



## Mandatory Medical Device Problem Reporting Form for Industry

### CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets  
Fields required to be completed for updates/final reports are indicated by an \*

Page 1 of 2

#### A. REPORTER INFORMATION

1. i. Reporter Type

☐ Manufacturer ☒ Importer

*In the case where the reporter is the importer:*

ii. Did the importer report the incident to the manufacturer?

☐ Yes ☒ No

iii. Is the importer also submitting the report on behalf of the manufacturer?

☐ Yes ☒ No

2. Reporter Contact Information \*

Kwang Ju (Grace) Nam, QA Associate  
Accuristix  
121 Stone Ridge Road, Vaughan, ON, L4H 0A5  
KNam@accuristix.com  
Phone: 416-637-3273 EXT 5032

3. Reporter File No. \*

2019-7141-QA-ST

4. Health Canada File No. (if applicable) \*

N/A

5. Type of Report \*

☐ Preliminary ☐ Update ☒ Final ☐ Preliminary & Final

If "preliminary" only, anticipated date for the final report:

If "update/final", date the previous report was submitted to Health Canada: (YYYY-MM-DD)  
2019-12-13

6. Date Submitted \*

2020-02-24 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland	Accuristix 6090 White Hart Lane, Mississauga, Ontario, L5R 3Y4 Canada
8. Health Canada assigned company identification number (if known):	141952	119556
9. Establishment License Number (if applicable):	N/A	1923

#### B. INCIDENT INFORMATION

1. Classification of Incident \*

- i. ☐ 10-Day ☒ 30-Day  
ii. ☒ Canadian ☐ Foreign  
iii. ☐ Investigational testing ☐ Special Access Program  
☐ Radiation emitting device (if applicable)

2. Date of Incident

2019-11-29 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-11-29 (YYYY-MM-DD)

4. Patient Consequences

The customer was not feeling sick, did not self-medicate, he did not change his diet and he did not seek medical attention.

5. Details of Incident

A customer called to report that he obtained variable blood glucose results on his Contour Next One Meter. The results in question were 21.9 mmol/L and 5.8 mmol/L, which were received within one minute of each other.

LAST 5 RESULTS:

5.8 mmol/L 07:56 PM 29/11/2019  
21.9 mmol/L 07:55 PM 29/11/2019  
5.2 mmol/L 07:52 PM 28/11/2019  
6.1 mmol/L 12:10 PM 27/11/2019  
5.7 mmol/L 07:48 PM 27/11/2019

Compared blood results fall within Zone "C" of the Parkes Error Grid being outside of the fitness-to-use limits.

This incident was flagged as a Mandatory Problem Report due to the fact that the comparison between two blood results taken within 1 minute of each other landed in Zone "C" of the Parkes Error Grid.

**MEDICAL DEVICE INFORMATION**

1. Trade/Brand Name  
Contour Next One Meter

2. Country of Origin (p.p.)  
1 295 2

3. Expiration Date  
(YY-MM-DD)

4. i. Device Classification  
☐ I ☐ II ☒ III ☐ IV

ii. Device License No.  
98283

iii. Device Identification No.  
817063

iv. Manufacturer's Medical Device Identifier  
(catalogue/model no.)  
9764

5. Software Version

6. Age of Device  
2017-01-16

7. How long was the device in use?  
Year 7 Month

Was the device labelled as sterile?  
☒ Yes ☐ No

Availability of device for evaluation  
☐ Destroyed ☐ Returned to Manufacturer  
☐ Neither (write explanation)

See section E

**D. COMPLAINANT INFORMATION**

1. Complainant is a:  
☒ Consumer ☐ Health professional ☐ Other

2. Name of Complainant  
Raj Taneja

3. Name of Health Care Facility (if applicable)  
N/A

4. Address  
896 CH. DE SAINT-EFLORE  
SHAWINIGAN, QC  
G7S 5K1

5. Telephone No. and/or E-mail Address  
(819)533-5648

**Privacy Notice Statement:** For the purposes of the Canada Vigilance Medical Device Problem Reporting Program, information related to the identity of the complainant and reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank/Health Canada Health Products Food Branch Brand Incident Reporting System, HC 100889-0001/0002/0003/0004/0005/0006/0007/0008/0009/0010/0011/0012/0013/0014/0015/0016/0017/0018/0019/0020/0021/0022/0023/0024/0025/0026/0027/0028/0029/0030/0031/0032/0033/0034/0035/0036/0037/0038/0039/0040/0041/0042/0043/0044/0045/0046/0047/0048/0049/0050/0051/0052/0053/0054/0055/0056/0057/0058/0059/0060/0061/0062/0063/0064/0065/0066/0067/0068/0069/0070/0071/0072/0073/0074/0075/0076/0077/0078/0079/0080/0081/0082/0083/0084/0085/0086/0087/0088/0089/0090/0091/0092/0093/0094/0095/0096/0097/0098/0099/0100/0101/0102/0103/0104/0105/0106/0107/0108/0109/0110/0111/0112/0113/0114/0115/0116/0117/0118/0119/0120/0121/0122/0123/0124/0125/0126/0127/0128/0129/0130/0131/0132/0133/0134/0135/0136/0137/0138/0139/0140/0141/0142/0143/0144/0145/0146/0147/0148/0149/0150/0151/0152/0153/0154/0155/0156/0157/0158/0159/0160/0161/0162/0163/0164/0165/0166/0167/0168/0169/0170/0171/0172/0173/0174/0175/0176/0177/0178/0179/0180/0181/0182/0183/0184/0185/0186/0187/0188/0189/0190/0191/0192/0193/0194/0195/0196/0197/0198/0199/0200/0201/0202/0203/0204/0205/0206/0207/0208/0209/0210/0211/0212/0213/0214/0215/0216/0217/0218/0219/0220/0221/0222/0223/0224/0225/0226/0227/0228/0229/0230/0231/0232/0233/0234/0235/0236/0237/0238/0239/0240/0241/0242/0243/0244/0245/0246/0247/0248/0249/0250/0251/0252/0253/0254/0255/0256/0257/0258/0259/0260/0261/0262/0263/0264/0265/0266/0267/0268/0269/0270/0271/0272/0273/0274/0275/0276/0277/0278/0279/0280/0281/0282/0283/0284/0285/0286/0287/0288/0289/0290/0291/0292/0293/0294/0295/0296/0297/0298/0299/0300/0301/0302/0303/0304/0305/0306/0307/0308/0309/0310/0311/0312/0313/0314/0315/0316/0317/0318/0319/0320/0321/0322/0323/0324/0325/0326/0327/0328/0329/0330/0331/0332/0333/0334/0335/0336/0337/0338/0339/0340/0341/0342/0343/0344/0345/0346/0347/0348/0349/0350/0351/0352/0353/0354/0355/0356/0357/0358/0359/0360/0361/0362/0363/0364/0365/0366/0367/0368/0369/0370/0371/0372/0373/0374/0375/0376/0377/0378/0379/0380/0381/0382/0383/0384/0385/0386/0387/0388/0389/0390/0391/0392/0393/0394/0395/0396/0397/0398/0399/0400/0401/0402/0403/0404/0405/0406/0407/0408/0409/0410/0411/0412/0413/0414/0415/0416/0417/0418/0419/0420/0421/0422/0423/0424/0425/0426/0427/0428/0429/0430/0431/0432/0433/0434/0435/0436/0437/0438/0439/0440/0441/0442/0443/0444/0445/0446/0447/0448/0449/0450/0451/0452/0453/0454/0455/0456/0457/0458/0459/0460/0461/0462/0463/0464/0465/0466/0467/0468/0469/0470/0471/0472/0473/0474/0475/0476/0477/0478/0479/0480/0481/0482/0483/0484/0485/0486/0487/0488/0489/0490/0491/0492/0493/0494/0495/0496/0497/0498/0499/0500/0501/0502/0503/0504/0505/0506/0507/0508/0509/0510/0511/0512/0513/0514/0515/0516/0517/0518/0519/0520/0521/0522/0523/0524/0525/0526/0527/0528/0529/0530/0531/0532/0533/0534/0535/0536/0537/0538/0539/0540/0541/0542/0543/0544/0545/0546/0547/0548/0549/0550/0551/0552/0553/0554/0555/0556/0557/0558/0559/0560/0561/0562/0563/0564/0565/0566/0567/0568/0569/0570/0571/0572/0573/0574/0575/0576/0577/0578/0579/0580/0581/0582/0583/0584/0585/0586/0587/0588/0589/0590/0591/0592/0593/0594/0595/0596/0597/0598/0599/0600/0601/0602/0603/0604/0605/0606/0607/0608/0609/0610/0611/0612/0613/0614/0615/0616/0617/0618/0619/0620/0621/0622/0623/0624/0625/0626/0627/0628/0629/0630/0631/0632/0633/0634/0635/0636/0637/0638/0639/0640/0641/0642/0643/0644/0645/0646/0647/0648/0649/0650/0651/0652/0653/0654/0655/0656/0657/0658/0659/0660/0661/0662/0663/0664/0665/0666/0667/0668/0669/0670/0671/0672/0673/0674/0675/0676/0677/0678/0679/0680/0681/0682/0683/0684/0685/0686/0687/0688/0689/0690/0691/0692/0693/0694/0695/0696/0697/0698/0699/0700/0701/0702/0703/0704/0705/0706/0707/0708/0709/0710/0711/0712/0713/0714/0715/0716/0717/0718/0719/0720/0721/0722/0723/0724/0725/0726/0727/0728/0729/0730/0731/0732/0733/0734/0735/0736/0737/0738/0739/0740/0741/0742/0743/0744/0745/0746/0747/0748/0749/0750/0751/0752/0753/0754/0755/0756/0757/0758/0759/0760/0761/0762/0763/0764/0765/0766/0767/0768/0769/0770/0771/0772/0773/0774/0775/0776/0777/0778/0779/0780/0781/0782/0783/0784/0785/0786/0787/0788/0789/0790/0791/0792/0793/0794/0795/0796/0797/0798/0799/0800/0801/0802/0803/0804/0805/0806/0807/0808/0809/0810/0811/0812/0813/0814/0815/0816/0817/0818/0819/0820/0821/0822/0823/0824/0825/0826/0827/0828/0829/0830/0831/0832/0833/0834/0835/0836/0837/0838/0839/0840/0841/0842/0843/0844/0845/0846/0847/0848/0849/0850/0851/0852/0853/0854/0855/0856/0857/0858/0859/0860/0861/0862/0863/0864/0865/0866/0867/0868/0869/0870/0871/0872/0873/0874/0875/0876/0877/0878/0879/0880/0881/0882/0883/0884/0885/0886/0887/0888/0889/0890/0891/0892/0893/0894/0895/0896/0897/0898/0899/0900/0901/0902/0903/0904/0905/0906/0907/0908/0909/0910/0911/0912/0913/0914/0915/0916/0917/0918/0919/0920/0921/0922/0923/0924/0925/0926/0927/0928/0929/0930/0931/0932/0933/0934/0935/0936/0937/0938/0939/0940/0941/0942/0943/0944/0945/0946/0947/0948/0949/0950/0951/0952/0953/0954/0955/0956/0957/0958/0959/0960/0961/0962/0963/0964/0965/0966/0967/0968/0969/0970/0971/0972/0973/0974/0975/0976/0977/0978/0979/0980/0981/0982/0983/0984/0985/0986/0987/0988/0989/0990/0991/0992/0993/0994/0995/0996/0997/0998/0999/1000/1001/1002/1003/1004/1005/1006/1007/1008/1009/1010/1011/1012/1013/1014/1015/1016/1017/1018/1019/1020/1021/1022/1023/1024/1025/1026/1027/1028/1029/1030/1031/1032/1033/1034/1035/1036/1037/1038/1039/1040/1041/1042/1043/1044/1045/1046/1047/1048/1049/1050/1051/1052/1053/1054/1055/1056/1057/1058/1059/1060/1061/1062/1063/1064/1065/1066/1067/1068/1069/1070/1071/1072/1073/1074/1075/1076/1077/1078/1079/1080/1081/1082/1083/1084/1085/1086/1087/1088/1089/1090/1091/1092/1093/1094/1095/1096/1097/1098/1099/1100/1101/1102/1103/1104/1105/1106/1107/1108/1109/1110/1111/1112/1113/1114/1115/1116/1117/1118/1119/1120/1121/1122/1123/1124/1125/1126/1127/1128/1129/1130/1131/1132/1133/1134/1135/1136/1137/1138/1139/1140/1141/1142/1143/1144/1145/1146/1147/1148/1149/1150/1151/1152/1153/1154/1155/1156/1157/1158/1159/1160/1161/1162/1163/1164/1165/1166/1167/1168/1169/1170/1171/1172/1173/1174/1175/1176/1177/1178/1179/1180/1181/1182/1183/1184/1185/1186/1187/1188/1189/1190/1191/1192/1193/1194/1195/1196/1197/1198/1199/1200/1201/1202/1203/1204/1205/1206/1207/1208/1209/1210/1211/1212/1213/1214/1215/1216/1217/1218/1219/1220/1221/1222/1223/1224/1225/1226/1227/1228/1229/1230/1231/1232/1233/1234/1235/1236/1237/1238/1239/1240/1241/1242/1243/1244/1245/1246/1247/1248/1249/1250/1251/1252/1253/1254/1255/1256/1257/1258/1259/1260/1261/1262/1263/1264/1265/1266/1267/1268/1269/1270/1271/1272/1273/1274/1275/1276/1277/1278/1279/1280/1281/1282/1283/1284/1285/1286/1287/1288/1289/1290/1291/1292/1293/1294/1295/1296/1297/1298/1299/1300/1301/1302/1303/1304/1305/1306/1307/1308/1309/1310/1311/1312/1313/1314/1315/1316/1317/1318/1319/1320/1321/1322/1323/1324/1325/1326/1327/1328/1329/1330/1331/1332/1333/1334/1335/1336/1337/1338/1339/1340/1341/1342/1343/1344/1345/1346/1347/1348/1349/1350/1351/1352/1353/1354/1355/1356/1357/1358/1359/1360/1361/1362/1363/1364/1365/1366/1367/1368/1369/1370/1371/1372/1373/1374/1375/1376/1377/1378/1379/1380/1381/1382/1383/1384/1385/1386/1387/1388/1389/1390/1391/1392/1393/1394/1395/1396/1397/1398/1399/1400/1401/1402/1403/1404/1405/1406/1407/1408/1409/1410/1411/1412/1413/1414/1415/1416/1417/1418/1419/1420/1421/1422/1423/1424/1425/1426/1427/1428/1429/1430/1431/1432/1433/1434/1435/1436/1437/1438/1439/1440/1441/1442/1443/1444/1445/1446/1447/1448/1449/1450/1451/1452/1453/1454/1455/1456/1457/1458/1459/1460/1461/1462/1463/1464/1465/1466/1467/1468/1469/1470/1471/1472/1473/1474/1475/1476/1477/1478/1479/1480/1481/1482/1483/1484/1485/1486/1487/1488/1489/1490/1491/1492/1493/1494/1495/1496/1497/1498/1499/1500/1501/1502/1503/1504/1505/1506/1507/1508/1509/1510/1511/1512/1513/1514/1515/1516/1517/1518/1519/1520/1521/1522/1523/1524/1525/1526/1527/1528/1529/1530/1531/1532/1533/1534/1535/1536/1537/1538/1539/1540/1541/1542/1543/1544/1545/1546/1547/1548/1549/1550/1551/1552/1553/1554/1555/1556/1557/1558/1559/1560/1561/1562/1563/1564/1565/1566/1567/1568/1569/1570/1571/1572/1573/1574/1575/1576/1577/1578/1579/1580/1581/1582/1583/1584/1585/1586/1587/1588/1589/1590/1591/1592/1593/1594/1595/1596/1597/1598/1599/1600/1601/1602/1603/1604/1605/1606/1607/1608/1609/1610/1611/1612/1613/1614/1615/1616/1617/1618/1619/1620/1621/1622/1623/1624/1625/1626/1627/1628/1629/1630/1631/1632/1633/1634/1635/1636/1637/1638/1639/1640/1641/1642/1643/1644/1645/1646/1647/1648/1649/1650/1651/1652/1653/1654/1655/1656/1657/1658/1659/1660/1661/1662/1663/1664/1665/1666/1667/1668/1669/1670/1671/1672/1673/1674/1675/1676/1677/1678/1679/1680/1681/1682/1683/1684/1685/1686/1687/1688/1689/1690/1691/1692/1693/1694/1695/1696/1697/1698/1699/1700/1701/1702/1703/1704/1705/1706/1707/1708/1709/1710/1711/1712/1713/1714/1715/1716/1717/1718/1719/1720/1721/1722/1723/1724/1725/1726/1727/1728/1729/1730/1731/1732/1733/1734/1735/1736/1737/1738/1739/1740/1741/1742/1743/1744/1745/1746/1747/1748/1749/1750/1751/1752/1753/1754/1755/1756/1757/1758/1759/1760/1761/1762/1763/1764/1765/1766/1767/1768/1769/1770/1771/1772/1773/1774/1775/1776/1777/1778/1779/1780/1781/1782/1783/1784/1785/1786/1787/1788/1789/1790/1791/1792/1793/1794/1795/1796/1797/1798/1799/1800/1801/1802/1803/1804/1805/1806/1807/1808/1809/1810/1811/1812/1813/1814/1815/1816/1817/1818/1819/1820/1821/1822/1823/1824/1825/1826/1827/1828/1829/1830/1831/1832/1833/1834/1835/1836/1837/1838/1839/1840/1841/1842/1843/1844/1845/1846/1847/1848/1849/1850/1851/1852/1853/1854/1855/1856/1857/1858/1859/1860/1861/1862/1863/1864/1865/1866/1867/1868/1869/1870/1871/1872/1873/1874/1875/1876/1877/1878/1879/1880/1881/1882/1883/1884/1885/1886/1887/1888/1889/1890/1891/1892/1893/1894/1895/1896/1897/1898/1899/1900/1901/1902/1903/1904/1905/1906/1907/1908/1909/1910/1911/1912/1913/1914/1915/1916/1917/1918/1919/1920/1921/1922/1923/1924/1925/1926/1927/1928/1929/1930/1931/1932/1933/1934/1935/1936/1937/1938/1939/1940/1941/1942/1943/1944/1945/1946/1947/1948/1949/1950/1951/1952/1953/1954/1955/1956/1957/1958/1959/1960/1961/1962/1963/1964/1965/1966/1967/1968/1969/1970/1971/1972/1973/1974/1975/1976/1977/1978/1979/1980/1981/1982/1983/1984/1985/1986/1987/1988/1989/1990/1991/1992/1993/1994/1995/1996/1997/1998/1999/2000/2001/2002/2003/2004/2005/2006/2007/2008/2009/2010/2011/2012/2013/2014/2015/2016/2017/2018/2019/2020/2021/2022/2023/2024/2025/2026/2027/2028/2029/2030/2031/2032/2033/2034/2035/2036/2037/2038/2039/2040/2041/2042/2043/2044/2045/2046/2047/2048/2049/2050/2051/2052/2053/2054/2055/2056/2057/2058/2059/2060/2061/2062/2063/2064/2065/2066/2067/2068/2069/2070/2071/2072/2073/2074/2075/2076/2077/2078/2079/2080/2081/2082/2083/2084/2085/2086/2087/2088/2089/2090/2091/2092/2093/2094/2095/2096/2097/2098/2099/2100/2101/2102/2103/2104/2105/2106/2107/2108/2109/2110/2111/2112/2113/2114/2115/2116/2117/2118/2119/2120/2121/2122/2123/2124/2125/2126/2127/2128/2129/2130/2131/2132/2133/2134/2135/2136/2137/2138/2139/2140/2141/2142/2143/2144/2145/2146/2147/2148/2149/2150/2151/2152/2153/2154/2155/2156/2157/2158/2159/2160/2161/2162/2163/2164/2165/2166/2167/2168/2169/2170/2171/2172/2173/2174/2175/2176/2177/2178/2179/2180/2181/2182/2183/2184/2185/2186/2187/2188/2189/2190/2191/2192/2193/2194/2195/2196/2197/2198/2199/2200/2201/2202/2203/2204/2205/2206/2207/2208/2209/2210/2211/2212/2213/2214/2215/2216/2217/2218/2219/2220/2221/2222/2223/2224/2225/2226/2227/2228/2229/2230/2231/2232/2233/2234/2235/2236/2237/2238/2239/2240/2241/2242/2243/2244/2245/2246/2247/2248/2249/2250/2251/2252/2253/2254/2255/2256/2257/2258/2259/2260/2261/2262/2263/2264/2265/2266/2267/2268/2269/2270/2271/2272/2273/2274/2275/2276/2277/2278/2279/2280/2281/2282/2283/2284/2285/2286/2287/2288/2289/2290/2291/2292/2293/2294/2295/2296/2297/2298/2299/2300/2301/2302/2303/2304/2305/2306/2307/2308/2309/2310/2311/2312/2313/2314/2315/2316/2317/2318/2319/2320/2321/2322/2323

## **Crisan, Simona (HC/SC)**

---

**From:** Kwang Ju Nam <KNam@accuristix.com>  
**Sent:** 2020-02-24 4:50 PM  
**To:** mdpr / dimm (HC/SC)  
**Cc:** Kevin Chin; Gordon Rockett; Cuong Nguyen; Kwang Ju Nam; QA Summerlea  
**Subject:** MDPR\_2020-7182-QA-ST\_689506\_F  
**Attach ments:** MDPR\_2020-7182-QA-ST\_689506\_F.pdf

Hello,

Please find attached Final MDPR.

Thank you ,

**Kwang Ju Grace Nam**  
Quality Assurance Associate



**T** 416.637.3273 ext5032  
[www.accuristix.com](http://www.accuristix.com)

121 Stone Ridge Road,  
Vaughan, ON L4H 0A5