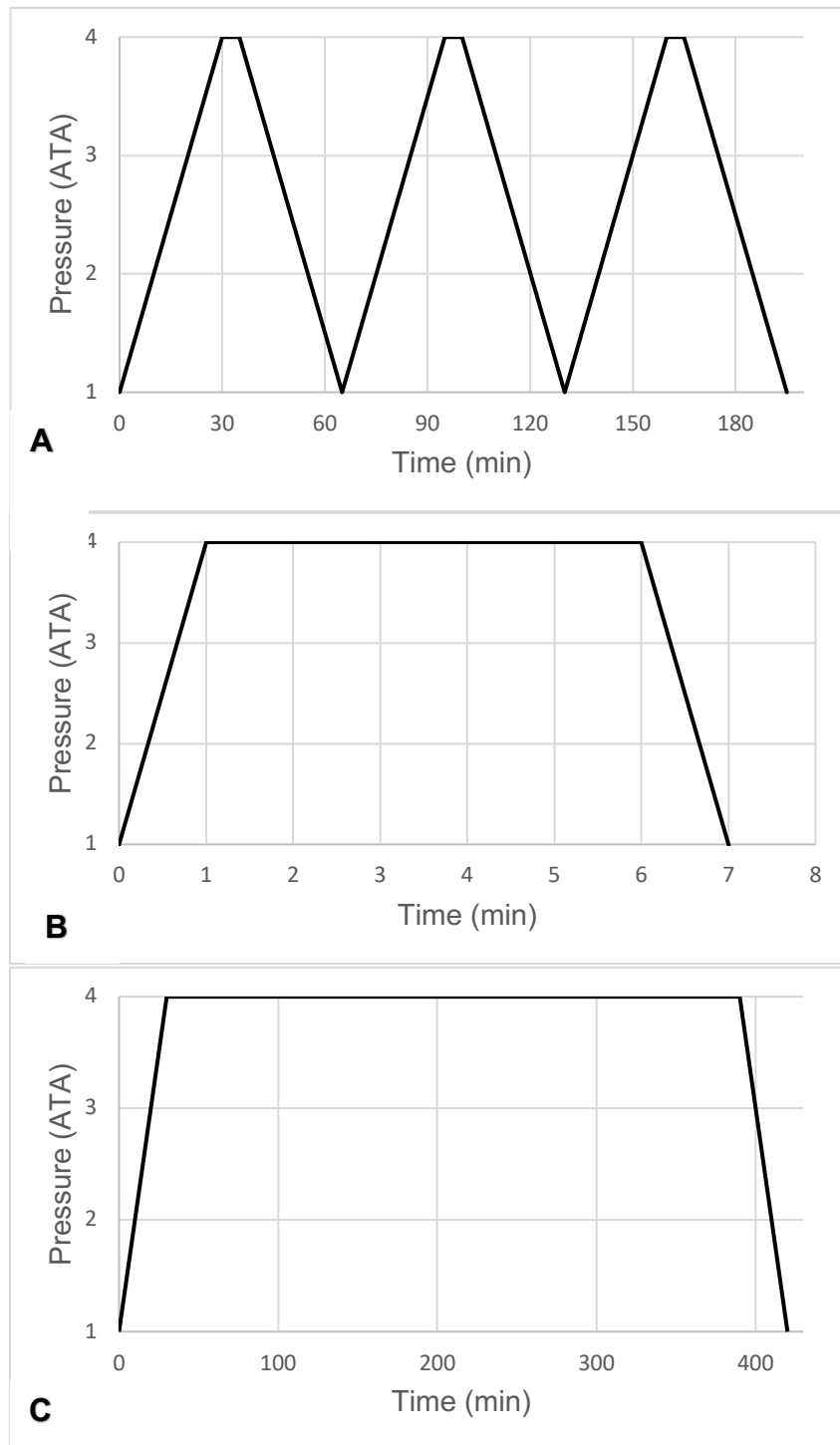




Additional File 1: Risk assessment before hyperbaric use of devices not CE-marked

Panel A: device is submitted to serial compressions to 4 ATA. **Panel B:** Then, if device functioning is optimal, a quick compression to 4 ATA is achieved **Panel C:** Effect of saturation is tested with a long compression to 4 ATA. (Session duration 7 hours). After these 3 steps, if device functioning is approved, installation in hyperbaric chamber is allowed. ATA: Atmosphere absolute (unit of pressure) with 1 ATA = Atmospheric pressure.