Medical Equipment Performance and Safety

- Clinical effectiveness vs. performance
- Life span of medical equipment

17.1.2 Relate Medical Equipment Performance to Safety

Unit C 17.1 Medical Equipment Safety

Module 279-17-C Regulations, Standards and Ethics

Clinical effectiveness vs. performance

A device is **Clinically Effective** when it produces the effect
intended by the manufacturer relative to the medical condition.

For example, if a device is intended for pain relief, it is clinically effective if it actually relieves pain.

Clinical effectiveness is a good indicator of device performance
(i.e. normally, if the device is effective, it is also performing well)

But: for a device to demonstrate a good ***performance*** **it is not enough to be clinically effective**:
also other technical features need to function/perform well.
For example, an alarm feature may not directly contribute to clinical effectiveness but may be necessary for good performance.

Performance (does the device function as intended) is easier to measure than clinical effectiveness.

That's why most Regulation refers to Performance, rather than Clinical Effectivity!

Safety is closely aligned with device performance

Risks are often associated with non-performance of a device
i.e.
risk occurs often when a device is malfunctioning

A car is effective when it can drive, but it is dangerous if its tires are worn or its lights malfunctions

Driving is always dangerous, but it gets especially dangerous when the car breaks down

For example, a patient monitor that does not perform well can pose serious clinical safety problems to the patient.

Thus, the **safety** and **performance** of medical devices are normally considered together.

Safety, performance and preventive maintenance

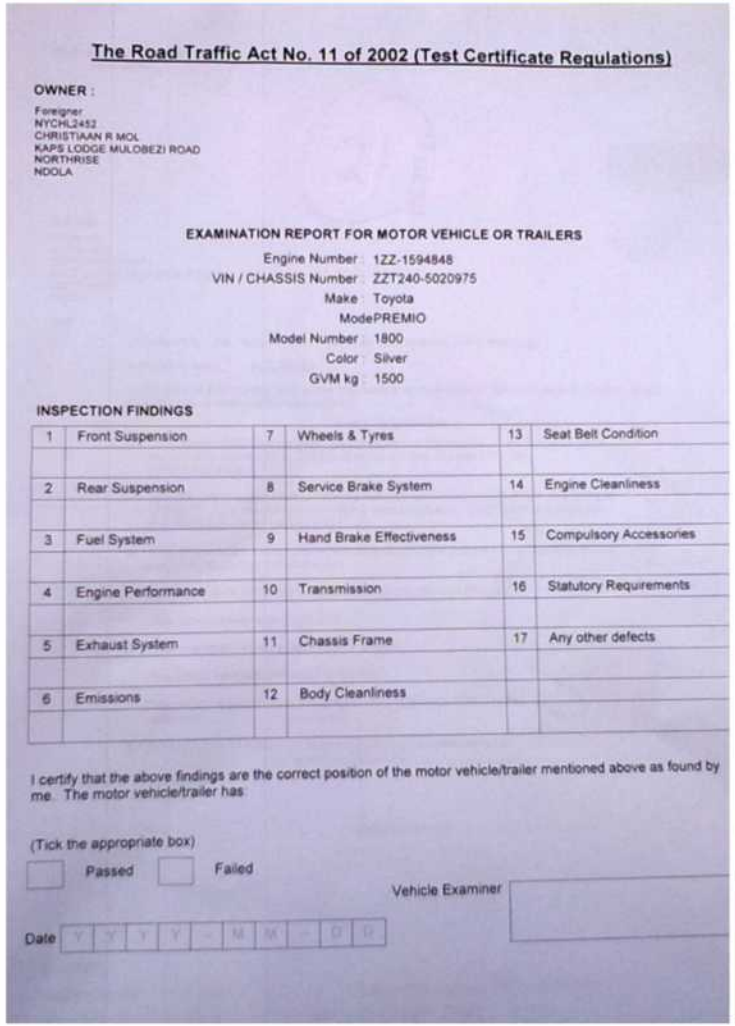
During **preventive maintenance** of medical equipment we check:

- **equipment performance as specified (check use !)**
- technical parameters (electrical safety, …)
- wearing and tearing
- …

Much like the annual car ‘road testing’

Preventive Maintenance is important for improving Safety!

Annual RDSA 'Preventive Maintenance' test form



The Road Traffic Act No. 11 of 2002 (Test Certificate Regulations)

OWNER :

Foreigner
NYCHL2452
CHRISTIAAN R MOL
KAPS LODGE MULOBEZI ROAD
NORTHRISE
NDOLA

EXAMINATION REPORT FOR MOTOR VEHICLE OR TRAILERS

Engine Number : 1ZZ-1594848
VIN / CHASSIS Number : ZZT240-5020975
Make : Toyota
Mode PREMIO
Model Number : 1800
Color : Silver
GVM kg : 1500

INSPECTION FINDINGS

1	Front Suspension	7	Wheels & Tyres	13	Seat Belt Condition
2	Rear Suspension	8	Service Brake System	14	Engine Cleanliness
3	Fuel System	9	Hand Brake Effectiveness	15	Compulsory Accessories
4	Engine Performance	10	Transmission	16	Statutory Requirements
5	Exhaust System	11	Chassis Frame	17	Any other defects
6	Emissions	12	Body Cleanliness		

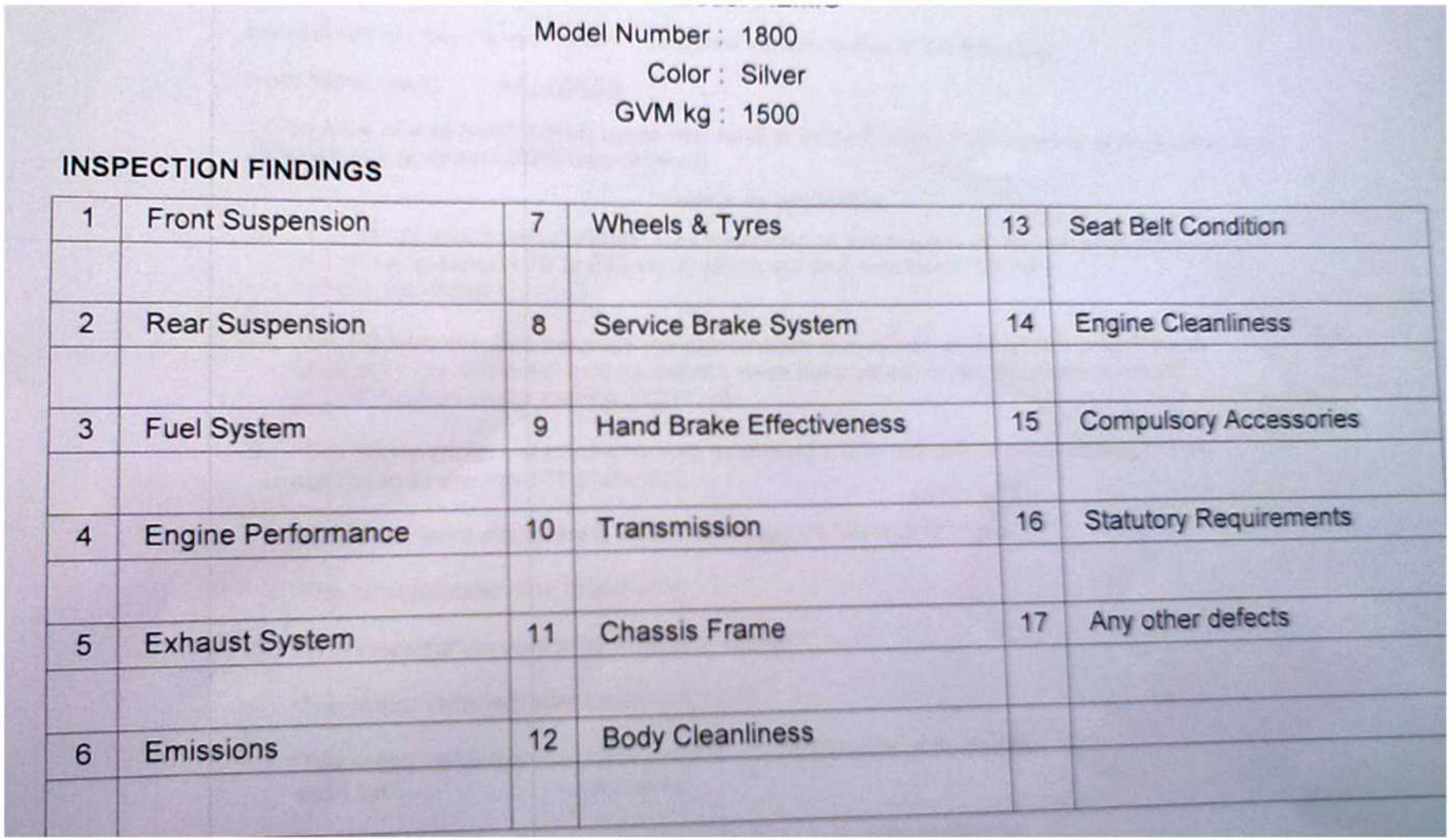
I certify that the above findings are the correct position of the motor vehicle/trailer mentioned above as found by me. The motor vehicle/trailer has

(Tick the appropriate box)

☐ Passed ☐ Failed

Vehicle Examiner

Date Y Y Y Y - M M - D D



Model Number : 1800
Color : Silver
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Safety throughout the life cycle

A device needs to be safe always,

not only just after installation….

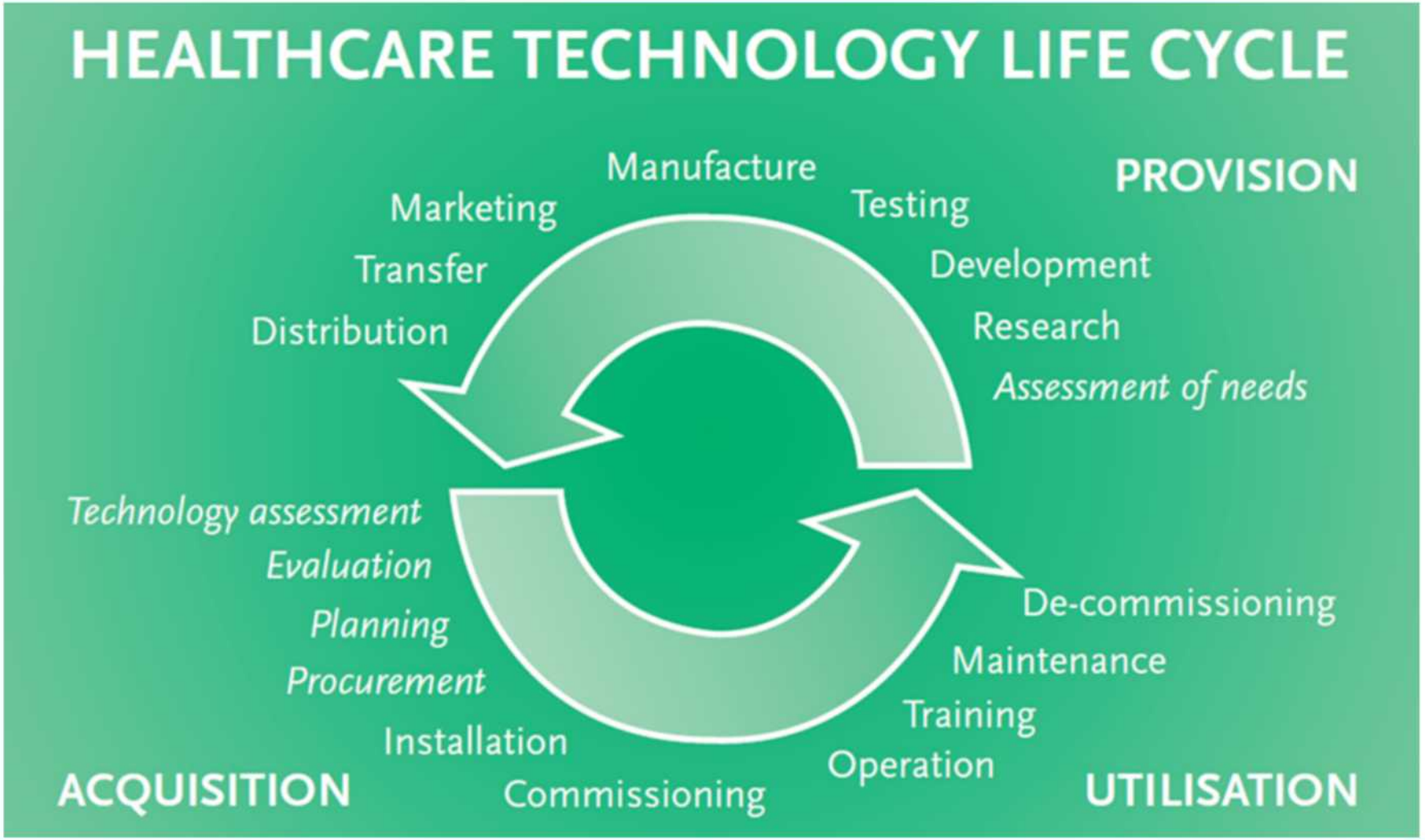
Therefore, there are regulations for all phases

throughout the equipment life cycle

Life span of Medical Equipment: Extended

supplier / manufacturer →

user / hospital →



Major phases in the life cycle of medical equipment

This diagram is simplified to make it easier to understand the regulatory system.
For example, in reality the development phase can be subdivided in development planning, design verification/validation, prototype testing and clinical trials.

In practice, the various phases overlap and interact.

All of these phases can affect the safety and performance of a medical device,
and therefore all phases are regulated!

Conception and development

CONCEPTION AND DEVELOPMENT

The **scientific principles** upon which a device is based are **fundamental to its safety and performance**.
For example, a cardiac pacemaker should deliver a small electrical impulse of a certain size and shape that simulates the natural functioning of the heart. Significant deviation from this may compromise safety and performance.

The more complex the device, the higher the risk of user error. Soundness of concept and adequacy of design, construction, and testing (including verification, validation and clinical trials) require the scrutiny of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks.

Manufacture

MANUFACTURE

Good, functional medical devices are only produced when the manufacturing process is **adequately managed**.

Poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, **even when the original prototype has been well-designed.**

This consideration has led to the development of **Good Manufacturing Practice** (GMP) for drugs, biological products and medical devices. GMP is more commonly referred to as "**quality systems in manufacturing**".

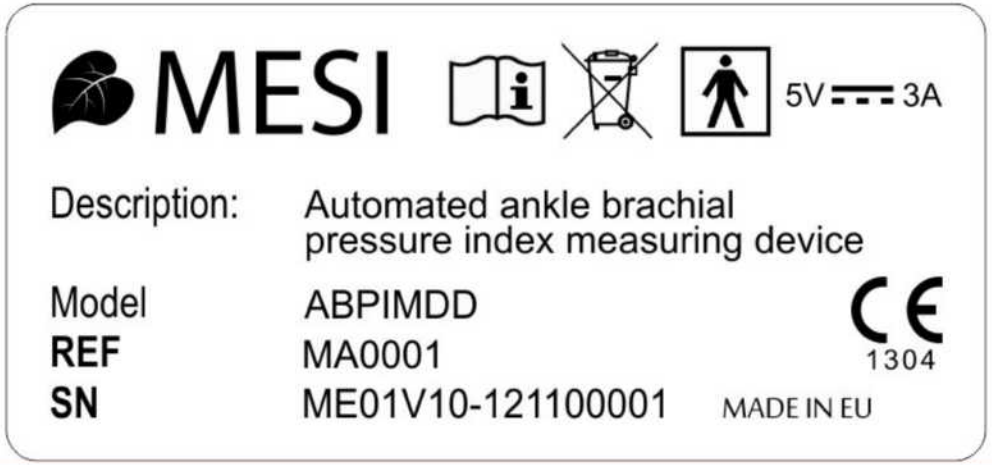
Package and labelling

PACKAGING AND LABELLING

It is important that well-designed packaging systems deliver **clean, sterile and protected** medical devices to the point of use. Properly packaged medical devices are **safe to handle**, even if the medical device is **biohazardous**.

Shipping is one of the hazards that a medical device and its packaging must survive. Subtle damage can result during transportation and handling unless the total packaging system is designed robustly and can withstand various stresses. **sealed packaging** is essential for those medical devices that must be maintained sterile.

Labelling is crucial in **identifying** the medical device and **specifying instructions for its proper use**. As for drugs, mislabelling of medical devices can result in serious consequences for the user. **Hazard warnings or cautions and clear instructions** for use are very important.



Advertising

Advertisement has the potential to create expectations and to strongly **influence the belief** in a medical device's capabilities.

Therefore, medical device marketing and advertising must be regulated to prevent **misrepresentation** of a medical device and its performance.

Misleading or fraudulent advertising of medical devices may increase sales. However, from the buyer's perspective, the purchase of an inappropriate medical device is a **waste of money** that may deprive the patient of more appropriate treatment and could lead to patient or user **injury**.

Sale

SALE

The **sale** of medical devices by the vendor is a critical stage that leads to the device being put into actual use.

If the **vendor** is not subject to **regulation**, then there is higher risk of exposing the public to **low quality or ineffective devices**.

Use

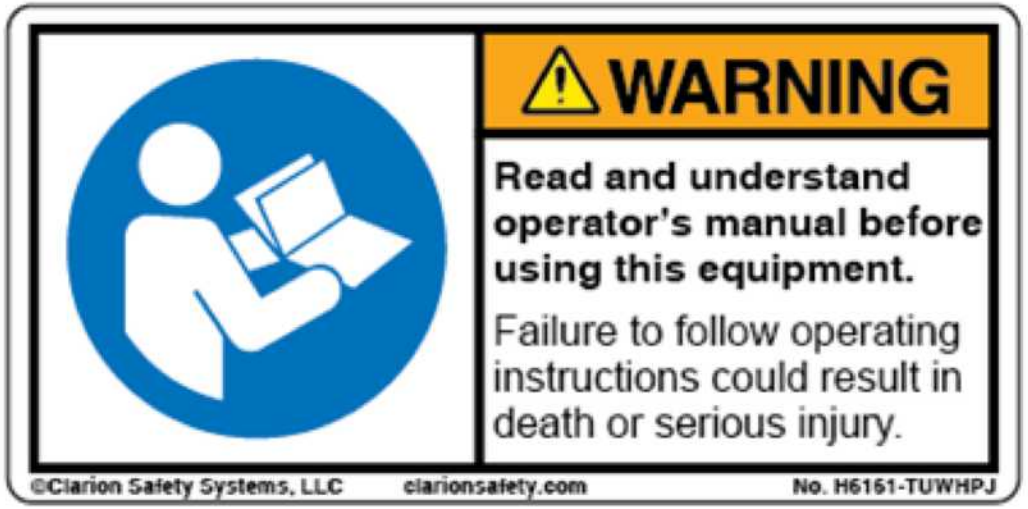
USE

Users of medical devices can have a profound effect on their safety and effective performance. **Unfamiliarity** with a certain technology or operating procedure, and **of products** for clinical indications **outside the scope** of those specified in the labelling, can cause device failure even in the absence of any inherent design or manufacturing defects.

Within the clinical engineering community it is widely believed that **user error underlies at least half of all medical device-related injuries and deaths.**

The **re-use of disposable devices** contrary to the manufacturers instructions, and without proper control or precautions for minimizing associated risks, can be dangerous.

The **lack of, or inappropriate, calibration and maintenance** of medical devices can seriously jeopardize their safety and performance.



Disposal

Disposal of certain types of devices should follow specific and stringent **safety rules.**

For example, devices that are **contaminated** after use (e.g. syringes) or devices that contain **toxic chemicals**, can present hazards to people or the environment and must be disposed of properly.

Many people are involved in medical equipment safety

It is people who manage each phase in the life span of a medical device, and these **people should be identified** and called on to participate in ensuring medical device safety.

This is the topic of the next lecture…..

END

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see https://www.thet.org/