

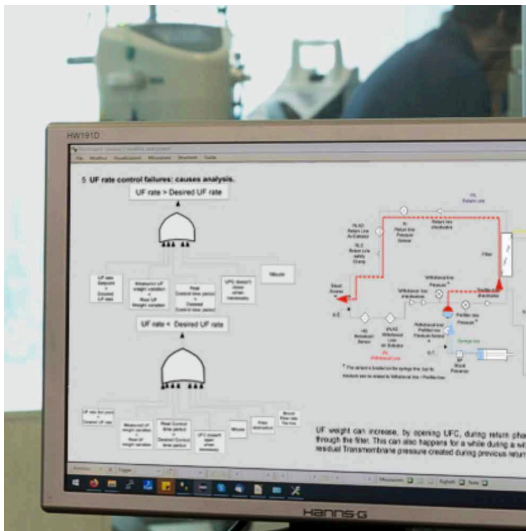


Risk Management

Leading *Advanced Medical Solutions*

An example of the application of risk management in a cycle is as follows:

- Identification of product specifications
- Identification of potential hazards connected with the product
- Risk analysis and evaluation of each hazard
- For each hazard, identification of the hazardous events related to the equipment.



- Fault Tree Analysis for each hazardous event
- Failure Mode and Effect Analysis for each leaf of the FTA, corresponding to a device component at the requested level of detail.
- Risk assessment
- Risk tolerability evaluation
- Identification and development of risk reduction measures
- Hazard evaluation of risk reduction measures
- Final evaluation of all the identified hazards
- Result of risk management – product safety evaluation

