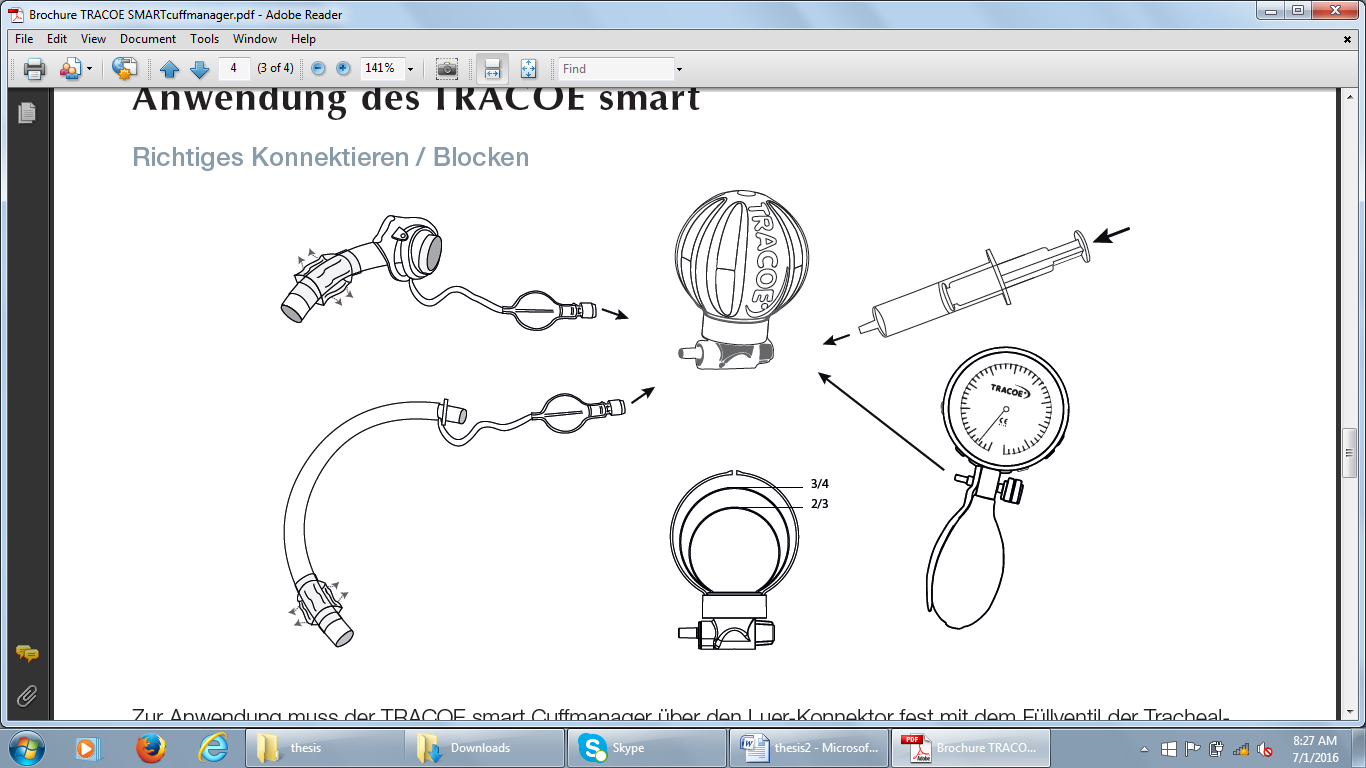
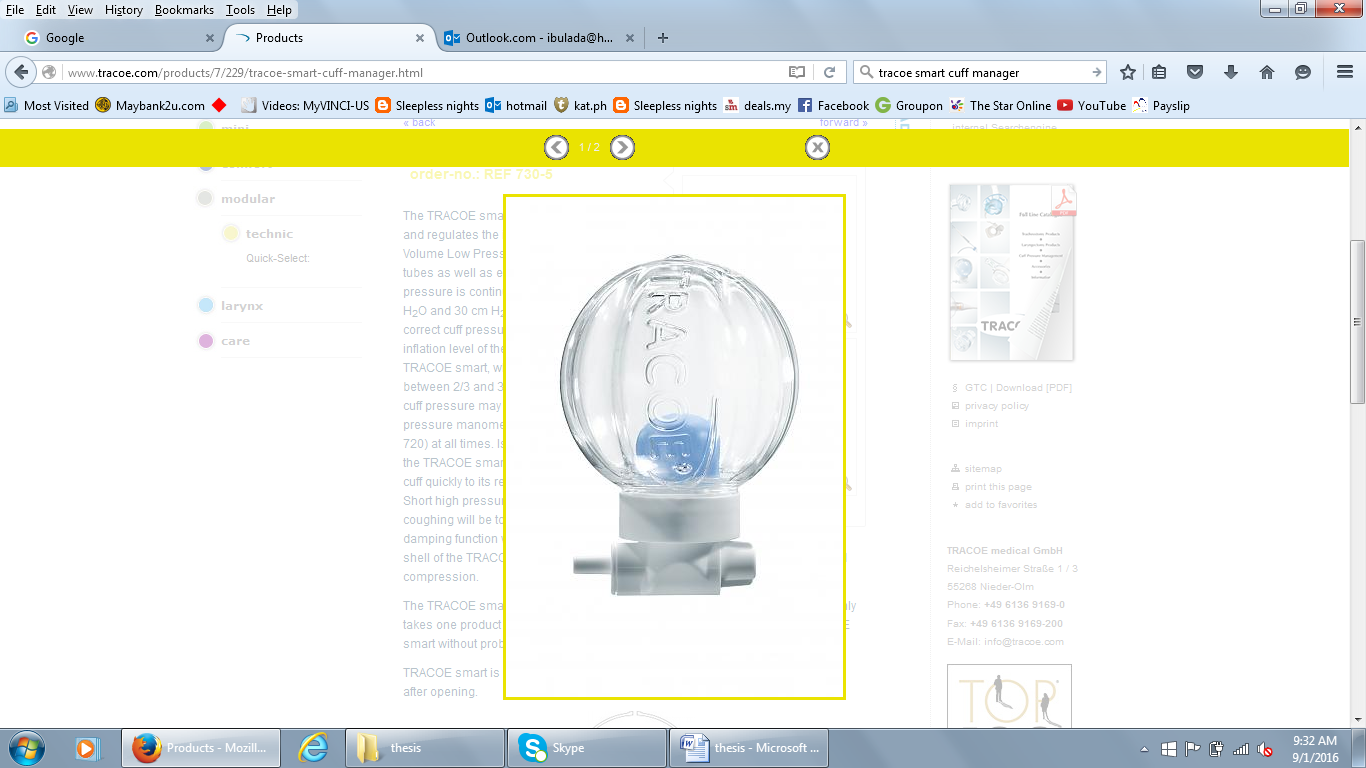
**Product Overview – TRACOE Smart Cuff Manager**

****

The TRACOE smart cuff manager performs continuous cuff pressure regulation between 20-30cmH2O, hence reducing cuff pressure variations and pressure peaks. This minimizes the risk of complications relating to microaspiration and tracheal mucosal injury. It is a single patient use product with a usage time of maximum 29 days and is latex free and DEHP free.

**Application of the TRACOE smart**

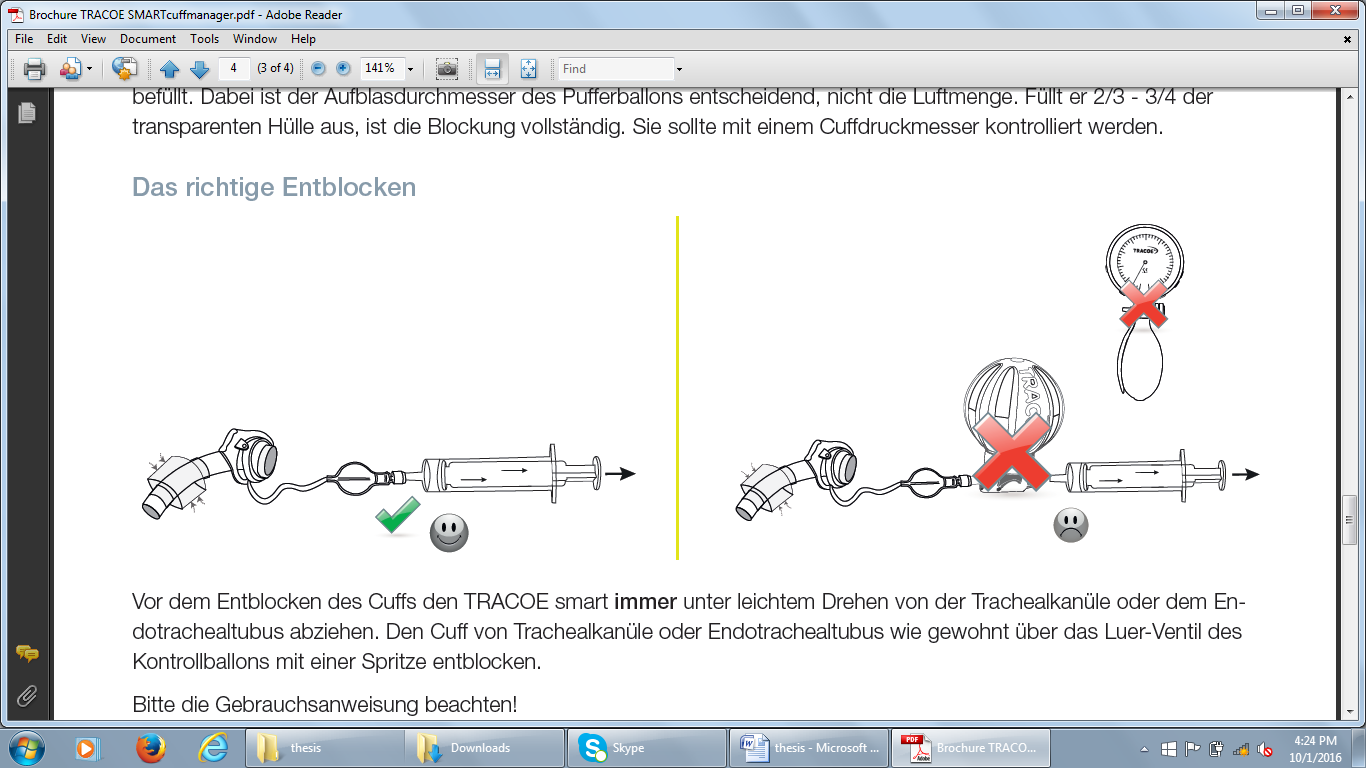
1. Connect the Luer connector (male) of the TRACOE smart cuff manager firmly to the cuff-filling valve of the endotracheal tube.
2. Attach a large-volume syringe to the Luer connector (female) of the TRACOE smart to inflate the blue balloon to 2/3 up to ¾ of the volume of the outer shell (approximately 60ml air). The solid shell of the TRACOE smart protects the highly elastic blue balloon from unwanted compression.

Before inflation

After balloon inflation

1. If the cuff pressure is too low, the TRACOE smart refills the cuff quickly to its recommended pressure.
2. Short high pressure peaks (e.g coughing) will be tolerated by the integrated buffer function which inhibits the air from escaping instantly from the cuff. This maintains the self-sealing-effect of the cuff.
3. Permanent excessive cuff pressure (e.g new positioning of the patient) will be levelled.
4. Prior to deflation (during extubation), the TRACOE smart needs to be disconnected by gently turning and pulling the TRACOE smart off the tubes valve in one motion. The cuff of the endotracheal tube remains inflated and can now be deflated as usual via the pilot balloon using a syringe.



**Study procedure**

The study will be divided into three phases as follows:

1. Phase one involve data collection on nurses’ knowledge and practice at the pre-intervention level (baseline knowledge) and educational intervention. The intervention comprises theoretical educational sessions and this will be followed by the introduction of the TRACOE smart cuff manager which continuously regulate cuff pressure. Educational intervention aimed to improve nurses’ knowledge and skill in relation to cuff pressure management will be conducted as continuous nursing educational sessions for one month. It will include demonstration of skills on cuff pressure monitoring and management using both methods, traditional method and using TRACOE smart cuff manager. This will be followed by the pilot study.
2. Phase two will involve actual implementation of – traditional and TRACOE smart cuff manager. Data collection on patient outcomes – cuff pressure, VAP and patient mortality and morbidity will be carried out based on the steps below:
   1. All patients who are admitted to the ICU will be assessed by the trainee Anaesthetist after their admission based on Form 1 (Appendix 1).
   2. If all criteria are fulfilled, written consent will be taken from family members (Appendix 4) and the trainee Anaesthetist will then choose one envelope from a file which will contain 100 envelopes which each contain a piece of paper written TRACOE or Manometer.
   3. Patients who are randomized to TRACOE will be connected to the TRACOE Smart Cuff Manager and the balloon will be inflated with air until it is 2/3 to ¾ (usually 60ml) the volume of the outer shell.
   4. A cuff pressure reading will be taken from both population of patient and will be recorded in Form 2 (Appendix 2). All patients will subsequently have their cuff pressure measured every 6 hours until they are extubated or until day 15 of intubation (whichever is longer) and this will be recorded by the staff nurse.
   5. If either the cuff pressure is lower than optimal, it will be inflated and the amount inflated to achieve the intended cuff pressure is recorded. If the cuff pressure is too high, then air is to be removed from the cuff and the amount of air removed is recorded.
   6. The patients are also assessed daily for VAP according to the MRIC criteria by the attending Speacialist and Trainee Anaesthetist. If the patient is suspected to have VAP, a tracheal culture is to be sent for laboratory analysis and Form 3 (Appendix 3) is filled up. The patients will be monitored for VAP up to 48 hours post extubation.

Post-test assessment of nurses’ knowledge on endotracheal cuff management and care post-intervention and practice will also be carried out in this phase.

1. In phase three, the nurses’ perceptions of the endotracheal cuff management in actual practice will collected using focus group interviews.

Phase One

Pre-test assessment of nurses knowledge on endotracheal cuff management and care

* Educational intervention on endotracheal cuff management and care – traditional and TRACOE smart cuff manager
* Pilot study

**3 months**

**Phase Two**

* Implementation of – traditional and TRACOE smart cuff manager
* Data collection on patient ourcomes – cuff pressure, VAP and self-extubation.
* Post-test assessment of nurses knowledge on endotracheal cuff management and care outcomes post-intervention.

**6 months**

**2 months**

**Phase Four**

* Qualitative study - nurses’ perceptions of the endotracheal cuff management

Figure 1: Flow chart of stages of study design and schedule of data collection