



RCA Case Study

Product
Development

Materials Engineering

Background

A large medical products manufacturer was receiving complaints from customers indicating that heated nebulizer housings were melting during product use. Investigation found that under certain conditions, the plastic nebulizer housings were coming into contact with the heater, and enough heat was generated to literally melt the housing material.

Challenge

A quick solution was needed due to significant customer dissatisfaction and the potential loss of customers to competitor products.

Approach

Materials engineering was undertaken to find a material that could reliably withstand heat exposure during the heated nebulization process, but still be injection-molded in the same injection mold tooling. Highly temperature resistant materials such as polysulfone and polyetherimide were investigated, but ruled out due to the high cost of the material and the need for new injection mold tooling.

The materials investigation found that the use of a homopolymer polypropylene material rather than the current polypropylene-ethylene copolymer would raise the melting point of the material by about twenty (20) degrees F. Functional and biocompatibility testing were executed to verify that all design inputs were met, and field trial product was produced and shipped to customers who had experienced the issues with melting housings.

Result

The field trial was successful and the full scale conversion to the new material was quickly implemented because no changes to the injection mold tooling were needed. Post market tracking of customer complaints confirmed that cases of melting nebulizer housings were no longer occurring.

References

1. Code of Federal Regulations (CFR) – Title 21, Parts 820.30 – Design Controls