identification based on request identifier
- identification based on medical report identifier
- barcode on the document requesting the examination and intervention



ológiai vizsgálatokhoz

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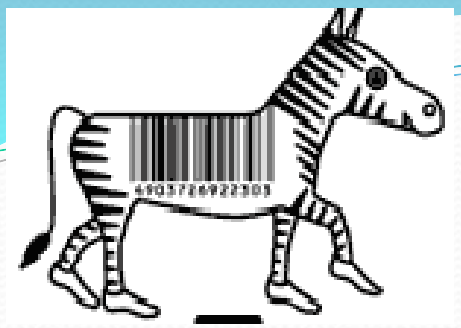


Benefits and implementation experience

- *The development had to be carried out in such a way that the new procedures and screens did not interfere with the daily routine and working methods that had been used in other hospitals.*
- *All data entered with the help of barcodes is entered into the database without data loss both during receipt and during use.*
- *The workload of data recorders has decreased by more than 30-40%.*
- *Warehouse employees can perform other storage activities during the freed up working hours.*
- *Wireless technology can also be used during implementation.*
- *Users get access to the materials and tools that are important to them earlier.*
- *On-line recording has become feasible at the point of use.*
- *The multi-level management of the GTIN code of the packaging units has been solved.*
- *Based on the development of GOKVI, the developed software can also be used in other hospitals.*

Project management 1.

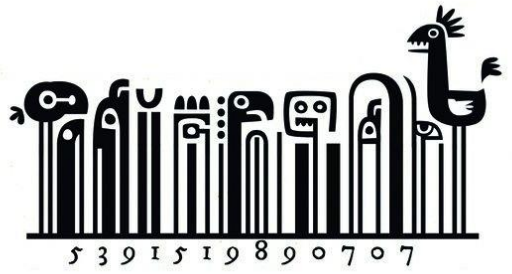
- *All delays during the procedure occur at the project management level.*
- *During the implementation of the project, the subcontractor of the subcontractors must also be managed so that the deadlines can be met.*
- *The formal rules related to the settlement of projects are not clear.*
- *The rules for project photography are not complicated.*
- *A multi-level project meeting was necessary according to the professional connection of the modules.*

Project management 2.

- *Foreign partner among the implementers*
- *You have to adapt to the health environment.*
- *Different requirements for contractor and subcontract contracts.*
- *Product change during introduction.*
- *Emigration of professionals involved in the implementation of the project during the writing of the application and its implementation.*

Future projects

- *Sectoral introduction of a bedside work support system.*
- *A large number of wristband printers and barcode readers are being installed in hospitals.*
- *Any information can be added to the wristbands.*
- *Patient identification and transmission of health data are sent to the HIS systems and the EESZT.*
- *Radiological remote diagnostics support.*
- *Ambulatory management system support.*
- *They can be included in the audit of work processes within the institute in order to increase the effectiveness of secure patient identification*



GS1 Healthcare Reference Book 2018 - 2019

s in the Gottsegen György Hungarian Institute of Cardiology - Hungary

providers

raceability of medical devices in the Gottsegen György Hungarian Institute of Cardiology

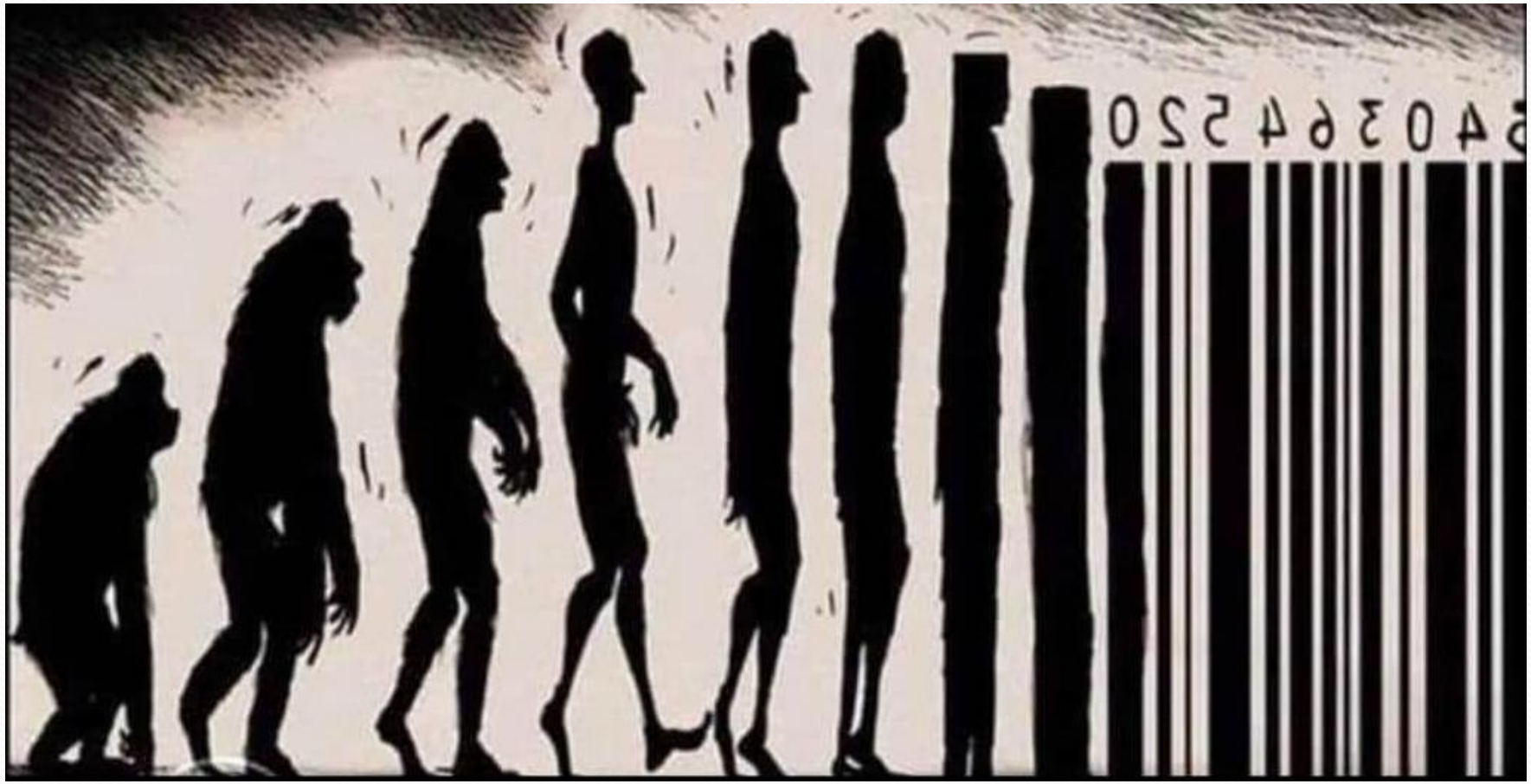
The Gottsegen György Hungarian Institute of Cardiology has always been a pioneer in the introduction and adoption of new surgical techniques and modern devices. So, when the institute learned about GS1 standards, it wanted to become the first to deploy and use this technology in its inventory management processes and financial systems. The institute has found that GS1 standards offer significant opportunities for the identification of medical devices with the ultimate goal to improve patient safety. Going forward, the institute intends to adapt existing applications in other parts of its hospital operations and systems.

By Professor Peter Andreka MD, István Nagy and Balázs Sommer

GOTTSEGEN GYÖRGY ORSZÁGOS KARDIOLÓGIAI INTÉZET

https://www.gs1.org/case-study/download-form/32420/7010

The choice is ours!



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