Day 2
Breakout Session 1
Room 2

Evaluation for Clinical Usability of CLC Devices

Question 1

What are the appropriate risk analysis techniques or processes for identifying PCLC medical device hazards resulting from user *overreliance* or *complacency* on autonomous medical device?

For each device hazards, what are the possible risk mitigation strategies that can be used to address user overreliance or complacency?

And how to evaluate the effectiveness of these risk mitigation strategies?

Question 2

PCLC medical device workflows require minimal user responses and occasionally involves fast-pace and infrequent user responses; what are some of the interface design considerations in terms of physical controls and display elements for visual, audio or tactile (touch) to improve user information perception, cognition and responses to normal and anomalous situations?

Please provide suggestions for improving the current patient-machine interface.

Question 3

For human-automation interaction (HAI), what is the general approach for designing simulated based training?

How do you determine and prioritize risk, use-based scenarios, and operational conditions or use environments for simulated base training?

Question 4

There may be infrequent critical events in the routine operation of PCLC medical devices, how would you use simulator based training approach to evaluate safety of PCLC medical devices?

What are some of the possible clinical setting design or use scenario considerations?

How would you evaluate users' responses during simulator based training?

Question 5

What design features can be in place to allow a clinician to recognize if a patient may not be responsive to therapy controlled by PCLC medical device?

Question 6

From a clinical perspective, what factors can be considered in assessing validity of the physiological model for performance evaluation of PCLC devices?