

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                                              | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                              | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Systolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                              |                                            |       |        |                                            |       |        |
| N                                            | 50                                         |       |        | 20                                         |       |        |
| MEAN                                         | 100.2                                      |       |        | 100.0                                      |       |        |
| SEM                                          | 2.00                                       |       |        | 3.12                                       |       |        |
| MEDIAN                                       | 100.0                                      |       |        | 100.5                                      |       |        |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>               |                                            |       |        |                                            |       |        |
| N                                            | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                         | 100.2                                      | 103.7 | 3.5    | 100.0                                      | 105.5 | 5.6    |
| SEM                                          | 2.00                                       | 1.79  | 1.36   | 3.12                                       | 3.74  | 2.34   |
| MEDIAN                                       | 100.0                                      | 103.0 | 2.0    | 100.5                                      | 104.5 | 3.0    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b>             |                                            |       |        |                                            |       |        |
| N                                            | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                         | 100.2                                      | 101.4 | 1.1    | 100.0                                      | 100.6 | 0.6    |
| SEM                                          | 2.00                                       | 1.86  | 1.43   | 3.12                                       | 3.66  | 1.80   |
| MEDIAN                                       | 100.0                                      | 100.5 | 0.0    | 100.5                                      | 101.0 | 1.5    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |

Table 4.1.2  
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Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                  | 100.2                                      | 103.5 | 3.3    | 100.0                                      | 103.1 | 3.1    |
| SEM                   | 2.00                                       | 1.85  | 1.38   | 3.12                                       | 2.95  | 1.64   |
| MEDIAN                | 100.0                                      | 101.5 | 1.5    | 100.5                                      | 102.5 | 2.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 778                                        |       |        | 396                                        |       |        |
| MEAN                                  | 121.0                                      |       |        | 120.3                                      |       |        |
| SEM                                   | 0.56                                       |       |        | 0.78                                       |       |        |
| MEDIAN                                | 120.0                                      |       |        | 120.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 778                                        | 778   | 778    | 396                                        | 396   | 396    |
| MEAN                                  | 121.0                                      | 120.4 | -0.6   | 120.3                                      | 120.3 | -0.0   |
| SEM                                   | 0.56                                       | 0.56  | 0.38   | 0.78                                       | 0.79  | 0.61   |
| MEDIAN                                | 120.0                                      | 120.0 | 0.0    | 120.0                                      | 120.0 | 0.0    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 776                                        | 776   | 776    | 396                                        | 396   | 396    |
| MEAN                                  | 120.9                                      | 118.5 | -2.4   | 120.3                                      | 119.3 | -1.1   |
| SEM                                   | 0.56                                       | 0.55  | 0.42   | 0.78                                       | 0.86  | 0.67   |
| MEDIAN                                | 120.0                                      | 118.0 | -2.0   | 120.0                                      | 118.0 | -2.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 777                                        | 777   | 777    | 396                                        | 396   | 396    |
| MEAN                  | 120.9                                      | 120.5 | -0.4   | 120.3                                      | 120.2 | -0.2   |
| SEM                   | 0.56                                       | 0.57  | 0.42   | 0.78                                       | 0.79  | 0.60   |
| MEDIAN                | 120.0                                      | 119.0 | 0.0    | 120.0                                      | 118.0 | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 43                                         |       |        | 23                                         |       |        |
| MEAN                                  | 139.5                                      |       |        | 138.6                                      |       |        |
| SEM                                   | 2.45                                       |       |        | 3.77                                       |       |        |
| MEDIAN                                | 140.0                                      |       |        | 138.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 43                                         | 43    | 43     | 21                                         | 21    | 21     |
| MEAN                                  | 139.5                                      | 138.4 | -1.1   | 139.9                                      | 141.3 | 1.4    |
| SEM                                   | 2.45                                       | 2.58  | 2.02   | 4.01                                       | 4.98  | 3.02   |
| MEDIAN                                | 140.0                                      | 138.0 | 1.0    | 138.0                                      | 135.0 | 3.0    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                                  | 139.5                                      | 137.3 | -2.3   | 139.0                                      | 135.5 | -3.5   |
| SEM                                   | 2.45                                       | 2.70  | 2.16   | 3.93                                       | 3.72  | 3.42   |
| MEDIAN                                | 140.0                                      | 138.0 | 0.0    | 138.0                                      | 127.5 | -0.5   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                  | 139.5                                      | 139.1 | -0.5   | 139.5                                      | 141.1 | 1.6    |
| SEM                   | 2.45                                       | 3.22  | 2.58   | 3.85                                       | 4.14  | 2.81   |
| MEDIAN                | 140.0                                      | 140.0 | 0.0    | 138.0                                      | 144.0 | 1.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                                              | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                              | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Systolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                              |                                            |       |        |                                            |       |        |
| N                                            | 11                                         |       |        | 4                                          |       |        |
| MEAN                                         | 142.0                                      |       |        | 144.8                                      |       |        |
| SEM                                          | 6.38                                       |       |        | 9.01                                       |       |        |
| MEDIAN                                       | 140.0                                      |       |        | 149.5                                      |       |        |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>               |                                            |       |        |                                            |       |        |
| N                                            | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                         | 142.0                                      | 142.1 | 0.1    | 144.8                                      | 147.0 | 2.3    |
| SEM                                          | 6.38                                       | 5.40  | 3.57   | 9.01                                       | 6.42  | 3.33   |
| MEDIAN                                       | 140.0                                      | 143.0 | 1.0    | 149.5                                      | 148.5 | 2.5    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b>             |                                            |       |        |                                            |       |        |
| N                                            | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                         | 142.0                                      | 141.5 | -0.5   | 144.8                                      | 145.5 | 0.8    |
| SEM                                          | 6.38                                       | 4.65  | 4.57   | 9.01                                       | 8.80  | 1.89   |
| MEDIAN                                       | 140.0                                      | 143.0 | 6.0    | 149.5                                      | 151.0 | 0.0    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |

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Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                  | 142.0                                      | 137.8 | -4.2   | 144.8                                      | 149.5 | 4.8    |
| SEM                   | 6.38                                       | 5.60  | 4.20   | 9.01                                       | 9.95  | 6.52   |
| MEDIAN                | 140.0                                      | 145.0 | -4.0   | 149.5                                      | 155.0 | 2.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                                        | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 50                                         |       |        | 20                                         |       |        |
| MEAN                                   | 64.6                                       |       |        | 65.8                                       |       |        |
| SEM                                    | 1.68                                       |       |        | 2.76                                       |       |        |
| MEDIAN                                 | 66.0                                       |       |        | 67.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                   | 64.6                                       | 66.4  | 1.8    | 65.8                                       | 67.7  | 1.9    |
| SEM                                    | 1.68                                       | 1.44  | 0.97   | 2.76                                       | 3.73  | 2.57   |
| MEDIAN                                 | 66.0                                       | 66.5  | 2.0    | 67.0                                       | 66.0  | 3.5    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                   | 64.6                                       | 63.5  | -1.1   | 65.8                                       | 61.9  | -3.9   |
| SEM                                    | 1.68                                       | 1.53  | 1.05   | 2.76                                       | 3.70  | 2.83   |
| MEDIAN                                 | 66.0                                       | 64.0  | 0.0    | 67.0                                       | 62.0  | -0.5   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                  | 64.6                                       | 67.1  | 2.5    | 65.8                                       | 64.2  | -1.6   |
| SEM                   | 1.68                                       | 1.62  | 1.20   | 2.76                                       | 3.19  | 2.15   |
| MEDIAN                | 66.0                                       | 68.0  | 2.0    | 67.0                                       | 64.0  | -2.5   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 778                                        |       |        | 396                                        |       |        |
| MEAN                                   | 74.7                                       |       |        | 74.2                                       |       |        |
| SEM                                    | 0.39                                       |       |        | 0.53                                       |       |        |
| MEDIAN                                 | 74.0                                       |       |        | 73.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 778                                        | 778   | 778    | 396                                        | 396   | 396    |
| MEAN                                   | 74.7                                       | 73.0  | -1.7   | 74.2                                       | 73.0  | -1.2   |
| SEM                                    | 0.39                                       | 0.37  | 0.28   | 0.53                                       | 0.55  | 0.44   |
| MEDIAN                                 | 74.0                                       | 72.0  | -1.0   | 73.0                                       | 72.0  | -1.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 776                                        | 776   | 776    | 396                                        | 396   | 396    |
| MEAN                                   | 74.7                                       | 71.2  | -3.5   | 74.2                                       | 71.2  | -3.0   |
| SEM                                    | 0.39                                       | 0.40  | 0.31   | 0.53                                       | 0.54  | 0.43   |
| MEDIAN                                 | 74.0                                       | 70.0  | -3.0   | 73.0                                       | 70.0  | -2.5   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 777                                        | 777   | 777    | 396                                        | 396   | 396    |
| MEAN                  | 74.6                                       | 74.1  | -0.6   | 74.2                                       | 74.8  | 0.6    |
| SEM                   | 0.39                                       | 0.41  | 0.32   | 0.53                                       | 0.58  | 0.48   |
| MEDIAN                | 74.0                                       | 73.0  | 0.0    | 73.0                                       | 74.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 43                                         |       |        | 23                                         |       |        |
| MEAN                                   | 77.8                                       |       |        | 79.6                                       |       |        |
| SEM                                    | 1.35                                       |       |        | 1.68                                       |       |        |
| MEDIAN                                 | 77.0                                       |       |        | 80.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 43                                         | 43    | 43     | 21                                         | 21    | 21     |
| MEAN                                   | 77.8                                       | 76.1  | -1.7   | 79.6                                       | 77.6  | -2.0   |
| SEM                                    | 1.35                                       | 1.39  | 1.28   | 1.84                                       | 2.04  | 1.83   |
| MEDIAN                                 | 77.0                                       | 76.0  | -2.0   | 81.0                                       | 76.0  | 0.0    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                                   | 77.8                                       | 72.9  | -4.9   | 79.6                                       | 75.2  | -4.4   |
| SEM                                    | 1.35                                       | 1.52  | 1.18   | 1.76                                       | 1.98  | 1.93   |
| MEDIAN                                 | 77.0                                       | 70.0  | -6.0   | 80.5                                       | 75.0  | -2.5   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                  | 77.8                                       | 76.7  | -1.1   | 79.5                                       | 78.5  | -1.1   |
| SEM                   | 1.35                                       | 1.52  | 1.39   | 1.76                                       | 2.25  | 1.73   |
| MEDIAN                | 77.0                                       | 78.0  | -2.0   | 80.5                                       | 77.5  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 11                                         |       |        | 4                                          |       |        |
| MEAN                                   | 79.7                                       |       |        | 82.0                                       |       |        |
| SEM                                    | 0.81                                       |       |        | 2.71                                       |       |        |
| MEDIAN                                 | 80.0                                       |       |        | 80.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                   | 79.7                                       | 75.3  | -4.5   | 82.0                                       | 81.3  | -0.8   |
| SEM                                    | 0.81                                       | 2.69  | 2.41   | 2.71                                       | 2.78  | 2.10   |
| MEDIAN                                 | 80.0                                       | 78.0  | -1.0   | 80.0                                       | 81.0  | -1.5   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                   | 79.7                                       | 76.5  | -3.3   | 82.0                                       | 76.3  | -5.8   |
| SEM                                    | 0.81                                       | 2.78  | 2.18   | 2.71                                       | 5.56  | 4.31   |
| MEDIAN                                 | 80.0                                       | 78.0  | 0.0    | 80.0                                       | 79.5  | -5.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                  | 79.7                                       | 77.5  | -2.2   | 82.0                                       | 76.5  | -5.5   |
| SEM                   | 0.81                                       | 3.77  | 3.34   | 2.71                                       | 5.20  | 3.93   |
| MEDIAN                | 80.0                                       | 78.0  | 0.0    | 80.0                                       | 79.5  | -4.5   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 50                                         |       |        | 20                                         |       |        |
| MEAN                                    | 105.3                                      |       |        | 103.8                                      |       |        |
| SEM                                     | 1.88                                       |       |        | 2.50                                       |       |        |
| MEDIAN                                  | 105.0                                      |       |        | 102.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                    | 105.3                                      | 107.0 | 1.7    | 103.8                                      | 106.3 | 2.6    |
| SEM                                     | 1.88                                       | 2.06  | 1.31   | 2.50                                       | 2.52  | 1.42   |
| MEDIAN                                  | 105.0                                      | 104.0 | 1.5    | 102.0                                      | 105.5 | 1.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 778                                        |       |        | 395                                        |       |        |
| MEAN                                    | 126.1                                      |       |        | 124.7                                      |       |        |
| SEM                                     | 0.61                                       |       |        | 0.84                                       |       |        |
| MEDIAN                                  | 123.5                                      |       |        | 122.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 768                                        | 768   | 768    | 388                                        | 388   | 388    |
| MEAN                                    | 125.9                                      | 126.6 | 0.8    | 124.6                                      | 126.0 | 1.4    |
| SEM                                     | 0.61                                       | 0.62  | 0.49   | 0.85                                       | 0.90  | 0.66   |
| MEDIAN                                  | 123.0                                      | 124.0 | 0.0    | 122.0                                      | 122.0 | 0.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 43                                         |       |        | 22                                         |       |        |
| MEAN                                    | 141.3                                      |       |        | 140.5                                      |       |        |
| SEM                                     | 3.23                                       |       |        | 3.39                                       |       |        |
| MEDIAN                                  | 141.0                                      |       |        | 142.5                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 42                                         | 42    | 42     | 21                                         | 21    | 21     |
| MEAN                                    | 141.2                                      | 140.1 | -1.0   | 141.5                                      | 140.6 | -0.9   |
| SEM                                     | 3.31                                       | 3.23  | 3.12   | 3.41                                       | 4.13  | 3.80   |
| MEDIAN                                  | 140.5                                      | 140.0 | 1.5    | 143.0                                      | 142.0 | 1.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 11                                         |       |        | 4                                          |       |        |
| MEAN                                    | 147.9                                      |       |        | 144.8                                      |       |        |
| SEM                                     | 6.73                                       |       |        | 12.26                                      |       |        |
| MEDIAN                                  | 150.0                                      |       |        | 153.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                    | 147.9                                      | 142.7 | -5.2   | 144.8                                      | 150.0 | 5.3    |
| SEM                                     | 6.73                                       | 4.45  | 6.53   | 12.26                                      | 13.39 | 5.27   |
| MEDIAN                                  | 150.0                                      | 148.0 | -2.0   | 153.0                                      | 162.0 | 0.5    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 50                                         |       |        | 20                                         |       |        |
| MEAN                                     | 66.7                                       |       |        | 69.2                                       |       |        |
| SEM                                      | 1.55                                       |       |        | 2.89                                       |       |        |
| MEDIAN                                   | 68.0                                       |       |        | 70.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                                     | 66.7                                       | 69.8  | 3.1    | 69.2                                       | 71.5  | 2.3    |
| SEM                                      | 1.55                                       | 1.59  | 1.18   | 2.89                                       | 2.42  | 2.14   |
| MEDIAN                                   | 68.0                                       | 70.5  | 0.0    | 70.0                                       | 72.0  | 1.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 778                                        |       |        | 395                                        |       |        |
| MEAN                                     | 81.1                                       |       |        | 80.9                                       |       |        |
| SEM                                      | 0.42                                       |       |        | 0.59                                       |       |        |
| MEDIAN                                   | 80.0                                       |       |        | 80.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 768                                        | 768   | 768    | 388                                        | 388   | 388    |
| MEAN                                     | 81.0                                       | 80.8  | -0.2   | 80.8                                       | 81.4  | 0.5    |
| SEM                                      | 0.41                                       | 0.43  | 0.34   | 0.60                                       | 0.64  | 0.51   |
| MEDIAN                                   | 80.0                                       | 80.0  | 0.0    | 80.0                                       | 80.0  | 0.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 43                                         |       |        | 22                                         |       |        |
| MEAN                                     | 82.9                                       |       |        | 84.5                                       |       |        |
| SEM                                      | 1.74                                       |       |        | 2.42                                       |       |        |
| MEDIAN                                   | 83.0                                       |       |        | 85.5                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 42                                         | 42    | 42     | 21                                         | 21    | 21     |
| MEAN                                     | 82.9                                       | 82.6  | -0.3   | 84.8                                       | 86.0  | 1.3    |
| SEM                                      | 1.78                                       | 1.96  | 1.76   | 2.53                                       | 2.79  | 2.44   |
| MEDIAN                                   | 83.5                                       | 83.5  | -0.5   | 86.0                                       | 88.0  | 0.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 11                                         |       |        | 4                                          |       |        |
| MEAN                                     | 88.8                                       |       |        | 85.0                                       |       |        |
| SEM                                      | 6.76                                       |       |        | 4.06                                       |       |        |
| MEDIAN                                   | 84.0                                       |       |        | 86.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                                     | 88.8                                       | 81.3  | -7.5   | 85.0                                       | 88.5  | 3.5    |
| SEM                                      | 6.76                                       | 3.48  | 8.84   | 4.06                                       | 6.84  | 7.73   |
| MEDIAN                                   | 84.0                                       | 82.0  | -2.0   | 86.0                                       | 85.0  | -2.0   |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |



Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>        |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 50                                         |       |        | 20                                         |       |        |
| MEAN                      | 81.9                                       |       |        | 78.2                                       |       |        |
| SEM                       | 1.70                                       |       |        | 3.61                                       |       |        |
| MEDIAN                    | 81.0                                       |       |        | 80.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| <hr/>                     |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                      | 81.9                                       | 86.0  | 4.0    | 78.2                                       | 85.0  | 6.8    |
| SEM                       | 1.70                                       | 1.73  | 1.58   | 3.61                                       | 2.81  | 1.83   |
| MEDIAN                    | 81.0                                       | 85.0  | 2.0    | 80.0                                       | 85.0  | 6.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| <hr/>                     |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                      | 81.9                                       | 84.9  | 3.0    | 78.2                                       | 81.8  | 3.7    |
| SEM                       | 1.70                                       | 1.42  | 1.35   | 3.61                                       | 3.00  | 1.84   |
| MEDIAN                    | 81.0                                       | 83.0  | 2.0    | 80.0                                       | 84.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| <hr/>                     |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                  | 81.9                                       | 84.8  | 2.9    | 78.2                                       | 82.4  | 4.3    |
| SEM                   | 1.70                                       | 1.31  | 1.17   | 3.61                                       | 3.24  | 2.81   |
| MEDIAN                | 81.0                                       | 84.0  | 2.0    | 80.0                                       | 84.5  | 1.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 778                                        |       |        | 396                                        |       |        |
| MEAN                             | 73.6                                       |       |        | 74.4                                       |       |        |
| SEM                              | 0.45                                       |       |        | 0.63                                       |       |        |
| MEDIAN                           | 72.0                                       |       |        | 73.5                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 778                                        | 778   | 778    | 396                                        | 396   | 396    |
| MEAN                             | 73.6                                       | 75.3  | 1.7    | 74.4                                       | 76.5  | 2.1    |
| SEM                              | 0.45                                       | 0.46  | 0.34   | 0.63                                       | 0.70  | 0.50   |
| MEDIAN                           | 72.0                                       | 74.0  | 0.5    | 73.5                                       | 76.0  | 1.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 776                                        | 776   | 776    | 396                                        | 396   | 396    |
| MEAN                             | 73.6                                       | 75.4  | 1.8    | 74.4                                       | 75.9  | 1.6    |
| SEM                              | 0.46                                       | 0.47  | 0.34   | 0.63                                       | 0.65  | 0.47   |
| MEDIAN                           | 72.0                                       | 74.0  | 1.0    | 73.5                                       | 75.0  | 1.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                       | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 777                                        | 777   | 777    | 396                                        | 396   | 396    |
| MEAN                  | 73.6                                       | 72.3  | -1.2   | 74.4                                       | 72.9  | -1.4   |
| SEM                   | 0.45                                       | 0.42  | 0.37   | 0.63                                       | 0.61  | 0.47   |
| MEDIAN                | 72.0                                       | 71.0  | -1.0   | 73.5                                       | 71.5  | -1.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| Baseline                         |                                            |       |        |                                            |       |        |
| N                                | 43                                         |       |        | 23                                         |       |        |
| MEAN                             | 72.8                                       |       |        | 69.5                                       |       |        |
| SEM                              | 1.81                                       |       |        | 1.80                                       |       |        |
| MEDIAN                           | 72.0                                       |       |        | 70.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                             | 72.8                                       | 73.1  | 0.4    | 69.1                                       | 72.2  | 3.1    |
| SEM                              | 1.81                                       | 1.87  | 0.98   | 1.84                                       | 1.95  | 1.10   |
| MEDIAN                           | 72.0                                       | 73.0  | 0.0    | 70.0                                       | 72.0  | 4.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                             | 72.8                                       | 73.0  | 0.2    | 69.1                                       | 72.4  | 3.3    |
| SEM                              | 1.81                                       | 1.83  | 0.98   | 1.84                                       | 1.96  | 1.49   |
| MEDIAN                           | 72.0                                       | 73.0  | 0.0    | 70.0                                       | 72.0  | 2.5    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                  | 72.8                                       | 70.2  | -2.6   | 69.1                                       | 66.8  | -2.3   |
| SEM                   | 1.81                                       | 1.76  | 1.12   | 1.84                                       | 1.62  | 1.61   |
| MEDIAN                | 72.0                                       | 69.0  | -3.0   | 70.0                                       | 65.5  | -2.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Pulse (BPM)               |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 11                                         |       |        | 4                                          |       |        |
| MEAN                      | 71.9                                       |       |        | 73.0                                       |       |        |
| SEM                       | 2.92                                       |       |        | 1.00                                       |       |        |
| MEDIAN                    | 70.0                                       |       |        | 72.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                      | 71.9                                       | 72.8  | 0.9    | 73.0                                       | 76.5  | 3.5    |
| SEM                       | 2.92                                       | 2.99  | 0.97   | 1.00                                       | 2.06  | 1.71   |
| MEDIAN                    | 70.0                                       | 73.0  | 1.0    | 72.0                                       | 77.0  | 3.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                      | 71.9                                       | 69.7  | -2.2   | 73.0                                       | 76.0  | 3.0    |
| SEM                       | 2.92                                       | 3.02  | 3.30   | 1.00                                       | 3.29  | 4.06   |
| MEDIAN                    | 70.0                                       | 68.0  | 0.0    | 72.0                                       | 76.0  | 4.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                  | 71.9                                       | 69.2  | -2.7   | 73.0                                       | 71.8  | -1.3   |
| SEM                   | 2.92                                       | 2.79  | 2.60   | 1.00                                       | 3.84  | 4.71   |
| MEDIAN                | 70.0                                       | 68.0  | -2.0   | 72.0                                       | 72.5  | 0.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Respirations (/minute)</b>    |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 50                                         |       |        | 20                                         |       |        |
| MEAN                             | 18.0                                       |       |        | 19.0                                       |       |        |
| SEM                              | 0.46                                       |       |        | 0.69                                       |       |        |
| MEDIAN                           | 18.0                                       |       |        | 18.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                             | 18.0                                       | 18.7  | 0.7    | 19.0                                       | 18.8  | -0.2   |
| SEM                              | 0.46                                       | 0.42  | 0.27   | 0.69                                       | 0.72  | 0.43   |
| MEDIAN                           | 18.0                                       | 19.0  | 0.0    | 18.0                                       | 18.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                             | 18.0                                       | 18.5  | 0.4    | 19.0                                       | 18.6  | -0.5   |
| SEM                              | 0.46                                       | 0.43  | 0.23   | 0.69                                       | 0.73  | 0.30   |
| MEDIAN                           | 18.0                                       | 18.0  | 0.0    | 18.0                                       | 18.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 50                                         | 50    | 50     | 20                                         | 20    | 20     |
| MEAN                  | 18.0                                       | 18.6  | 0.5    | 19.0                                       | 18.9  | -0.1   |
| SEM                   | 0.46                                       | 0.39  | 0.24   | 0.69                                       | 0.76  | 0.35   |
| MEDIAN                | 18.0                                       | 18.0  | 0.0    | 18.0                                       | 18.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Respirations (/minute)</b>    |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 776                                        |       |        | 396                                        |       |        |
| MEAN                             | 17.1                                       |       |        | 17.0                                       |       |        |
| SEM                              | 0.13                                       |       |        | 0.17                                       |       |        |
| MEDIAN                           | 16.0                                       |       |        | 16.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 776                                        | 776   | 776    | 396                                        | 396   | 396    |
| MEAN                             | 17.1                                       | 17.5  | 0.4    | 17.0                                       | 17.5  | 0.6    |
| SEM                              | 0.13                                       | 0.13  | 0.09   | 0.17                                       | 0.18  | 0.13   |
| MEDIAN                           | 16.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 773                                        | 773   | 773    | 396                                        | 396   | 396    |
| MEAN                             | 17.1                                       | 17.4  | 0.3    | 17.0                                       | 17.2  | 0.2    |
| SEM                              | 0.13                                       | 0.13  | 0.09   | 0.17                                       | 0.17  | 0.12   |
| MEDIAN                           | 16.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 774                                        | 774   | 774    | 395                                        | 395   | 395    |
| MEAN                  | 17.1                                       | 16.9  | -0.2   | 17.0                                       | 17.0  | 0.0    |
| SEM                   | 0.13                                       | 0.12  | 0.09   | 0.17                                       | 0.16  | 0.12   |
| MEDIAN                | 16.0                                       | 16.0  | 0.0    | 16.0                                       | 16.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Respirations (/minute)</b>    |                                            |       |        |                                            |       |        |
| Baseline                         |                                            |       |        |                                            |       |        |
| N                                | 43                                         |       |        | 23                                         |       |        |
| MEAN                             | 18.1                                       |       |        | 17.0                                       |       |        |
| SEM                              | 0.47                                       |       |        | 0.75                                       |       |        |
| MEDIAN                           | 18.0                                       |       |        | 17.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                             | 18.1                                       | 18.5  | 0.4    | 17.0                                       | 17.2  | 0.2    |
| SEM                              | 0.47                                       | 0.43  | 0.30   | 0.78                                       | 0.78  | 0.43   |
| MEDIAN                           | 18.0                                       | 18.0  | 0.0    | 17.5                                       | 16.5  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                             | 18.1                                       | 18.6  | 0.5    | 17.0                                       | 17.4  | 0.4    |
| SEM                              | 0.47                                       | 0.41  | 0.39   | 0.78                                       | 0.86  | 0.54   |
| MEDIAN                           | 18.0                                       | 18.0  | 0.0    | 17.5                                       | 17.5  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 43                                         | 43    | 43     | 22                                         | 22    | 22     |
| MEAN                  | 18.1                                       | 17.9  | -0.2   | 17.0                                       | 17.2  | 0.2    |
| SEM                   | 0.47                                       | 0.46  | 0.34   | 0.78                                       | 0.86  | 0.53   |
| MEDIAN                | 18.0                                       | 18.0  | 0.0    | 17.5                                       | 17.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 11                                         |       |        | 4                                          |       |        |
| MEAN                      | 17.6                                       |       |        | 15.8                                       |       |        |
| SEM                       | 1.40                                       |       |        | 1.65                                       |       |        |
| MEDIAN                    | 16.0                                       |       |        | 15.5                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                      | 17.6                                       | 18.2  | 0.5    | 15.8                                       | 20.8  | 5.0    |
| SEM                       | 1.40                                       | 1.37  | 0.41   | 1.65                                       | 3.25  | 2.08   |
| MEDIAN                    | 16.0                                       | 18.0  | 0.0    | 15.5                                       | 19.0  | 5.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                      | 17.6                                       | 18.5  | 0.8    | 15.8                                       | 18.8  | 3.0    |
| SEM                       | 1.40                                       | 1.46  | 0.48   | 1.65                                       | 3.50  | 1.91   |
| MEDIAN                    | 16.0                                       | 18.0  | 0.0    | 15.5                                       | 17.5  | 2.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.2  
Summary of Mean Change From Baseline in Vital Signs by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 11                                         | 11    | 11     | 4                                          | 4     | 4      |
| MEAN                  | 17.6                                       | 17.6  | 0.0    | 15.8                                       | 19.0  | 3.3    |
| SEM                   | 1.40                                       | 1.31  | 0.45   | 1.65                                       | 3.19  | 1.84   |
| MEDIAN                | 16.0                                       | 17.0  | 0.0    | 15.5                                       | 17.0  | 3.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 647                                        |       |        | 330                                        |       |        |
| MEAN                                  | 122.2                                      |       |        | 121.4                                      |       |        |
| SEM                                   | 0.67                                       |       |        | 0.91                                       |       |        |
| MEDIAN                                | 120.0                                      |       |        | 120.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 647                                        | 647   | 647    | 328                                        | 328   | 328    |
| MEAN                                  | 122.2                                      | 121.8 | -0.4   | 121.3                                      | 121.3 | -0.0   |
| SEM                                   | 0.67                                       | 0.65  | 0.43   | 0.91                                       | 0.93  | 0.70   |
| MEDIAN                                | 120.0                                      | 120.0 | 0.0    | 120.0                                      | 120.0 | 0.0    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                                  | 122.1                                      | 119.3 | -2.8   | 121.3                                      | 119.5 | -1.8   |
| SEM                                   | 0.67                                       | 0.64  | 0.48   | 0.91                                       | 0.97  | 0.74   |
| MEDIAN                                | 120.0                                      | 118.0 | -2.0   | 120.0                                      | 118.0 | -2.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                  | 122.1                                      | 121.5 | -0.6   | 121.4                                      | 121.2 | -0.1   |
| SEM                   | 0.67                                       | 0.67  | 0.50   | 0.91                                       | 0.94  | 0.69   |
| MEDIAN                | 120.0                                      | 120.0 | 0.0    | 120.0                                      | 118.0 | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 74                                         |       |        | 34                                         |       |        |
| MEAN                                  | 122.4                                      |       |        | 128.8                                      |       |        |
| SEM                                   | 1.88                                       |       |        | 3.35                                       |       |        |
| MEDIAN                                | 120.0                                      |       |        | 127.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                                  | 122.4                                      | 123.3 | 0.8    | 128.8                                      | 130.3 | 1.5    |
| SEM                                   | 1.88                                       | 2.02  | 1.33   | 3.35                                       | 3.06  | 1.87   |
| MEDIAN                                | 120.0                                      | 120.5 | 0.0    | 127.0                                      | 128.0 | 1.5    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                                  | 122.4                                      | 124.2 | 1.8    | 128.8                                      | 131.9 | 3.1    |
| SEM                                   | 1.88                                       | 2.17  | 1.50   | 3.35                                       | 3.55  | 2.26   |
| MEDIAN                                | 120.0                                      | 120.0 | 0.5    | 127.0                                      | 128.0 | 0.5    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                  | 122.4                                      | 125.4 | 2.9    | 128.8                                      | 131.1 | 2.2    |
| SEM                   | 1.88                                       | 2.22  | 1.38   | 3.35                                       | 2.80  | 1.79   |
| MEDIAN                | 120.0                                      | 123.0 | 3.0    | 127.0                                      | 128.0 | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 44                                         |       |        | 27                                         |       |        |
| MEAN                                  | 117.0                                      |       |        | 113.6                                      |       |        |
| SEM                                   | 2.38                                       |       |        | 2.18                                       |       |        |
| MEDIAN                                | 118.0                                      |       |        | 112.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                                  | 117.0                                      | 113.8 | -3.2   | 113.6                                      | 112.4 | -1.2   |
| SEM                                   | 2.38                                       | 2.17  | 1.66   | 2.18                                       | 1.95  | 1.49   |
| MEDIAN                                | 118.0                                      | 113.5 | -2.0   | 112.0                                      | 111.0 | -1.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 43                                         | 43    | 43     | 27                                         | 27    | 27     |
| MEAN                                  | 116.6                                      | 112.7 | -3.9   | 113.6                                      | 111.2 | -2.4   |
| SEM                                   | 2.41                                       | 2.06  | 1.63   | 2.18                                       | 1.78  | 1.72   |
| MEDIAN                                | 118.0                                      | 110.0 | 0.0    | 112.0                                      | 110.0 | -2.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                  | 117.0                                      | 114.5 | -2.5   | 113.6                                      | 112.6 | -1.0   |
| SEM                   | 2.38                                       | 2.26  | 1.51   | 2.18                                       | 2.08  | 1.68   |
| MEDIAN                | 118.0                                      | 114.5 | 0.0    | 112.0                                      | 112.0 | 2.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                              | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                              | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Systolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                              |                                            |       |        |                                            |       |        |
| N                                            | 94                                         |       |        | 42                                         |       |        |
| MEAN                                         | 114.4                                      |       |        | 111.4                                      |       |        |
| SEM                                          | 1.66                                       |       |        | 2.34                                       |       |        |
| MEDIAN                                       | 112.5                                      |       |        | 110.5                                      |       |        |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>               |                                            |       |        |                                            |       |        |
| N                                            | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                         | 114.4                                      | 114.6 | 0.2    | 111.4                                      | 116.2 | 4.8    |
| SEM                                          | 1.66                                       | 1.49  | 1.12   | 2.34                                       | 2.95  | 1.87   |
| MEDIAN                                       | 112.5                                      | 112.0 | 0.0    | 110.5                                      | 118.0 | 2.0    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b>             |                                            |       |        |                                            |       |        |
| N                                            | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                         | 114.4                                      | 113.6 | -0.8   | 111.4                                      | 114.6 | 3.2    |
| SEM                                          | 1.66                                       | 1.59  | 0.88   | 2.34                                       | 3.03  | 1.94   |
| MEDIAN                                       | 112.5                                      | 114.5 | 0.0    | 110.5                                      | 115.0 | 0.0    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                  | 114.4                                      | 115.1 | 0.8    | 111.4                                      | 113.7 | 2.4    |
| SEM                   | 1.66                                       | 1.60  | 0.98   | 2.34                                       | 2.57  | 1.41   |
| MEDIAN                | 112.5                                      | 116.0 | 0.0    | 110.5                                      | 115.0 | 1.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 23                                         |       |        | 10                                         |       |        |
| MEAN                                  | 116.9                                      |       |        | 124.6                                      |       |        |
| SEM                                   | 3.79                                       |       |        | 5.87                                       |       |        |
| MEDIAN                                | 111.0                                      |       |        | 124.0                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                  | 116.9                                      | 115.5 | -1.4   | 124.6                                      | 118.5 | -6.1   |
| SEM                                   | 3.79                                       | 4.27  | 1.76   | 5.87                                       | 5.74  | 1.83   |
| MEDIAN                                | 111.0                                      | 110.0 | -2.0   | 124.0                                      | 120.5 | -5.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                  | 116.9                                      | 116.4 | -0.5   | 124.6                                      | 118.7 | -5.9   |
| SEM                                   | 3.79                                       | 4.42  | 1.55   | 5.87                                       | 6.55  | 3.80   |
| MEDIAN                                | 111.0                                      | 110.0 | -2.0   | 124.0                                      | 120.0 | -4.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change from Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                  | 116.9                                      | 116.9 | -0.0   | 124.6                                      | 119.0 | -5.6   |
| SEM                   | 3.79                                       | 4.55  | 1.54   | 5.87                                       | 5.43  | 2.65   |
| MEDIAN                | 111.0                                      | 110.0 | 0.0    | 124.0                                      | 121.5 | -5.5   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                                               | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                               | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Diastolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| Baseline                                      |                                            |       |        |                                            |       |        |
| N                                             | 647                                        |       |        | 330                                        |       |        |
| MEAN                                          | 74.7                                       |       |        | 74.0                                       |       |        |
| SEM                                           | 0.43                                       |       |        | 0.58                                       |       |        |
| MEDIAN                                        | 74.0                                       |       |        | 73.0                                       |       |        |
| MIN                                           |                                            |       |        |                                            |       |        |
| MAX                                           |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>                |                                            |       |        |                                            |       |        |
| N                                             | 647                                        | 647   | 647    | 328                                        | 328   | 328    |
| MEAN                                          | 74.7                                       | 72.7  | -2.0   | 74.0                                       | 72.4  | -1.6   |
| SEM                                           | 0.43                                       | 0.41  | 0.30   | 0.58                                       | 0.60  | 0.45   |
| MEDIAN                                        | 74.0                                       | 72.0  | -2.0   | 73.0                                       | 71.0  | -1.0   |
| MIN                                           |                                            |       |        |                                            |       |        |
| MAX                                           |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b>              |                                            |       |        |                                            |       |        |
| N                                             | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                                          | 74.7                                       | 70.7  | -3.9   | 74.0                                       | 70.3  | -3.7   |
| SEM                                           | 0.43                                       | 0.44  | 0.34   | 0.58                                       | 0.60  | 0.46   |
| MEDIAN                                        | 74.0                                       | 70.0  | -4.0   | 73.0                                       | 70.0  | -4.0   |
| MIN                                           |                                            |       |        |                                            |       |        |
| MAX                                           |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                       | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                  | 74.6                                       | 73.7  | -0.9   | 74.0                                       | 74.0  | 0.1    |
| SEM                   | 0.43                                       | 0.44  | 0.36   | 0.58                                       | 0.66  | 0.55   |
| MEDIAN                | 74.0                                       | 72.0  | 0.0    | 73.0                                       | 73.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                                        | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 74                                         |       |        | 34                                         |       |        |
| MEAN                                   | 77.1                                       |       |        | 80.2                                       |       |        |
| SEM                                    | 1.34                                       |       |        | 1.95                                       |       |        |
| MEDIAN                                 | 76.5                                       |       |        | 78.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                                   | 77.1                                       | 76.2  | -0.9   | 80.2                                       | 79.8  | -0.4   |
| SEM                                    | 1.34                                       | 1.18  | 0.97   | 1.95                                       | 1.70  | 1.37   |
| MEDIAN                                 | 76.5                                       | 76.0  | 0.0    | 78.0                                       | 82.0  | 0.0    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                                   | 77.1                                       | 74.6  | -2.5   | 80.2                                       | 78.8  | -1.4   |
| SEM                                    | 1.34                                       | 1.17  | 0.94   | 1.95                                       | 1.81  | 1.42   |
| MEDIAN                                 | 76.5                                       | 74.0  | -2.0   | 78.0                                       | 79.5  | -0.5   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                  | 77.1                                       | 78.6  | 1.5    | 80.2                                       | 82.6  | 2.4    |
| SEM                   | 1.34                                       | 1.47  | 1.04   | 1.95                                       | 1.78  | 1.20   |
| MEDIAN                | 76.5                                       | 78.0  | 0.0    | 78.0                                       | 81.5  | 2.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 44                                         |       |        | 27                                         |       |        |
| MEAN                                   | 71.8                                       |       |        | 73.5                                       |       |        |
| SEM                                    | 1.70                                       |       |        | 1.70                                       |       |        |
| MEDIAN                                 | 74.5                                       |       |        | 74.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                                   | 71.8                                       | 70.2  | -1.6   | 73.5                                       | 70.4  | -3.1   |
| SEM                                    | 1.70                                       | 1.49  | 1.45   | 1.70                                       | 1.92  | 1.40   |
| MEDIAN                                 | 74.5                                       | 71.0  | 0.0    | 74.0                                       | 70.0  | -3.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 43                                         | 43    | 43     | 27                                         | 27    | 27     |
| MEAN                                   | 71.8                                       | 69.9  | -1.9   | 73.5                                       | 70.3  | -3.2   |
| SEM                                    | 1.74                                       | 1.61  | 1.21   | 1.70                                       | 1.32  | 1.44   |
| MEDIAN                                 | 75.0                                       | 70.0  | -2.0   | 74.0                                       | 70.0  | -1.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                  | 71.8                                       | 70.9  | -0.9   | 73.5                                       | 73.8  | 0.3    |
| SEM                   | 1.70                                       | 1.68  | 1.20   | 1.70                                       | 1.87  | 1.36   |
| MEDIAN                | 74.5                                       | 72.0  | 0.0    | 74.0                                       | 76.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                               | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                               | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Diastolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                               |                                            |       |        |                                            |       |        |
| N                                             | 94                                         |       |        | 42                                         |       |        |
| MEAN                                          | 71.8                                       |       |        | 70.1                                       |       |        |
| SEM                                           | 1.10                                       |       |        | 1.61                                       |       |        |
| MEDIAN                                        | 73.0                                       |       |        | 71.0                                       |       |        |
| MIN                                           |                                            |       |        |                                            |       |        |
| MAX                                           |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>                |                                            |       |        |                                            |       |        |
| N                                             | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                          | 71.8                                       | 72.2  | 0.4    | 70.1                                       | 74.0  | 3.8    |
| SEM                                           | 1.10                                       | 1.15  | 0.81   | 1.61                                       | 2.20  | 2.05   |
| MEDIAN                                        | 73.0                                       | 72.0  | 0.0    | 71.0                                       | 74.0  | 2.0    |
| MIN                                           |                                            |       |        |                                            |       | -21.0  |
| MAX                                           |                                            |       |        |                                            |       | 69.0   |
| <b>Five Minutes Post-therapy</b>              |                                            |       |        |                                            |       |        |
| N                                             | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                          | 71.8                                       | 69.7  | -2.2   | 70.1                                       | 69.0  | -1.1   |
| SEM                                           | 1.10                                       | 1.14  | 0.78   | 1.61                                       | 2.16  | 1.66   |
| MEDIAN                                        | 73.0                                       | 71.0  | -2.0   | 71.0                                       | 68.0  | 0.0    |
| MIN                                           |                                            |       |        |                                            |       |        |
| MAX                                           |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                  | 71.8                                       | 72.3  | 0.5    | 70.1                                       | 71.2  | 1.1    |
| SEM                   | 1.10                                       | 1.01  | 0.81   | 1.61                                       | 1.84  | 1.19   |
| MEDIAN                | 73.0                                       | 72.0  | 0.0    | 71.0                                       | 71.0  | 1.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 23                                         |       |        | 10                                         |       |        |
| MEAN                                   | 70.4                                       |       |        | 76.9                                       |       |        |
| SEM                                    | 2.55                                       |       |        | 3.12                                       |       |        |
| MEDIAN                                 | 68.0                                       |       |        | 78.5                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                   | 70.4                                       | 71.0  | 0.7    | 76.9                                       | 76.0  | -0.9   |
| SEM                                    | 2.55                                       | 2.47  | 1.47   | 3.12                                       | 2.83  | 1.97   |
| MEDIAN                                 | 68.0                                       | 70.0  | 0.0    | 78.5                                       | 76.0  | 0.0    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                   | 70.4                                       | 70.3  | -0.0   | 76.9                                       | 77.5  | 0.6    |
| SEM                                    | 2.55                                       | 2.85  | 1.57   | 3.12                                       | 4.21  | 4.07   |
| MEDIAN                                 | 68.0                                       | 70.0  | -2.0   | 78.5                                       | 77.5  | 0.0    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                  | 70.4                                       | 74.1  | 3.7    | 76.9                                       | 77.2  | 0.3    |
| SEM                   | 2.55                                       | 2.59  | 1.45   | 3.12                                       | 2.64  | 2.26   |
| MEDIAN                | 68.0                                       | 72.0  | 2.0    | 78.5                                       | 79.5  | 2.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                                         | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 647                                        |       |        | 328                                        |       |        |
| MEAN                                    | 127.5                                      |       |        | 126.5                                      |       |        |
| SEM                                     | 0.72                                       |       |        | 0.97                                       |       |        |
| MEDIAN                                  | 125.0                                      |       |        | 124.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 638                                        | 638   | 638    | 320                                        | 320   | 320    |
| MEAN                                    | 127.2                                      | 127.7 | 0.5    | 126.5                                      | 127.2 | 0.7    |
| SEM                                     | 0.72                                       | 0.71  | 0.58   | 0.99                                       | 1.03  | 0.77   |
| MEDIAN                                  | 124.0                                      | 126.0 | 0.0    | 124.0                                      | 124.0 | 0.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 74                                         |       |        | 34                                         |       |        |
| MEAN                                    | 129.3                                      |       |        | 130.8                                      |       |        |
| SEM                                     | 2.02                                       |       |        | 3.23                                       |       |        |
| MEDIAN                                  | 125.0                                      |       |        | 130.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 72                                         | 72    | 72     | 34                                         | 34    | 34     |
| MEAN                                    | 129.1                                      | 131.4 | 2.3    | 130.8                                      | 135.7 | 4.9    |
| SEM                                     | 2.05                                       | 2.16  | 1.71   | 3.23                                       | 3.35  | 2.09   |
| MEDIAN                                  | 125.0                                      | 128.0 | 2.0    | 130.0                                      | 131.5 | 2.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 44                                         |       |        | 27                                         |       |        |
| MEAN                                    | 118.5                                      |       |        | 113.0                                      |       |        |
| SEM                                     | 2.16                                       |       |        | 1.70                                       |       |        |
| MEDIAN                                  | 118.0                                      |       |        | 116.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                                    | 118.5                                      | 119.3 | 0.8    | 113.0                                      | 114.5 | 1.5    |
| SEM                                     | 2.16                                       | 2.63  | 1.49   | 1.70                                       | 2.12  | 1.64   |
| MEDIAN                                  | 118.0                                      | 117.5 | 0.0    | 116.0                                      | 115.0 | 2.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 94                                         |       |        | 42                                         |       |        |
| MEAN                                    | 116.8                                      |       |        | 113.3                                      |       |        |
| SEM                                     | 1.70                                       |       |        | 2.02                                       |       |        |
| MEDIAN                                  | 118.0                                      |       |        | 114.5                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                    | 116.8                                      | 118.1 | 1.3    | 113.3                                      | 116.9 | 3.6    |
| SEM                                     | 1.70                                       | 1.70  | 0.98   | 2.02                                       | 2.41  | 1.27   |
| MEDIAN                                  | 118.0                                      | 118.0 | 0.0    | 114.5                                      | 117.0 | 2.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 23                                         |       |        | 10                                         |       |        |
| MEAN                                    | 122.4                                      |       |        | 122.8                                      |       |        |
| SEM                                     | 3.82                                       |       |        | 5.39                                       |       |        |
| MEDIAN                                  | 120.0                                      |       |        | 123.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                    | 122.4                                      | 120.3 | -2.2   | 122.8                                      | 124.0 | 1.2    |
| SEM                                     | 3.82                                       | 4.22  | 1.50   | 5.39                                       | 5.55  | 2.21   |
| MEDIAN                                  | 120.0                                      | 120.0 | -2.0   | 123.0                                      | 124.0 | 1.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                                          | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 647                                        |       |        | 328                                        |       |        |
| MEAN                                     | 81.3                                       |       |        | 81.5                                       |       |        |
| SEM                                      | 0.49                                       |       |        | 0.68                                       |       |        |
| MEDIAN                                   | 81.0                                       |       |        | 81.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 638                                        | 638   | 638    | 320                                        | 320   | 320    |
| MEAN                                     | 81.2                                       | 80.8  | -0.4   | 81.4                                       | 81.5  | 0.1    |
| SEM                                      | 0.49                                       | 0.49  | 0.41   | 0.69                                       | 0.73  | 0.60   |
| MEDIAN                                   | 80.0                                       | 80.0  | 0.0    | 81.0                                       | 80.0  | 0.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline:                                |                                            |       |        |                                            |       |        |
| N                                        | 74                                         |       |        | 34                                         |       |        |
| MEAN                                     | 81.3                                       |       |        | 83.9                                       |       |        |
| SEM                                      | 1.44                                       |       |        | 1.91                                       |       |        |
| MEDIAN                                   | 80.0                                       |       |        | 82.5                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 72                                         | 72    | 72     | 34                                         | 34    | 34     |
| MEAN                                     | 81.2                                       | 84.2  | 2.9    | 83.9                                       | 88.6  | 4.6    |
| SEM                                      | 1.43                                       | 1.53  | 1.18   | 1.91                                       | 2.17  | 1.50   |
| MEDIAN                                   | 80.0                                       | 83.5  | 2.0    | 82.5                                       | 84.0  | 4.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change from Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                                          | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 44                                         |       |        | 27                                         |       |        |
| MEAN                                     | 77.3                                       |       |        | 75.7                                       |       |        |
| SEM                                      | 1.34                                       |       |        | 1.47                                       |       |        |
| MEDIAN                                   | 79.5                                       |       |        | 79.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                                     | 77.3                                       | 78.3  | 1.0    | 75.7                                       | 75.9  | 0.1    |
| SEM                                      | 1.34                                       | 1.56  | 1.40   | 1.47                                       | 1.62  | 1.29   |
| MEDIAN                                   | 79.5                                       | 78.5  | 0.0    | 79.0                                       | 79.0  | 1.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                          | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 94                                         |       |        | 42                                         |       |        |
| MEAN                                     | 75.4                                       |       |        | 74.3                                       |       |        |
| SEM                                      | 1.08                                       |       |        | 1.75                                       |       |        |
| MEDIAN                                   | 77.0                                       |       |        | 78.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                                     | 75.4                                       | 75.5  | 0.1    | 74.3                                       | 76.3  | 2.0    |
| SEM                                      | 1.08                                       | 1.03  | 0.82   | 1.75                                       | 1.58  | 1.19   |
| MEDIAN                                   | 77.0                                       | 76.0  | -0.5   | 78.0                                       | 78.0  | 1.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 23                                         |       |        | 10                                         |       |        |
| MEAN                                     | 80.1                                       |       |        | 78.2                                       |       |        |
| SEM                                      | 2.09                                       |       |        | 2.45                                       |       |        |
| MEDIAN                                   | 78.0                                       |       |        | 78.5                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                                     | 80.1                                       | 77.5  | -2.6   | 78.2                                       | 82.2  | 4.0    |
| SEM                                      | 2.09                                       | 2.15  | 1.06   | 2.45                                       | 2.27  | 2.29   |
| MEDIAN                                   | 78.0                                       | 78.0  | -2.0   | 78.5                                       | 82.5  | 4.5    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                                  | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 647                                        |       |        | 330                                        |       |        |
| MEAN                             | 73.4                                       |       |        | 73.5                                       |       |        |
| SEM                              | 0.50                                       |       |        | 0.69                                       |       |        |
| MEDIAN                           | 72.0                                       |       |        | 72.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 647                                        | 647   | 647    | 329                                        | 329   | 329    |
| MEAN                             | 73.4                                       | 74.9  | 1.5    | 73.5                                       | 76.3  | 2.8    |
| SEM                              | 0.50                                       | 0.52  | 0.37   | 0.69                                       | 0.77  | 0.55   |
| MEDIAN                           | 72.0                                       | 73.0  | 1.0    | 72.0                                       | 74.0  | 2.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                             | 73.4                                       | 75.2  | 1.8    | 73.5                                       | 75.4  | 1.9    |
| SEM                              | 0.50                                       | 0.52  | 0.37   | 0.69                                       | 0.71  | 0.51   |
| MEDIAN                           | 72.0                                       | 74.0  | 2.0    | 72.0                                       | 74.0  | 2.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 646                                        | 646   | 646    | 329                                        | 329   | 329    |
| MEAN                  | 73.4                                       | 71.7  | -1.7   | 73.5                                       | 72.1  | -1.4   |
| SEM                   | 0.50                                       | 0.47  | 0.41   | 0.69                                       | 0.67  | 0.52   |
| MEDIAN                | 72.0                                       | 70.0  | -1.0   | 72.0                                       | 70.0  | -1.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 74                                         |       |        | 34                                         |       |        |
| MEAN                             | 74.9                                       |       |        | 75.0                                       |       |        |
| SEM                              | 1.43                                       |       |        | 1.77                                       |       |        |
| MEDIAN                           | 74.5                                       |       |        | 74.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                             | 74.9                                       | 77.4  | 2.6    | 75.0                                       | 77.2  | 2.3    |
| SEM                              | 1.43                                       | 1.31  | 0.94   | 1.77                                       | 1.61  | 1.22   |
| MEDIAN                           | 74.5                                       | 77.0  | 1.5    | 74.0                                       | 76.5  | 1.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                             | 74.9                                       | 76.6  | 1.8    | 75.0                                       | 78.4  | 3.4    |
| SEM                              | 1.43                                       | 1.33  | 0.86   | 1.77                                       | 1.71  | 1.12   |
| MEDIAN                           | 74.5                                       | 76.0  | 2.0    | 74.0                                       | 80.5  | 3.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                  | 74.9                                       | 74.6  | -0.2   | 75.0                                       | 74.3  | -0.6   |
| SEM                   | 1.43                                       | 1.24  | 1.12   | 1.77                                       | 1.83  | 1.33   |
| MEDIAN                | 74.5                                       | 76.0  | -0.5   | 74.0                                       | 72.5  | 0.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 44                                         |       |        | 27                                         |       |        |
| MEAN                             | 75.2                                       |       |        | 79.6                                       |       |        |
| SEM                              | 1.92                                       |       |        | 2.54                                       |       |        |
| MEDIAN                           | 74.0                                       |       |        | 79.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                             | 75.2                                       | 75.1  | -0.0   | 79.6                                       | 79.8  | 0.2    |
| SEM                              | 1.92                                       | 1.76  | 1.62   | 2.54                                       | 2.91  | 1.65   |
| MEDIAN                           | 74.0                                       | 74.0  | -1.5   | 79.0                                       | 78.0  | -1.0   |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 43                                         | 43    | 43     | 27                                         | 27    | 27     |
| MEAN                             | 75.3                                       | 75.0  | -0.3   | 79.6                                       | 79.1  | -0.5   |
| SEM                              | 1.97                                       | 2.04  | 1.85   | 2.54                                       | 2.57  | 1.88   |
| MEDIAN                           | 74.0                                       | 72.0  | 0.0    | 79.0                                       | 80.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                       | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                  | 75.2                                       | 73.8  | -1.4   | 79.6                                       | 76.9  | -2.7   |
| SEM                   | 1.92                                       | 1.70  | 1.80   | 2.54                                       | 2.45  | 1.73   |
| MEDIAN                | 74.0                                       | 72.0  | -2.0   | 79.0                                       | 77.0  | -2.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                  | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 94                                         |       |        | 42                                         |       |        |
| MEAN                             | 76.5                                       |       |        | 75.1                                       |       |        |
| SEM                              | 1.27                                       |       |        | 2.14                                       |       |        |
| MEDIAN                           | 76.5                                       |       |        | 75.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                             | 76.5                                       | 80.4  | 3.9    | 75.1                                       | 77.0  | 1.9    |
| SEM                              | 1.27                                       | 1.30  | 1.08   | 2.14                                       | 2.17  | 1.49   |
| MEDIAN                           | 76.5                                       | 79.0  | 2.0    | 75.0                                       | 76.0  | 2.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                             | 76.5                                       | 79.6  | 3.1    | 75.1                                       | 77.0  | 1.9    |
| SEM                              | 1.27                                       | 1.24  | 1.11   | 2.14                                       | 2.12  | 1.64   |
| MEDIAN                           | 76.5                                       | 80.0  | 1.0    | 75.0                                       | 78.0  | -0.5   |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                  | 76.5                                       | 78.6  | 2.2    | 75.1                                       | 77.0  | 1.8    |
| SEM                   | 1.27                                       | 1.14  | 0.90   | 2.14                                       | 2.20  | 1.62   |
| MEDIAN                | 76.5                                       | 80.0  | 0.5    | 75.0                                       | 76.0  | 0.5    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 23                                         |       |        | 10                                         |       |        |
| MEAN                             | 76.1                                       |       |        | 79.1                                       |       |        |
| SEM                              | 2.70                                       |       |        | 3.13                                       |       |        |
| MEDIAN                           | 76.0                                       |       |        | 79.5                                       |       |        |
| MIN                              | ---                                        |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                             | 76.1                                       | 74.8  | -1.3   | 79.1                                       | 77.3  | -1.8   |
| SEM                              | 2.70                                       | 2.72  | 1.14   | 3.13                                       | 4.86  | 3.42   |
| MEDIAN                           | 76.0                                       | 74.0  | -1.0   | 79.5                                       | 80.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                             | 76.1                                       | 74.5  | -1.6   | 79.1                                       | 75.3  | -3.8   |
| SEM                              | 2.70                                       | 2.49  | 1.36   | 3.13                                       | 3.94  | 2.83   |
| MEDIAN                           | 76.0                                       | 75.0  | -1.0   | 79.5                                       | 78.0  | -3.0   |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                  | 76.1                                       | 75.8  | -0.3   | 79.1                                       | 72.3  | -6.8   |
| SEM                   | 2.70                                       | 2.44  | 1.31   | 3.13                                       | 3.39  | 2.36   |
| MEDIAN                | 76.0                                       | 76.0  | 0.0    | 79.5                                       | 76.5  | -6.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                           | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 645                                        |       |        | 330                                        |       |        |
| MEAN                      | 17.2                                       |       |        | 17.2                                       |       |        |
| SEM                       | 0.14                                       |       |        | 0.19                                       |       |        |
| MEDIAN                    | 16.0                                       |       |        | 16.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 645                                        | 645   | 645    | 329                                        | 329   | 329    |
| MEAN                      | 17.2                                       | 17.6  | 0.4    | 17.2                                       | 17.7  | 0.5    |
| SEM                       | 0.14                                       | 0.14  | 0.09   | 0.19                                       | 0.20  | 0.14   |
| MEDIAN                    | 16.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 643                                        | 643   | 643    | 329                                        | 329   | 329    |
| MEAN                      | 17.2                                       | 17.5  | 0.3    | 17.2                                       | 17.4  | 0.2    |
| SEM                       | 0.14                                       | 0.15  | 0.10   | 0.19                                       | 0.20  | 0.13   |
| MEDIAN                    | 16.0                                       | 18.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 643                                        | 643   | 643    | 328                                        | 328   | 328    |
| MEAN                  | 17.2                                       | 17.0  | -0.2   | 17.2                                       | 17.2  | 0.1    |
| SEM                   | 0.14                                       | 0.14  | 0.09   | 0.19                                       | 0.19  | 0.13   |
| MEDIAN                | 16.0                                       | 16.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 74                                         |       |        | 34                                         |       |        |
| MEAN                      | 17.4                                       |       |        | 16.7                                       |       |        |
| SEM                       | 0.39                                       |       |        | 0.62                                       |       |        |
| MEDIAN                    | 18.0                                       |       |        | 17.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                      | 17.4                                       | 18.1  | 0.7    | 16.7                                       | 17.1  | 0.4    |
| SEM                       | 0.39                                       | 0.43  | 0.31   | 0.62                                       | 0.62  | 0.50   |
| MEDIAN                    | 18.0                                       | 18.0  | 0.0    | 17.0                                       | 16.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                      | 17.4                                       | 17.7  | 0.3    | 16.7                                       | 16.8  | 0.1    |
| SEM                       | 0.39                                       | 0.41  | 0.27   | 0.62                                       | 0.58  | 0.40   |
| MEDIAN                    | 18.0                                       | 17.5  | 0.0    | 17.0                                       | 16.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 74                                         | 74    | 74     | 34                                         | 34    | 34     |
| MEAN                  | 17.4                                       | 17.4  | -0.1   | 16.7                                       | 16.7  | -0.0   |
| SEM                   | 0.39                                       | 0.39  | 0.32   | 0.62                                       | 0.62  | 0.48   |
| MEDIAN                | 18.0                                       | 17.0  | 0.0    | 17.0                                       | 16.5  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 44                                         |       |        | 27                                         |       |        |
| MEAN                      | 17.8                                       |       |        | 16.9                                       |       |        |
| SEM                       | 0.63                                       |       |        | 0.45                                       |       |        |
| MEDIAN                    | 18.0                                       |       |        | 16.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                      | 17.8                                       | 18.2  | 0.4    | 16.9                                       | 17.7  | 0.8    |
| SEM                       | 0.63                                       | 0.54  | 0.31   | 0.45                                       | 0.53  | 0.51   |
| MEDIAN                    | 18.0                                       | 18.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 43                                         | 43    | 43     | 27                                         | 27    | 27     |
| MEAN                      | 17.8                                       | 17.7  | -0.2   | 16.9                                       | 16.9  | 0.0    |
| SEM                       | 0.64                                       | 0.52  | 0.36   | 0.45                                       | 0.47  | 0.47   |
| MEDIAN                    | 18.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 44                                         | 44    | 44     | 27                                         | 27    | 27     |
| MEAN                  | 17.8                                       | 17.5  | -0.3   | 16.9                                       | 16.9  | -0.0   |
| SEM                   | 0.63                                       | 0.48  | 0.41   | 0.45                                       | 0.42  | 0.38   |
| MEDIAN                | 18.0                                       | 17.0  | 0.0    | 16.0                                       | 16.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Respirations (/minute)</b>    |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 94                                         |       |        | 42                                         |       |        |
| MEAN                             | 17.0                                       |       |        | 16.5                                       |       |        |
| SEM                              | 0.30                                       |       |        | 0.53                                       |       |        |
| MEDIAN                           | 18.0                                       |       |        | 16.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                             | 17.0                                       | 17.3  | 0.3    | 16.5                                       | 17.2  | 0.8    |
| SEM                              | 0.30                                       | 0.31  | 0.23   | 0.53                                       | 0.45  | 0.37   |
| MEDIAN                           | 18.0                                       | 18.0  | 0.0    | 16.0                                       | 18.0  | 0.5    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                             | 17.0                                       | 17.4  | 0.4    | 16.5                                       | 16.7  | 0.3    |
| SEM                              | 0.30                                       | 0.30  | 0.24   | 0.53                                       | 0.46  | 0.40   |
| MEDIAN                           | 18.0                                       | 18.0  | 0.0    | 16.0                                       | 16.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 94                                         | 94    | 94     | 42                                         | 42    | 42     |
| MEAN                  | 17.0                                       | 17.3  | 0.3    | 16.5                                       | 16.7  | 0.2    |
| SEM                   | 0.30                                       | 0.26  | 0.21   | 0.53                                       | 0.50  | 0.30   |
| MEDIAN                | 18.0                                       | 18.0  | 0.0    | 16.0                                       | 16.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                           | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 23                                         |       |        | 10                                         |       |        |
| MEAN                      | 16.7                                       |       |        | 17.2                                       |       |        |
| SEM                       | 0.52                                       |       |        | 1.13                                       |       |        |
| MEDIAN                    | 16.0                                       |       |        | 18.0                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                      | 16.7                                       | 17.8  | 1.0    | 17.2                                       | 17.1  | -0.1   |
| SEM                       | 0.52                                       | 0.66  | 0.46   | 1.13                                       | 0.77  | 0.77   |
| MEDIAN                    | 16.0                                       | 18.0  | 2.0    | 18.0                                       | 18.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                      | 16.7                                       | 16.8  | 0.0    | 17.2                                       | 16.6  | -0.6   |
| SEM                       | 0.52                                       | 0.62  | 0.44   | 1.13                                       | 1.22  | 0.96   |
| MEDIAN                    | 16.0                                       | 16.0  | 0.0    | 18.0                                       | 16.5  | -1.5   |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.3  
Summary of Mean Change From Baseline in Vital Signs by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 23                                         | 23    | 23     | 10                                         | 10    | 10     |
| MEAN                  | 16.7                                       | 17.2  | 0.4    | 17.2                                       | 16.8  | -0.4   |
| SEM                   | 0.52                                       | 0.60  | 0.54   | 1.13                                       | 1.35  | 1.07   |
| MEDIAN                | 16.0                                       | 18.0  | 0.0    | 18.0                                       | 17.5  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                              | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                              | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Supine Systolic Blood Pressure (mmHg)</b> |                                            |       |        |                                            |       |        |
| Baseline                                     |                                            |       |        |                                            |       |        |
| N                                            | 464                                        |       |        | 259                                        |       |        |
| MEAN                                         | 117.8                                      |       |        | 117.3                                      |       |        |
| SEM                                          | 0.78                                       |       |        | 1.03                                       |       |        |
| MEDIAN                                       | 116.0                                      |       |        | 117.0                                      |       |        |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>               |                                            |       |        |                                            |       |        |
| N                                            | 464                                        | 464   | 464    | 257                                        | 257   | 257    |
| MEAN                                         | 117.8                                      | 117.4 | -0.5   | 117.2                                      | 117.9 | 0.7    |
| SEM                                          | 0.78                                       | 0.76  | 0.51   | 1.03                                       | 1.05  | 0.76   |
| MEDIAN                                       | 116.0                                      | 116.0 | 0.0    | 116.0                                      | 117.0 | 0.0    |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b>             |                                            |       |        |                                            |       |        |
| N                                            | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                                         | 117.8                                      | 115.7 | -2.1   | 117.3                                      | 116.3 | -1.0   |
| SEM                                          | 0.78                                       | 0.77  | 0.53   | 1.03                                       | 1.08  | 0.74   |
| MEDIAN                                       | 116.0                                      | 114.0 | -2.0   | 116.5                                      | 115.0 | -1.0   |
| MIN                                          |                                            |       |        |                                            |       |        |
| MAX                                          |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                  | 117.8                                      | 118.0 | 0.1    | 117.3                                      | 117.6 | 0.3    |
| SEM                   | 0.78                                       | 0.81  | 0.54   | 1.03                                       | 1.03  | 0.74   |
| MEDIAN                | 116.0                                      | 116.0 | 0.0    | 116.5                                      | 115.0 | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                              |                                            |       |        |                                            |       |        |
| N                                     | 418                                        |       |        | 184                                        |       |        |
| MEAN                                  | 124.4                                      |       |        | 125.2                                      |       |        |
| SEM                                   | 0.81                                       |       |        | 1.20                                       |       |        |
| MEDIAN                                | 122.0                                      |       |        | 123.5                                      |       |        |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| One Minute Post-therapy               |                                            |       |        |                                            |       |        |
| N                                     | 418                                        | 418   | 418    | 184                                        | 184   | 184    |
| MEAN                                  | 124.4                                      | 124.2 | -0.3   | 125.2                                      | 125.1 | -0.2   |
| SEM                                   | 0.81                                       | 0.79  | 0.52   | 1.20                                       | 1.25  | 0.90   |
| MEDIAN                                | 122.0                                      | 122.0 | 0.0    | 123.5                                      | 122.5 | 0.0    |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy             |                                            |       |        |                                            |       |        |
| N                                     | 416                                        | 416   | 416    | 184                                        | 184   | 184    |
| MEAN                                  | 124.3                                      | 122.1 | -2.2   | 125.2                                      | 123.9 | -1.3   |
| SEM                                   | 0.81                                       | 0.80  | 0.59   | 1.20                                       | 1.35  | 1.10   |
| MEDIAN                                | 122.0                                      | 120.0 | -2.0   | 123.5                                      | 120.5 | -2.0   |
| MIN                                   |                                            |       |        |                                            |       |        |
| MAX                                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 417                                        | 417   | 417    | 184                                        | 184   | 184    |
| MEAN                  | 124.4                                      | 123.7 | -0.7   | 125.2                                      | 125.1 | -0.1   |
| SEM                   | 0.81                                       | 0.81  | 0.61   | 1.20                                       | 1.25  | 0.88   |
| MEDIAN                | 122.0                                      | 121.0 | 0.0    | 123.5                                      | 120.5 | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 464                                        |       |        | 259                                        |       |        |
| MEAN                                   | 72.6                                       |       |        | 73.0                                       |       |        |
| SEM                                    | 0.49                                       |       |        | 0.64                                       |       |        |
| MEDIAN                                 | 72.0                                       |       |        | 72.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 464                                        | 464   | 464    | 257                                        | 257   | 257    |
| MEAN                                   | 72.6                                       | 71.3  | -1.2   | 72.9                                       | 72.2  | -0.8   |
| SEM                                    | 0.49                                       | 0.48  | 0.38   | 0.64                                       | 0.69  | 0.55   |
| MEDIAN                                 | 72.0                                       | 71.0  | -1.0   | 72.0                                       | 71.0  | 0.0    |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                                   | 72.6                                       | 69.3  | -3.3   | 73.0                                       | 70.3  | -2.7   |
| SEM                                    | 0.49                                       | 0.51  | 0.40   | 0.64                                       | 0.69  | 0.52   |
| MEDIAN                                 | 72.0                                       | 68.5  | -3.0   | 72.0                                       | 69.0  | -2.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                  | 72.6                                       | 72.6  | 0.0    | 73.0                                       | 73.5  | 0.6    |
| SEM                   | 0.49                                       | 0.51  | 0.40   | 0.64                                       | 0.74  | 0.58   |
| MEDIAN                | 72.0                                       | 72.0  | 0.0    | 72.0                                       | 73.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                                        | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                        | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Supine Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                               |                                            |       |        |                                            |       |        |
| N                                      | 418                                        |       |        | 184                                        |       |        |
| MEAN                                   | 76.3                                       |       |        | 75.8                                       |       |        |
| SEM                                    | 0.55                                       |       |        | 0.81                                       |       |        |
| MEDIAN                                 | 76.0                                       |       |        | 75.0                                       |       |        |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| One Minute Post-therapy                |                                            |       |        |                                            |       |        |
| N                                      | 418                                        | 418   | 418    | 184                                        | 184   | 184    |
| MEAN                                   | 76.3                                       | 74.4  | -1.9   | 75.8                                       | 74.3  | -1.5   |
| SEM                                    | 0.55                                       | 0.51  | 0.35   | 0.81                                       | 0.85  | 0.64   |
| MEDIAN                                 | 76.0                                       | 74.0  | -1.0   | 75.0                                       | 74.0  | -1.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy              |                                            |       |        |                                            |       |        |
| N                                      | 416                                        | 416   | 416    | 184                                        | 184   | 184    |
| MEAN                                   | 76.2                                       | 72.6  | -3.6   | 75.8                                       | 72.0  | -3.8   |
| SEM                                    | 0.55                                       | 0.53  | 0.40   | 0.81                                       | 0.85  | 0.68   |
| MEDIAN                                 | 76.0                                       | 72.0  | -3.0   | 75.0                                       | 72.0  | -4.0   |
| MIN                                    |                                            |       |        |                                            |       |        |
| MAX                                    |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 417                                        | 417   | 417    | 184                                        | 184   | 184    |
| MEAN                  | 76.2                                       | 75.2  | -0.9   | 75.8                                       | 75.8  | 0.1    |
| SEM                   | 0.55                                       | 0.57  | 0.45   | 0.81                                       | 0.87  | 0.71   |
| MEDIAN                | 76.0                                       | 75.0  | 0.0    | 75.0                                       | 76.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 464                                        |       |        | 258                                        |       |        |
| MEAN                                    | 123.0                                      |       |        | 121.5                                      |       |        |
| SEM                                     | 0.84                                       |       |        | 1.07                                       |       |        |
| MEDIAN                                  | 120.0                                      |       |        | 119.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 460                                        | 460   | 460    | 255                                        | 255   | 255    |
| MEAN                                    | 122.9                                      | 123.8 | 0.8    | 121.4                                      | 122.7 | 1.3    |
| SEM                                     | 0.84                                       | 0.83  | 0.63   | 1.08                                       | 1.14  | 0.81   |
| MEDIAN                                  | 120.0                                      | 122.0 | 0.0    | 119.0                                      | 120.0 | 0.0    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                                         | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                         | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Systolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                |                                            |       |        |                                            |       |        |
| N                                       | 418                                        |       |        | 183                                        |       |        |
| MEAN                                    | 129.2                                      |       |        | 129.2                                      |       |        |
| SEM                                     | 0.87                                       |       |        | 1.27                                       |       |        |
| MEDIAN                                  | 128.0                                      |       |        | 127.0                                      |       |        |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |
| Post Dental Procedure                   |                                            |       |        |                                            |       |        |
| N                                       | 411                                        | 411   | 411    | 178                                        | 178   | 178    |
| MEAN                                    | 128.8                                      | 129.3 | 0.5    | 129.3                                      | 130.7 | 1.5    |
| SEM                                     | 0.87                                       | 0.89  | 0.70   | 1.29                                       | 1.35  | 0.98   |
| MEDIAN                                  | 128.0                                      | 127.0 | 0.0    | 126.5                                      | 128.0 | 1.5    |
| MIN                                     |                                            |       |        |                                            |       |        |
| MAX                                     |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 464                                        |       |        | 258                                        |       |        |
| MEAN                                     | 78.7                                       |       |        | 79.4                                       |       |        |
| SEM                                      | 0.55                                       |       |        | 0.74                                       |       |        |
| MEDIAN                                   | 79.0                                       |       |        | 80.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 460                                        | 460   | 460    | 255                                        | 255   | 255    |
| MEAN                                     | 78.7                                       | 79.0  | 0.4    | 79.3                                       | 79.9  | 0.7    |
| SEM                                      | 0.55                                       | 0.57  | 0.43   | 0.75                                       | 0.78  | 0.67   |
| MEDIAN                                   | 79.0                                       | 78.0  | 0.0    | 79.0                                       | 79.0  | 0.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                                          | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|------------------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                          | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Standing Diastolic Blood Pressure (mmHg) |                                            |       |        |                                            |       |        |
| Baseline                                 |                                            |       |        |                                            |       |        |
| N                                        | 418                                        |       |        | 183                                        |       |        |
| MEAN                                     | 82.5                                       |       |        | 82.2                                       |       |        |
| SEM                                      | 0.60                                       |       |        | 0.89                                       |       |        |
| MEDIAN                                   | 82.0                                       |       |        | 82.0                                       |       |        |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |
| Post Dental Procedure                    |                                            |       |        |                                            |       |        |
| N                                        | 411                                        | 411   | 411    | 178                                        | 178   | 178    |
| MEAN                                     | 82.2                                       | 81.7  | -0.6   | 82.3                                       | 83.0  | 0.7    |
| SEM                                      | 0.60                                       | 0.59  | 0.52   | 0.91                                       | 0.95  | 0.70   |
| MEDIAN                                   | 82.0                                       | 82.0  | 0.0    | 82.0                                       | 82.0  | 0.0    |
| MIN                                      |                                            |       |        |                                            |       |        |
| MAX                                      |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 464                                        |       |        | 259                                        |       |        |
| MEAN                             | 74.8                                       |       |        | 75.1                                       |       |        |
| SEM                              | 0.57                                       |       |        | 0.77                                       |       |        |
| MEDIAN                           | 74.0                                       |       |        | 74.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                             | 74.8                                       | 77.0  | 2.2    | 75.1                                       | 78.0  | 2.9    |
| SEM                              | 0.57                                       | 0.59  | 0.48   | 0.77                                       | 0.85  | 0.66   |
| MEDIAN                           | 74.0                                       | 75.5  | 1.0    | 74.0                                       | 77.0  | 2.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                             | 74.8                                       | 76.9  | 2.1    | 75.1                                       | 77.2  | 2.1    |
| SEM                              | 0.57                                       | 0.60  | 0.48   | 0.77                                       | 0.77  | 0.59   |
| MEDIAN                           | 74.0                                       | 76.0  | 2.0    | 74.0                                       | 76.0  | 1.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 464                                        | 464   | 464    | 258                                        | 258   | 258    |
| MEAN                  | 74.8                                       | 73.6  | -1.2   | 75.1                                       | 74.0  | -1.1   |
| SEM                   | 0.57                                       | 0.54  | 0.47   | 0.77                                       | 0.78  | 0.62   |
| MEDIAN                | 74.0                                       | 73.0  | -1.0   | 74.0                                       | 72.0  | -1.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |



Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Pulse (BPM)</b>               |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 418                                        |       |        | 184                                        |       |        |
| MEAN                             | 73.1                                       |       |        | 73.1                                       |       |        |
| SEM                              | 0.64                                       |       |        | 0.94                                       |       |        |
| MEDIAN                           | 72.0                                       |       |        | 72.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 418                                        | 418   | 418    | 184                                        | 184   | 184    |
| MEAN                             | 73.1                                       | 74.3  | 1.2    | 73.1                                       | 74.8  | 1.7    |
| SEM                              | 0.64                                       | 0.64  | 0.40   | 0.94                                       | 1.00  | 0.60   |
| MEDIAN                           | 72.0                                       | 73.0  | 0.0    | 72.0                                       | 74.0  | 1.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 416                                        | 416   | 416    | 184                                        | 184   | 184    |
| MEAN                             | 73.1                                       | 74.5  | 1.4    | 73.1                                       | 74.4  | 1.2    |
| SEM                              | 0.64                                       | 0.64  | 0.41   | 0.94                                       | 0.96  | 0.64   |
| MEDIAN                           | 72.0                                       | 73.0  | 1.0    | 72.0                                       | 72.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 417                                        | 417   | 417    | 184                                        | 184   | 184    |
| MEAN                  | 73.1                                       | 72.1  | -0.9   | 73.1                                       | 71.7  | -1.4   |
| SEM                   | 0.64                                       | 0.60  | 0.50   | 0.94                                       | 0.88  | 0.63   |
| MEDIAN                | 72.0                                       | 71.0  | 0.0    | 72.0                                       | 70.0  | -1.0   |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                                  | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|----------------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                                  | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| <b>Respirations (/minute)</b>    |                                            |       |        |                                            |       |        |
| <b>Baseline</b>                  |                                            |       |        |                                            |       |        |
| N                                | 463                                        |       |        | 259                                        |       |        |
| MEAN                             | 17.3                                       |       |        | 17.1                                       |       |        |
| SEM                              | 0.16                                       |       |        | 0.21                                       |       |        |
| MEDIAN                           | 16.0                                       |       |        | 16.0                                       |       |        |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>One Minute Post-therapy</b>   |                                            |       |        |                                            |       |        |
| N                                | 463                                        | 463   | 463    | 258                                        | 258   | 258    |
| MEAN                             | 17.3                                       | 17.7  | 0.4    | 17.1                                       | 17.7  | 0.6    |
| SEM                              | 0.16                                       | 0.16  | 0.11   | 0.21                                       | 0.22  | 0.16   |
| MEDIAN                           | 16.0                                       | 18.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |
| <b>Five Minutes Post-therapy</b> |                                            |       |        |                                            |       |        |
| N                                | 462                                        | 462   | 462    | 258                                        | 258   | 258    |
| MEAN                             | 17.3                                       | 17.5  | 0.2    | 17.1                                       | 17.3  | 0.2    |
| SEM                              | 0.16                                       | 0.17  | 0.12   | 0.21                                       | 0.21  | 0.15   |
| MEDIAN                           | 16.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                              |                                            |       |        |                                            |       |        |
| MAX                              |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

|                       | 4% Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2% Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 463                                        | 463   | 463    | 258                                        | 258   | 258    |
| MEAN                  | 17.3                                       | 17.2  | -0.1   | 17.1                                       | 17.3  | 0.2    |
| SEM                   | 0.16                                       | 0.15  | 0.11   | 0.21                                       | 0.20  | 0.14   |
| MEDIAN                | 16.0                                       | 17.0  | 0.0    | 16.0                                       | 17.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                           | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|---------------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                           | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Respirations (/minute)    |                                            |       |        |                                            |       |        |
| Baseline                  |                                            |       |        |                                            |       |        |
| N                         | 417                                        |       |        | 184                                        |       |        |
| MEAN                      | 17.1                                       |       |        | 17.0                                       |       |        |
| SEM                       | 0.18                                       |       |        | 0.26                                       |       |        |
| MEDIAN                    | 16.0                                       |       |        | 16.5                                       |       |        |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| One Minute Post-therapy   |                                            |       |        |                                            |       |        |
| N                         | 417                                        | 417   | 417    | 184                                        | 184   | 184    |
| MEAN                      | 17.1                                       | 17.6  | 0.5    | 17.0                                       | 17.4  | 0.4    |
| SEM                       | 0.18                                       | 0.18  | 0.11   | 0.26                                       | 0.27  | 0.17   |
| MEDIAN                    | 16.0                                       | 18.0  | 0.0    | 16.5                                       | 18.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |
| Five Minutes Post-therapy |                                            |       |        |                                            |       |        |
| N                         | 415                                        | 415   | 415    | 184                                        | 184   | 184    |
| MEAN                      | 17.1                                       | 17.5  | 0.4    | 17.0                                       | 17.2  | 0.2    |
| SEM                       | 0.18                                       | 0.18  | 0.12   | 0.26                                       | 0.27  | 0.18   |
| MEDIAN                    | 16.0                                       | 18.0  | 0.0    | 16.5                                       | 17.0  | 0.0    |
| MIN                       |                                            |       |        |                                            |       |        |
| MAX                       |                                            |       |        |                                            |       |        |

Table 4.1.4  
Summary of Mean Change From Baseline in Vital Signs by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

|                       | 4X Articaine HCl/<br>1:100,000 Epinephrine |       |        | 2X Lidocaine HCl/<br>1:100,000 Epinephrine |       |        |
|-----------------------|--------------------------------------------|-------|--------|--------------------------------------------|-------|--------|
|                       | Baseline                                   | Visit | Change | Baseline                                   | Visit | Change |
| Post Dental Procedure |                                            |       |        |                                            |       |        |
| N                     | 415                                        | 415   | 415    | 183                                        | 183   | 183    |
| MEAN                  | 17.1                                       | 16.9  | -0.2   | 17.0                                       | 16.9  | -0.1   |
| SEM                   | 0.18                                       | 0.16  | 0.11   | 0.26                                       | 0.26  | 0.18   |
| MEDIAN                | 16.0                                       | 16.0  | 0.0    | 17.0                                       | 16.0  | 0.0    |
| MIN                   |                                            |       |        |                                            |       |        |
| MAX                   |                                            |       |        |                                            |       |        |