Advances in Medical Device Package Manufacturing

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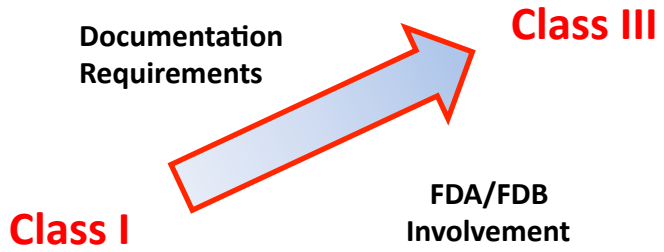
The Regulatory and Technology Challenges Associated With Medical Device Packaging

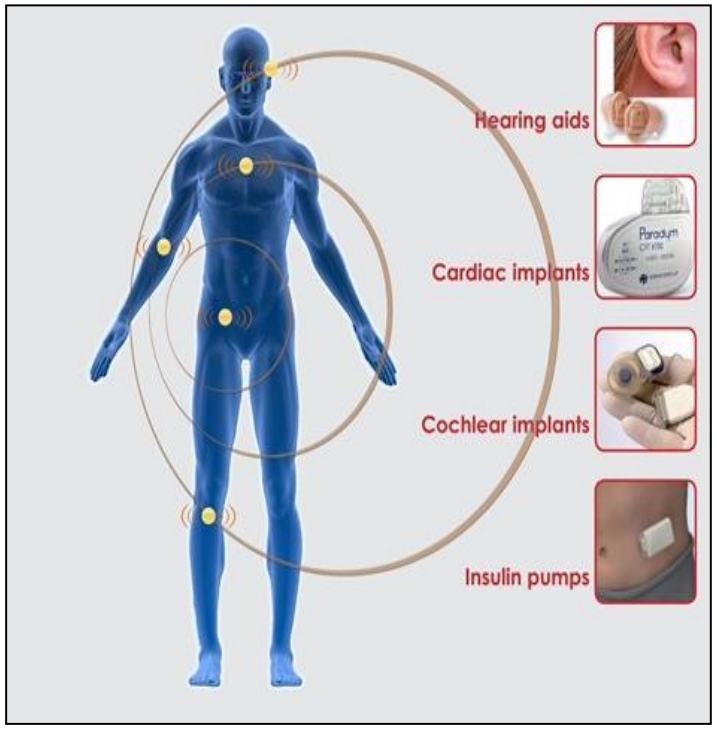
- Regulatory and Quality Demands
  - ISO 13485
  - FDA 21 CFR Part 820
  - FDB (CA) Sherman Act (Articles 5 and 6)
- Documentation
- Product Architectures
- Technical Solutions – Stable and Automatable

Electronic "Medical" Devices Are Booming

We wear these ON our bodies (Class I)



These go IN our bodies (Class III)

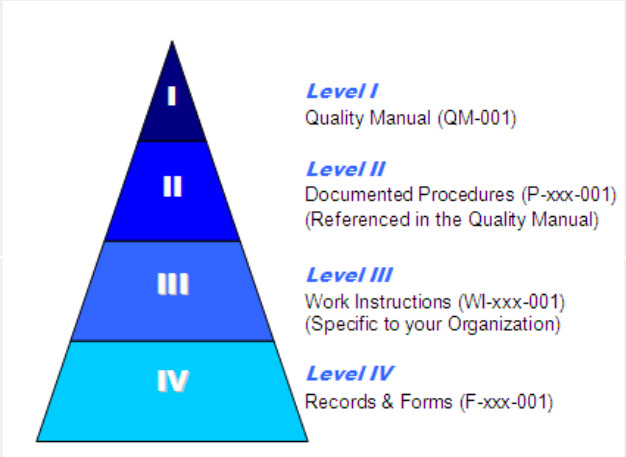


Medical Device Quality Management System (QMS)

- ISO Registration and CFR Requirements
- Extensive Documentation
  - Design Control (Design History File)
  - Process, Components & Materials (Device History Record)
  - Production Records (Device Master Record)
  - Equipment & Operator Training Records
  - Medical Product Lifetime Records Retention
- Full & Regular Audits (ISO/FDA/FDB)
  - Unannounced NB (Notified Body) Audits

ISO Registration

ISO 13485:2003 specifies the requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.



The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems.

As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements.

FDA 21 CFR Part 820

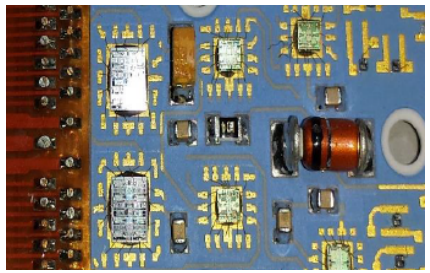
Defines Good Manufacturing Practices and Quality Control Requirements

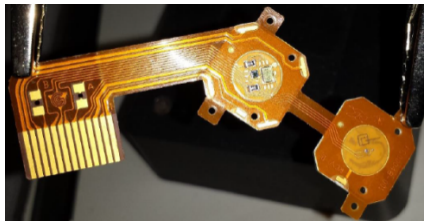
- Part 820 - QUALITY SYSTEM REGULATION
  - Toc - Table Of Contents (Parts 820 - 820)
  - Subpart A - General Provisions
  - Subpart B - Quality System Requirements
  - Subpart C - Design Controls
  - Subpart D - Document Controls
  - Subpart E - Purchasing Controls
  - Subpart F - Identification and Traceability
  - Subpart G - Production and Process Controls
  - Subpart H - Acceptance Activities
  - Subpart I - Nonconforming Product
  - Subpart J - Corrective and Preventive Action
  - Subpart K - Labeling and Packaging Control
  - Subpart L - Handling, Storage, Distribution, and Installation
  - Subpart M - Records
  - Subpart N - Servicing
  - Subpart O - Statistical Techniques

Equipment and Process Validation/Documentation

Product Failure Mode & Effects Analysis pFMEA	pFMEA evaluates the manufacturing process to determine the likelihood of a process failure negatively effecting a clinical outcome to ensure adequate process quality controls are utilized.
Installation Qualification IQ	IQ Protocol verifies the appropriate installation and configuration of a hardware system functioning as expected by the manufacturer.
Operation Qualification OQ	OQ protocol establishes and verifies the high and low process parameter settings for a unit process to meet customer requirements. The FDA will insist on automated processing when possible.
Process Qualification PQ	PQ protocol validates the overall process performance The PQ protocol involves all hardware and software components, associated equipment, manufacturing areas, manufacturing assembly documents and procedures that are part of the manufacturing process.

Product Architecture Demands For In-Body & Implantable Devices

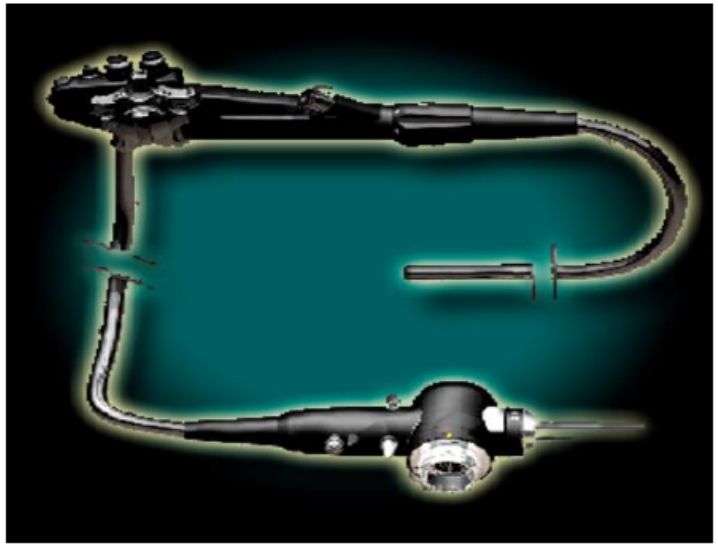




- Small Footprint – Nonintrusive
  - Chip-On-Board
  - Rigid – Flex Substrates
  - "3D" Stacked Components
- Integrated Optical Components
  - Precision Placement (+/- 5 microns) in 3 Axis
  - Particle Control
- Sterilizable – Hermetic (100's of Autoclave Cycles)

Endoscopes – Instructive Example

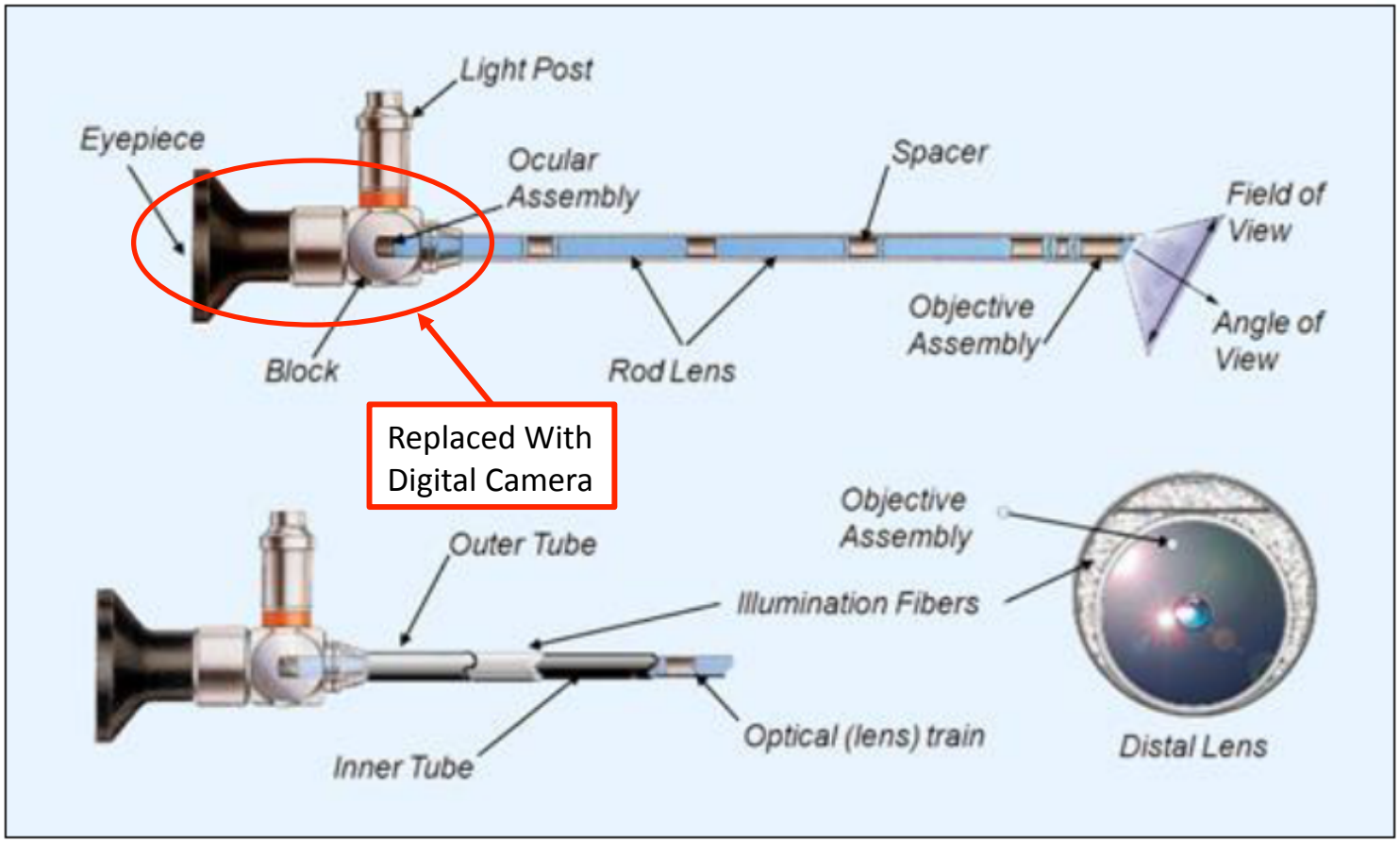
An Instrument Used To Examine The Interior Of The Human Body



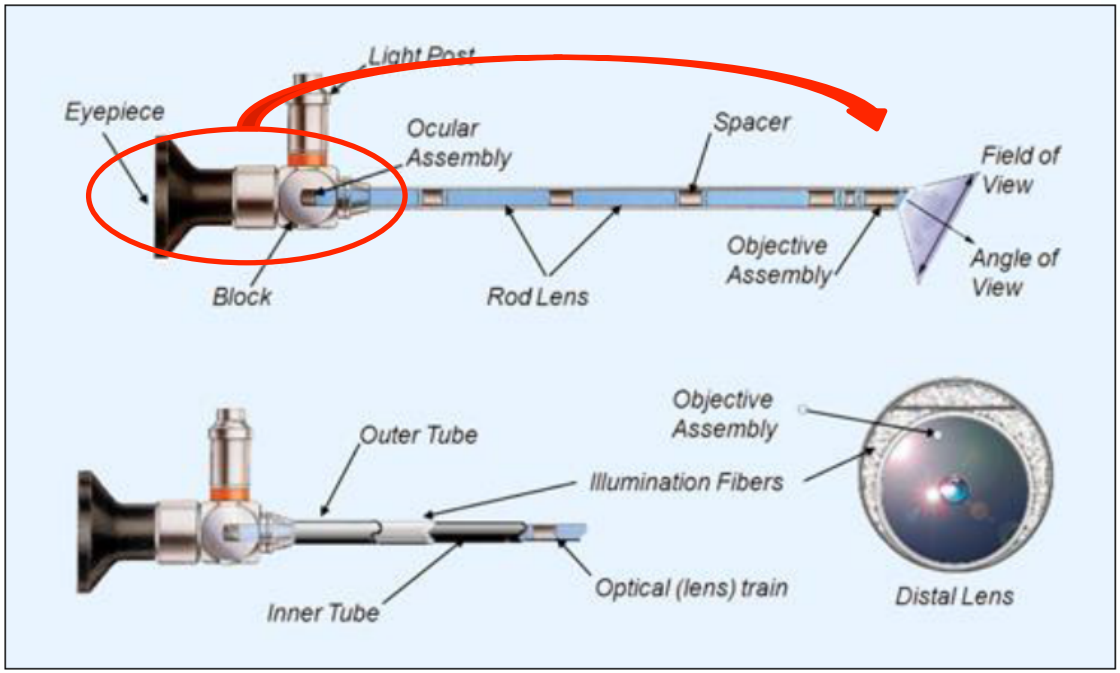
There are many types, each named according to the organs or area they are used to examine. For example:

- Arthroscope – Joint examination
- Bronchoscope – Lungs and airways
- Cystoscope – Bladder
- Laparoscope – Abdominal organs

Typical Endoscope Design



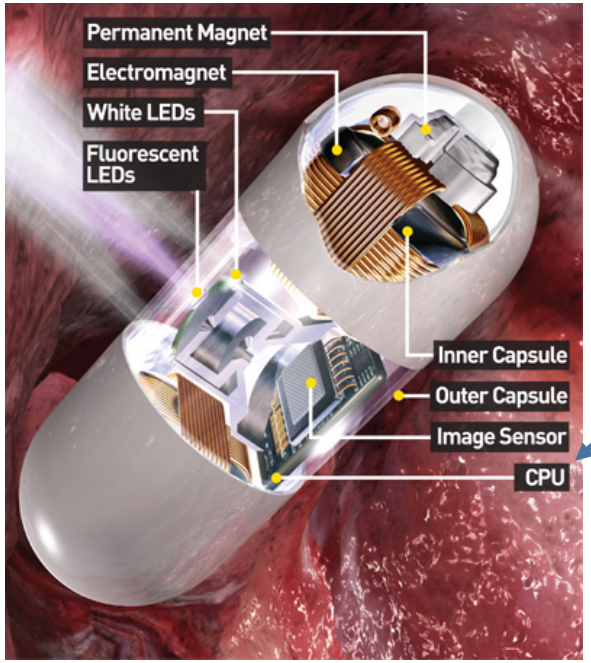
Next Generation Endoscope Design

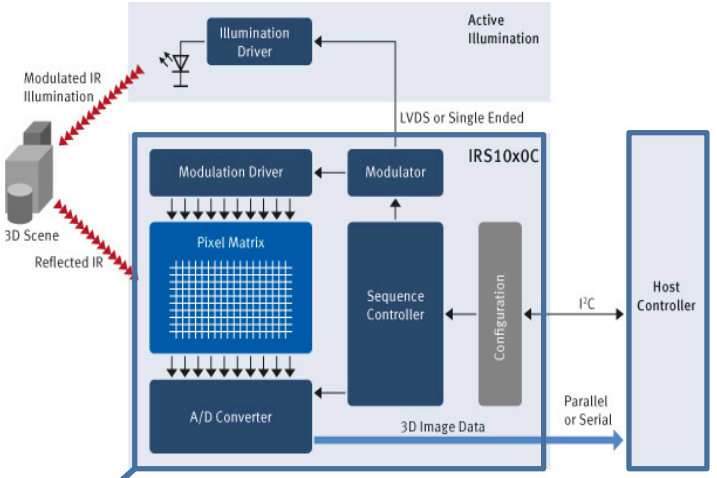


Move Camera To The Tip Of The Endoscope

- Sharper Picture
- Simpler Optical Train
- Easier to Integrate
- Smaller, Easier to Handle, Less Intrusive

The Capsule Endoscope





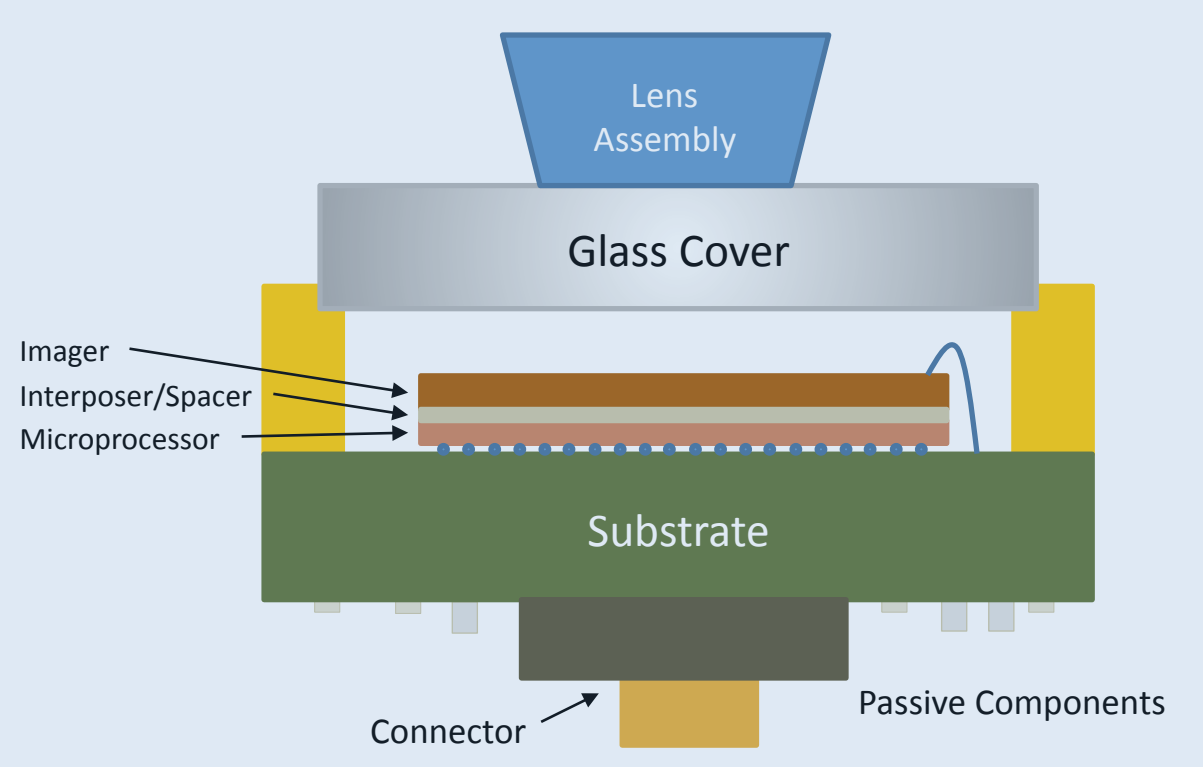
Endoscope Cameras Require 3D Assembly

- 3D Assembly = Assembly of semiconductor components in a stacked configuration to pack more function in less space

- This can be achieved by using mostly conventional means:
  - Flip Chip, Waterfall bonding, or Combinations
  - Flip Chip and On-Chip Thru Silicon Vias (TSVs)
  - Mature, fully automated processes

- Conventional substrates may be used:
  - Rigid-Flex Assemblies
  - Flex-Only Assemblies
  - Ceramic – Used frequently for power dissipation & hermeticity

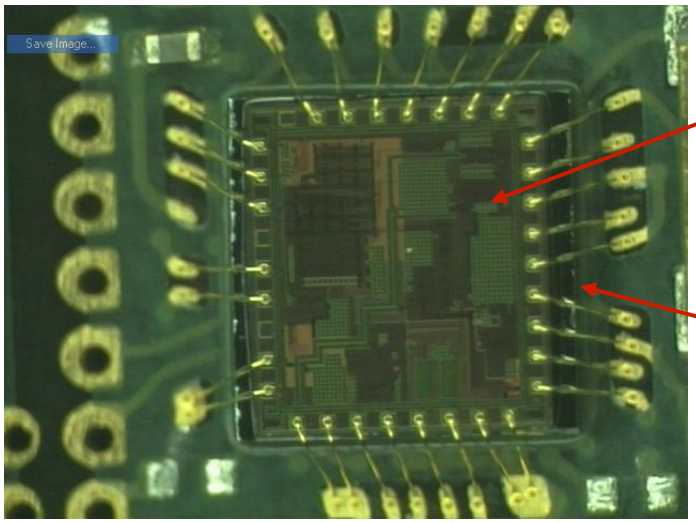
3D Stacked Camera Assembly

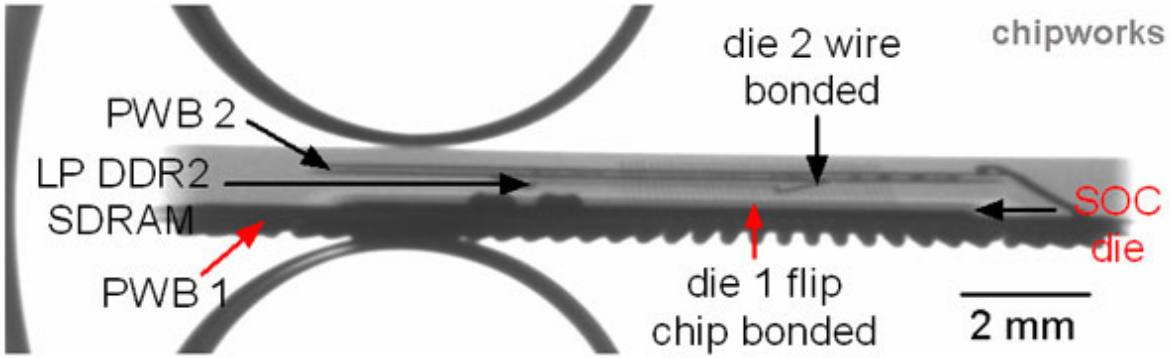


Features

- Passive Alignment of Lens Assembly to the Package.
- Alignment of the Imager Die to the Package: +/- 10 µ.
- Z Axis Control for Optical Plane Alignment: +/- 15 µ.
- Ceramic Substrate – Hermetic for Autoclave Sterilization.
- Tight Dimensional Specs on All Package Components.
- Microprocessor Flip Chip Attached, Imager Wire Bonded.
- Class 10 (or better) clean room environment required.

Examples of Stacked Die with FC & WB





Conclusion

Medical Device manufacturing is characterized by:

- Tight regulatory oversight
- Lifetime BoM and Process documentation
- Demanding layout size control
- Mixed assembly processes (SMT, Die Processing, Optical Assembly)
- Development of stable, automated processes
- Longer time to market

However

Once a process has been fully developed and properly document it remains unchanged for the life of the product due to the costs associated with making any modifications