

VALIDATE - To support or corroborate on a sound or authoritative basis (Merriam-Webster Dictionary).



What is the commonly accepted definition of a validatable heat sealer? To date, it has been understood by most manufacturers that checking and verifying the speed and temperature of the sealer on a fixed schedule, usually six (6) months, was sufficient for production. We, at Urania, find that reasoning totally unacceptable for manufacturing a quality product. Our refined definition of validatability consists of:

1. Continuous verification of temperature while operational.
2. Continuous verification of speed while operational.
3. Continuous verification of sealer bar force (pressure) while operational.

Direct action is taken to disallow the product from being processed through the sealer if any of the three (3) major sealing parameters are not within the prescribed range. The three (3) **continuously** monitored parameters are speed, temperature, and force (pressure). Reversal of the sealing belts will occur if parameters are not within the preprogrammed range. Belt reversal occurs during "warm up" and, subsequently, if any parameter changes or goes "out of range" for any reason during production. Belt reversal during production disallows possible improperly sealed pouches from proceeding through the sealer as if they were acceptable.



Figure 1: A photograph of a laboratory machine used for validating the sealing of pharmaceutical containers. The machine features a motorized unit on the left, a central chamber with a lid, and two large orange rollers at the bottom. A white container is positioned within the machine, and a small white object is visible on the right side.