Titel: The GentaSafe - A Time Controlled Medical Storage Device

In this work, we will present the construction of the GentaSafe, an engineering solution to the problem of inadvertent overdosage of premature or newborn babies. Purpose of the device is to make the administration of the frequently prescribed drug Gentamicin safer on the neonatal unit. This drug is unique in that it is administered either once every 36 or once every 24 hours (depending upon the prematurity of the newborn baby) and therefore due to this irregular dosing schedule, it is one of the most frequent drugs to be administered in error (for example 12 or 24 hours too soon). Unfortunately, this early administration is a class of over-dosage, which is associated with hearing loss and kidney damage. Our solution is to have each individual patient's gentamicin stored in their own box (the GentaSafe), which is time locked such that the box will not allow the dispensation of the drug until the correct time interval has elapsed.

The solution presented is based on a drawer design with a microcontroller taking control of all relevant functions, such as the locking mechanism and the time base. A resistive touch screen allows for control of the device as well as displaying relevant information such as the patient's name, the interval until the next dose needs to be delivered as well as a graphical about the doses, which have been delivered up to this point. A log-in system was implemented, so the nurse delivering the drug is correctly identified. A transparent window in the top of the box allows for optical investigation of the number of doses left for delivery. All events are being logged on a removable memory card to give pharmacy and nursing stuff the possibility to check on the hours, where the deliveries have taken place and who was currently logged into the device at the point of release of the drug.

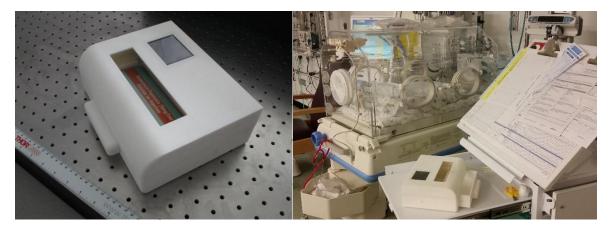


Figure 1. The final prototype ready for clinical testing in the workshop (left) and in the clinical setting (right). The box of gentamicin can be seen through the window of the device.

The whole device is battery powered to allow the box to be moved together with the patient, which allows that the same GentaSafe is connected to a patient even if this patient changes the

ward. The time base is powered by a separate battery to ensure correct timing intervals even if the main battery had failed or an error in the system had occurred.

The development consisted of two phases, with a demonstrator being developed first in order to gain feedback from the nursing staff. Based on the input a second prototype was designed and thoroughly tested in terms of battery lifetime, operational functionality and fail safety.

After these engineering tests have been concluded positively, the first devices are now under test at the premature baby ward at Queens Medical Centre Nottingham, UK.