cor science

MDR Impact

Example: Defibrillation Devices

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Defibrillation - History

- 18th century: first experiments
  - „Leidener Flasche“ (100pF, 50kV, 125J, 5mC)
  - Charles Kite: An Essay on the Recovery of the Apparently Dead, London, 1788

Quelle: Efimov, Igor: History of fibrillation and defibrillation

- 19th century: first defibrillation (animal)
  - Jean-Louis Prevost / Federico Battelli:
    Journal de Physiologie et de Pathologie Générale, 1899

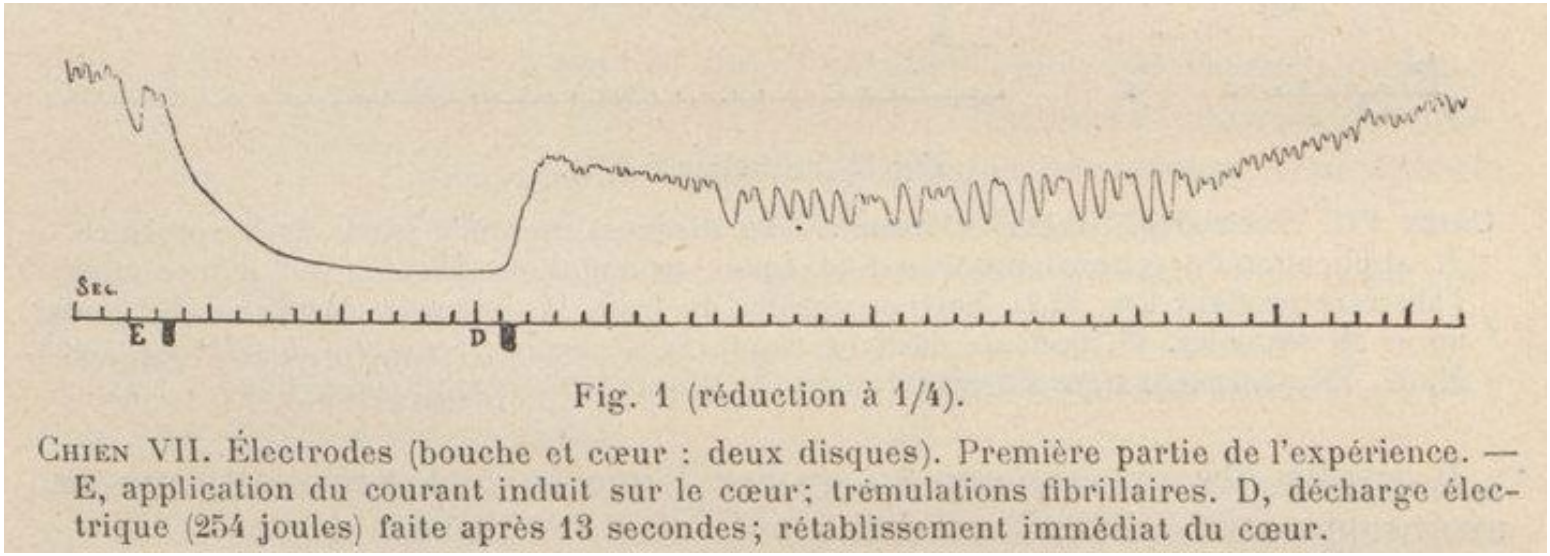


Fig. 1 (réduction à 1/4).

Chien VII. Électrodes (bouche et cœur : deux disques). Première partie de l'expérience. — E, application du courant induit sur le cœur; trémulations fibrillaires. D, décharge électrique (254 joules) faite après 13 secondes; rétablissement immédiat du cœur.

Quelle: Prevost, Battelli: Quelques Effets des Decharges Electrique - Sur le Coeur des Mammiferes, 1900.

Defibrillation - History

1947 Claude S. Beck:
first internal defibrillation
AC 60Hz, 1,5A, 110V

1956 Paul Zoll:
first external defibrillation
AC 60Hz, up to 750V; 0,15s

1970 first AED
Arch Diack,
Stanley Welborn,
Robert Rullman

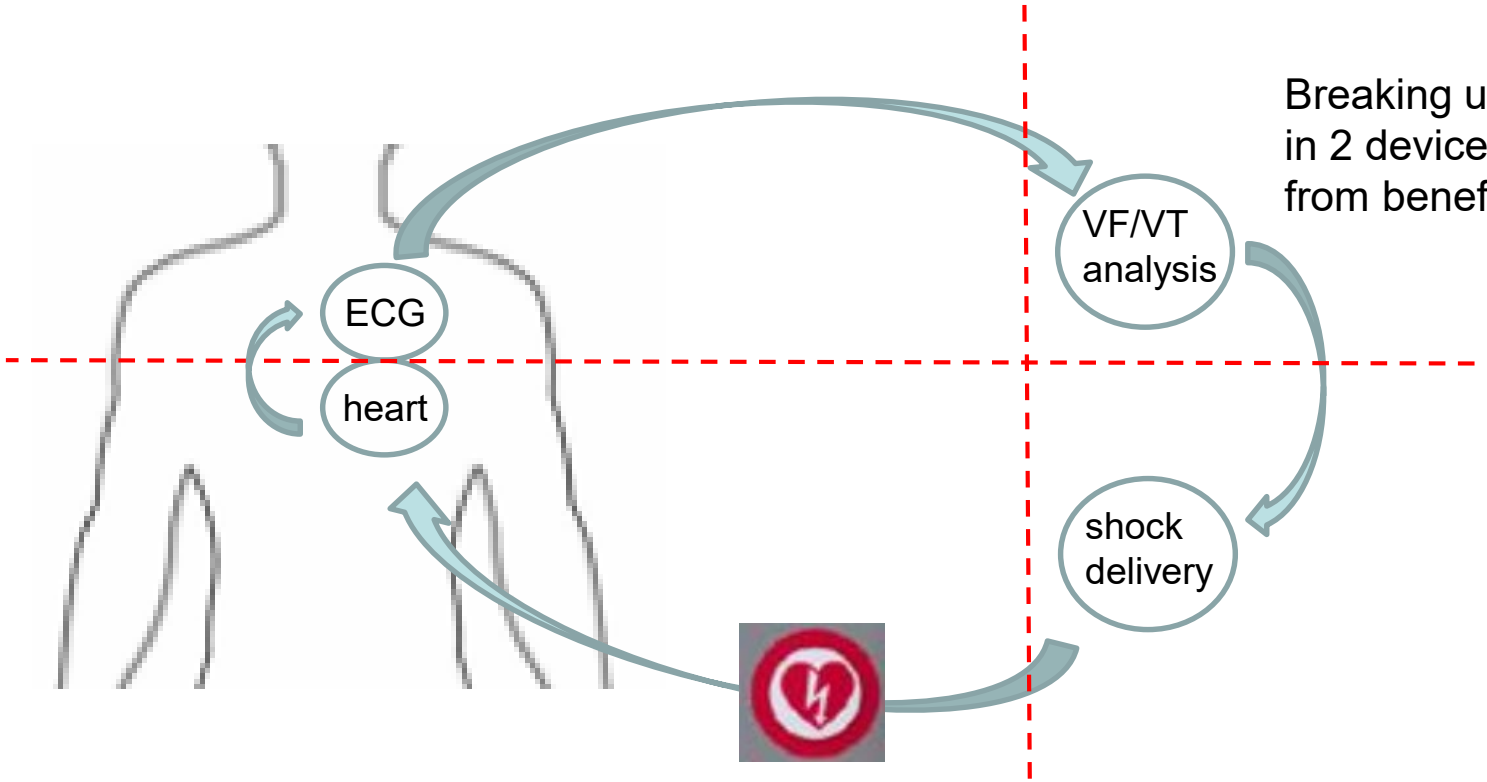
Quellen:
http://www.hrsonline.org/News/ep-history
Cakulev, Ivan :Cardioversion: past, present and future
www.defib.us.com/the-first-aed/

Defibrillation – Classification Rules

- MDD
  - Rule 9: All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

- MDR
  - Rule 9: All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.
  - Rule 22: Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

Defibrillation – closed loop system



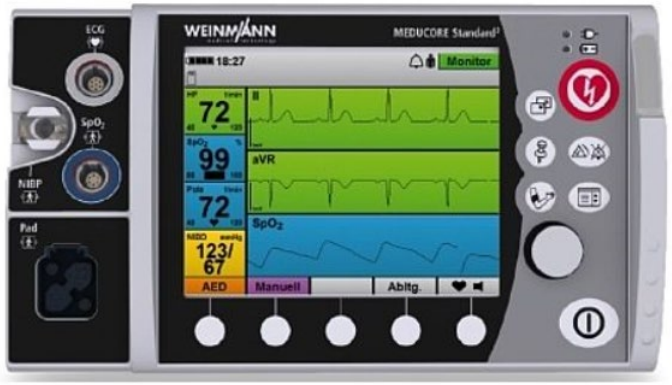
Breaking up the defibrillator in 2 devices is not acceptable from benefit-risk evaluation

Shock button is NOT breaking up the loop system

ventricular fibrillation
ventricular tachycardia

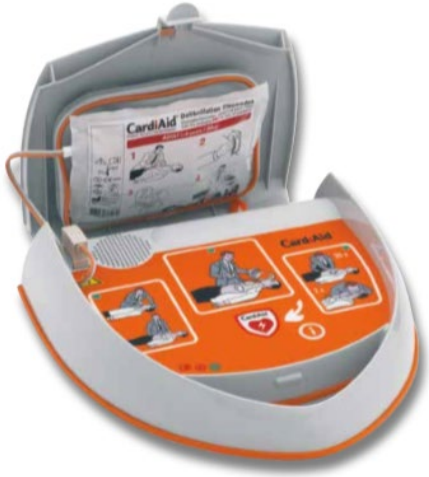
Defibrillation – Product Examples

Professional Defibrillator:



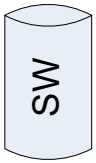
Weinmann: Meducore Standard²

AED:

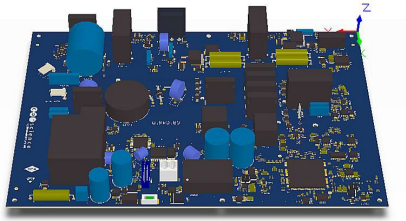


Cardia International:
CardiAid CT0207RS

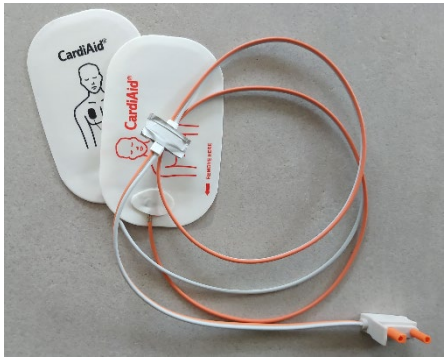
Components:



Corscience: HES AED



Corscience: BDM75



Cardia International: CA-10ES

Defibrillation – Components (SW)

- VF/VT algorithm: Integrated SW is no medical device
  - EN 62304 still applies
  - MDR Annex I, chapter 14.2c:
    the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts
  - MDR Annex I, chapter 17.2: For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation
  - MDR Annex I, chapter 17.4: Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended
  - MDR Annex I, chapter 32.4ab: for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

➢ The topic “cyber security” is coming into focus
(but far less than experienced from FDA guidelines)

➢ no real big impact from MDR

Defibrillation – Components (HW, electrode)

- PCB inside the defibrillator
  - MDR Annex II, chapter 1.1d: principles of operation of the device and its mode of action, scientifically demonstrated if necessary
  - MDR Annex II, chapter 1.1j a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams

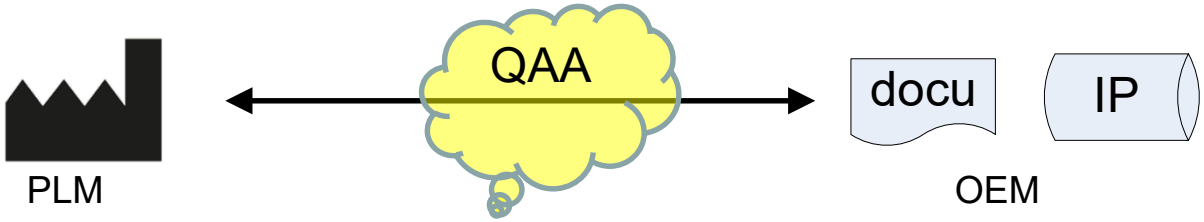
  ➢ no real big impact from MDR

- Defibrillation electrodes
  - Annex VIII, 3.2: If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used
  - Annex VIII, 2.8: 'Injured skin or mucous membrane' means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound

  ➢ Biocompatibility maybe affected by extended definition of "injured skin"
  ➢ no real big impact from MDR

Defibrillation – Components - PLM/OEM

- Article 10.4:
  - Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.
- Article 109:
  - Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following



➢ Timely view-only access and detail of technical documentation from module suppliers is required and has to be defined in an updated QAA (quality assurance agreement)

EK-MED / ZLG papers are at least partly obsolete

(309_1010_B_16, Zertifizierung von OEM-Produkten)

Defibrillation – Clinical Investigation

- MDD
  - Class III is explicitly mentioned in 4 points (outside the classification rules)
  - only 2 out of these are class III specific
- MDR
  - Class III is explicitly mentioned in 29 points (outside the classification rules)
  - only 13 out of these are class III specific

➢ key burden:

Introduction (63) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

➢ XIV Clinical evaluation and post-market clinical follow-up

➢ XV Clinical investigations

MedDev papers are at least partly obsolete

(MEDDEV 2.7.1/Rev4 CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC)

Defibrillation – Business Continuity

- MDR §61(6a)
  - Article §61: 6.The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices: (a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation: — is based on sufficient clinical data, and — is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available;

  - for already marketed devices no clinical investigation is required
  - Documents: CER, 60601-2-4 report

- MDR §61(4)
  - Article §61: 4.In the case of implantable devices and class III devices, clinical investigations shall be performed, except if: — the device has been designed by modifications of a device already marketed by the same manufacturer, — the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and — the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements. In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

  - for modifications of an already marketed device no clinical investigation required
  - Documents: CER, PMCF and positive evaluation of PMCF from NB

Defibrillation – Clinical Investigation

- MDR §8(1) and §9(2) and §71(3)
  - Article §8(1): 1.Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.
  - Article §9(2): 2.Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.
  - Article §71(3): 3.Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

    - for new devices based on harmonized standards or common specifications (CS) conformity shall be presumed
    - risk of clinical investigation shall be justified for devices following harmonized standards or common specifications (CS)
    - clinical investigation ???

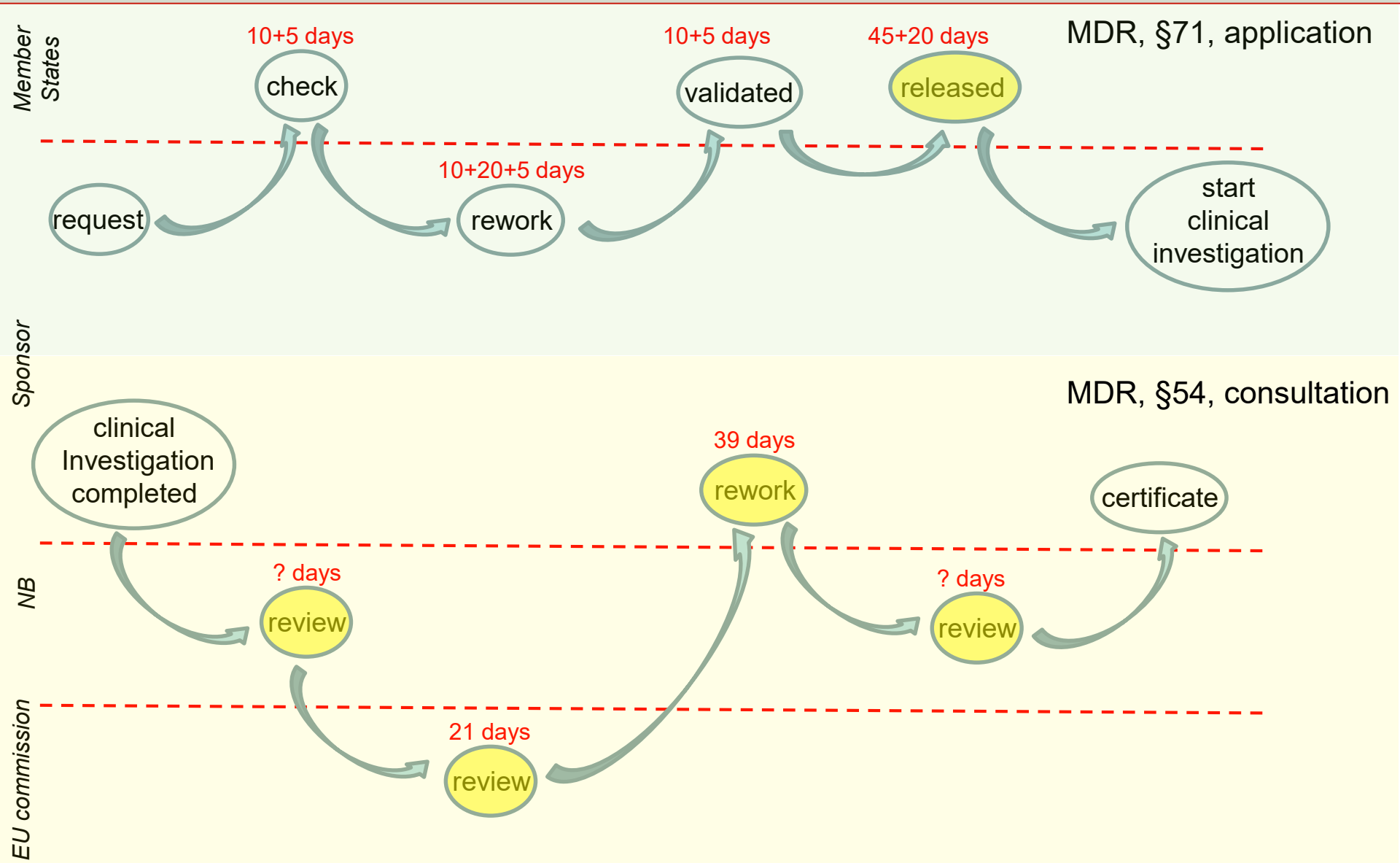
Defibrillation – Expert Panel

- MDR details / expert panel
  - Introduction (57) For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.
  - Article §61: 2.For all class III devices and for the class IIb devices referred to in point (b) of Article 54(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.

  - ➢ Additional alignment on clinical evaluation plan necessary
  - ➢ But the result is not reliable:

    The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure

Defibrillation – clinical investigation



Defibrillation – Other Class III Aspects

- MDR details / labelling
  - Article §123 (f) for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;

  ➢ Timeline for UDI labelling

- MDR details / surveillance by NB
  - Annex IX, 3.5: In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

  - Annex XI, 7: In the case of class III devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type and correspond to the quantities of finished devices.

  ➢ Preventive action for breast implant scandal (PIP)

Defibrillation – placed on the market…

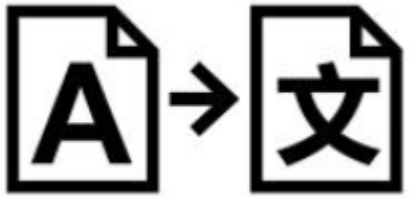
Defibrillation – placed on the market…

- MDR details / reporting
  - Introduction (48): For implantable devices and for class III devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.
  - Article §32: 1.For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.
  - Article §86: 2.For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.
  - Annex VI: 2.14. in the case of class III or implantable devices, the summary of safety and clinical performance,
  - Article §61: 11.The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.

  ➢ Upload to EUDAMED

Defibrillation – other aspects

- MDR
  - Annex I, 32.1: Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following
  - Article §16,2a: provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State
  - ➢ some responsibility is now at the distributor



- MDD - MPG - member state specifics
  - Medical device consultant only defined here
  - ➢ consultancy even for class III devices now open for all persons ?

- MPBetreibV – member state specifics
  - Guideline is based on MDD (see §1 of MPBetreibV)
  - Update not yet available
  - ➢ §11 (STK) and §14 (MTK) now obsolete ?

Thank you for your attention…

1970 – 2020: 50 years of AED and now first time class III

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