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Japan's Shimadzu receives US FDA's premarketing notification for Positive PET system

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Contributing to the early diagnosis and prediction of the progression of dementia



Japan's Shimadzu Corporation has obtained premarketing notification from the US Food and Drug Administration (FDA) for its Positive PET system that is specialised for head and breast examinations and starts marketing in the US. Positron emission tomography (PET) is a non-invasive diagnostic imaging method by administering drugs into the body that accumulate at specific targets.

PET could be used for obtaining images of the accumulation of abnormal proteins, amyloid-? and tau, in the brain, which is the cause of Alzheimer's dementia, and cancers. The PET detector ring of this product has a diameter of 28 cm, which is smaller than the approximate 80 cm diameter found in a whole-body PET system, so it can take images closer to the target locations. That results in providing high-definition PET images with up to about double the resolution of a whole-body PET system.

The United States was the first country to use amyloid PET examinations to identify amyloid-? accumulations in the brain for deciding whether to administer therapeutic drugs for Alzheimer's and to determine their therapeutic effect. Shimadzu will offer the system in response to that demand. Also, it is expected that the demand for amyloid PET testing will increase further as the number of cases of Alzheimer's dementia increases in the future and as research progresses.

In addition, it is envisaged that the system will be used for imaging the accumulation of the tau protein in the brain, which is another cause of Alzheimer's dementia. The tau protein can accumulate locally in minute areas within the brain, and it is known that there is a correlation between these accumulation sites and the symptoms of dementia. With the advancement of research on tau protein-targeted therapies and its distribution in the brain, there is an increasing expectation for the necessity of tau PET imaging using high-resolution PET devices.

By continuing to provide this product, Shimadzu will contribute to the early diagnosis and prediction of the progression of dementia, including Alzheimer's dementia, and to research and development of treatments that aim to delay the onset and progression of dementia.