

LABORATORY REPORT



Materials Evaluation and Engineering, Inc

Program Manager
Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN 55441-5443

Report Date: May 6, 2011
Date Submitted: February 11, 2011
MEE Project: AGD1101A
Sample ID: Pulse Oximeters
P.O. No.: Verbal

PROJECT TITLE: Analysis of Solder on PCBs of Pulse Oximeters

INTRODUCTION

A metallurgical evaluation was requested to investigate the elemental composition of solder joints on printed circuit boards (PCBs) of eight pulse oximeters. The objective of the evaluation was to determine if the solder used on the PCBs was a lead-rich solder or a solder alloy with little or no lead.

The eight pulse oximeters that were tested were the:

- Barrington Diagnostics Model 50-102-003
- Beijing Choice Electronic Technology Co. Ltd. Model MD300C1
- Contec Model CMS50DL
- Devon Medical Model 300C-1B
- OxiPulse Pulse Insight Model PI2000
- Landon Medical Model PC00030361
- Nonin GO₂
- Nonin Onyx

SUMMARY AND CONCLUSIONS

Five of the eight pulse oximeters had PCBs soldered with a lead-rich solder. The PCBs for three of the eight pulse oximeters, Nonin GO₂, Nonin Onyx, and Landon Medical Model PC00030361, were soldered with alloys containing little or no lead.

TEST PROCEDURES

The solder joints on the PCB of each pulse oximeter were examined by scanning electron microscopy (SEM) using backscattered electron imaging (BEI). In conjunction with the SEM examination, qualitative chemical analyses were performed on the solder for two components on each PCB by energy dispersive x-ray spectroscopy (EDS).

RESULTS

EDS analysis of the solder in five of the eight pulse oximeters detected an elemental composition of predominantly lead and tin, (Figures 1 - 15). The pulse oximeters with solder that had significant concentrations of lead were the:

- Barrington Diagnostics Model 50-102-003
- Beijing Choice Electronic Technology Co. Ltd. Model MD300C1
- Contec Model CMS50DL
- Devon Medical Model 300C-1B
- OxiPulse Pulse Insight Model PI2000

EDS analysis of the solder for three of the eight pulse oximeters detected an elemental composition of primarily tin, (Figures 16 - 24). No lead was detected in the solder for these samples. (The EDS detection limit for lead is <1% by weight.) The pulse oximeters with solder containing primarily tin were the:

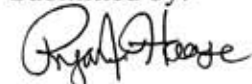
- Landon Medical Model PC00030361
- Nonin GO₂
- Nonin Onyx

EDS analysis also detected smaller concentrations of carbon, oxygen, fluorine, copper, sodium, magnesium, aluminum, silicon, sulfur, chlorine, silver, chromium, iron, and nickel on the solder joints.

SAMPLE DISPOSITION AND DATA STORAGE

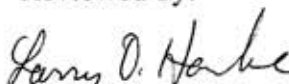
The samples from this project will be returned at the completion of the project. All data will be kept on file, and additional report copies can be obtained upon request.

Submitted by:



Ryan Haase
Materials Engineer

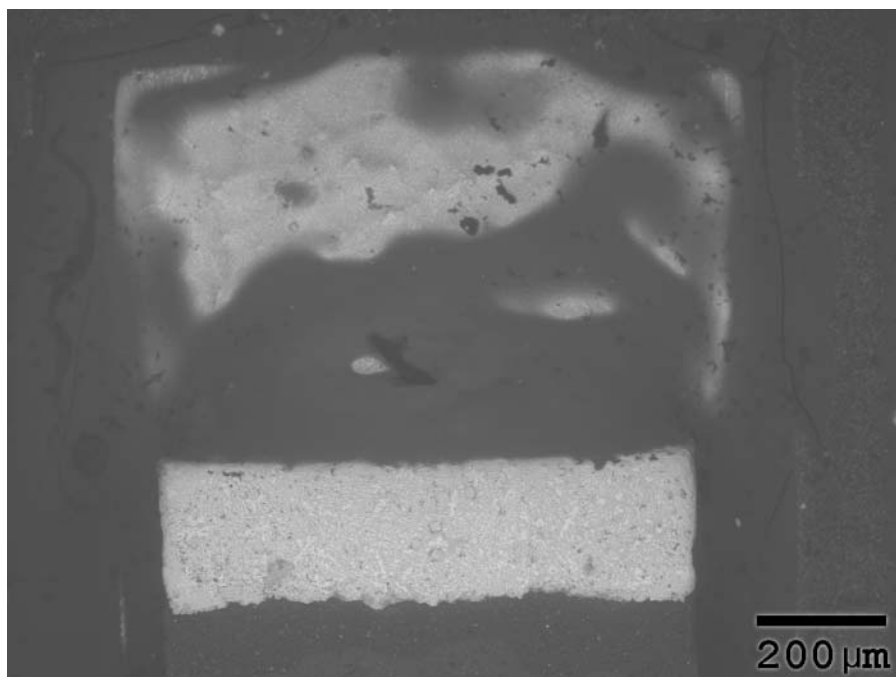
Reviewed by:



Larry D. Hanke, P.E.
Principal Engineer



(a) Sample As Received



Backscattered Electron Image

Magnification: 90X

(b) Representative Solder Joint

Figure 1 Barrington Diagnostics Model 50-102-003.

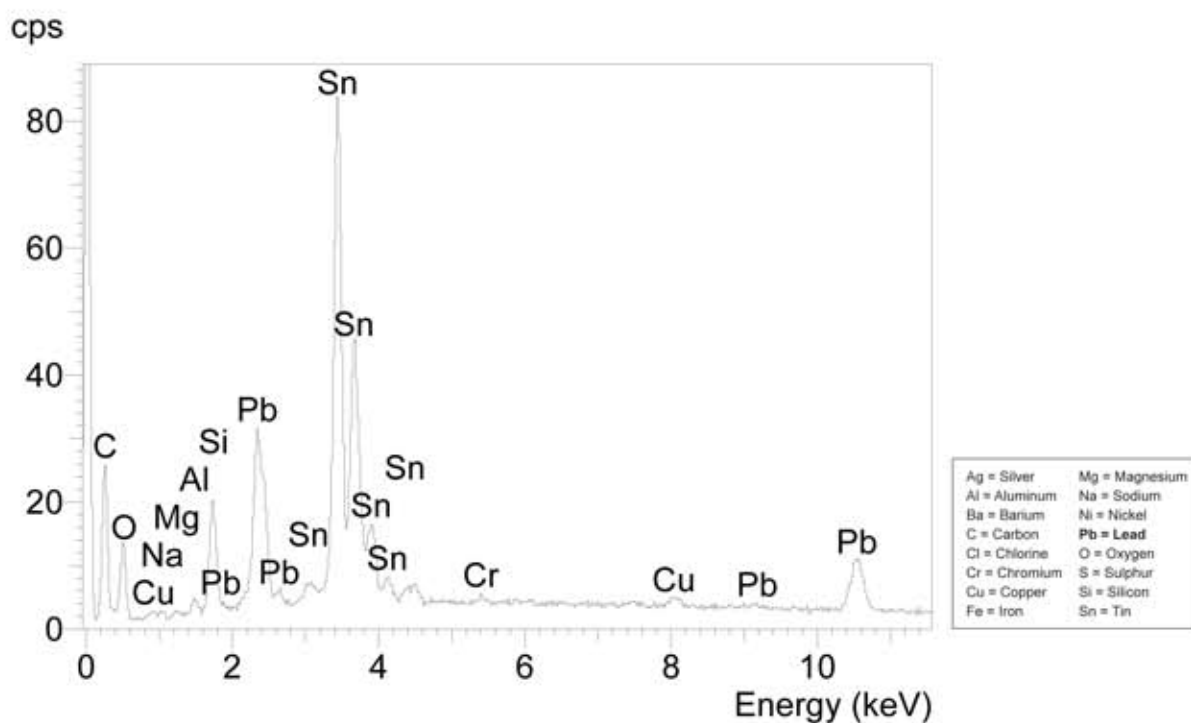


Figure 2 Spectrum for EDS analysis of a solder joint on the Barrington Diagnostics Model # 50-102-003.

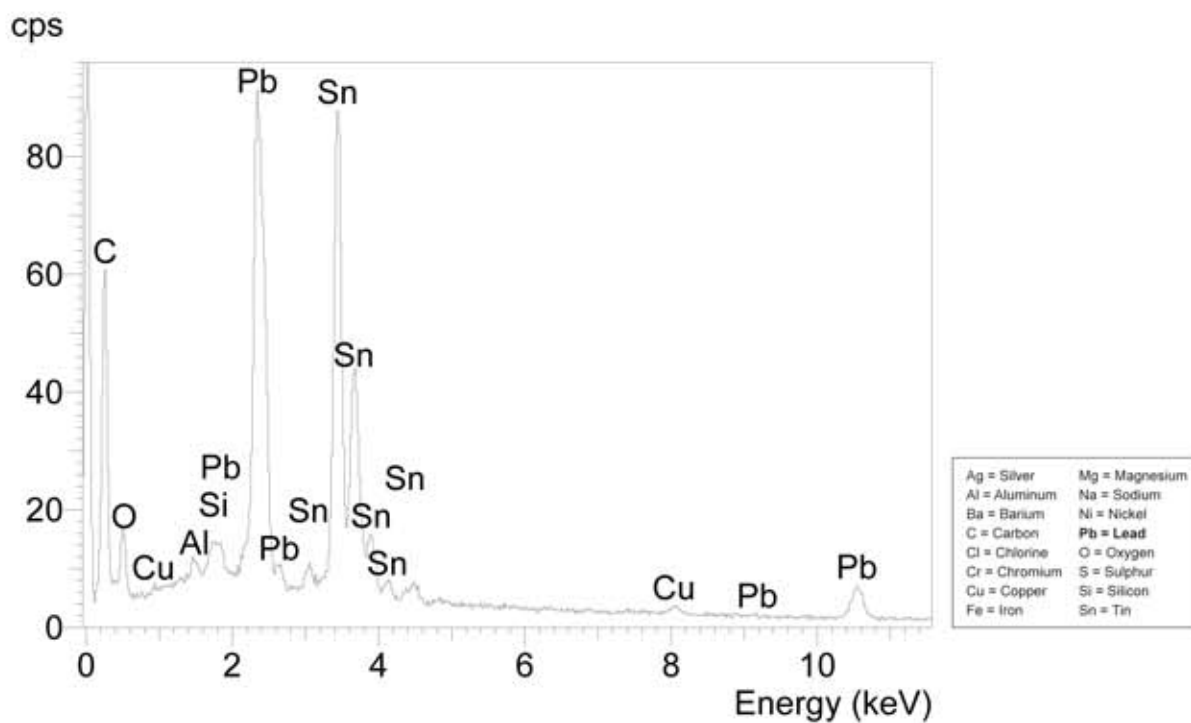
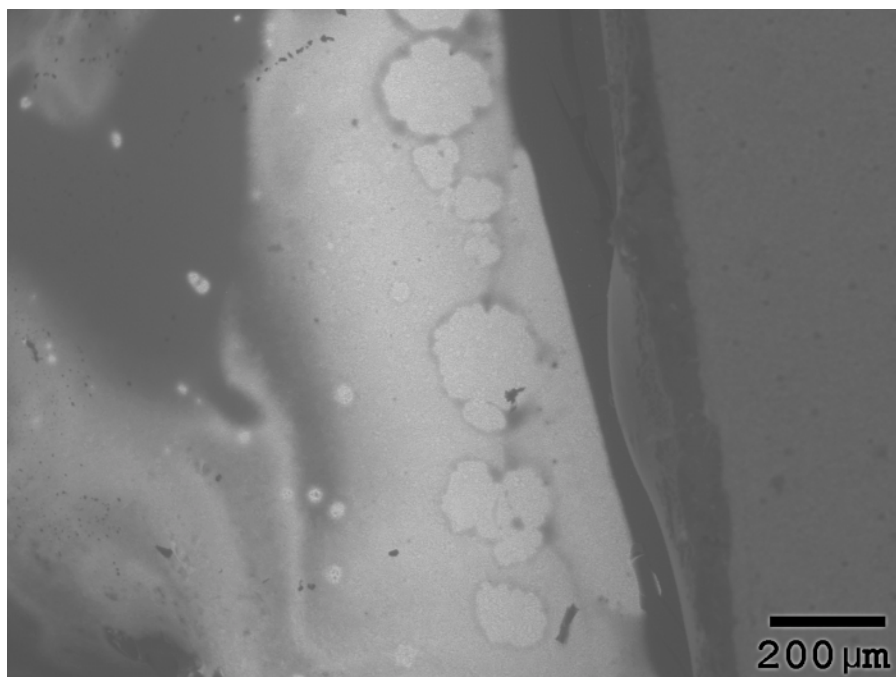


Figure 3 Spectrum for EDS analysis of a second solder joint on the Barrington Diagnostics Model # 50-102-003.



(a) Sample As Received



Backscattered Electron Image

Magnification: 80X

(b) Representative Solder Joint

Figure 4 Beijing Choice Electronic Technology Co. Ltd. Model MD300C1.

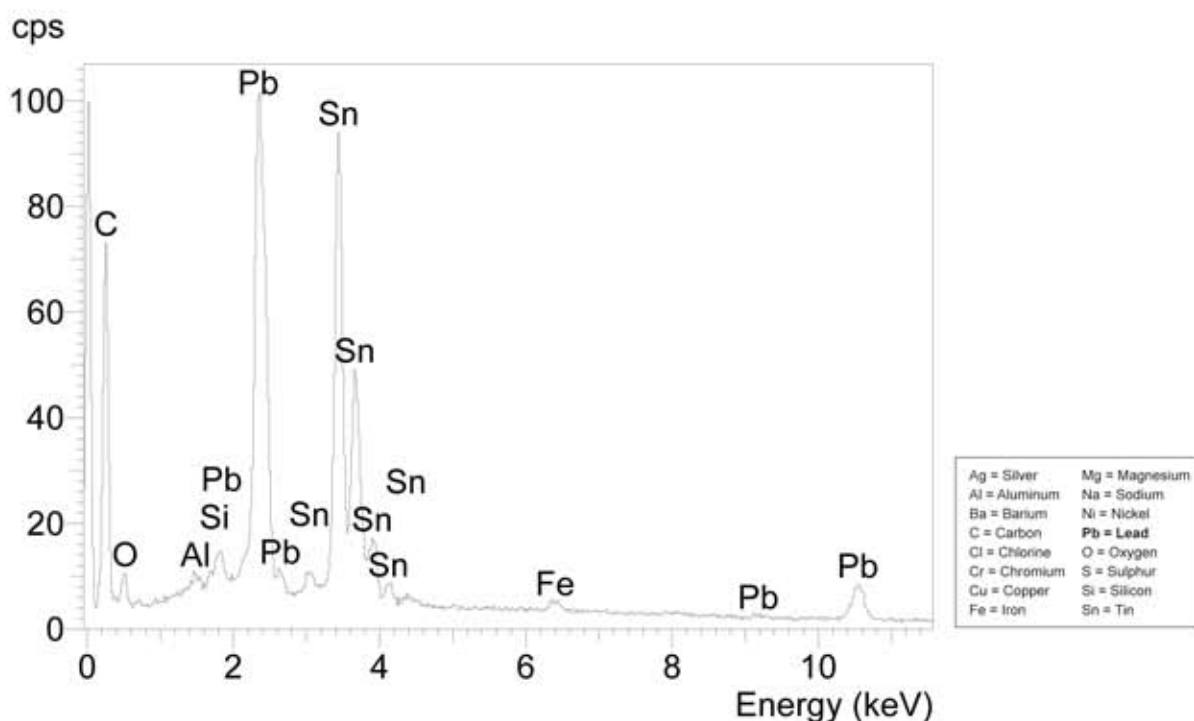


Figure 5 Spectrum for EDS analysis of a solder joint on the Beijing Choice Electronic Technology Co. Ltd. Model MD300C1

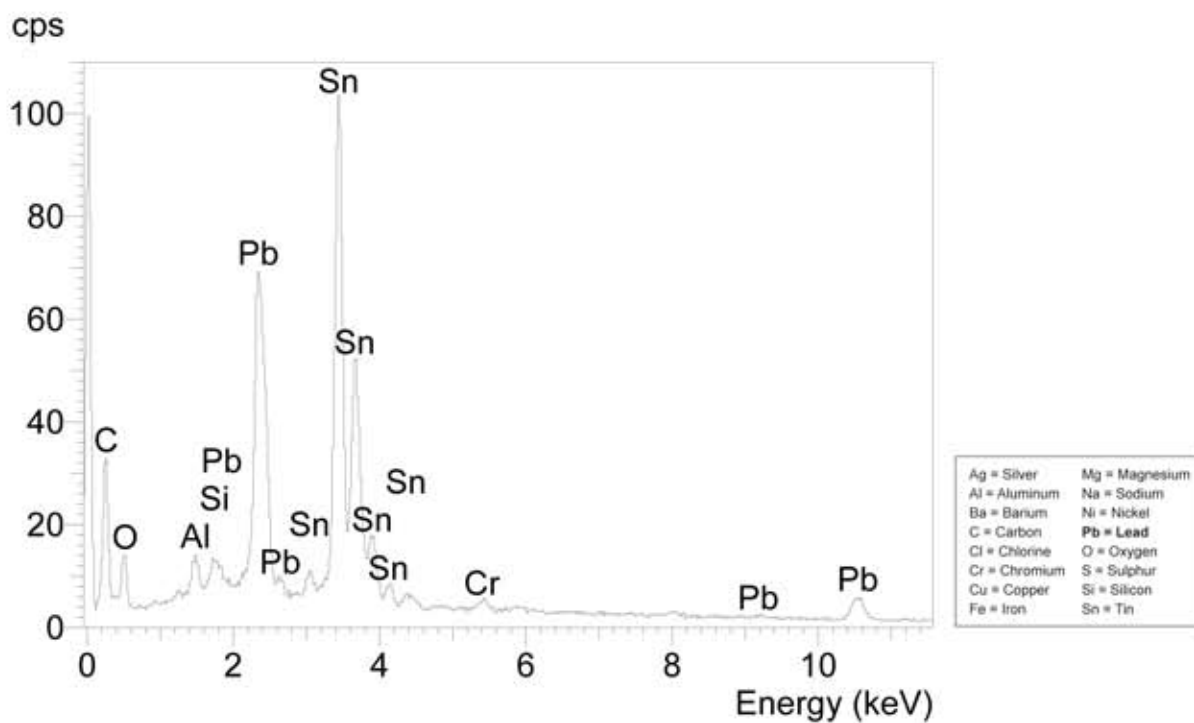
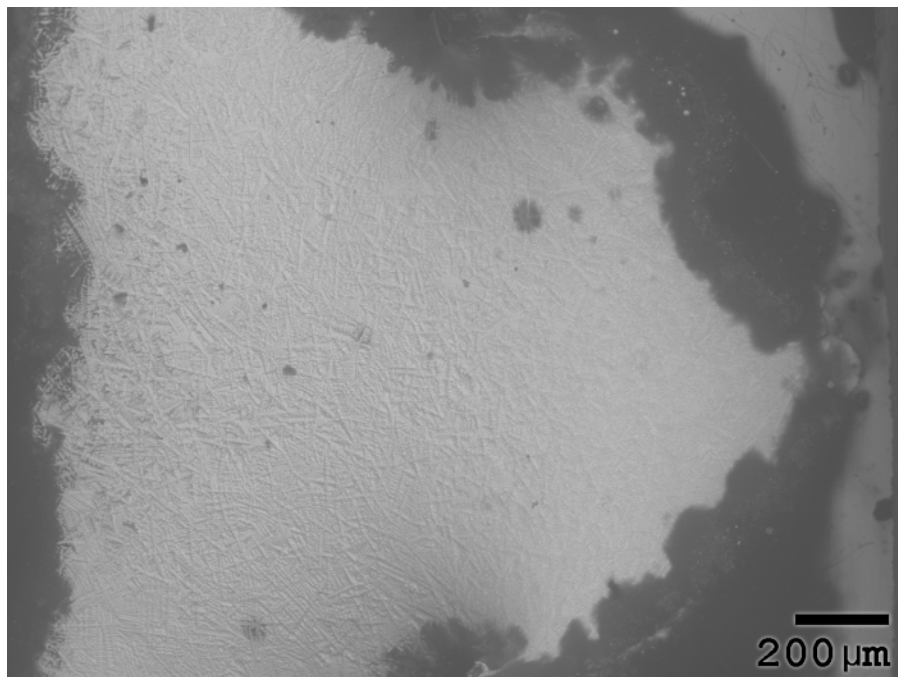


Figure 6 Spectrum for EDS analysis of a second solder joint on the Beijing Choice Electronic Technology Co. Ltd. Model MD300C1.



(a) Sample As Received



Backscattered Electron Image

Magnification: 65X

(b) Representative Solder Joint

Figure 7 Contec Model CMS50DL.

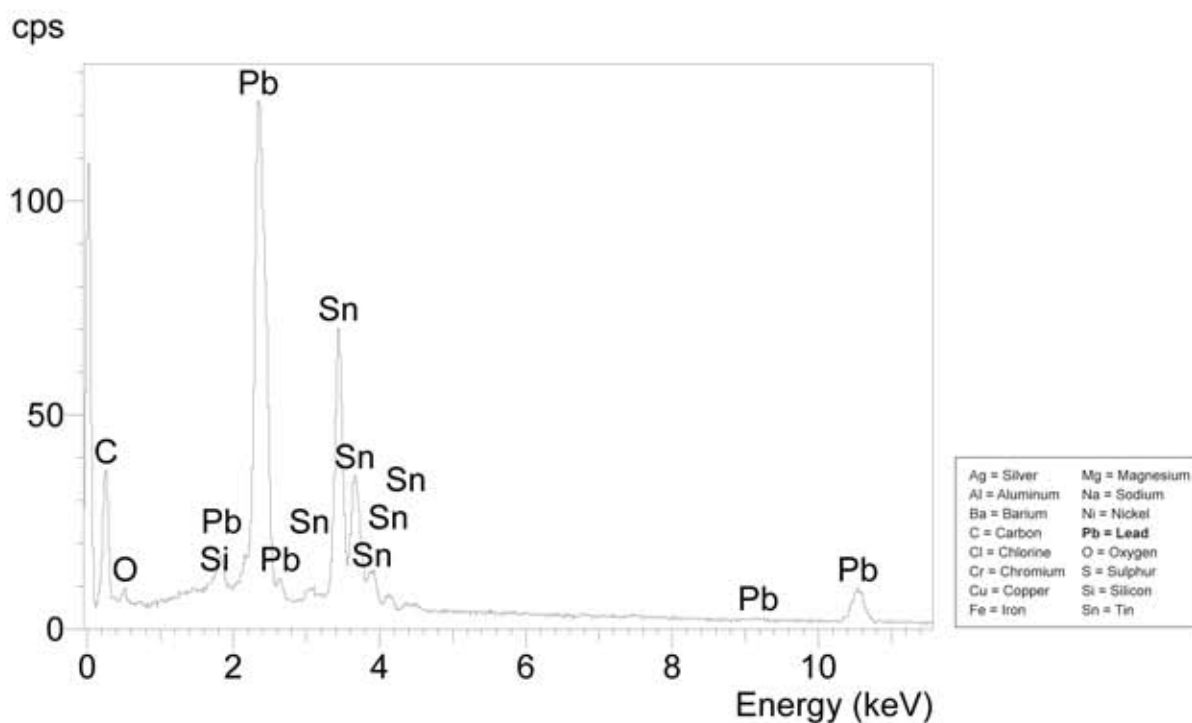


Figure 8 Spectrum for EDS analysis of a solder joint on the Contec Model CMS50DL.

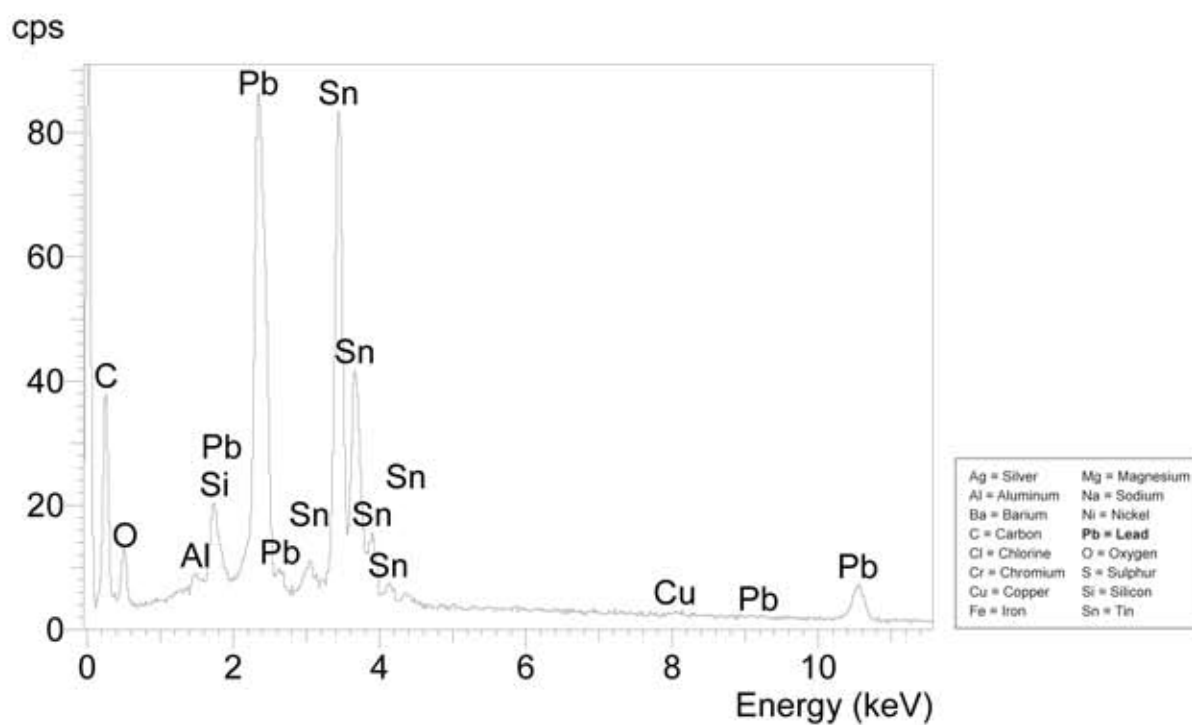
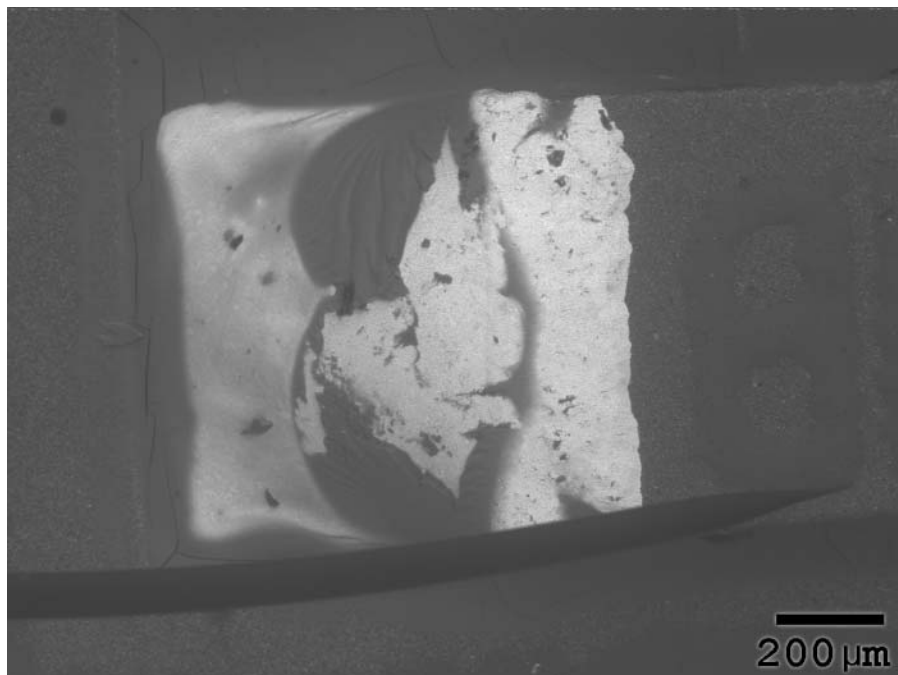


Figure 9 Spectrum for EDS analysis of a second solder joint on the Contec Model CMS50DL.



(a) Sample As Received



Backscattered Electron Image

Magnification: 75X

(b) Representative Solder Joint

Figure 10 Devon Medical Model 300C-1B.

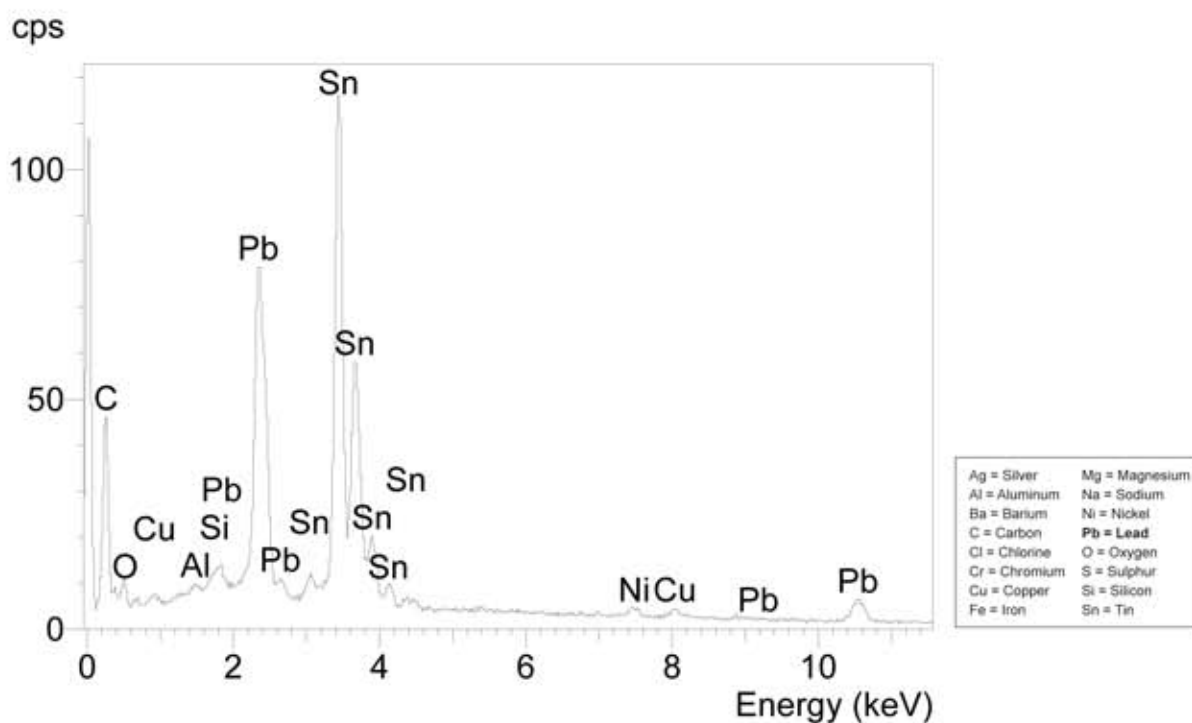


Figure 11 Spectrum for EDS analysis of a solder joint on the Devon Medical Model 300C-1B.

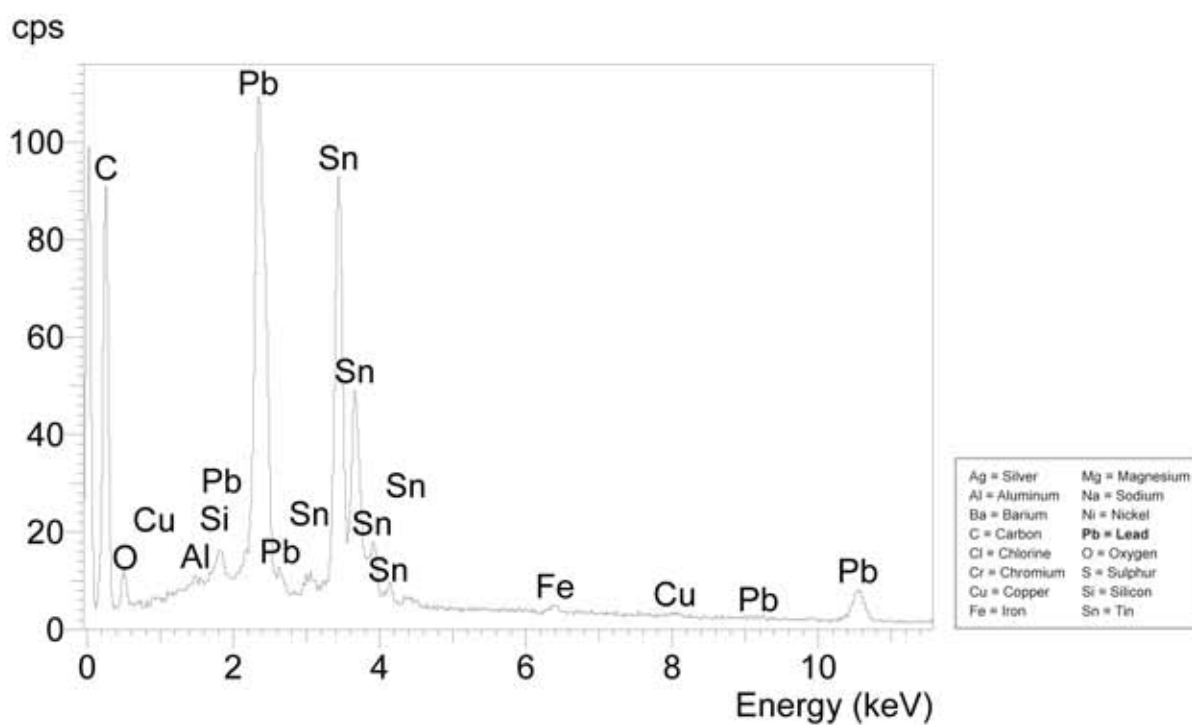
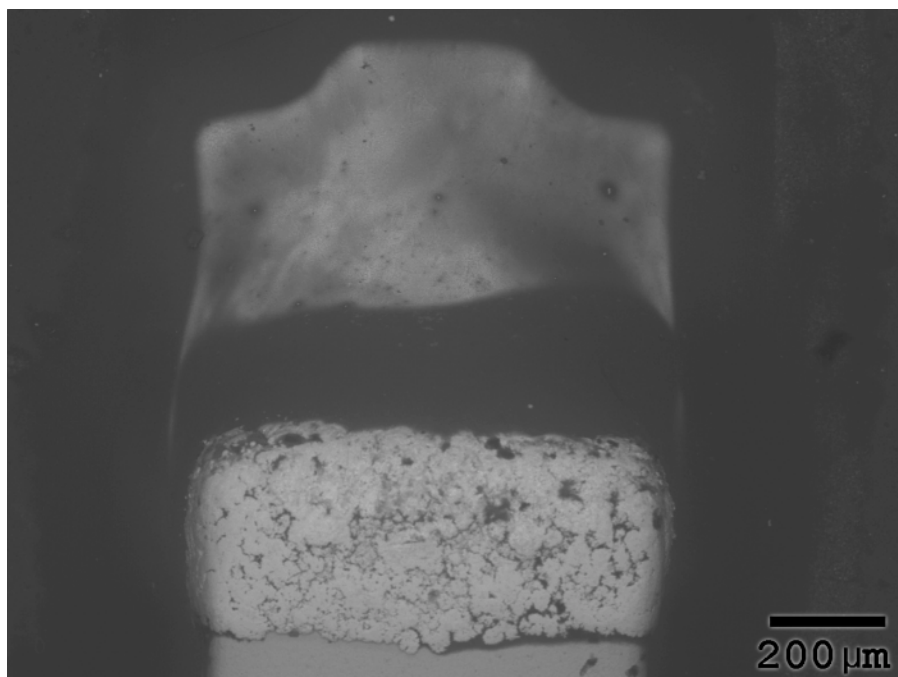


Figure 12 Spectrum for EDS analysis of a second solder joint on the Devon Medical Model 300C-1B.



(a) Sample As Received



Backscattered Electron Image

Magnification: 80X

(b) Representative Solder Joint

Figure 13 OxiPulse Pulse Insight Model PI2000.

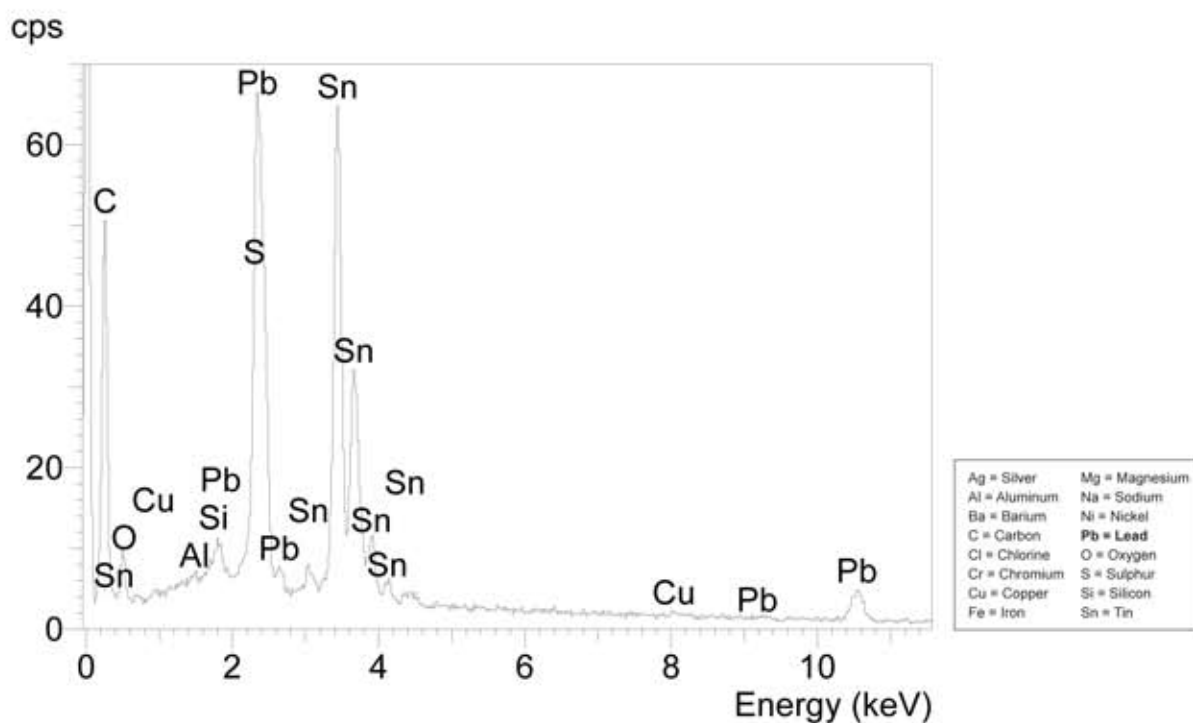


Figure 14 Spectrum for EDS analysis of a solder joint on the OxiPulse Pulse Insight Model PI2000.

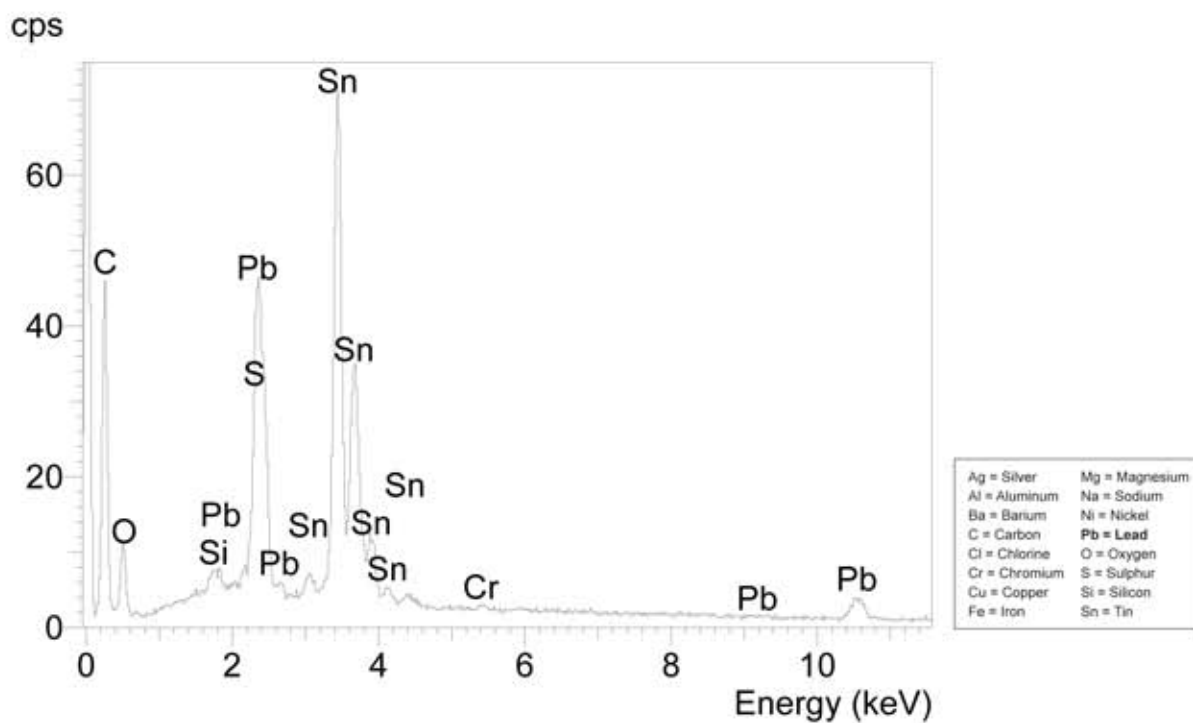
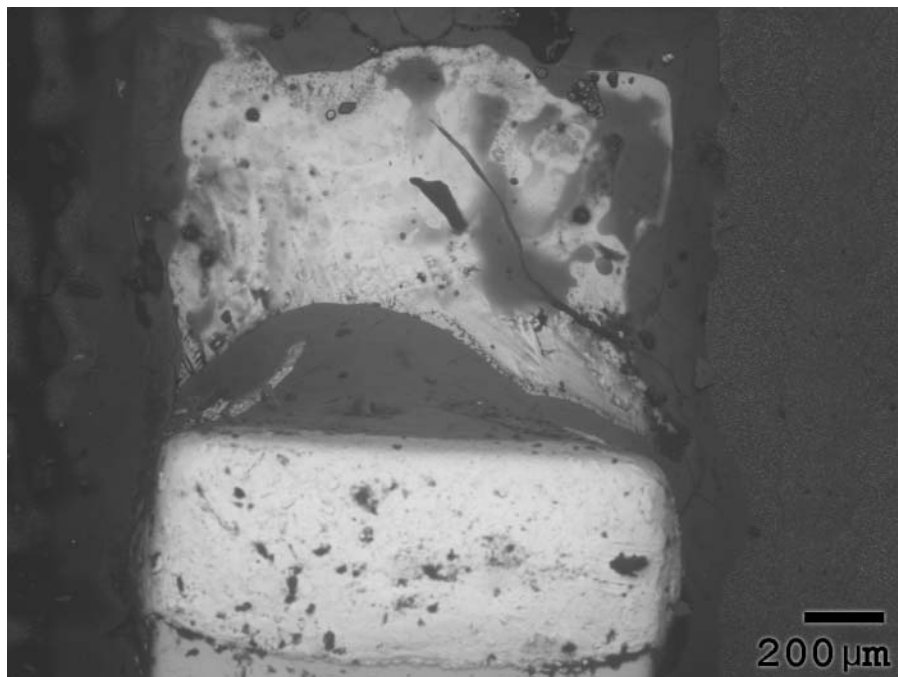


Figure 15 Spectrum for EDS analysis of a second solder joint on the OxiPulse Pulse Insight Model PI2000.



(a) Sample As Received



Backscattered Electron Image

Magnification: 55X

(b) Representative Solder Joint

Figure 16 Landon Medical Model PC00030361.

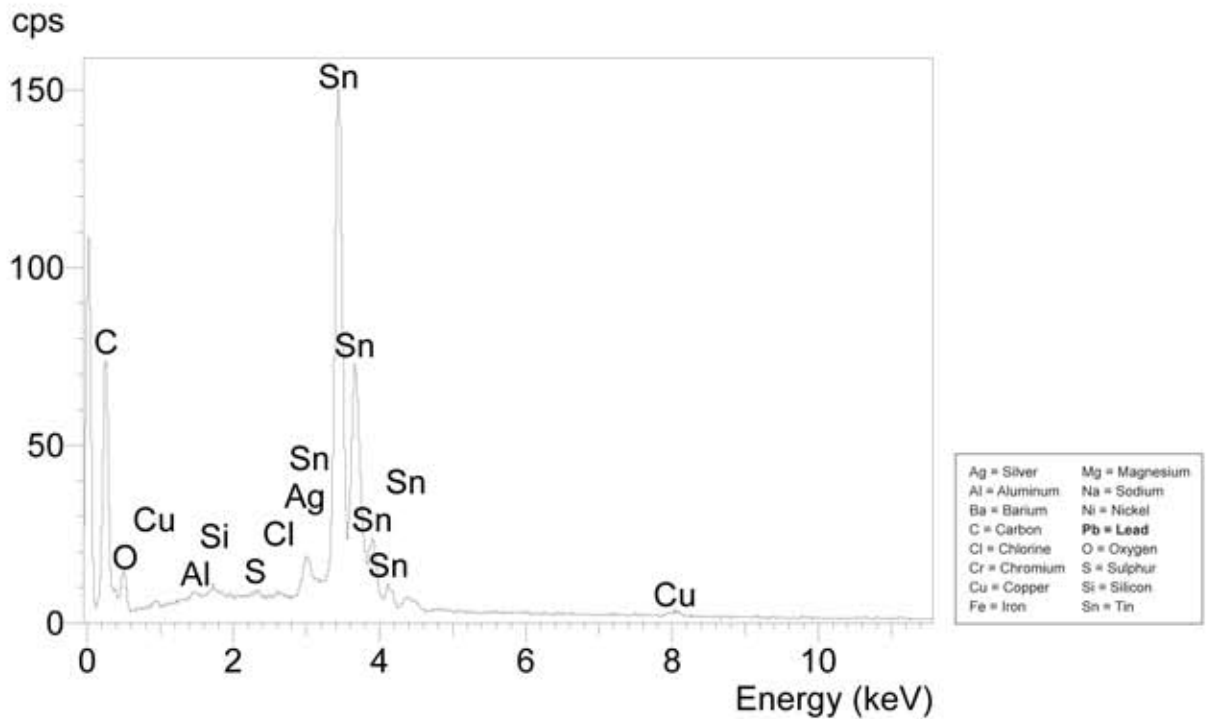


Figure 17 Spectrum for EDS analysis of a solder joint on the Landon Medical Model PC00030361.

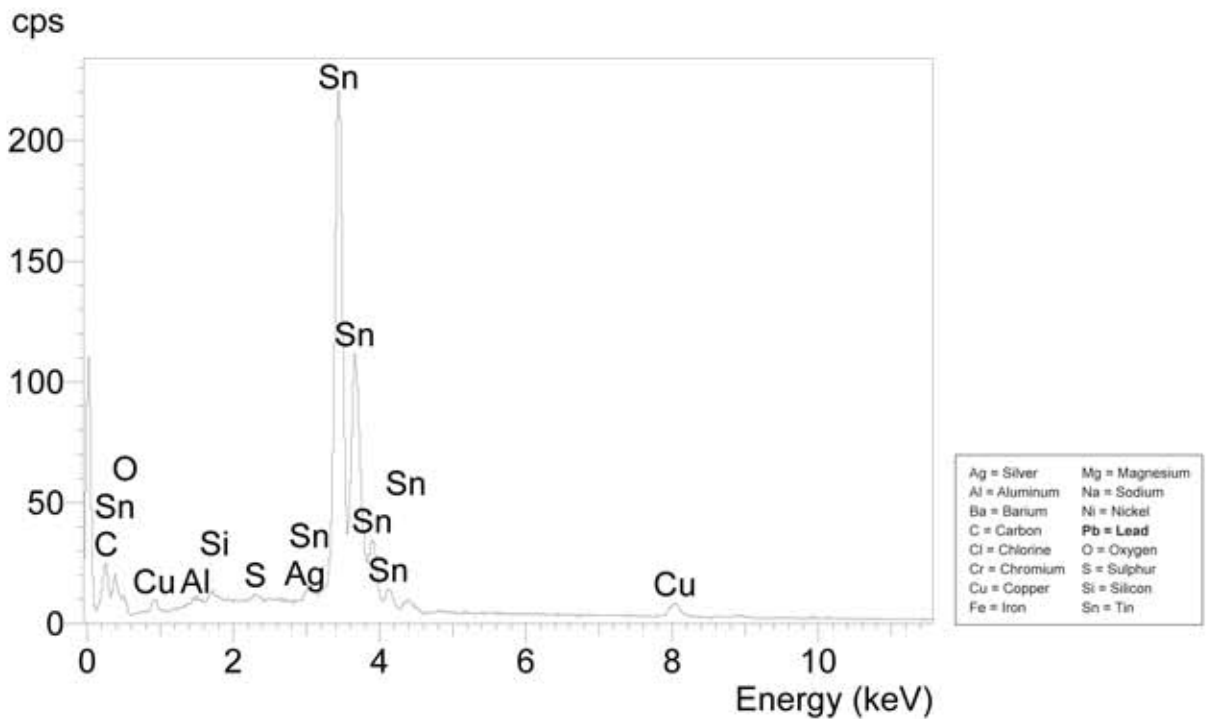
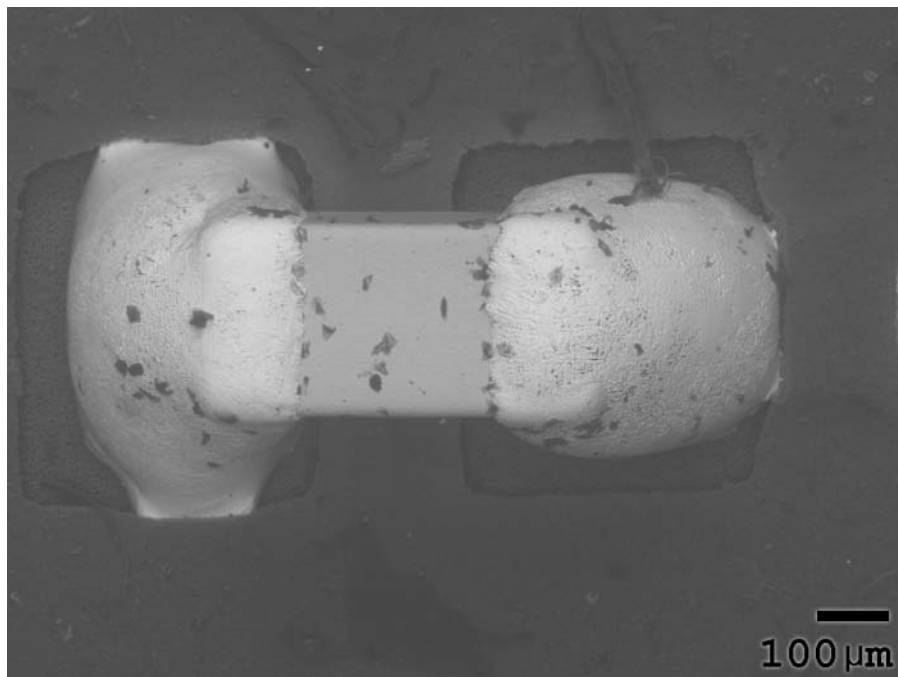


Figure 18 Spectrum for EDS analysis of a second solder joint on the Landon Medical Model PC00030361.



(a) Sample As Received



Backscattered Electron Image

Magnification: 100X

(b) Representative Solder Joint

Figure 19 Nonin GO_2 .

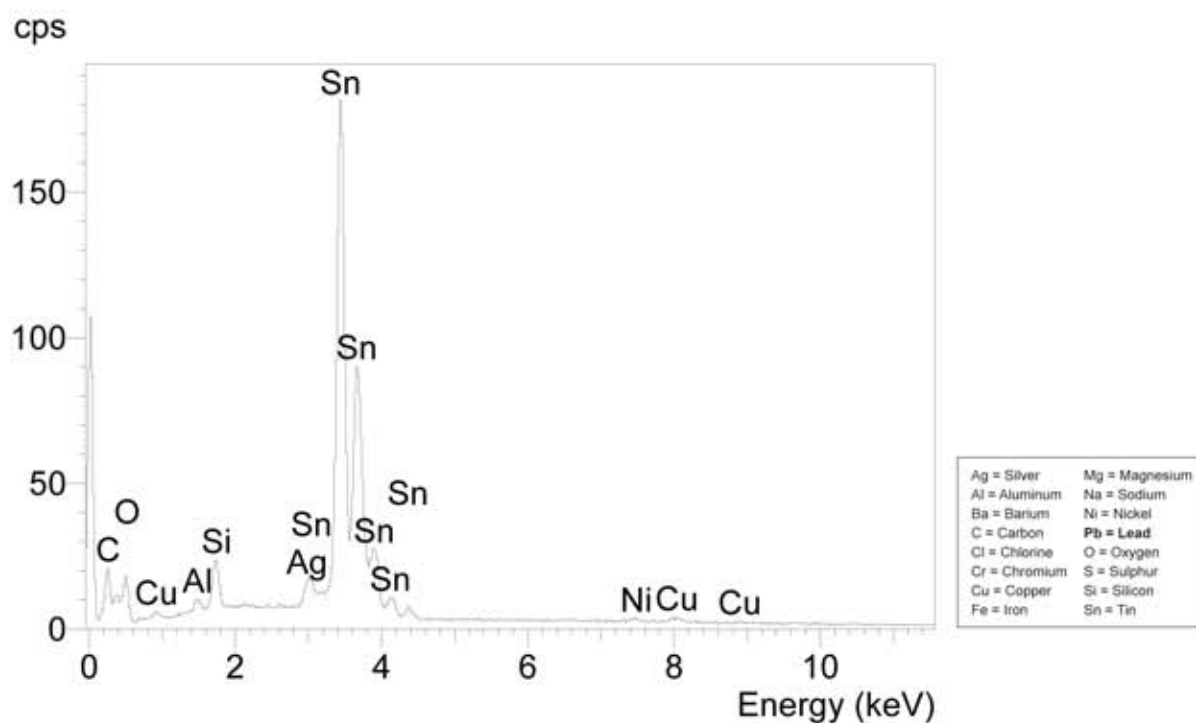


Figure 20 Spectrum for EDS analysis of a solder joint on the Nonin GO₂.

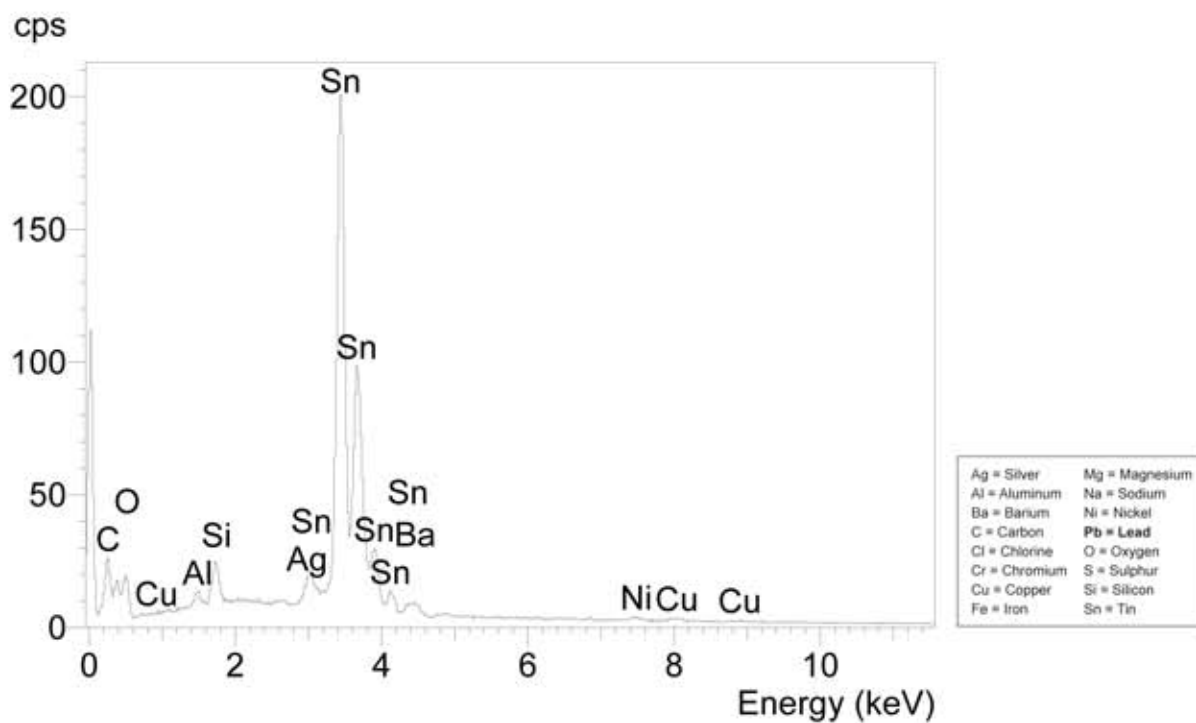
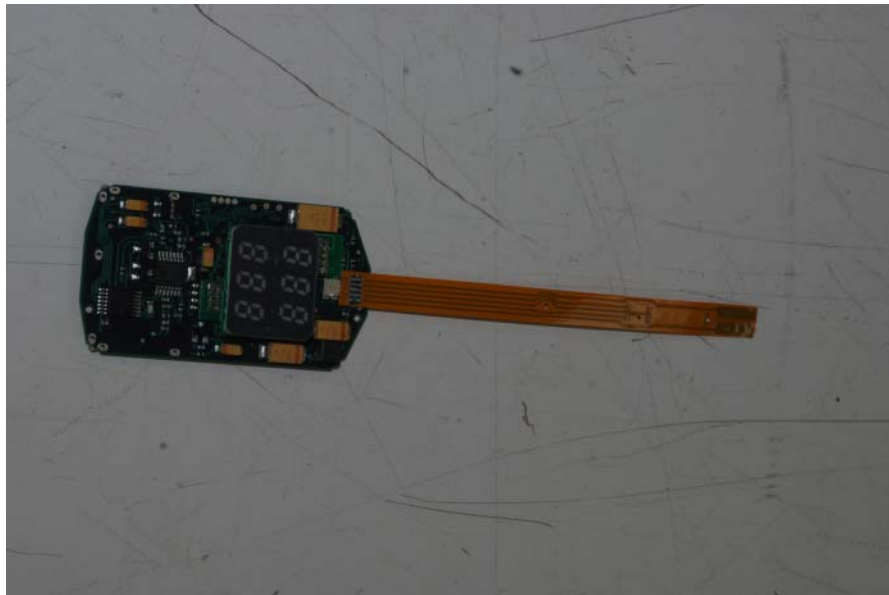
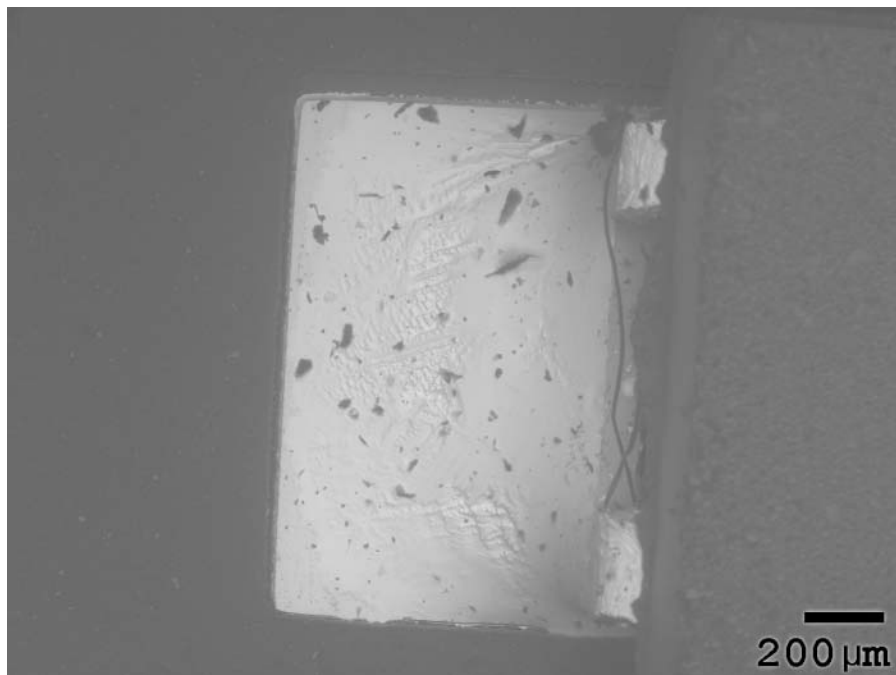


Figure 21 Spectrum for EDS analysis of a second solder joint on the Nonin GO₂.



(a) Sample As Received



Backscattered Electron Image

Magnification: 55X

(b) Representative Solder Joint

Figure 22 Nonin Onyx.

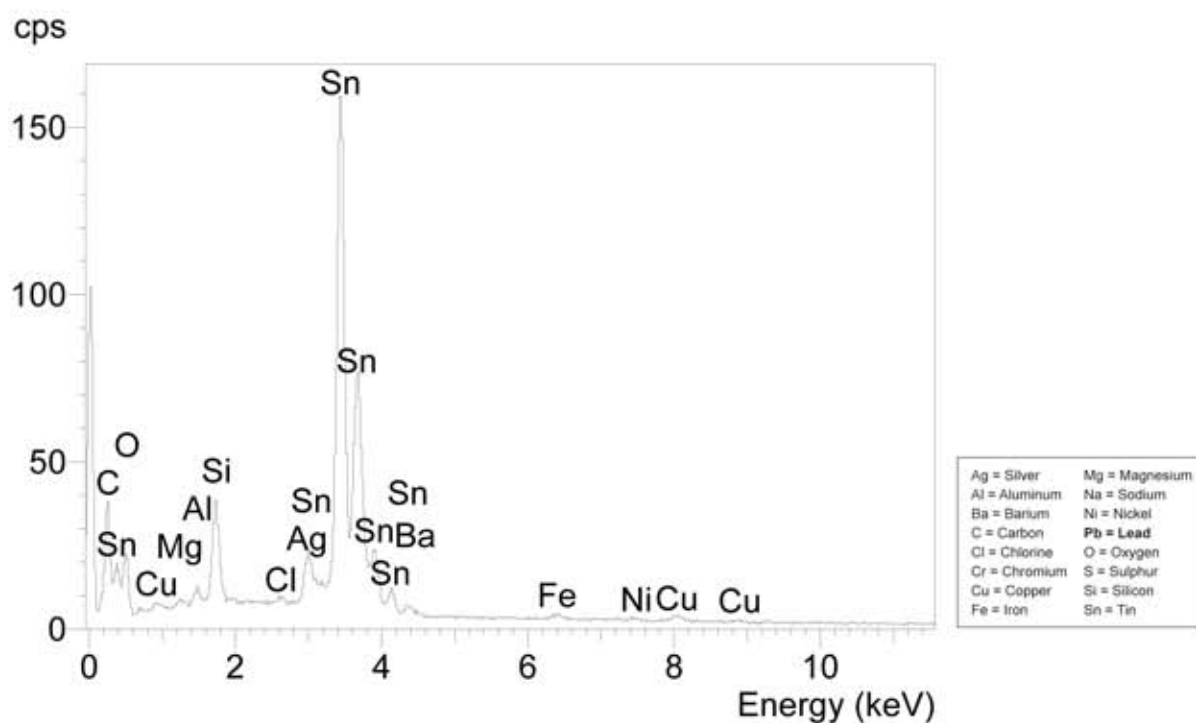


Figure 23 Spectrum for EDS analysis of a solder joint on the Nonin Onyx.

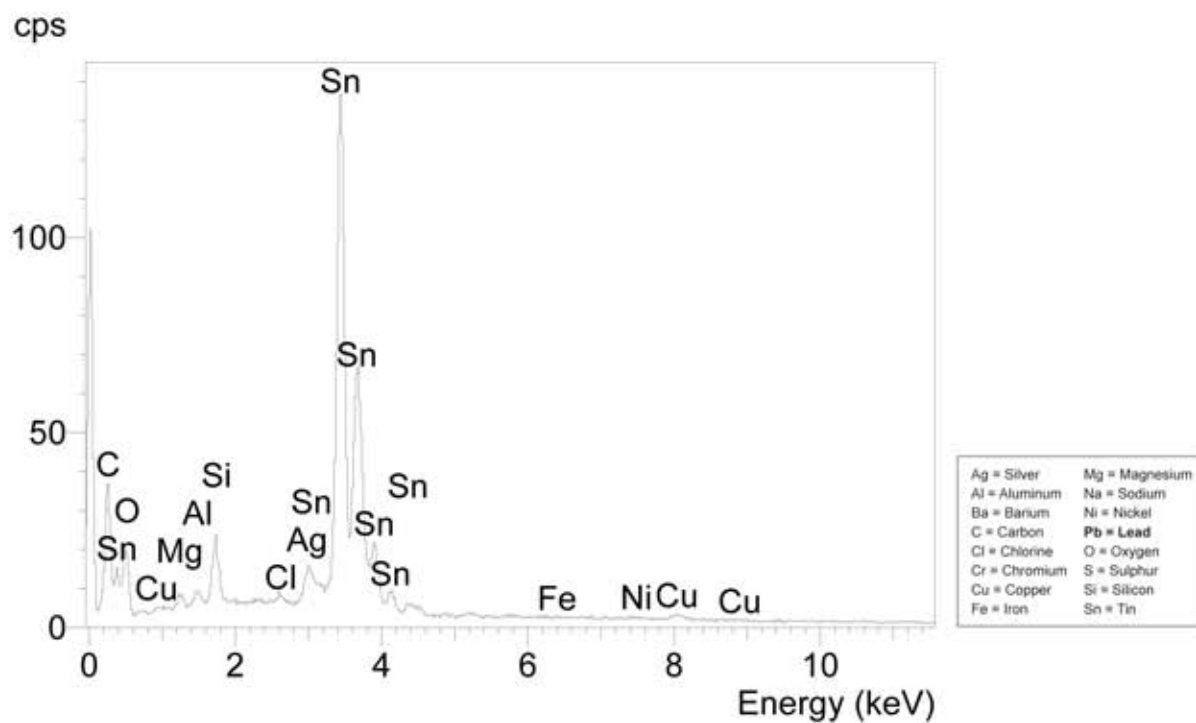


Figure 24 Spectrum for EDS analysis of a second solder joint on the Nonin Onyx.